D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)	
Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

(Version: AZ2309 2023-09-14)

What was the Protocol milestone?	Main Informed Consent
What was the main informed consent date?	Fixed Unit: yyyy mon dd

What was the Protocol milestone?	Optional Consent
Optional consent category	● Participation to Optional Blood Tests ☐ Optional services and the transfer of contact details to service providers ☐ Use of coded data (including images), biosamples and analysis of genetic information as required for future research ☐ Participation to Optional Biopsy at first day of Cycle 3 of study treatment ☐ Participation to Optional Biopsy at Cancer Progression
Optional consent/assent obtained	☐ No ☐ Yes ☐ Not applicable
Optional consent date	Fixed Unit: yyyy mon dd

Optional consent category	☐ Participation to Optional Blood Tests ☐ Optional services and the transfer of contact details to service providers ☐ Use of coded data (including images), biosamples and analysis of genetic information as required for future research

	Participation to Optional Biopsy at first day of Cycle 3 of study treatment ■ Participation to Optional Biopsy at Cancer Progression ☐
Optional consent/assent obtained	No ☐ Yes ☐ Not applicable ☐
Optional consent date	Fixed Unit: yyyy mon dd
Optional consent category	Participation to Optional Blood Tests ☐ Optional services and the transfer of contact details to service providers ☐ Use of coded data (including images), biosamples and analysis of genetic information as required for future research ☐ Participation to Optional Biopsy at first day of Cycle 3 of study treatment ☐ Participation to Optional Biopsy at Cancer Progression ■
Optional consent/assent obtained	No ☐ Yes ☐ Not applicable ☐
Optional consent date	Fixed Unit: yyyy mon dd
Optional consent category	Participation to Optional Blood Tests ☐ Optional services and the transfer of contact details to service providers ■

	Use of coded data (including images), biosamples and analysis of genetic information as required for future research ☐ Participation to Optional Biopsy at first day of Cycle 3 of study treatment ☐ Participation to Optional Biopsy at Cancer Progression ☐
Optional consent/assent obtained	No ☐ Yes ☐ Not applicable ☐
Optional consent date	Fixed Unit: yyyy mon dd

Optional consent category	Participation to Optional Blood Tests ☐ Optional services and the transfer of contact details to service providers ☐ Use of coded data (including images), biosamples and analysis of genetic information as required for future research ■ Participation to Optional Biopsy at first day of Cycle 3 of study treatment ☐ Participation to Optional Biopsy at Cancer Progression ☐
Optional consent/assent obtained	No ☐ Yes ☐ Not applicable ☐
Optional consent date	Fixed Unit: yyyy mon dd

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Demographics (DM)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2203 2023-11-02)

What is the Subject's date of birth?	Fixed Unit: yyyy mon dd
What is the Subject's age?	
What is the age unit used?	Years
What is the sex of the Subject?	Female Male

Ask the Subject following questions.
Study participants should self-report ethnicity, with ethnicity being asked about before race.

Do you consider yourself Hispanic/Latino or not Hispanic/Latino?	Hispanic or Latino Not Hispanic or Latino Not reported
Race - select all that apply:	
Which racial designation best describes you - Black or African American?	Black or African American
Which racial designation best describes you - Native Hawaiian or other Pacific Islander?	Native Hawaiian or other Pacific Islander
Which racial designation best describes you - American Indian or Alaska Native?	American Indian or Alaska Native
Which racial designation best describes you - Asian?	Asian
Which racial designation best describes you - White?	White
Which racial designation best describes you? (Not reported)	Not reported
Which racial designation best describes you - Other?	Other
What was the Other race?	
RSG Field for Ethnic origin	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Informed Consent - Genomics Initiative (ICFGEN)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-06)

What was the Protocol milestone?	Genomics Initiative Informed Consent
What was the genomics initiative informed consent date?	Fixed Unit: yyyy mon dd
Optional genomics initiative consent	Use of coded data and biosamples for optional multi-omics research including the analyses of genomic information ■
Optional consent/assent obtained	No ☐ Yes ☐ Not applicable ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Inclusion/Exclusion Criteria Not Met (IE)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2506 2025-06-30)

Were all eligibility criteria met?	No ☐
	Yes ☐
	Not applicable ☐

If No, record Exception criterion identifier for each Criterion type that was not met.

Criterion type	Exclusion ☐
	Inclusion ☐
Exception criterion identifier	_____
Exception criterion identifier	_____
What was the Protocol version?	_____

(Version: ON2503 2025-05-05)

Metastatic/locally advanced	Locally advanced ☐ Metastatic ☐
Anatomical location	Adrenal gland ☐ Ascites ☐ Biliary tract ☐ Bladder ☐ Bone ☐ Brain ☐ Distant lymph node ☐ Esophagus ☐ Gallbladder ☐ Genitourinary system ☐ Kidney ☐ Large intestine ☐ Liver ☐ Lung ☐ Mediastinum ☐ Omentum ☐ Pancreas ☐ Pericardial effusion ☐ Peritoneum ☐ Pleura ☐ Pleural effusion ☐ Rectum ☐ Regional lymph node ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Other locally advanced sites ☐ Other metastatic sites ☐

Other locally advanced site, specify	
Other metastatic site, specify	
For below field, Answer Yes if there was recurrence after previous curative intent resection. Answer No if disease was initially unresectable	
Was there recurrence after curative intent resection of BTC?	No ☐ Yes ☐
"Date of recurrence" should only be entered if “Was there recurrence after curative intent resection of BTC?” is Yes.	
Date of recurrence	Fixed Unit: yyyy mon dd

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: General Medical History (1MH)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2309 2024-02-15)

Has the Subject experienced any past and/or concomitant diseases?	No ☐ Yes ☐
Medical history term	_____
Ongoing (at the time of enrollment)	No ☐ Yes ☐
Start date	Fixed Unit: yyyy mon dd _____
End date	Fixed Unit: yyyy mon dd _____
Any current medication	No ☐ Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Pre-specified medical conditions or events (2MH)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2309 2024-02-15)

Medical history term	Hepatic cirrhosis
[Medical condition/event]	No ☐
	Yes ☐
	Unknown ☐
Medical history event prespecified	Yes ■

Medical history term	Hepatitis B
[Medical condition/event]	No ☐
	Yes ☐
	Unknown ☐
Medical history event prespecified	Yes ■

Medical history term	Hepatitis C
[Medical condition/event]	No ☐
	Yes ☐
	Unknown ☐
Medical history event prespecified	Yes ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Surgical History (HISS)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-16)

What was the category of the procedure?	SURGICAL PROCEDURE
Were any surgical procedures performed? (prior to enrollment)	No ☐ Yes ☐
Procedure name	_____
Start date	Fixed Unit: yyyy mon dd _____
Current medication	No ☐ Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Assessment(s) Performed Triggering Form (ASMTRIG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2402 2024-02-16)

Select 'Yes' if all assessment forms are to be triggered	Yes ☐

Assessment(s) type	Extent of Disease Upon Entry to Study (DISEXT) ☐
	Pathology: at Screening (PATHGOM) ☐
	General Medical History (1MH) ☐
	Pre-specified medical conditions or events (2MH) ☐
	Surgical History (HISS) ☐
	Physical Examination (PE) ☐
	Vital Signs - Weight, Height (VS) ☐
	Vital Signs - Before Infusion (VS1) ☐
	Vital Signs - End of Infusion (VS2) ☐
	Vital Signs - Excluding Weight (VS3) ☐
	Vital Signs (VS4) ☐
	ECOG Performance Status (ECOG) ☐
	ECG Test Results (EG) ☐
	Additional ECG (EG1) ☐
	Additional ECG (EG2) ☐
	Echocardiography (ECHOC) ☐
	Non-central Laboratory Test Results - Chemistry (LB) ☐
	Non-central Laboratory Test Results - Hematology (LB1) ☐
	Non-central Laboratory Test Results - Coagulation (LB2) ☐
	Non-central Laboratory Test Results - Thyroid function test (LB3) ☐

- ☐ Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
- ☐ Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
- ☐ Non-central Laboratory Test Results - Urinalysis (LB6)
- ☐ Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
- ☐ Non-central Laboratory Test Results - Hy's Law (LB8)
- ☐ Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
- ☐ Non-central Laboratory Test Results - Tuberculosis testing (LB10)
- ☐ Non-central Laboratory Test Results - HIV testing (LB11)
- ☐ Non-central Laboratory Test Results - Additional Chemistry (LB12)
- ☐ Sample Collection, Predose_ADA Sample (SPCBEDB)
- ☐ Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
- ☐ PBMC for immune profiling_Pre dose (SPCBEDB2)
- ☐ Whole blood for RNA analysis_Pre-dose (SPCBEDB3)
- ☐ Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)

	Sample Collection, ADA Sample (SPCBEDB5) ☐
	Blood sample for plasma ctDNA (SPCBEDB6) ☐
	Optional on study tumor sample at recurrence (SPCBEDT) ☐
	Mandatory tumor sample from surgical resection for PDL1 analysis (SPCBEDT1) ☐
	Biological Sample Collection, Pre-dose PK (SPCPKB) ☐
	Biological Sample Collection, Post-dose PK (SPCPKB1) ☐
	Biological Sample Collection, PK (SPCPKB2) ☐
	Substance Use - Nicotine (SU_NIC) ☐
	Substance Use - Alcohol (SU_ALC) ☐
	Prior Cancer Therapy (CAPRX) ☐
	Prior Radiotherapy (CAPRXR) ☐
	Survival Status (SURVIVE) ☐
Assessment form to be triggered	No ☐
	Yes ☐
Reason assessment form is not to be triggered	Assessment not performed ☐
	Assessment not required ☐
	Subject discontinuation ☐
	Screen failure ☐

(Version: ON2407 2025-07-15)

Original diagnosis date	Fixed Unit: yyyy mon dd
Primary tumor location	Extrahepatic bile duct (distal) ☐ Extrahepatic bile duct (perhilar) ☐ Gallbladder ☐ Intrahepatic bile duct ☐ Other ☐
If Other, specify	
Histology type	Adenosquamous carcinoma ☐ Adenocarcinoma ☐ Other ☐
If Other, specify	
Indicate TNM classification for each section Primary tumor	TX ☐ T1 ☐ T1a ☐ T1b ☐ T2 ☐ T2a ☐ T2b ☐ T3 ☐ T4 ☐
Regional lymph nodes	N0 ☐ N1 ☐ N2 ☐ NX ☐
Distant metastases	M0 ☐ Mx ☐ M1 ☐
Tumor grade	Well differentiated (G1) ☐ Moderately differentiated (G2) ☐

	Poorly differentiated (G3) ☐
	Unassessable (GX) ☐
Stage/AJCC stage	Stage I ☐
	Stage IA ☐
	Stage IB ☐
	Stage II ☐
	Stage IIA ☐
	Stage IIB ☐
	Stage III ☐
	Stage IIIA ☐
	Stage IIIB ☐
	Stage IIIC ☐
	Stage IV ☐
	Stage IVA ☐
	Stage IVB ☐

(Version: ON2311 2025-03-12)

Date of Diagnosis of unresectable locally advanced or metastatic BTC	Fixed Unit: yyyy mon dd
Primary tumor location	Extrahepatic bile duct (distal) ☐ Extrahepatic bile duct (perhilar) ☐ Gallbladder ☐ Intrahepatic bile duct ☐ Other ☐
If 'Primary Tumor location' is 'Other' then provide the specification If Other, specify	
Histology type	Adenosquamous carcinoma ☐ Adenocarcinoma ☐ Other ☐
If "Histology type" is 'Other' then provide the details. Histology type details	
Indicate TNM classification for each section Primary tumor	TX ☐ T1 ☐ T1a ☐ T1b ☐ T2 ☐ T2a ☐ T2b ☐ T3 ☐ T4 ☐
Regional lymph nodes	N0 ☐ N1 ☐ N2 ☐ NX ☐
Distant metastases	M0 ☐ Mx ☐

	M1 ☐
Tumor grade	Well differentiated (G1) ☐
	Moderately differentiated (G2) ☐
	Poorly differentiated (G3) ☐
	Unassessable (GX) ☐
Stage/AJCC stage	Stage II ☐
	Stage IIA ☐
	Stage IIB ☐
	Stage III ☐
	Stage IIIA ☐
	Stage IIIB ☐
	Stage IIIC ☐
	Stage IV ☐
	Stage IVA ☐
	Stage IVB ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Substance Use - Nicotine (SU_NIC)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2409 2024-10-24)

What was the category of substance used?	Nicotine ■
Has the Subject ever smoked tobacco?	Current ☐
	Former ☐
	Never ☐
Number of pack years	_____

(Version: AZ1906 2024-11-19)

What was the category of the substance used?	Alcohol ■
Has the Subject ever used the substance?	Current ☐
	Former ☐
	Never ☐

If 'Current' or 'Former' is selected, complete additional Alcohol use information below.

Type of substance	Wine ■
	Wine, fortified ☐
	Beer ☐
	Cider ☐
	Liquor/Spirits ☐
	Alcopop ☐
	Other ☐
If Other, specify	
Alcohol consumption (units)	
Frequency	Daily ☐
	Per week ☐
	Per month ☐

Type of substance	Wine ☐
	Wine, fortified ■
	Beer ☐
	Cider ☐
	Liquor/Spirits ☐
	Alcopop ☐
	Other ☐
If Other, specify	
Alcohol consumption (units)	
Frequency	Daily ☐
	Per week ☐
	Per month ☐

Type of substance	Wine ☐
	Wine, fortified ☐

	Beer ■
	Cider ☐
	Liquor/Spirits ☐
	Alcopop ☐
	Other ☐
If Other, specify	
Alcohol consumption (units)	
Frequency	Daily ☐
	Per week ☐
	Per month ☐
Type of substance	Wine ☐
	Wine, fortified ☐
	Beer ☐
	Cider ■
	Liquor/Spirits ☐
	Alcopop ☐
	Other ☐
If Other, specify	
Alcohol consumption (units)	
Frequency	Daily ☐
	Per week ☐
	Per month ☐
Type of substance	Wine ☐
	Wine, fortified ☐
	Beer ☐
	Cider ☐
	Liquor/Spirits ■
	Alcopop ☐
	Other ☐
If Other, specify	
Alcohol consumption (units)	
Frequency	Daily ☐

	Per week ☐
	Per month ☐
Type of substance	Wine ☐
	Wine, fortified ☐
	Beer ☐
	Cider ☐
	Liquor/Spirits ☐
	Alcopop ■
	Other ☐
If Other, specify	_____
Alcohol consumption (units)	_____
Frequency	Daily ☐
	Per week ☐
	Per month ☐
Type of substance	Wine ☐
	Wine, fortified ☐
	Beer ☐
	Cider ☐
	Liquor/Spirits ☐
	Alcopop ☐
	Other ■
If Other, specify	_____
Alcohol consumption (units)	_____
Frequency	Daily ☐
	Per week ☐
	Per month ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Physical Examination (PE)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ1609 2019-04-19)

For baseline: Following items should be checked during baseline physical examination (A full physical examination will be performed and include assessments of the following: general appearance, respiratory, cardiovascular system, abdomen, skin, head and neck (including ears, eyes, nose, and throat), lymph nodes, thyroid, musculoskeletal (including spine and extremities), urogenital, dermatological, gastrointestinal, endocrine, hematologic/lymphatic, and neurological systems.).

For follow-up: Following items should be checked during follow-up physical examination (A targeted physical examination will include, at a minimum, assessments of skin, lungs, cardiovascular system, and abdomen (liver and spleen).

If the physical finding started prior to enrolment, it must be recorded as medical history.
If the physical finding started or worsened after enrolment, it must be recorded as an Adverse Event.

Was the physical examination performed?	No ☐ Yes ☐
What was the date of the physical examination?	Fixed Unit: yyyy mon dd

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Vital Signs - Weight, Height (VS)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd
Time	Fixed Unit: 24-hour clock
Pulse	Fixed Unit: beats/min
SBP	Fixed Unit: mmHg
DBP	Fixed Unit: mmHg
Respiration rate	Fixed Unit: breaths/min
Temperature	
Temperature unit	C
Peripheral oxygen saturation	Fixed Unit: %
Weight	
Weight unit	kg
Height	
Height unit	cm
EHRID	

(Version: ON2406 2024-06-04)

Clinical classification category	ECOG
What was the date the response or clinical classification was performed?	Fixed Unit: yyyy mon dd
Performance status	0-Fully active, able to carry on all pre-disease performance without restriction ☐ 1-Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work ☐ 2-Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours ☐ 3-Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours ☐ 4-Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair ☐ 5-Dead ☐

Ref: Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55). WHO Ref: World Health Organization (1979).Handbook for Reporting Results of Cancer Treatment Pb (WHO Offset Publications).

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: ECG Test Results (EG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2112 2024-08-09)

Was the ECG performed?	No ☐ Yes ☐
What was the date of the ECG?	Fixed Unit: yyyy mon dd
ECG time	Fixed Unit: 24-hour clock
ECG mean heart rate	Fixed Unit: beats/min
QRS duration	Fixed Unit: ms
RR interval	Fixed Unit: ms
PR interval	Fixed Unit: ms
QT interval	Fixed Unit: ms
QTc interval Fridericia	Fixed Unit: ms
What was the interpretation of the ECG?	Normal ☐ Abnormal ☐
Reason, abnormal overall ECG evaluation	
Was the ECG clinically significant?	No ☐ Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Additional ECG (EG1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2112 2024-08-09)

Was the ECG performed?	No ☐ Yes ☐
What was the date of the ECG?	Fixed Unit: yyyy mon dd
ECG time	Fixed Unit: 24-hour clock
ECG mean heart rate	Fixed Unit: beats/min
QRS duration	Fixed Unit: ms
RR interval	Fixed Unit: ms
PR interval	Fixed Unit: ms
QT interval	Fixed Unit: ms
QTc interval Fridericia	Fixed Unit: ms
What was the interpretation of the ECG?	Normal ☐ Abnormal ☐
Reason, abnormal overall ECG evaluation	
Was the ECG clinically significant?	No ☐ Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Additional ECG (EG2)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2112 2024-08-09)

Was the ECG performed?	No ☐ Yes ☐
What was the date of the ECG?	Fixed Unit: yyyy mon dd
ECG time	Fixed Unit: 24-hour clock
ECG mean heart rate	Fixed Unit: beats/min
QRS duration	Fixed Unit: ms
RR interval	Fixed Unit: ms
PR interval	Fixed Unit: ms
QT interval	Fixed Unit: ms
QTc interval Fridericia	Fixed Unit: ms
What was the interpretation of the ECG?	Normal ☐ Abnormal ☐
Reason, abnormal overall ECG evaluation	
Was the ECG clinically significant?	No ☐ Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Echocardiography (ECHOC)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2201 2024-09-27)

What was the date of the echocardiography?	Fixed Unit: yyyy mon dd
What was the time of the echocardiography?	Fixed Unit: 24-hour clock
What was the method used for the examination?	Echocardiography ☐ Multiple Gated Acquisition (MUGA) ☐
Was the image quality sufficient?	No ☐ Yes ☐
What was the overall ECHOC evaluation?	Normal ☐ Abnormal ☐
What is the reason the overall ECHOC evaluation was abnormal?	
What was the left ventricular ejection fraction?	Fixed Unit: %
What was the LV end diastolic volume?	Fixed Unit: mL
What was the LV end systolic volume?	Fixed Unit: mL

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Pregnancy Test - Screening (PREG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2008 2024-03-01)

Assessment applicable for Subject
- ☐ No
- ☐ Yes

Sampling date — Fixed Unit: yyyy mon dd

Pregnancy test (serum)
- ☐ Negative
- ☐ Positive

For a positive pregnancy test after first dose of study drug, fill in PREGREP (or the 'Pregnancy Outcome Report Form' [Part 1]) and send to the AstraZeneca Monitor.

If positive pregnancy test, the administration of study drug to that Subject must be discontinued immediately and the End of Study Treatment form (ETRT) filled in.

If Positive pregnancy test, and considered an AE, please fill in Adverse Event (AE) Form
(Pregnancy itself is not regarded as an adverse event unless there is a suspicion that AstraZeneca product may have interfered with the effectiveness of a contraceptive medication.)

Hidden Field (used for CF programming)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Liver Function Tests Alanine Aminotransferase (Serum/Plasma)	_____
Alkaline Phosphatase (Serum/Plasma)	_____
Aspartate Aminotransferase (Serum/Plasma)	_____
Bilirubin, Total (Serum/Plasma)	_____
Bilirubin, Direct, (Conj) (Serum/Plasma)	_____
Bilirubin, Indirect (Unconj.) (Serum/Plasma)	_____
Gamma-Glutamyltransferase (Serum/Plasma)	_____
Lactate Dehydrogenase (LDH) (Serum/Plasma)	_____
Protein, Total (Serum/Plasma)	_____
Pancreatic Enzymes Amylase (Serum/Plasma)	_____
Lipase (Serum/Plasma)	_____
Renal Function Tests Creatinine (Serum/Plasma)	_____
Creatinine Clearance, Calculated (Urine 24h)	_____
Creatinine Clearance, Cockcroft-Gault (Plasma)	_____
Creatinine Clearance, Cockcroft-Gault (Serum)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Plasma)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Serum)	_____

Lab Name:	
Urea (Serum/Plasma)	
Urea Nitrogen (BUN) (Serum/Plasma)	
Electrolytes Calcium, Ionized (Serum)	
Total Calcium (Serum/Plasma)	
Chloride (Serum/Plasma)	
Magnesium (Serum/Plasma)	
Phosphate (Phosphorus) (Serum/Plasma)	
Potassium (Serum/Plasma)	
Sodium (Serum/Plasma)	
Proteins Albumin (Serum/Plasma)	
Glucose Metabolism Glucose, Fasting (Serum/Plasma)	
Glucose,Random (Serum/Plasma)	
Hidden for Bilirubin	
Hidden for Aspartate	
Hidden for Alanine	
Hidden for Alanine Range	
Hidden for Asparate Range	
Hidden for Bilirubin Range	
Derived field to call CF	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Non-central Laboratory Test Results - Hematology (LB1)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	☐ No ☐ Yes
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	■ Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hemoglobin (Blood)	_____
Hematocrit (Blood)	_____
Leucocytes, Absolute Count (WBC) (Blood)	_____
Platelet count (Blood)	_____
Mean corpuscular volume (Blood)	_____
Absolute Neutrophil Count (Blood)	_____
Absolute Lymphocytes Count (Blood)	_____
Absolute Monocytes Count (Blood)	_____
Absolute Eosinophils,Count (Blood)	_____
Neutrophils, %/Ratio (Blood)	_____
Lymphocytes, %/Ratio (Blood)	_____
Monocytes, %/Ratio (Blood)	_____
Eosinophils, % /Ratio (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Non-central Laboratory Test Results - Coagulation (LB2)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ■ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Activated Partial Thromboplastin Time (APTT) (sec) (Blood)	_____
Activated Partial Thromboplast. Time,Rel (APTT relative) (%, ratio) (Blood)	_____
Fibrinogen (Blood)	_____
Partial Thromboplastin Time (PTT) (sec) (Blood)	_____
Partial Thromboplastin Time, Rel (PTT Relative) (%, ratio) (Blood)	_____
Prothrombin Complex INR (Blood) (%,ratio) (Blood)	_____
Prothrombin Time (PT) (sec) (Blood)	_____
Prothrombin Time, Relative (PT Relative) (%, ratio) (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Non-central Laboratory Test Results - Thyroid function test (LB3)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Thyroid Stimulating Hormone(Serum/Plasma)	_____
T4 (Thyroxine), Free(Serum/Plasma)	_____
T3 (Triiodothyronine), Free(Serum/Plasma)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Creatine Kinase (Serum/Plasma)	_____
Troponin T (Serum/Plasma)	_____
Troponin I (Serum/Plasma)	_____
High- sensitivity Troponin T (Serum/Plasma)	_____
High- sensitivity Troponin I (Serum/Plasma)	_____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ■ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Albumin, Strip, Qual (Urine)	Negative ☐ Trace ☐ Positive ☐ + ☐ ++ ☐ +++ ☐ >+++ ☐ +- ☐
Bilirubin, Strip, Qual (Urine)	Negative ☐ Trace ☐ Positive ☐ + ☐ ++ ☐ +++ ☐ >+++ ☐ +- ☐
Blood, Qual (Urine)	Negative ☐ Trace ☐

	Positive ☐
	+ ☐
	++ ☐
	+++ ☐
	>+++ ☐
	+- ☐
Glucose, Strip, Qual (Urine)	Negative ☐
	Trace ☐
	Positive ☐
	+ ☐
	++ ☐
	+++ ☐
	>+++ ☐
	+- ☐
Ketone Bodies, Strip, Qual (Urine)	Negative ☐
	Trace ☐
	Positive ☐
	+ ☐
	++ ☐
	+++ ☐
	>+++ ☐
	+- ☐
Protein, Strip, Qual (Urine)	Negative ☐
	Trace ☐
	Positive ☐
	+ ☐
	++ ☐
	+++ ☐
	>+++ ☐
	+- ☐
Appearance (Qual) (Urine)	_____
Color (Qual) (Urine)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Non-central Laboratory Test Results - Urinalysis (LB6)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

Albumin, Quant (Urine)	
Bilirubin, Quant(Urine)	
Glucose, Random, Quant (Urine)	
Ketone Bodies, Quant (Urine)	
Protein, Total, Quant (Urine)	
Urine-Blood, Quant (Urine)	
pH (Urine)	
Specific Gravity (Urine)	
Sediment, Erythrocytes, Quant (no/vis fld) (Urine)	
Sediment, Leucocytes, Quant (no/vis fld) (Urine)	
Leucocytes, Quant (10**6/L) (Volume) (Urine)	
Erythrocytes, Quant (1/uL) (Volume) (Urine)	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ■
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hepatitis B Surface Antigen (Qual) (HBsAg) (Blood)	Negative ☐ Positive ☐ +-borderline ☐
Hepatitis B Surface Antibody (HBsAb) (Blood)	Negative ☐ Positive ☐ +-borderline ☐
Hepatitis B Core Antibody, Qual (anti-HBc) (Blood)	Negative ☐ Positive ☐ +-borderline ☐
Hepatitis C Antibody (HCV ab) (Blood)	Negative ☐ Positive ☐ +-borderline ☐
Hepatitis D Antibody (Blood)	Negative ☐ Positive ☐ +-borderline ☐
Hepatitis B Viral Load, Quant (IU/mL) (Blood)	_____
Hepatitis B Viral Load, Quant (DNA copies/mL) (Blood)	_____
Hepatitis C Viral Load, Quant (IU/mL) (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

Hepatitis C Viral Load, Quant (RNA copies/mL) (Blood)	_____
Hepatitis D Virus RNA, Quant (Serum/Plasma)	_____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ■
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock
Culture, Mycobacterium Tuberculosis(Sputum)	Negative ☐ Positive ☐ +-borderline ☐
Quantiferon Tuberculosis Gold (Plasma)	Negative ☐ Positive ☐ +-borderline ☐
Quantiferon Tuberculosis Gold (Blood)	Negative ☐ Positive ☐ +-borderline ☐

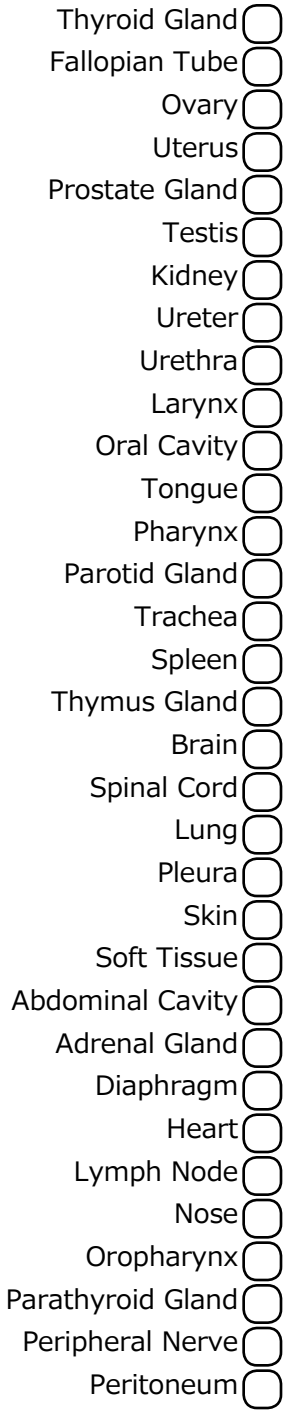
D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Non-central Laboratory Test Results - HIV testing (LB11)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ■
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
HIV-1/2 Antibody Screen (Blood)	Negative ☐ Positive ☐ +-borderline ☐
HIV Viral Load, Quant, PCR (Blood)	_____
CD4+, abs(cells/uL) (Blood)	_____

(Version: AZ2310 2025-07-01)

What was the sample collection category?	Biomarkers/exploratory research/diagnostic, solid tissue
Sample collected	No
	Yes
Sample collection method	Core Needle Biopsy
	Excisional Biopsy
	Incisional Biopsy
Biopsy tissue type	Primary tumor
	Metastatic tumor
Organ	Abdomen
	Bronchus (Main Stem)
	Fat
	Oesophagus
	Pituitary
	Urinary Bladder
	Esophagogastric Junction
	Hypopharynx
	Duodenum
	Cervix Uteri
	Epididymis
	Gallbladder
	Large Intestine
	Appendix
	Colon
	Small Intestine
	Ileum
	Jejunum
	Rectum
	Stomach
	Liver
	Pancreas


Thyroid Gland
Fallopian Tube
Ovary
Uterus
Prostate Gland
Testis
Kidney
Ureter
Urethra
Larynx
Oral Cavity
Tongue
Pharynx
Parotid Gland
Trachea
Spleen
Thymus Gland
Brain
Spinal Cord
Lung
Pleura
Skin
Soft Tissue
Abdominal Cavity
Adrenal Gland
Diaphragm
Heart
Lymph Node
Nose
Oropharynx
Parathyroid Gland
Peripheral Nerve
Peritoneum

	Tonsil ☐
	Breast ☐
	Joint ☐
	Muscle ☐
	Gastroesophageal Junction ☐
	Mesentery ☐
	Omentum ☐
	Anus ☐
	Abdominal Wall ☐
	Other (Not Specified) ☐
Sample format	FFPE block ☐
	FFPE unstained slides ☐
Unstained slides sectioning date	Fixed Unit: yyyy mon dd
Date of Biopsy	Fixed Unit: yyyy mon dd
Sample condition	Sample acceptable ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Date of storage	Fixed Unit: yyyy mon dd
Time of storage	Fixed Unit: 24-hour clock
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Prior Cancer Therapy (CAPRX)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: ON2406 2024-08-20)

Has cancer therapy been previous/current/post withdrawn of IP?	Previous ■ Post ☐
Has the Subject had any cancer therapy?	No ☐ Yes ☐ Not applicable ☐
If Not applicable, specify	_____
Cancer therapy agent	_____
Cancer therapy agent start date	Fixed Unit: yyyy mon dd _____
Cancer therapy agent stop date	Fixed Unit: yyyy mon dd _____
Best overall response	Complete response ☐ Partial response ☐ Stable disease ☐ Progressive disease ☐ Not evaluable ☐ Not applicable ☐
Treatment status	Adjuvant ☐ Neo-adjuvant ☐ Not applicable ☐
Concomitant chemoradiotherapy If Yes, Radiotherapy must be recorded on the Prior Radiotherapy (CAPRXR) page	No ☐ Yes ☐
Indication	Biliary Tract Cancer ☐ Other anticancer indication ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Prior Radiotherapy (CAPRXR)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: ON2505 2025-05-07)

Has cancer therapy been previous/current/post withdrawn of IP?	Previous ■ Current (non-study intervention) ☐ Post ☐
Was radiotherapy performed?	No ☐ Yes ☐
If Yes, specify below	
Concomitant chemoradiotherapy	No ☐ Yes ☐
Treatment setting	Adjuvant ☐ Neo-Adjuvant ☐ Palliative ☐ Other ☐
If Other, specify	_____
Number of sites/regions treated simultaneously	_____
Radiotherapy site/region treated location	Lung - Lower Lobe ☐ Lung - Middle Lobe ☐ Lung - Upper Lobe ☐ Bone ☐ Liver ☐ Brain ☐ Spinal Cord ☐ Pleura ☐ Skin ☐ Adrenal Gland ☐ Pelvic Bone ☐ Regional Lymph Node ☐ Distant Lymph Node ☐ Gallbladder ☐ Biliary Tract ☐ Other ☐
If Other, specify	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Screening (Day-28 to -1)
Form: Prior Radiotherapy (CAPRXR)
Generated On: 2025 Nov 20 12:27 (GMT)

Radiotherapy site/region laterality	Right ☐ Left ☐ Bilateral ☐ Not applicable ☐
Radiotherapy technique	3-D conformal ☐ Intensity modulated radiotherapy (IMRT) ☐ Stereotactic intracranial radiotherapy ☐ Stereotactic body radiotherapy (SBRT) ☐ Stereotactic radiosurgery (SRS) ☐ Whole brain radiotherapy (WBRT) ☐ Selective Internal Radiotherapy (SIRT) ☐ Other ☐
If Other, specify	_____
Radiotherapy start date	Fixed Unit: yyyy mon dd _____
Radiotherapy stop date	Fixed Unit: yyyy mon dd _____
Dose per fraction	_____
Dose per fraction unit	Gy ☐ Other ☐
If Other, specify	_____
Number of fraction doses	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Rescreening
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)	
Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

(Version: AZ2309 2023-09-14)

What was the Protocol milestone?	Main Informed Consent
What was the main informed consent date?	Fixed Unit: yyyy mon dd

What was the Protocol milestone?	Optional Consent
Optional consent category	Participation to Optional Blood Tests ●
	Optional services and the transfer of contact details to service providers ☐
	Use of coded data (including images), biosamples and analysis of genetic information as required for future research ☐
	Participation to Optional Biopsy at first day of Cycle 3 of study treatment ☐
	Participation to Optional Biopsy at Cancer Progression ☐
Optional consent/assent obtained	No ☐
	Yes ☐
	Not applicable ☐
Optional consent date	Fixed Unit: yyyy mon dd

Optional consent category	
	Participation to Optional Blood Tests ☐
	Optional services and the transfer of contact details to service providers ☐
	Use of coded data (including images), biosamples and analysis of genetic information as required for future research ☐

	Participation to Optional Biopsy at first day of Cycle 3 of study treatment ■ Participation to Optional Biopsy at Cancer Progression ☐
Optional consent/assent obtained	No ☐ Yes ☐ Not applicable ☐
Optional consent date	Fixed Unit: yyyy mon dd
Optional consent category	Participation to Optional Blood Tests ☐ Optional services and the transfer of contact details to service providers ☐ Use of coded data (including images), biosamples and analysis of genetic information as required for future research ☐ Participation to Optional Biopsy at first day of Cycle 3 of study treatment ☐ Participation to Optional Biopsy at Cancer Progression ■
Optional consent/assent obtained	No ☐ Yes ☐ Not applicable ☐
Optional consent date	Fixed Unit: yyyy mon dd
Optional consent category	Participation to Optional Blood Tests ☐ Optional services and the transfer of contact details to service providers ■

	Use of coded data (including images), biosamples and analysis of genetic information as required for future research ☐ Participation to Optional Biopsy at first day of Cycle 3 of study treatment ☐ Participation to Optional Biopsy at Cancer Progression ☐
Optional consent/assent obtained	No ☐ Yes ☐ Not applicable ☐
Optional consent date	Fixed Unit: yyyy mon dd

Optional consent category	Participation to Optional Blood Tests ☐ Optional services and the transfer of contact details to service providers ☐ Use of coded data (including images), biosamples and analysis of genetic information as required for future research ■ Participation to Optional Biopsy at first day of Cycle 3 of study treatment ☐ Participation to Optional Biopsy at Cancer Progression ☐
Optional consent/assent obtained	No ☐ Yes ☐ Not applicable ☐
Optional consent date	Fixed Unit: yyyy mon dd

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Rescreening
Form: Informed Consent - Genomics Initiative (ICFGEN)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-06)

What was the Protocol milestone?	Genomics Initiative Informed Consent
What was the genomics initiative informed consent date?	Fixed Unit: yyyy mon dd
Optional genomics initiative consent	Use of coded data and biosamples for optional multi-omics research including the analyses of genomic information
Optional consent/assent obtained	No ☐ Yes ☐ Not applicable ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Rescreening
Form: Inclusion/Exclusion Criteria Not Met (IE)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2506 2025-06-30)

Were all eligibility criteria met?	No ☐
	Yes ☐
	Not applicable ☐

If No, record Exception criterion identifier for each Criterion type that was not met.

Criterion type	Exclusion ☐
	Inclusion ☐
Exception criterion identifier	_____
Exception criterion identifier	_____
What was the Protocol version?	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Rescreening
Form: Assessment(s) Performed Triggering Form (ASMTRIG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2402 2024-02-16)

Select 'Yes' if all assessment forms are to be triggered	Yes ☐

Assessment(s) type	Extent of Disease Upon Entry to Study (DISEXT) ☐
	Pathology: at Screening (PATHGOM) ☐
	General Medical History (1MH) ☐
	Pre-specified medical conditions or events (2MH) ☐
	Surgical History (HISS) ☐
	Physical Examination (PE) ☐
	Vital Signs - Weight, Height (VS) ☐
	Vital Signs - Before Infusion (VS1) ☐
	Vital Signs - End of Infusion (VS2) ☐
	Vital Signs - Excluding Weight (VS3) ☐
	Vital Signs (VS4) ☐
	ECOG Performance Status (ECOG) ☐
	ECG Test Results (EG) ☐
	Additional ECG (EG1) ☐
	Additional ECG (EG2) ☐
	Echocardiography (ECHOC) ☐
	Non-central Laboratory Test Results - Chemistry (LB) ☐
	Non-central Laboratory Test Results - Hematology (LB1) ☐
	Non-central Laboratory Test Results - Coagulation (LB2) ☐
	Non-central Laboratory Test Results - Thyroid function test (LB3) ☐

- ☐ Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
- ☐ Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
- ☐ Non-central Laboratory Test Results - Urinalysis (LB6)
- ☐ Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
- ☐ Non-central Laboratory Test Results - Hy's Law (LB8)
- ☐ Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
- ☐ Non-central Laboratory Test Results - Tuberculosis testing (LB10)
- ☐ Non-central Laboratory Test Results - HIV testing (LB11)
- ☐ Non-central Laboratory Test Results - Additional Chemistry (LB12)
- ☐ Sample Collection, Predose_ADA Sample (SPCBEDB)
- ☐ Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
- ☐ PBMC for immune profiling_Pre dose (SPCBEDB2)
- ☐ Whole blood for RNA analysis_Pre-dose (SPCBEDB3)
- ☐ Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)

	Sample Collection, ADA Sample (SPCBEDB5) ☐
	Blood sample for plasma ctDNA (SPCBEDB6) ☐
	Optional on study tumor sample at recurrence (SPCBEDT) ☐
	Mandatory tumor sample from surgical resection for PDL1 analysis (SPCBEDT1) ☐
	Biological Sample Collection, Pre-dose PK (SPCPKB) ☐
	Biological Sample Collection, Post-dose PK (SPCPKB1) ☐
	Biological Sample Collection, PK (SPCPKB2) ☐
	Substance Use - Nicotine (SU_NIC) ☐
	Substance Use - Alcohol (SU_ALC) ☐
	Prior Cancer Therapy (CAPRX) ☐
	Prior Radiotherapy (CAPRXR) ☐
	Survival Status (SURVIVE) ☐
Assessment form to be triggered	No ☐
	Yes ☐
Reason assessment form is not to be triggered	Assessment not performed ☐
	Assessment not required ☐
	Subject discontinuation ☐
	Screen failure ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Rescreening
Form: Physical Examination (PE)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ1609 2019-04-19)

For baseline: Following items should be checked during baseline physical examination (A full physical examination will be performed and include assessments of the following: general appearance, respiratory, cardiovascular system, abdomen, skin, head and neck (including ears, eyes, nose, and throat), lymph nodes, thyroid, musculoskeletal (including spine and extremities), urogenital, dermatological, gastrointestinal, endocrine, hematologic/lymphatic, and neurological systems.).

For follow-up: Following items should be checked during follow-up physical examination (A targeted physical examination will include, at a minimum, assessments of skin, lungs, cardiovascular system, and abdomen (liver and spleen).

If the physical finding started prior to enrolment, it must be recorded as medical history.
If the physical finding started or worsened after enrolment, it must be recorded as an Adverse Event.

Was the physical examination performed?	No ☐ Yes ☐
What was the date of the physical examination?	Fixed Unit: yyyy mon dd

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Rescreening
Form: Vital Signs - Weight, Height (VS)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd
Time	Fixed Unit: 24-hour clock
Pulse	Fixed Unit: beats/min
SBP	Fixed Unit: mmHg
DBP	Fixed Unit: mmHg
Respiration rate	Fixed Unit: breaths/min
Temperature	
Temperature unit	C ●
Peripheral oxygen saturation	Fixed Unit: %
Weight	
Weight unit	kg ●
Height	
Height unit	cm ●
EHRID	

(Version: ON2406 2024-06-04)

Clinical classification category	ECOG
What was the date the response or clinical classification was performed?	Fixed Unit: yyyy mon dd
Performance status	0-Fully active, able to carry on all pre-disease performance without restriction ☐ 1-Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work ☐ 2-Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours ☐ 3-Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours ☐ 4-Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair ☐ 5-Dead ☐

Ref: Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55). WHO Ref: World Health Organization (1979).Handbook for Reporting Results of Cancer Treatment Pb (WHO Offset Publications).

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Rescreening
Form: ECG Test Results (EG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2112 2024-08-09)

Was the ECG performed?	No ☐ Yes ☐
What was the date of the ECG?	Fixed Unit: yyyy mon dd
ECG time	Fixed Unit: 24-hour clock
ECG mean heart rate	Fixed Unit: beats/min
QRS duration	Fixed Unit: ms
RR interval	Fixed Unit: ms
PR interval	Fixed Unit: ms
QT interval	Fixed Unit: ms
QTc interval Fridericia	Fixed Unit: ms
What was the interpretation of the ECG?	Normal ☐ Abnormal ☐
Reason, abnormal overall ECG evaluation	
Was the ECG clinically significant?	No ☐ Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Rescreening
Form: Additional ECG (EG1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2112 2024-08-09)

Was the ECG performed?	No ☐ Yes ☐
What was the date of the ECG?	Fixed Unit: yyyy mon dd
ECG time	Fixed Unit: 24-hour clock
ECG mean heart rate	Fixed Unit: beats/min
QRS duration	Fixed Unit: ms
RR interval	Fixed Unit: ms
PR interval	Fixed Unit: ms
QT interval	Fixed Unit: ms
QTc interval Fridericia	Fixed Unit: ms
What was the interpretation of the ECG?	Normal ☐ Abnormal ☐
Reason, abnormal overall ECG evaluation	
Was the ECG clinically significant?	No ☐ Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Rescreening
Form: Additional ECG (EG2)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2112 2024-08-09)

Was the ECG performed?	No ☐ Yes ☐
What was the date of the ECG?	Fixed Unit: yyyy mon dd
ECG time	Fixed Unit: 24-hour clock
ECG mean heart rate	Fixed Unit: beats/min
QRS duration	Fixed Unit: ms
RR interval	Fixed Unit: ms
PR interval	Fixed Unit: ms
QT interval	Fixed Unit: ms
QTc interval Fridericia	Fixed Unit: ms
What was the interpretation of the ECG?	Normal ☐ Abnormal ☐
Reason, abnormal overall ECG evaluation	
Was the ECG clinically significant?	No ☐ Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Rescreening
Form: Echocardiography (ECHOC)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2201 2024-09-27)

What was the date of the echocardiography?	Fixed Unit: yyyy mon dd
What was the time of the echocardiography?	Fixed Unit: 24-hour clock
What was the method used for the examination?	Echocardiography ☐ Multiple Gated Acquisition (MUGA) ☐
Was the image quality sufficient?	No ☐ Yes ☐
What was the overall ECHOC evaluation?	Normal ☐ Abnormal ☐
What is the reason the overall ECHOC evaluation was abnormal?	
What was the left ventricular ejection fraction?	Fixed Unit: %
What was the LV end diastolic volume?	Fixed Unit: mL
What was the LV end systolic volume?	Fixed Unit: mL

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Rescreening
Form: Pregnancy Test - Screening (PREG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2008 2024-03-01)

Assessment applicable for Subject — No ☐ Yes ☐

Sampling date — Fixed Unit: yyyy mon dd

Pregnancy test (serum) — Negative ☐ Positive ☐

For a positive pregnancy test after first dose of study drug, fill in PREGREP (or the 'Pregnancy Outcome Report Form' [Part 1]) and send to the AstraZeneca Monitor.

If positive pregnancy test, the administration of study drug to that Subject must be discontinued immediately and the End of Study Treatment form (ETRT) filled in.

If Positive pregnancy test, and considered an AE, please fill in Adverse Event (AE) Form
(Pregnancy itself is not regarded as an adverse event unless there is a suspicion that AstraZeneca product may have interfered with the effectiveness of a contraceptive medication.)

Hidden Field (used for CF programming)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Rescreening
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Liver Function Tests Alanine Aminotransferase (Serum/Plasma)	_____
Alkaline Phosphatase (Serum/Plasma)	_____
Aspartate Aminotransferase (Serum/Plasma)	_____
Bilirubin, Total (Serum/Plasma)	_____
Bilirubin, Direct, (Conj) (Serum/Plasma)	_____
Bilirubin, Indirect (Unconj.) (Serum/Plasma)	_____
Gamma-Glutamyltransferase (Serum/Plasma)	_____
Lactate Dehydrogenase (LDH) (Serum/Plasma)	_____
Protein, Total (Serum/Plasma)	_____
Pancreatic Enzymes Amylase (Serum/Plasma)	_____
Lipase (Serum/Plasma)	_____
Renal Function Tests Creatinine (Serum/Plasma)	_____
Creatinine Clearance, Calculated (Urine 24h)	_____
Creatinine Clearance, Cockcroft-Gault (Plasma)	_____
Creatinine Clearance, Cockcroft-Gault (Serum)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Plasma)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Serum)	_____

Lab Name:	
Urea (Serum/Plasma)	
Urea Nitrogen (BUN) (Serum/Plasma)	
Electrolytes Calcium, Ionized (Serum)	
Total Calcium (Serum/Plasma)	
Chloride (Serum/Plasma)	
Magnesium (Serum/Plasma)	
Phosphate (Phosphorus) (Serum/Plasma)	
Potassium (Serum/Plasma)	
Sodium (Serum/Plasma)	
Proteins Albumin (Serum/Plasma)	
Glucose Metabolism Glucose, Fasting (Serum/Plasma)	
Glucose,Random (Serum/Plasma)	
Hidden for Bilirubin	
Hidden for Aspartate	
Hidden for Alanine	
Hidden for Alanine Range	
Hidden for Asparate Range	
Hidden for Bilirubin Range	
Derived field to call CF	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Rescreening
Form: Non-central Laboratory Test Results - Hematology (LB1)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ■ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hemoglobin (Blood)	_____
Hematocrit (Blood)	_____
Leucocytes, Absolute Count (WBC) (Blood)	_____
Platelet count (Blood)	_____
Mean corpuscular volume (Blood)	_____
Absolute Neutrophil Count (Blood)	_____
Absolute Lymphocytes Count (Blood)	_____
Absolute Monocytes Count (Blood)	_____
Absolute Eosinophils,Count (Blood)	_____
Neutrophils, %/Ratio (Blood)	_____
Lymphocytes, %/Ratio (Blood)	_____
Monocytes, %/Ratio (Blood)	_____
Eosinophils, % /Ratio (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Rescreening
Form: Non-central Laboratory Test Results - Coagulation (LB2)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ■ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock
Activated Partial Thromboplastin Time (APTT) (sec) (Blood)	
Activated Partial Thromboplast. Time,Rel (APTT relative) (%, ratio) (Blood)	
Fibrinogen (Blood)	
Partial Thromboplastin Time (PTT) (sec) (Blood)	
Partial Thromboplastin Time, Rel (PTT Relative) (%, ratio) (Blood)	
Prothrombin Complex INR (Blood) (%,ratio) (Blood)	
Prothrombin Time (PT) (sec) (Blood)	
Prothrombin Time, Relative (PT Relative) (%, ratio) (Blood)	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Rescreening
Form: Non-central Laboratory Test Results - Thyroid function test (LB3)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Thyroid Stimulating Hormone(Serum/Plasma)	_____
T4 (Thyroxine), Free(Serum/Plasma)	_____
T3 (Triiodothyronine), Free(Serum/Plasma)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Rescreening
Form: Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Creatine Kinase (Serum/Plasma)	_____
Troponin T (Serum/Plasma)	_____
Troponin I (Serum/Plasma)	_____
High- sensitivity Troponin T (Serum/Plasma)	_____
High- sensitivity Troponin I (Serum/Plasma)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Rescreening
Form: Non-central Laboratory Test Results - Urinalysis (LB6)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ■ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Albumin, Strip, Qual (Urine)	Negative ☐ Trace ☐ Positive ☐ + ☐ ++ ☐ +++ ☐ >+++ ☐ +- ☐
Bilirubin, Strip, Qual (Urine)	Negative ☐ Trace ☐ Positive ☐ + ☐ ++ ☐ +++ ☐ >+++ ☐ +- ☐
Blood, Qual (Urine)	Negative ☐ Trace ☐

	Positive ☐
	+ ☐
	++ ☐
	+++ ☐
	>+++ ☐
	+- ☐
Glucose, Strip, Qual (Urine)	Negative ☐
	Trace ☐
	Positive ☐
	+ ☐
	++ ☐
	+++ ☐
	>+++ ☐
	+- ☐
Ketone Bodies, Strip, Qual (Urine)	Negative ☐
	Trace ☐
	Positive ☐
	+ ☐
	++ ☐
	+++ ☐
	>+++ ☐
	+- ☐
Protein, Strip, Qual (Urine)	Negative ☐
	Trace ☐
	Positive ☐
	+ ☐
	++ ☐
	+++ ☐
	>+++ ☐
	+- ☐
Appearance (Qual) (Urine)	_____
Color (Qual) (Urine)	_____

Lab Name:	
Albumin, Quant (Urine)	
Bilirubin, Quant(Urine)	
Glucose, Random, Quant (Urine)	
Ketone Bodies, Quant (Urine)	
Protein, Total, Quant (Urine)	
Urine-Blood, Quant (Urine)	
pH (Urine)	
Specific Gravity (Urine)	
Sediment, Erythrocytes, Quant (no/vis fld) (Urine)	
Sediment, Leucocytes, Quant (no/vis fld) (Urine)	
Leucocytes, Quant (10**6/L) (Volume) (Urine)	
Erythrocytes, Quant (1/uL) (Volume) (Urine)	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Rescreening
Form: Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ■
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hepatitis B Surface Antigen (Qual) (HBsAg) (Blood)	Negative ☐ Positive ☐ +-borderline ☐
Hepatitis B Surface Antibody (HBsAb) (Blood)	Negative ☐ Positive ☐ +-borderline ☐
Hepatitis B Core Antibody, Qual (anti-HBc) (Blood)	Negative ☐ Positive ☐ +-borderline ☐
Hepatitis C Antibody (HCV ab) (Blood)	Negative ☐ Positive ☐ +-borderline ☐
Hepatitis D Antibody (Blood)	Negative ☐ Positive ☐ +-borderline ☐
Hepatitis B Viral Load, Quant (IU/mL) (Blood)	_____
Hepatitis B Viral Load, Quant (DNA copies/mL) (Blood)	_____
Hepatitis C Viral Load, Quant (IU/mL) (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Rescreening
Form: Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

Hepatitis C Viral Load, Quant (RNA copies/mL) (Blood)	_____
Hepatitis D Virus RNA, Quant (Serum/Plasma)	_____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ■
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock
Culture, Mycobacterium Tuberculosis(Sputum)	Negative ☐ Positive ☐ +-borderline ☐
Quantiferon Tuberculosis Gold (Plasma)	Negative ☐ Positive ☐ +-borderline ☐
Quantiferon Tuberculosis Gold (Blood)	Negative ☐ Positive ☐ +-borderline ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Rescreening
Form: Non-central Laboratory Test Results - HIV testing (LB11)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ■
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
HIV-1/2 Antibody Screen (Blood)	Negative ☐ Positive ☐ +-borderline ☐
HIV Viral Load, Quant, PCR (Blood)	_____
CD4+, abs(cells/uL) (Blood)	_____

(Version: AZ2310 2025-07-01)

What was the sample collection category?	Biomarkers/exploratory research/diagnostic, solid tissue
Sample collected	No
	Yes
Sample collection method	Core Needle Biopsy
	Excisional Biopsy
	Incisional Biopsy
Biopsy tissue type	Primary tumor
	Metastatic tumor
Organ	Abdomen
	Bronchus (Main Stem)
	Fat
	Oesophagus
	Pituitary
	Urinary Bladder
	Esophagogastric Junction
	Hypopharynx
	Duodenum
	Cervix Uteri
	Epididymis
	Gallbladder
	Large Intestine
	Appendix
	Colon
	Small Intestine
	Ileum
	Jejunum
	Rectum
	Stomach
	Liver
	Pancreas

Thyroid Gland ☐
Fallopian Tube ☐
Ovary ☐
Uterus ☐
Prostate Gland ☐
Testis ☐
Kidney ☐
Ureter ☐
Urethra ☐
Larynx ☐
Oral Cavity ☐
Tongue ☐
Pharynx ☐
Parotid Gland ☐
Trachea ☐
Spleen ☐
Thymus Gland ☐
Brain ☐
Spinal Cord ☐
Lung ☐
Pleura ☐
Skin ☐
Soft Tissue ☐
Abdominal Cavity ☐
Adrenal Gland ☐
Diaphragm ☐
Heart ☐
Lymph Node ☐
Nose ☐
Oropharynx ☐
Parathyroid Gland ☐
Peripheral Nerve ☐
Peritoneum ☐

	Tonsil ☐
	Breast ☐
	Joint ☐
	Muscle ☐
	Gastroesophageal Junction ☐
	Mesentery ☐
	Omentum ☐
	Anus ☐
	Abdominal Wall ☐
	Other (Not Specified) ☐
Sample format	FFPE block ☐
	FFPE unstained slides ☐
Unstained slides sectioning date	Fixed Unit: yyyy mon dd
Date of Biopsy	Fixed Unit: yyyy mon dd
Sample condition	Sample acceptable ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Date of storage	Fixed Unit: yyyy mon dd
Time of storage	Fixed Unit: 24-hour clock
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 01
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)

Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 01
Form: Inclusion/Exclusion Criteria Not Met - Randomization (IE1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2506 2025-06-30)

Were all eligibility criteria met?	No ☐
	Yes ☐
	Not applicable ☐

If Yes, complete Randomization details

If No, record Exception criterion identifier for each Criterion type that was not met.

Criterion type	Exclusion ☐
	Inclusion ☐
Exception criterion identifier	_____
Exception criterion identifier	_____
What was the Protocol version?	_____
Was Subject allocated a randomization code?	No ☐
	Yes ☐

If No, discontinue/withdraw Subject and fill in study disposition (termination) form

If Yes, randomization code	_____
What was the randomization date?	Fixed Unit: yyyy mon dd
	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 01
Form: Group (GROUP)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2008 2020-08-05)

What was the group allocation?	Experimental arm (Rilvegostomig) ☐ Control arm (Durvalumab) ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 01
Form: Assessment(s) Performed Triggering Form (ASMTRIG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2402 2024-02-16)

Select 'Yes' if all assessment forms are to be triggered	Yes ☐
Assessment(s) type	Extent of Disease Upon Entry to Study (DISEXT) ☐
	Pathology: at Screening (PATHGOM) ☐
	General Medical History (1MH) ☐
	Pre-specified medical conditions or events (2MH) ☐
	Surgical History (HISS) ☐
	Physical Examination (PE) ☐
	Vital Signs - Weight, Height (VS) ☐
	Vital Signs - Before Infusion (VS1) ☐
	Vital Signs - End of Infusion (VS2) ☐
	Vital Signs - Excluding Weight (VS3) ☐
	Vital Signs (VS4) ☐
	ECOG Performance Status (ECOG) ☐
	ECG Test Results (EG) ☐
	Additional ECG (EG1) ☐
	Additional ECG (EG2) ☐
	Echocardiography (ECHOC) ☐
	Non-central Laboratory Test Results - Chemistry (LB) ☐
	Non-central Laboratory Test Results - Hematology (LB1) ☐
	Non-central Laboratory Test Results - Coagulation (LB2) ☐
	Non-central Laboratory Test Results - Thyroid function test (LB3) ☐

- ☐ Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
- ☐ Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
- ☐ Non-central Laboratory Test Results - Urinalysis (LB6)
- ☐ Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
- ☐ Non-central Laboratory Test Results - Hy's Law (LB8)
- ☐ Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
- ☐ Non-central Laboratory Test Results - Tuberculosis testing (LB10)
- ☐ Non-central Laboratory Test Results - HIV testing (LB11)
- ☐ Non-central Laboratory Test Results - Additional Chemistry (LB12)
- ☐ Sample Collection, Predose_ADA Sample (SPCBEDB)
- ☐ Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
- ☐ PBMC for immune profiling_Pre dose (SPCBEDB2)
- ☐ Whole blood for RNA analysis_Pre-dose (SPCBEDB3)
- ☐ Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)

	Sample Collection, ADA Sample (SPCBEDB5) ☐
	Blood sample for plasma ctDNA (SPCBEDB6) ☐
	Optional on study tumor sample at recurrence (SPCBEDT) ☐
	Mandatory tumor sample from surgical resection for PDL1 analysis (SPCBEDT1) ☐
	Biological Sample Collection, Pre-dose PK (SPCPKB) ☐
	Biological Sample Collection, Post-dose PK (SPCPKB1) ☐
	Biological Sample Collection, PK (SPCPKB2) ☐
	Substance Use - Nicotine (SU_NIC) ☐
	Substance Use - Alcohol (SU_ALC) ☐
	Prior Cancer Therapy (CAPRX) ☐
	Prior Radiotherapy (CAPRXR) ☐
	Survival Status (SURVIVE) ☐
Assessment form to be triggered	No ☐
	Yes ☐
Reason assessment form is not to be triggered	Assessment not performed ☐
	Assessment not required ☐
	Subject discontinuation ☐
	Screen failure ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 01
Form: Physical Examination (PE)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ1609 2019-04-19)

For baseline: Following items should be checked during baseline physical examination (A full physical examination will be performed and include assessments of the following: general appearance, respiratory, cardiovascular system, abdomen, skin, head and neck (including ears, eyes, nose, and throat), lymph nodes, thyroid, musculoskeletal (including spine and extremities), urogenital, dermatological, gastrointestinal, endocrine, hematologic/lymphatic, and neurological systems.).

For follow-up: Following items should be checked during follow-up physical examination (A targeted physical examination will include, at a minimum, assessments of skin, lungs, cardiovascular system, and abdomen (liver and spleen).

If the physical finding started prior to enrolment, it must be recorded as medical history.
If the physical finding started or worsened after enrolment, it must be recorded as an Adverse Event.

Was the physical examination performed?	No ☐ Yes ☐
What was the date of the physical examination?	Fixed Unit: yyyy mon dd

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 01
Form: Vital Signs - Before Infusion (VS1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd
Protocol schedule	Prior to Infusion
Time	Fixed Unit: 24-hour clock
Pulse	Fixed Unit: beats/min
SBP	Fixed Unit: mmHg
DBP	Fixed Unit: mmHg
Respiration rate	Fixed Unit: breaths/min
Temperature	
Temperature unit	C ●
Peripheral oxygen saturation	Fixed Unit: %
Weight	
Weight unit	kg ●
EHRID	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 01
Form: Vital Signs - End of Infusion (VS2)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd
Protocol schedule	End of Infusion
Time	Fixed Unit: 24-hour clock
Pulse	Fixed Unit: beats/min
SBP	Fixed Unit: mmHg
DBP	Fixed Unit: mmHg
Respiration rate	Fixed Unit: breaths/min
Temperature	
Temperature unit	C
Peripheral oxygen saturation	Fixed Unit: %
EHRID	

(Version: ON2406 2024-06-04)

Clinical classification category	ECOG
What was the date the response or clinical classification was performed?	Fixed Unit: yyyy mon dd
Performance status	0-Fully active, able to carry on all pre-disease performance without restriction ☐ 1-Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work ☐ 2-Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours ☐ 3-Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours ☐ 4-Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair ☐ 5-Dead ☐

Ref: Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55). WHO Ref: World Health Organization (1979).Handbook for Reporting Results of Cancer Treatment Pb (WHO Offset Publications).

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 01
Form: ECG Test Results (EG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2112 2024-08-09)

Was the ECG performed?	No ☐ Yes ☐
What was the date of the ECG?	Fixed Unit: yyyy mon dd
ECG time	Fixed Unit: 24-hour clock
ECG mean heart rate	Fixed Unit: beats/min
QRS duration	Fixed Unit: ms
RR interval	Fixed Unit: ms
PR interval	Fixed Unit: ms
QT interval	Fixed Unit: ms
QTc interval Fridericia	Fixed Unit: ms
What was the interpretation of the ECG?	Normal ☐ Abnormal ☐
Reason, abnormal overall ECG evaluation	
Was the ECG clinically significant?	No ☐ Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 01
Form: Pregnancy Test (PREG1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2008 2024-03-01)

Assessment applicable for Subject — No ☐ Yes ☐

Sampling date — Fixed Unit: yyyy mon dd

Pregnancy test (serum) — Negative ☐ Positive ☐

Pregnancy test (urine) — Negative ☐ Positive ☐

For a positive pregnancy test after first dose of study drug, fill in PREGREP (or the 'Pregnancy Outcome Report Form' [Part 1]) and send to the AstraZeneca Monitor.

If positive pregnancy test, the administration of study drug to that Subject must be discontinued immediately and the End of Study Treatment form (ETRT) filled in.

If Positive pregnancy test, and considered an AE, please fill in Adverse Event (AE) Form
(Pregnancy itself is not regarded as an adverse event unless there is a suspicion that AstraZeneca product may have interfered with the effectiveness of a contraceptive medication.)

Hidden Field (used for CF programming)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 01
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Liver Function Tests Alanine Aminotransferase (Serum/Plasma)	_____
Alkaline Phosphatase (Serum/Plasma)	_____
Aspartate Aminotransferase (Serum/Plasma)	_____
Bilirubin, Total (Serum/Plasma)	_____
Bilirubin, Direct, (Conj) (Serum/Plasma)	_____
Bilirubin, Indirect (Unconj.) (Serum/Plasma)	_____
Gamma-Glutamyltransferase (Serum/Plasma)	_____
Lactate Dehydrogenase (LDH) (Serum/Plasma)	_____
Protein, Total (Serum/Plasma)	_____
Pancreatic Enzymes Amylase (Serum/Plasma)	_____
Lipase (Serum/Plasma)	_____
Renal Function Tests Creatinine (Serum/Plasma)	_____
Creatinine Clearance, Calculated (Urine 24h)	_____
Creatinine Clearance, Cockcroft-Gault (Plasma)	_____
Creatinine Clearance, Cockcroft-Gault (Serum)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Plasma)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Serum)	_____

Lab Name:	
Urea (Serum/Plasma)	
Urea Nitrogen (BUN) (Serum/Plasma)	
Electrolytes Calcium, Ionized (Serum)	
Total Calcium (Serum/Plasma)	
Chloride (Serum/Plasma)	
Magnesium (Serum/Plasma)	
Phosphate (Phosphorus) (Serum/Plasma)	
Potassium (Serum/Plasma)	
Sodium (Serum/Plasma)	
Proteins Albumin (Serum/Plasma)	
Glucose Metabolism Glucose, Fasting (Serum/Plasma)	
Glucose,Random (Serum/Plasma)	
Hidden for Bilirubin	
Hidden for Aspartate	
Hidden for Alanine	
Hidden for Alanine Range	
Hidden for Asparate Range	
Hidden for Bilirubin Range	
Derived field to call CF	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 01
Form: Non-central Laboratory Test Results - Hematology (LB1)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ■ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hemoglobin (Blood)	_____
Hematocrit (Blood)	_____
Leucocytes, Absolute Count (WBC) (Blood)	_____
Platelet count (Blood)	_____
Mean corpuscular volume (Blood)	_____
Absolute Neutrophil Count (Blood)	_____
Absolute Lymphocytes Count (Blood)	_____
Absolute Monocytes Count (Blood)	_____
Absolute Eosinophils,Count (Blood)	_____
Neutrophils, %/Ratio (Blood)	_____
Lymphocytes, %/Ratio (Blood)	_____
Monocytes, %/Ratio (Blood)	_____
Eosinophils, % /Ratio (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 01
Form: Non-central Laboratory Test Results - Coagulation (LB2)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ■ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Activated Partial Thromboplastin Time (APTT) (sec) (Blood)	_____
Activated Partial Thromboplast. Time,Rel (APTT relative) (%, ratio) (Blood)	_____
Fibrinogen (Blood)	_____
Partial Thromboplastin Time (PTT) (sec) (Blood)	_____
Partial Thromboplastin Time, Rel (PTT Relative) (%, ratio) (Blood)	_____
Prothrombin Complex INR (Blood) (%,ratio) (Blood)	_____
Prothrombin Time (PT) (sec) (Blood)	_____
Prothrombin Time, Relative (PT Relative) (%, ratio) (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 01
Form: Non-central Laboratory Test Results - Thyroid function test (LB3)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Thyroid Stimulating Hormone(Serum/Plasma)	_____
T4 (Thyroxine), Free(Serum/Plasma)	_____
T3 (Triiodothyronine), Free(Serum/Plasma)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 01
Form: Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock
Creatine Kinase (Serum/Plasma)	
Troponin T (Serum/Plasma)	
Troponin I (Serum/Plasma)	
High- sensitivity Troponin T (Serum/Plasma)	
High- sensitivity Troponin I (Serum/Plasma)	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 01
Form: Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Carcinoembryonic Antigen (Serum/Plasma) (ng/mL)	_____
Carbohydrate Antigen 19-9 (Serum) (U/mL)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 01
Form: Non-central Laboratory Test Results - Hepatitis B and C testing - Post Screening (LB13)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ■
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hepatitis B Viral Load, Quant (IU/mL) (Blood)	_____
Hepatitis B Viral Load, Quant (DNA copies/mL) (Blood)	_____
Hepatitis C Viral Load, Quant (IU/mL) (Blood)	_____
Hepatitis C Viral Load, Quant (RNA copies/mL) (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 01
Form: Sample Collection, Predose_ADA Sample (SPCBEDB)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ☐
	cfDNA-BCT ☐
	Blood ■
Biofluid processed	PBMC ☐
	Blood ☐
	Serum ■
	Plasma ☐
Sample format	DNA ☐
	Fresh ☐
	Frozen ■
	RNA ☐
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Protocol schedule	Pre Dose
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 01
Form: Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ☐
	cfDNA-BCT ■
	Blood ☐
Biofluid processed	PBMC ☐
	Blood ☐
	Serum ☐
	Plasma ■
Sample format	DNA ■
	Fresh ☐
	Frozen ☐
	RNA ☐
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Protocol schedule	Pre Dose
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 01
Form: PBMC for immune profiling_Pre dose (SPCBEDB2)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ■
	cfDNA-BCT ☐
	Blood ☐
Biofluid processed	PBMC ■
	Blood ☐
	Serum ☐
	Plasma ☐
Sample format	DNA ☐
	Fresh ■
	Frozen ☐
	RNA ☐
Date of collection	Fixed Unit: yyyy mon dd _____
Time of collection	Fixed Unit: 24-hour clock _____
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	_____
Protocol schedule	Pre Dose
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 01
Form: Whole blood for RNA analysis_Pre-dose (SPCBEDB3)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ☐
	cfDNA-BCT ☐
	Blood ■
Biofluid processed	PBMC ☐
	Blood ■
	Serum ☐
	Plasma ☐
Sample format	DNA ☐
	Fresh ☐
	Frozen ☐
	RNA ■
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Protocol schedule	Pre Dose
Laboratory ID	Labcorp ■

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ☐
	cfDNA-BCT ☐
	Blood ■
Biofluid processed	PBMC ☐
	Blood ☐
	Serum ■
	Plasma ☐
Sample format	DNA ☐
	Fresh ☐
	Frozen ■
	RNA ☐
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Protocol schedule	Pre Dose
Laboratory ID	Labcorp ■

(Version: AZ2310 2023-10-26)

Was assessment applicable?	No ☐
	Yes ☐
What was the sample category?	Genetics Inherited, Biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood ■
Sample format	Brushings ☐
	cDNA ☐
	Cell culture ☐
	Cells ☐
	Cells suspension ☐
	Cells microarray ☐
	cRNA ☐
	Cytospin ☐
	DNA ☐
	DNA microarray ☐
	FFPE ☐
	FFPE shavings ☐
	Formalin fixed ☐
	Fresh ☐
	Fresh frozen ☐
	Frozen ■
	H&E stained slide ☐
	IHC slide ☐
	Microarray ☐
	Microsomes ☐
	OCT embedded ☐
	Protein ☐
	Protein microarray ☐
	RNA ☐

	RNA microarray ☐
	Supernatant ☐
	Tissue microarray (TMA) ☐
	Unstained section ☐
	Cells frozen ☐
	Cells lysate ☐
	FFPE Block ☐
	FFPE Unstained slides ☐
Date of collection	Fixed Unit: yyyy mon dd
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Sample collection comment	
Date of storage	Fixed Unit: yyyy mon dd
Time of storage	Fixed Unit: 24-hour clock
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 01
Form: Biological Sample Collection, Pre-dose PK (SPCPKB)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample collection category?	PK, biofluid
Sample collected	No ☐ Yes ☐
Last investigational product date	Fixed Unit: yyyy mon dd
Last investigational product time	Fixed Unit: 24-hour clock
Biofluid collected (parent sample)	Blood
Biofluid processed	Serum
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐ Hemolyzed ☐ Clotted ☐ Lipemic ☐ Quantity less than expected ☐ Sample discarded ☐ Other ☐
If Other, specify	
Date of storage	Fixed Unit: yyyy mon dd
Time of storage	Fixed Unit: 24-hour clock
Protocol schedule	Pre Dose
Protocol schedule day	1
Protocol schedule hour	-99
Protocol schedule minute	-99
Laboratory ID	Labcorp

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 01
Form: Biological Sample Collection, Post-dose PK (SPCPKB1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample collection category?	PK, biofluid
Sample collected	No ☐ Yes ☐
Last investigational product date	Fixed Unit: yyyy mon dd
Last investigational product time	Fixed Unit: 24-hour clock
Biofluid collected (parent sample)	Blood
Biofluid processed	Serum
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐ Hemolyzed ☐ Clotted ☐ Lipemic ☐ Quantity less than expected ☐ Sample discarded ☐ Other ☐
If Other, specify	
Date of storage	Fixed Unit: yyyy mon dd
Time of storage	Fixed Unit: 24-hour clock
Protocol schedule	15 mins Post Dose
Protocol schedule day	1
Protocol schedule hour	0
Protocol schedule minute	15
Laboratory ID	Labcorp

Subject Continues to the Next Visit?	No ☐
	Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 08
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)	
Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 08
Form: Assessment(s) Performed Triggering Form (ASMTRIG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2402 2024-02-16)

Select 'Yes' if all assessment forms are to be triggered	Yes ☐
Assessment(s) type	Extent of Disease Upon Entry to Study (DISEXT) ☐
	Pathology: at Screening (PATHGOM) ☐
	General Medical History (1MH) ☐
	Pre-specified medical conditions or events (2MH) ☐
	Surgical History (HISS) ☐
	Physical Examination (PE) ☐
	Vital Signs - Weight, Height (VS) ☐
	Vital Signs - Before Infusion (VS1) ☐
	Vital Signs - End of Infusion (VS2) ☐
	Vital Signs - Excluding Weight (VS3) ☐
	Vital Signs (VS4) ☐
	ECOG Performance Status (ECOG) ☐
	ECG Test Results (EG) ☐
	Additional ECG (EG1) ☐
	Additional ECG (EG2) ☐
	Echocardiography (ECHOC) ☐
	Non-central Laboratory Test Results - Chemistry (LB) ☐
	Non-central Laboratory Test Results - Hematology (LB1) ☐
	Non-central Laboratory Test Results - Coagulation (LB2) ☐
	Non-central Laboratory Test Results - Thyroid function test (LB3) ☐

Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)

Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)

Non-central Laboratory Test Results - Urinalysis (LB6)

Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)

Non-central Laboratory Test Results - Hy's Law (LB8)

Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)

Non-central Laboratory Test Results - Tuberculosis testing (LB10)

Non-central Laboratory Test Results - HIV testing (LB11)

Non-central Laboratory Test Results - Additional Chemistry (LB12)

Sample Collection, Predose_ADA Sample (SPCBEDB)

Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)

PBMC for immune profiling_Pre dose (SPCBEDB2)

Whole blood for RNA analysis_Pre-dose (SPCBEDB3)

Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)

	Sample Collection, ADA Sample (SPCBEDB5) ☐
	Blood sample for plasma ctDNA (SPCBEDB6) ☐
	Optional on study tumor sample at recurrence (SPCBEDT) ☐
	Mandatory tumor sample from surgical resection for PDL1 analysis (SPCBEDT1) ☐
	Biological Sample Collection, Pre-dose PK (SPCPKB) ☐
	Biological Sample Collection, Post-dose PK (SPCPKB1) ☐
	Biological Sample Collection, PK (SPCPKB2) ☐
	Substance Use - Nicotine (SU_NIC) ☐
	Substance Use - Alcohol (SU_ALC) ☐
	Prior Cancer Therapy (CAPRX) ☐
	Prior Radiotherapy (CAPRXR) ☐
	Survival Status (SURVIVE) ☐
Assessment form to be triggered	No ☐
	Yes ☐
Reason assessment form is not to be triggered	Assessment not performed ☐
	Assessment not required ☐
	Subject discontinuation ☐
	Screen failure ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 08
Form: Vital Signs - Excluding Weight (VS3)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd
Time	Fixed Unit: 24-hour clock
Pulse	Fixed Unit: beats/min
SBP	Fixed Unit: mmHg
DBP	Fixed Unit: mmHg
Respiration rate	Fixed Unit: breaths/min
Temperature	
Temperature unit	C ●
Peripheral oxygen saturation	Fixed Unit: %
EHRID	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 08
Form: ECOG Performance Status (ECOG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: ON2406 2024-06-04)

Clinical classification category	ECOG
What was the date the response or clinical classification was performed?	Fixed Unit: yyyy mon dd
Performance status	0-Fully active, able to carry on all pre-disease performance without restriction ☐ 1-Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work ☐ 2-Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours ☐ 3-Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours ☐ 4-Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair ☐ 5-Dead ☐

Ref: Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55). WHO Ref: World Health Organization (1979).Handbook for Reporting Results of Cancer Treatment Pb (WHO Offset Publications).

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 08
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Liver Function Tests Alanine Aminotransferase (Serum/Plasma)	_____
Alkaline Phosphatase (Serum/Plasma)	_____
Aspartate Aminotransferase (Serum/Plasma)	_____
Bilirubin, Total (Serum/Plasma)	_____
Bilirubin, Direct, (Conj) (Serum/Plasma)	_____
Bilirubin, Indirect (Unconj.) (Serum/Plasma)	_____
Gamma-Glutamyltransferase (Serum/Plasma)	_____
Lactate Dehydrogenase (LDH) (Serum/Plasma)	_____
Protein, Total (Serum/Plasma)	_____
Pancreatic Enzymes Amylase (Serum/Plasma)	_____
Lipase (Serum/Plasma)	_____
Renal Function Tests Creatinine (Serum/Plasma)	_____
Creatinine Clearance, Calculated (Urine 24h)	_____
Creatinine Clearance, Cockcroft-Gault (Plasma)	_____
Creatinine Clearance, Cockcroft-Gault (Serum)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Plasma)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Serum)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 08
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

Urea (Serum/Plasma)	
Urea Nitrogen (BUN) (Serum/Plasma)	
Electrolytes Calcium, Ionized (Serum)	
Total Calcium (Serum/Plasma)	
Chloride (Serum/Plasma)	
Magnesium (Serum/Plasma)	
Phosphate (Phosphorus) (Serum/Plasma)	
Potassium (Serum/Plasma)	
Sodium (Serum/Plasma)	
Proteins Albumin (Serum/Plasma)	
Glucose Metabolism Glucose, Fasting (Serum/Plasma)	
Glucose,Random (Serum/Plasma)	
Hidden for Bilirubin	
Hidden for Aspartate	
Hidden for Alanine	
Hidden for Alanine Range	
Hidden for Asparate Range	
Hidden for Bilirubin Range	
Derived field to call CF	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 08
Form: Non-central Laboratory Test Results - Hematology (LB1)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ■ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hemoglobin (Blood)	_____
Hematocrit (Blood)	_____
Leucocytes, Absolute Count (WBC) (Blood)	_____
Platelet count (Blood)	_____
Mean corpuscular volume (Blood)	_____
Absolute Neutrophil Count (Blood)	_____
Absolute Lymphocytes Count (Blood)	_____
Absolute Monocytes Count (Blood)	_____
Absolute Eosinophils,Count (Blood)	_____
Neutrophils, %/Ratio (Blood)	_____
Lymphocytes, %/Ratio (Blood)	_____
Monocytes, %/Ratio (Blood)	_____
Eosinophils, % /Ratio (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 08
Form: PBMC for immune profiling_Pre dose (SPCBEDB2)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ●
Sample collected	No ○
	Yes ○
Sample collection method	Blood draw ●
Biofluid collected (parent sample)	Blood Na heparin ●
	cfDNA-BCT ○
	Blood ○
Biofluid processed	PBMC ●
	Blood ○
	Serum ○
	Plasma ○
Sample format	DNA ○
	Fresh ●
	Frozen ○
	RNA ○
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ○
	Hemolyzed ○
	Clotted ○
	Lipemic ○
	Quantity less than expected ○
	Sample discarded ○
	Other ○
If Other, specify	
Protocol schedule	Pre Dose
Laboratory ID	Labcorp ●

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ☐
	cfDNA-BCT ☐
	Blood ■
Biofluid processed	PBMC ☐
	Blood ■
	Serum ☐
	Plasma ☐
Sample format	DNA ☐
	Fresh ☐
	Frozen ☐
	RNA ■
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Protocol schedule	Pre Dose
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 01 Day 08
Form: Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ☐
	cfDNA-BCT ☐
	Blood ■
Biofluid processed	PBMC ☐
	Blood ☐
	Serum ■
	Plasma ☐
Sample format	DNA ☐
	Fresh ☐
	Frozen ■
	RNA ☐
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Protocol schedule	Pre Dose
Laboratory ID	Labcorp ■

Subject Continues to the Next Visit?	No ☐
	Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 02 Day 01
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)	
Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 02 Day 01
Form: Assessment(s) Performed Triggering Form (ASMTRIG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2402 2024-02-16)

Select 'Yes' if all assessment forms are to be triggered	Yes ☐
Assessment(s) type	Extent of Disease Upon Entry to Study (DISEXT) ☐
	Pathology: at Screening (PATHGOM) ☐
	General Medical History (1MH) ☐
	Pre-specified medical conditions or events (2MH) ☐
	Surgical History (HISS) ☐
	Physical Examination (PE) ☐
	Vital Signs - Weight, Height (VS) ☐
	Vital Signs - Before Infusion (VS1) ☐
	Vital Signs - End of Infusion (VS2) ☐
	Vital Signs - Excluding Weight (VS3) ☐
	Vital Signs (VS4) ☐
	ECOG Performance Status (ECOG) ☐
	ECG Test Results (EG) ☐
	Additional ECG (EG1) ☐
	Additional ECG (EG2) ☐
	Echocardiography (ECHOC) ☐
	Non-central Laboratory Test Results - Chemistry (LB) ☐
	Non-central Laboratory Test Results - Hematology (LB1) ☐
	Non-central Laboratory Test Results - Coagulation (LB2) ☐
	Non-central Laboratory Test Results - Thyroid function test (LB3) ☐

- ☐ Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
- ☐ Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
- ☐ Non-central Laboratory Test Results - Urinalysis (LB6)
- ☐ Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
- ☐ Non-central Laboratory Test Results - Hy's Law (LB8)
- ☐ Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
- ☐ Non-central Laboratory Test Results - Tuberculosis testing (LB10)
- ☐ Non-central Laboratory Test Results - HIV testing (LB11)
- ☐ Non-central Laboratory Test Results - Additional Chemistry (LB12)
- ☐ Sample Collection, Predose_ADA Sample (SPCBEDB)
- ☐ Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
- ☐ PBMC for immune profiling_Pre dose (SPCBEDB2)
- ☐ Whole blood for RNA analysis_Pre-dose (SPCBEDB3)
- ☐ Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)

	Sample Collection, ADA Sample (SPCBEDB5) ☐
	Blood sample for plasma ctDNA (SPCBEDB6) ☐
	Optional on study tumor sample at recurrence (SPCBEDT) ☐
	Mandatory tumor sample from surgical resection for PDL1 analysis (SPCBEDT1) ☐
	Biological Sample Collection, Pre-dose PK (SPCPKB) ☐
	Biological Sample Collection, Post-dose PK (SPCPKB1) ☐
	Biological Sample Collection, PK (SPCPKB2) ☐
	Substance Use - Nicotine (SU_NIC) ☐
	Substance Use - Alcohol (SU_ALC) ☐
	Prior Cancer Therapy (CAPRX) ☐
	Prior Radiotherapy (CAPRXR) ☐
	Survival Status (SURVIVE) ☐
Assessment form to be triggered	No ☐
	Yes ☐
Reason assessment form is not to be triggered	Assessment not performed ☐
	Assessment not required ☐
	Subject discontinuation ☐
	Screen failure ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 02 Day 01
Form: Physical Examination (PE)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ1609 2019-04-19)

For baseline: Following items should be checked during baseline physical examination (A full physical examination will be performed and include assessments of the following: general appearance, respiratory, cardiovascular system, abdomen, skin, head and neck (including ears, eyes, nose, and throat), lymph nodes, thyroid, musculoskeletal (including spine and extremities), urogenital, dermatological, gastrointestinal, endocrine, hematologic/lymphatic, and neurological systems.).

For follow-up: Following items should be checked during follow-up physical examination (A targeted physical examination will include, at a minimum, assessments of skin, lungs, cardiovascular system, and abdomen (liver and spleen).

If the physical finding started prior to enrolment, it must be recorded as medical history.
If the physical finding started or worsened after enrolment, it must be recorded as an Adverse Event.

Was the physical examination performed?	No ☐ Yes ☐
What was the date of the physical examination?	Fixed Unit: yyyy mon dd

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 02 Day 01
Form: Vital Signs - Before Infusion (VS1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd
Protocol schedule	Prior to Infusion
Time	Fixed Unit: 24-hour clock
Pulse	Fixed Unit: beats/min
SBP	Fixed Unit: mmHg
DBP	Fixed Unit: mmHg
Respiration rate	Fixed Unit: breaths/min
Temperature	
Temperature unit	C
Peripheral oxygen saturation	Fixed Unit: %
Weight	
Weight unit	kg
EHRID	

(Version: ON2406 2024-06-04)

Clinical classification category	ECOG
What was the date the response or clinical classification was performed?	Fixed Unit: yyyy mon dd
Performance status	0-Fully active, able to carry on all pre-disease performance without restriction ☐ 1-Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work ☐ 2-Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours ☐ 3-Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours ☐ 4-Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair ☐ 5-Dead ☐

Ref: Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55). WHO Ref: World Health Organization (1979).Handbook for Reporting Results of Cancer Treatment Pb (WHO Offset Publications).

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 02 Day 01
Form: Pregnancy Test (PREG1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2008 2024-03-01)

Assessment applicable for Subject	No ☐
	Yes ☐
Sampling date	Fixed Unit: yyyy mon dd
Pregnancy test (serum)	Negative ☐
	Positive ☐
Pregnancy test (urine)	Negative ☐
	Positive ☐

For a positive pregnancy test after first dose of study drug, fill in PREGREP (or the 'Pregnancy Outcome Report Form' [Part 1]) and send to the AstraZeneca Monitor.

If positive pregnancy test, the administration of study drug to that Subject must be discontinued immediately and the End of Study Treatment form (ETRT) filled in.

If Positive pregnancy test, and considered an AE, please fill in Adverse Event (AE) Form
(Pregnancy itself is not regarded as an adverse event unless there is a suspicion that AstraZeneca product may have interfered with the effectiveness of a contraceptive medication.)

Hidden Field (used for CF programming)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 02 Day 01
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Liver Function Tests Alanine Aminotransferase (Serum/Plasma)	_____
Alkaline Phosphatase (Serum/Plasma)	_____
Aspartate Aminotransferase (Serum/Plasma)	_____
Bilirubin, Total (Serum/Plasma)	_____
Bilirubin, Direct, (Conj) (Serum/Plasma)	_____
Bilirubin, Indirect (Unconj.) (Serum/Plasma)	_____
Gamma-Glutamyltransferase (Serum/Plasma)	_____
Lactate Dehydrogenase (LDH) (Serum/Plasma)	_____
Protein, Total (Serum/Plasma)	_____
Pancreatic Enzymes Amylase (Serum/Plasma)	_____
Lipase (Serum/Plasma)	_____
Renal Function Tests Creatinine (Serum/Plasma)	_____
Creatinine Clearance, Calculated (Urine 24h)	_____
Creatinine Clearance, Cockcroft-Gault (Plasma)	_____
Creatinine Clearance, Cockcroft-Gault (Serum)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Plasma)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Serum)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 02 Day 01
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:27 (GMT)

Lab Name:	
Urea (Serum/Plasma)	
Urea Nitrogen (BUN) (Serum/Plasma)	
Electrolytes Calcium, Ionized (Serum)	
Total Calcium (Serum/Plasma)	
Chloride (Serum/Plasma)	
Magnesium (Serum/Plasma)	
Phosphate (Phosphorus) (Serum/Plasma)	
Potassium (Serum/Plasma)	
Sodium (Serum/Plasma)	
Proteins Albumin (Serum/Plasma)	
Glucose Metabolism Glucose, Fasting (Serum/Plasma)	
Glucose,Random (Serum/Plasma)	
Hidden for Bilirubin	
Hidden for Aspartate	
Hidden for Alanine	
Hidden for Alanine Range	
Hidden for Asparate Range	
Hidden for Bilirubin Range	
Derived field to call CF	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 02 Day 01
Form: Non-central Laboratory Test Results - Hematology (LB1)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ■ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hemoglobin (Blood)	_____
Hematocrit (Blood)	_____
Leucocytes, Absolute Count (WBC) (Blood)	_____
Platelet count (Blood)	_____
Mean corpuscular volume (Blood)	_____
Absolute Neutrophil Count (Blood)	_____
Absolute Lymphocytes Count (Blood)	_____
Absolute Monocytes Count (Blood)	_____
Absolute Eosinophils,Count (Blood)	_____
Neutrophils, %/Ratio (Blood)	_____
Lymphocytes, %/Ratio (Blood)	_____
Monocytes, %/Ratio (Blood)	_____
Eosinophils, % /Ratio (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 02 Day 01
Form: Non-central Laboratory Test Results - Thyroid function test (LB3)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Thyroid Stimulating Hormone(Serum/Plasma)	_____
T4 (Thyroxine), Free(Serum/Plasma)	_____
T3 (Triiodothyronine), Free(Serum/Plasma)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 02 Day 01
Form: Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock
Creatine Kinase (Serum/Plasma)	
Troponin T (Serum/Plasma)	
Troponin I (Serum/Plasma)	
High- sensitivity Troponin T (Serum/Plasma)	
High- sensitivity Troponin I (Serum/Plasma)	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 02 Day 01
Form: Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Carcinoembryonic Antigen (Serum/Plasma) (ng/mL)	_____
Carbohydrate Antigen 19-9 (Serum) (U/mL)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 02 Day 01
Form: Non-central Laboratory Test Results - Hepatitis B and C testing - Post Screening (LB13)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ■
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hepatitis B Viral Load, Quant (IU/mL) (Blood)	_____
Hepatitis B Viral Load, Quant (DNA copies/mL) (Blood)	_____
Hepatitis C Viral Load, Quant (IU/mL) (Blood)	_____
Hepatitis C Viral Load, Quant (RNA copies/mL) (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 02 Day 01
Form: Sample Collection, Predose_ADA Sample (SPCBEDB)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ☐
	cfDNA-BCT ☐
	Blood ■
Biofluid processed	PBMC ☐
	Blood ☐
	Serum ■
	Plasma ☐
Sample format	DNA ☐
	Fresh ☐
	Frozen ■
	RNA ☐
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Protocol schedule	Pre Dose
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 02 Day 01
Form: PBMC for immune profiling_Pre dose (SPCBEDB2)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ■
	cfDNA-BCT ☐
	Blood ☐
Biofluid processed	PBMC ■
	Blood ☐
	Serum ☐
	Plasma ☐
Sample format	DNA ☐
	Fresh ■
	Frozen ☐
	RNA ☐
Date of collection	Fixed Unit: yyyy mon dd _____
Time of collection	Fixed Unit: 24-hour clock _____
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	_____
Protocol schedule	Pre Dose
Laboratory ID	Labcorp ■

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ☐
	cfDNA-BCT ☐
	Blood ■
Biofluid processed	PBMC ☐
	Blood ■
	Serum ☐
	Plasma ☐
Sample format	DNA ☐
	Fresh ☐
	Frozen ☐
	RNA ■
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Protocol schedule	Pre Dose
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 02 Day 01
Form: Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ☐
	cfDNA-BCT ☐
	Blood ■
Biofluid processed	PBMC ☐
	Blood ☐
	Serum ■
	Plasma ☐
Sample format	DNA ☐
	Fresh ☐
	Frozen ■
	RNA ☐
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Protocol schedule	Pre Dose
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 02 Day 01
Form: Biological Sample Collection, Pre-dose PK (SPCPKB)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample collection category?	PK, biofluid ■
Sample collected	No ☐ Yes ☐
Last investigational product date	Fixed Unit: yyyy mon dd
Last investigational product time	Fixed Unit: 24-hour clock
Biofluid collected (parent sample)	Blood ■
Biofluid processed	Serum ■
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐ Hemolyzed ☐ Clotted ☐ Lipemic ☐ Quantity less than expected ☐ Sample discarded ☐ Other ☐
If Other, specify	
Date of storage	Fixed Unit: yyyy mon dd
Time of storage	Fixed Unit: 24-hour clock
Protocol schedule	Pre Dose
Protocol schedule day	1
Protocol schedule hour	-99
Protocol schedule minute	-99
Laboratory ID	Labcorp ■

Subject Continues to the Next Visit?	No ☐
	Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 02 Day 08
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)	
Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 02 Day 08
Form: Assessment(s) Performed Triggering Form (ASMTRIG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2402 2024-02-16)

Select 'Yes' if all assessment forms are to be triggered	Yes ☐
Assessment(s) type	Extent of Disease Upon Entry to Study (DISEXT) ☐
	Pathology: at Screening (PATHGOM) ☐
	General Medical History (1MH) ☐
	Pre-specified medical conditions or events (2MH) ☐
	Surgical History (HISS) ☐
	Physical Examination (PE) ☐
	Vital Signs - Weight, Height (VS) ☐
	Vital Signs - Before Infusion (VS1) ☐
	Vital Signs - End of Infusion (VS2) ☐
	Vital Signs - Excluding Weight (VS3) ☐
	Vital Signs (VS4) ☐
	ECOG Performance Status (ECOG) ☐
	ECG Test Results (EG) ☐
	Additional ECG (EG1) ☐
	Additional ECG (EG2) ☐
	Echocardiography (ECHOC) ☐
	Non-central Laboratory Test Results - Chemistry (LB) ☐
	Non-central Laboratory Test Results - Hematology (LB1) ☐
	Non-central Laboratory Test Results - Coagulation (LB2) ☐
	Non-central Laboratory Test Results - Thyroid function test (LB3) ☐

- ☐ Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
- ☐ Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
- ☐ Non-central Laboratory Test Results - Urinalysis (LB6)
- ☐ Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
- ☐ Non-central Laboratory Test Results - Hy's Law (LB8)
- ☐ Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
- ☐ Non-central Laboratory Test Results - Tuberculosis testing (LB10)
- ☐ Non-central Laboratory Test Results - HIV testing (LB11)
- ☐ Non-central Laboratory Test Results - Additional Chemistry (LB12)
- ☐ Sample Collection, Predose_ADA Sample (SPCBEDB)
- ☐ Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
- ☐ PBMC for immune profiling_Pre dose (SPCBEDB2)
- ☐ Whole blood for RNA analysis_Pre-dose (SPCBEDB3)
- ☐ Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)

	Sample Collection, ADA Sample (SPCBEDB5) ☐
	Blood sample for plasma ctDNA (SPCBEDB6) ☐
	Optional on study tumor sample at recurrence (SPCBEDT) ☐
	Mandatory tumor sample from surgical resection for PDL1 analysis (SPCBEDT1) ☐
	Biological Sample Collection, Pre-dose PK (SPCPKB) ☐
	Biological Sample Collection, Post-dose PK (SPCPKB1) ☐
	Biological Sample Collection, PK (SPCPKB2) ☐
	Substance Use - Nicotine (SU_NIC) ☐
	Substance Use - Alcohol (SU_ALC) ☐
	Prior Cancer Therapy (CAPRX) ☐
	Prior Radiotherapy (CAPRXR) ☐
	Survival Status (SURVIVE) ☐
Assessment form to be triggered	No ☐
	Yes ☐
Reason assessment form is not to be triggered	Assessment not performed ☐
	Assessment not required ☐
	Subject discontinuation ☐
	Screen failure ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 02 Day 08
Form: Vital Signs - Excluding Weight (VS3)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd
Time	Fixed Unit: 24-hour clock
Pulse	Fixed Unit: beats/min
SBP	Fixed Unit: mmHg
DBP	Fixed Unit: mmHg
Respiration rate	Fixed Unit: breaths/min
Temperature	
Temperature unit	C ●
Peripheral oxygen saturation	Fixed Unit: %
EHRID	

(Version: ON2406 2024-06-04)

Clinical classification category	ECOG
What was the date the response or clinical classification was performed?	Fixed Unit: yyyy mon dd
Performance status	0-Fully active, able to carry on all pre-disease performance without restriction ☐ 1-Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work ☐ 2-Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours ☐ 3-Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours ☐ 4-Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair ☐ 5-Dead ☐

Ref: Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55). WHO Ref: World Health Organization (1979).Handbook for Reporting Results of Cancer Treatment Pb (WHO Offset Publications).

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 02 Day 08
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Liver Function Tests Alanine Aminotransferase (Serum/Plasma)	_____
Alkaline Phosphatase (Serum/Plasma)	_____
Aspartate Aminotransferase (Serum/Plasma)	_____
Bilirubin, Total (Serum/Plasma)	_____
Bilirubin, Direct, (Conj) (Serum/Plasma)	_____
Bilirubin, Indirect (Unconj.) (Serum/Plasma)	_____
Gamma-Glutamyltransferase (Serum/Plasma)	_____
Lactate Dehydrogenase (LDH) (Serum/Plasma)	_____
Protein, Total (Serum/Plasma)	_____
Pancreatic Enzymes Amylase (Serum/Plasma)	_____
Lipase (Serum/Plasma)	_____
Renal Function Tests Creatinine (Serum/Plasma)	_____
Creatinine Clearance, Calculated (Urine 24h)	_____
Creatinine Clearance, Cockcroft-Gault (Plasma)	_____
Creatinine Clearance, Cockcroft-Gault (Serum)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Plasma)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Serum)	_____

Lab Name:	
Urea (Serum/Plasma)	
Urea Nitrogen (BUN) (Serum/Plasma)	
Electrolytes Calcium, Ionized (Serum)	
Total Calcium (Serum/Plasma)	
Chloride (Serum/Plasma)	
Magnesium (Serum/Plasma)	
Phosphate (Phosphorus) (Serum/Plasma)	
Potassium (Serum/Plasma)	
Sodium (Serum/Plasma)	
Proteins Albumin (Serum/Plasma)	
Glucose Metabolism Glucose, Fasting (Serum/Plasma)	
Glucose,Random (Serum/Plasma)	
Hidden for Bilirubin	
Hidden for Aspartate	
Hidden for Alanine	
Hidden for Alanine Range	
Hidden for Asparate Range	
Hidden for Bilirubin Range	
Derived field to call CF	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 02 Day 08
Form: Non-central Laboratory Test Results - Hematology (LB1)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ■ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hemoglobin (Blood)	_____
Hematocrit (Blood)	_____
Leucocytes, Absolute Count (WBC) (Blood)	_____
Platelet count (Blood)	_____
Mean corpuscular volume (Blood)	_____
Absolute Neutrophil Count (Blood)	_____
Absolute Lymphocytes Count (Blood)	_____
Absolute Monocytes Count (Blood)	_____
Absolute Eosinophils,Count (Blood)	_____
Neutrophils, %/Ratio (Blood)	_____
Lymphocytes, %/Ratio (Blood)	_____
Monocytes, %/Ratio (Blood)	_____
Eosinophils, % /Ratio (Blood)	_____

Subject Continues to the Next Visit?	No ☐
	Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 03 Day 01
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)	
Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 03 Day 01
Form: Assessment(s) Performed Triggering Form (ASMTRIG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2402 2024-02-16)

Select 'Yes' if all assessment forms are to be triggered	Yes ☐
Assessment(s) type	Extent of Disease Upon Entry to Study (DISEXT) ☐
	Pathology: at Screening (PATHGOM) ☐
	General Medical History (1MH) ☐
	Pre-specified medical conditions or events (2MH) ☐
	Surgical History (HISS) ☐
	Physical Examination (PE) ☐
	Vital Signs - Weight, Height (VS) ☐
	Vital Signs - Before Infusion (VS1) ☐
	Vital Signs - End of Infusion (VS2) ☐
	Vital Signs - Excluding Weight (VS3) ☐
	Vital Signs (VS4) ☐
	ECOG Performance Status (ECOG) ☐
	ECG Test Results (EG) ☐
	Additional ECG (EG1) ☐
	Additional ECG (EG2) ☐
	Echocardiography (ECHOC) ☐
	Non-central Laboratory Test Results - Chemistry (LB) ☐
	Non-central Laboratory Test Results - Hematology (LB1) ☐
	Non-central Laboratory Test Results - Coagulation (LB2) ☐
	Non-central Laboratory Test Results - Thyroid function test (LB3) ☐

- ☐ Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
- ☐ Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
- ☐ Non-central Laboratory Test Results - Urinalysis (LB6)
- ☐ Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
- ☐ Non-central Laboratory Test Results - Hy's Law (LB8)
- ☐ Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
- ☐ Non-central Laboratory Test Results - Tuberculosis testing (LB10)
- ☐ Non-central Laboratory Test Results - HIV testing (LB11)
- ☐ Non-central Laboratory Test Results - Additional Chemistry (LB12)
- ☐ Sample Collection, Predose_ADA Sample (SPCBEDB)
- ☐ Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
- ☐ PBMC for immune profiling_Pre dose (SPCBEDB2)
- ☐ Whole blood for RNA analysis_Pre-dose (SPCBEDB3)
- ☐ Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)

	Sample Collection, ADA Sample (SPCBEDB5) ☐
	Blood sample for plasma ctDNA (SPCBEDB6) ☐
	Optional on study tumor sample at recurrence (SPCBEDT) ☐
	Mandatory tumor sample from surgical resection for PDL1 analysis (SPCBEDT1) ☐
	Biological Sample Collection, Pre-dose PK (SPCPKB) ☐
	Biological Sample Collection, Post-dose PK (SPCPKB1) ☐
	Biological Sample Collection, PK (SPCPKB2) ☐
	Substance Use - Nicotine (SU_NIC) ☐
	Substance Use - Alcohol (SU_ALC) ☐
	Prior Cancer Therapy (CAPRX) ☐
	Prior Radiotherapy (CAPRXR) ☐
	Survival Status (SURVIVE) ☐
Assessment form to be triggered	No ☐
	Yes ☐
Reason assessment form is not to be triggered	Assessment not performed ☐
	Assessment not required ☐
	Subject discontinuation ☐
	Screen failure ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 03 Day 01
Form: Physical Examination (PE)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ1609 2019-04-19)

For baseline: Following items should be checked during baseline physical examination (A full physical examination will be performed and include assessments of the following: general appearance, respiratory, cardiovascular system, abdomen, skin, head and neck (including ears, eyes, nose, and throat), lymph nodes, thyroid, musculoskeletal (including spine and extremities), urogenital, dermatological, gastrointestinal, endocrine, hematologic/lymphatic, and neurological systems.).

For follow-up: Following items should be checked during follow-up physical examination (A targeted physical examination will include, at a minimum, assessments of skin, lungs, cardiovascular system, and abdomen (liver and spleen).

If the physical finding started prior to enrolment, it must be recorded as medical history.
If the physical finding started or worsened after enrolment, it must be recorded as an Adverse Event.

Was the physical examination performed?	No ☐ Yes ☐
What was the date of the physical examination?	Fixed Unit: yyyy mon dd

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 03 Day 01
Form: Vital Signs - Before Infusion (VS1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd
Protocol schedule	Prior to Infusion
Time	Fixed Unit: 24-hour clock
Pulse	Fixed Unit: beats/min
SBP	Fixed Unit: mmHg
DBP	Fixed Unit: mmHg
Respiration rate	Fixed Unit: breaths/min
Temperature	
Temperature unit	C
Peripheral oxygen saturation	Fixed Unit: %
Weight	
Weight unit	kg
EHRID	

(Version: ON2406 2024-06-04)

Clinical classification category	ECOG
What was the date the response or clinical classification was performed?	Fixed Unit: yyyy mon dd
Performance status	0-Fully active, able to carry on all pre-disease performance without restriction ☐ 1-Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work ☐ 2-Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours ☐ 3-Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours ☐ 4-Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair ☐ 5-Dead ☐

Ref: Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55). WHO Ref: World Health Organization (1979).Handbook for Reporting Results of Cancer Treatment Pb (WHO Offset Publications).

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 03 Day 01
Form: Pregnancy Test (PREG1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2008 2024-03-01)

Assessment applicable for Subject	No ☐
	Yes ☐
Sampling date	Fixed Unit: yyyy mon dd
Pregnancy test (serum)	Negative ☐
	Positive ☐
Pregnancy test (urine)	Negative ☐
	Positive ☐

For a positive pregnancy test after first dose of study drug, fill in PREGREP (or the 'Pregnancy Outcome Report Form' [Part 1]) and send to the AstraZeneca Monitor.

If positive pregnancy test, the administration of study drug to that Subject must be discontinued immediately and the End of Study Treatment form (ETRT) filled in.

If Positive pregnancy test, and considered an AE, please fill in Adverse Event (AE) Form
(Pregnancy itself is not regarded as an adverse event unless there is a suspicion that AstraZeneca product may have interfered with the effectiveness of a contraceptive medication.)

Hidden Field (used for CF programming)

Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Liver Function Tests Alanine Aminotransferase (Serum/Plasma)	_____
Alkaline Phosphatase (Serum/Plasma)	_____
Aspartate Aminotransferase (Serum/Plasma)	_____
Bilirubin, Total (Serum/Plasma)	_____
Bilirubin, Direct, (Conj) (Serum/Plasma)	_____
Bilirubin, Indirect (Unconj.) (Serum/Plasma)	_____
Gamma-Glutamyltransferase (Serum/Plasma)	_____
Lactate Dehydrogenase (LDH) (Serum/Plasma)	_____
Protein, Total (Serum/Plasma)	_____
Pancreatic Enzymes Amylase (Serum/Plasma)	_____
Lipase (Serum/Plasma)	_____
Renal Function Tests Creatinine (Serum/Plasma)	_____
Creatinine Clearance, Calculated (Urine 24h)	_____
Creatinine Clearance, Cockcroft-Gault (Plasma)	_____
Creatinine Clearance, Cockcroft-Gault (Serum)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Plasma)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Serum)	_____

Lab Name:	
Urea (Serum/Plasma)	
Urea Nitrogen (BUN) (Serum/Plasma)	
Electrolytes Calcium, Ionized (Serum)	
Total Calcium (Serum/Plasma)	
Chloride (Serum/Plasma)	
Magnesium (Serum/Plasma)	
Phosphate (Phosphorus) (Serum/Plasma)	
Potassium (Serum/Plasma)	
Sodium (Serum/Plasma)	
Proteins Albumin (Serum/Plasma)	
Glucose Metabolism Glucose, Fasting (Serum/Plasma)	
Glucose,Random (Serum/Plasma)	
Hidden for Bilirubin	
Hidden for Aspartate	
Hidden for Alanine	
Hidden for Alanine Range	
Hidden for Asparate Range	
Hidden for Bilirubin Range	
Derived field to call CF	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 03 Day 01
Form: Non-central Laboratory Test Results - Hematology (LB1)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ■ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hemoglobin (Blood)	_____
Hematocrit (Blood)	_____
Leucocytes, Absolute Count (WBC) (Blood)	_____
Platelet count (Blood)	_____
Mean corpuscular volume (Blood)	_____
Absolute Neutrophil Count (Blood)	_____
Absolute Lymphocytes Count (Blood)	_____
Absolute Monocytes Count (Blood)	_____
Absolute Eosinophils,Count (Blood)	_____
Neutrophils, %/Ratio (Blood)	_____
Lymphocytes, %/Ratio (Blood)	_____
Monocytes, %/Ratio (Blood)	_____
Eosinophils, % /Ratio (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 03 Day 01
Form: Non-central Laboratory Test Results - Thyroid function test (LB3)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Thyroid Stimulating Hormone(Serum/Plasma)	_____
T4 (Thyroxine), Free(Serum/Plasma)	_____
T3 (Triiodothyronine), Free(Serum/Plasma)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 03 Day 01
Form: Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock
Creatine Kinase (Serum/Plasma)	
Troponin T (Serum/Plasma)	
Troponin I (Serum/Plasma)	
High- sensitivity Troponin T (Serum/Plasma)	
High- sensitivity Troponin I (Serum/Plasma)	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 03 Day 01
Form: Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Carcinoembryonic Antigen (Serum/Plasma) (ng/mL)	_____
Carbohydrate Antigen 19-9 (Serum) (U/mL)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 03 Day 01
Form: Non-central Laboratory Test Results - Hepatitis B and C testing - Post Screening (LB13)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ■
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hepatitis B Viral Load, Quant (IU/mL) (Blood)	_____
Hepatitis B Viral Load, Quant (DNA copies/mL) (Blood)	_____
Hepatitis C Viral Load, Quant (IU/mL) (Blood)	_____
Hepatitis C Viral Load, Quant (RNA copies/mL) (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 03 Day 01
Form: Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ☐
	cfDNA-BCT ■
	Blood ☐
Biofluid processed	PBMC ☐
	Blood ☐
	Serum ☐
	Plasma ■
Sample format	DNA ■
	Fresh ☐
	Frozen ☐
	RNA ☐
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Protocol schedule	Pre Dose
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 03 Day 01
Form: PBMC for immune profiling_Pre dose (SPCBEDB2)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ■
	cfDNA-BCT ☐
	Blood ☐
Biofluid processed	PBMC ■
	Blood ☐
	Serum ☐
	Plasma ☐
Sample format	DNA ☐
	Fresh ■
	Frozen ☐
	RNA ☐
Date of collection	Fixed Unit: yyyy mon dd _____
Time of collection	Fixed Unit: 24-hour clock _____
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	_____
Protocol schedule	Pre Dose
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 03 Day 01
Form: Whole blood for RNA analysis_Pre-dose (SPCBEDB3)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ☐
	cfDNA-BCT ☐
	Blood ■
Biofluid processed	PBMC ☐
	Blood ■
	Serum ☐
	Plasma ☐
Sample format	DNA ☐
	Fresh ☐
	Frozen ☐
	RNA ■
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Protocol schedule	Pre Dose
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 03 Day 01
Form: Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ☐
	cfDNA-BCT ☐
	Blood ■
Biofluid processed	PBMC ☐
	Blood ☐
	Serum ■
	Plasma ☐
Sample format	DNA ☐
	Fresh ☐
	Frozen ■
	RNA ☐
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Protocol schedule	Pre Dose
Laboratory ID	Labcorp ■

(Version: AZ2310 2025-07-01)

What was the sample collection category?	Biomarkers/exploratory research/diagnostic, solid tissue
Sample collected	No
	Yes
Sample collection method	Core Needle Biopsy
	Excisional Biopsy
	Incisional Biopsy
Biopsy tissue type	Primary tumor
	Metastatic tumor
Organ	Abdomen
	Bronchus (Main Stem)
	Fat
	Oesophagus
	Pituitary
	Urinary Bladder
	Esophagogastric Junction
	Hypopharynx
	Duodenum
	Cervix Uteri
	Epididymis
	Gallbladder
	Large Intestine
	Appendix
	Colon
	Small Intestine
	Ileum
	Jejunum
	Rectum
	Stomach
	Liver
	Pancreas

Thyroid Gland
Fallopian Tube
Ovary
Uterus
Prostate Gland
Testis
Kidney
Ureter
Urethra
Larynx
Oral Cavity
Tongue
Pharynx
Parotid Gland
Trachea
Spleen
Thymus Gland
Brain
Spinal Cord
Lung
Pleura
Skin
Soft Tissue
Abdominal Cavity
Adrenal Gland
Diaphragm
Heart
Lymph Node
Nose
Oropharynx
Parathyroid Gland
Peripheral Nerve
Peritoneum

	Tonsil ☐
	Breast ☐
	Joint ☐
	Muscle ☐
	Gastroesophageal Junction ☐
	Mesentery ☐
	Omentum ☐
	Anus ☐
	Abdominal Wall ☐
	Other (Not Specified) ☐
Sample format	FFPE block ☐
	FFPE unstained slides ☐
Unstained slides sectioning date	Fixed Unit: yyyy mon dd
Date of Biopsy	Fixed Unit: yyyy mon dd
Sample condition	Sample acceptable ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Date of storage	Fixed Unit: yyyy mon dd
Time of storage	Fixed Unit: 24-hour clock
Laboratory ID	Labcorp ■

Subject Continues to the Next Visit?	No ☐
	Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 03 Day 08
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)	
Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 03 Day 08
Form: Assessment(s) Performed Triggering Form (ASMTRIG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2402 2024-02-16)

Select 'Yes' if all assessment forms are to be triggered	Yes ☐
Assessment(s) type	Extent of Disease Upon Entry to Study (DISEXT) ☐
	Pathology: at Screening (PATHGOM) ☐
	General Medical History (1MH) ☐
	Pre-specified medical conditions or events (2MH) ☐
	Surgical History (HISS) ☐
	Physical Examination (PE) ☐
	Vital Signs - Weight, Height (VS) ☐
	Vital Signs - Before Infusion (VS1) ☐
	Vital Signs - End of Infusion (VS2) ☐
	Vital Signs - Excluding Weight (VS3) ☐
	Vital Signs (VS4) ☐
	ECOG Performance Status (ECOG) ☐
	ECG Test Results (EG) ☐
	Additional ECG (EG1) ☐
	Additional ECG (EG2) ☐
	Echocardiography (ECHOC) ☐
	Non-central Laboratory Test Results - Chemistry (LB) ☐
	Non-central Laboratory Test Results - Hematology (LB1) ☐
	Non-central Laboratory Test Results - Coagulation (LB2) ☐
	Non-central Laboratory Test Results - Thyroid function test (LB3) ☐

- ☐ Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
- ☐ Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
- ☐ Non-central Laboratory Test Results - Urinalysis (LB6)
- ☐ Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
- ☐ Non-central Laboratory Test Results - Hy's Law (LB8)
- ☐ Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
- ☐ Non-central Laboratory Test Results - Tuberculosis testing (LB10)
- ☐ Non-central Laboratory Test Results - HIV testing (LB11)
- ☐ Non-central Laboratory Test Results - Additional Chemistry (LB12)
- ☐ Sample Collection, Predose_ADA Sample (SPCBEDB)
- ☐ Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
- ☐ PBMC for immune profiling_Pre dose (SPCBEDB2)
- ☐ Whole blood for RNA analysis_Pre-dose (SPCBEDB3)
- ☐ Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)

	Sample Collection, ADA Sample (SPCBEDB5) ☐
	Blood sample for plasma ctDNA (SPCBEDB6) ☐
	Optional on study tumor sample at recurrence (SPCBEDT) ☐
	Mandatory tumor sample from surgical resection for PDL1 analysis (SPCBEDT1) ☐
	Biological Sample Collection, Pre-dose PK (SPCPKB) ☐
	Biological Sample Collection, Post-dose PK (SPCPKB1) ☐
	Biological Sample Collection, PK (SPCPKB2) ☐
	Substance Use - Nicotine (SU_NIC) ☐
	Substance Use - Alcohol (SU_ALC) ☐
	Prior Cancer Therapy (CAPRX) ☐
	Prior Radiotherapy (CAPRXR) ☐
	Survival Status (SURVIVE) ☐
Assessment form to be triggered	No ☐
	Yes ☐
Reason assessment form is not to be triggered	Assessment not performed ☐
	Assessment not required ☐
	Subject discontinuation ☐
	Screen failure ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 03 Day 08
Form: Vital Signs - Excluding Weight (VS3)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd
Time	Fixed Unit: 24-hour clock
Pulse	Fixed Unit: beats/min
SBP	Fixed Unit: mmHg
DBP	Fixed Unit: mmHg
Respiration rate	Fixed Unit: breaths/min
Temperature	
Temperature unit	C ●
Peripheral oxygen saturation	Fixed Unit: %
EHRID	

(Version: ON2406 2024-06-04)

Clinical classification category	ECOG
What was the date the response or clinical classification was performed?	Fixed Unit: yyyy mon dd
Performance status	0-Fully active, able to carry on all pre-disease performance without restriction ☐ 1-Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work ☐ 2-Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours ☐ 3-Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours ☐ 4-Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair ☐ 5-Dead ☐

Ref: Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55). WHO Ref: World Health Organization (1979).Handbook for Reporting Results of Cancer Treatment Pb (WHO Offset Publications).

Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Liver Function Tests Alanine Aminotransferase (Serum/Plasma)	_____
Alkaline Phosphatase (Serum/Plasma)	_____
Aspartate Aminotransferase (Serum/Plasma)	_____
Bilirubin, Total (Serum/Plasma)	_____
Bilirubin, Direct, (Conj) (Serum/Plasma)	_____
Bilirubin, Indirect (Unconj.) (Serum/Plasma)	_____
Gamma-Glutamyltransferase (Serum/Plasma)	_____
Lactate Dehydrogenase (LDH) (Serum/Plasma)	_____
Protein, Total (Serum/Plasma)	_____
Pancreatic Enzymes Amylase (Serum/Plasma)	_____
Lipase (Serum/Plasma)	_____
Renal Function Tests Creatinine (Serum/Plasma)	_____
Creatinine Clearance, Calculated (Urine 24h)	_____
Creatinine Clearance, Cockcroft-Gault (Plasma)	_____
Creatinine Clearance, Cockcroft-Gault (Serum)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Plasma)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Serum)	_____

Lab Name:	
Urea (Serum/Plasma)	
Urea Nitrogen (BUN) (Serum/Plasma)	
Electrolytes Calcium, Ionized (Serum)	
Total Calcium (Serum/Plasma)	
Chloride (Serum/Plasma)	
Magnesium (Serum/Plasma)	
Phosphate (Phosphorus) (Serum/Plasma)	
Potassium (Serum/Plasma)	
Sodium (Serum/Plasma)	
Proteins Albumin (Serum/Plasma)	
Glucose Metabolism Glucose, Fasting (Serum/Plasma)	
Glucose,Random (Serum/Plasma)	
Hidden for Bilirubin	
Hidden for Aspartate	
Hidden for Alanine	
Hidden for Alanine Range	
Hidden for Asparate Range	
Hidden for Bilirubin Range	
Derived field to call CF	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 03 Day 08
Form: Non-central Laboratory Test Results - Hematology (LB1)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ■ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hemoglobin (Blood)	_____
Hematocrit (Blood)	_____
Leucocytes, Absolute Count (WBC) (Blood)	_____
Platelet count (Blood)	_____
Mean corpuscular volume (Blood)	_____
Absolute Neutrophil Count (Blood)	_____
Absolute Lymphocytes Count (Blood)	_____
Absolute Monocytes Count (Blood)	_____
Absolute Eosinophils,Count (Blood)	_____
Neutrophils, %/Ratio (Blood)	_____
Lymphocytes, %/Ratio (Blood)	_____
Monocytes, %/Ratio (Blood)	_____
Eosinophils, % /Ratio (Blood)	_____

Subject Continues to the Next Visit?	No ☐
	Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 04 Day 01
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)	
Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 04 Day 01
Form: Assessment(s) Performed Triggering Form (ASMTRIG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2402 2024-02-16)

Select 'Yes' if all assessment forms are to be triggered	Yes ☐
Assessment(s) type	Extent of Disease Upon Entry to Study (DISEXT) ☐
	Pathology: at Screening (PATHGOM) ☐
	General Medical History (1MH) ☐
	Pre-specified medical conditions or events (2MH) ☐
	Surgical History (HISS) ☐
	Physical Examination (PE) ☐
	Vital Signs - Weight, Height (VS) ☐
	Vital Signs - Before Infusion (VS1) ☐
	Vital Signs - End of Infusion (VS2) ☐
	Vital Signs - Excluding Weight (VS3) ☐
	Vital Signs (VS4) ☐
	ECOG Performance Status (ECOG) ☐
	ECG Test Results (EG) ☐
	Additional ECG (EG1) ☐
	Additional ECG (EG2) ☐
	Echocardiography (ECHOC) ☐
	Non-central Laboratory Test Results - Chemistry (LB) ☐
	Non-central Laboratory Test Results - Hematology (LB1) ☐
	Non-central Laboratory Test Results - Coagulation (LB2) ☐
	Non-central Laboratory Test Results - Thyroid function test (LB3) ☐

- ☐ Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
- ☐ Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
- ☐ Non-central Laboratory Test Results - Urinalysis (LB6)
- ☐ Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
- ☐ Non-central Laboratory Test Results - Hy's Law (LB8)
- ☐ Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
- ☐ Non-central Laboratory Test Results - Tuberculosis testing (LB10)
- ☐ Non-central Laboratory Test Results - HIV testing (LB11)
- ☐ Non-central Laboratory Test Results - Additional Chemistry (LB12)
- ☐ Sample Collection, Predose_ADA Sample (SPCBEDB)
- ☐ Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
- ☐ PBMC for immune profiling_Pre dose (SPCBEDB2)
- ☐ Whole blood for RNA analysis_Pre-dose (SPCBEDB3)
- ☐ Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)

	Sample Collection, ADA Sample (SPCBEDB5) ☐
	Blood sample for plasma ctDNA (SPCBEDB6) ☐
	Optional on study tumor sample at recurrence (SPCBEDT) ☐
	Mandatory tumor sample from surgical resection for PDL1 analysis (SPCBEDT1) ☐
	Biological Sample Collection, Pre-dose PK (SPCPKB) ☐
	Biological Sample Collection, Post-dose PK (SPCPKB1) ☐
	Biological Sample Collection, PK (SPCPKB2) ☐
	Substance Use - Nicotine (SU_NIC) ☐
	Substance Use - Alcohol (SU_ALC) ☐
	Prior Cancer Therapy (CAPRX) ☐
	Prior Radiotherapy (CAPRXR) ☐
	Survival Status (SURVIVE) ☐
Assessment form to be triggered	No ☐
	Yes ☐
Reason assessment form is not to be triggered	Assessment not performed ☐
	Assessment not required ☐
	Subject discontinuation ☐
	Screen failure ☐

(Version: AZ1609 2019-04-19)

For baseline: Following items should be checked during baseline physical examination (A full physical examination will be performed and include assessments of the following: general appearance, respiratory, cardiovascular system, abdomen, skin, head and neck (including ears, eyes, nose, and throat), lymph nodes, thyroid, musculoskeletal (including spine and extremities), urogenital, dermatological, gastrointestinal, endocrine, hematologic/lymphatic, and neurological systems.).

For follow-up: Following items should be checked during follow-up physical examination (A targeted physical examination will include, at a minimum, assessments of skin, lungs, cardiovascular system, and abdomen (liver and spleen).

If the physical finding started prior to enrolment, it must be recorded as medical history.
If the physical finding started or worsened after enrolment, it must be recorded as an Adverse Event.

Was the physical examination performed?	No ☐ Yes ☐
What was the date of the physical examination?	Fixed Unit: yyyy mon dd

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 04 Day 01
Form: Vital Signs - Before Infusion (VS1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd
Protocol schedule	Prior to Infusion
Time	Fixed Unit: 24-hour clock
Pulse	Fixed Unit: beats/min
SBP	Fixed Unit: mmHg
DBP	Fixed Unit: mmHg
Respiration rate	Fixed Unit: breaths/min
Temperature	
Temperature unit	C ●
Peripheral oxygen saturation	Fixed Unit: %
Weight	
Weight unit	kg ●
EHRID	

(Version: ON2406 2024-06-04)

Clinical classification category	ECOG
What was the date the response or clinical classification was performed?	Fixed Unit: yyyy mon dd
Performance status	0-Fully active, able to carry on all pre-disease performance without restriction ☐ 1-Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work ☐ 2-Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours ☐ 3-Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours ☐ 4-Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair ☐ 5-Dead ☐

Ref: Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55). WHO Ref: World Health Organization (1979).Handbook for Reporting Results of Cancer Treatment Pb (WHO Offset Publications).

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 04 Day 01
Form: Pregnancy Test (PREG1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2008 2024-03-01)

Assessment applicable for Subject	No ☐
	Yes ☐
Sampling date	Fixed Unit: yyyy mon dd
Pregnancy test (serum)	Negative ☐
	Positive ☐
Pregnancy test (urine)	Negative ☐
	Positive ☐

For a positive pregnancy test after first dose of study drug, fill in PREGREP (or the 'Pregnancy Outcome Report Form' [Part 1]) and send to the AstraZeneca Monitor.

If positive pregnancy test, the administration of study drug to that Subject must be discontinued immediately and the End of Study Treatment form (ETRT) filled in.

If Positive pregnancy test, and considered an AE, please fill in Adverse Event (AE) Form
(Pregnancy itself is not regarded as an adverse event unless there is a suspicion that AstraZeneca product may have interfered with the effectiveness of a contraceptive medication.)

Hidden Field (used for CF programming)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 04 Day 01
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Liver Function Tests Alanine Aminotransferase (Serum/Plasma)	_____
Alkaline Phosphatase (Serum/Plasma)	_____
Aspartate Aminotransferase (Serum/Plasma)	_____
Bilirubin, Total (Serum/Plasma)	_____
Bilirubin, Direct, (Conj) (Serum/Plasma)	_____
Bilirubin, Indirect (Unconj.) (Serum/Plasma)	_____
Gamma-Glutamyltransferase (Serum/Plasma)	_____
Lactate Dehydrogenase (LDH) (Serum/Plasma)	_____
Protein, Total (Serum/Plasma)	_____
Pancreatic Enzymes Amylase (Serum/Plasma)	_____
Lipase (Serum/Plasma)	_____
Renal Function Tests Creatinine (Serum/Plasma)	_____
Creatinine Clearance, Calculated (Urine 24h)	_____
Creatinine Clearance, Cockcroft-Gault (Plasma)	_____
Creatinine Clearance, Cockcroft-Gault (Serum)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Plasma)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Serum)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 04 Day 01
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:27 (GMT)

Lab Name:	
Urea (Serum/Plasma)	
Urea Nitrogen (BUN) (Serum/Plasma)	
Electrolytes Calcium, Ionized (Serum)	
Total Calcium (Serum/Plasma)	
Chloride (Serum/Plasma)	
Magnesium (Serum/Plasma)	
Phosphate (Phosphorus) (Serum/Plasma)	
Potassium (Serum/Plasma)	
Sodium (Serum/Plasma)	
Proteins Albumin (Serum/Plasma)	
Glucose Metabolism Glucose, Fasting (Serum/Plasma)	
Glucose,Random (Serum/Plasma)	
Hidden for Bilirubin	
Hidden for Aspartate	
Hidden for Alanine	
Hidden for Alanine Range	
Hidden for Asparate Range	
Hidden for Bilirubin Range	
Derived field to call CF	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 04 Day 01
Form: Non-central Laboratory Test Results - Hematology (LB1)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ■ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hemoglobin (Blood)	_____
Hematocrit (Blood)	_____
Leucocytes, Absolute Count (WBC) (Blood)	_____
Platelet count (Blood)	_____
Mean corpuscular volume (Blood)	_____
Absolute Neutrophil Count (Blood)	_____
Absolute Lymphocytes Count (Blood)	_____
Absolute Monocytes Count (Blood)	_____
Absolute Eosinophils,Count (Blood)	_____
Neutrophils, %/Ratio (Blood)	_____
Lymphocytes, %/Ratio (Blood)	_____
Monocytes, %/Ratio (Blood)	_____
Eosinophils, % /Ratio (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 04 Day 01
Form: Non-central Laboratory Test Results - Thyroid function test (LB3)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	☐ No ☐ Yes
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	☐ Hematology ■ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Thyroid Stimulating Hormone(Serum/Plasma)	_____
T4 (Thyroxine), Free(Serum/Plasma)	_____
T3 (Triiodothyronine), Free(Serum/Plasma)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 04 Day 01
Form: Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock
Creatine Kinase (Serum/Plasma)	
Troponin T (Serum/Plasma)	
Troponin I (Serum/Plasma)	
High- sensitivity Troponin T (Serum/Plasma)	
High- sensitivity Troponin I (Serum/Plasma)	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 04 Day 01
Form: Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Carcinoembryonic Antigen (Serum/Plasma) (ng/mL)	_____
Carbohydrate Antigen 19-9 (Serum) (U/mL)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 04 Day 01
Form: Non-central Laboratory Test Results - Hepatitis B and C testing - Post Screening (LB13)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ■
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hepatitis B Viral Load, Quant (IU/mL) (Blood)	_____
Hepatitis B Viral Load, Quant (DNA copies/mL) (Blood)	_____
Hepatitis C Viral Load, Quant (IU/mL) (Blood)	_____
Hepatitis C Viral Load, Quant (RNA copies/mL) (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 04 Day 01
Form: Sample Collection, Predose_ADA Sample (SPCBEDB)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ☐
	cfDNA-BCT ☐
	Blood ■
Biofluid processed	PBMC ☐
	Blood ☐
	Serum ■
	Plasma ☐
Sample format	DNA ☐
	Fresh ☐
	Frozen ■
	RNA ☐
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Protocol schedule	Pre Dose
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 04 Day 01
Form: Biological Sample Collection, Pre-dose PK (SPCPKB)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample collection category?	PK, biofluid
Sample collected	No Yes
Last investigational product date	Fixed Unit: yyyy mon dd
Last investigational product time	Fixed Unit: 24-hour clock
Biofluid collected (parent sample)	Blood
Biofluid processed	Serum
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable Hemolyzed Clotted Lipemic Quantity less than expected Sample discarded Other
If Other, specify	
Date of storage	Fixed Unit: yyyy mon dd
Time of storage	Fixed Unit: 24-hour clock
Protocol schedule	Pre Dose
Protocol schedule day	1
Protocol schedule hour	-99
Protocol schedule minute	-99
Laboratory ID	Labcorp

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 04 Day 01
Form: Biological Sample Collection, Post-dose PK (SPCPKB1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample collection category?	PK, biofluid
Sample collected	No Yes
Last investigational product date	Fixed Unit: yyyy mon dd
Last investigational product time	Fixed Unit: 24-hour clock
Biofluid collected (parent sample)	Blood
Biofluid processed	Serum
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable Hemolyzed Clotted Lipemic Quantity less than expected Sample discarded Other
If Other, specify	
Date of storage	Fixed Unit: yyyy mon dd
Time of storage	Fixed Unit: 24-hour clock
Protocol schedule	15 mins Post Dose
Protocol schedule day	1
Protocol schedule hour	0
Protocol schedule minute	15
Laboratory ID	Labcorp

Subject Continues to the Next Visit?	No ☐
	Yes ☐

(Version: AZ2305 2023-05-29)

Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 04 Day 08
Form: Assessment(s) Performed Triggering Form (ASMTRIG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2402 2024-02-16)

Select 'Yes' if all assessment forms are to be triggered	Yes ☐

Assessment(s) type	Extent of Disease Upon Entry to Study (DISEXT) ☐
	Pathology: at Screening (PATHGOM) ☐
	General Medical History (1MH) ☐
	Pre-specified medical conditions or events (2MH) ☐
	Surgical History (HISS) ☐
	Physical Examination (PE) ☐
	Vital Signs - Weight, Height (VS) ☐
	Vital Signs - Before Infusion (VS1) ☐
	Vital Signs - End of Infusion (VS2) ☐
	Vital Signs - Excluding Weight (VS3) ☐
	Vital Signs (VS4) ☐
	ECOG Performance Status (ECOG) ☐
	ECG Test Results (EG) ☐
	Additional ECG (EG1) ☐
	Additional ECG (EG2) ☐
	Echocardiography (ECHOC) ☐
	Non-central Laboratory Test Results - Chemistry (LB) ☐
	Non-central Laboratory Test Results - Hematology (LB1) ☐
	Non-central Laboratory Test Results - Coagulation (LB2) ☐
	Non-central Laboratory Test Results - Thyroid function test (LB3) ☐

- ☐ Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
- ☐ Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
- ☐ Non-central Laboratory Test Results - Urinalysis (LB6)
- ☐ Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
- ☐ Non-central Laboratory Test Results - Hy's Law (LB8)
- ☐ Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
- ☐ Non-central Laboratory Test Results - Tuberculosis testing (LB10)
- ☐ Non-central Laboratory Test Results - HIV testing (LB11)
- ☐ Non-central Laboratory Test Results - Additional Chemistry (LB12)
- ☐ Sample Collection, Predose_ADA Sample (SPCBEDB)
- ☐ Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
- ☐ PBMC for immune profiling_Pre dose (SPCBEDB2)
- ☐ Whole blood for RNA analysis_Pre-dose (SPCBEDB3)
- ☐ Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)

	Sample Collection, ADA Sample (SPCBEDB5) ☐
	Blood sample for plasma ctDNA (SPCBEDB6) ☐
	Optional on study tumor sample at recurrence (SPCBEDT) ☐
	Mandatory tumor sample from surgical resection for PDL1 analysis (SPCBEDT1) ☐
	Biological Sample Collection, Pre-dose PK (SPCPKB) ☐
	Biological Sample Collection, Post-dose PK (SPCPKB1) ☐
	Biological Sample Collection, PK (SPCPKB2) ☐
	Substance Use - Nicotine (SU_NIC) ☐
	Substance Use - Alcohol (SU_ALC) ☐
	Prior Cancer Therapy (CAPRX) ☐
	Prior Radiotherapy (CAPRXR) ☐
	Survival Status (SURVIVE) ☐
Assessment form to be triggered	No ☐
	Yes ☐
Reason assessment form is not to be triggered	Assessment not performed ☐
	Assessment not required ☐
	Subject discontinuation ☐
	Screen failure ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 04 Day 08
Form: Vital Signs - Excluding Weight (VS3)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd
Time	Fixed Unit: 24-hour clock
Pulse	Fixed Unit: beats/min
SBP	Fixed Unit: mmHg
DBP	Fixed Unit: mmHg
Respiration rate	Fixed Unit: breaths/min
Temperature	
Temperature unit	C ●
Peripheral oxygen saturation	Fixed Unit: %
EHRID	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 04 Day 08
Form: ECOG Performance Status (ECOG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: ON2406 2024-06-04)

Clinical classification category	ECOG
What was the date the response or clinical classification was performed?	Fixed Unit: yyyy mon dd
Performance status	0-Fully active, able to carry on all pre-disease performance without restriction ☐ 1-Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work ☐ 2-Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours ☐ 3-Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours ☐ 4-Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair ☐ 5-Dead ☐

Ref: Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55). WHO Ref: World Health Organization (1979).Handbook for Reporting Results of Cancer Treatment Pb (WHO Offset Publications).

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 04 Day 08
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Liver Function Tests Alanine Aminotransferase (Serum/Plasma)	_____
Alkaline Phosphatase (Serum/Plasma)	_____
Aspartate Aminotransferase (Serum/Plasma)	_____
Bilirubin, Total (Serum/Plasma)	_____
Bilirubin, Direct, (Conj) (Serum/Plasma)	_____
Bilirubin, Indirect (Unconj.) (Serum/Plasma)	_____
Gamma-Glutamyltransferase (Serum/Plasma)	_____
Lactate Dehydrogenase (LDH) (Serum/Plasma)	_____
Protein, Total (Serum/Plasma)	_____
Pancreatic Enzymes Amylase (Serum/Plasma)	_____
Lipase (Serum/Plasma)	_____
Renal Function Tests Creatinine (Serum/Plasma)	_____
Creatinine Clearance, Calculated (Urine 24h)	_____
Creatinine Clearance, Cockcroft-Gault (Plasma)	_____
Creatinine Clearance, Cockcroft-Gault (Serum)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Plasma)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Serum)	_____

Lab Name:	
Urea (Serum/Plasma)	
Urea Nitrogen (BUN) (Serum/Plasma)	
Electrolytes Calcium, Ionized (Serum)	
Total Calcium (Serum/Plasma)	
Chloride (Serum/Plasma)	
Magnesium (Serum/Plasma)	
Phosphate (Phosphorus) (Serum/Plasma)	
Potassium (Serum/Plasma)	
Sodium (Serum/Plasma)	
Proteins Albumin (Serum/Plasma)	
Glucose Metabolism Glucose, Fasting (Serum/Plasma)	
Glucose,Random (Serum/Plasma)	
Hidden for Bilirubin	
Hidden for Aspartate	
Hidden for Alanine	
Hidden for Alanine Range	
Hidden for Asparate Range	
Hidden for Bilirubin Range	
Derived field to call CF	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 04 Day 08
Form: Non-central Laboratory Test Results - Hematology (LB1)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ■ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hemoglobin (Blood)	_____
Hematocrit (Blood)	_____
Leucocytes, Absolute Count (WBC) (Blood)	_____
Platelet count (Blood)	_____
Mean corpuscular volume (Blood)	_____
Absolute Neutrophil Count (Blood)	_____
Absolute Lymphocytes Count (Blood)	_____
Absolute Monocytes Count (Blood)	_____
Absolute Eosinophils,Count (Blood)	_____
Neutrophils, %/Ratio (Blood)	_____
Lymphocytes, %/Ratio (Blood)	_____
Monocytes, %/Ratio (Blood)	_____
Eosinophils, % /Ratio (Blood)	_____

Subject Continues to the Next Visit?	No ☐
	Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 05 Day 01
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)

Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 05 Day 01
Form: Assessment(s) Performed Triggering Form (ASMTRIG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2402 2024-02-16)

Select 'Yes' if all assessment forms are to be triggered	Yes ☐
Assessment(s) type	Extent of Disease Upon Entry to Study (DISEXT) ☐
	Pathology: at Screening (PATHGOM) ☐
	General Medical History (1MH) ☐
	Pre-specified medical conditions or events (2MH) ☐
	Surgical History (HISS) ☐
	Physical Examination (PE) ☐
	Vital Signs - Weight, Height (VS) ☐
	Vital Signs - Before Infusion (VS1) ☐
	Vital Signs - End of Infusion (VS2) ☐
	Vital Signs - Excluding Weight (VS3) ☐
	Vital Signs (VS4) ☐
	ECOG Performance Status (ECOG) ☐
	ECG Test Results (EG) ☐
	Additional ECG (EG1) ☐
	Additional ECG (EG2) ☐
	Echocardiography (ECHOC) ☐
	Non-central Laboratory Test Results - Chemistry (LB) ☐
	Non-central Laboratory Test Results - Hematology (LB1) ☐
	Non-central Laboratory Test Results - Coagulation (LB2) ☐
	Non-central Laboratory Test Results - Thyroid function test (LB3) ☐

- ☐ Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
- ☐ Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
- ☐ Non-central Laboratory Test Results - Urinalysis (LB6)
- ☐ Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
- ☐ Non-central Laboratory Test Results - Hy's Law (LB8)
- ☐ Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
- ☐ Non-central Laboratory Test Results - Tuberculosis testing (LB10)
- ☐ Non-central Laboratory Test Results - HIV testing (LB11)
- ☐ Non-central Laboratory Test Results - Additional Chemistry (LB12)
- ☐ Sample Collection, Predose_ADA Sample (SPCBEDB)
- ☐ Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
- ☐ PBMC for immune profiling_Pre dose (SPCBEDB2)
- ☐ Whole blood for RNA analysis_Pre-dose (SPCBEDB3)
- ☐ Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)

	Sample Collection, ADA Sample (SPCBEDB5) ☐
	Blood sample for plasma ctDNA (SPCBEDB6) ☐
	Optional on study tumor sample at recurrence (SPCBEDT) ☐
	Mandatory tumor sample from surgical resection for PDL1 analysis (SPCBEDT1) ☐
	Biological Sample Collection, Pre-dose PK (SPCPKB) ☐
	Biological Sample Collection, Post-dose PK (SPCPKB1) ☐
	Biological Sample Collection, PK (SPCPKB2) ☐
	Substance Use - Nicotine (SU_NIC) ☐
	Substance Use - Alcohol (SU_ALC) ☐
	Prior Cancer Therapy (CAPRX) ☐
	Prior Radiotherapy (CAPRXR) ☐
	Survival Status (SURVIVE) ☐
Assessment form to be triggered	No ☐
	Yes ☐
Reason assessment form is not to be triggered	Assessment not performed ☐
	Assessment not required ☐
	Subject discontinuation ☐
	Screen failure ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 05 Day 01
Form: Physical Examination (PE)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ1609 2019-04-19)

For baseline: Following items should be checked during baseline physical examination (A full physical examination will be performed and include assessments of the following: general appearance, respiratory, cardiovascular system, abdomen, skin, head and neck (including ears, eyes, nose, and throat), lymph nodes, thyroid, musculoskeletal (including spine and extremities), urogenital, dermatological, gastrointestinal, endocrine, hematologic/lymphatic, and neurological systems.).

For follow-up: Following items should be checked during follow-up physical examination (A targeted physical examination will include, at a minimum, assessments of skin, lungs, cardiovascular system, and abdomen (liver and spleen).

If the physical finding started prior to enrolment, it must be recorded as medical history.
If the physical finding started or worsened after enrolment, it must be recorded as an Adverse Event.

Was the physical examination performed?	No ☐ Yes ☐
What was the date of the physical examination?	Fixed Unit: yyyy mon dd

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 05 Day 01
Form: Vital Signs - Before Infusion (VS1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd
Protocol schedule	Prior to Infusion
Time	Fixed Unit: 24-hour clock
Pulse	Fixed Unit: beats/min
SBP	Fixed Unit: mmHg
DBP	Fixed Unit: mmHg
Respiration rate	Fixed Unit: breaths/min
Temperature	
Temperature unit	C
Peripheral oxygen saturation	Fixed Unit: %
Weight	
Weight unit	kg
EHRID	

(Version: ON2406 2024-06-04)

Clinical classification category	ECOG
What was the date the response or clinical classification was performed?	Fixed Unit: yyyy mon dd
Performance status	0-Fully active, able to carry on all pre-disease performance without restriction ☐ 1-Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work ☐ 2-Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours ☐ 3-Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours ☐ 4-Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair ☐ 5-Dead ☐

Ref: Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55). WHO Ref: World Health Organization (1979).Handbook for Reporting Results of Cancer Treatment Pb (WHO Offset Publications).

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 05 Day 01
Form: Pregnancy Test (PREG1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2008 2024-03-01)

Assessment applicable for Subject	No ☐
	Yes ☐
Sampling date	Fixed Unit: yyyy mon dd
Pregnancy test (serum)	Negative ☐
	Positive ☐
Pregnancy test (urine)	Negative ☐
	Positive ☐

For a positive pregnancy test after first dose of study drug, fill in PREGREP (or the 'Pregnancy Outcome Report Form' [Part 1]) and send to the AstraZeneca Monitor.

If positive pregnancy test, the administration of study drug to that Subject must be discontinued immediately and the End of Study Treatment form (ETRT) filled in.

If Positive pregnancy test, and considered an AE, please fill in Adverse Event (AE) Form
(Pregnancy itself is not regarded as an adverse event unless there is a suspicion that AstraZeneca product may have interfered with the effectiveness of a contraceptive medication.)

Hidden Field (used for CF programming)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 05 Day 01
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Liver Function Tests Alanine Aminotransferase (Serum/Plasma)	_____
Alkaline Phosphatase (Serum/Plasma)	_____
Aspartate Aminotransferase (Serum/Plasma)	_____
Bilirubin, Total (Serum/Plasma)	_____
Bilirubin, Direct, (Conj) (Serum/Plasma)	_____
Bilirubin, Indirect (Unconj.) (Serum/Plasma)	_____
Gamma-Glutamyltransferase (Serum/Plasma)	_____
Lactate Dehydrogenase (LDH) (Serum/Plasma)	_____
Protein, Total (Serum/Plasma)	_____
Pancreatic Enzymes Amylase (Serum/Plasma)	_____
Lipase (Serum/Plasma)	_____
Renal Function Tests Creatinine (Serum/Plasma)	_____
Creatinine Clearance, Calculated (Urine 24h)	_____
Creatinine Clearance, Cockcroft-Gault (Plasma)	_____
Creatinine Clearance, Cockcroft-Gault (Serum)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Plasma)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Serum)	_____

Lab Name:	
Urea (Serum/Plasma)	
Urea Nitrogen (BUN) (Serum/Plasma)	
Electrolytes Calcium, Ionized (Serum)	
Total Calcium (Serum/Plasma)	
Chloride (Serum/Plasma)	
Magnesium (Serum/Plasma)	
Phosphate (Phosphorus) (Serum/Plasma)	
Potassium (Serum/Plasma)	
Sodium (Serum/Plasma)	
Proteins Albumin (Serum/Plasma)	
Glucose Metabolism Glucose, Fasting (Serum/Plasma)	
Glucose,Random (Serum/Plasma)	
Hidden for Bilirubin	
Hidden for Aspartate	
Hidden for Alanine	
Hidden for Alanine Range	
Hidden for Asparate Range	
Hidden for Bilirubin Range	
Derived field to call CF	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 05 Day 01
Form: Non-central Laboratory Test Results - Hematology (LB1)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ■ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hemoglobin (Blood)	_____
Hematocrit (Blood)	_____
Leucocytes, Absolute Count (WBC) (Blood)	_____
Platelet count (Blood)	_____
Mean corpuscular volume (Blood)	_____
Absolute Neutrophil Count (Blood)	_____
Absolute Lymphocytes Count (Blood)	_____
Absolute Monocytes Count (Blood)	_____
Absolute Eosinophils,Count (Blood)	_____
Neutrophils, %/Ratio (Blood)	_____
Lymphocytes, %/Ratio (Blood)	_____
Monocytes, %/Ratio (Blood)	_____
Eosinophils, % /Ratio (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 05 Day 01
Form: Non-central Laboratory Test Results - Thyroid function test (LB3)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Thyroid Stimulating Hormone(Serum/Plasma)	_____
T4 (Thyroxine), Free(Serum/Plasma)	_____
T3 (Triiodothyronine), Free(Serum/Plasma)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 05 Day 01
Form: Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Carcinoembryonic Antigen (Serum/Plasma) (ng/mL)	_____
Carbohydrate Antigen 19-9 (Serum) (U/mL)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 05 Day 01
Form: Non-central Laboratory Test Results - Hepatitis B and C testing - Post Screening (LB13)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ■
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hepatitis B Viral Load, Quant (IU/mL) (Blood)	_____
Hepatitis B Viral Load, Quant (DNA copies/mL) (Blood)	_____
Hepatitis C Viral Load, Quant (IU/mL) (Blood)	_____
Hepatitis C Viral Load, Quant (RNA copies/mL) (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 05 Day 01
Form: PBMC for immune profiling_Pre dose (SPCBEDB2)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ■
	cfDNA-BCT ☐
	Blood ☐
Biofluid processed	PBMC ■
	Blood ☐
	Serum ☐
	Plasma ☐
Sample format	DNA ☐
	Fresh ■
	Frozen ☐
	RNA ☐
Date of collection	Fixed Unit: yyyy mon dd _____
Time of collection	Fixed Unit: 24-hour clock _____
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	_____
Protocol schedule	Pre Dose
Laboratory ID	Labcorp ■

Subject Continues to the Next Visit?	No ☐
	Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 05 Day 08
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)	
Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 05 Day 08
Form: Assessment(s) Performed Triggering Form (ASMTRIG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2402 2024-02-16)

Select 'Yes' if all assessment forms are to be triggered	Yes ☐
Assessment(s) type	Extent of Disease Upon Entry to Study (DISEXT) ☐
	Pathology: at Screening (PATHGOM) ☐
	General Medical History (1MH) ☐
	Pre-specified medical conditions or events (2MH) ☐
	Surgical History (HISS) ☐
	Physical Examination (PE) ☐
	Vital Signs - Weight, Height (VS) ☐
	Vital Signs - Before Infusion (VS1) ☐
	Vital Signs - End of Infusion (VS2) ☐
	Vital Signs - Excluding Weight (VS3) ☐
	Vital Signs (VS4) ☐
	ECOG Performance Status (ECOG) ☐
	ECG Test Results (EG) ☐
	Additional ECG (EG1) ☐
	Additional ECG (EG2) ☐
	Echocardiography (ECHOC) ☐
	Non-central Laboratory Test Results - Chemistry (LB) ☐
	Non-central Laboratory Test Results - Hematology (LB1) ☐
	Non-central Laboratory Test Results - Coagulation (LB2) ☐
	Non-central Laboratory Test Results - Thyroid function test (LB3) ☐

Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
Non-central Laboratory Test Results - Urinalysis (LB6)
Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
Non-central Laboratory Test Results - Hy's Law (LB8)
Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
Non-central Laboratory Test Results - Tuberculosis testing (LB10)
Non-central Laboratory Test Results - HIV testing (LB11)
Non-central Laboratory Test Results - Additional Chemistry (LB12)
Sample Collection, Predose_ADA Sample (SPCBEDB)
Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
PBMC for immune profiling_Pre dose (SPCBEDB2)
Whole blood for RNA analysis_Pre-dose (SPCBEDB3)
Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)

	Sample Collection, ADA Sample (SPCBEDB5) ☐
	Blood sample for plasma ctDNA (SPCBEDB6) ☐
	Optional on study tumor sample at recurrence (SPCBEDT) ☐
	Mandatory tumor sample from surgical resection for PDL1 analysis (SPCBEDT1) ☐
	Biological Sample Collection, Pre-dose PK (SPCPKB) ☐
	Biological Sample Collection, Post-dose PK (SPCPKB1) ☐
	Biological Sample Collection, PK (SPCPKB2) ☐
	Substance Use - Nicotine (SU_NIC) ☐
	Substance Use - Alcohol (SU_ALC) ☐
	Prior Cancer Therapy (CAPRX) ☐
	Prior Radiotherapy (CAPRXR) ☐
	Survival Status (SURVIVE) ☐
Assessment form to be triggered	No ☐
	Yes ☐
Reason assessment form is not to be triggered	Assessment not performed ☐
	Assessment not required ☐
	Subject discontinuation ☐
	Screen failure ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 05 Day 08
Form: Vital Signs - Excluding Weight (VS3)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd
Time	Fixed Unit: 24-hour clock
Pulse	Fixed Unit: beats/min
SBP	Fixed Unit: mmHg
DBP	Fixed Unit: mmHg
Respiration rate	Fixed Unit: breaths/min
Temperature	
Temperature unit	C ●
Peripheral oxygen saturation	Fixed Unit: %
EHRID	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 05 Day 08
Form: ECOG Performance Status (ECOG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: ON2406 2024-06-04)

Clinical classification category	ECOG
What was the date the response or clinical classification was performed?	Fixed Unit: yyyy mon dd
Performance status	0-Fully active, able to carry on all pre-disease performance without restriction ☐ 1-Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work ☐ 2-Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours ☐ 3-Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours ☐ 4-Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair ☐ 5-Dead ☐

Ref: Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55). WHO Ref: World Health Organization (1979).Handbook for Reporting Results of Cancer Treatment Pb (WHO Offset Publications).

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 05 Day 08
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Liver Function Tests Alanine Aminotransferase (Serum/Plasma)	_____
Alkaline Phosphatase (Serum/Plasma)	_____
Aspartate Aminotransferase (Serum/Plasma)	_____
Bilirubin, Total (Serum/Plasma)	_____
Bilirubin, Direct, (Conj) (Serum/Plasma)	_____
Bilirubin, Indirect (Unconj.) (Serum/Plasma)	_____
Gamma-Glutamyltransferase (Serum/Plasma)	_____
Lactate Dehydrogenase (LDH) (Serum/Plasma)	_____
Protein, Total (Serum/Plasma)	_____
Pancreatic Enzymes Amylase (Serum/Plasma)	_____
Lipase (Serum/Plasma)	_____
Renal Function Tests Creatinine (Serum/Plasma)	_____
Creatinine Clearance, Calculated (Urine 24h)	_____
Creatinine Clearance, Cockcroft-Gault (Plasma)	_____
Creatinine Clearance, Cockcroft-Gault (Serum)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Plasma)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Serum)	_____

Lab Name:	
Urea (Serum/Plasma)	
Urea Nitrogen (BUN) (Serum/Plasma)	
Electrolytes Calcium, Ionized (Serum)	
Total Calcium (Serum/Plasma)	
Chloride (Serum/Plasma)	
Magnesium (Serum/Plasma)	
Phosphate (Phosphorus) (Serum/Plasma)	
Potassium (Serum/Plasma)	
Sodium (Serum/Plasma)	
Proteins Albumin (Serum/Plasma)	
Glucose Metabolism Glucose, Fasting (Serum/Plasma)	
Glucose,Random (Serum/Plasma)	
Hidden for Bilirubin	
Hidden for Aspartate	
Hidden for Alanine	
Hidden for Alanine Range	
Hidden for Asparate Range	
Hidden for Bilirubin Range	
Derived field to call CF	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 05 Day 08
Form: Non-central Laboratory Test Results - Hematology (LB1)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ■ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hemoglobin (Blood)	_____
Hematocrit (Blood)	_____
Leucocytes, Absolute Count (WBC) (Blood)	_____
Platelet count (Blood)	_____
Mean corpuscular volume (Blood)	_____
Absolute Neutrophil Count (Blood)	_____
Absolute Lymphocytes Count (Blood)	_____
Absolute Monocytes Count (Blood)	_____
Absolute Eosinophils,Count (Blood)	_____
Neutrophils, %/Ratio (Blood)	_____
Lymphocytes, %/Ratio (Blood)	_____
Monocytes, %/Ratio (Blood)	_____
Eosinophils, % /Ratio (Blood)	_____

Subject Continues to the Next Visit?	No ☐
	Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 06 Day 01
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)	
Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 06 Day 01
Form: Assessment(s) Performed Triggering Form (ASMTRIG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2402 2024-02-16)

Select 'Yes' if all assessment forms are to be triggered	Yes ☐
Assessment(s) type	Extent of Disease Upon Entry to Study (DISEXT) ☐
	Pathology: at Screening (PATHGOM) ☐
	General Medical History (1MH) ☐
	Pre-specified medical conditions or events (2MH) ☐
	Surgical History (HISS) ☐
	Physical Examination (PE) ☐
	Vital Signs - Weight, Height (VS) ☐
	Vital Signs - Before Infusion (VS1) ☐
	Vital Signs - End of Infusion (VS2) ☐
	Vital Signs - Excluding Weight (VS3) ☐
	Vital Signs (VS4) ☐
	ECOG Performance Status (ECOG) ☐
	ECG Test Results (EG) ☐
	Additional ECG (EG1) ☐
	Additional ECG (EG2) ☐
	Echocardiography (ECHOC) ☐
	Non-central Laboratory Test Results - Chemistry (LB) ☐
	Non-central Laboratory Test Results - Hematology (LB1) ☐
	Non-central Laboratory Test Results - Coagulation (LB2) ☐
	Non-central Laboratory Test Results - Thyroid function test (LB3) ☐

- ☐ Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
- ☐ Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
- ☐ Non-central Laboratory Test Results - Urinalysis (LB6)
- ☐ Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
- ☐ Non-central Laboratory Test Results - Hy's Law (LB8)
- ☐ Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
- ☐ Non-central Laboratory Test Results - Tuberculosis testing (LB10)
- ☐ Non-central Laboratory Test Results - HIV testing (LB11)
- ☐ Non-central Laboratory Test Results - Additional Chemistry (LB12)
- ☐ Sample Collection, Predose_ADA Sample (SPCBEDB)
- ☐ Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
- ☐ PBMC for immune profiling_Pre dose (SPCBEDB2)
- ☐ Whole blood for RNA analysis_Pre-dose (SPCBEDB3)
- ☐ Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)

	Sample Collection, ADA Sample (SPCBEDB5) ☐
	Blood sample for plasma ctDNA (SPCBEDB6) ☐
	Optional on study tumor sample at recurrence (SPCBEDT) ☐
	Mandatory tumor sample from surgical resection for PDL1 analysis (SPCBEDT1) ☐
	Biological Sample Collection, Pre-dose PK (SPCPKB) ☐
	Biological Sample Collection, Post-dose PK (SPCPKB1) ☐
	Biological Sample Collection, PK (SPCPKB2) ☐
	Substance Use - Nicotine (SU_NIC) ☐
	Substance Use - Alcohol (SU_ALC) ☐
	Prior Cancer Therapy (CAPRX) ☐
	Prior Radiotherapy (CAPRXR) ☐
	Survival Status (SURVIVE) ☐
Assessment form to be triggered	No ☐
	Yes ☐
Reason assessment form is not to be triggered	Assessment not performed ☐
	Assessment not required ☐
	Subject discontinuation ☐
	Screen failure ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 06 Day 01
Form: Physical Examination (PE)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ1609 2019-04-19)

For baseline: Following items should be checked during baseline physical examination (A full physical examination will be performed and include assessments of the following: general appearance, respiratory, cardiovascular system, abdomen, skin, head and neck (including ears, eyes, nose, and throat), lymph nodes, thyroid, musculoskeletal (including spine and extremities), urogenital, dermatological, gastrointestinal, endocrine, hematologic/lymphatic, and neurological systems.).

For follow-up: Following items should be checked during follow-up physical examination (A targeted physical examination will include, at a minimum, assessments of skin, lungs, cardiovascular system, and abdomen (liver and spleen).

If the physical finding started prior to enrolment, it must be recorded as medical history.
If the physical finding started or worsened after enrolment, it must be recorded as an Adverse Event.

Was the physical examination performed?	No ☐ Yes ☐
What was the date of the physical examination?	Fixed Unit: yyyy mon dd

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 06 Day 01
Form: Vital Signs - Before Infusion (VS1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd
Protocol schedule	Prior to Infusion
Time	Fixed Unit: 24-hour clock
Pulse	Fixed Unit: beats/min
SBP	Fixed Unit: mmHg
DBP	Fixed Unit: mmHg
Respiration rate	Fixed Unit: breaths/min
Temperature	
Temperature unit	C ●
Peripheral oxygen saturation	Fixed Unit: %
Weight	
Weight unit	kg ●
EHRID	

(Version: ON2406 2024-06-04)

Clinical classification category	ECOG
What was the date the response or clinical classification was performed?	Fixed Unit: yyyy mon dd
Performance status	0-Fully active, able to carry on all pre-disease performance without restriction ☐ 1-Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work ☐ 2-Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours ☐ 3-Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours ☐ 4-Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair ☐ 5-Dead ☐

Ref: Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55). WHO Ref: World Health Organization (1979).Handbook for Reporting Results of Cancer Treatment Pb (WHO Offset Publications).

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 06 Day 01
Form: Pregnancy Test (PREG1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2008 2024-03-01)

Assessment applicable for Subject	No ☐
	Yes ☐
Sampling date	Fixed Unit: yyyy mon dd
Pregnancy test (serum)	Negative ☐
	Positive ☐
Pregnancy test (urine)	Negative ☐
	Positive ☐

For a positive pregnancy test after first dose of study drug, fill in PREGREP (or the 'Pregnancy Outcome Report Form' [Part 1]) and send to the AstraZeneca Monitor.

If positive pregnancy test, the administration of study drug to that Subject must be discontinued immediately and the End of Study Treatment form (ETRT) filled in.

If Positive pregnancy test, and considered an AE, please fill in Adverse Event (AE) Form
(Pregnancy itself is not regarded as an adverse event unless there is a suspicion that AstraZeneca product may have interfered with the effectiveness of a contraceptive medication.)

Hidden Field (used for CF programming)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 06 Day 01
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Liver Function Tests Alanine Aminotransferase (Serum/Plasma)	_____
Alkaline Phosphatase (Serum/Plasma)	_____
Aspartate Aminotransferase (Serum/Plasma)	_____
Bilirubin, Total (Serum/Plasma)	_____
Bilirubin, Direct, (Conj) (Serum/Plasma)	_____
Bilirubin, Indirect (Unconj.) (Serum/Plasma)	_____
Gamma-Glutamyltransferase (Serum/Plasma)	_____
Lactate Dehydrogenase (LDH) (Serum/Plasma)	_____
Protein, Total (Serum/Plasma)	_____
Pancreatic Enzymes Amylase (Serum/Plasma)	_____
Lipase (Serum/Plasma)	_____
Renal Function Tests Creatinine (Serum/Plasma)	_____
Creatinine Clearance, Calculated (Urine 24h)	_____
Creatinine Clearance, Cockcroft-Gault (Plasma)	_____
Creatinine Clearance, Cockcroft-Gault (Serum)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Plasma)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Serum)	_____

Lab Name:	
Urea (Serum/Plasma)	
Urea Nitrogen (BUN) (Serum/Plasma)	
Electrolytes Calcium, Ionized (Serum)	
Total Calcium (Serum/Plasma)	
Chloride (Serum/Plasma)	
Magnesium (Serum/Plasma)	
Phosphate (Phosphorus) (Serum/Plasma)	
Potassium (Serum/Plasma)	
Sodium (Serum/Plasma)	
Proteins Albumin (Serum/Plasma)	
Glucose Metabolism Glucose, Fasting (Serum/Plasma)	
Glucose,Random (Serum/Plasma)	
Hidden for Bilirubin	
Hidden for Aspartate	
Hidden for Alanine	
Hidden for Alanine Range	
Hidden for Asparate Range	
Hidden for Bilirubin Range	
Derived field to call CF	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 06 Day 01
Form: Non-central Laboratory Test Results - Hematology (LB1)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ■ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hemoglobin (Blood)	_____
Hematocrit (Blood)	_____
Leucocytes, Absolute Count (WBC) (Blood)	_____
Platelet count (Blood)	_____
Mean corpuscular volume (Blood)	_____
Absolute Neutrophil Count (Blood)	_____
Absolute Lymphocytes Count (Blood)	_____
Absolute Monocytes Count (Blood)	_____
Absolute Eosinophils,Count (Blood)	_____
Neutrophils, %/Ratio (Blood)	_____
Lymphocytes, %/Ratio (Blood)	_____
Monocytes, %/Ratio (Blood)	_____
Eosinophils, % /Ratio (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 06 Day 01
Form: Non-central Laboratory Test Results - Thyroid function test (LB3)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Thyroid Stimulating Hormone(Serum/Plasma)	_____
T4 (Thyroxine), Free(Serum/Plasma)	_____
T3 (Triiodothyronine), Free(Serum/Plasma)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 06 Day 01
Form: Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Carcinoembryonic Antigen (Serum/Plasma) (ng/mL)	_____
Carbohydrate Antigen 19-9 (Serum) (U/mL)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 06 Day 01
Form: Non-central Laboratory Test Results - Hepatitis B and C testing - Post Screening (LB13)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ■
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hepatitis B Viral Load, Quant (IU/mL) (Blood)	_____
Hepatitis B Viral Load, Quant (DNA copies/mL) (Blood)	_____
Hepatitis C Viral Load, Quant (IU/mL) (Blood)	_____
Hepatitis C Viral Load, Quant (RNA copies/mL) (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 06 Day 01
Form: Sample Collection, Predose_ADA Sample (SPCBEDB)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ☐
	cfDNA-BCT ☐
	Blood ■
Biofluid processed	PBMC ☐
	Blood ☐
	Serum ■
	Plasma ☐
Sample format	DNA ☐
	Fresh ☐
	Frozen ■
	RNA ☐
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Protocol schedule	Pre Dose
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 06 Day 01
Form: Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ☐
	cfDNA-BCT ■
	Blood ☐
Biofluid processed	PBMC ☐
	Blood ☐
	Serum ☐
	Plasma ■
Sample format	DNA ■
	Fresh ☐
	Frozen ☐
	RNA ☐
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Protocol schedule	Pre Dose
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 06 Day 01
Form: Biological Sample Collection, Pre-dose PK (SPCPKB)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample collection category?	PK, biofluid ■
Sample collected	No ☐ Yes ☐
Last investigational product date	Fixed Unit: yyyy mon dd
Last investigational product time	Fixed Unit: 24-hour clock
Biofluid collected (parent sample)	Blood ■
Biofluid processed	Serum ■
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐ Hemolyzed ☐ Clotted ☐ Lipemic ☐ Quantity less than expected ☐ Sample discarded ☐ Other ☐
If Other, specify	
Date of storage	Fixed Unit: yyyy mon dd
Time of storage	Fixed Unit: 24-hour clock
Protocol schedule	Pre Dose
Protocol schedule day	1
Protocol schedule hour	-99
Protocol schedule minute	-99
Laboratory ID	Labcorp ■

Subject Continues to the Next Visit?	No ☐
	Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 06 Day 08
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)	
Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 06 Day 08
Form: Assessment(s) Performed Triggering Form (ASMTRIG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2402 2024-02-16)

Select 'Yes' if all assessment forms are to be triggered	Yes ☐
Assessment(s) type	Extent of Disease Upon Entry to Study (DISEXT) ☐
	Pathology: at Screening (PATHGOM) ☐
	General Medical History (1MH) ☐
	Pre-specified medical conditions or events (2MH) ☐
	Surgical History (HISS) ☐
	Physical Examination (PE) ☐
	Vital Signs - Weight, Height (VS) ☐
	Vital Signs - Before Infusion (VS1) ☐
	Vital Signs - End of Infusion (VS2) ☐
	Vital Signs - Excluding Weight (VS3) ☐
	Vital Signs (VS4) ☐
	ECOG Performance Status (ECOG) ☐
	ECG Test Results (EG) ☐
	Additional ECG (EG1) ☐
	Additional ECG (EG2) ☐
	Echocardiography (ECHOC) ☐
	Non-central Laboratory Test Results - Chemistry (LB) ☐
	Non-central Laboratory Test Results - Hematology (LB1) ☐
	Non-central Laboratory Test Results - Coagulation (LB2) ☐
	Non-central Laboratory Test Results - Thyroid function test (LB3) ☐

Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
Non-central Laboratory Test Results - Urinalysis (LB6)
Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
Non-central Laboratory Test Results - Hy's Law (LB8)
Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
Non-central Laboratory Test Results - Tuberculosis testing (LB10)
Non-central Laboratory Test Results - HIV testing (LB11)
Non-central Laboratory Test Results - Additional Chemistry (LB12)
Sample Collection, Predose_ADA Sample (SPCBEDB)
Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
PBMC for immune profiling_Pre dose (SPCBEDB2)
Whole blood for RNA analysis_Pre-dose (SPCBEDB3)
Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)

	Sample Collection, ADA Sample (SPCBEDB5) ☐
	Blood sample for plasma ctDNA (SPCBEDB6) ☐
	Optional on study tumor sample at recurrence (SPCBEDT) ☐
	Mandatory tumor sample from surgical resection for PDL1 analysis (SPCBEDT1) ☐
	Biological Sample Collection, Pre-dose PK (SPCPKB) ☐
	Biological Sample Collection, Post-dose PK (SPCPKB1) ☐
	Biological Sample Collection, PK (SPCPKB2) ☐
	Substance Use - Nicotine (SU_NIC) ☐
	Substance Use - Alcohol (SU_ALC) ☐
	Prior Cancer Therapy (CAPRX) ☐
	Prior Radiotherapy (CAPRXR) ☐
	Survival Status (SURVIVE) ☐
Assessment form to be triggered	No ☐
	Yes ☐
Reason assessment form is not to be triggered	Assessment not performed ☐
	Assessment not required ☐
	Subject discontinuation ☐
	Screen failure ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 06 Day 08
Form: Vital Signs - Excluding Weight (VS3)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd
Time	Fixed Unit: 24-hour clock
Pulse	Fixed Unit: beats/min
SBP	Fixed Unit: mmHg
DBP	Fixed Unit: mmHg
Respiration rate	Fixed Unit: breaths/min
Temperature	
Temperature unit	C ●
Peripheral oxygen saturation	Fixed Unit: %
EHRID	

(Version: ON2406 2024-06-04)

Clinical classification category	ECOG
What was the date the response or clinical classification was performed?	Fixed Unit: yyyy mon dd
Performance status	0-Fully active, able to carry on all pre-disease performance without restriction ☐ 1-Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work ☐ 2-Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours ☐ 3-Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours ☐ 4-Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair ☐ 5-Dead ☐

Ref: Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55). WHO Ref: World Health Organization (1979).Handbook for Reporting Results of Cancer Treatment Pb (WHO Offset Publications).

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 06 Day 08
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Liver Function Tests Alanine Aminotransferase (Serum/Plasma)	_____
Alkaline Phosphatase (Serum/Plasma)	_____
Aspartate Aminotransferase (Serum/Plasma)	_____
Bilirubin, Total (Serum/Plasma)	_____
Bilirubin, Direct, (Conj) (Serum/Plasma)	_____
Bilirubin, Indirect (Unconj.) (Serum/Plasma)	_____
Gamma-Glutamyltransferase (Serum/Plasma)	_____
Lactate Dehydrogenase (LDH) (Serum/Plasma)	_____
Protein, Total (Serum/Plasma)	_____
Pancreatic Enzymes Amylase (Serum/Plasma)	_____
Lipase (Serum/Plasma)	_____
Renal Function Tests Creatinine (Serum/Plasma)	_____
Creatinine Clearance, Calculated (Urine 24h)	_____
Creatinine Clearance, Cockcroft-Gault (Plasma)	_____
Creatinine Clearance, Cockcroft-Gault (Serum)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Plasma)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Serum)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 06 Day 08
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:27 (GMT)

Lab Name:	
Urea (Serum/Plasma)	
Urea Nitrogen (BUN) (Serum/Plasma)	
Electrolytes Calcium, Ionized (Serum)	
Total Calcium (Serum/Plasma)	
Chloride (Serum/Plasma)	
Magnesium (Serum/Plasma)	
Phosphate (Phosphorus) (Serum/Plasma)	
Potassium (Serum/Plasma)	
Sodium (Serum/Plasma)	
Proteins Albumin (Serum/Plasma)	
Glucose Metabolism Glucose, Fasting (Serum/Plasma)	
Glucose,Random (Serum/Plasma)	
Hidden for Bilirubin	
Hidden for Aspartate	
Hidden for Alanine	
Hidden for Alanine Range	
Hidden for Asparate Range	
Hidden for Bilirubin Range	
Derived field to call CF	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 06 Day 08
Form: Non-central Laboratory Test Results - Hematology (LB1)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ■ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hemoglobin (Blood)	_____
Hematocrit (Blood)	_____
Leucocytes, Absolute Count (WBC) (Blood)	_____
Platelet count (Blood)	_____
Mean corpuscular volume (Blood)	_____
Absolute Neutrophil Count (Blood)	_____
Absolute Lymphocytes Count (Blood)	_____
Absolute Monocytes Count (Blood)	_____
Absolute Eosinophils,Count (Blood)	_____
Neutrophils, %/Ratio (Blood)	_____
Lymphocytes, %/Ratio (Blood)	_____
Monocytes, %/Ratio (Blood)	_____
Eosinophils, % /Ratio (Blood)	_____

Subject Continues to the Next Visit?	No ☐
	Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 07 Day 01
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)	
Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 07 Day 01
Form: Assessment(s) Performed Triggering Form (ASMTRIG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2402 2024-02-16)

Select 'Yes' if all assessment forms are to be triggered	Yes ☐
Assessment(s) type	Extent of Disease Upon Entry to Study (DISEXT) ☐
	Pathology: at Screening (PATHGOM) ☐
	General Medical History (1MH) ☐
	Pre-specified medical conditions or events (2MH) ☐
	Surgical History (HISS) ☐
	Physical Examination (PE) ☐
	Vital Signs - Weight, Height (VS) ☐
	Vital Signs - Before Infusion (VS1) ☐
	Vital Signs - End of Infusion (VS2) ☐
	Vital Signs - Excluding Weight (VS3) ☐
	Vital Signs (VS4) ☐
	ECOG Performance Status (ECOG) ☐
	ECG Test Results (EG) ☐
	Additional ECG (EG1) ☐
	Additional ECG (EG2) ☐
	Echocardiography (ECHOC) ☐
	Non-central Laboratory Test Results - Chemistry (LB) ☐
	Non-central Laboratory Test Results - Hematology (LB1) ☐
	Non-central Laboratory Test Results - Coagulation (LB2) ☐
	Non-central Laboratory Test Results - Thyroid function test (LB3) ☐

- ☐ Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
- ☐ Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
- ☐ Non-central Laboratory Test Results - Urinalysis (LB6)
- ☐ Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
- ☐ Non-central Laboratory Test Results - Hy's Law (LB8)
- ☐ Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
- ☐ Non-central Laboratory Test Results - Tuberculosis testing (LB10)
- ☐ Non-central Laboratory Test Results - HIV testing (LB11)
- ☐ Non-central Laboratory Test Results - Additional Chemistry (LB12)
- ☐ Sample Collection, Predose_ADA Sample (SPCBEDB)
- ☐ Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
- ☐ PBMC for immune profiling_Pre dose (SPCBEDB2)
- ☐ Whole blood for RNA analysis_Pre-dose (SPCBEDB3)
- ☐ Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)

	Sample Collection, ADA Sample (SPCBEDB5) ☐
	Blood sample for plasma ctDNA (SPCBEDB6) ☐
	Optional on study tumor sample at recurrence (SPCBEDT) ☐
	Mandatory tumor sample from surgical resection for PDL1 analysis (SPCBEDT1) ☐
	Biological Sample Collection, Pre-dose PK (SPCPKB) ☐
	Biological Sample Collection, Post-dose PK (SPCPKB1) ☐
	Biological Sample Collection, PK (SPCPKB2) ☐
	Substance Use - Nicotine (SU_NIC) ☐
	Substance Use - Alcohol (SU_ALC) ☐
	Prior Cancer Therapy (CAPRX) ☐
	Prior Radiotherapy (CAPRXR) ☐
	Survival Status (SURVIVE) ☐
Assessment form to be triggered	No ☐
	Yes ☐
Reason assessment form is not to be triggered	Assessment not performed ☐
	Assessment not required ☐
	Subject discontinuation ☐
	Screen failure ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 07 Day 01
Form: Physical Examination (PE)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ1609 2019-04-19)

For baseline: Following items should be checked during baseline physical examination (A full physical examination will be performed and include assessments of the following: general appearance, respiratory, cardiovascular system, abdomen, skin, head and neck (including ears, eyes, nose, and throat), lymph nodes, thyroid, musculoskeletal (including spine and extremities), urogenital, dermatological, gastrointestinal, endocrine, hematologic/lymphatic, and neurological systems.).

For follow-up: Following items should be checked during follow-up physical examination (A targeted physical examination will include, at a minimum, assessments of skin, lungs, cardiovascular system, and abdomen (liver and spleen).

If the physical finding started prior to enrolment, it must be recorded as medical history.
If the physical finding started or worsened after enrolment, it must be recorded as an Adverse Event.

Was the physical examination performed?	No ☐ Yes ☐
What was the date of the physical examination?	Fixed Unit: yyyy mon dd

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 07 Day 01
Form: Vital Signs - Before Infusion (VS1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd
Protocol schedule	Prior to Infusion
Time	Fixed Unit: 24-hour clock
Pulse	Fixed Unit: beats/min
SBP	Fixed Unit: mmHg
DBP	Fixed Unit: mmHg
Respiration rate	Fixed Unit: breaths/min
Temperature	
Temperature unit	C
Peripheral oxygen saturation	Fixed Unit: %
Weight	
Weight unit	kg
EHRID	

(Version: ON2406 2024-06-04)

Clinical classification category	ECOG
What was the date the response or clinical classification was performed?	Fixed Unit: yyyy mon dd
Performance status	0-Fully active, able to carry on all pre-disease performance without restriction ☐ 1-Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work ☐ 2-Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours ☐ 3-Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours ☐ 4-Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair ☐ 5-Dead ☐

Ref: Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55). WHO Ref: World Health Organization (1979).Handbook for Reporting Results of Cancer Treatment Pb (WHO Offset Publications).

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 07 Day 01
Form: Pregnancy Test (PREG1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2008 2024-03-01)

Assessment applicable for Subject	No ☐
	Yes ☐
Sampling date	Fixed Unit: yyyy mon dd
Pregnancy test (serum)	Negative ☐
	Positive ☐
Pregnancy test (urine)	Negative ☐
	Positive ☐

For a positive pregnancy test after first dose of study drug, fill in PREGREP (or the 'Pregnancy Outcome Report Form' [Part 1]) and send to the AstraZeneca Monitor.

If positive pregnancy test, the administration of study drug to that Subject must be discontinued immediately and the End of Study Treatment form (ETRT) filled in.

If Positive pregnancy test, and considered an AE, please fill in Adverse Event (AE) Form
(Pregnancy itself is not regarded as an adverse event unless there is a suspicion that AstraZeneca product may have interfered with the effectiveness of a contraceptive medication.)

Hidden Field (used for CF programming)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 07 Day 01
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Liver Function Tests Alanine Aminotransferase (Serum/Plasma)	_____
Alkaline Phosphatase (Serum/Plasma)	_____
Aspartate Aminotransferase (Serum/Plasma)	_____
Bilirubin, Total (Serum/Plasma)	_____
Bilirubin, Direct, (Conj) (Serum/Plasma)	_____
Bilirubin, Indirect (Unconj.) (Serum/Plasma)	_____
Gamma-Glutamyltransferase (Serum/Plasma)	_____
Lactate Dehydrogenase (LDH) (Serum/Plasma)	_____
Protein, Total (Serum/Plasma)	_____
Pancreatic Enzymes Amylase (Serum/Plasma)	_____
Lipase (Serum/Plasma)	_____
Renal Function Tests Creatinine (Serum/Plasma)	_____
Creatinine Clearance, Calculated (Urine 24h)	_____
Creatinine Clearance, Cockcroft-Gault (Plasma)	_____
Creatinine Clearance, Cockcroft-Gault (Serum)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Plasma)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Serum)	_____

Lab Name:	
Urea (Serum/Plasma)	
Urea Nitrogen (BUN) (Serum/Plasma)	
Electrolytes Calcium, Ionized (Serum)	
Total Calcium (Serum/Plasma)	
Chloride (Serum/Plasma)	
Magnesium (Serum/Plasma)	
Phosphate (Phosphorus) (Serum/Plasma)	
Potassium (Serum/Plasma)	
Sodium (Serum/Plasma)	
Proteins Albumin (Serum/Plasma)	
Glucose Metabolism Glucose, Fasting (Serum/Plasma)	
Glucose,Random (Serum/Plasma)	
Hidden for Bilirubin	
Hidden for Aspartate	
Hidden for Alanine	
Hidden for Alanine Range	
Hidden for Asparate Range	
Hidden for Bilirubin Range	
Derived field to call CF	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 07 Day 01
Form: Non-central Laboratory Test Results - Hematology (LB1)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ■ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hemoglobin (Blood)	_____
Hematocrit (Blood)	_____
Leucocytes, Absolute Count (WBC) (Blood)	_____
Platelet count (Blood)	_____
Mean corpuscular volume (Blood)	_____
Absolute Neutrophil Count (Blood)	_____
Absolute Lymphocytes Count (Blood)	_____
Absolute Monocytes Count (Blood)	_____
Absolute Eosinophils,Count (Blood)	_____
Neutrophils, %/Ratio (Blood)	_____
Lymphocytes, %/Ratio (Blood)	_____
Monocytes, %/Ratio (Blood)	_____
Eosinophils, % /Ratio (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 07 Day 01
Form: Non-central Laboratory Test Results - Thyroid function test (LB3)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Thyroid Stimulating Hormone(Serum/Plasma)	_____
T4 (Thyroxine), Free(Serum/Plasma)	_____
T3 (Triiodothyronine), Free(Serum/Plasma)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 07 Day 01
Form: Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock
Creatine Kinase (Serum/Plasma)	
Troponin T (Serum/Plasma)	
Troponin I (Serum/Plasma)	
High- sensitivity Troponin T (Serum/Plasma)	
High- sensitivity Troponin I (Serum/Plasma)	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 07 Day 01
Form: Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Carcinoembryonic Antigen (Serum/Plasma) (ng/mL)	_____
Carbohydrate Antigen 19-9 (Serum) (U/mL)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 07 Day 01
Form: Non-central Laboratory Test Results - Hepatitis B and C testing - Post Screening (LB13)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ■
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hepatitis B Viral Load, Quant (IU/mL) (Blood)	_____
Hepatitis B Viral Load, Quant (DNA copies/mL) (Blood)	_____
Hepatitis C Viral Load, Quant (IU/mL) (Blood)	_____
Hepatitis C Viral Load, Quant (RNA copies/mL) (Blood)	_____

Subject Continues to the Next Visit?	No ☐
	Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 07 Day 08
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)	
Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 07 Day 08
Form: Assessment(s) Performed Triggering Form (ASMTRIG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2402 2024-02-16)

Select 'Yes' if all assessment forms are to be triggered	Yes ☐
Assessment(s) type	Extent of Disease Upon Entry to Study (DISEXT) ☐
	Pathology: at Screening (PATHGOM) ☐
	General Medical History (1MH) ☐
	Pre-specified medical conditions or events (2MH) ☐
	Surgical History (HISS) ☐
	Physical Examination (PE) ☐
	Vital Signs - Weight, Height (VS) ☐
	Vital Signs - Before Infusion (VS1) ☐
	Vital Signs - End of Infusion (VS2) ☐
	Vital Signs - Excluding Weight (VS3) ☐
	Vital Signs (VS4) ☐
	ECOG Performance Status (ECOG) ☐
	ECG Test Results (EG) ☐
	Additional ECG (EG1) ☐
	Additional ECG (EG2) ☐
	Echocardiography (ECHOC) ☐
	Non-central Laboratory Test Results - Chemistry (LB) ☐
	Non-central Laboratory Test Results - Hematology (LB1) ☐
	Non-central Laboratory Test Results - Coagulation (LB2) ☐
	Non-central Laboratory Test Results - Thyroid function test (LB3) ☐

Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
Non-central Laboratory Test Results - Urinalysis (LB6)
Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
Non-central Laboratory Test Results - Hy's Law (LB8)
Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
Non-central Laboratory Test Results - Tuberculosis testing (LB10)
Non-central Laboratory Test Results - HIV testing (LB11)
Non-central Laboratory Test Results - Additional Chemistry (LB12)
Sample Collection, Predose_ADA Sample (SPCBEDB)
Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
PBMC for immune profiling_Pre dose (SPCBEDB2)
Whole blood for RNA analysis_Pre-dose (SPCBEDB3)
Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)

	Sample Collection, ADA Sample (SPCBEDB5) ☐
	Blood sample for plasma ctDNA (SPCBEDB6) ☐
	Optional on study tumor sample at recurrence (SPCBEDT) ☐
	Mandatory tumor sample from surgical resection for PDL1 analysis (SPCBEDT1) ☐
	Biological Sample Collection, Pre-dose PK (SPCPKB) ☐
	Biological Sample Collection, Post-dose PK (SPCPKB1) ☐
	Biological Sample Collection, PK (SPCPKB2) ☐
	Substance Use - Nicotine (SU_NIC) ☐
	Substance Use - Alcohol (SU_ALC) ☐
	Prior Cancer Therapy (CAPRX) ☐
	Prior Radiotherapy (CAPRXR) ☐
	Survival Status (SURVIVE) ☐
Assessment form to be triggered	No ☐
	Yes ☐
Reason assessment form is not to be triggered	Assessment not performed ☐
	Assessment not required ☐
	Subject discontinuation ☐
	Screen failure ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 07 Day 08
Form: Vital Signs - Excluding Weight (VS3)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd
Time	Fixed Unit: 24-hour clock
Pulse	Fixed Unit: beats/min
SBP	Fixed Unit: mmHg
DBP	Fixed Unit: mmHg
Respiration rate	Fixed Unit: breaths/min
Temperature	
Temperature unit	C ●
Peripheral oxygen saturation	Fixed Unit: %
EHRID	

(Version: ON2406 2024-06-04)

Clinical classification category	ECOG
What was the date the response or clinical classification was performed?	Fixed Unit: yyyy mon dd
Performance status	0-Fully active, able to carry on all pre-disease performance without restriction ☐ 1-Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work ☐ 2-Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours ☐ 3-Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours ☐ 4-Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair ☐ 5-Dead ☐

Ref: Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55). WHO Ref: World Health Organization (1979).Handbook for Reporting Results of Cancer Treatment Pb (WHO Offset Publications).

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 07 Day 08
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Liver Function Tests Alanine Aminotransferase (Serum/Plasma)	_____
Alkaline Phosphatase (Serum/Plasma)	_____
Aspartate Aminotransferase (Serum/Plasma)	_____
Bilirubin, Total (Serum/Plasma)	_____
Bilirubin, Direct, (Conj) (Serum/Plasma)	_____
Bilirubin, Indirect (Unconj.) (Serum/Plasma)	_____
Gamma-Glutamyltransferase (Serum/Plasma)	_____
Lactate Dehydrogenase (LDH) (Serum/Plasma)	_____
Protein, Total (Serum/Plasma)	_____
Pancreatic Enzymes Amylase (Serum/Plasma)	_____
Lipase (Serum/Plasma)	_____
Renal Function Tests Creatinine (Serum/Plasma)	_____
Creatinine Clearance, Calculated (Urine 24h)	_____
Creatinine Clearance, Cockcroft-Gault (Plasma)	_____
Creatinine Clearance, Cockcroft-Gault (Serum)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Plasma)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Serum)	_____

Lab Name:	
Urea (Serum/Plasma)	
Urea Nitrogen (BUN) (Serum/Plasma)	
Electrolytes Calcium, Ionized (Serum)	
Total Calcium (Serum/Plasma)	
Chloride (Serum/Plasma)	
Magnesium (Serum/Plasma)	
Phosphate (Phosphorus) (Serum/Plasma)	
Potassium (Serum/Plasma)	
Sodium (Serum/Plasma)	
Proteins Albumin (Serum/Plasma)	
Glucose Metabolism Glucose, Fasting (Serum/Plasma)	
Glucose,Random (Serum/Plasma)	
Hidden for Bilirubin	
Hidden for Aspartate	
Hidden for Alanine	
Hidden for Alanine Range	
Hidden for Asparate Range	
Hidden for Bilirubin Range	
Derived field to call CF	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 07 Day 08
Form: Non-central Laboratory Test Results - Hematology (LB1)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ■ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hemoglobin (Blood)	_____
Hematocrit (Blood)	_____
Leucocytes, Absolute Count (WBC) (Blood)	_____
Platelet count (Blood)	_____
Mean corpuscular volume (Blood)	_____
Absolute Neutrophil Count (Blood)	_____
Absolute Lymphocytes Count (Blood)	_____
Absolute Monocytes Count (Blood)	_____
Absolute Eosinophils,Count (Blood)	_____
Neutrophils, %/Ratio (Blood)	_____
Lymphocytes, %/Ratio (Blood)	_____
Monocytes, %/Ratio (Blood)	_____
Eosinophils, % /Ratio (Blood)	_____

Subject Continues to the Next Visit?	No ☐
	Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 08 Day 01
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)	
Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 08 Day 01
Form: Assessment(s) Performed Triggering Form (ASMTRIG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2402 2024-02-16)

Select 'Yes' if all assessment forms are to be triggered	Yes ☐
Assessment(s) type	Extent of Disease Upon Entry to Study (DISEXT) ☐
	Pathology: at Screening (PATHGOM) ☐
	General Medical History (1MH) ☐
	Pre-specified medical conditions or events (2MH) ☐
	Surgical History (HISS) ☐
	Physical Examination (PE) ☐
	Vital Signs - Weight, Height (VS) ☐
	Vital Signs - Before Infusion (VS1) ☐
	Vital Signs - End of Infusion (VS2) ☐
	Vital Signs - Excluding Weight (VS3) ☐
	Vital Signs (VS4) ☐
	ECOG Performance Status (ECOG) ☐
	ECG Test Results (EG) ☐
	Additional ECG (EG1) ☐
	Additional ECG (EG2) ☐
	Echocardiography (ECHOC) ☐
	Non-central Laboratory Test Results - Chemistry (LB) ☐
	Non-central Laboratory Test Results - Hematology (LB1) ☐
	Non-central Laboratory Test Results - Coagulation (LB2) ☐
	Non-central Laboratory Test Results - Thyroid function test (LB3) ☐

- ☐ Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
- ☐ Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
- ☐ Non-central Laboratory Test Results - Urinalysis (LB6)
- ☐ Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
- ☐ Non-central Laboratory Test Results - Hy's Law (LB8)
- ☐ Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
- ☐ Non-central Laboratory Test Results - Tuberculosis testing (LB10)
- ☐ Non-central Laboratory Test Results - HIV testing (LB11)
- ☐ Non-central Laboratory Test Results - Additional Chemistry (LB12)
- ☐ Sample Collection, Predose_ADA Sample (SPCBEDB)
- ☐ Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
- ☐ PBMC for immune profiling_Pre dose (SPCBEDB2)
- ☐ Whole blood for RNA analysis_Pre-dose (SPCBEDB3)
- ☐ Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)

	Sample Collection, ADA Sample (SPCBEDB5) ☐
	Blood sample for plasma ctDNA (SPCBEDB6) ☐
	Optional on study tumor sample at recurrence (SPCBEDT) ☐
	Mandatory tumor sample from surgical resection for PDL1 analysis (SPCBEDT1) ☐
	Biological Sample Collection, Pre-dose PK (SPCPKB) ☐
	Biological Sample Collection, Post-dose PK (SPCPKB1) ☐
	Biological Sample Collection, PK (SPCPKB2) ☐
	Substance Use - Nicotine (SU_NIC) ☐
	Substance Use - Alcohol (SU_ALC) ☐
	Prior Cancer Therapy (CAPRX) ☐
	Prior Radiotherapy (CAPRXR) ☐
	Survival Status (SURVIVE) ☐
Assessment form to be triggered	No ☐
	Yes ☐
Reason assessment form is not to be triggered	Assessment not performed ☐
	Assessment not required ☐
	Subject discontinuation ☐
	Screen failure ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 08 Day 01
Form: Physical Examination (PE)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ1609 2019-04-19)

For baseline: Following items should be checked during baseline physical examination (A full physical examination will be performed and include assessments of the following: general appearance, respiratory, cardiovascular system, abdomen, skin, head and neck (including ears, eyes, nose, and throat), lymph nodes, thyroid, musculoskeletal (including spine and extremities), urogenital, dermatological, gastrointestinal, endocrine, hematologic/lymphatic, and neurological systems.).

For follow-up: Following items should be checked during follow-up physical examination (A targeted physical examination will include, at a minimum, assessments of skin, lungs, cardiovascular system, and abdomen (liver and spleen).

If the physical finding started prior to enrolment, it must be recorded as medical history.
If the physical finding started or worsened after enrolment, it must be recorded as an Adverse Event.

Was the physical examination performed?	No ☐ Yes ☐
What was the date of the physical examination?	Fixed Unit: yyyy mon dd

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 08 Day 01
Form: Vital Signs - Before Infusion (VS1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd
Protocol schedule	Prior to Infusion
Time	Fixed Unit: 24-hour clock
Pulse	Fixed Unit: beats/min
SBP	Fixed Unit: mmHg
DBP	Fixed Unit: mmHg
Respiration rate	Fixed Unit: breaths/min
Temperature	
Temperature unit	C
Peripheral oxygen saturation	Fixed Unit: %
Weight	
Weight unit	kg
EHRID	

(Version: ON2406 2024-06-04)

Clinical classification category	ECOG
What was the date the response or clinical classification was performed?	Fixed Unit: yyyy mon dd
Performance status	0-Fully active, able to carry on all pre-disease performance without restriction ☐ 1-Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work ☐ 2-Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours ☐ 3-Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours ☐ 4-Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair ☐ 5-Dead ☐

Ref: Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55). WHO Ref: World Health Organization (1979).Handbook for Reporting Results of Cancer Treatment Pb (WHO Offset Publications).

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 08 Day 01
Form: Pregnancy Test (PREG1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2008 2024-03-01)

Assessment applicable for Subject	No ☐
	Yes ☐
Sampling date	Fixed Unit: yyyy mon dd
Pregnancy test (serum)	Negative ☐
	Positive ☐
Pregnancy test (urine)	Negative ☐
	Positive ☐

For a positive pregnancy test after first dose of study drug, fill in PREGREP (or the 'Pregnancy Outcome Report Form' [Part 1]) and send to the AstraZeneca Monitor.

If positive pregnancy test, the administration of study drug to that Subject must be discontinued immediately and the End of Study Treatment form (ETRT) filled in.

If Positive pregnancy test, and considered an AE, please fill in Adverse Event (AE) Form
(Pregnancy itself is not regarded as an adverse event unless there is a suspicion that AstraZeneca product may have interfered with the effectiveness of a contraceptive medication.)

Hidden Field (used for CF programming)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 08 Day 01
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Liver Function Tests Alanine Aminotransferase (Serum/Plasma)	_____
Alkaline Phosphatase (Serum/Plasma)	_____
Aspartate Aminotransferase (Serum/Plasma)	_____
Bilirubin, Total (Serum/Plasma)	_____
Bilirubin, Direct, (Conj) (Serum/Plasma)	_____
Bilirubin, Indirect (Unconj.) (Serum/Plasma)	_____
Gamma-Glutamyltransferase (Serum/Plasma)	_____
Lactate Dehydrogenase (LDH) (Serum/Plasma)	_____
Protein, Total (Serum/Plasma)	_____
Pancreatic Enzymes Amylase (Serum/Plasma)	_____
Lipase (Serum/Plasma)	_____
Renal Function Tests Creatinine (Serum/Plasma)	_____
Creatinine Clearance, Calculated (Urine 24h)	_____
Creatinine Clearance, Cockcroft-Gault (Plasma)	_____
Creatinine Clearance, Cockcroft-Gault (Serum)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Plasma)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Serum)	_____

Lab Name:	
Urea (Serum/Plasma)	
Urea Nitrogen (BUN) (Serum/Plasma)	
Electrolytes Calcium, Ionized (Serum)	
Total Calcium (Serum/Plasma)	
Chloride (Serum/Plasma)	
Magnesium (Serum/Plasma)	
Phosphate (Phosphorus) (Serum/Plasma)	
Potassium (Serum/Plasma)	
Sodium (Serum/Plasma)	
Proteins Albumin (Serum/Plasma)	
Glucose Metabolism Glucose, Fasting (Serum/Plasma)	
Glucose,Random (Serum/Plasma)	
Hidden for Bilirubin	
Hidden for Aspartate	
Hidden for Alanine	
Hidden for Alanine Range	
Hidden for Asparate Range	
Hidden for Bilirubin Range	
Derived field to call CF	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 08 Day 01
Form: Non-central Laboratory Test Results - Hematology (LB1)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ■ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hemoglobin (Blood)	_____
Hematocrit (Blood)	_____
Leucocytes, Absolute Count (WBC) (Blood)	_____
Platelet count (Blood)	_____
Mean corpuscular volume (Blood)	_____
Absolute Neutrophil Count (Blood)	_____
Absolute Lymphocytes Count (Blood)	_____
Absolute Monocytes Count (Blood)	_____
Absolute Eosinophils,Count (Blood)	_____
Neutrophils, %/Ratio (Blood)	_____
Lymphocytes, %/Ratio (Blood)	_____
Monocytes, %/Ratio (Blood)	_____
Eosinophils, % /Ratio (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 08 Day 01
Form: Non-central Laboratory Test Results - Thyroid function test (LB3)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	☐ No ☐ Yes
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	☐ Hematology ■ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Thyroid Stimulating Hormone(Serum/Plasma)	_____
T4 (Thyroxine), Free(Serum/Plasma)	_____
T3 (Triiodothyronine), Free(Serum/Plasma)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 08 Day 01
Form: Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Carcinoembryonic Antigen (Serum/Plasma) (ng/mL)	_____
Carbohydrate Antigen 19-9 (Serum) (U/mL)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 08 Day 01
Form: Non-central Laboratory Test Results - Hepatitis B and C testing - Post Screening (LB13)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ■
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hepatitis B Viral Load, Quant (IU/mL) (Blood)	_____
Hepatitis B Viral Load, Quant (DNA copies/mL) (Blood)	_____
Hepatitis C Viral Load, Quant (IU/mL) (Blood)	_____
Hepatitis C Viral Load, Quant (RNA copies/mL) (Blood)	_____

Subject Continues to the Next Visit?	No ☐
	Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 08 Day 08
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)

Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 08 Day 08
Form: Assessment(s) Performed Triggering Form (ASMTRIG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2402 2024-02-16)

Select 'Yes' if all assessment forms are to be triggered	Yes ☐

Assessment(s) type	Extent of Disease Upon Entry to Study (DISEXT) ☐
	Pathology: at Screening (PATHGOM) ☐
	General Medical History (1MH) ☐
	Pre-specified medical conditions or events (2MH) ☐
	Surgical History (HISS) ☐
	Physical Examination (PE) ☐
	Vital Signs - Weight, Height (VS) ☐
	Vital Signs - Before Infusion (VS1) ☐
	Vital Signs - End of Infusion (VS2) ☐
	Vital Signs - Excluding Weight (VS3) ☐
	Vital Signs (VS4) ☐
	ECOG Performance Status (ECOG) ☐
	ECG Test Results (EG) ☐
	Additional ECG (EG1) ☐
	Additional ECG (EG2) ☐
	Echocardiography (ECHOC) ☐
	Non-central Laboratory Test Results - Chemistry (LB) ☐
	Non-central Laboratory Test Results - Hematology (LB1) ☐
	Non-central Laboratory Test Results - Coagulation (LB2) ☐
	Non-central Laboratory Test Results - Thyroid function test (LB3) ☐

- ☐ Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
- ☐ Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
- ☐ Non-central Laboratory Test Results - Urinalysis (LB6)
- ☐ Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
- ☐ Non-central Laboratory Test Results - Hy's Law (LB8)
- ☐ Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
- ☐ Non-central Laboratory Test Results - Tuberculosis testing (LB10)
- ☐ Non-central Laboratory Test Results - HIV testing (LB11)
- ☐ Non-central Laboratory Test Results - Additional Chemistry (LB12)
- ☐ Sample Collection, Predose_ADA Sample (SPCBEDB)
- ☐ Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
- ☐ PBMC for immune profiling_Pre dose (SPCBEDB2)
- ☐ Whole blood for RNA analysis_Pre-dose (SPCBEDB3)
- ☐ Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)

	Sample Collection, ADA Sample (SPCBEDB5) ☐
	Blood sample for plasma ctDNA (SPCBEDB6) ☐
	Optional on study tumor sample at recurrence (SPCBEDT) ☐
	Mandatory tumor sample from surgical resection for PDL1 analysis (SPCBEDT1) ☐
	Biological Sample Collection, Pre-dose PK (SPCPKB) ☐
	Biological Sample Collection, Post-dose PK (SPCPKB1) ☐
	Biological Sample Collection, PK (SPCPKB2) ☐
	Substance Use - Nicotine (SU_NIC) ☐
	Substance Use - Alcohol (SU_ALC) ☐
	Prior Cancer Therapy (CAPRX) ☐
	Prior Radiotherapy (CAPRXR) ☐
	Survival Status (SURVIVE) ☐
Assessment form to be triggered	No ☐
	Yes ☐
Reason assessment form is not to be triggered	Assessment not performed ☐
	Assessment not required ☐
	Subject discontinuation ☐
	Screen failure ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 08 Day 08
Form: Vital Signs - Excluding Weight (VS3)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd
Time	Fixed Unit: 24-hour clock
Pulse	Fixed Unit: beats/min
SBP	Fixed Unit: mmHg
DBP	Fixed Unit: mmHg
Respiration rate	Fixed Unit: breaths/min
Temperature	
Temperature unit	C ●
Peripheral oxygen saturation	Fixed Unit: %
EHRID	

(Version: ON2406 2024-06-04)

Clinical classification category	ECOG
What was the date the response or clinical classification was performed?	Fixed Unit: yyyy mon dd
Performance status	0-Fully active, able to carry on all pre-disease performance without restriction ☐ 1-Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work ☐ 2-Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours ☐ 3-Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours ☐ 4-Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair ☐ 5-Dead ☐

Ref: Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55). WHO Ref: World Health Organization (1979).Handbook for Reporting Results of Cancer Treatment Pb (WHO Offset Publications).

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 08 Day 08
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Liver Function Tests Alanine Aminotransferase (Serum/Plasma)	_____
Alkaline Phosphatase (Serum/Plasma)	_____
Aspartate Aminotransferase (Serum/Plasma)	_____
Bilirubin, Total (Serum/Plasma)	_____
Bilirubin, Direct, (Conj) (Serum/Plasma)	_____
Bilirubin, Indirect (Unconj.) (Serum/Plasma)	_____
Gamma-Glutamyltransferase (Serum/Plasma)	_____
Lactate Dehydrogenase (LDH) (Serum/Plasma)	_____
Protein, Total (Serum/Plasma)	_____
Pancreatic Enzymes Amylase (Serum/Plasma)	_____
Lipase (Serum/Plasma)	_____
Renal Function Tests Creatinine (Serum/Plasma)	_____
Creatinine Clearance, Calculated (Urine 24h)	_____
Creatinine Clearance, Cockcroft-Gault (Plasma)	_____
Creatinine Clearance, Cockcroft-Gault (Serum)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Plasma)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Serum)	_____

Lab Name:	
Urea (Serum/Plasma)	
Urea Nitrogen (BUN) (Serum/Plasma)	
Electrolytes Calcium, Ionized (Serum)	
Total Calcium (Serum/Plasma)	
Chloride (Serum/Plasma)	
Magnesium (Serum/Plasma)	
Phosphate (Phosphorus) (Serum/Plasma)	
Potassium (Serum/Plasma)	
Sodium (Serum/Plasma)	
Proteins Albumin (Serum/Plasma)	
Glucose Metabolism Glucose, Fasting (Serum/Plasma)	
Glucose,Random (Serum/Plasma)	
Hidden for Bilirubin	
Hidden for Aspartate	
Hidden for Alanine	
Hidden for Alanine Range	
Hidden for Asparate Range	
Hidden for Bilirubin Range	
Derived field to call CF	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle 08 Day 08
Form: Non-central Laboratory Test Results - Hematology (LB1)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ■ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hemoglobin (Blood)	_____
Hematocrit (Blood)	_____
Leucocytes, Absolute Count (WBC) (Blood)	_____
Platelet count (Blood)	_____
Mean corpuscular volume (Blood)	_____
Absolute Neutrophil Count (Blood)	_____
Absolute Lymphocytes Count (Blood)	_____
Absolute Monocytes Count (Blood)	_____
Absolute Eosinophils,Count (Blood)	_____
Neutrophils, %/Ratio (Blood)	_____
Lymphocytes, %/Ratio (Blood)	_____
Monocytes, %/Ratio (Blood)	_____
Eosinophils, % /Ratio (Blood)	_____

Subject Continues to the Next Visit?	No ☐
	Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)

Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle
Form: Assessment(s) Performed Triggering Form (ASMTRIG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2402 2024-02-16)

Select 'Yes' if all assessment forms are to be triggered	Yes ☐
Assessment(s) type	Extent of Disease Upon Entry to Study (DISEXT) ☐
	Pathology: at Screening (PATHGOM) ☐
	General Medical History (1MH) ☐
	Pre-specified medical conditions or events (2MH) ☐
	Surgical History (HISS) ☐
	Physical Examination (PE) ☐
	Vital Signs - Weight, Height (VS) ☐
	Vital Signs - Before Infusion (VS1) ☐
	Vital Signs - End of Infusion (VS2) ☐
	Vital Signs - Excluding Weight (VS3) ☐
	Vital Signs (VS4) ☐
	ECOG Performance Status (ECOG) ☐
	ECG Test Results (EG) ☐
	Additional ECG (EG1) ☐
	Additional ECG (EG2) ☐
	Echocardiography (ECHOC) ☐
	Non-central Laboratory Test Results - Chemistry (LB) ☐
	Non-central Laboratory Test Results - Hematology (LB1) ☐
	Non-central Laboratory Test Results - Coagulation (LB2) ☐
	Non-central Laboratory Test Results - Thyroid function test (LB3) ☐

- [ ] Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
- [ ] Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
- [ ] Non-central Laboratory Test Results - Urinalysis (LB6)
- [ ] Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
- [ ] Non-central Laboratory Test Results - Hy's Law (LB8)
- [ ] Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
- [ ] Non-central Laboratory Test Results - Tuberculosis testing (LB10)
- [ ] Non-central Laboratory Test Results - HIV testing (LB11)
- [ ] Non-central Laboratory Test Results - Additional Chemistry (LB12)
- [ ] Sample Collection, Predose_ADA Sample (SPCBEDB)
- [ ] Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
- [ ] PBMC for immune profiling_Pre dose (SPCBEDB2)
- [ ] Whole blood for RNA analysis_Pre-dose (SPCBEDB3)
- [ ] Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)

	Sample Collection, ADA Sample (SPCBEDB5) ☐
	Blood sample for plasma ctDNA (SPCBEDB6) ☐
	Optional on study tumor sample at recurrence (SPCBEDT) ☐
	Mandatory tumor sample from surgical resection for PDL1 analysis (SPCBEDT1) ☐
	Biological Sample Collection, Pre-dose PK (SPCPKB) ☐
	Biological Sample Collection, Post-dose PK (SPCPKB1) ☐
	Biological Sample Collection, PK (SPCPKB2) ☐
	Substance Use - Nicotine (SU_NIC) ☐
	Substance Use - Alcohol (SU_ALC) ☐
	Prior Cancer Therapy (CAPRX) ☐
	Prior Radiotherapy (CAPRXR) ☐
	Survival Status (SURVIVE) ☐
Assessment form to be triggered	No ☐
	Yes ☐
Reason assessment form is not to be triggered	Assessment not performed ☐
	Assessment not required ☐
	Subject discontinuation ☐
	Screen failure ☐

(Version: AZ1609 2019-04-19)

For baseline: Following items should be checked during baseline physical examination (A full physical examination will be performed and include assessments of the following: general appearance, respiratory, cardiovascular system, abdomen, skin, head and neck (including ears, eyes, nose, and throat), lymph nodes, thyroid, musculoskeletal (including spine and extremities), urogenital, dermatological, gastrointestinal, endocrine, hematologic/lymphatic, and neurological systems.).

For follow-up: Following items should be checked during follow-up physical examination (A targeted physical examination will include, at a minimum, assessments of skin, lungs, cardiovascular system, and abdomen (liver and spleen).

If the physical finding started prior to enrolment, it must be recorded as medical history.
If the physical finding started or worsened after enrolment, it must be recorded as an Adverse Event.

Was the physical examination performed?	No ☐ Yes ☐
What was the date of the physical examination?	Fixed Unit: yyyy mon dd

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle
Form: Vital Signs - Before Infusion (VS1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd
Protocol schedule	Prior to Infusion
Time	Fixed Unit: 24-hour clock
Pulse	Fixed Unit: beats/min
SBP	Fixed Unit: mmHg
DBP	Fixed Unit: mmHg
Respiration rate	Fixed Unit: breaths/min
Temperature	
Temperature unit	C ●
Peripheral oxygen saturation	Fixed Unit: %
Weight	
Weight unit	kg ●
EHRID	

(Version: ON2406 2024-06-04)

Clinical classification category	ECOG
What was the date the response or clinical classification was performed?	Fixed Unit: yyyy mon dd
Performance status	0-Fully active, able to carry on all pre-disease performance without restriction ☐ 1-Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work ☐ 2-Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours ☐ 3-Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours ☐ 4-Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair ☐ 5-Dead ☐

Ref: Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55). WHO Ref: World Health Organization (1979).Handbook for Reporting Results of Cancer Treatment Pb (WHO Offset Publications).

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle
Form: Pregnancy Test (PREG1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2008 2024-03-01)

Assessment applicable for Subject
No ☐
Yes ☐

Sampling date
Fixed Unit: yyyy mon dd

Pregnancy test (serum)
Negative ☐
Positive ☐

Pregnancy test (urine)
Negative ☐
Positive ☐

For a positive pregnancy test after first dose of study drug, fill in PREGREP (or the 'Pregnancy Outcome Report Form' [Part 1]) and send to the AstraZeneca Monitor.

If positive pregnancy test, the administration of study drug to that Subject must be discontinued immediately and the End of Study Treatment form (ETRT) filled in.

If Positive pregnancy test, and considered an AE, please fill in Adverse Event (AE) Form
(Pregnancy itself is not regarded as an adverse event unless there is a suspicion that AstraZeneca product may have interfered with the effectiveness of a contraceptive medication.)

Hidden Field (used for CF programming)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Liver Function Tests Alanine Aminotransferase (Serum/Plasma)	_____
Alkaline Phosphatase (Serum/Plasma)	_____
Aspartate Aminotransferase (Serum/Plasma)	_____
Bilirubin, Total (Serum/Plasma)	_____
Bilirubin, Direct, (Conj) (Serum/Plasma)	_____
Bilirubin, Indirect (Unconj.) (Serum/Plasma)	_____
Gamma-Glutamyltransferase (Serum/Plasma)	_____
Lactate Dehydrogenase (LDH) (Serum/Plasma)	_____
Protein, Total (Serum/Plasma)	_____
Pancreatic Enzymes Amylase (Serum/Plasma)	_____
Lipase (Serum/Plasma)	_____
Renal Function Tests Creatinine (Serum/Plasma)	_____
Creatinine Clearance, Calculated (Urine 24h)	_____
Creatinine Clearance, Cockcroft-Gault (Plasma)	_____
Creatinine Clearance, Cockcroft-Gault (Serum)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Plasma)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Serum)	_____

Lab Name:	
Urea (Serum/Plasma)	
Urea Nitrogen (BUN) (Serum/Plasma)	
Electrolytes Calcium, Ionized (Serum)	
Total Calcium (Serum/Plasma)	
Chloride (Serum/Plasma)	
Magnesium (Serum/Plasma)	
Phosphate (Phosphorus) (Serum/Plasma)	
Potassium (Serum/Plasma)	
Sodium (Serum/Plasma)	
Proteins Albumin (Serum/Plasma)	
Glucose Metabolism Glucose, Fasting (Serum/Plasma)	
Glucose,Random (Serum/Plasma)	
Hidden for Bilirubin	
Hidden for Aspartate	
Hidden for Alanine	
Hidden for Alanine Range	
Hidden for Asparate Range	
Hidden for Bilirubin Range	
Derived field to call CF	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle
Form: Non-central Laboratory Test Results - Hematology (LB1)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ■ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hemoglobin (Blood)	_____
Hematocrit (Blood)	_____
Leucocytes, Absolute Count (WBC) (Blood)	_____
Platelet count (Blood)	_____
Mean corpuscular volume (Blood)	_____
Absolute Neutrophil Count (Blood)	_____
Absolute Lymphocytes Count (Blood)	_____
Absolute Monocytes Count (Blood)	_____
Absolute Eosinophils,Count (Blood)	_____
Neutrophils, %/Ratio (Blood)	_____
Lymphocytes, %/Ratio (Blood)	_____
Monocytes, %/Ratio (Blood)	_____
Eosinophils, % /Ratio (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle
Form: Non-central Laboratory Test Results - Thyroid function test (LB3)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Thyroid Stimulating Hormone(Serum/Plasma)	_____
T4 (Thyroxine), Free(Serum/Plasma)	_____
T3 (Triiodothyronine), Free(Serum/Plasma)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle
Form: Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock
Creatine Kinase (Serum/Plasma)	
Troponin T (Serum/Plasma)	
Troponin I (Serum/Plasma)	
High- sensitivity Troponin T (Serum/Plasma)	
High- sensitivity Troponin I (Serum/Plasma)	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle
Form: Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Carcinoembryonic Antigen (Serum/Plasma) (ng/mL)	_____
Carbohydrate Antigen 19-9 (Serum) (U/mL)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle
Form: Non-central Laboratory Test Results - Hepatitis B and C testing - Post Screening (LB13)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ■
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hepatitis B Viral Load, Quant (IU/mL) (Blood)	_____
Hepatitis B Viral Load, Quant (DNA copies/mL) (Blood)	_____
Hepatitis C Viral Load, Quant (IU/mL) (Blood)	_____
Hepatitis C Viral Load, Quant (RNA copies/mL) (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle
Form: Sample Collection, Predose_ADA Sample (SPCBEDB)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ☐
	cfDNA-BCT ☐
	Blood ■
Biofluid processed	PBMC ☐
	Blood ☐
	Serum ■
	Plasma ☐
Sample format	DNA ☐
	Fresh ☐
	Frozen ■
	RNA ☐
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Protocol schedule	Pre Dose
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Cycle
Form: Biological Sample Collection, Pre-dose PK (SPCPKB)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample collection category?	PK, biofluid
Sample collected	No Yes
Last investigational product date	Fixed Unit: yyyy mon dd
Last investigational product time	Fixed Unit: 24-hour clock
Biofluid collected (parent sample)	Blood
Biofluid processed	Serum
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable Hemolyzed Clotted Lipemic Quantity less than expected Sample discarded Other
If Other, specify	
Date of storage	Fixed Unit: yyyy mon dd
Time of storage	Fixed Unit: 24-hour clock
Protocol schedule	Pre Dose
Protocol schedule day	1
Protocol schedule hour	-99
Protocol schedule minute	-99
Laboratory ID	Labcorp

Subject Continues to the Next Visit?	No ☐
	Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: End of Treatment
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)	
Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: End of Treatment
Form: Assessment(s) Performed Triggering Form (ASMTRIG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2402 2024-02-16)

Select 'Yes' if all assessment forms are to be triggered	Yes ☐
Assessment(s) type	Extent of Disease Upon Entry to Study (DISEXT) ☐
	Pathology: at Screening (PATHGOM) ☐
	General Medical History (1MH) ☐
	Pre-specified medical conditions or events (2MH) ☐
	Surgical History (HISS) ☐
	Physical Examination (PE) ☐
	Vital Signs - Weight, Height (VS) ☐
	Vital Signs - Before Infusion (VS1) ☐
	Vital Signs - End of Infusion (VS2) ☐
	Vital Signs - Excluding Weight (VS3) ☐
	Vital Signs (VS4) ☐
	ECOG Performance Status (ECOG) ☐
	ECG Test Results (EG) ☐
	Additional ECG (EG1) ☐
	Additional ECG (EG2) ☐
	Echocardiography (ECHOC) ☐
	Non-central Laboratory Test Results - Chemistry (LB) ☐
	Non-central Laboratory Test Results - Hematology (LB1) ☐
	Non-central Laboratory Test Results - Coagulation (LB2) ☐
	Non-central Laboratory Test Results - Thyroid function test (LB3) ☐

- ☐ Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
- ☐ Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
- ☐ Non-central Laboratory Test Results - Urinalysis (LB6)
- ☐ Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
- ☐ Non-central Laboratory Test Results - Hy's Law (LB8)
- ☐ Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
- ☐ Non-central Laboratory Test Results - Tuberculosis testing (LB10)
- ☐ Non-central Laboratory Test Results - HIV testing (LB11)
- ☐ Non-central Laboratory Test Results - Additional Chemistry (LB12)
- ☐ Sample Collection, Predose_ADA Sample (SPCBEDB)
- ☐ Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
- ☐ PBMC for immune profiling_Pre dose (SPCBEDB2)
- ☐ Whole blood for RNA analysis_Pre-dose (SPCBEDB3)
- ☐ Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)

	Sample Collection, ADA Sample (SPCBEDB5) ☐
	Blood sample for plasma ctDNA (SPCBEDB6) ☐
	Optional on study tumor sample at recurrence (SPCBEDT) ☐
	Mandatory tumor sample from surgical resection for PDL1 analysis (SPCBEDT1) ☐
	Biological Sample Collection, Pre-dose PK (SPCPKB) ☐
	Biological Sample Collection, Post-dose PK (SPCPKB1) ☐
	Biological Sample Collection, PK (SPCPKB2) ☐
	Substance Use - Nicotine (SU_NIC) ☐
	Substance Use - Alcohol (SU_ALC) ☐
	Prior Cancer Therapy (CAPRX) ☐
	Prior Radiotherapy (CAPRXR) ☐
	Survival Status (SURVIVE) ☐
Assessment form to be triggered	No ☐
	Yes ☐
Reason assessment form is not to be triggered	Assessment not performed ☐
	Assessment not required ☐
	Subject discontinuation ☐
	Screen failure ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: End of Treatment
Form: Physical Examination (PE)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ1609 2019-04-19)

For baseline: Following items should be checked during baseline physical examination (A full physical examination will be performed and include assessments of the following: general appearance, respiratory, cardiovascular system, abdomen, skin, head and neck (including ears, eyes, nose, and throat), lymph nodes, thyroid, musculoskeletal (including spine and extremities), urogenital, dermatological, gastrointestinal, endocrine, hematologic/lymphatic, and neurological systems.).

For follow-up: Following items should be checked during follow-up physical examination (A targeted physical examination will include, at a minimum, assessments of skin, lungs, cardiovascular system, and abdomen (liver and spleen).

If the physical finding started prior to enrolment, it must be recorded as medical history.
If the physical finding started or worsened after enrolment, it must be recorded as an Adverse Event.

Was the physical examination performed?	No ☐ Yes ☐
What was the date of the physical examination?	Fixed Unit: yyyy mon dd

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: End of Treatment
Form: Vital Signs (VS4)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd
Time	Fixed Unit: 24-hour clock
Pulse	Fixed Unit: beats/min
SBP	Fixed Unit: mmHg
DBP	Fixed Unit: mmHg
Respiration rate	Fixed Unit: breaths/min
Temperature	
Temperature unit	C ■
Peripheral oxygen saturation	Fixed Unit: %
Weight	
Weight unit	kg ■
EHRID	

(Version: ON2406 2024-06-04)

Clinical classification category	ECOG
What was the date the response or clinical classification was performed?	Fixed Unit: yyyy mon dd
Performance status	0-Fully active, able to carry on all pre-disease performance without restriction ☐ 1-Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work ☐ 2-Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours ☐ 3-Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours ☐ 4-Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair ☐ 5-Dead ☐

Ref: Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55). WHO Ref: World Health Organization (1979).Handbook for Reporting Results of Cancer Treatment Pb (WHO Offset Publications).

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: End of Treatment
Form: Echocardiography (ECHOC)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2201 2024-09-27)

What was the date of the echocardiography?	Fixed Unit: yyyy mon dd
What was the time of the echocardiography?	Fixed Unit: 24-hour clock
What was the method used for the examination?	Echocardiography ☐ Multiple Gated Acquisition (MUGA) ☐
Was the image quality sufficient?	No ☐ Yes ☐
What was the overall ECHOC evaluation?	Normal ☐ Abnormal ☐
What is the reason the overall ECHOC evaluation was abnormal?	
What was the left ventricular ejection fraction?	Fixed Unit: %
What was the LV end diastolic volume?	Fixed Unit: mL
What was the LV end systolic volume?	Fixed Unit: mL

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: End of Treatment
Form: Pregnancy Test (PREG1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2008 2024-03-01)

Assessment applicable for Subject	No ☐
	Yes ☐
Sampling date	Fixed Unit: yyyy mon dd
Pregnancy test (serum)	Negative ☐
	Positive ☐
Pregnancy test (urine)	Negative ☐
	Positive ☐

For a positive pregnancy test after first dose of study drug, fill in PREGREP (or the 'Pregnancy Outcome Report Form' [Part 1]) and send to the AstraZeneca Monitor.

If positive pregnancy test, the administration of study drug to that Subject must be discontinued immediately and the End of Study Treatment form (ETRT) filled in.

If Positive pregnancy test, and considered an AE, please fill in Adverse Event (AE) Form
(Pregnancy itself is not regarded as an adverse event unless there is a suspicion that AstraZeneca product may have interfered with the effectiveness of a contraceptive medication.)

Hidden Field (used for CF programming)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: End of Treatment
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Liver Function Tests Alanine Aminotransferase (Serum/Plasma)	_____
Alkaline Phosphatase (Serum/Plasma)	_____
Aspartate Aminotransferase (Serum/Plasma)	_____
Bilirubin, Total (Serum/Plasma)	_____
Bilirubin, Direct, (Conj) (Serum/Plasma)	_____
Bilirubin, Indirect (Unconj.) (Serum/Plasma)	_____
Gamma-Glutamyltransferase (Serum/Plasma)	_____
Lactate Dehydrogenase (LDH) (Serum/Plasma)	_____
Protein, Total (Serum/Plasma)	_____
Pancreatic Enzymes Amylase (Serum/Plasma)	_____
Lipase (Serum/Plasma)	_____
Renal Function Tests Creatinine (Serum/Plasma)	_____
Creatinine Clearance, Calculated (Urine 24h)	_____
Creatinine Clearance, Cockcroft-Gault (Plasma)	_____
Creatinine Clearance, Cockcroft-Gault (Serum)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Plasma)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Serum)	_____

Lab Name:	
Urea (Serum/Plasma)	
Urea Nitrogen (BUN) (Serum/Plasma)	
Electrolytes Calcium, Ionized (Serum)	
Total Calcium (Serum/Plasma)	
Chloride (Serum/Plasma)	
Magnesium (Serum/Plasma)	
Phosphate (Phosphorus) (Serum/Plasma)	
Potassium (Serum/Plasma)	
Sodium (Serum/Plasma)	
Proteins Albumin (Serum/Plasma)	
Glucose Metabolism Glucose, Fasting (Serum/Plasma)	
Glucose,Random (Serum/Plasma)	
Hidden for Bilirubin	
Hidden for Aspartate	
Hidden for Alanine	
Hidden for Alanine Range	
Hidden for Asparate Range	
Hidden for Bilirubin Range	
Derived field to call CF	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: End of Treatment
Form: Non-central Laboratory Test Results - Hematology (LB1)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ■ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hemoglobin (Blood)	_____
Hematocrit (Blood)	_____
Leucocytes, Absolute Count (WBC) (Blood)	_____
Platelet count (Blood)	_____
Mean corpuscular volume (Blood)	_____
Absolute Neutrophil Count (Blood)	_____
Absolute Lymphocytes Count (Blood)	_____
Absolute Monocytes Count (Blood)	_____
Absolute Eosinophils,Count (Blood)	_____
Neutrophils, %/Ratio (Blood)	_____
Lymphocytes, %/Ratio (Blood)	_____
Monocytes, %/Ratio (Blood)	_____
Eosinophils, % /Ratio (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: End of Treatment
Form: Non-central Laboratory Test Results - Thyroid function test (LB3)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Thyroid Stimulating Hormone(Serum/Plasma)	_____
T4 (Thyroxine), Free(Serum/Plasma)	_____
T3 (Triiodothyronine), Free(Serum/Plasma)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: End of Treatment
Form: Non-central Laboratory Test Results - Urinalysis (LB6)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ■ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Albumin, Strip, Qual (Urine)	Negative ☐ Trace ☐ Positive ☐ + ☐ ++ ☐ +++ ☐ >+++ ☐ +- ☐
Bilirubin, Strip, Qual (Urine)	Negative ☐ Trace ☐ Positive ☐ + ☐ ++ ☐ +++ ☐ >+++ ☐ +- ☐
Blood, Qual (Urine)	Negative ☐ Trace ☐

	Positive ☐
	+ ☐
	++ ☐
	+++ ☐
	>+++ ☐
	+- ☐
Glucose, Strip, Qual (Urine)	Negative ☐
	Trace ☐
	Positive ☐
	+ ☐
	++ ☐
	+++ ☐
	>+++ ☐
	+- ☐
Ketone Bodies, Strip, Qual (Urine)	Negative ☐
	Trace ☐
	Positive ☐
	+ ☐
	++ ☐
	+++ ☐
	>+++ ☐
	+- ☐
Protein, Strip, Qual (Urine)	Negative ☐
	Trace ☐
	Positive ☐
	+ ☐
	++ ☐
	+++ ☐
	>+++ ☐
	+- ☐
Appearance (Qual) (Urine)	_____
Color (Qual) (Urine)	_____

Lab Name:	
Albumin, Quant (Urine)	
Bilirubin, Quant(Urine)	
Glucose, Random, Quant (Urine)	
Ketone Bodies, Quant (Urine)	
Protein, Total, Quant (Urine)	
Urine-Blood, Quant (Urine)	
pH (Urine)	
Specific Gravity (Urine)	
Sediment, Erythrocytes, Quant (no/vis fld) (Urine)	
Sediment, Leucocytes, Quant (no/vis fld) (Urine)	
Leucocytes, Quant (10**6/L) (Volume) (Urine)	
Erythrocytes, Quant (1/uL) (Volume) (Urine)	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: End of Treatment
Form: Sample Collection, ADA Sample (SPCBEDB5)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ☐
	cfDNA-BCT ☐
	Blood ■
Biofluid processed	PBMC ☐
	Blood ☐
	Serum ■
	Plasma ☐
Sample format	DNA ☐
	Fresh ☐
	Frozen ■
	RNA ☐
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: End of Treatment
Form: Blood sample for plasma ctDNA (SPCBEDB6)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ☐
	cfDNA-BCT ■
	Blood ☐
Biofluid processed	PBMC ☐
	Blood ☐
	Serum ☐
	Plasma ■
Sample format	DNA ■
	Fresh ☐
	Frozen ☐
	RNA ☐
Date of collection	Fixed Unit: yyyy mon dd _____
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	_____
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: End of Treatment
Form: Biological Sample Collection, PK (SPCPKB2)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample collection category?	PK, biofluid ■
Sample collected	No ☐ Yes ☐
Last investigational product date	Fixed Unit: yyyy mon dd
Last investigational product time	Fixed Unit: 24-hour clock
Biofluid collected (parent sample)	Blood ■
Biofluid processed	Serum ■
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐ Hemolyzed ☐ Clotted ☐ Lipemic ☐ Quantity less than expected ☐ Sample discarded ☐ Other ☐
If Other, specify	
Date of storage	Fixed Unit: yyyy mon dd
Time of storage	Fixed Unit: 24-hour clock
Protocol schedule day	9999
Protocol schedule hour	-999
Protocol schedule minute	-99
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: End of Treatment
Form: Survival Status (SURVIVE)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: ON2102 2022-03-07)

Date Subject confirmed to be alive	Fixed Unit: yyyy mon dd
Date of the latest unsuccessful contact attempt	Fixed Unit: yyyy mon dd

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Post-treatment 90 Days Safety follow-up
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)

Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Post-treatment 90 Days Safety follow-up
Form: Assessment(s) Performed Triggering Form (ASMTRIG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2402 2024-02-16)

Select 'Yes' if all assessment forms are to be triggered	Yes ☐

Assessment(s) type	Extent of Disease Upon Entry to Study (DISEXT) ☐
	Pathology: at Screening (PATHGOM) ☐
	General Medical History (1MH) ☐
	Pre-specified medical conditions or events (2MH) ☐
	Surgical History (HISS) ☐
	Physical Examination (PE) ☐
	Vital Signs - Weight, Height (VS) ☐
	Vital Signs - Before Infusion (VS1) ☐
	Vital Signs - End of Infusion (VS2) ☐
	Vital Signs - Excluding Weight (VS3) ☐
	Vital Signs (VS4) ☐
	ECOG Performance Status (ECOG) ☐
	ECG Test Results (EG) ☐
	Additional ECG (EG1) ☐
	Additional ECG (EG2) ☐
	Echocardiography (ECHOC) ☐
	Non-central Laboratory Test Results - Chemistry (LB) ☐
	Non-central Laboratory Test Results - Hematology (LB1) ☐
	Non-central Laboratory Test Results - Coagulation (LB2) ☐
	Non-central Laboratory Test Results - Thyroid function test (LB3) ☐

- ☐ Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
- ☐ Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
- ☐ Non-central Laboratory Test Results - Urinalysis (LB6)
- ☐ Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
- ☐ Non-central Laboratory Test Results - Hy's Law (LB8)
- ☐ Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
- ☐ Non-central Laboratory Test Results - Tuberculosis testing (LB10)
- ☐ Non-central Laboratory Test Results - HIV testing (LB11)
- ☐ Non-central Laboratory Test Results - Additional Chemistry (LB12)
- ☐ Sample Collection, Predose_ADA Sample (SPCBEDB)
- ☐ Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
- ☐ PBMC for immune profiling_Pre dose (SPCBEDB2)
- ☐ Whole blood for RNA analysis_Pre-dose (SPCBEDB3)
- ☐ Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)

	Sample Collection, ADA Sample (SPCBEDB5) ☐
	Blood sample for plasma ctDNA (SPCBEDB6) ☐
	Optional on study tumor sample at recurrence (SPCBEDT) ☐
	Mandatory tumor sample from surgical resection for PDL1 analysis (SPCBEDT1) ☐
	Biological Sample Collection, Pre-dose PK (SPCPKB) ☐
	Biological Sample Collection, Post-dose PK (SPCPKB1) ☐
	Biological Sample Collection, PK (SPCPKB2) ☐
	Substance Use - Nicotine (SU_NIC) ☐
	Substance Use - Alcohol (SU_ALC) ☐
	Prior Cancer Therapy (CAPRX) ☐
	Prior Radiotherapy (CAPRXR) ☐
	Survival Status (SURVIVE) ☐
Assessment form to be triggered	No ☐
	Yes ☐
Reason assessment form is not to be triggered	Assessment not performed ☐
	Assessment not required ☐
	Subject discontinuation ☐
	Screen failure ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Post-treatment 90 Days Safety follow-up
Form: Physical Examination (PE)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ1609 2019-04-19)

For baseline: Following items should be checked during baseline physical examination (A full physical examination will be performed and include assessments of the following: general appearance, respiratory, cardiovascular system, abdomen, skin, head and neck (including ears, eyes, nose, and throat), lymph nodes, thyroid, musculoskeletal (including spine and extremities), urogenital, dermatological, gastrointestinal, endocrine, hematologic/lymphatic, and neurological systems.).

For follow-up: Following items should be checked during follow-up physical examination (A targeted physical examination will include, at a minimum, assessments of skin, lungs, cardiovascular system, and abdomen (liver and spleen).

If the physical finding started prior to enrolment, it must be recorded as medical history.
If the physical finding started or worsened after enrolment, it must be recorded as an Adverse Event.

Was the physical examination performed?	No ☐ Yes ☐
What was the date of the physical examination?	Fixed Unit: yyyy mon dd

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Post-treatment 90 Days Safety follow-up
Form: Vital Signs (VS4)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd
Time	Fixed Unit: 24-hour clock
Pulse	Fixed Unit: beats/min
SBP	Fixed Unit: mmHg
DBP	Fixed Unit: mmHg
Respiration rate	Fixed Unit: breaths/min
Temperature	
Temperature unit	C ●
Peripheral oxygen saturation	Fixed Unit: %
Weight	
Weight unit	kg ●
EHRID	

(Version: ON2406 2024-06-04)

Clinical classification category	ECOG
What was the date the response or clinical classification was performed?	Fixed Unit: yyyy mon dd
Performance status	0-Fully active, able to carry on all pre-disease performance without restriction ☐ 1-Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work ☐ 2-Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours ☐ 3-Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours ☐ 4-Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair ☐ 5-Dead ☐

Ref: Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55). WHO Ref: World Health Organization (1979).Handbook for Reporting Results of Cancer Treatment Pb (WHO Offset Publications).

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Post-treatment 90 Days Safety follow-up
Form: Pregnancy Test (PREG1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2008 2024-03-01)

Assessment applicable for Subject
- No ☐
- Yes ☐

Sampling date — Fixed Unit: yyyy mon dd

Pregnancy test (serum)
- Negative ☐
- Positive ☐

Pregnancy test (urine)
- Negative ☐
- Positive ☐

For a positive pregnancy test after first dose of study drug, fill in PREGREP (or the 'Pregnancy Outcome Report Form' [Part 1]) and send to the AstraZeneca Monitor.

If positive pregnancy test, the administration of study drug to that Subject must be discontinued immediately and the End of Study Treatment form (ETRT) filled in.

If Positive pregnancy test, and considered an AE, please fill in Adverse Event (AE) Form
(Pregnancy itself is not regarded as an adverse event unless there is a suspicion that AstraZeneca product may have interfered with the effectiveness of a contraceptive medication.)

Hidden Field (used for CF programming)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Post-treatment 90 Days Safety follow-up
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Liver Function Tests Alanine Aminotransferase (Serum/Plasma)	_____
Alkaline Phosphatase (Serum/Plasma)	_____
Aspartate Aminotransferase (Serum/Plasma)	_____
Bilirubin, Total (Serum/Plasma)	_____
Bilirubin, Direct, (Conj) (Serum/Plasma)	_____
Bilirubin, Indirect (Unconj.) (Serum/Plasma)	_____
Gamma-Glutamyltransferase (Serum/Plasma)	_____
Lactate Dehydrogenase (LDH) (Serum/Plasma)	_____
Protein, Total (Serum/Plasma)	_____
Pancreatic Enzymes Amylase (Serum/Plasma)	_____
Lipase (Serum/Plasma)	_____
Renal Function Tests Creatinine (Serum/Plasma)	_____
Creatinine Clearance, Calculated (Urine 24h)	_____
Creatinine Clearance, Cockcroft-Gault (Plasma)	_____
Creatinine Clearance, Cockcroft-Gault (Serum)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Plasma)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Serum)	_____

Lab Name:	
Urea (Serum/Plasma)	
Urea Nitrogen (BUN) (Serum/Plasma)	
Electrolytes Calcium, Ionized (Serum)	
Total Calcium (Serum/Plasma)	
Chloride (Serum/Plasma)	
Magnesium (Serum/Plasma)	
Phosphate (Phosphorus) (Serum/Plasma)	
Potassium (Serum/Plasma)	
Sodium (Serum/Plasma)	
Proteins Albumin (Serum/Plasma)	
Glucose Metabolism Glucose, Fasting (Serum/Plasma)	
Glucose,Random (Serum/Plasma)	
Hidden for Bilirubin	
Hidden for Aspartate	
Hidden for Alanine	
Hidden for Alanine Range	
Hidden for Asparate Range	
Hidden for Bilirubin Range	
Derived field to call CF	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Post-treatment 90 Days Safety follow-up
Form: Non-central Laboratory Test Results - Hematology (LB1)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ■ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hemoglobin (Blood)	_____
Hematocrit (Blood)	_____
Leucocytes, Absolute Count (WBC) (Blood)	_____
Platelet count (Blood)	_____
Mean corpuscular volume (Blood)	_____
Absolute Neutrophil Count (Blood)	_____
Absolute Lymphocytes Count (Blood)	_____
Absolute Monocytes Count (Blood)	_____
Absolute Eosinophils,Count (Blood)	_____
Neutrophils, %/Ratio (Blood)	_____
Lymphocytes, %/Ratio (Blood)	_____
Monocytes, %/Ratio (Blood)	_____
Eosinophils, % /Ratio (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Post-treatment 90 Days Safety follow-up
Form: Non-central Laboratory Test Results - Thyroid function test (LB3)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Thyroid Stimulating Hormone(Serum/Plasma)	_____
T4 (Thyroxine), Free(Serum/Plasma)	_____
T3 (Triiodothyronine), Free(Serum/Plasma)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Post-treatment 90 Days Safety follow-up
Form: Sample Collection, ADA Sample (SPCBEDB5)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ☐
	cfDNA-BCT ☐
	Blood ■
Biofluid processed	PBMC ☐
	Blood ☐
	Serum ■
	Plasma ☐
Sample format	DNA ☐
	Fresh ☐
	Frozen ■
	RNA ☐
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Post-treatment 90 Days Safety follow-up
Form: Biological Sample Collection, PK (SPCPKB2)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample collection category?	PK, biofluid ■
Sample collected	No ☐ Yes ☐
Last investigational product date	Fixed Unit: yyyy mon dd
Last investigational product time	Fixed Unit: 24-hour clock
Biofluid collected (parent sample)	Blood ■
Biofluid processed	Serum ■
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐ Hemolyzed ☐ Clotted ☐ Lipemic ☐ Quantity less than expected ☐ Sample discarded ☐ Other ☐
If Other, specify	
Date of storage	Fixed Unit: yyyy mon dd
Time of storage	Fixed Unit: 24-hour clock
Protocol schedule day	9999
Protocol schedule hour	-999
Protocol schedule minute	-99
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Post-treatment 90 Days Safety follow-up
Form: Survival Status (SURVIVE)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: ON2102 2022-03-07)

Date Subject confirmed to be alive	Fixed Unit: yyyy mon dd
Date of the latest unsuccessful contact attempt	Fixed Unit: yyyy mon dd

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Survival follow-up
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)	
Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd _____
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	_____
Visit was impacted by global/country situation	Yes ☐
IVRS Date	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Survival follow-up
Form: Second Time of Progression (PFS2)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: ON2007 2021-04-27)

Assessment performed	No ☐ Yes ☐
Date of scan/assessment for second progression	Fixed Unit: yyyy mon dd _____
Investigator assessment of Subject's response	Progressive disease ☐ Non progressive disease ☐ Not evaluable ☐
If progression, specify the type of progression	Symptomatic Progression ☐ Objective radiological progression ☐ Other ☐
If Other, specify	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Survival follow-up
Form: Survival Status (SURVIVE)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: ON2102 2022-03-07)	
Date Subject confirmed to be alive	Fixed Unit: yyyy mon dd
Date of the latest unsuccessful contact attempt	Fixed Unit: yyyy mon dd

Were any adverse events experienced?	No ☐
	Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Adverse Event
Form: Adverse Events (AE)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2504 2025-04-09)	
Now Derivation(This field required for CF approach)	_____
AE No.	_____
Adverse Event	_____
Start date	Fixed Unit: yyyy mon dd _____
End date	Fixed Unit: yyyy mon dd _____
Outcome	Recovered/Resolved ☐ Recovering/Resolving ☐ Recovered/Resolved with sequelae ☐ Not recovered/Not resolved ☐ Fatal ☐
Serious	No ☐ Yes ☐
Investigational product	Rilvegostomig
Action taken due to AE, Rilvegostomig	Dose not changed ☐ Drug interrupted ☐ Drug permanently discontinued ☐ Not applicable ☐
Reasonable possibility AE caused by Rilvegostomig	No ☐ Yes ☐
Investigational product 1	Durvalumab
Action taken due to AE, Durvalumab	Dose not changed ☐ Drug interrupted ☐ Drug permanently discontinued ☐ Not applicable ☐
Reasonable possibility AE caused by Durvalumab	No ☐ Yes ☐
Investigational product 2	Gemcitabine
Action taken due to AE, Gemcitabine	Dose Not Changed ☐

	Dose Increased ☐
	Dose Reduced ☐
	Drug Interrupted ☐
	Drug Permanently Discontinued ☐
	Not Applicable ☐
Reasonable possibility AE caused by Gemcitabine	No ☐
	Yes ☐
Investigational product 3	Cisplatin
Action taken due to AE, Cisplatin	Dose Not Changed ☐
	Dose Increased ☐
	Dose Reduced ☐
	Drug Interrupted ☐
	Drug Permanently Discontinued ☐
	Not Applicable ☐
Reasonable possibility AE caused by Cisplatin	No ☐
	Yes ☐
Reasonable possibility AE caused by Device Event	No ☐
	Yes ☐
Device Event	_____
Device Event number	_____
CTCAE grade at start of AE	Grade 1 Mild AE ☐
	Grade 2 Moderate AE ☐
	Grade 3 Severe AE ☐
	Grade 4 Life-threatening or disabling AE ☐
	Grade 5 Death related to AE ☐
Is this an Adverse Event of Special Interest?	No ☐
	Yes ☐
Adverse event of special interest category	Potential Endocrinopathies ☐
	Potential Hepatic Events ☐
	Potential Nephritis or Renal Dysfunction ☐

	Potential Neuropathy/Neuro-muscular Toxicity ☐
	Potential Pancreatitis ☐
	Potential Rash or Dermatitis ☐
	Potential GI Toxicity ☐
	Potential Myositis/Polymyositis ☐
	Potential Myocarditis ☐
	Potential Pneumonitis ☐
	Infusion Related Reaction Including Anaphylaxis ☐
	Combined Elevations of Aminotransferases and Bilirubin ☐
	Cytokine Release Syndrome ☐
	Encephalitis ☐
	Other ☐
Concomitant or additional treatment given If 'Yes', ensure corresponding AE number is reported on the [Prior and Concomitant Medications (CM), Procedures (1PR)]	No ☐ Yes ☐
1. Date AE CTCAE grade changed	Fixed Unit: yyyy mon dd _____
1. CTCAE grade	Grade 1 Mild AE ☐ Grade 2 Moderate AE ☐ Grade 3 Severe AE ☐ Grade 4 Life-threatening or disabling AE ☐ Grade 5 Death related to AE ☐
2. Date AE CTCAE grade changed	Fixed Unit: yyyy mon dd _____
2. CTCAE grade	Grade 1 Mild AE ☐ Grade 2 Moderate AE ☐ Grade 3 Severe AE ☐

	Grade 4 Life-threatening or disabling AE ☐ Grade 5 Death related to AE ☐
3. Date AE CTCAE grade changed	Fixed Unit: yyyy mon dd
3. CTCAE grade	Grade 1 Mild AE ☐ Grade 2 Moderate AE ☐ Grade 3 Severe AE ☐ Grade 4 Life-threatening or disabling AE ☐ Grade 5 Death related to AE ☐
4. Date AE CTCAE grade changed	Fixed Unit: yyyy mon dd
4. CTCAE grade	Grade 1 Mild AE ☐ Grade 2 Moderate AE ☐ Grade 3 Severe AE ☐ Grade 4 Life-threatening or disabling AE ☐ Grade 5 Death related to AE ☐
5. Date AE CTCAE grade changed	Fixed Unit: yyyy mon dd
5. CTCAE grade	Grade 1 Mild AE ☐ Grade 2 Moderate AE ☐ Grade 3 Severe AE ☐ Grade 4 Life-threatening or disabling AE ☐ Grade 5 Death related to AE ☐
6. Date AE CTCAE grade changed	Fixed Unit: yyyy mon dd
6. CTCAE grade	Grade 1 Mild AE ☐ Grade 2 Moderate AE ☐ Grade 3 Severe AE ☐

	Grade 4 Life-threatening or disabling AE ☐
	Grade 5 Death related to AE ☐
7. Date AE CTCAE grade changed	Fixed Unit: yyyy mon dd
7. CTCAE grade	Grade 1 Mild AE ☐
	Grade 2 Moderate AE ☐
	Grade 3 Severe AE ☐
	Grade 4 Life-threatening or disabling AE ☐
	Grade 5 Death related to AE ☐
8. Date AE CTCAE grade changed	Fixed Unit: yyyy mon dd
8. CTCAE grade	Grade 1 Mild AE ☐
	Grade 2 Moderate AE ☐
	Grade 3 Severe AE ☐
	Grade 4 Life-threatening or disabling AE ☐
	Grade 5 Death related to AE ☐
9. Date AE CTCAE grade changed	Fixed Unit: yyyy mon dd
9. CTCAE grade	Grade 1 Mild AE ☐
	Grade 2 Moderate AE ☐
	Grade 3 Severe AE ☐
	Grade 4 Life-threatening or disabling AE ☐
	Grade 5 Death related to AE ☐
CTCAE Version	5.0
Immune-mediated AE	No ☐
	Yes ☐
Infusion reaction AE	No ☐
	Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Adverse Event
Form: Adverse Events (AE)
Generated On: 2025 Nov 20 12:27 (GMT)

Generated CASEID	
Initial email sent(This field required for CF approach)	
Downgrade Mail Sent(This field required for CF approach)	
Hidden field for DE Alert	

(Version: OM2107 2024-07-23)

AE number	_____
Adverse event	_____
AE of special interest	Potential endocrinopathies ☐ Potential hepatic events ☐ Potential nephritis or renal dysfunction ☐ Potential neuropathy/neuro-muscular toxicity ☐ Potential pancreatitis ☐ Potential rash or dermatitis ☐ Potential GI Toxicity ☐ Potential myositis/polymyositis ☐ Potential myocarditis ☐ Potential pneumonitis ☐ Infusion related reaction including anaphylaxis ☐ Combined elevations of aminotransferases and bilirubin ☐ Cytokine release syndrome ☐ Encephalitis ☐ Other ☐
If Other, specify	_____
Number of bowel movements at baseline	_____
Current bowel movements CTCAE grade	Mild AE (increase of <4 stools/day over baseline) ☐ Moderate AE (increase of 4-6 stools/day over baseline) ☐ Severe AE (increase of ≥7 stools/day over baseline) ☐ Life-threatening or disabling AE ☐ Death related to AE ☐
Body surface area covered	<10% ☐

	10-30% ☐
	>30% ☐
Anatomical site 01	Lower leg ☐
	Abdominal cavity ☐
	Inguinal region ☐
	Back ☐
	Neck ☐
	Face ☐
	Chest ☐
	Arm ☐
	Foot ☐
	Hand ☐
	Buttock ☐
	Scalp ☐
	Eye ☐
	Not applicable ☐
	Other ☐
Anatomical site 02	Lower leg ☐
	Abdominal cavity ☐
	Inguinal region ☐
	Back ☐
	Neck ☐
	Face ☐
	Chest ☐
	Arm ☐
	Foot ☐
	Hand ☐
	Buttock ☐
	Scalp ☐
	Eye ☐
	Not applicable ☐
	Other ☐
Anatomical site 03	Lower leg ☐

	Abdominal cavity ☐
	Inguinal region ☐
	Back ☐
	Neck ☐
	Face ☐
	Chest ☐
	Arm ☐
	Foot ☐
	Hand ☐
	Buttock ☐
	Scalp ☐
	Eye ☐
	Not applicable ☐
	Other ☐
Anatomical site 04	Lower leg ☐
	Abdominal cavity ☐
	Inguinal region ☐
	Back ☐
	Neck ☐
	Face ☐
	Chest ☐
	Arm ☐
	Foot ☐
	Hand ☐
	Buttock ☐
	Scalp ☐
	Eye ☐
	Not applicable ☐
	Other ☐
Anatomical site 05	Lower leg ☐
	Abdominal cavity ☐
	Inguinal region ☐
	Back ☐

	Neck ☐
	Face ☐
	Chest ☐
	Arm ☐
	Foot ☐
	Hand ☐
	Buttock ☐
	Scalp ☐
	Eye ☐
	Not applicable ☐
	Other ☐
Signs and symptoms	
Signs and symptoms, other	
Was a specialist consulted?	No ☐
	Yes ☐
Services and result description	
Any additional laboratory investigations performed?	No ☐
	Yes ☐
If Yes, complete LABADD module	
Any significant medical or surgical history relevant to this event?	No ☐
	Yes ☐
If Yes, specify the Medical/Surgical History number and text	
Medical history number/text 1	
Medical history number 1	
Medical history text 1	
Surgical history number/text 1	
Surgical history number 1	
Surgical history text 1	
Any concomitant medication that triggered the event?	No ☐
	Yes ☐
If Yes, please specify the medication number and name	
Concomitant medication number/name 1	
Concomitant medication number 1	

Concomitant medication name 1	_____
Could disease progression have triggered the event?	No ☐ Yes ☐
If Yes, specify below	
Can the event be attributed to disease/metastasis?	No ☐ Yes ☐
Anatomic location	Distant Lymph Nodes ☐ Stomach ☐ Liver ☐ Pancreas ☐ Ovary ☐ Spleen ☐ Brain ☐ Lung ☐ Pleura ☐ Skin ☐ Adrenal Gland ☐ Regional Lymph Node ☐ Other ☐
Any potential alternate etiology excluding disease progression?	No ☐ Yes ☐
If Yes, specify	_____
Additional comments	_____

(Version: OM2208 2022-08-04)

AE number _____

Adverse event _____

AE of special interest

- ☐ Potential endocrinopathies
- ☐ Potential hepatic events
- ☐ Potential nephritis or renal dysfunction
- ☐ Potential neuropathy/neuro-muscular toxicity
- ☐ Potential pancreatitis
- ☐ Potential rash or dermatitis
- ☐ Potential GI toxicity
- ☐ Potential myositis/polymyositis
- ☐ Potential myocarditis
- ☐ Potential Pneumonitis
- ☐ Infusion Related Reaction Including Anaphylaxis
- ☐ Combined Elevations of Aminotransferases and Bilirubin
- ☐ Cytokine Release Syndrome
- ☐ Encephalitis
- ☐ Other

If Other, specify _____

Investigation

- ☐ MRCP
- ☐ Colonoscopy
- ☐ ERCP
- ☐ Electromyogram
- ☐ Nerve conduction investigations
- ☐ Repetitive stimulation
- ☐ Cultures
- ☐ ECG
- ☐ Eye exam

	ACTH (Cosyntropin) stimulation test ☐
	Biopsy ☐
	Endoscopy ☐
	MRI ☐
	CT Scan ☐
	Ultrasound ☐
	X-Ray ☐
	Other ☐
If other, specify	
Please specify Procedure number and text Procedure number/text 1	
Procedure number 1	
Procedure text 1	
Procedure number/text 2	
Procedure number 2	
Procedure text 2	
Procedure number/text 3	
Procedure number 3	
Procedure text 3	
Procedure number/text 4	
Procedure number 4	
Procedure text 4	
Procedure number/text 5	
Procedure number 5	
Procedure text 5	
Result description	
Result description 1	
Result description 2	
Result description 3	
Result description 4	
Result description 5	
Result description 6	
Result description 7	
Result description 8	
Result description 9	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Adverse Event of Special Interest
Form: Additional Laboratory Evaluations (LABADD)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: OM1907 2022-11-09)	
AE number	
AE number (derived, no entry required)	
Adverse event (derived, no entry required)	
AE of special interest (derived, no entry required)	
If Other, specify	
Collection date	Fixed Unit: yyyy mon dd
Test name	Hba1c (Blood) ☐ Thyrotropin Receptor Antibody (Serum) ☐ Thyroid Peroxidase Antibody (Serum) ☐ Thyroglobulin Antibody (Serum) ☐ Glutamic Acid Decarboxylase Antibody, Quant ☐ Islet Cell Autoantibodies, Qual ☐ Islet Cell Autoantibodies, Quant ☐ Other ☐
If Other, specify	
Result	
Laboratory value comment	
Low normal	
High normal	
Units	
Clinically significant	No ☐ Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Adverse Event of Special Interest
Form: Infusion Related Reaction TQS (IRRTQS)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version:DK2303 2023-07-25)

AE number _____

Adverse event _____

AE of special interest _____

Include all concomitant medications (including any prescription/non-prescription drugs and herbals/supplements) you consider to have a causal relationship with the AE.

Provide formulation if applicable
Suspect drug name +/- additives / excipients (trade name) _____

Timing between suspect drug administration and AE onset — Fixed Unit: 24-hours clock

_____

Was premedication given? — No ☐ Yes ☐

Acetaminophen — No ☐ Yes ☐

Antihistamines — No ☐ Yes ☐

Glucocorticoids — No ☐ Yes ☐

Indicate all IRR symptoms that apply, but do not record them as separated AEs. Include the nature and severity of symptoms, timing to symptom onset in relation to infusion, and time to symptom resolution in the case narrative in the eCRF

Skin signs / symptoms:

Maculopapular rash — No ☐ Yes ☐

Hives/urticaria — No ☐ Yes ☐

Macular rash — No ☐ Yes ☐

Papular rash — No ☐ Yes ☐

Vesicular rash — No ☐ Yes ☐

Skin exfoliation	No ☐ Yes ☐
Vasculitic rash	No ☐ Yes ☐
Eczematoid rash	No ☐ Yes ☐
Bullous lesions	No ☐ Yes ☐
Acute generalized exanthemous pustulosis (AGEP)	No ☐ Yes ☐
Only Pruritus	No ☐ Yes ☐
Angioedema	No ☐ Yes ☐
Respiratory symptoms:	
Cough	No ☐ Yes ☐
Dyspnea	No ☐ Yes ☐
Bronchospasm/wheezing	No ☐ Yes ☐
Sensation of throat tightening or closing / dysphonia / change in voice quality	No ☐ Yes ☐
Hyperventilation	No ☐ Yes ☐
Cardiovascular signs / symptoms:	
Palpitations/tachycardia	No ☐ Yes ☐
Hypotension	No ☐ Yes ☐
Chest discomfort/tightness/pain	No ☐

	Yes ☐
Arrythmia	No ☐
	Yes ☐
Gastrointestinal symptoms:	
Nausea	No ☐
	Yes ☐
Vomiting	No ☐
	Yes ☐
Diarrhea	No ☐
	Yes ☐
Abdominal pain/GI cramps	No ☐
	Yes ☐
Dysphagia (difficulty of swallowing)	No ☐
	Yes ☐
Psychological symptoms (before or during infusion; please specify in narrative):	
Fear/panic reaction	No ☐
	Yes ☐
Other associated signs / symptoms :	
Fever	No ☐
	Yes ☐
Flushing	No ☐
	Yes ☐
Erythema	No ☐
	Yes ☐
Headache	No ☐
	Yes ☐
Chills/rigors (shivering)	No ☐
	Yes ☐
Cold, clammy sensation/extremities	No ☐
	Yes ☐
Injection site pain, burn, extravasation	No ☐

	Yes ☐
Paresthesia (abnormal sensation)	No ☐
	Yes ☐
Lightheadedness	No ☐
	Yes ☐
Edema	No ☐
	Yes ☐
Back pain	No ☐
	Yes ☐
Arthralgia/myalgia (joint/muscle pain)	No ☐
	Yes ☐
Pre-syncope/dizziness	No ☐
	Yes ☐
Syncope	No ☐
	Yes ☐
Blurred vision	No ☐
	Yes ☐
Seizure/convulsions	No ☐
	Yes ☐
Cardiac arrest	No ☐
	Yes ☐
Other	No ☐
	Yes ☐
Other, specify	_____
Was non-drug treatment given for management of the adverse event?	No ☐
	Yes ☐
Infusion speed reduction	No ☐
	Yes ☐
Supine positioning	No ☐
	Yes ☐

Cardiopulmonary resuscitation (CPR)	No ☐ Yes ☐
Oxygen therapy	No ☐ Yes ☐
Airway management (bag-mask ventilation, etc.)	No ☐ Yes ☐
Was treatment given in consultation with a specialist?	No ☐ Yes ☐
Specialist consulted for treatment, specify	_____

If a specialist (e.g., allergist) was consulted, indicate any concluding interpretations if applicable:

Specialist concluding interpretation	Type 1 reaction (ige mediated; anaphylactic response) ☐ Type II reaction (cytotoxic-mediated) ☐ Type III reaction (immune complex-mediated) ☐ Type IV reaction (cell-mediated, late- or delayed-type reaction) ☐ Pseudoallergic reaction ☐ Pharmacological reaction ☐ Psychophysiological reaction ☐ Other ☐
Specialist concluding interpretation, specify	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Serious Adverse Event
Form: Serious Adverse Event Report (SERAE)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2506 2025-06-30)

This form is dynamically created based on response to Serious Criteria on the Adverse Event form.
Serious Adverse forms should never be inactivated or reactivated manually. To inactivate a Serious Adverse Event form, update response to Serious question on the Adverse Event form.
Once inactivated the SAE form will never get reactivated. Only option is to create a new SAE form by updating the Serious question from No to Yes on Adverse Event form.
If there is a need to edit adverse event data already entered and saved, never use field-level Edit icons (Pencils to the right of the fields) as individual e-mail alerts will be sent for every single modified field. Instead, use the form-level Edit icon (Pencil on top of the form) and open the whole form for edition, enter all required changes and save the data.

Investigator review completed By checking this box, the investigator or sub-investigator indicates he/she has reviewed and confirmed the SAE information, including the causality assessment.	
What is the AE number?	
What is the adverse event term?	
What was the date AE met criteria for serious AE?	Fixed Unit: yyyy mon dd
What was the date investigator became aware of serious AE?	Fixed Unit: yyyy mon dd
AE is serious due to:	
Death	No ☐ Yes ☐
Inpatient hospitalization or prolongation of existing inpatient hospitalization	No ☐ Yes ☐
Congenital anomaly or birth defect	No ☐ Yes ☐
Life threatening	No ☐ Yes ☐
Persistent or significant disability/incapacity	No ☐

	Yes ☐
Important medical event	No ☐ Yes ☐
Foetal distress, foetal death or congenital physical or mental or birth defect	No ☐ Yes ☐
Permanent impairment/Chronic disease	No ☐ Yes ☐
Medical or surgical intervention	No ☐ Yes ☐
If Hospitalization is selected as Yes, complete below:	
Date of hospitalization	Fixed Unit: yyyy mon dd
Date of discharge	Fixed Unit: yyyy mon dd
Reasonable possibility SAE caused by other medication	No ☐ Yes ☐
If Yes, specify trade name(s)	
Reasonable possibility SAE caused by study procedure(s)	No ☐ Yes ☐
If Yes, specify procedure(s)	
Description of AE	

SAE description in chronological order:

•details of symptoms with the start date

•results of relevant diagnostic investigations, laboratory tests with units and reference ranges (in absence of reference ranges use clinical assessment: normal/high/low) to support the diagnosis

•underlying cause (etiology) of the SAE

•clinical course of the SAE, general information about treatment (medication, surgical procedure, etc.) and response to the treatment

•Subject's status at discharge and medical recommendations including changes in treatment due to SAE

•relevant follow-up information

CaseID	
Date AZ aware of serious AE	

(Version: AZ21:10 Date:2021-10-13)	
AE Number(from AE)	
Events Linked for the Case	
Serious (from AE)	No ☐ Yes ☐
Date AE started (from AE)	Fixed Unit: yyyy mmm dd
Date AE stopped (from AE)	Fixed Unit: yyyy mmm dd
Outcome (from AE)	Recovered/Resolved ☐ Recovering/Resolving ☐ Recovered/Resolved with sequelae ☐ Not recovered/Not resolved ☐ Fatal ☐
Reasonable possibility AE caused by Rilvegostomig	No ☐ Yes ☐
Reasonable possibility AE caused by Durvalumab	No ☐ Yes ☐
Reasonable possibility AE caused by Gemcitabine	No ☐ Yes ☐
Reasonable possibility AE caused by Cisplatin	No ☐ Yes ☐
Maximum CTCAE grade (from AE)	Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Grade 4 ☐ Grade 5 ☐
Date AZ aware of serious AE	Fixed Unit: yyyy mmm dd
Date AE met criteria for serious AE	Fixed Unit: yyyy mmm dd

Death	No ☐ Yes ☐
Life threatening	No ☐ Yes ☐
In-patient hospitalization or prolongation of existing	No ☐ Yes ☐
Persistent or significant disability/incapacity	No ☐ Yes ☐
A congenital abnormality/birth defect	No ☐ Yes ☐
Important medical event	No ☐ Yes ☐
Date of hospitalization	Fixed Unit: yyyy mmm dd
Date of discharge	Fixed Unit: yyyy mmm dd
SAE caused by other medication trade name(s)	
SAE caused by study procedure(s)	
SAE Comments	
Details of Narrative:	
Formatted CASEID	
E2B File Sent	
E2B Initial Date	
E2B Change Date	
CASEID (Populated from AE)	
Is Previous SAE ?	No ☐ Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: SAE Case
Form: AZ Rave Safety Gateway Form (AZRSGF)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version:AZ2103 2021-06-25)	
Field created for RSG to calculate weight	
Field created for RSG to calculate height	
RSG Field for Date of Death	
RSG Field for Autopsy performed	No ☐ Yes ☐ Unknown ☐
RSG Field for Primary Cause of Death	
RSG Field for Secondary Cause of death	
RSG Field for Country Code	
RSG Field for Pregnancy Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Interstitial Lung Disease Assessment
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)	
Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Interstitial Lung Disease Assessment
Form: Pulmonary Function Test (PULMOA)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: ON2502 2025-06-27)	
Was Pulmonary Function Test performed?	No ☐ Yes ☐
Date of collection	Fixed Unit: yyyy mon dd
Peripheral oxygen saturation	Fixed Unit: %
PaO2	
PaO2 unit	kPa ●
FiO2 (Fraction of inspired oxygen)	
Subject been prescribed oxygen therapy	No ☐ Yes ☐
Oxygen treatment start date	Fixed Unit: yyyy mon dd
Oxygen treatment stop date	Fixed Unit: yyyy mon dd
Oxygen treatment prior to study start	Yes ☐
Oxygen treatment continues	Yes ☐
Method oxygen provided	Nasal cannula ☐ Mask ☐ Other ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Interstitial Lung Disease Assessment
Form: Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock
1,3-Beta-D-Glucan (Serum)	
Carcinoembryonic Antigen (Serum/Plasma) (ng/mL)	
Carcinoembryonic Antigen (Serum/Plasma) (in Units (IU/mL))	
C-Reactive Protein (Blood)	
C-Reactive Protein (Serum/Plasma)	
Lactate Dehydrogenase (Serum/Plasma)	
Sialylated Carbohydrate Antigen KL-6 (Serum)	
Surfactant Protein A (Serum)	
Surfactant Protein D (Serum/Plasma)	
Surfactant Protein D (Sputum)	

(Version: ON2206 2024-06-05)

What was the AE number?	_____
What was the AE grade change number?	0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐

Symptoms associated with Interstitial Lung Disease

Did the Subject have a fever?	No ☐ Yes ☐
Did the Subject have dyspnea?	No ☐ Yes ☐
Did the Subject have a cough?	No ☐ Yes ☐
Was cough productive?	No ☐ Yes ☐
Did the Subject have any other symptoms?	No ☐ Yes ☐
If Other, specify	_____
What was the method used for the diagnosis?	Bronchoalveolar lavage ☐ Lung biopsy ☐ ILD markers ☐ MRI ☐ CT scan ☐ High resolution CT ☐ X-ray ☐ Other ☐

If Other, specify	_____
What was the axial distribution of lung findings?	Central lung predominant ☐ Peripheral lung predominant ☐ Both ☐
What was the zonal distribution of lung findings?	Upper lung predominant ☐ Middle lung predominant ☐ Lower lung predominant ☐ Not applicable ☐
What was distribution pattern of findings?	Focal pattern ☐ Multifocal pattern ☐ Diffuse pattern ☐ Mixed pattern ☐
Was there lobar involvement in the right upper lobe?	No ☐ Yes ☐
Was there lobar involvement in the right middle lobe?	No ☐ Yes ☐
Was there lobar involvement in the right lower lobe?	No ☐ Yes ☐
Was there lobar involvement in the left upper lobe?	No ☐ Yes ☐
Was there lobar involvement in the left lower lobe?	No ☐ Yes ☐
Were ground glass opacities found in CT?	No ☐ Yes ☐
Were reticular opacities found in CT?	No ☐ Yes ☐
Was consolidation found in CT?	No ☐ Yes ☐
Was traction bronchiectasis found in CT?	No ☐ Yes ☐
Was centrilobular nodularity found in CT?	No ☐

	Yes ☐
Was honeycombing found in CT?	No ☐ Yes ☐
Were there any further findings?	

Note: Provide chronological findings (specify dates and exams), information on previous radiologic reports should be included along with the reports from the pulmonary event. High resolution CT (HRCT) is critical in diagnosing pulmonary events. Send duplicate anonymized HRCT images in DICOM format on a CD/DVD to the study team.
Fill out MH and/or AE if patient has Autoimmune diseases, Crohn's disease, SLE, Rheumatoid disease, Sjogren's syndrome, Malaria, Organ transplant, Cardiac failure, Wegner's granulomatosis.

At the time of diagnosis of the pulmonary event was there any sign of cancer progression within the thorax?	No ☐ Yes ☐
What was the description of cancer progression within the thorax?	
At the time of diagnosis of the pulmonary event, was there any evidence of bacterial infection?	No ☐ Yes ☐
At the time of diagnosis of the pulmonary event, was there any evidence of viral infection?	No ☐ Yes ☐
At the time of diagnosis of the pulmonary event, was there any evidence of fungal infection?	No ☐ Yes ☐
At the time of diagnosis of the pulmonary event, was there any other type of evidence of infection?	No ☐ Yes ☐
Was the lung biopsy performed?	No ☐ Yes ☐
Type of biopsy	Transbronchial ☐ Bronchial biopsy ☐ Cryobiopsy ☐ Other ☐
If Other biopsy, specify	
What was the date the biopsy was performed?	Fixed Unit: yyyy mon dd
What were the biopsy findings, specify	
Was bronchoalveolar lavage (BAL) performed?	No ☐

	Yes ☐
What was the date of examination of BAL?	Fixed Unit: yyyy mon dd _____
Specify results of this examination	
What was the total cells count?	_____
What was the unit of total cells count?	10^8/L
What was the lymphocyte cell count?	_____
What was the unit of lymphocyte cell count?	%
What was the neutrophil count?	_____
What was the unit of neutrophil count?	%
What was the macrophage count?	_____
What was the unit of macrophage count?	%
What was the eosinophil count?	_____
What was the unit of eosinophil count?	%
What was the basophil count?	_____
What was the unit of basophil count?	%
What was the CD4/CD8 count?	_____
What was the unit of CD4/CD8 count?	RATIO
If there are any pathological findings in BAL, specify	_____
Were there malignant cells in cytology?	No ☐ Yes ☐
If there were malignant cells on cytology, specify results	_____
Did pleural effusion co-exist with the event?	No ☐ Yes ☐
Was cytology of pleural fluid done?	No ☐ Yes ☐
Were malignant cells present in cytology of pleural fluid?	No ☐ Yes ☐
If malignant cells were present in cytology of pleural fluid, specify results	_____
Were blood gases performed at the time of the suspected pulmonary event?	No ☐ Yes ☐

If 'Yes', record the lab data of blood gases in PULMOA module.

Is there a history of radiotherapy to the thorax prior to entering the study?	No ☐ Yes ☐

If 'Yes', fill out CAPRXR to complete the radiotherapy to thorax in eCRF.

Has the Subject ever had pleurodesis performed?	No ☐ Yes ☐

If 'Yes', fill out MH or PR to complete details of pleurodesis.

What was the type of pleurodesis?	Talc ☐ Picibanil (ok-432) ☐ Tetracycline ☐ Bleomycine ☐ Other ☐
If Other, specify	_____
At the time of the event, was there any evidence of an inflammatory reaction?	No ☐ Yes ☐
If not captured on AE / LB, then add details here	_____
At the time of the event, was there any evidence of allergic reaction?	No ☐ Yes ☐
If not captured on AE / LB, then add details here	_____
Was prior radiation administered to the chest?	No ☐ Yes ☐
What were the radiological findings?	Confined to radiation field only ☐ Outside of radiation field only ☐ Both ☐ No radiological findings ☐
What was the pneumonitis type?	Radiation pneumonitis ☐ Drug-induced pneumonitis/Interstitial lung disease ☐ Other ☐
If Other, specify	_____
Analytes	Common bacteria ■

	Acid fast bacillus ☐
	Tubercle bacillus ☐
	Legionnaire ☐
	Pneumocystis ☐
	Cytomegalovirus ☐
	COVID-19 ☐
	Influenza ☐
	Mycoplasma ☐
	Aspergillus ☐
	Cryptococcus ☐
	Candida ☐
	Other ☐
Test method	Sputum culture ☐
	Blood culture ☐
	Serum antibody titer ☐
	Broncho-alveolar lavage ☐
	Other fungal ☐
	Other ☐
Date of examination	Fixed Unit: yyyy mon dd _____
Result	Negative ☐
	Positive ☐
Other, specify	_____
Analytes	Common bacteria ☐
	Acid fast bacillus ■
	Tubercle bacillus ☐
	Legionnaire ☐
	Pneumocystis ☐
	Cytomegalovirus ☐
	COVID-19 ☐
	Influenza ☐
	Mycoplasma ☐

	Aspergillus ☐
	Cryptococcus ☐
	Candida ☐
	Other ☐
Test method	Sputum culture ☐
	Blood culture ☐
	Serum antibody titer ☐
	Broncho-alveolar lavage ☐
	Other fungal ☐
	Other ☐
Date of examination	Fixed Unit: yyyy mon dd _____
Result	Negative ☐
	Positive ☐
Other, specify	_____
Analytes	Common bacteria ☐
	Acid fast bacillus ☐
	Tubercle bacillus ■
	Legionnaire ☐
	Pneumocystis ☐
	Cytomegalovirus ☐
	COVID-19 ☐
	Influenza ☐
	Mycoplasma ☐
	Aspergillus ☐
	Cryptococcus ☐
	Candida ☐
	Other ☐
Test method	Sputum culture ☐
	Blood culture ☐
	Serum antibody titer ☐
	Broncho-alveolar lavage ☐

	Other fungal ☐
	Other ☐
Date of examination	Fixed Unit: yyyy mon dd
Result	Negative ☐
	Positive ☐
Other, specify	
Analytes	Common bacteria ☐
	Acid fast bacillus ☐
	Tubercle bacillus ☐
	Legionnaire ■
	Pneumocystis ☐
	Cytomegalovirus ☐
	COVID-19 ☐
	Influenza ☐
	Mycoplasma ☐
	Aspergillus ☐
	Cryptococcus ☐
	Candida ☐
	Other ☐
Test method	Sputum culture ☐
	Blood culture ☐
	Serum antibody titer ☐
	Broncho-alveolar lavage ☐
	Other fungal ☐
	Other ☐
Date of examination	Fixed Unit: yyyy mon dd
Result	Negative ☐
	Positive ☐
Other, specify	
Analytes	Common bacteria ☐

	Acid fast bacillus ☐
	Tubercle bacillus ☐
	Legionnaire ☐
	Pneumocystis ■
	Cytomegalovirus ☐
	COVID-19 ☐
	Influenza ☐
	Mycoplasma ☐
	Aspergillus ☐
	Cryptococcus ☐
	Candida ☐
	Other ☐
Test method	Sputum culture ☐
	Blood culture ☐
	Serum antibody titer ☐
	Broncho-alveolar lavage ☐
	Other fungal ☐
	Other ☐
Date of examination	Fixed Unit: yyyy mon dd _____
Result	Negative ☐
	Positive ☐
Other, specify	_____
Analytes	Common bacteria ☐
	Acid fast bacillus ☐
	Tubercle bacillus ☐
	Legionnaire ☐
	Pneumocystis ☐
	Cytomegalovirus ■
	COVID-19 ☐
	Influenza ☐
	Mycoplasma ☐

	Aspergillus ☐
	Cryptococcus ☐
	Candida ☐
	Other ☐
Test method	Sputum culture ☐
	Blood culture ☐
	Serum antibody titer ☐
	Broncho-alveolar lavage ☐
	Other fungal ☐
	Other ☐
Date of examination	Fixed Unit: yyyy mon dd _____
Result	Negative ☐
	Positive ☐
Other, specify	_____
Analytes	Common bacteria ☐
	Acid fast bacillus ☐
	Tubercle bacillus ☐
	Legionnaire ☐
	Pneumocystis ☐
	Cytomegalovirus ☐
	COVID-19 ■
	Influenza ☐
	Mycoplasma ☐
	Aspergillus ☐
	Cryptococcus ☐
	Candida ☐
	Other ☐
Test method	Sputum culture ☐
	Blood culture ☐
	Serum antibody titer ☐
	Broncho-alveolar lavage ☐

	Other fungal ☐
	Other ☐
Date of examination	Fixed Unit: yyyy mon dd
Result	Negative ☐
	Positive ☐
Other, specify	
Analytes	Common bacteria ☐
	Acid fast bacillus ☐
	Tubercle bacillus ☐
	Legionnaire ☐
	Pneumocystis ☐
	Cytomegalovirus ☐
	COVID-19 ☐
	Influenza ■
	Mycoplasma ☐
	Aspergillus ☐
	Cryptococcus ☐
	Candida ☐
	Other ☐
Test method	Sputum culture ☐
	Blood culture ☐
	Serum antibody titer ☐
	Broncho-alveolar lavage ☐
	Other fungal ☐
	Other ☐
Date of examination	Fixed Unit: yyyy mon dd
Result	Negative ☐
	Positive ☐
Other, specify	
Analytes	Common bacteria ☐

	Acid fast bacillus ☐
	Tubercle bacillus ☐
	Legionnaire ☐
	Pneumocystis ☐
	Cytomegalovirus ☐
	COVID-19 ☐
	Influenza ☐
	Mycoplasma ■
	Aspergillus ☐
	Cryptococcus ☐
	Candida ☐
	Other ☐
Test method	Sputum culture ☐
	Blood culture ☐
	Serum antibody titer ☐
	Broncho-alveolar lavage ☐
	Other fungal ☐
	Other ☐
Date of examination	Fixed Unit: yyyy mon dd _____
Result	Negative ☐
	Positive ☐
Other, specify	_____
Analytes	Common bacteria ☐
	Acid fast bacillus ☐
	Tubercle bacillus ☐
	Legionnaire ☐
	Pneumocystis ☐
	Cytomegalovirus ☐
	COVID-19 ☐
	Influenza ☐
	Mycoplasma ☐

	Aspergillus ■
	Cryptococcus ☐
	Candida ☐
	Other ☐
Test method	Sputum culture ☐
	Blood culture ☐
	Serum antibody titer ☐
	Broncho-alveolar lavage ☐
	Other fungal ☐
	Other ☐
Date of examination	Fixed Unit: yyyy mon dd _____
Result	Negative ☐
	Positive ☐
Other, specify	_____
Analytes	Common bacteria ☐
	Acid fast bacillus ☐
	Tubercle bacillus ☐
	Legionnaire ☐
	Pneumocystis ☐
	Cytomegalovirus ☐
	COVID-19 ☐
	Influenza ☐
	Mycoplasma ☐
	Aspergillus ☐
	Cryptococcus ■
	Candida ☐
	Other ☐
Test method	Sputum culture ☐
	Blood culture ☐
	Serum antibody titer ☐
	Broncho-alveolar lavage ☐

	Other fungal ☐
	Other ☐
Date of examination	Fixed Unit: yyyy mon dd
Result	Negative ☐
	Positive ☐
Other, specify	
Analytes	Common bacteria ☐
	Acid fast bacillus ☐
	Tubercle bacillus ☐
	Legionnaire ☐
	Pneumocystis ☐
	Cytomegalovirus ☐
	COVID-19 ☐
	Influenza ☐
	Mycoplasma ☐
	Aspergillus ☐
	Cryptococcus ☐
	Candida ■
	Other ☐
Test method	Sputum culture ☐
	Blood culture ☐
	Serum antibody titer ☐
	Broncho-alveolar lavage ☐
	Other fungal ☐
	Other ☐
Date of examination	Fixed Unit: yyyy mon dd
Result	Negative ☐
	Positive ☐
Other, specify	
Analytes	Common bacteria ☐

	Acid fast bacillus ☐
	Tubercle bacillus ☐
	Legionnaire ☐
	Pneumocystis ☐
	Cytomegalovirus ☐
	COVID-19 ☐
	Influenza ☐
	Mycoplasma ☐
	Aspergillus ☐
	Cryptococcus ☐
	Candida ☐
	Other ■
Test method	Sputum culture ☐
	Blood culture ☐
	Serum antibody titer ☐
	Broncho-alveolar lavage ☐
	Other fungal ☐
	Other ☐
Date of examination	Fixed Unit: yyyy mon dd
Result	Negative ☐
	Positive ☐
Other, specify	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: CRS Signs and Symptoms
Form: CRS Signs and Symptoms (CRSSS)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: ON2410 2024-10-03)	
AE No.	_____
Adverse Event	_____
CTCAE Version	5
NOTE: Where interventions are noted e.g., medication or ventilation/dialysis etc. or medication for CRS given please be sure to add the detailed records of these to the 'Prior and Concomitant Medications' or 'Procedures' page as appropriate.	
Sign/symptom reported term	_____
CTCAE grade	Grade 1 Mild AE ☐ Grade 2 Moderate AE ☐ Grade 3 Severe AE ☐ Grade 4 Life-threatening or disabling AE ☐ Grade 5 Death related to AE ☐
Sign/symptom start date	Fixed Unit: yyyy mon dd _____
Sign/symptom end date	Fixed Unit: yyyy mon dd _____
Sign/symptom ongoing	Yes ☐
Description of Cytokine Release Syndrome	_____
Were any medication given prior to study drug infusion for prophylaxis of CRS?	No ☐ Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: CRS Signs and Symptoms
Form: CRS ASTCT Criteria (CRASTCT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: ON2211 2025-03-12)	
AE No.	_____
Adverse Event	_____
ASTCT CRS Criteria Version	LEE ASTCT 2019

NOTE: Record the relevant values for the vital signs at onset, peak (if different from onset) and resolution for the symptoms of fever, hypotension and hypoxia as appropriate

Body temperature	<38.0C (100.4F) ☐
	38.0-39.0C (100.4-102.2F) ☐
	>39.0-40.0C (102.3-104.0F) ☐
	>40C (>104.0F) for =<24 hours ☐
	>40C (>104.0F) for >24 hours ☐
Hypotension	None ☐
	Not requiring vasopressor ☐
	Requiring vasopressor with or without vasopressin ☐
	Requiring multiple vasopressors (excluding vasopressin) ☐
Hypoxia	None ☐
	Requiring low flow nasal cannula or blow-by ☐
	Requiring high flow nasal cannula, facemask, non-rebreather mask or venturi mask ☐
	Requiring positive pressure (e.g. CPAP, BiPAP) ☐
	Requiring intubation & mechanical ventilation ☐
ASTCT CRS grade	Grade 1 ☐
	Grade 2 ☐
	Grade 3 ☐
	Grade 4 ☐
	Grade 5 ☐

Start date	Fixed Unit: yyyy mon dd
End date	Fixed Unit: yyyy mon dd

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Baseline RECIST
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)

Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Baseline RECIST
Form: Target lesions, Baseline (1RECIST1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: ON2212 2025-03-26)

Target lesions, Baseline

Were there any target lesions present?	No ☐
	Yes ☐
What was the date of last scan?	Fixed Unit: yyyy mon dd

For lymph nodes, the short axis diameter must be recorded, and must be >= 15mm

No more than 2 lesions per site are to be recorded

Lesion number	1
Anatomical location	Esophagus, Upper Thoracic ☐
	Esophagus, Middle Thoracic ☐
	Esophagus, Lower Thoracic ☐
	Retroperitoneum ☐
	Liver ☐
	Pleura ☐
	Adrenal gland ☐
	Lung, Left Lower Lobe ☐
	Lung, Left Upper Lobe ☐
	Lung, Right Lower Lobe ☐
	Lung, Right Middle Lobe ☐
	Lung, Right Upper Lobe ☐
	Regional lymph node ☐
	Distant lymph node ☐
	Bone ☐
	Stomach ☐
	Ovary ☐
	Spleen ☐
	Pancreas ☐
	Intrahepatic Bile Duct ☐
	Extrahepatic Bile Duct ☐
	Mediastinum ☐
	Gallbladder ☐
	Peritoneum ☐

	Other ☐
Tumor laterality	Bilateral ☐
	Right ☐
	Left ☐
	Not applicable ☐
Specify location within site	_____
Specify liver location	Liver-caudate lobe, segment I ☐
	Liver-left lobe, segment II ☐
	Liver-left lobe, segment III ☐
	Liver-left lobe, segment IV ☐
	Liver-right lobe, segment V ☐
	Liver-right lobe, segment VI ☐
	Liver-right lobe, segment VII ☐
	Liver-right lobe, segment VIII ☐
	Liver, left lobe ☐
	Liver, right lobe ☐
	Liver, specify ☐
Location within liver specification	_____
Method	MRI ☐
	CT scan ☐
	Not done ☐
Longest diameter	Fixed Unit: mm _____
Lesion number	2
Anatomical location	Esophagus, Upper Thoracic ☐
	Esophagus, Middle Thoracic ☐
	Esophagus, Lower Thoracic ☐
	Retroperitoneum ☐
	Liver ☐
	Pleura ☐

	Adrenal gland ☐
	Lung, Left Lower Lobe ☐
	Lung, Left Upper Lobe ☐
	Lung, Right Lower Lobe ☐
	Lung, Right Middle Lobe ☐
	Lung, Right Upper Lobe ☐
	Regional lymph node ☐
	Distant lymph node ☐
	Bone ☐
	Stomach ☐
	Ovary ☐
	Spleen ☐
	Pancreas ☐
	Intrahepatic Bile Duct ☐
	Extrahepatic Bile Duct ☐
	Mediastinum ☐
	Gallbladder ☐
	Peritoneum ☐
	Other ☐
Tumor laterality	Bilateral ☐
	Right ☐
	Left ☐
	Not applicable ☐
Specify location within site	_____
Specify liver location	Liver-caudate lobe, segment I ☐
	Liver-left lobe, segment II ☐
	Liver-left lobe, segment III ☐
	Liver-left lobe, segment IV ☐
	Liver-right lobe, segment V ☐
	Liver-right lobe, segment VI ☐
	Liver-right lobe, segment VII ☐

	Liver-right lobe, segment VIII ☐
	Liver, left lobe ☐
	Liver, right lobe ☐
	Liver, specify ☐
Location within liver specification	_____
Method	MRI ☐
	CT scan ☐
	Not done ☐
Longest diameter	Fixed Unit: mm _____
Lesion number	3
Anatomical location	Esophagus, Upper Thoracic ☐
	Esophagus, Middle Thoracic ☐
	Esophagus, Lower Thoracic ☐
	Retroperitoneum ☐
	Liver ☐
	Pleura ☐
	Adrenal gland ☐
	Lung, Left Lower Lobe ☐
	Lung, Left Upper Lobe ☐
	Lung, Right Lower Lobe ☐
	Lung, Right Middle Lobe ☐
	Lung, Right Upper Lobe ☐
	Regional lymph node ☐
	Distant lymph node ☐
	Bone ☐
	Stomach ☐
	Ovary ☐
	Spleen ☐
	Pancreas ☐
	Intrahepatic Bile Duct ☐
	Extrahepatic Bile Duct ☐

	Mediastinum ☐
	Gallbladder ☐
	Peritoneum ☐
	Other ☐
Tumor laterality	Bilateral ☐
	Right ☐
	Left ☐
	Not applicable ☐
Specify location within site	
Specify liver location	Liver-caudate lobe, segment I ☐
	Liver-left lobe, segment II ☐
	Liver-left lobe, segment III ☐
	Liver-left lobe, segment IV ☐
	Liver-right lobe, segment V ☐
	Liver-right lobe, segment VI ☐
	Liver-right lobe, segment VII ☐
	Liver-right lobe, segment VIII ☐
	Liver, left lobe ☐
	Liver, right lobe ☐
	Liver, specify ☐
Location within liver specification	
Method	MRI ☐
	CT scan ☐
	Not done ☐
Longest diameter	Fixed Unit: mm
Lesion number	4
Anatomical location	Esophagus, Upper Thoracic ☐
	Esophagus, Middle Thoracic ☐
	Esophagus, Lower Thoracic ☐

	Retroperitoneum ☐
	Liver ☐
	Pleura ☐
	Adrenal gland ☐
	Lung, Left Lower Lobe ☐
	Lung, Left Upper Lobe ☐
	Lung, Right Lower Lobe ☐
	Lung, Right Middle Lobe ☐
	Lung, Right Upper Lobe ☐
	Regional lymph node ☐
	Distant lymph node ☐
	Bone ☐
	Stomach ☐
	Ovary ☐
	Spleen ☐
	Pancreas ☐
	Intrahepatic Bile Duct ☐
	Extrahepatic Bile Duct ☐
	Mediastinum ☐
	Gallbladder ☐
	Peritoneum ☐
	Other ☐
Tumor laterality	Bilateral ☐
	Right ☐
	Left ☐
	Not applicable ☐
Specify location within site	_____
Specify liver location	Liver-caudate lobe, segment I ☐
	Liver-left lobe, segment II ☐
	Liver-left lobe, segment III ☐
	Liver-left lobe, segment IV ☐
	Liver-right lobe, segment V ☐

	Liver-right lobe, segment VI ☐
	Liver-right lobe, segment VII ☐
	Liver-right lobe, segment VIII ☐
	Liver, left lobe ☐
	Liver, right lobe ☐
	Liver, specify ☐
Location within liver specification	_____
Method	MRI ☐
	CT scan ☐
	Not done ☐
Longest diameter	Fixed Unit: mm
	_____
Lesion number	5
Anatomical location	Esophagus, Upper Thoracic ☐
	Esophagus, Middle Thoracic ☐
	Esophagus, Lower Thoracic ☐
	Retroperitoneum ☐
	Liver ☐
	Pleura ☐
	Adrenal gland ☐
	Lung, Left Lower Lobe ☐
	Lung, Left Upper Lobe ☐
	Lung, Right Lower Lobe ☐
	Lung, Right Middle Lobe ☐
	Lung, Right Upper Lobe ☐
	Regional lymph node ☐
	Distant lymph node ☐
	Bone ☐
	Stomach ☐
	Ovary ☐
	Spleen ☐

	Pancreas ☐
	Intrahepatic Bile Duct ☐
	Extrahepatic Bile Duct ☐
	Mediastinum ☐
	Gallbladder ☐
	Peritoneum ☐
	Other ☐
Tumor laterality	Bilateral ☐
	Right ☐
	Left ☐
	Not applicable ☐
Specify location within site	_____
Specify liver location	Liver-caudate lobe, segment I ☐
	Liver-left lobe, segment II ☐
	Liver-left lobe, segment III ☐
	Liver-left lobe, segment IV ☐
	Liver-right lobe, segment V ☐
	Liver-right lobe, segment VI ☐
	Liver-right lobe, segment VII ☐
	Liver-right lobe, segment VIII ☐
	Liver, left lobe ☐
	Liver, right lobe ☐
	Liver, specify ☐
Location within liver specification	_____
Method	MRI ☐
	CT scan ☐
	Not done ☐
Longest diameter	Fixed Unit: mm
	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Baseline RECIST
Form: Non-target lesions, Baseline (2RECIST1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: ON2212 2025-03-26)

Non-target lesions, Baseline

Was any non-target lesion present?	No ☐
	Yes ☐
What was the date of the last scan?	Fixed Unit: yyyy mon dd
Anatomical location	Brain Frontal Lobe ☐
	Brain Parietal Lobe ☐
	Brain Occipital Lobe ☐
	Brain stem ☐
	Brain Midbrain ☐
	Brain, third ventricle ☐
	Bone ☐
	Liver ☐
	Spinal cord ☐
	Pleura ☐
	Adrenal gland ☐
	Lung, Left Lower Lobe ☐
	Lung, Left Upper Lobe ☐
	Lung, Right Lower Lobe ☐
	Lung, Right Middle Lobe ☐
	Lung, Right Upper Lobe ☐
	Regional lymph node ☐
	Distant lymph node ☐
	Mediastinum ☐
	Pericardial Effusion ☐
	Pleural Effusion ☐
	Other ☐
Tumor laterality	Bilateral ☐
	Right ☐
	Left ☐
	Not applicable ☐
Method	MRI ☐

CT scan ☐
X-ray ☐
Scintigraphy ☐
FDGPET ☐

Multiple non-target lesions involving the same site code should be recorded on a single line when the same method of assessment has been used.

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Follow Up RECIST
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)

Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Follow Up RECIST
Form: Target lesions, Follow-up (3RECIST1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: ON2212 2025-03-26)

Have target lesions been assessed?	No ☐
	Yes ☐
	Not applicable ☐
What was the date of last scan?	Fixed Unit: yyyy mon dd

For lymph nodes, the shortest axis must be recorded.

Lesion number	1
Anatomical location	Esophagus, Upper Thoracic ☐
	Esophagus, Middle Thoracic ☐
	Esophagus, Lower Thoracic ☐
	Retroperitoneum ☐
	Liver ☐
	Pleura ☐
	Adrenal gland ☐
	Lung, Left Lower Lobe ☐
	Lung, Left Upper Lobe ☐
	Lung, Right Lower Lobe ☐
	Lung, Right Middle Lobe ☐
	Lung, Right Upper Lobe ☐
	Regional lymph node ☐
	Distant lymph node ☐
	Bone ☐
	Stomach ☐
	Ovary ☐
	Spleen ☐
	Pancreas ☐
	Intrahepatic Bile Duct ☐
	Extrahepatic Bile Duct ☐
	Mediastinum ☐
	Gallbladder ☐
	Peritoneum ☐
	Other ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Follow Up RECIST
Form: Target lesions, Follow-up (3RECIST1)
Generated On: 2025 Nov 20 12:27 (GMT)

Tumor laterality	Bilateral ☐ Right ☐ Left ☐ Not applicable ☐
Specify location within site	_____
Specify liver location	Liver-caudate lobe, segment I ☐ Liver-left lobe, segment II ☐ Liver-left lobe, segment III ☐ Liver-left lobe, segment IV ☐ Liver-right lobe, segment V ☐ Liver-right lobe, segment VI ☐ Liver-right lobe, segment VII ☐ Liver-right lobe, segment VIII ☐ Liver, left lobe ☐ Liver, right lobe ☐ Liver, specify ☐
Location within liver specification	_____
Method	MRI ☐ CT scan ☐ Not done ☐
Longest diameter	Fixed Unit: mm _____
If no longer measurable, reason	Tumor too large to accurately measure ☐ Tumor too small to accurately measure ☐ Not evaluable ☐
Lesion intervention	Yes ☐
Lesion number	2
Anatomical location	Esophagus, Upper Thoracic ☐ Esophagus, Middle Thoracic ☐

	Esophagus, Lower Thoracic ☐
	Retroperitoneum ☐
	Liver ☐
	Pleura ☐
	Adrenal gland ☐
	Lung, Left Lower Lobe ☐
	Lung, Left Upper Lobe ☐
	Lung, Right Lower Lobe ☐
	Lung, Right Middle Lobe ☐
	Lung, Right Upper Lobe ☐
	Regional lymph node ☐
	Distant lymph node ☐
	Bone ☐
	Stomach ☐
	Ovary ☐
	Spleen ☐
	Pancreas ☐
	Intrahepatic Bile Duct ☐
	Extrahepatic Bile Duct ☐
	Mediastinum ☐
	Gallbladder ☐
	Peritoneum ☐
	Other ☐
Tumor laterality	Bilateral ☐
	Right ☐
	Left ☐
	Not applicable ☐
Specify location within site	_____
Specify liver location	Liver-caudate lobe, segment I ☐
	Liver-left lobe, segment II ☐
	Liver-left lobe, segment III ☐
	Liver-left lobe, segment IV ☐

	Liver-right lobe, segment V ☐
	Liver-right lobe, segment VI ☐
	Liver-right lobe, segment VII ☐
	Liver-right lobe, segment VIII ☐
	Liver, left lobe ☐
	Liver, right lobe ☐
	Liver, specify ☐
Location within liver specification	_____
Method	MRI ☐
	CT scan ☐
	Not done ☐
Longest diameter	Fixed Unit: mm _____
If no longer measurable, reason	Tumor too large to accurately measure ☐
	Tumor too small to accurately measure ☐
	Not evaluable ☐
Lesion intervention	Yes ☐
Lesion number	3
Anatomical location	Esophagus, Upper Thoracic ☐
	Esophagus, Middle Thoracic ☐
	Esophagus, Lower Thoracic ☐
	Retroperitoneum ☐
	Liver ☐
	Pleura ☐
	Adrenal gland ☐
	Lung, Left Lower Lobe ☐
	Lung, Left Upper Lobe ☐
	Lung, Right Lower Lobe ☐
	Lung, Right Middle Lobe ☐
	Lung, Right Upper Lobe ☐

	Regional lymph node ☐
	Distant lymph node ☐
	Bone ☐
	Stomach ☐
	Ovary ☐
	Spleen ☐
	Pancreas ☐
	Intrahepatic Bile Duct ☐
	Extrahepatic Bile Duct ☐
	Mediastinum ☐
	Gallbladder ☐
	Peritoneum ☐
	Other ☐
Tumor laterality	Bilateral ☐
	Right ☐
	Left ☐
	Not applicable ☐
Specify location within site	_____
Specify liver location	Liver-caudate lobe, segment I ☐
	Liver-left lobe, segment II ☐
	Liver-left lobe, segment III ☐
	Liver-left lobe, segment IV ☐
	Liver-right lobe, segment V ☐
	Liver-right lobe, segment VI ☐
	Liver-right lobe, segment VII ☐
	Liver-right lobe, segment VIII ☐
	Liver, left lobe ☐
	Liver, right lobe ☐
	Liver, specify ☐
Location within liver specification	_____
Method	MRI ☐

	CT scan ☐
	Not done ☐
Longest diameter	Fixed Unit: mm _____
If no longer measurable, reason	Tumor too large to accurately measure ☐
	Tumor too small to accurately measure ☐
	Not evaluable ☐
Lesion intervention	Yes ☐
Lesion number	4
Anatomical location	Esophagus, Upper Thoracic ☐
	Esophagus, Middle Thoracic ☐
	Esophagus, Lower Thoracic ☐
	Retroperitoneum ☐
	Liver ☐
	Pleura ☐
	Adrenal gland ☐
	Lung, Left Lower Lobe ☐
	Lung, Left Upper Lobe ☐
	Lung, Right Lower Lobe ☐
	Lung, Right Middle Lobe ☐
	Lung, Right Upper Lobe ☐
	Regional lymph node ☐
	Distant lymph node ☐
	Bone ☐
	Stomach ☐
	Ovary ☐
	Spleen ☐
	Pancreas ☐
	Intrahepatic Bile Duct ☐
	Extrahepatic Bile Duct ☐
	Mediastinum ☐

	Gallbladder ☐
	Peritoneum ☐
	Other ☐
Tumor laterality	Bilateral ☐
	Right ☐
	Left ☐
	Not applicable ☐
Specify location within site	_____
Specify liver location	Liver-caudate lobe, segment I ☐
	Liver-left lobe, segment II ☐
	Liver-left lobe, segment III ☐
	Liver-left lobe, segment IV ☐
	Liver-right lobe, segment V ☐
	Liver-right lobe, segment VI ☐
	Liver-right lobe, segment VII ☐
	Liver-right lobe, segment VIII ☐
	Liver, left lobe ☐
	Liver, right lobe ☐
	Liver, specify ☐
Location within liver specification	_____
Method	MRI ☐
	CT scan ☐
	Not done ☐
Longest diameter	Fixed Unit: mm _____
If no longer measurable, reason	Tumor too large to accurately measure ☐
	Tumor too small to accurately measure ☐
	Not evaluable ☐
Lesion intervention	Yes ☐

Lesion number	5
Anatomical location	Esophagus, Upper Thoracic ☐
	Esophagus, Middle Thoracic ☐
	Esophagus, Lower Thoracic ☐
	Retroperitoneum ☐
	Liver ☐
	Pleura ☐
	Adrenal gland ☐
	Lung, Left Lower Lobe ☐
	Lung, Left Upper Lobe ☐
	Lung, Right Lower Lobe ☐
	Lung, Right Middle Lobe ☐
	Lung, Right Upper Lobe ☐
	Regional lymph node ☐
	Distant lymph node ☐
	Bone ☐
	Stomach ☐
	Ovary ☐
	Spleen ☐
	Pancreas ☐
	Intrahepatic Bile Duct ☐
	Extrahepatic Bile Duct ☐
	Mediastinum ☐
	Gallbladder ☐
	Peritoneum ☐
	Other ☐
Tumor laterality	Bilateral ☐
	Right ☐
	Left ☐
	Not applicable ☐
Specify location within site	_____
Specify liver location	Liver-caudate lobe, segment I ☐

	Liver-left lobe, segment II ☐
	Liver-left lobe, segment III ☐
	Liver-left lobe, segment IV ☐
	Liver-right lobe, segment V ☐
	Liver-right lobe, segment VI ☐
	Liver-right lobe, segment VII ☐
	Liver-right lobe, segment VIII ☐
	Liver, left lobe ☐
	Liver, right lobe ☐
	Liver, specify ☐
Location within liver specification	_____
Method	MRI ☐
	CT scan ☐
	Not done ☐
Longest diameter	Fixed Unit: mm
	_____
If no longer measurable, reason	Tumor too large to accurately measure ☐
	Tumor too small to accurately measure ☐
	Not evaluable ☐
Lesion intervention	Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Follow Up RECIST
Form: Non-target lesions, Follow-up (4RECIST1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: ON2212 2025-03-26)

Have non-target lesions been assessed?	No ☐ Yes ☐ Not applicable ☐
What was the date of last scan?	Fixed Unit: yyyy mon dd _____
What was the response of non-target lesions at this assessment?	Complete response ☐ Progressive disease ☐ Non-complete response/non-progressive disease ☐ Not evaluable ☐
Anatomical location	Brain Frontal Lobe ☐ Brain Parietal Lobe ☐ Brain Occipital Lobe ☐ Brain stem ☐ Brain Midbrain ☐ Brain, third ventricle ☐ Bone ☐ Liver ☐ Spinal cord ☐ Pleura ☐ Adrenal gland ☐ Lung, Left Lower Lobe ☐ Lung, Left Upper Lobe ☐ Lung, Right Lower Lobe ☐ Lung, Right Middle Lobe ☐ Lung, Right Upper Lobe ☐ Regional lymph node ☐ Distant lymph node ☐ Mediastinum ☐ Pericardial Effusion ☐ Pleural Effusion ☐ Other ☐

Method	MRI ☐
	CT scan ☐
	X-ray ☐
	Scintigraphy ☐
	FDGPET ☐

(Version: ON2310 2025-03-26)

New lesions

Are there any new lesions since baseline?	No ☐ Yes ☐
What was the date of earliest scan/clinical examination detecting new lesions?	Fixed Unit: yyyy mon dd _____
Anatomical location	Pericardial effusion ☐ Pleural effusion ☐ Bone ☐ Liver ☐ Brain ☐ Spinal cord ☐ Pleura ☐ Skin ☐ Adrenal gland ☐ Regional lymph node ☐ Distant lymph node ☐ Ascites ☐ Extrahepatic Bile Duct ☐ Intrahepatic Bile Duct ☐ Gallbladder ☐ Lung ☐ Pancreas ☐ Peritoneum ☐ Spleen ☐ Other ☐
If Other, specify	_____
Method	FDGPET ☐ MRI ☐ CT scan ☐ X-ray ☐ Scintigraphy ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Follow Up RECIST
Form: New Lesions and Investigator Assessment of Response (RECIST2)
Generated On: 2025 Nov 20 12:27 (GMT)

New equivocal lesion present	No ☐
	Yes ☐
Equivocal lesion converted to unequivocal	No ☐
	Yes ☐
	Not applicable ☐
Date of scan equivocal lesion first detected	Fixed Unit: yyyy mon dd
Overall visit response	
What is the RECIST response?	Complete response ☐
	Partial response ☐
	Stable disease ☐
	Progressive disease ☐
	Not evaluable ☐
Criteria type	RECIST 1.1 ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Follow Up RECIST
Form: New Lesions Additional Information (NLESADD)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: OM20407 2024-07-18)

Assessment date	Fixed Unit: yyyy mon dd
New lesion number	
Has biopsy been performed?	No ☐ Yes ☐
Date of biopsy	Fixed Unit: yyyy mon dd
Did the pathology results of the biopsy confirm a new primary malignancy?	No ☐ Yes ☐
Did the pathology results of the biopsy confirm metastasis from the primary disease?	No ☐ Yes ☐
Did the pathology results of the biopsy confirm the metastasis from a new primary malignancy?	No ☐ Yes ☐
Enter details of pathology results e.g. infection, inflammation, cytology or details of new cancer, Pathology results, specify	

Were any concomitant medications taken?	No ☐
	Yes ☐

(Version: AZ2409 2024-11-25)	
Medication number	_____
Medication verbatim name	_____
Indication	_____
Therapy reason	Adverse event ☐ Medical history ☐ Prophylaxis ☐ Disease under study ☐ Protocol specified pre-medication ☐ Other ☐
If Other, specify	_____
AE number(s) for which medication taken	_____
AE number(s) for which medication taken 1	_____
AE number(s) for which medication taken 2	_____
AE number(s) for which medication taken 3	_____
AE number(s) for which medication taken 4	_____
Medical history condition(s) number for which medication taken	_____
Medical history condition(s) number for which medication taken 1	_____
Medical history condition(s) number for which medication taken 2	_____
Dose per administration	_____
Frequency	Daily ☐ Twice per day ☐ Per month ☐ As needed ☐ Every hour ☐ Every 2 hours ☐ Every 4 hours ☐ Every other day ☐ 1 time per week ☐ 3 times per day ☐ 4 times per day ☐

	Once ☐
	2 times per week ☐
	3 times per week ☐
	4 times per week ☐
	Every week ☐
	Every 2 weeks ☐
	Every 3 weeks ☐
	Every 4 weeks ☐
	Other ☐
	Unknown ☐
If Other, specify	_____
Dose unit	% ☐
	mg ☐
	mL ☐
	ug ☐
	g ☐
	CAPSULE ☐
	L ☐
	umol ☐
	mCi ☐
	mEq ☐
	mmol ☐
	ng ☐
	TABLET ☐
	IU ☐
	PUFF ☐
	ug/m2 ☐
	IU/kg ☐
	ug/kg ☐
	mg/kg ☐
	mg/m2 ☐
	gtt ☐
	kIU ☐

	MBq ☐
	UNKNOWN ☐
	OTHER ☐
If Other, specify	
Route	Respiratory (inhalation) ☐
	Intravenous ☐
	Oral ☐
	Rectal ☐
	Subcutaneous ☐
	Topical ☐
	Cutaneous ☐
	Other ☐
If Other, specify	
Start date	Fixed Unit: yyyy mon dd
Taken prior to Study Treatment Start	Yes ☐
Ongoing	No ☐
	Yes ☐
If No, complete section below End date	Fixed Unit: yyyy mon dd
Stopped prior to Study Treatment Start	Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Concomitant Medication
Form: Procedures (1PR)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2311 2023-11-24)

Any procedures performed?	No ☐ Yes ☐
Procedure name	_____
Start date	Fixed Unit: yyyy mon dd _____
End date	Fixed Unit: yyyy mon dd _____
Ongoing	Yes ☐
Indication	Adverse event ☐ Medical history ☐ Disease Under Study ☐ Other ☐
Adverse event number	_____
Medical history event identifier	_____
If Other, specify	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)	
Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Unscheduled Visit (UNS_VIS)
Generated On: 2025 Nov 20 12:27 (GMT)

Please choose the form(s) required for this unscheduled visit	
Physical Examination (PE)	
Vital Signs (VS4)	
ECOG Performance Status (ECOG)	
ECG Test Results (EG)	
Additional ECG (EG1)	
Additional ECG (EG2)	
Echocardiography (ECHOC)	
Pregnancy Test (PREG1)	
Non-central Laboratory Test Results - Chemistry (LB)	
Non-central Laboratory Test Results - Hematology (LB1)	
Non-central Laboratory Test Results - Coagulation (LB2)	
Non-central Laboratory Test Results - Thyroid function test (LB3)	
Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)	
Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)	
Non-central Laboratory Test Results - Urinalysis (LB6)	
Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)	
Non-central Laboratory Test Results - Hy’s Law (LB8)	
Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)	
Non-central Laboratory Test Results - Tuberculosis testing (LB10)	
Non-central Laboratory Test Results - HIV testing (LB11)	
Non-central Laboratory Test Results - Additional Chemistry (LB12)	
Sample Collection, Predose_ADA Sample (SPCBEDB)	
Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)	
PBMC for immune profiling_Pre dose (SPCBEDB2)	
Whole blood for RNA analysis_Pre-dose (SPCBEDB3)	
Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)	
Sample Collection, ADA Sample (SPCBEDB5)	
Blood sample for plasma ctDNA (SPCBEDB6)	

Genomics Initiative (optional), exploratory genetic sample (SPCGB)	
Optional on study tumor sample (SPCBEDT)	
Biological Sample Collection, PK (SPCPKB2)	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Physical Examination (PE)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ1609 2019-04-19)

For baseline: Following items should be checked during baseline physical examination (A full physical examination will be performed and include assessments of the following: general appearance, respiratory, cardiovascular system, abdomen, skin, head and neck (including ears, eyes, nose, and throat), lymph nodes, thyroid, musculoskeletal (including spine and extremities), urogenital, dermatological, gastrointestinal, endocrine, hematologic/lymphatic, and neurological systems.).

For follow-up: Following items should be checked during follow-up physical examination (A targeted physical examination will include, at a minimum, assessments of skin, lungs, cardiovascular system, and abdomen (liver and spleen).

If the physical finding started prior to enrolment, it must be recorded as medical history.
If the physical finding started or worsened after enrolment, it must be recorded as an Adverse Event.

Was the physical examination performed?	No ☐ Yes ☐
What was the date of the physical examination?	Fixed Unit: yyyy mon dd

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Vital Signs (VS4)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd
Time	Fixed Unit: 24-hour clock
Pulse	Fixed Unit: beats/min
SBP	Fixed Unit: mmHg
DBP	Fixed Unit: mmHg
Respiration rate	Fixed Unit: breaths/min
Temperature	
Temperature unit	C ●
Peripheral oxygen saturation	Fixed Unit: %
Weight	
Weight unit	kg ●
EHRID	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: ECOG Performance Status (ECOG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: ON2406 2024-06-04)

Clinical classification category	ECOG
What was the date the response or clinical classification was performed?	Fixed Unit: yyyy mon dd
Performance status	0-Fully active, able to carry on all pre-disease performance without restriction ☐ 1-Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work ☐ 2-Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours ☐ 3-Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours ☐ 4-Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair ☐ 5-Dead ☐

Ref: Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55). WHO Ref: World Health Organization (1979).Handbook for Reporting Results of Cancer Treatment Pb (WHO Offset Publications).

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: ECG Test Results (EG)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2112 2024-08-09)

Was the ECG performed?	No ☐ Yes ☐
What was the date of the ECG?	Fixed Unit: yyyy mon dd
ECG time	Fixed Unit: 24-hour clock
ECG mean heart rate	Fixed Unit: beats/min
QRS duration	Fixed Unit: ms
RR interval	Fixed Unit: ms
PR interval	Fixed Unit: ms
QT interval	Fixed Unit: ms
QTc interval Fridericia	Fixed Unit: ms
What was the interpretation of the ECG?	Normal ☐ Abnormal ☐
Reason, abnormal overall ECG evaluation	
Was the ECG clinically significant?	No ☐ Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Additional ECG (EG1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2112 2024-08-09)

Was the ECG performed?	No ☐ Yes ☐
What was the date of the ECG?	Fixed Unit: yyyy mon dd
ECG time	Fixed Unit: 24-hour clock
ECG mean heart rate	Fixed Unit: beats/min
QRS duration	Fixed Unit: ms
RR interval	Fixed Unit: ms
PR interval	Fixed Unit: ms
QT interval	Fixed Unit: ms
QTc interval Fridericia	Fixed Unit: ms
What was the interpretation of the ECG?	Normal ☐ Abnormal ☐
Reason, abnormal overall ECG evaluation	
Was the ECG clinically significant?	No ☐ Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Additional ECG (EG2)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2112 2024-08-09)

Was the ECG performed?	No ☐ Yes ☐
What was the date of the ECG?	Fixed Unit: yyyy mon dd
ECG time	Fixed Unit: 24-hour clock
ECG mean heart rate	Fixed Unit: beats/min
QRS duration	Fixed Unit: ms
RR interval	Fixed Unit: ms
PR interval	Fixed Unit: ms
QT interval	Fixed Unit: ms
QTc interval Fridericia	Fixed Unit: ms
What was the interpretation of the ECG?	Normal ☐ Abnormal ☐
Reason, abnormal overall ECG evaluation	
Was the ECG clinically significant?	No ☐ Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Echocardiography (ECHOC)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2201 2024-09-27)

What was the date of the echocardiography?	Fixed Unit: yyyy mon dd
What was the time of the echocardiography?	Fixed Unit: 24-hour clock
What was the method used for the examination?	Echocardiography ☐ Multiple Gated Acquisition (MUGA) ☐
Was the image quality sufficient?	No ☐ Yes ☐
What was the overall ECHOC evaluation?	Normal ☐ Abnormal ☐
What is the reason the overall ECHOC evaluation was abnormal?	
What was the left ventricular ejection fraction?	Fixed Unit: %
What was the LV end diastolic volume?	Fixed Unit: mL
What was the LV end systolic volume?	Fixed Unit: mL

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Pregnancy Test (PREG1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2008 2024-03-01)

Assessment applicable for Subject	No ☐
	Yes ☐
Sampling date	Fixed Unit: yyyy mon dd
Pregnancy test (serum)	Negative ☐
	Positive ☐
Pregnancy test (urine)	Negative ☐
	Positive ☐

For a positive pregnancy test after first dose of study drug, fill in PREGREP (or the 'Pregnancy Outcome Report Form' [Part 1]) and send to the AstraZeneca Monitor.

If positive pregnancy test, the administration of study drug to that Subject must be discontinued immediately and the End of Study Treatment form (ETRT) filled in.

If Positive pregnancy test, and considered an AE, please fill in Adverse Event (AE) Form
(Pregnancy itself is not regarded as an adverse event unless there is a suspicion that AstraZeneca product may have interfered with the effectiveness of a contraceptive medication.)

Hidden Field (used for CF programming)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Liver Function Tests Alanine Aminotransferase (Serum/Plasma)	_____
Alkaline Phosphatase (Serum/Plasma)	_____
Aspartate Aminotransferase (Serum/Plasma)	_____
Bilirubin, Total (Serum/Plasma)	_____
Bilirubin, Direct, (Conj) (Serum/Plasma)	_____
Bilirubin, Indirect (Unconj.) (Serum/Plasma)	_____
Gamma-Glutamyltransferase (Serum/Plasma)	_____
Lactate Dehydrogenase (LDH) (Serum/Plasma)	_____
Protein, Total (Serum/Plasma)	_____
Pancreatic Enzymes Amylase (Serum/Plasma)	_____
Lipase (Serum/Plasma)	_____
Renal Function Tests Creatinine (Serum/Plasma)	_____
Creatinine Clearance, Calculated (Urine 24h)	_____
Creatinine Clearance, Cockcroft-Gault (Plasma)	_____
Creatinine Clearance, Cockcroft-Gault (Serum)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Plasma)	_____
Glomerular Filtration Rate (51Cr-EDTA) (Serum)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

Urea (Serum/Plasma)	
Urea Nitrogen (BUN) (Serum/Plasma)	
Electrolytes Calcium, Ionized (Serum)	
Total Calcium (Serum/Plasma)	
Chloride (Serum/Plasma)	
Magnesium (Serum/Plasma)	
Phosphate (Phosphorus) (Serum/Plasma)	
Potassium (Serum/Plasma)	
Sodium (Serum/Plasma)	
Proteins Albumin (Serum/Plasma)	
Glucose Metabolism Glucose, Fasting (Serum/Plasma)	
Glucose,Random (Serum/Plasma)	
Hidden for Bilirubin	
Hidden for Aspartate	
Hidden for Alanine	
Hidden for Alanine Range	
Hidden for Asparate Range	
Hidden for Bilirubin Range	
Derived field to call CF	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Non-central Laboratory Test Results - Hematology (LB1)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ■ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hemoglobin (Blood)	_____
Hematocrit (Blood)	_____
Leucocytes, Absolute Count (WBC) (Blood)	_____
Platelet count (Blood)	_____
Mean corpuscular volume (Blood)	_____
Absolute Neutrophil Count (Blood)	_____
Absolute Lymphocytes Count (Blood)	_____
Absolute Monocytes Count (Blood)	_____
Absolute Eosinophils,Count (Blood)	_____
Neutrophils, %/Ratio (Blood)	_____
Lymphocytes, %/Ratio (Blood)	_____
Monocytes, %/Ratio (Blood)	_____
Eosinophils, % /Ratio (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Non-central Laboratory Test Results - Coagulation (LB2)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ■ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock
Activated Partial Thromboplastin Time (APTT) (sec) (Blood)	
Activated Partial Thromboplast. Time,Rel (APTT relative) (%, ratio) (Blood)	
Fibrinogen (Blood)	
Partial Thromboplastin Time (PTT) (sec) (Blood)	
Partial Thromboplastin Time, Rel (PTT Relative) (%, ratio) (Blood)	
Prothrombin Complex INR (Blood) (%,ratio) (Blood)	
Prothrombin Time (PT) (sec) (Blood)	
Prothrombin Time, Relative (PT Relative) (%, ratio) (Blood)	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Non-central Laboratory Test Results - Thyroid function test (LB3)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Thyroid Stimulating Hormone(Serum/Plasma)	_____
T4 (Thyroxine), Free(Serum/Plasma)	_____
T3 (Triiodothyronine), Free(Serum/Plasma)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Creatine Kinase (Serum/Plasma)	_____
Troponin T (Serum/Plasma)	_____
Troponin I (Serum/Plasma)	_____
High- sensitivity Troponin T (Serum/Plasma)	_____
High- sensitivity Troponin I (Serum/Plasma)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Carcinoembryonic Antigen (Serum/Plasma) (ng/mL)	_____
Carbohydrate Antigen 19-9 (Serum) (U/mL)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Non-central Laboratory Test Results - Urinalysis (LB6)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ■ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Albumin, Strip, Qual (Urine)	Negative ☐ Trace ☐ Positive ☐ + ☐ ++ ☐ +++ ☐ >+++ ☐ +- ☐
Bilirubin, Strip, Qual (Urine)	Negative ☐ Trace ☐ Positive ☐ + ☐ ++ ☐ +++ ☐ >+++ ☐ +- ☐
Blood, Qual (Urine)	Negative ☐ Trace ☐

	Positive ☐
	+ ☐
	++ ☐
	+++ ☐
	>+++ ☐
	+- ☐
Glucose, Strip, Qual (Urine)	Negative ☐
	Trace ☐
	Positive ☐
	+ ☐
	++ ☐
	+++ ☐
	>+++ ☐
	+- ☐
Ketone Bodies, Strip, Qual (Urine)	Negative ☐
	Trace ☐
	Positive ☐
	+ ☐
	++ ☐
	+++ ☐
	>+++ ☐
	+- ☐
Protein, Strip, Qual (Urine)	Negative ☐
	Trace ☐
	Positive ☐
	+ ☐
	++ ☐
	+++ ☐
	>+++ ☐
	+- ☐
Appearance (Qual) (Urine)	_____
Color (Qual) (Urine)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Non-central Laboratory Test Results - Urinalysis (LB6)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

Albumin, Quant (Urine)	
Bilirubin, Quant(Urine)	
Glucose, Random, Quant (Urine)	
Ketone Bodies, Quant (Urine)	
Protein, Total, Quant (Urine)	
Urine-Blood, Quant (Urine)	
pH (Urine)	
Specific Gravity (Urine)	
Sediment, Erythrocytes, Quant (no/vis fld) (Urine)	
Sediment, Leucocytes, Quant (no/vis fld) (Urine)	
Leucocytes, Quant (10**6/L) (Volume) (Urine)	
Erythrocytes, Quant (1/uL) (Volume) (Urine)	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	☐ No ☐ Yes
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	☐ Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ■ Serology/Immunology
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Hepatitis B Surface Antigen (Qual) (HBsAg) (Blood)	☐ Negative ☐ Positive ☐ +-borderline
Hepatitis B Surface Antibody (HBsAb) (Blood)	☐ Negative ☐ Positive ☐ +-borderline
Hepatitis B Core Antibody, Qual (anti-HBc) (Blood)	☐ Negative ☐ Positive ☐ +-borderline
Hepatitis C Antibody (HCV ab) (Blood)	☐ Negative ☐ Positive ☐ +-borderline
Hepatitis D Antibody (Blood)	☐ Negative ☐ Positive ☐ +-borderline
Hepatitis B Viral Load, Quant (IU/mL) (Blood)	_____
Hepatitis B Viral Load, Quant (DNA copies/mL) (Blood)	_____
Hepatitis C Viral Load, Quant (IU/mL) (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

Hepatitis C Viral Load, Quant (RNA copies/mL) (Blood)	_____
Hepatitis D Virus RNA, Quant (Serum/Plasma)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Non-central Laboratory Test Results - Hy's Law (LB8)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name:

(Version: AZ2211 2025-08-05)	
Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock
Alanine Aminotransferase (Serum/Plasma)	
Alkaline Phosphatase (Serum/Plasma)	
Aspartate Aminotransferase (Serum/Plasma)	
Bilirubin, Total (Serum/Plasma)	
Hidden for Bilirubin	
Hidden for Aspartate	
Hidden for Alanine	
Hidden for Alanine Range	
Hidden for Aspartate Range	
Hidden for Bilirubin Range	
Derived field to call CF	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
1,3-Beta-D-Glucan (Serum)	_____
Carcinoembryonic Antigen (Serum/Plasma) (ng/mL)	_____
Carcinoembryonic Antigen (Serum/Plasma) (in Units (IU/mL))	_____
C-Reactive Protein (Blood)	_____
C-Reactive Protein (Serum/Plasma)	_____
Lactate Dehydrogenase (Serum/Plasma)	_____
Sialylated Carbohydrate Antigen KL-6 (Serum)	_____
Surfactant Protein A (Serum)	_____
Surfactant Protein D (Serum/Plasma)	_____
Surfactant Protein D (Sputum)	_____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ■
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock
Culture, Mycobacterium Tuberculosis(Sputum)	Negative ☐ Positive ☐ +-borderline ☐
Quantiferon Tuberculosis Gold (Plasma)	Negative ☐ Positive ☐ +-borderline ☐
Quantiferon Tuberculosis Gold (Blood)	Negative ☐ Positive ☐ +-borderline ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Non-central Laboratory Test Results - HIV testing (LB11)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ■
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
HIV-1/2 Antibody Screen (Blood)	Negative ☐ Positive ☐ +-borderline ☐
HIV Viral Load, Quant, PCR (Blood)	_____
CD4+, abs(cells/uL) (Blood)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Non-central Laboratory Test Results - Additional Chemistry (LB12)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name: _____

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	_____
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____
Ferritin (Serum/Plasma)	_____
Hba1c (IFCC-mmol/mol)	_____
Hba1c(% ,Ratio)	_____
Iron (Serum/Plasma)	_____
Thyroglobulin Antibody (Serum)	_____
Thyroid Peroxidase Antibody (Serum)	_____
Thyrotropin Receptor Antibody (Serum)	_____
Uric acid (Urate) (Serum/Plasma)	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Sample Collection, Predose_ADA Sample (SPCBEDB)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ☐
	cfDNA-BCT ☐
	Blood ■
Biofluid processed	PBMC ☐
	Blood ☐
	Serum ■
	Plasma ☐
Sample format	DNA ☐
	Fresh ☐
	Frozen ■
	RNA ☐
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Protocol schedule	Pre Dose
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ☐
	cfDNA-BCT ■
	Blood ☐
Biofluid processed	PBMC ☐
	Blood ☐
	Serum ☐
	Plasma ■
Sample format	DNA ■
	Fresh ☐
	Frozen ☐
	RNA ☐
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Protocol schedule	Pre Dose
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: PBMC for immune profiling_Pre dose (SPCBEDB2)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid
Sample collected	No
	Yes
Sample collection method	Blood draw
Biofluid collected (parent sample)	Blood Na heparin
	cfDNA-BCT
	Blood
Biofluid processed	PBMC
	Blood
	Serum
	Plasma
Sample format	DNA
	Fresh
	Frozen
	RNA
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable
	Hemolyzed
	Clotted
	Lipemic
	Quantity less than expected
	Sample discarded
	Other
If Other, specify	
Protocol schedule	Pre Dose
Laboratory ID	Labcorp

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Whole blood for RNA analysis_Pre-dose (SPCBEDB3)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ☐
	cfDNA-BCT ☐
	Blood ■
Biofluid processed	PBMC ☐
	Blood ■
	Serum ☐
	Plasma ☐
Sample format	DNA ☐
	Fresh ☐
	Frozen ☐
	RNA ■
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Protocol schedule	Pre Dose
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ☐
	cfDNA-BCT ☐
	Blood ■
Biofluid processed	PBMC ☐
	Blood ☐
	Serum ■
	Plasma ☐
Sample format	DNA ☐
	Fresh ☐
	Frozen ■
	RNA ☐
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Protocol schedule	Pre Dose
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Sample Collection, ADA Sample (SPCBEDB5)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ☐
	cfDNA-BCT ☐
	Blood ■
Biofluid processed	PBMC ☐
	Blood ☐
	Serum ■
	Plasma ☐
Sample format	DNA ☐
	Fresh ☐
	Frozen ■
	RNA ☐
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Blood sample for plasma ctDNA (SPCBEDB6)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood Na heparin ☐
	cfDNA-BCT ■
	Blood ☐
Biofluid processed	PBMC ☐
	Blood ☐
	Serum ☐
	Plasma ■
Sample format	DNA ■
	Fresh ☐
	Frozen ☐
	RNA ☐
Date of collection	Fixed Unit: yyyy mon dd _____
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	_____
Laboratory ID	Labcorp ■

(Version: AZ2310 2025-07-01)

What was the sample collection category?	Biomarkers/exploratory research/diagnostic, solid tissue
Sample collected	No
	Yes
Sample collection method	Core Needle Biopsy
	Excisional Biopsy
	Incisional Biopsy
Biopsy tissue type	Primary tumor
	Metastatic tumor
Organ	Abdomen
	Bronchus (Main Stem)
	Fat
	Oesophagus
	Pituitary
	Urinary Bladder
	Esophagogastric Junction
	Hypopharynx
	Duodenum
	Cervix Uteri
	Epididymis
	Gallbladder
	Large Intestine
	Appendix
	Colon
	Small Intestine
	Ileum
	Jejunum
	Rectum
	Stomach
	Liver
	Pancreas

- [ ] Thyroid Gland
- [ ] Fallopian Tube
- [ ] Ovary
- [ ] Uterus
- [ ] Prostate Gland
- [ ] Testis
- [ ] Kidney
- [ ] Ureter
- [ ] Urethra
- [ ] Larynx
- [ ] Oral Cavity
- [ ] Tongue
- [ ] Pharynx
- [ ] Parotid Gland
- [ ] Trachea
- [ ] Spleen
- [ ] Thymus Gland
- [ ] Brain
- [ ] Spinal Cord
- [ ] Lung
- [ ] Pleura
- [ ] Skin
- [ ] Soft Tissue
- [ ] Abdominal Cavity
- [ ] Adrenal Gland
- [ ] Diaphragm
- [ ] Heart
- [ ] Lymph Node
- [ ] Nose
- [ ] Oropharynx
- [ ] Parathyroid Gland
- [ ] Peripheral Nerve
- [ ] Peritoneum

	Tonsil ☐
	Breast ☐
	Joint ☐
	Muscle ☐
	Gastroesophageal Junction ☐
	Mesentery ☐
	Omentum ☐
	Anus ☐
	Abdominal Wall ☐
	Other (Not Specified) ☐
Sample format	FFPE block ☐
	FFPE unstained slides ☐
Unstained slides sectioning date	Fixed Unit: yyyy mon dd
Date of Biopsy	Fixed Unit: yyyy mon dd
Sample condition	Sample acceptable ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Date of storage	Fixed Unit: yyyy mon dd
Time of storage	Fixed Unit: 24-hour clock
Laboratory ID	Labcorp ■

(Version: AZ2310 2023-10-26)

Was assessment applicable?	No ☐
	Yes ☐
What was the sample category?	Genetics Inherited, Biofluid ■
Sample collected	No ☐
	Yes ☐
Sample collection method	Blood draw ■
Biofluid collected (parent sample)	Blood ■
Sample format	Brushings ☐
	cDNA ☐
	Cell culture ☐
	Cells ☐
	Cells suspension ☐
	Cells microarray ☐
	cRNA ☐
	Cytospin ☐
	DNA ☐
	DNA microarray ☐
	FFPE ☐
	FFPE shavings ☐
	Formalin fixed ☐
	Fresh ☐
	Fresh frozen ☐
	Frozen ■
	H&E stained slide ☐
	IHC slide ☐
	Microarray ☐
	Microsomes ☐
	OCT embedded ☐
	Protein ☐
	Protein microarray ☐
	RNA ☐

	RNA microarray ☐
	Supernatant ☐
	Tissue microarray (TMA) ☐
	Unstained section ☐
	Cells frozen ☐
	Cells lysate ☐
	FFPE Block ☐
	FFPE Unstained slides ☐
Date of collection	Fixed Unit: yyyy mon dd
Sample condition	Sample acceptable ☐
	Hemolyzed ☐
	Clotted ☐
	Lipemic ☐
	Quantity less than expected ☐
	Sample discarded ☐
	Other ☐
If Other, specify	
Sample collection comment	
Date of storage	Fixed Unit: yyyy mon dd
Time of storage	Fixed Unit: 24-hour clock
Laboratory ID	Labcorp ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Unscheduled Visit
Form: Biological Sample Collection, PK (SPCPKB2)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample collection category?	PK, biofluid
Sample collected	No Yes
Last investigational product date	Fixed Unit: yyyy mon dd
Last investigational product time	Fixed Unit: 24-hour clock
Biofluid collected (parent sample)	Blood
Biofluid processed	Serum
Date of collection	Fixed Unit: yyyy mon dd
Time of collection	Fixed Unit: 24-hour clock
Sample condition	Sample acceptable Hemolyzed Clotted Lipemic Quantity less than expected Sample discarded Other
If Other, specify	
Date of storage	Fixed Unit: yyyy mon dd
Time of storage	Fixed Unit: 24-hour clock
Protocol schedule day	9999
Protocol schedule hour	-999
Protocol schedule minute	-99
Laboratory ID	Labcorp

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Main Informed Consent - Reconsent
Form: Informed Consent- Reconsent (CONSENT1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2309 2023-09-14)	
What was the Protocol version?	
What was the Protocol milestone?	Main Informed Consent
What was the main informed consent date?	Fixed Unit: yyyy mon dd
What was the Protocol milestone?	Optional Consent
Optional consent category	Participation to Optional Blood Tests Optional services and the transfer of contact details to service providers Use of coded data (including images), biosamples and analysis of genetic information as required for future research Participation to Optional Biopsy at first day of Cycle 3 of study treatment Participation to Optional Biopsy at Cancer Progression
Optional consent/assent obtained	No Yes Not applicable
Optional consent date	Fixed Unit: yyyy mon dd
Optional consent category	Participation to Optional Blood Tests Optional services and the transfer of contact details to service providers Use of coded data (including images), biosamples and analysis of genetic information as required for future research

	Participation to Optional Biopsy at first day of Cycle 3 of study treatment ■ Participation to Optional Biopsy at Cancer Progression ☐
Optional consent/assent obtained	No ☐ Yes ☐ Not applicable ☐
Optional consent date	Fixed Unit: yyyy mon dd
Optional consent category	Participation to Optional Blood Tests ☐ Optional services and the transfer of contact details to service providers ☐ Use of coded data (including images), biosamples and analysis of genetic information as required for future research ☐ Participation to Optional Biopsy at first day of Cycle 3 of study treatment ☐ Participation to Optional Biopsy at Cancer Progression ■
Optional consent/assent obtained	No ☐ Yes ☐ Not applicable ☐
Optional consent date	Fixed Unit: yyyy mon dd
Optional consent category	Participation to Optional Blood Tests ☐ Optional services and the transfer of contact details to service providers ■

	Use of coded data (including images), biosamples and analysis of genetic information as required for future research ☐ Participation to Optional Biopsy at first day of Cycle 3 of study treatment ☐ Participation to Optional Biopsy at Cancer Progression ☐
Optional consent/assent obtained	No ☐ Yes ☐ Not applicable ☐
Optional consent date	Fixed Unit: yyyy mon dd

Optional consent category	Participation to Optional Blood Tests ☐ Optional services and the transfer of contact details to service providers ☐ Use of coded data (including images), biosamples and analysis of genetic information as required for future research ■ Participation to Optional Biopsy at first day of Cycle 3 of study treatment ☐ Participation to Optional Biopsy at Cancer Progression ☐
Optional consent/assent obtained	No ☐ Yes ☐ Not applicable ☐
Optional consent date	Fixed Unit: yyyy mon dd

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Administration and Discontinuation of IP
Form: Exposure as Collected - Rilvegostomig (EC)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2403 2025-05-05)

Were any study drugs taken?	No ☐
	Yes ☐

If any changes in administration of investigational product were made because of an adverse event or disease progression, please fill in AE or RECIST2

Study drug	Rilvegostomig
Cycle number	C1D1 ☐
	C2D1 ☐
	C3D1 ☐
	C4D1 ☐
	C5D1 ☐
	C6D1 ☐
	C7D1 ☐
	C8D1 ☐
	C9D1 ☐
	C10D1 ☐
	C11D1 ☐
	C12D1 ☐
	C13D1 ☐
	C14D1 ☐
	C15D1 ☐
	C16D1 ☐
	C17D1 ☐
	C18D1 ☐
	C19D1 ☐
	C20D1 ☐
	C21D1 ☐
	C22D1 ☐
	C23D1 ☐
	C24D1 ☐
	C25D1 ☐
	C26D1 ☐
	C27D1 ☐

C28D1 ☐
C29D1 ☐
C30D1 ☐
C31D1 ☐
C32D1 ☐
C33D1 ☐
C34D1 ☐
C35D1 ☐
C36D1 ☐
C37D1 ☐
C38D1 ☐
C39D1 ☐
C40D1 ☐
C41D1 ☐
C42D1 ☐
C43D1 ☐
C44D1 ☐
C45D1 ☐
C46D1 ☐
C47D1 ☐
C48D1 ☐
C49D1 ☐
C50D1 ☐
C51D1 ☐
C52D1 ☐
C53D1 ☐
C54D1 ☐
C55D1 ☐
C56D1 ☐
C57D1 ☐
C58D1 ☐
C59D1 ☐
C60D1 ☐

	C61D1 ☐ C62D1 ☐ C63D1 ☐ C64D1 ☐ C65D1 ☐ C66D1 ☐ C67D1 ☐ C68D1 ☐ C69D1 ☐ C70D1 ☐
Cycle number	_____
Start date	Fixed Unit: yyyy mon dd _____
Start time	Fixed Unit: 24-hour clock _____
End date	Fixed Unit: yyyy mon dd _____
End time	Fixed Unit: 24-hour clock _____
Planned study drug dose for this cycle	_____
Planned dose units	mg ■ mg/m2 ☐
Actual study drug dose for this cycle	_____
Actual study drug dose unit	mg ■ mg/m2 ☐
Action taken with study drug	Dose Not Changed ☐ Drug Interrupted ☐ Not Applicable ☐
Was this the last dose of study drug given?	Yes ☐
Reason adjusted	Adverse event ☐ Technical issue ☐ Subject decision ☐

	Other ☐
If reason adjusted is equal to 'Other', specify Reason adjusted, specify	
AE number 1	
AE number 2	
AE number 3	
AE number 4	
Volume of infusion before administration	
Volume of infusion after administration	
Infusion volume unit	mL ■
Treatment cycle delayed	No ☐ Yes ☐
Reason treatment cycle delayed	Adverse event ☐ Subject decision ☐ Lab abnormality not reported as an AE ☐ Other ☐
Treatment delayed AE number 1	
Treatment delayed AE number 2	
Treatment delayed AE number 3	
Treatment delayed AE number 4	
If Reason treatment cycle delayed is equal to 'Other', specify Reason treatment cycle delayed, Specify	
Study drug administration/location impacted by global/country situation	Yes ☐
Study drug location status - global/country situation	Site ☐ Other ☐
If Other, specify	
Administration performed by - global/country situation	Health care professional ☐ Other ☐
If Other, specify	

(Version: AZ2403 2025-05-05)

Were any study drugs taken?	No ☐
	Yes ☐

If any changes in administration of investigational product were made because of an adverse event or disease progression, please fill in AE or RECIST2

Study drug	Durvalumab
Cycle number	C1D1 ☐
	C2D1 ☐
	C3D1 ☐
	C4D1 ☐
	C5D1 ☐
	C6D1 ☐
	C7D1 ☐
	C8D1 ☐
	C9D1 ☐
	C10D1 ☐
	C11D1 ☐
	C12D1 ☐
	C13D1 ☐
	C14D1 ☐
	C15D1 ☐
	C16D1 ☐
	C17D1 ☐
	C18D1 ☐
	C19D1 ☐
	C20D1 ☐
	C21D1 ☐
	C22D1 ☐
	C23D1 ☐
	C24D1 ☐
	C25D1 ☐
	C26D1 ☐
	C27D1 ☐

C28D1 ☐
C29D1 ☐
C30D1 ☐
C31D1 ☐
C32D1 ☐
C33D1 ☐
C34D1 ☐
C35D1 ☐
C36D1 ☐
C37D1 ☐
C38D1 ☐
C39D1 ☐
C40D1 ☐
C41D1 ☐
C42D1 ☐
C43D1 ☐
C44D1 ☐
C45D1 ☐
C46D1 ☐
C47D1 ☐
C48D1 ☐
C49D1 ☐
C50D1 ☐
C51D1 ☐
C52D1 ☐
C53D1 ☐
C54D1 ☐
C55D1 ☐
C56D1 ☐
C57D1 ☐
C58D1 ☐
C59D1 ☐
C60D1 ☐

	C61D1 ☐
	C62D1 ☐
	C63D1 ☐
	C64D1 ☐
	C65D1 ☐
	C66D1 ☐
	C67D1 ☐
	C68D1 ☐
	C69D1 ☐
	C70D1 ☐
Cycle number	_____
Start date	Fixed Unit: yyyy mon dd _____
Start time	Fixed Unit: 24-hour clock _____
End date	Fixed Unit: yyyy mon dd _____
End time	Fixed Unit: 24-hour clock _____
Planned study drug dose for this cycle	_____
Planned dose units	mg ■ mg/m2 ☐
Actual study drug dose for this cycle	_____
Actual study drug dose unit	mg ■ mg/m2 ☐
Action taken with study drug	Dose Not Changed ☐ Drug Interrupted ☐ Not Applicable ☐
Was this the last dose of study drug given?	Yes ☐
Reason adjusted	Adverse event ☐ Technical issue ☐ Subject decision ☐

	Other ☐
If reason adjusted is equal to 'Other', specify Reason adjusted, specify	
AE number 1	
AE number 2	
AE number 3	
AE number 4	
Volume of infusion before administration	
Volume of infusion after administration	
Infusion volume unit	mL ■
Treatment cycle delayed	No ☐
	Yes ☐
Reason treatment cycle delayed	Adverse event ☐
	Subject decision ☐
	Lab abnormality not reported as an AE ☐
	Other ☐
Treatment delayed AE number 1	
Treatment delayed AE number 2	
Treatment delayed AE number 3	
Treatment delayed AE number 4	
If Reason treatment cycle delayed is equal to 'Other', specify Reason treatment cycle delayed, Specify	
Study drug administration/location impacted by global/country situation	Yes ☐
Study drug location status - global/country situation	Site ☐
	Other ☐
If Other, specify	
Administration performed by - global/country situation	Health care professional ☐
	Other ☐
If Other, specify	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Administration and Discontinuation of IP
Form: Exposure as Collected - Gemcitabine (EC1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2403 2025-05-05)

Were any study drugs taken?	No ☐
	Yes ☐

If any changes in administration of investigational product were made because of an adverse event or disease progression, please fill in AE or RECIST2

Study drug	Gemcitabine
Cycle number	C1D1 ☐
	C1D8 ☐
	C2D1 ☐
	C2D8 ☐
	C3D1 ☐
	C3D8 ☐
	C4D1 ☐
	C4D8 ☐
	C5D1 ☐
	C5D8 ☐
	C6D1 ☐
	C6D8 ☐
	C7D1 ☐
	C7D8 ☐
	C8D1 ☐
	C8D8 ☐
Cycle number	_____
Start date	Fixed Unit: yyyy mon dd
	_____
Start time	Fixed Unit: 24-hour clock
	_____
End date	Fixed Unit: yyyy mon dd
	_____
End time	Fixed Unit: 24-hour clock
	_____
Planned study drug dose for this cycle	_____
Planned dose units	mg ☐

	mg/m2 ■
Actual study drug dose for this cycle	_____
Actual study drug dose unit	mg ■
	mg/m2 ☐
Action taken with study drug	Dose not changed ☐
	Dose increased ☐
	Dose reduced ☐
	Drug interrupted ☐
	Not applicable ☐
Was this the last dose of study drug given?	Yes ☐
Reason adjusted	Adverse event ☐
	Technical issue ☐
	Subject decision ☐
	Other ☐
If reason adjusted is equal to 'Other', specify Reason adjusted, specify	_____
AE number 1	_____
AE number 2	_____
AE number 3	_____
AE number 4	_____
Volume of infusion before administration	_____
Volume of infusion after administration	_____
Infusion volume unit	mL ■
Treatment cycle delayed	No ☐
	Yes ☐
Reason treatment cycle delayed	Adverse event ☐
	Subject decision ☐
	Lab abnormality not reported as an AE ☐
	Other ☐
Treatment delayed AE number 1	_____
Treatment delayed AE number 2	_____
Treatment delayed AE number 3	_____

Treatment delayed AE number 4	_____
If Reason treatment cycle delayed is equal to 'Other', specify Reason treatment cycle delayed, Specify	_____
Study drug administration/location impacted by global/country situation	Yes ☐
Study drug location status - global/country situation	Site ☐ Other ☐
If Other, specify	_____
Administration performed by - global/country situation	Health care professional ☐ Other ☐
If Other, specify	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Administration and Discontinuation of IP
Form: Exposure as Collected - Cisplatin (EC2)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2403 2025-05-05)

Were any study drugs taken?	No ☐
	Yes ☐

If any changes in administration of investigational product were made because of an adverse event or disease progression, please fill in AE or RECIST2

Study drug	Cisplatin
Cycle number	C1D1 ☐
	C1D8 ☐
	C2D1 ☐
	C2D8 ☐
	C3D1 ☐
	C3D8 ☐
	C4D1 ☐
	C4D8 ☐
	C5D1 ☐
	C5D8 ☐
	C6D1 ☐
	C6D8 ☐
	C7D1 ☐
	C7D8 ☐
	C8D1 ☐
	C8D8 ☐
Cycle number	
Start date	Fixed Unit: yyyy mon dd
Start time	Fixed Unit: 24-hour clock
End date	Fixed Unit: yyyy mon dd
End time	Fixed Unit: 24-hour clock
Planned study drug dose for this cycle	
Planned dose units	mg ☐

	mg/m2 ■
Actual study drug dose for this cycle	_____
Actual study drug dose unit	mg ■
	mg/m2 ☐
Action taken with study drug	Dose not changed ☐
	Dose increased ☐
	Dose reduced ☐
	Drug interrupted ☐
	Not applicable ☐
Was this the last dose of study drug given?	Yes ☐
Reason adjusted	Adverse event ☐
	Technical issue ☐
	Subject decision ☐
	Other ☐
If reason adjusted is equal to 'Other', specify Reason adjusted, specify	_____
AE number 1	_____
AE number 2	_____
AE number 3	_____
AE number 4	_____
Volume of infusion before administration	_____
Volume of infusion after administration	_____
Infusion volume unit	mL ■
Treatment cycle delayed	No ☐
	Yes ☐
Reason treatment cycle delayed	Adverse event ☐
	Subject decision ☐
	Lab abnormality not reported as an AE ☐
	Other ☐
Treatment delayed AE number 1	_____
Treatment delayed AE number 2	_____
Treatment delayed AE number 3	_____

Treatment delayed AE number 4	
If Reason treatment cycle delayed is equal to 'Other', specify Reason treatment cycle delayed, Specify	
Study drug administration/location impacted by global/country situation	Yes ☐
Study drug location status - global/country situation	Site ☐ Other ☐
If Other, specify	
Administration performed by - global/country situation	Health care professional ☐ Other ☐
If Other, specify	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Administration and Discontinuation of IP
Form: End of Study Treatment - Rilvegostomig (ETRT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2402 2024-02-12)

This form should be completed at the time of study treatment completion or discontinuation.

What was the category of the disposition?	DISPOSITION EVENT
What was the subcategory for disposition event?	Rilvegostomig
What was the study treatment discontinuation date?	Fixed Unit: yyyy mon dd
What was the date when the decision was made to permanently discontinue study treatment?	Fixed Unit: yyyy mon dd
Reason for study treatment discontinuation	Subject Decision ☐ Adverse Event ☐ Severe Non-Compliance to Protocol ☐ Objective Disease Progression ☐ Lost to Follow-Up ☐ Subjective Disease Progression ☐ Investigator Decision ☐ Pregnancy ☐ Study Terminated by Sponsor ☐ Death ☐ Other ☐
Specify, if main reason is 'Other' or 'Severe non-compliance to protocol'	

If main reason is "Adverse event", make sure that Adverse event (AE) form, has been filled in.

If main reason is "Death" make sure that Death Details (DD) form has been filled in.

Specify, if main reason is 'Subject decision'	Subject Perceives the Study Treatment to be Ineffective ☐ Subject is Unable to Comply with Protocol-specified Visits and/or Procedures Due to Conflicts Not Related to Clinical Trial

	Subject Perceives Logistics to be Unacceptable ☐
	Subject Wishes to Participate in Another Clinical Trial ☐
	Subject Wishes to Take a Treatment That is Not Allowed in This Study ☐
	An AE or Laboratory Abnormality is of Concern to the Subject, but Not Clinically Significant to Physician ☐
	Other ☐
If Other, specify	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Administration and Discontinuation of IP
Form: End of Study Treatment - Durvalumab (ETRT3)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2402 2024-02-12)

This form should be completed at the time of study treatment completion or discontinuation.

What was the category of the disposition?	DISPOSITION EVENT
What was the subcategory for disposition event?	Durvalumab
What was the study treatment discontinuation date?	Fixed Unit: yyyy mon dd
What was the date when the decision was made to permanently discontinue study treatment?	Fixed Unit: yyyy mon dd
Reason for study treatment discontinuation	Subject Decision ☐ Adverse Event ☐ Severe Non-Compliance to Protocol ☐ Objective Disease Progression ☐ Lost to Follow-Up ☐ Subjective Disease Progression ☐ Investigator Decision ☐ Pregnancy ☐ Study Terminated by Sponsor ☐ Death ☐ Other ☐
Specify, if main reason is 'Other' or 'Severe non-compliance to protocol'	

If main reason is "Adverse event", make sure that Adverse event (AE) form, has been filled in.

If main reason is "Death" make sure that Death Details (DD) form has been filled in.

Specify, if main reason is 'Subject decision'	Subject Perceives the Study Treatment to be Ineffective ☐ Subject is Unable to Comply with Protocol-specified Visits and/or Procedures Due to Conflicts Not Related to Clinical Trial ☐

	Subject Perceives Logistics to be Unacceptable ☐
	Subject Wishes to Participate in Another Clinical Trial ☐
	Subject Wishes to Take a Treatment That is Not Allowed in This Study ☐
	An AE or Laboratory Abnormality is of Concern to the Subject, but Not Clinically Significant to Physician ☐
	Other ☐
If Other, specify	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Administration and Discontinuation of IP
Form: End of Study Treatment - Gemcitabine (ETRT1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2402 2024-02-12)

This form should be completed at the time of study treatment completion or discontinuation.

What was the category of the disposition?	DISPOSITION EVENT
What was the subcategory for disposition event?	Gemcitabine
What was the study treatment completion or discontinuation date?	Fixed Unit: yyyy mon dd
What was the date when the decision was made to permanently discontinue study treatment?	Fixed Unit: yyyy mon dd
Completion or reason for study treatment discontinuation	Subject decision ☐ Adverse event ☐ Severe non-compliance to protocol ☐ Objective disease progression ☐ Lost to follow-up ☐ Subjective disease progression ☐ Completed ☐ Investigator decision ☐ Pregnancy ☐ Study terminated by sponsor ☐ Death ☐ Other ☐
Specify, if main reason is 'Other' or 'Severe non-compliance to protocol'	

If main reason is "Adverse event", make sure that Adverse event (AE) form, has been filled in.

If main reason is "Death" make sure that Death Details (DD) form has been filled in.

Specify, if main reason is 'Subject decision'	Subject is unable to comply with Protocol-specified visits and/or procedures due to conflicts not related to clinical trial ☐

	Subject perceives logistics to be unacceptable ☐
	Subject wishes to take a treatment that is not allowed in this study ☐
	An AE or laboratory abnormality is of concern to the subject, but not clinically significant to physician ☐
	Other ☐
If Other, specify	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Administration and Discontinuation of IP
Form: End of Study Treatment - Cisplatin (ETRT2)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2402 2024-02-12)

This form should be completed at the time of study treatment completion or discontinuation.

What was the category of the disposition?	DISPOSITION EVENT
What was the subcategory for disposition event?	Cisplatin
What was the study treatment completion or discontinuation date?	Fixed Unit: yyyy mon dd
What was the date when the decision was made to permanently discontinue study treatment?	Fixed Unit: yyyy mon dd
Completion or reason for study treatment discontinuation	Subject decision ☐ Adverse event ☐ Severe non-compliance to protocol ☐ Objective disease progression ☐ Lost to follow-up ☐ Subjective disease progression ☐ Completed ☐ Investigator decision ☐ Pregnancy ☐ Study terminated by sponsor ☐ Death ☐ Other ☐
Specify, if main reason is 'Other' or 'Severe non-compliance to protocol'	

If main reason is "Adverse event", make sure that Adverse event (AE) form, has been filled in.

If main reason is "Death" make sure that Death Details (DD) form has been filled in.

Specify, if main reason is 'Subject decision'	Subject is unable to comply with Protocol-specified visits and/or procedures due to conflicts not related to clinical trial ☐

	Subject perceives logistics to be unacceptable ☐
	Subject wishes to take a treatment that is not allowed in this study ☐
	An AE or laboratory abnormality is of concern to the subject, but not clinically significant to physician ☐
	Other ☐
If Other, specify	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Surgery for Subsequent Anticancer Therapy
Form: Surgery for Subsequent Anticancer Therapy (1PR1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2311 2023-11-24)

Any procedures performed?	No ☐ Yes ☐
Procedure name	
Start date	Fixed Unit: yyyy mon dd
End date	Fixed Unit: yyyy mon dd
Ongoing	Yes ☐
Indication	Disease Under Study ■

(Version: ON2406 2024-08-20)

Has cancer therapy been previous/current/post withdrawn of IP?	Previous ☐ Post ■
Has the Subject had any cancer therapy?	No ☐ Yes ☐ Not applicable ☐
If Not applicable, specify	_____
If Yes, specify below	
Cancer therapy agent	_____
Cancer therapy agent start date	Fixed Unit: yyyy mon dd _____
Cancer therapy agent stop date	Fixed Unit: yyyy mon dd _____
Best overall response	Complete response ☐ Partial response ☐ Stable disease ☐ Progressive disease ☐ Not evaluable ☐ Not applicable ☐
Treatment status	First Line ☐ Second Line ☐ Third Line ☐ > Third Line ☐ Not Applicable ☐
Reason for therapy failure	Toxicity ☐ Progression on therapy ☐ Progression following completion of therapy ☐ Unknown ☐ Not applicable ☐
Concomitant chemoradiotherapy If Yes, Radiotherapy must be recorded on the Post Treatment Radiotherapy (CAPRXR2) page	No ☐ Yes ☐

Indication	Biliary Tract Cancer ☐ Other anticancer indication ☐

(Version: ON2505 2025-05-07)

Has cancer therapy been previous/current/post withdrawn of IP?	Previous ☐ Current (non-study intervention) ☐ Post ■
Was radiotherapy performed?	No ☐ Yes ☐

If Yes, specify below

Select Palliative when radiotherapy is used primarily to manage symptoms.

Select Definitive when radiotherapy is delivered as a distinct line of anti-cancer treatment.

Concomitant chemoradiotherapy	No ☐ Yes ☐
Treatment setting	Definitive ☐ Palliative ☐ Other ☐
If Other, specify	_____
If Definitive, specify Line of Treatment	1 ☐ 2 ☐ 3 ☐ >3 ☐
Number of sites/regions treated simultaneously	_____
Radiotherapy site/region treated location	Bone ☐ Liver ☐ Brain ☐ Spinal Cord ☐ Pleura ☐ Skin ☐ Adrenal Gland ☐ Pelvic Bone ☐ Regional Lymph Node ☐ Distant Lymph Node ☐ Gallbladder ☐

	Lung ☐ Biliary Tract ☐ Other ☐
If Other, specify	
Radiotherapy site/region laterality	Right ☐ Left ☐ Bilateral ☐ Not applicable ☐
Radiotherapy technique	3-D Conformal ☐ Intensity Modulated Radiotherapy (IMRT) ☐ Stereotactic Intracranial Radiotherapy ☐ Stereotactic Body Radiotherapy (SBRT) ☐ Stereotactic Radiosurgery (SRS) ☐ Selective Internal Radiotherapy (SIRT) ☐ Other ☐
If Other, specify	
Radiotherapy start date	Fixed Unit: yyyy mon dd
Radiotherapy stop date	Fixed Unit: yyyy mon dd
Dose per fraction	
Dose per fraction unit	Gy ☐ Other ☐
If Other, specify	
Number of fraction doses	

(Version: ON2505 2025-05-07)

Has cancer therapy been previous/current/post withdrawn of IP?	Previous ☐ Current (non-study intervention) ■ Post ☐
Was radiotherapy performed?	No ☐ Yes ☐
Concomitant chemoradiotherapy	No ☐ Yes ☐
Treatment setting	Palliative ■
Number of sites/regions treated simultaneously	_____
Radiotherapy site/region treated location	Bone ☐ Liver ☐ Brain ☐ Spinal Cord ☐ Pleura ☐ Skin ☐ Adrenal Gland ☐ Pelvic Bone ☐ Regional Lymph Node ☐ Distant Lymph Node ☐ Gallbladder ☐ Lung ☐ Biliary Tract ☐ Other ☐
If Other, specify	_____
Radiotherapy site/region laterality	Right ☐ Left ☐ Bilateral ☐ Not applicable ☐
Radiotherapy technique	3-D Conformal ☐ Intensity Modulated Radiotherapy (IMRT) ☐

	Stereotactic Intracranial Radiotherapy ☐ Stereotactic Body Radiotherapy (SBRT) ☐ Stereotactic Radiosurgery (SRS) ☐ Selective Internal Radiotherapy (SIRT) ☐ Other ☐
If Other, specify	
Radiotherapy start date	Fixed Unit: yyyy mon dd
Radiotherapy stop date	Fixed Unit: yyyy mon dd
Dose per fraction	
Dose per fraction unit	Gy ☐ Other ☐
If Other, specify	
Number of fraction doses	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Hospital Admissions Details
Form: Hospital Admissions Details (HOSPAD)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: ON2310 2023-10-19)

Any hospital/ inpatient/ emergency room visit	No ☐ Yes ☐
Type of attendance	Outpatient/physician office attendance ☐ Planned hospital admission with no emergency room visit ☐ Unplanned hospital admission with no emergency room visit ☐ Emergency room attendance only (Patient was discharged direct from the emergency room) ☐ Emergency room attendance resulting in a hospital admission at the same time (Further hospital care outside the emergency room) ☐
Start date of admission or attendance	Fixed Unit: yyyy mon dd
Stop date of admission or attendance	Fixed Unit: yyyy mon dd
Admission or attendance continues	Yes ☐
ICU/HDU stay during hospital admission	No ☐ Yes ☐
Start date of ICU/HDU stay	Fixed Unit: yyyy mon dd
End date of ICU/HDU stay	Fixed Unit: yyyy mon dd
ICU/HDU stay continues	Yes ☐
Primary symptom for hospital /inpatient/ emergency room visit	Pain ☐ Fatigue ☐ Diarrhea ☐ Swelling ☐

	Fever ☐
	Numbness/tingling ☐
	Dehydration ☐
	Stomach or abdominal cramps/pain ☐
	Stomach or abdominal bloating/swelling ☐
	Difficulty in eating/feeling full quickly ☐
	Jaundice ☐
	Rash ☐
	Other (disease related) ☐
	Other (non disease related) ☐
If Other, specify	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Pregnancy Report
Form: Pregnancy Report (PREGREP)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2307 2024-10-23)

What was the date the reproductive system question was collected?	Fixed Unit: yyyy mon dd
Date of last menstrual period	Fixed Unit: yyyy mon dd
Date of expected delivery	Fixed Unit: yyyy mon dd
Using hormonal contraception or IUD	No ☐ Yes ☐
Hormonal contraception/IUD specification	
Number of previous pregnancies	
Number of normal deliveries	
Number of spontaneous abortions	
Number of other previous pregnancies	
Other previous pregnancies, specify	
Relevant pregnancy risk factor	
Relevant family history	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Potential Hy's Law
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2305 2023-05-29)

Visit not done	Yes ☐
What is the date of the visit?	Fixed Unit: yyyy mon dd
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐
If Other, specify	
Visit was impacted by global/country situation	Yes ☐
IVRS Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Potential Hy's Law
Form: Non-central Laboratory Test Results - Hy's Law (LB8)
Generated On: 2025 Nov 20 12:27 (GMT)
Lab Name:

(Version: AZ2211 2025-08-05)	
Was the sample collected?	No ☐ Yes ☐
What was the reason that the sample was not collected?	
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock
Alanine Aminotransferase (Serum/Plasma)	
Alkaline Phosphatase (Serum/Plasma)	
Aspartate Aminotransferase (Serum/Plasma)	
Bilirubin, Total (Serum/Plasma)	
Hidden for Bilirubin	
Hidden for Aspartate	
Hidden for Alanine	
Hidden for Alanine Range	
Hidden for Aspartate Range	
Hidden for Bilirubin Range	
Derived field to call CF	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Potential Hy's Law
Form: Liver Diagnostic Investigations (LIVERDI)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2411 2024-11-08)	
What is the category of the liver event?	POTENTIAL HY'S LAW
What is the subcategory of the liver event?	DIAGNOSTIC INVESTIGATION
What is the potential Hy's law case number?	
AE number	
Now Derivation(This field required for CF approach)	
[Hidden Dummy] Previous Potential Hy's law case number	

Liver diagnostic investigation	Ultrasound
	CT scan
	MRI
	Magnetic resonance cholangiopancreatography
	Endoscopic retrograde cholangiopancreatography
	Biopsy
	X-ray
	Tox screening for acetaminophen/paracetamol
	Tox screening for ethanol
	Tox screening, other
	Specialist (e.g. hepatologist) consulted
	Serology for hepatitis A
	Serology for hepatitis B
	Serology for hepatitis C
	Serology for hepatitis D
	Serology for hepatitis E
	Serology for cytomegalovirus (CMV)
	Serology for Epstein Barr Virus (EBV)
	Serology for Herpes Simplex Virus (HSV)
	Autoimmune serology

	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Examination(s) performed	No ☐
	Yes ☐
Liver diagnostic investigation specification	_____
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd
	_____
Liver diagnostic investigation results	_____
Liver diagnostic investigation	Ultrasound ☐
	CT scan ■
	MRI ☐
	Magnetic resonance cholangiopancreatography ☐
	Endoscopic retrograde cholangiopancreatography ☐
	Biopsy ☐
	X-ray ☐
	Tox screening for acetaminophen/paracetamol ☐
	Tox screening for ethanol ☐
	Tox screening, other ☐
	Specialist (e.g. hepatologist) consulted ☐
	Serology for hepatitis A ☐
	Serology for hepatitis B ☐
	Serology for hepatitis C ☐
	Serology for hepatitis D ☐
	Serology for hepatitis E ☐
	Serology for cytomegalovirus (CMV) ☐

	Serology for Epstein Barr Virus (EBV) ☐
	Serology for Herpes Simplex Virus (HSV) ☐
	Autoimmune serology ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Examination(s) performed	No ☐
	Yes ☐
Liver diagnostic investigation specification	
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd
Liver diagnostic investigation results	
Liver diagnostic investigation	Ultrasound ☐
	CT scan ☐
	MRI ■
	Magnetic resonance cholangiopancreatography ☐
	Endoscopic retrograde cholangiopancreatography ☐
	Biopsy ☐
	X-ray ☐
	Tox screening for acetaminophen/paracetamol ☐
	Tox screening for ethanol ☐
	Tox screening, other ☐
	Specialist (e.g. hepatologist) consulted ☐
	Serology for hepatitis A ☐
	Serology for hepatitis B ☐
	Serology for hepatitis C ☐

	Serology for hepatitis D ☐
	Serology for hepatitis E ☐
	Serology for cytomegalovirus (CMV) ☐
	Serology for Epstein Barr Virus (EBV) ☐
	Serology for Herpes Simplex Virus (HSV) ☐
	Autoimmune serology ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Examination(s) performed	No ☐
	Yes ☐
Liver diagnostic investigation specification	_____
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd _____
Liver diagnostic investigation results	_____
Liver diagnostic investigation	Ultrasound ☐
	CT scan ☐
	MRI ☐
	Magnetic resonance cholangiopancreatography ■
	Endoscopic retrograde cholangiopancreatography ☐
	Biopsy ☐
	X-ray ☐
	Tox screening for acetaminophen/paracetamol ☐
	Tox screening for ethanol ☐
	Tox screening, other ☐

	Specialist (e.g. hepatologist) consulted ☐
	Serology for hepatitis A ☐
	Serology for hepatitis B ☐
	Serology for hepatitis C ☐
	Serology for hepatitis D ☐
	Serology for hepatitis E ☐
	Serology for cytomegalovirus (CMV) ☐
	Serology for Epstein Barr Virus (EBV) ☐
	Serology for Herpes Simplex Virus (HSV) ☐
	Autoimmune serology ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Examination(s) performed	No ☐
	Yes ☐
Liver diagnostic investigation specification	_____
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd
	_____
Liver diagnostic investigation results	_____
Liver diagnostic investigation	Ultrasound ☐
	CT scan ☐
	MRI ☐
	Magnetic resonance cholangiopancreatography ☐
	Endoscopic retrograde cholangiopancreatography ■
	Biopsy ☐
	X-ray ☐

	Tox screening for acetaminophen/paracetamol ☐
	Tox screening for ethanol ☐
	Tox screening, other ☐
	Specialist (e.g. hepatologist) consulted ☐
	Serology for hepatitis A ☐
	Serology for hepatitis B ☐
	Serology for hepatitis C ☐
	Serology for hepatitis D ☐
	Serology for hepatitis E ☐
	Serology for cytomegalovirus (CMV) ☐
	Serology for Epstein Barr Virus (EBV) ☐
	Serology for Herpes Simplex Virus (HSV) ☐
	Autoimmune serology ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Examination(s) performed	No ☐
	Yes ☐
Liver diagnostic investigation specification	_____
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd
	_____
Liver diagnostic investigation results	_____
Liver diagnostic investigation	Ultrasound ☐
	CT scan ☐
	MRI ☐
	Magnetic resonance cholangiopancreatography ☐

	Endoscopic retrograde cholangiopancreatography ☐
	Biopsy ■
	X-ray ☐
	Tox screening for acetaminophen/paracetamol ☐
	Tox screening for ethanol ☐
	Tox screening, other ☐
	Specialist (e.g. hepatologist) consulted ☐
	Serology for hepatitis A ☐
	Serology for hepatitis B ☐
	Serology for hepatitis C ☐
	Serology for hepatitis D ☐
	Serology for hepatitis E ☐
	Serology for cytomegalovirus (CMV) ☐
	Serology for Epstein Barr Virus (EBV) ☐
	Serology for Herpes Simplex Virus (HSV) ☐
	Autoimmune serology ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Examination(s) performed	No ☐
	Yes ☐
Liver diagnostic investigation specification	_____
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd
	_____
Liver diagnostic investigation results	_____
Liver diagnostic investigation	Ultrasound ☐

	CT scan ☐
	MRI ☐
	Magnetic resonance cholangiopancreatography ☐
	Endoscopic retrograde cholangiopancreatography ☐
	Biopsy ☐
	X-ray ■
	Tox screening for acetaminophen/paracetamol ☐
	Tox screening for ethanol ☐
	Tox screening, other ☐
	Specialist (e.g. hepatologist) consulted ☐
	Serology for hepatitis A ☐
	Serology for hepatitis B ☐
	Serology for hepatitis C ☐
	Serology for hepatitis D ☐
	Serology for hepatitis E ☐
	Serology for cytomegalovirus (CMV) ☐
	Serology for Epstein Barr Virus (EBV) ☐
	Serology for Herpes Simplex Virus (HSV) ☐
	Autoimmune serology ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Examination(s) performed	No ☐
	Yes ☐
Liver diagnostic investigation specification	_____

Liver diagnostic investigation date	Fixed Unit: yyyy mon dd
Liver diagnostic investigation results	
Liver diagnostic investigation	Ultrasound ☐ CT scan ☐ MRI ☐ Magnetic resonance cholangiopancreatography ☐ Endoscopic retrograde cholangiopancreatography ☐ Biopsy ☐ X-ray ☐ Tox screening for acetaminophen/paracetamol ■ Tox screening for ethanol ☐ Tox screening, other ☐ Specialist (e.g. hepatologist) consulted ☐ Serology for hepatitis A ☐ Serology for hepatitis B ☐ Serology for hepatitis C ☐ Serology for hepatitis D ☐ Serology for hepatitis E ☐ Serology for cytomegalovirus (CMV) ☐ Serology for Epstein Barr Virus (EBV) ☐ Serology for Herpes Simplex Virus (HSV) ☐ Autoimmune serology ☐ Other 1 ☐ Other 2 ☐ Other 3 ☐ Other 4 ☐ Other 5 ☐ Other 6 ☐

Examination(s) performed	No ☐ Yes ☐
Liver diagnostic investigation specification	
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd
Liver diagnostic investigation results	
Liver diagnostic investigation	Ultrasound ☐ CT scan ☐ MRI ☐ Magnetic resonance cholangiopancreatography ☐ Endoscopic retrograde cholangiopancreatography ☐ Biopsy ☐ X-ray ☐ Tox screening for acetaminophen/paracetamol ☐ Tox screening for ethanol ■ Tox screening, other ☐ Specialist (e.g. hepatologist) consulted ☐ Serology for hepatitis A ☐ Serology for hepatitis B ☐ Serology for hepatitis C ☐ Serology for hepatitis D ☐ Serology for hepatitis E ☐ Serology for cytomegalovirus (CMV) ☐ Serology for Epstein Barr Virus (EBV) ☐ Serology for Herpes Simplex Virus (HSV) ☐ Autoimmune serology ☐ Other 1 ☐ Other 2 ☐ Other 3 ☐

	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Examination(s) performed	No ☐
	Yes ☐
Liver diagnostic investigation specification	
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd
Liver diagnostic investigation results	
Liver diagnostic investigation	Ultrasound ☐
	CT scan ☐
	MRI ☐
	Magnetic resonance cholangiopancreatography ☐
	Endoscopic retrograde cholangiopancreatography ☐
	Biopsy ☐
	X-ray ☐
	Tox screening for acetaminophen/paracetamol ☐
	Tox screening for ethanol ☐
	Tox screening, other ■
	Specialist (e.g. hepatologist) consulted ☐
	Serology for hepatitis A ☐
	Serology for hepatitis B ☐
	Serology for hepatitis C ☐
	Serology for hepatitis D ☐
	Serology for hepatitis E ☐
	Serology for cytomegalovirus (CMV) ☐
	Serology for Epstein Barr Virus (EBV) ☐
	Serology for Herpes Simplex Virus (HSV) ☐

	Autoimmune serology ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Examination(s) performed	No ☐
	Yes ☐
Liver diagnostic investigation specification	
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd
Liver diagnostic investigation results	
Liver diagnostic investigation	Ultrasound ☐
	CT scan ☐
	MRI ☐
	Magnetic resonance cholangiopancreatography ☐
	Endoscopic retrograde cholangiopancreatography ☐
	Biopsy ☐
	X-ray ☐
	Tox screening for acetaminophen/paracetamol ☐
	Tox screening for ethanol ☐
	Tox screening, other ☐
	Specialist (e.g. hepatologist) consulted ■
	Serology for hepatitis A ☐
	Serology for hepatitis B ☐
	Serology for hepatitis C ☐
	Serology for hepatitis D ☐
	Serology for hepatitis E ☐

	Serology for cytomegalovirus (CMV) ☐
	Serology for Epstein Barr Virus (EBV) ☐
	Serology for Herpes Simplex Virus (HSV) ☐
	Autoimmune serology ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Examination(s) performed	No ☐
	Yes ☐
Liver diagnostic investigation specification	_____
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd _____
Liver diagnostic investigation results	_____
Liver diagnostic investigation	Ultrasound ☐
	CT scan ☐
	MRI ☐
	Magnetic resonance cholangiopancreatography ☐
	Endoscopic retrograde cholangiopancreatography ☐
	Biopsy ☐
	X-ray ☐
	Tox screening for acetaminophen/paracetamol ☐
	Tox screening for ethanol ☐
	Tox screening, other ☐
	Specialist (e.g. hepatologist) consulted ☐
	Serology for hepatitis A ■

	Serology for hepatitis B ☐
	Serology for hepatitis C ☐
	Serology for hepatitis D ☐
	Serology for hepatitis E ☐
	Serology for cytomegalovirus (CMV) ☐
	Serology for Epstein Barr Virus (EBV) ☐
	Serology for Herpes Simplex Virus (HSV) ☐
	Autoimmune serology ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Examination(s) performed	No ☐
	Yes ☐
Liver diagnostic investigation specification	_____
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd _____
Liver diagnostic investigation results	_____
Liver diagnostic investigation	Ultrasound ☐
	CT scan ☐
	MRI ☐
	Magnetic resonance cholangiopancreatography ☐
	Endoscopic retrograde cholangiopancreatography ☐
	Biopsy ☐
	X-ray ☐
	Tox screening for acetaminophen/paracetamol ☐
	Tox screening for ethanol ☐

	Tox screening, other ☐
	Specialist (e.g. hepatologist) consulted ☐
	Serology for hepatitis A ☐
	Serology for hepatitis B ■
	Serology for hepatitis C ☐
	Serology for hepatitis D ☐
	Serology for hepatitis E ☐
	Serology for cytomegalovirus (CMV) ☐
	Serology for Epstein Barr Virus (EBV) ☐
	Serology for Herpes Simplex Virus (HSV) ☐
	Autoimmune serology ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Examination(s) performed	No ☐
	Yes ☐
Liver diagnostic investigation specification	_____
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd
	_____
Liver diagnostic investigation results	_____
Liver diagnostic investigation	Ultrasound ☐
	CT scan ☐
	MRI ☐
	Magnetic resonance cholangiopancreatography ☐
	Endoscopic retrograde cholangiopancreatography ☐
	Biopsy ☐
	X-ray ☐

	Tox screening for acetaminophen/paracetamol ☐
	Tox screening for ethanol ☐
	Tox screening, other ☐
	Specialist (e.g. hepatologist) consulted ☐
	Serology for hepatitis A ☐
	Serology for hepatitis B ☐
	Serology for hepatitis C ■
	Serology for hepatitis D ☐
	Serology for hepatitis E ☐
	Serology for cytomegalovirus (CMV) ☐
	Serology for Epstein Barr Virus (EBV) ☐
	Serology for Herpes Simplex Virus (HSV) ☐
	Autoimmune serology ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Examination(s) performed	No ☐
	Yes ☐
Liver diagnostic investigation specification	_____
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd
	_____
Liver diagnostic investigation results	_____
Liver diagnostic investigation	Ultrasound ☐
	CT scan ☐
	MRI ☐
	Magnetic resonance cholangiopancreatography ☐

	Endoscopic retrograde cholangiopancreatography ☐
	Biopsy ☐
	X-ray ☐
	Tox screening for acetaminophen/paracetamol ☐
	Tox screening for ethanol ☐
	Tox screening, other ☐
	Specialist (e.g. hepatologist) consulted ☐
	Serology for hepatitis A ☐
	Serology for hepatitis B ☐
	Serology for hepatitis C ☐
	Serology for hepatitis D ■
	Serology for hepatitis E ☐
	Serology for cytomegalovirus (CMV) ☐
	Serology for Epstein Barr Virus (EBV) ☐
	Serology for Herpes Simplex Virus (HSV) ☐
	Autoimmune serology ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Examination(s) performed	No ☐
	Yes ☐
Liver diagnostic investigation specification	_____
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd
	_____
Liver diagnostic investigation results	_____
Liver diagnostic investigation	Ultrasound ☐

	CT scan ☐
	MRI ☐
	Magnetic resonance cholangiopancreatography ☐
	Endoscopic retrograde cholangiopancreatography ☐
	Biopsy ☐
	X-ray ☐
	Tox screening for acetaminophen/paracetamol ☐
	Tox screening for ethanol ☐
	Tox screening, other ☐
	Specialist (e.g. hepatologist) consulted ☐
	Serology for hepatitis A ☐
	Serology for hepatitis B ☐
	Serology for hepatitis C ☐
	Serology for hepatitis D ☐
	Serology for hepatitis E ■
	Serology for cytomegalovirus (CMV) ☐
	Serology for Epstein Barr Virus (EBV) ☐
	Serology for Herpes Simplex Virus (HSV) ☐
	Autoimmune serology ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Examination(s) performed	No ☐
	Yes ☐
Liver diagnostic investigation specification	_____

Liver diagnostic investigation date	Fixed Unit: yyyy mon dd
Liver diagnostic investigation results	
Liver diagnostic investigation	Ultrasound ☐ CT scan ☐ MRI ☐ Magnetic resonance cholangiopancreatography ☐ Endoscopic retrograde cholangiopancreatography ☐ Biopsy ☐ X-ray ☐ Tox screening for acetaminophen/paracetamol ☐ Tox screening for ethanol ☐ Tox screening, other ☐ Specialist (e.g. hepatologist) consulted ☐ Serology for hepatitis A ☐ Serology for hepatitis B ☐ Serology for hepatitis C ☐ Serology for hepatitis D ☐ Serology for hepatitis E ☐ Serology for cytomegalovirus (CMV) ■ Serology for Epstein Barr Virus (EBV) ☐ Serology for Herpes Simplex Virus (HSV) ☐ Autoimmune serology ☐ Other 1 ☐ Other 2 ☐ Other 3 ☐ Other 4 ☐ Other 5 ☐ Other 6 ☐

Examination(s) performed	No ☐ Yes ☐
Liver diagnostic investigation specification	_____
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd _____
Liver diagnostic investigation results	_____
Liver diagnostic investigation	Ultrasound ☐ CT scan ☐ MRI ☐ Magnetic resonance cholangiopancreatography ☐ Endoscopic retrograde cholangiopancreatography ☐ Biopsy ☐ X-ray ☐ Tox screening for acetaminophen/paracetamol ☐ Tox screening for ethanol ☐ Tox screening, other ☐ Specialist (e.g. hepatologist) consulted ☐ Serology for hepatitis A ☐ Serology for hepatitis B ☐ Serology for hepatitis C ☐ Serology for hepatitis D ☐ Serology for hepatitis E ☐ Serology for cytomegalovirus (CMV) ☐ Serology for Epstein Barr Virus (EBV) ■ Serology for Herpes Simplex Virus (HSV) ☐ Autoimmune serology ☐ Other 1 ☐ Other 2 ☐ Other 3 ☐

	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Examination(s) performed	No ☐
	Yes ☐
Liver diagnostic investigation specification	
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd
Liver diagnostic investigation results	
Liver diagnostic investigation	Ultrasound ☐
	CT scan ☐
	MRI ☐
	Magnetic resonance cholangiopancreatography ☐
	Endoscopic retrograde cholangiopancreatography ☐
	Biopsy ☐
	X-ray ☐
	Tox screening for acetaminophen/paracetamol ☐
	Tox screening for ethanol ☐
	Tox screening, other ☐
	Specialist (e.g. hepatologist) consulted ☐
	Serology for hepatitis A ☐
	Serology for hepatitis B ☐
	Serology for hepatitis C ☐
	Serology for hepatitis D ☐
	Serology for hepatitis E ☐
	Serology for cytomegalovirus (CMV) ☐
	Serology for Epstein Barr Virus (EBV) ☐
	Serology for Herpes Simplex Virus (HSV) ■

	Autoimmune serology ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Examination(s) performed	No ☐
	Yes ☐
Liver diagnostic investigation specification	_____
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd _____
Liver diagnostic investigation results	_____
Liver diagnostic investigation	Ultrasound ☐
	CT scan ☐
	MRI ☐
	Magnetic resonance cholangiopancreatography ☐
	Endoscopic retrograde cholangiopancreatography ☐
	Biopsy ☐
	X-ray ☐
	Tox screening for acetaminophen/paracetamol ☐
	Tox screening for ethanol ☐
	Tox screening, other ☐
	Specialist (e.g. hepatologist) consulted ☐
	Serology for hepatitis A ☐
	Serology for hepatitis B ☐
	Serology for hepatitis C ☐
	Serology for hepatitis D ☐
	Serology for hepatitis E ☐

	Serology for cytomegalovirus (CMV) ☐
	Serology for Epstein Barr Virus (EBV) ☐
	Serology for Herpes Simplex Virus (HSV) ☐
	Autoimmune serology ■
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Examination(s) performed	No ☐
	Yes ☐
Liver diagnostic investigation specification	_____
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd _____
Liver diagnostic investigation results	_____
Liver diagnostic investigation	Ultrasound ☐
	CT scan ☐
	MRI ☐
	Magnetic resonance cholangiopancreatography ☐
	Endoscopic retrograde cholangiopancreatography ☐
	Biopsy ☐
	X-ray ☐
	Tox screening for acetaminophen/paracetamol ☐
	Tox screening for ethanol ☐
	Tox screening, other ☐
	Specialist (e.g. hepatologist) consulted ☐
	Serology for hepatitis A ☐

	Serology for hepatitis B ☐
	Serology for hepatitis C ☐
	Serology for hepatitis D ☐
	Serology for hepatitis E ☐
	Serology for cytomegalovirus (CMV) ☐
	Serology for Epstein Barr Virus (EBV) ☐
	Serology for Herpes Simplex Virus (HSV) ☐
	Autoimmune serology ☐
	Other 1 ■
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Examination(s) performed	No ☐
	Yes ☐
Liver diagnostic investigation specification	_____
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd _____
Liver diagnostic investigation results	_____
Liver diagnostic investigation	Ultrasound ☐
	CT scan ☐
	MRI ☐
	Magnetic resonance cholangiopancreatography ☐
	Endoscopic retrograde cholangiopancreatography ☐
	Biopsy ☐
	X-ray ☐
	Tox screening for acetaminophen/paracetamol ☐
	Tox screening for ethanol ☐

	Tox screening, other ☐
	Specialist (e.g. hepatologist) consulted ☐
	Serology for hepatitis A ☐
	Serology for hepatitis B ☐
	Serology for hepatitis C ☐
	Serology for hepatitis D ☐
	Serology for hepatitis E ☐
	Serology for cytomegalovirus (CMV) ☐
	Serology for Epstein Barr Virus (EBV) ☐
	Serology for Herpes Simplex Virus (HSV) ☐
	Autoimmune serology ☐
	Other 1 ☐
	Other 2 ■
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Examination(s) performed	No ☐
	Yes ☐
Liver diagnostic investigation specification	_____
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd
	_____
Liver diagnostic investigation results	_____
Liver diagnostic investigation	Ultrasound ☐
	CT scan ☐
	MRI ☐
	Magnetic resonance cholangiopancreatography ☐
	Endoscopic retrograde cholangiopancreatography ☐
	Biopsy ☐
	X-ray ☐

	Tox screening for acetaminophen/paracetamol ☐
	Tox screening for ethanol ☐
	Tox screening, other ☐
	Specialist (e.g. hepatologist) consulted ☐
	Serology for hepatitis A ☐
	Serology for hepatitis B ☐
	Serology for hepatitis C ☐
	Serology for hepatitis D ☐
	Serology for hepatitis E ☐
	Serology for cytomegalovirus (CMV) ☐
	Serology for Epstein Barr Virus (EBV) ☐
	Serology for Herpes Simplex Virus (HSV) ☐
	Autoimmune serology ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ■
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Examination(s) performed	No ☐
	Yes ☐
Liver diagnostic investigation specification	_____
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd
	_____
Liver diagnostic investigation results	_____
Liver diagnostic investigation	Ultrasound ☐
	CT scan ☐
	MRI ☐
	Magnetic resonance cholangiopancreatography ☐

	Endoscopic retrograde cholangiopancreatography ☐
	Biopsy ☐
	X-ray ☐
	Tox screening for acetaminophen/paracetamol ☐
	Tox screening for ethanol ☐
	Tox screening, other ☐
	Specialist (e.g. hepatologist) consulted ☐
	Serology for hepatitis A ☐
	Serology for hepatitis B ☐
	Serology for hepatitis C ☐
	Serology for hepatitis D ☐
	Serology for hepatitis E ☐
	Serology for cytomegalovirus (CMV) ☐
	Serology for Epstein Barr Virus (EBV) ☐
	Serology for Herpes Simplex Virus (HSV) ☐
	Autoimmune serology ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ■
	Other 5 ☐
	Other 6 ☐
Examination(s) performed	No ☐
	Yes ☐
Liver diagnostic investigation specification	_____
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd
	_____
Liver diagnostic investigation results	_____
Liver diagnostic investigation	Ultrasound ☐

	CT scan ☐
	MRI ☐
	Magnetic resonance cholangiopancreatography ☐
	Endoscopic retrograde cholangiopancreatography ☐
	Biopsy ☐
	X-ray ☐
	Tox screening for acetaminophen/paracetamol ☐
	Tox screening for ethanol ☐
	Tox screening, other ☐
	Specialist (e.g. hepatologist) consulted ☐
	Serology for hepatitis A ☐
	Serology for hepatitis B ☐
	Serology for hepatitis C ☐
	Serology for hepatitis D ☐
	Serology for hepatitis E ☐
	Serology for cytomegalovirus (CMV) ☐
	Serology for Epstein Barr Virus (EBV) ☐
	Serology for Herpes Simplex Virus (HSV) ☐
	Autoimmune serology ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ■
	Other 6 ☐
Examination(s) performed	No ☐
	Yes ☐
Liver diagnostic investigation specification	_____

Liver diagnostic investigation date	Fixed Unit: yyyy mon dd
Liver diagnostic investigation results	
Liver diagnostic investigation	Ultrasound ☐ CT scan ☐ MRI ☐ Magnetic resonance cholangiopancreatography ☐ Endoscopic retrograde cholangiopancreatography ☐ Biopsy ☐ X-ray ☐ Tox screening for acetaminophen/paracetamol ☐ Tox screening for ethanol ☐ Tox screening, other ☐ Specialist (e.g. hepatologist) consulted ☐ Serology for hepatitis A ☐ Serology for hepatitis B ☐ Serology for hepatitis C ☐ Serology for hepatitis D ☐ Serology for hepatitis E ☐ Serology for cytomegalovirus (CMV) ☐ Serology for Epstein Barr Virus (EBV) ☐ Serology for Herpes Simplex Virus (HSV) ☐ Autoimmune serology ☐ Other 1 ☐ Other 2 ☐ Other 3 ☐ Other 4 ☐ Other 5 ☐ Other 6 ■

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Potential Hy's Law
Form: Liver Diagnostic Investigations (LIVERDI)
Generated On: 2025 Nov 20 12:27 (GMT)

Examination(s) performed	No ☐ Yes ☐
Liver diagnostic investigation specification	
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd
Liver diagnostic investigation results	

(Version: AZ2411 2024-11-06)

What is the assessment date?	Fixed Unit: yyyy mon dd
What is the Potential Hy's Law case number?	
AE number	
Now Derivation(This field required for CF approach)	
[Hidden Dummy] Previous Potential Hy's law case number	

Liver risk factor

- [x] Alcohol abuse
- [ ] Increased alcohol consumption in the 4 weeks prior to reported event
- [ ] IV drug abuse
- [ ] Tattoo
- [ ] Acupuncture
- [ ] Sexually transmitted diseases
- [ ] Toxic/Chemical agent exposure
- [ ] Travel (areas at risk in the last year)
- [ ] Pregnancy
- [ ] Parenteral nutrition
- [ ] Excessive physical exercise
- [ ] Changes diet/fasting episodes/weight loss diet
- [ ] Previous drug reaction (associated with an elevation of liver tests)
- [ ] Blood transfusion
- [ ] Patient exposed to anyone with jaundice in the 4 weeks
- [ ] History of hypotension
- [ ] Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value

	History of liver disease ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Liver risk factor occurrence	No ☐
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐
	Ongoing ☐
Liver risk factor details	_____
Liver risk factor start date	Fixed Unit: yyyy mon dd _____
Liver risk factor stop date	Fixed Unit: yyyy mon dd _____
Liver risk factor comment	_____
Liver risk factor	Alcohol abuse ☐
	Increased alcohol consumption in the 4 weeks prior to reported event ■
	IV drug abuse ☐
	Tattoo ☐
	Acupuncture ☐
	Sexually transmitted diseases ☐
	Toxic/Chemical agent exposure ☐
	Travel (areas at risk in the last year) ☐
	Pregnancy ☐
	Parenteral nutrition ☐
	Excessive physical exercise ☐

	Changes diet/fasting episodes/weight loss diet ☐
	Previous drug reaction (associated with an elevation of liver tests) ☐
	Blood transfusion ☐
	Patient exposed to anyone with jaundice in the 4 weeks ☐
	History of hypotension ☐
	Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value ☐
	History of liver disease ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Liver risk factor occurrence	No ☐
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐
	Ongoing ☐
Liver risk factor details	_____
Liver risk factor start date	Fixed Unit: yyyy mon dd _____
Liver risk factor stop date	Fixed Unit: yyyy mon dd _____
Liver risk factor comment	_____
Liver risk factor	Alcohol abuse ☐
	Increased alcohol consumption in the 4 weeks prior to reported event ☐

	IV drug abuse ■
	Tattoo ☐
	Acupuncture ☐
	Sexually transmitted diseases ☐
	Toxic/Chemical agent exposure ☐
	Travel (areas at risk in the last year) ☐
	Pregnancy ☐
	Parenteral nutrition ☐
	Excessive physical exercise ☐
	Changes diet/fasting episodes/weight loss diet ☐
	Previous drug reaction (associated with an elevation of liver tests) ☐
	Blood transfusion ☐
	Patient exposed to anyone with jaundice in the 4 weeks ☐
	History of hypotension ☐
	Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value ☐
	History of liver disease ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Liver risk factor occurrence	No ☐
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐
	Ongoing ☐

Liver risk factor details	
Liver risk factor start date	Fixed Unit: yyyy mon dd
Liver risk factor stop date	Fixed Unit: yyyy mon dd
Liver risk factor comment	
Liver risk factor	Alcohol abuse ☐ Increased alcohol consumption in the 4 weeks prior to reported event ☐ IV drug abuse ☐ Tattoo ■ Acupuncture ☐ Sexually transmitted diseases ☐ Toxic/Chemical agent exposure ☐ Travel (areas at risk in the last year) ☐ Pregnancy ☐ Parenteral nutrition ☐ Excessive physical exercise ☐ Changes diet/fasting episodes/weight loss diet ☐ Previous drug reaction (associated with an elevation of liver tests) ☐ Blood transfusion ☐ Patient exposed to anyone with jaundice in the 4 weeks ☐ History of hypotension ☐ Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value ☐ History of liver disease ☐ Other 1 ☐

	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Liver risk factor occurrence	No ☐
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐
	Ongoing ☐
Liver risk factor details	_____
Liver risk factor start date	Fixed Unit: yyyy mon dd _____
Liver risk factor stop date	Fixed Unit: yyyy mon dd _____
Liver risk factor comment	_____
Liver risk factor	Alcohol abuse ☐
	Increased alcohol consumption in the 4 weeks prior to reported event ☐
	IV drug abuse ☐
	Tattoo ☐
	Acupuncture ■
	Sexually transmitted diseases ☐
	Toxic/Chemical agent exposure ☐
	Travel (areas at risk in the last year) ☐
	Pregnancy ☐
	Parenteral nutrition ☐
	Excessive physical exercise ☐
	Changes diet/fasting episodes/weight loss diet ☐

	Previous drug reaction (associated with an elevation of liver tests) ☐
	Blood transfusion ☐
	Patient exposed to anyone with jaundice in the 4 weeks ☐
	History of hypotension ☐
	Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value ☐
	History of liver disease ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Liver risk factor occurrence	No ☐
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐
	Ongoing ☐
Liver risk factor details	_____
Liver risk factor start date	Fixed Unit: yyyy mon dd _____
Liver risk factor stop date	Fixed Unit: yyyy mon dd _____
Liver risk factor comment	_____
Liver risk factor	Alcohol abuse ☐
	Increased alcohol consumption in the 4 weeks prior to reported event ☐
	IV drug abuse ☐
	Tattoo ☐

	Acupuncture ☐
	Sexually transmitted diseases ■
	Toxic/Chemical agent exposure ☐
	Travel (areas at risk in the last year) ☐
	Pregnancy ☐
	Parenteral nutrition ☐
	Excessive physical exercise ☐
	Changes diet/fasting episodes/weight loss diet ☐
	Previous drug reaction (associated with an elevation of liver tests) ☐
	Blood transfusion ☐
	Patient exposed to anyone with jaundice in the 4 weeks ☐
	History of hypotension ☐
	Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value ☐
	History of liver disease ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Liver risk factor occurrence	No ☐
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐
	Ongoing ☐
Liver risk factor details	_____

Liver risk factor start date	Fixed Unit: yyyy mon dd
Liver risk factor stop date	Fixed Unit: yyyy mon dd
Liver risk factor comment	
Liver risk factor	Alcohol abuse ☐ Increased alcohol consumption in the 4 weeks prior to reported event ☐ IV drug abuse ☐ Tattoo ☐ Acupuncture ☐ Sexually transmitted diseases ☐ Toxic/Chemical agent exposure ■ Travel (areas at risk in the last year) ☐ Pregnancy ☐ Parenteral nutrition ☐ Excessive physical exercise ☐ Changes diet/fasting episodes/weight loss diet ☐ Previous drug reaction (associated with an elevation of liver tests) ☐ Blood transfusion ☐ Patient exposed to anyone with jaundice in the 4 weeks ☐ History of hypotension ☐ Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value ☐ History of liver disease ☐ Other 1 ☐

	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Liver risk factor occurrence	No ☐
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐
	Ongoing ☐
Liver risk factor details	_____
Liver risk factor start date	Fixed Unit: yyyy mon dd _____
Liver risk factor stop date	Fixed Unit: yyyy mon dd _____
Liver risk factor comment	_____
Liver risk factor	Alcohol abuse ☐
	Increased alcohol consumption in the 4 weeks prior to reported event ☐
	IV drug abuse ☐
	Tattoo ☐
	Acupuncture ☐
	Sexually transmitted diseases ☐
	Toxic/Chemical agent exposure ☐
	Travel (areas at risk in the last year) ■
	Pregnancy ☐
	Parenteral nutrition ☐
	Excessive physical exercise ☐
	Changes diet/fasting episodes/weight loss diet ☐

	Previous drug reaction (associated with an elevation of liver tests) ☐
	Blood transfusion ☐
	Patient exposed to anyone with jaundice in the 4 weeks ☐
	History of hypotension ☐
	Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value ☐
	History of liver disease ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Liver risk factor occurrence	No ☐
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐
	Ongoing ☐
Liver risk factor details	_____
Liver risk factor start date	Fixed Unit: yyyy mon dd _____
Liver risk factor stop date	Fixed Unit: yyyy mon dd _____
Liver risk factor comment	_____
Liver risk factor	Alcohol abuse ☐
	Increased alcohol consumption in the 4 weeks prior to reported event ☐
	IV drug abuse ☐
	Tattoo ☐

	Acupuncture ☐
	Sexually transmitted diseases ☐
	Toxic/Chemical agent exposure ☐
	Travel (areas at risk in the last year) ☐
	Pregnancy ■
	Parenteral nutrition ☐
	Excessive physical exercise ☐
	Changes diet/fasting episodes/weight loss diet ☐
	Previous drug reaction (associated with an elevation of liver tests) ☐
	Blood transfusion ☐
	Patient exposed to anyone with jaundice in the 4 weeks ☐
	History of hypotension ☐
	Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value ☐
	History of liver disease ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Liver risk factor occurrence	No ☐
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐
	Ongoing ☐
Liver risk factor details	_____

Liver risk factor start date	Fixed Unit: yyyy mon dd
Liver risk factor stop date	Fixed Unit: yyyy mon dd
Liver risk factor comment	
Liver risk factor	Alcohol abuse ☐ Increased alcohol consumption in the 4 weeks prior to reported event ☐ IV drug abuse ☐ Tattoo ☐ Acupuncture ☐ Sexually transmitted diseases ☐ Toxic/Chemical agent exposure ☐ Travel (areas at risk in the last year) ☐ Pregnancy ☐ Parenteral nutrition ■ Excessive physical exercise ☐ Changes diet/fasting episodes/weight loss diet ☐ Previous drug reaction (associated with an elevation of liver tests) ☐ Blood transfusion ☐ Patient exposed to anyone with jaundice in the 4 weeks ☐ History of hypotension ☐ Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value ☐ History of liver disease ☐ Other 1 ☐

	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Liver risk factor occurrence	No ☐
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐
	Ongoing ☐
Liver risk factor details	_____
Liver risk factor start date	Fixed Unit: yyyy mon dd _____
Liver risk factor stop date	Fixed Unit: yyyy mon dd _____
Liver risk factor comment	_____
Liver risk factor	Alcohol abuse ☐
	Increased alcohol consumption in the 4 weeks prior to reported event ☐
	IV drug abuse ☐
	Tattoo ☐
	Acupuncture ☐
	Sexually transmitted diseases ☐
	Toxic/Chemical agent exposure ☐
	Travel (areas at risk in the last year) ☐
	Pregnancy ☐
	Parenteral nutrition ☐
	Excessive physical exercise ■
	Changes diet/fasting episodes/weight loss diet ☐

	Previous drug reaction (associated with an elevation of liver tests) ☐
	Blood transfusion ☐
	Patient exposed to anyone with jaundice in the 4 weeks ☐
	History of hypotension ☐
	Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value ☐
	History of liver disease ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Liver risk factor occurrence	No ☐
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐
	Ongoing ☐
Liver risk factor details	_____
Liver risk factor start date	Fixed Unit: yyyy mon dd _____
Liver risk factor stop date	Fixed Unit: yyyy mon dd _____
Liver risk factor comment	_____
Liver risk factor	Alcohol abuse ☐
	Increased alcohol consumption in the 4 weeks prior to reported event ☐
	IV drug abuse ☐
	Tattoo ☐

	Acupuncture ☐
	Sexually transmitted diseases ☐
	Toxic/Chemical agent exposure ☐
	Travel (areas at risk in the last year) ☐
	Pregnancy ☐
	Parenteral nutrition ☐
	Excessive physical exercise ☐
	Changes diet/fasting episodes/weight loss diet ■
	Previous drug reaction (associated with an elevation of liver tests) ☐
	Blood transfusion ☐
	Patient exposed to anyone with jaundice in the 4 weeks ☐
	History of hypotension ☐
	Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value ☐
	History of liver disease ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Liver risk factor occurrence	No ☐
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐
	Ongoing ☐
Liver risk factor details	_____

Liver risk factor start date	Fixed Unit: yyyy mon dd
Liver risk factor stop date	Fixed Unit: yyyy mon dd
Liver risk factor comment	
Liver risk factor	Alcohol abuse ☐ Increased alcohol consumption in the 4 weeks prior to reported event ☐ IV drug abuse ☐ Tattoo ☐ Acupuncture ☐ Sexually transmitted diseases ☐ Toxic/Chemical agent exposure ☐ Travel (areas at risk in the last year) ☐ Pregnancy ☐ Parenteral nutrition ☐ Excessive physical exercise ☐ Changes diet/fasting episodes/weight loss diet ☐ Previous drug reaction (associated with an elevation of liver tests) ■ Blood transfusion ☐ Patient exposed to anyone with jaundice in the 4 weeks ☐ History of hypotension ☐ Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value ☐ History of liver disease ☐ Other 1 ☐

	Other 2 ☐ Other 3 ☐ Other 4 ☐ Other 5 ☐ Other 6 ☐
Liver risk factor occurrence	No ☐ Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐ Ongoing ☐
Liver risk factor details	_____
Liver risk factor start date	Fixed Unit: yyyy mon dd _____
Liver risk factor stop date	Fixed Unit: yyyy mon dd _____
Liver risk factor comment	_____
Liver risk factor	Alcohol abuse ☐ Increased alcohol consumption in the 4 weeks prior to reported event ☐ IV drug abuse ☐ Tattoo ☐ Acupuncture ☐ Sexually transmitted diseases ☐ Toxic/Chemical agent exposure ☐ Travel (areas at risk in the last year) ☐ Pregnancy ☐ Parenteral nutrition ☐ Excessive physical exercise ☐ Changes diet/fasting episodes/weight loss diet ☐

	Previous drug reaction (associated with an elevation of liver tests) ☐
	Blood transfusion ■
	Patient exposed to anyone with jaundice in the 4 weeks ☐
	History of hypotension ☐
	Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value ☐
	History of liver disease ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Liver risk factor occurrence	No ☐
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐
	Ongoing ☐
Liver risk factor details	_____
Liver risk factor start date	Fixed Unit: yyyy mon dd _____
Liver risk factor stop date	Fixed Unit: yyyy mon dd _____
Liver risk factor comment	_____
Liver risk factor	Alcohol abuse ☐
	Increased alcohol consumption in the 4 weeks prior to reported event ☐
	IV drug abuse ☐
	Tattoo ☐

	Acupuncture ☐
	Sexually transmitted diseases ☐
	Toxic/Chemical agent exposure ☐
	Travel (areas at risk in the last year) ☐
	Pregnancy ☐
	Parenteral nutrition ☐
	Excessive physical exercise ☐
	Changes diet/fasting episodes/weight loss diet ☐
	Previous drug reaction (associated with an elevation of liver tests) ☐
	Blood transfusion ☐
	Patient exposed to anyone with jaundice in the 4 weeks ■
	History of hypotension ☐
	Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value ☐
	History of liver disease ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Liver risk factor occurrence	No ☐
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐
	Ongoing ☐
Liver risk factor details	_____

Liver risk factor start date	Fixed Unit: yyyy mon dd
Liver risk factor stop date	Fixed Unit: yyyy mon dd
Liver risk factor comment	
Liver risk factor	Alcohol abuse ☐ Increased alcohol consumption in the 4 weeks prior to reported event ☐ IV drug abuse ☐ Tattoo ☐ Acupuncture ☐ Sexually transmitted diseases ☐ Toxic/Chemical agent exposure ☐ Travel (areas at risk in the last year) ☐ Pregnancy ☐ Parenteral nutrition ☐ Excessive physical exercise ☐ Changes diet/fasting episodes/weight loss diet ☐ Previous drug reaction (associated with an elevation of liver tests) ☐ Blood transfusion ☐ Patient exposed to anyone with jaundice in the 4 weeks ☐ History of hypotension ■ Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value ☐ History of liver disease ☐ Other 1 ☐

	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Liver risk factor occurrence	No ☐
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐
	Ongoing ☐
Liver risk factor details	_____
Liver risk factor start date	Fixed Unit: yyyy mon dd _____
Liver risk factor stop date	Fixed Unit: yyyy mon dd _____
Liver risk factor comment	_____
Liver risk factor	Alcohol abuse ☐
	Increased alcohol consumption in the 4 weeks prior to reported event ☐
	IV drug abuse ☐
	Tattoo ☐
	Acupuncture ☐
	Sexually transmitted diseases ☐
	Toxic/Chemical agent exposure ☐
	Travel (areas at risk in the last year) ☐
	Pregnancy ☐
	Parenteral nutrition ☐
	Excessive physical exercise ☐
	Changes diet/fasting episodes/weight loss diet ☐

	Previous drug reaction (associated with an elevation of liver tests) ☐
	Blood transfusion ☐
	Patient exposed to anyone with jaundice in the 4 weeks ☐
	History of hypotension ☐
	Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value ■
	History of liver disease ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Liver risk factor occurrence	No ☐
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐
	Ongoing ☐
Liver risk factor details	_____
Liver risk factor start date	Fixed Unit: yyyy mon dd _____
Liver risk factor stop date	Fixed Unit: yyyy mon dd _____
Liver risk factor comment	_____
Liver risk factor	Alcohol abuse ☐
	Increased alcohol consumption in the 4 weeks prior to reported event ☐
	IV drug abuse ☐
	Tattoo ☐

	Acupuncture ☐
	Sexually transmitted diseases ☐
	Toxic/Chemical agent exposure ☐
	Travel (areas at risk in the last year) ☐
	Pregnancy ☐
	Parenteral nutrition ☐
	Excessive physical exercise ☐
	Changes diet/fasting episodes/weight loss diet ☐
	Previous drug reaction (associated with an elevation of liver tests) ☐
	Blood transfusion ☐
	Patient exposed to anyone with jaundice in the 4 weeks ☐
	History of hypotension ☐
	Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value ☐
	History of liver disease ■
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Liver risk factor occurrence	No ☐
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐
	Ongoing ☐
Liver risk factor details	_____

Liver risk factor start date	Fixed Unit: yyyy mon dd
Liver risk factor stop date	Fixed Unit: yyyy mon dd
Liver risk factor comment	
Liver risk factor	Alcohol abuse ☐ Increased alcohol consumption in the 4 weeks prior to reported event ☐ IV drug abuse ☐ Tattoo ☐ Acupuncture ☐ Sexually transmitted diseases ☐ Toxic/Chemical agent exposure ☐ Travel (areas at risk in the last year) ☐ Pregnancy ☐ Parenteral nutrition ☐ Excessive physical exercise ☐ Changes diet/fasting episodes/weight loss diet ☐ Previous drug reaction (associated with an elevation of liver tests) ☐ Blood transfusion ☐ Patient exposed to anyone with jaundice in the 4 weeks ☐ History of hypotension ☐ Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value ☐ History of liver disease ☐ Other 1 ■

	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Liver risk factor occurrence	No ☐
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐
	Ongoing ☐
Liver risk factor details	_____
Liver risk factor start date	Fixed Unit: yyyy mon dd _____
Liver risk factor stop date	Fixed Unit: yyyy mon dd _____
Liver risk factor comment	_____
Liver risk factor	Alcohol abuse ☐
	Increased alcohol consumption in the 4 weeks prior to reported event ☐
	IV drug abuse ☐
	Tattoo ☐
	Acupuncture ☐
	Sexually transmitted diseases ☐
	Toxic/Chemical agent exposure ☐
	Travel (areas at risk in the last year) ☐
	Pregnancy ☐
	Parenteral nutrition ☐
	Excessive physical exercise ☐
	Changes diet/fasting episodes/weight loss diet ☐

	Previous drug reaction (associated with an elevation of liver tests) ☐
	Blood transfusion ☐
	Patient exposed to anyone with jaundice in the 4 weeks ☐
	History of hypotension ☐
	Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value ☐
	History of liver disease ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Liver risk factor occurrence	No ☐
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐
	Ongoing ☐
Liver risk factor details	_____
Liver risk factor start date	Fixed Unit: yyyy mon dd _____
Liver risk factor stop date	Fixed Unit: yyyy mon dd _____
Liver risk factor comment	_____
Liver risk factor	Alcohol abuse ☐
	Increased alcohol consumption in the 4 weeks prior to reported event ☐
	IV drug abuse ☐
	Tattoo ☐

	Acupuncture ☐
	Sexually transmitted diseases ☐
	Toxic/Chemical agent exposure ☐
	Travel (areas at risk in the last year) ☐
	Pregnancy ☐
	Parenteral nutrition ☐
	Excessive physical exercise ☐
	Changes diet/fasting episodes/weight loss diet ☐
	Previous drug reaction (associated with an elevation of liver tests) ☐
	Blood transfusion ☐
	Patient exposed to anyone with jaundice in the 4 weeks ☐
	History of hypotension ☐
	Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value ☐
	History of liver disease ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ■
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Liver risk factor occurrence	No ☐
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐
	Ongoing ☐
Liver risk factor details	_____

Liver risk factor start date	Fixed Unit: yyyy mon dd
Liver risk factor stop date	Fixed Unit: yyyy mon dd
Liver risk factor comment	
Liver risk factor	Alcohol abuse ☐ Increased alcohol consumption in the 4 weeks prior to reported event ☐ IV drug abuse ☐ Tattoo ☐ Acupuncture ☐ Sexually transmitted diseases ☐ Toxic/Chemical agent exposure ☐ Travel (areas at risk in the last year) ☐ Pregnancy ☐ Parenteral nutrition ☐ Excessive physical exercise ☐ Changes diet/fasting episodes/weight loss diet ☐ Previous drug reaction (associated with an elevation of liver tests) ☐ Blood transfusion ☐ Patient exposed to anyone with jaundice in the 4 weeks ☐ History of hypotension ☐ Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value ☐ History of liver disease ☐ Other 1 ☐

	Other 2 ☐
	Other 3 ☐
	Other 4 ■
	Other 5 ☐
	Other 6 ☐
Liver risk factor occurrence	No ☐
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐
	Ongoing ☐
Liver risk factor details	_____
Liver risk factor start date	Fixed Unit: yyyy mon dd _____
Liver risk factor stop date	Fixed Unit: yyyy mon dd _____
Liver risk factor comment	_____
Liver risk factor	Alcohol abuse ☐
	Increased alcohol consumption in the 4 weeks prior to reported event ☐
	IV drug abuse ☐
	Tattoo ☐
	Acupuncture ☐
	Sexually transmitted diseases ☐
	Toxic/Chemical agent exposure ☐
	Travel (areas at risk in the last year) ☐
	Pregnancy ☐
	Parenteral nutrition ☐
	Excessive physical exercise ☐
	Changes diet/fasting episodes/weight loss diet ☐

	Previous drug reaction (associated with an elevation of liver tests) ☐
	Blood transfusion ☐
	Patient exposed to anyone with jaundice in the 4 weeks ☐
	History of hypotension ☐
	Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value ☐
	History of liver disease ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Liver risk factor occurrence	No ☐
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐
	Ongoing ☐
Liver risk factor details	_____
Liver risk factor start date	Fixed Unit: yyyy mon dd _____
Liver risk factor stop date	Fixed Unit: yyyy mon dd _____
Liver risk factor comment	_____
Liver risk factor	Alcohol abuse ☐
	Increased alcohol consumption in the 4 weeks prior to reported event ☐
	IV drug abuse ☐
	Tattoo ☐

	Acupuncture ☐
	Sexually transmitted diseases ☐
	Toxic/Chemical agent exposure ☐
	Travel (areas at risk in the last year) ☐
	Pregnancy ☐
	Parenteral nutrition ☐
	Excessive physical exercise ☐
	Changes diet/fasting episodes/weight loss diet ☐
	Previous drug reaction (associated with an elevation of liver tests) ☐
	Blood transfusion ☐
	Patient exposed to anyone with jaundice in the 4 weeks ☐
	History of hypotension ☐
	Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value ☐
	History of liver disease ☐
	Other 1 ☐
	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ■
Liver risk factor occurrence	No ☐
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐
	Ongoing ☐
Liver risk factor details	_____

Liver risk factor start date	Fixed Unit: yyyy mon dd
Liver risk factor stop date	Fixed Unit: yyyy mon dd
Liver risk factor comment	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Potential Hy's Law
Form: Liver Signs and Symptoms (LIVERSS)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2411 2024-11-08)

What is the category of the clinical event?	POTENTIAL HY'S LAW
AE number	
What is the Potential Hy's Law case number?	
Now Derivation(This field required for CF approach)	
[Hidden Dummy] Previous Potential Hy's law case number	

Sign or symptom	Anorexia
	Asthenia
	Pyrexia
	Pruritus
	Jaundice
	Arthralgia
	Abdominal pain
	Abdominal tenderness
	Nausea
	Vomiting
	Rash
	Mucosal inflammation
	Purpura
	Hepatomegaly
	Splenomegaly
	Lymphadenopathy
	Ascites
	Confusional state
	Coma
	Upper quadrant tenderness
	Biliary obstruction
	Eosinophilia
	Dark urine
	Other 1
	Other 2
Sign or symptom occurrence	No

	Yes ☐
Start date	Fixed Unit: yyyy mon dd
Ongoing	Yes ☐
Stop date	Fixed Unit: yyyy mon dd
Intermittent	No ☐ Yes ☐
Liver sign/symptom specification	
Liver sign/symptom text	
Sign or symptom	Anorexia ☐ Asthenia ■ Pyrexia ☐ Pruritus ☐ Jaundice ☐ Arthralgia ☐ Abdominal pain ☐ Abdominal tenderness ☐ Nausea ☐ Vomiting ☐ Rash ☐ Mucosal inflammation ☐ Purpura ☐ Hepatomegaly ☐ Splenomegaly ☐ Lymphadenopathy ☐ Ascites ☐ Confusional state ☐ Coma ☐ Upper quadrant tenderness ☐ Biliary obstruction ☐ Eosinophilia ☐

	Dark urine ☐
	Other 1 ☐
	Other 2 ☐
Sign or symptom occurrence	No ☐
	Yes ☐
Start date	Fixed Unit: yyyy mon dd
Ongoing	Yes ☐
Stop date	Fixed Unit: yyyy mon dd
Intermittent	No ☐
	Yes ☐
Liver sign/symptom specification	
Liver sign/symptom text	
Sign or symptom	Anorexia ☐
	Asthenia ☐
	Pyrexia ■
	Pruritus ☐
	Jaundice ☐
	Arthralgia ☐
	Abdominal pain ☐
	Abdominal tenderness ☐
	Nausea ☐
	Vomiting ☐
	Rash ☐
	Mucosal inflammation ☐
	Purpura ☐
	Hepatomegaly ☐
	Splenomegaly ☐
	Lymphadenopathy ☐
	Ascites ☐
	Confusional state ☐

	Coma ☐
	Upper quadrant tenderness ☐
	Biliary obstruction ☐
	Eosinophilia ☐
	Dark urine ☐
	Other 1 ☐
	Other 2 ☐
Sign or symptom occurrence	No ☐
	Yes ☐
Start date	Fixed Unit: yyyy mon dd
Ongoing	Yes ☐
Stop date	Fixed Unit: yyyy mon dd
Intermittent	No ☐
	Yes ☐
Liver sign/symptom specification	
Liver sign/symptom text	
Sign or symptom	Anorexia ☐
	Asthenia ☐
	Pyrexia ☐
	Pruritus ■
	Jaundice ☐
	Arthralgia ☐
	Abdominal pain ☐
	Abdominal tenderness ☐
	Nausea ☐
	Vomiting ☐
	Rash ☐
	Mucosal inflammation ☐
	Purpura ☐
	Hepatomegaly ☐

	Splenomegaly ☐
	Lymphadenopathy ☐
	Ascites ☐
	Confusional state ☐
	Coma ☐
	Upper quadrant tenderness ☐
	Biliary obstruction ☐
	Eosinophilia ☐
	Dark urine ☐
	Other 1 ☐
	Other 2 ☐
Sign or symptom occurrence	No ☐
	Yes ☐
Start date	Fixed Unit: yyyy mon dd
Ongoing	Yes ☐
Stop date	Fixed Unit: yyyy mon dd
Intermittent	No ☐
	Yes ☐
Liver sign/symptom specification	
Liver sign/symptom text	
Sign or symptom	Anorexia ☐
	Asthenia ☐
	Pyrexia ☐
	Pruritus ☐
	Jaundice ■
	Arthralgia ☐
	Abdominal pain ☐
	Abdominal tenderness ☐
	Nausea ☐
	Vomiting ☐

	Rash ☐
	Mucosal inflammation ☐
	Purpura ☐
	Hepatomegaly ☐
	Splenomegaly ☐
	Lymphadenopathy ☐
	Ascites ☐
	Confusional state ☐
	Coma ☐
	Upper quadrant tenderness ☐
	Biliary obstruction ☐
	Eosinophilia ☐
	Dark urine ☐
	Other 1 ☐
	Other 2 ☐
Sign or symptom occurrence	No ☐
	Yes ☐
Start date	Fixed Unit: yyyy mon dd
Ongoing	Yes ☐
Stop date	Fixed Unit: yyyy mon dd
Intermittent	No ☐
	Yes ☐
Liver sign/symptom specification	
Liver sign/symptom text	
Sign or symptom	Anorexia ☐
	Asthenia ☐
	Pyrexia ☐
	Pruritus ☐
	Jaundice ☐
	Arthralgia ■

	Abdominal pain ☐
	Abdominal tenderness ☐
	Nausea ☐
	Vomiting ☐
	Rash ☐
	Mucosal inflammation ☐
	Purpura ☐
	Hepatomegaly ☐
	Splenomegaly ☐
	Lymphadenopathy ☐
	Ascites ☐
	Confusional state ☐
	Coma ☐
	Upper quadrant tenderness ☐
	Biliary obstruction ☐
	Eosinophilia ☐
	Dark urine ☐
	Other 1 ☐
	Other 2 ☐
Sign or symptom occurrence	No ☐
	Yes ☐
Start date	Fixed Unit: yyyy mon dd
Ongoing	Yes ☐
Stop date	Fixed Unit: yyyy mon dd
Intermittent	No ☐
	Yes ☐
Liver sign/symptom specification	
Liver sign/symptom text	
Sign or symptom	Anorexia ☐
	Asthenia ☐

	Pyrexia ☐
	Pruritus ☐
	Jaundice ☐
	Arthralgia ☐
	Abdominal pain ■
	Abdominal tenderness ☐
	Nausea ☐
	Vomiting ☐
	Rash ☐
	Mucosal inflammation ☐
	Purpura ☐
	Hepatomegaly ☐
	Splenomegaly ☐
	Lymphadenopathy ☐
	Ascites ☐
	Confusional state ☐
	Coma ☐
	Upper quadrant tenderness ☐
	Biliary obstruction ☐
	Eosinophilia ☐
	Dark urine ☐
	Other 1 ☐
	Other 2 ☐
Sign or symptom occurrence	No ☐
	Yes ☐
Start date	Fixed Unit: yyyy mon dd
	_____
Ongoing	Yes ☐
Stop date	Fixed Unit: yyyy mon dd
	_____
Intermittent	No ☐
	Yes ☐
Liver sign/symptom specification	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Potential Hy's Law
Form: Liver Signs and Symptoms (LIVERSS)
Generated On: 2025 Nov 20 12:27 (GMT)

Liver sign/symptom text	
Sign or symptom	Anorexia Asthenia Pyrexia Pruritus Jaundice Arthralgia Abdominal pain Abdominal tenderness Nausea Vomiting Rash Mucosal inflammation Purpura Hepatomegaly Splenomegaly Lymphadenopathy Ascites Confusional state Coma Upper quadrant tenderness Biliary obstruction Eosinophilia Dark urine Other 1 Other 2
Sign or symptom occurrence	No Yes
Start date	Fixed Unit: yyyy mon dd
Ongoing	Yes
Stop date	Fixed Unit: yyyy mon dd

Intermittent	No ☐
	Yes ☐
Liver sign/symptom specification	
Liver sign/symptom text	
Sign or symptom	Anorexia ☐
	Asthenia ☐
	Pyrexia ☐
	Pruritus ☐
	Jaundice ☐
	Arthralgia ☐
	Abdominal pain ☐
	Abdominal tenderness ☐
	Nausea ■
	Vomiting ☐
	Rash ☐
	Mucosal inflammation ☐
	Purpura ☐
	Hepatomegaly ☐
	Splenomegaly ☐
	Lymphadenopathy ☐
	Ascites ☐
	Confusional state ☐
	Coma ☐
	Upper quadrant tenderness ☐
	Biliary obstruction ☐
	Eosinophilia ☐
	Dark urine ☐
	Other 1 ☐
	Other 2 ☐
Sign or symptom occurrence	No ☐
	Yes ☐
Start date	Fixed Unit: yyyy mon dd

Ongoing	Yes ☐
Stop date	Fixed Unit: yyyy mon dd _____
Intermittent	No ☐ Yes ☐
Liver sign/symptom specification	_____
Liver sign/symptom text	_____
Sign or symptom	Anorexia ☐ Asthenia ☐ Pyrexia ☐ Pruritus ☐ Jaundice ☐ Arthralgia ☐ Abdominal pain ☐ Abdominal tenderness ☐ Nausea ☐ Vomiting ■ Rash ☐ Mucosal inflammation ☐ Purpura ☐ Hepatomegaly ☐ Splenomegaly ☐ Lymphadenopathy ☐ Ascites ☐ Confusional state ☐ Coma ☐ Upper quadrant tenderness ☐ Biliary obstruction ☐ Eosinophilia ☐ Dark urine ☐ Other 1 ☐ Other 2 ☐
Sign or symptom occurrence	No ☐

	Yes ☐
Start date	Fixed Unit: yyyy mon dd
Ongoing	Yes ☐
Stop date	Fixed Unit: yyyy mon dd
Intermittent	No ☐ Yes ☐
Liver sign/symptom specification	
Liver sign/symptom text	
Sign or symptom	Anorexia ☐ Asthenia ☐ Pyrexia ☐ Pruritus ☐ Jaundice ☐ Arthralgia ☐ Abdominal pain ☐ Abdominal tenderness ☐ Nausea ☐ Vomiting ☐ Rash ■ Mucosal inflammation ☐ Purpura ☐ Hepatomegaly ☐ Splenomegaly ☐ Lymphadenopathy ☐ Ascites ☐ Confusional state ☐ Coma ☐ Upper quadrant tenderness ☐ Biliary obstruction ☐ Eosinophilia ☐

	Dark urine ☐
	Other 1 ☐
	Other 2 ☐
Sign or symptom occurrence	No ☐
	Yes ☐
Start date	Fixed Unit: yyyy mon dd
Ongoing	Yes ☐
Stop date	Fixed Unit: yyyy mon dd
Intermittent	No ☐
	Yes ☐
Liver sign/symptom specification	
Liver sign/symptom text	
Sign or symptom	Anorexia ☐
	Asthenia ☐
	Pyrexia ☐
	Pruritus ☐
	Jaundice ☐
	Arthralgia ☐
	Abdominal pain ☐
	Abdominal tenderness ☐
	Nausea ☐
	Vomiting ☐
	Rash ☐
	Mucosal inflammation ■
	Purpura ☐
	Hepatomegaly ☐
	Splenomegaly ☐
	Lymphadenopathy ☐
	Ascites ☐
	Confusional state ☐

	Coma ☐
	Upper quadrant tenderness ☐
	Biliary obstruction ☐
	Eosinophilia ☐
	Dark urine ☐
	Other 1 ☐
	Other 2 ☐
Sign or symptom occurrence	No ☐
	Yes ☐
Start date	Fixed Unit: yyyy mon dd
Ongoing	Yes ☐
Stop date	Fixed Unit: yyyy mon dd
Intermittent	No ☐
	Yes ☐
Liver sign/symptom specification	
Liver sign/symptom text	
Sign or symptom	Anorexia ☐
	Asthenia ☐
	Pyrexia ☐
	Pruritus ☐
	Jaundice ☐
	Arthralgia ☐
	Abdominal pain ☐
	Abdominal tenderness ☐
	Nausea ☐
	Vomiting ☐
	Rash ☐
	Mucosal inflammation ☐
	Purpura ■
	Hepatomegaly ☐

	Splenomegaly ☐
	Lymphadenopathy ☐
	Ascites ☐
	Confusional state ☐
	Coma ☐
	Upper quadrant tenderness ☐
	Biliary obstruction ☐
	Eosinophilia ☐
	Dark urine ☐
	Other 1 ☐
	Other 2 ☐
Sign or symptom occurrence	No ☐
	Yes ☐
Start date	Fixed Unit: yyyy mon dd _____
Ongoing	Yes ☐
Stop date	Fixed Unit: yyyy mon dd _____
Intermittent	No ☐
	Yes ☐
Liver sign/symptom specification	_____
Liver sign/symptom text	_____
Sign or symptom	Anorexia ☐
	Asthenia ☐
	Pyrexia ☐
	Pruritus ☐
	Jaundice ☐
	Arthralgia ☐
	Abdominal pain ☐
	Abdominal tenderness ☐
	Nausea ☐
	Vomiting ☐

	Rash ☐
	Mucosal inflammation ☐
	Purpura ☐
	Hepatomegaly ■
	Splenomegaly ☐
	Lymphadenopathy ☐
	Ascites ☐
	Confusional state ☐
	Coma ☐
	Upper quadrant tenderness ☐
	Biliary obstruction ☐
	Eosinophilia ☐
	Dark urine ☐
	Other 1 ☐
	Other 2 ☐
Sign or symptom occurrence	No ☐
	Yes ☐
Start date	Fixed Unit: yyyy mon dd
Ongoing	Yes ☐
Stop date	Fixed Unit: yyyy mon dd
Intermittent	No ☐
	Yes ☐
Liver sign/symptom specification	
Liver sign/symptom text	
Sign or symptom	Anorexia ☐
	Asthenia ☐
	Pyrexia ☐
	Pruritus ☐
	Jaundice ☐
	Arthralgia ☐

	Abdominal pain ☐
	Abdominal tenderness ☐
	Nausea ☐
	Vomiting ☐
	Rash ☐
	Mucosal inflammation ☐
	Purpura ☐
	Hepatomegaly ☐
	Splenomegaly ■
	Lymphadenopathy ☐
	Ascites ☐
	Confusional state ☐
	Coma ☐
	Upper quadrant tenderness ☐
	Biliary obstruction ☐
	Eosinophilia ☐
	Dark urine ☐
	Other 1 ☐
	Other 2 ☐
Sign or symptom occurrence	No ☐
	Yes ☐
Start date	Fixed Unit: yyyy mon dd
Ongoing	Yes ☐
Stop date	Fixed Unit: yyyy mon dd
Intermittent	No ☐
	Yes ☐
Liver sign/symptom specification	
Liver sign/symptom text	
Sign or symptom	Anorexia ☐
	Asthenia ☐

	Pyrexia ☐
	Pruritus ☐
	Jaundice ☐
	Arthralgia ☐
	Abdominal pain ☐
	Abdominal tenderness ☐
	Nausea ☐
	Vomiting ☐
	Rash ☐
	Mucosal inflammation ☐
	Purpura ☐
	Hepatomegaly ☐
	Splenomegaly ☐
	Lymphadenopathy ■
	Ascites ☐
	Confusional state ☐
	Coma ☐
	Upper quadrant tenderness ☐
	Biliary obstruction ☐
	Eosinophilia ☐
	Dark urine ☐
	Other 1 ☐
	Other 2 ☐
Sign or symptom occurrence	No ☐
	Yes ☐
Start date	Fixed Unit: yyyy mon dd
	_____
Ongoing	Yes ☐
Stop date	Fixed Unit: yyyy mon dd
	_____
Intermittent	No ☐
	Yes ☐
Liver sign/symptom specification	_____

Liver sign/symptom text	
Sign or symptom	Anorexia ☐ Asthenia ☐ Pyrexia ☐ Pruritus ☐ Jaundice ☐ Arthralgia ☐ Abdominal pain ☐ Abdominal tenderness ☐ Nausea ☐ Vomiting ☐ Rash ☐ Mucosal inflammation ☐ Purpura ☐ Hepatomegaly ☐ Splenomegaly ☐ Lymphadenopathy ☐ Ascites ■ Confusional state ☐ Coma ☐ Upper quadrant tenderness ☐ Biliary obstruction ☐ Eosinophilia ☐ Dark urine ☐ Other 1 ☐ Other 2 ☐
Sign or symptom occurrence	No ☐ Yes ☐
Start date	Fixed Unit: yyyy mon dd
Ongoing	Yes ☐
Stop date	Fixed Unit: yyyy mon dd

Intermittent	No ☐ Yes ☐
Liver sign/symptom specification	_____
Liver sign/symptom text	_____
Sign or symptom	Anorexia ☐ Asthenia ☐ Pyrexia ☐ Pruritus ☐ Jaundice ☐ Arthralgia ☐ Abdominal pain ☐ Abdominal tenderness ☐ Nausea ☐ Vomiting ☐ Rash ☐ Mucosal inflammation ☐ Purpura ☐ Hepatomegaly ☐ Splenomegaly ☐ Lymphadenopathy ☐ Ascites ☐ Confusional state ■ Coma ☐ Upper quadrant tenderness ☐ Biliary obstruction ☐ Eosinophilia ☐ Dark urine ☐ Other 1 ☐ Other 2 ☐
Sign or symptom occurrence	No ☐ Yes ☐
Start date	Fixed Unit: yyyy mon dd _____

Ongoing	Yes ☐
Stop date	Fixed Unit: yyyy mon dd _____
Intermittent	No ☐ Yes ☐
Liver sign/symptom specification	_____
Liver sign/symptom text	_____
Sign or symptom	Anorexia ☐ Asthenia ☐ Pyrexia ☐ Pruritus ☐ Jaundice ☐ Arthralgia ☐ Abdominal pain ☐ Abdominal tenderness ☐ Nausea ☐ Vomiting ☐ Rash ☐ Mucosal inflammation ☐ Purpura ☐ Hepatomegaly ☐ Splenomegaly ☐ Lymphadenopathy ☐ Ascites ☐ Confusional state ☐ Coma ■ Upper quadrant tenderness ☐ Biliary obstruction ☐ Eosinophilia ☐ Dark urine ☐ Other 1 ☐ Other 2 ☐
Sign or symptom occurrence	No ☐

	Yes ☐
Start date	Fixed Unit: yyyy mon dd
Ongoing	Yes ☐
Stop date	Fixed Unit: yyyy mon dd
Intermittent	No ☐ Yes ☐
Liver sign/symptom specification	
Liver sign/symptom text	
Sign or symptom	Anorexia ☐ Asthenia ☐ Pyrexia ☐ Pruritus ☐ Jaundice ☐ Arthralgia ☐ Abdominal pain ☐ Abdominal tenderness ☐ Nausea ☐ Vomiting ☐ Rash ☐ Mucosal inflammation ☐ Purpura ☐ Hepatomegaly ☐ Splenomegaly ☐ Lymphadenopathy ☐ Ascites ☐ Confusional state ☐ Coma ☐ Upper quadrant tenderness ■ Biliary obstruction ☐ Eosinophilia ☐

	Dark urine ☐
	Other 1 ☐
	Other 2 ☐
Sign or symptom occurrence	No ☐
	Yes ☐
Start date	Fixed Unit: yyyy mon dd
Ongoing	Yes ☐
Stop date	Fixed Unit: yyyy mon dd
Intermittent	No ☐
	Yes ☐
Liver sign/symptom specification	
Liver sign/symptom text	
Sign or symptom	Anorexia ☐
	Asthenia ☐
	Pyrexia ☐
	Pruritus ☐
	Jaundice ☐
	Arthralgia ☐
	Abdominal pain ☐
	Abdominal tenderness ☐
	Nausea ☐
	Vomiting ☐
	Rash ☐
	Mucosal inflammation ☐
	Purpura ☐
	Hepatomegaly ☐
	Splenomegaly ☐
	Lymphadenopathy ☐
	Ascites ☐
	Confusional state ☐

	Coma ☐
	Upper quadrant tenderness ☐
	Biliary obstruction ■
	Eosinophilia ☐
	Dark urine ☐
	Other 1 ☐
	Other 2 ☐
Sign or symptom occurrence	No ☐
	Yes ☐
Start date	Fixed Unit: yyyy mon dd
Ongoing	Yes ☐
Stop date	Fixed Unit: yyyy mon dd
Intermittent	No ☐
	Yes ☐
Liver sign/symptom specification	
Liver sign/symptom text	
Sign or symptom	Anorexia ☐
	Asthenia ☐
	Pyrexia ☐
	Pruritus ☐
	Jaundice ☐
	Arthralgia ☐
	Abdominal pain ☐
	Abdominal tenderness ☐
	Nausea ☐
	Vomiting ☐
	Rash ☐
	Mucosal inflammation ☐
	Purpura ☐
	Hepatomegaly ☐

	Splenomegaly ☐
	Lymphadenopathy ☐
	Ascites ☐
	Confusional state ☐
	Coma ☐
	Upper quadrant tenderness ☐
	Biliary obstruction ☐
	Eosinophilia ■
	Dark urine ☐
	Other 1 ☐
	Other 2 ☐
Sign or symptom occurrence	No ☐
	Yes ☐
Start date	Fixed Unit: yyyy mon dd
	_____
Ongoing	Yes ☐
Stop date	Fixed Unit: yyyy mon dd
	_____
Intermittent	No ☐
	Yes ☐
Liver sign/symptom specification	_____
Liver sign/symptom text	_____
Sign or symptom	Anorexia ☐
	Asthenia ☐
	Pyrexia ☐
	Pruritus ☐
	Jaundice ☐
	Arthralgia ☐
	Abdominal pain ☐
	Abdominal tenderness ☐
	Nausea ☐
	Vomiting ☐

	Rash ☐
	Mucosal inflammation ☐
	Purpura ☐
	Hepatomegaly ☐
	Splenomegaly ☐
	Lymphadenopathy ☐
	Ascites ☐
	Confusional state ☐
	Coma ☐
	Upper quadrant tenderness ☐
	Biliary obstruction ☐
	Eosinophilia ☐
	Dark urine ■
	Other 1 ☐
	Other 2 ☐
Sign or symptom occurrence	No ☐
	Yes ☐
Start date	Fixed Unit: yyyy mon dd
Ongoing	Yes ☐
Stop date	Fixed Unit: yyyy mon dd
Intermittent	No ☐
	Yes ☐
Liver sign/symptom specification	
Liver sign/symptom text	
Sign or symptom	Anorexia ☐
	Asthenia ☐
	Pyrexia ☐
	Pruritus ☐
	Jaundice ☐
	Arthralgia ☐

	Abdominal pain ☐
	Abdominal tenderness ☐
	Nausea ☐
	Vomiting ☐
	Rash ☐
	Mucosal inflammation ☐
	Purpura ☐
	Hepatomegaly ☐
	Splenomegaly ☐
	Lymphadenopathy ☐
	Ascites ☐
	Confusional state ☐
	Coma ☐
	Upper quadrant tenderness ☐
	Biliary obstruction ☐
	Eosinophilia ☐
	Dark urine ☐
	Other 1 ■
	Other 2 ☐
Sign or symptom occurrence	No ☐
	Yes ☐
Start date	Fixed Unit: yyyy mon dd
Ongoing	Yes ☐
Stop date	Fixed Unit: yyyy mon dd
Intermittent	No ☐
	Yes ☐
Liver sign/symptom specification	
Liver sign/symptom text	
Sign or symptom	Anorexia ☐
	Asthenia ☐

	Pyrexia ☐
	Pruritus ☐
	Jaundice ☐
	Arthralgia ☐
	Abdominal pain ☐
	Abdominal tenderness ☐
	Nausea ☐
	Vomiting ☐
	Rash ☐
	Mucosal inflammation ☐
	Purpura ☐
	Hepatomegaly ☐
	Splenomegaly ☐
	Lymphadenopathy ☐
	Ascites ☐
	Confusional state ☐
	Coma ☐
	Upper quadrant tenderness ☐
	Biliary obstruction ☐
	Eosinophilia ☐
	Dark urine ☐
	Other 1 ☐
	Other 2 ■
Sign or symptom occurrence	No ☐
	Yes ☐
Start date	Fixed Unit: yyyy mon dd
	_____
Ongoing	Yes ☐
Stop date	Fixed Unit: yyyy mon dd
	_____
Intermittent	No ☐
	Yes ☐
Liver sign/symptom specification	_____

Liver sign/symptom text

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Medication Error Report
Form: Medication Error Report (MER)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2006 2023-07-27)	
IMP and/or suspect device associated with Medication Error	IMP
Date of medication error	Fixed Unit: yyyy mon dd
Medication error occurrence	Actual error Intercepted error Potential error
Stage of error occur (storage)	No Yes
Stage of error occur (dispensing)	No Yes
Stage of error occur (preparation for administration)	No Yes
Stage of error occur (administration)	No Yes
AE on medication error	Medication error without any associated AE Medication error with non-serious AE Medication error with SAE
AE number	
AE number	
Adverse Event	
Error associated to product defect	No Yes
Error associated to product defect, specify	
Description of error occurrence, action taken	
Description of potential error and possible harm	
Derived field to call CF	
[Hidden Dummy] Used for email alert	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Overdose Report
Form: Overdose Report (OVERDOSE)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2311 2023-11-22)

Study drug	Rilvegostomig ☐ Durvalumab ☐ Gemcitabine ☐ Cisplatin ☐
Route	Intravenous ■
Total dose	
Unit	mg ☐ mg/m2 ☐
Date overdose started	Fixed Unit: yyyy mon dd
Date overdose stopped	Fixed Unit: yyyy mon dd
Intentional overdose	No ☐ Yes ☐
Overdose associated with AE	No ☐ Yes ☐
AE number associated with overdose	
AE number associated with overdose	
CRF text for AE associated with overdose	
CRF text for AE associated with overdose	
Further information (for non SAE)	
Hidden Trade name Field	
Hidden Number for AE Field	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Second Time of Progression
Form: Second Time of Progression (PFS2)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: ON2007 2021-04-27)	
Assessment performed	No ☐ Yes ☐
Date of scan/assessment for second progression	Fixed Unit: yyyy mon dd _____
Investigator assessment of Subject's response	Progressive disease ☐ Non progressive disease ☐ Not evaluable ☐
If progression, specify the type of progression	Symptomatic Progression ☐ Objective radiological progression ☐ Other ☐
If Other, specify	_____

(Version: AZ2502 2025-02-13)

Has the drug been permanently discontinued?	No ☐ Yes ☐
Patient follow up options	Agrees to continue according to the current CSP visit plan/schedule ☐ Agrees to continue in the study with a modified visit plan ☐ Agrees to continue in the study but will not come to the site for visits but can be contacted by phone according to CSP visit plan ☐ Agrees to come to the site at the end of the study (or at time of data analysis) but does not want to be contacted or come to the site until then ☐ Agrees to be contacted by phone at the end of the study (or at time of data analysis) but does not want to be contacted or come to the site until then ☐ Does not want to be contacted but agrees that personal and medical information about him or her can be collected from medical records ☐ Agrees to be contacted by phone when needed but will not come to the site for visits ☐ Agrees for contact to be made with a treating physician or relative but will not come to the site for visits ☐
Patient follow up option selection	Yes ☐

Decision date	Fixed Unit: yyyy mon dd

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Contact
Form: Contact (CONTACT)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ1211 2020-04-24)

Was any contact made?	No ☐ Yes ☐
If 'No', specify reason	_____
If 'Yes', specify below	
What was the contact date?	Fixed Unit: yyyy mon dd _____
Who was the contact respondent?	Study subject ☐ Caregiver ☐
What was the type of contact?	Telephone ☐ Home visit ☐ Letter ☐ e-mail ☐ Other ☐
If 'Other', specify	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Review of PRO/Questionnaire/Diary
Form: Review of PRO/Questionnaire/Diary (REVPRDI)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2010 2021-10-01)

Questionnaire Name	REVIEW OF PRO/QUESTIONNAIRE/DIARY
If No, specify the reason below Reason Subject did not complete questionnaire	Unwilling ☐ Cannot understand instructions ☐ Technical problems with device ☐ Too sick, other than disease under investigation ☐ Cannot use device due to physical limitations ☐ Too affected by symptoms of disease under investigation ☐ Relevant language version not available ☐ Administrative failure distribute questionnaire to Subject ☐ Illiterate ☐ Patient forgot ☐ Unsolvable patient device training issues ☐ Other ☐
If Other, specify	_____
Questionnaire Expected Completion Date	Fixed Unit: yyyy mon dd _____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Withdrawal Of Informed Consent
Form: Withdrawal of Informed Consent (CONSWD)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2309 2024-07-03)

Consent withdrawal category	Optional Blood Tests ■ Participation to Optional Biopsy at first day of Cycle 3 of study treatment ☐ Participation to Optional Biopsy at Cancer Progression ☐ Use of Optional Services and Transfer of Contact Details to Service Providers ☐ Use of Coded Data (Including Images), Biosamples and Analysis of Genetic Information for Future Research ☐ Optional Multi-omics Research and Analysis of Their Multi-omics Information, including Their Genetic Information ☐ Withdrawal from the Study, but the Patient Agrees for Data and Biosamples to be Used as Consented for the Current Study, Including the Samples and Data Collected During the Withdrawal Visit ☐ Withdrawal from the Study and any Use of Already Collected Biosamples (Including Data and Biosamples for Future Research and Multi-omics if Applicable) ☐ Patient Withdrew Informed Consent without Providing any Detailed Information ☐
Consent withdrawn	No ☐ Yes ☐

	Not applicable ☐
Informed consent withdrawal date	Fixed Unit: yyyy mon dd
Consent withdrawal category	Optional Blood Tests ☐ Participation to Optional Biopsy at first day of Cycle 3 of study treatment ■ Participation to Optional Biopsy at Cancer Progression ☐ Use of Optional Services and Transfer of Contact Details to Service Providers ☐ Use of Coded Data (Including Images), Biosamples and Analysis of Genetic Information for Future Research ☐ Optional Multi-omics Research and Analysis of Their Multi-omics Information, including Their Genetic Information ☐ Withdrawal from the Study, but the Patient Agrees for Data and Biosamples to be Used as Consented for the Current Study, Including the Samples and Data Collected During the Withdrawal Visit ☐ Withdrawal from the Study and any Use of Already Collected Biosamples (Including Data and Biosamples for Future Research and Multi-omics if Applicable) ☐ Patient Withdrew Informed Consent without Providing any Detailed Information ☐

Consent withdrawn	No ☐ Yes ☐ Not applicable ☐
Informed consent withdrawal date	Fixed Unit: yyyy mon dd
Consent withdrawal category	Optional Blood Tests ☐ Participation to Optional Biopsy at first day of Cycle 3 of study treatment ☐ Participation to Optional Biopsy at Cancer Progression ■ Use of Optional Services and Transfer of Contact Details to Service Providers ☐ Use of Coded Data (Including Images), Biosamples and Analysis of Genetic Information for Future Research ☐ Optional Multi-omics Research and Analysis of Their Multi-omics Information, including Their Genetic Information ☐ Withdrawal from the Study, but the Patient Agrees for Data and Biosamples to be Used as Consented for the Current Study, Including the Samples and Data Collected During the Withdrawal Visit ☐ Withdrawal from the Study and any Use of Already Collected Biosamples (Including Data and Biosamples for Future Research and Multi-omics if Applicable) ☐

	Patient Withdrew Informed Consent without Providing any Detailed Information ☐
Consent withdrawn	No ☐ Yes ☐ Not applicable ☐
Informed consent withdrawal date	Fixed Unit: yyyy mon dd
Consent withdrawal category	Optional Blood Tests ☐ Participation to Optional Biopsy at first day of Cycle 3 of study treatment ☐ Participation to Optional Biopsy at Cancer Progression ☐ Use of Optional Services and Transfer of Contact Details to Service Providers ■ Use of Coded Data (Including Images), Biosamples and Analysis of Genetic Information for Future Research ☐ Optional Multi-omics Research and Analysis of Their Multi-omics Information, including Their Genetic Information ☐ Withdrawal from the Study, but the Patient Agrees for Data and Biosamples to be Used as Consented for the Current Study, Including the Samples and Data Collected During the Withdrawal Visit ☐

	Withdrawal from the Study and any Use of Already Collected Biosamples (Including Data and Biosamples for Future Research and Multi-omics if Applicable) ☐
	Patient Withdrew Informed Consent without Providing any Detailed Information ☐
Consent withdrawn	No ☐
	Yes ☐
	Not applicable ☐
Informed consent withdrawal date	Fixed Unit: yyyy mon dd
Consent withdrawal category	Optional Blood Tests ☐
	Participation to Optional Biopsy at first day of Cycle 3 of study treatment ☐
	Participation to Optional Biopsy at Cancer Progression ☐
	Use of Optional Services and Transfer of Contact Details to Service Providers ☐
	Use of Coded Data (Including Images), Biosamples and Analysis of Genetic Information for Future Research ■
	Optional Multi-omics Research and Analysis of Their Multi-omics Information, including Their Genetic Information ☐

	Withdrawal from the Study, but the Patient Agrees for Data and Biosamples to be Used as Consented for the Current Study, Including the Samples and Data Collected During the Withdrawal Visit ☐ Withdrawal from the Study and any Use of Already Collected Biosamples (Including Data and Biosamples for Future Research and Multi-omics if Applicable) ☐ Patient Withdrew Informed Consent without Providing any Detailed Information ☐
Consent withdrawn	No ☐ Yes ☐ Not applicable ☐
Informed consent withdrawal date	Fixed Unit: yyyy mon dd
Consent withdrawal category	Optional Blood Tests ☐ Participation to Optional Biopsy at first day of Cycle 3 of study treatment ☐ Participation to Optional Biopsy at Cancer Progression ☐ Use of Optional Services and Transfer of Contact Details to Service Providers ☐ Use of Coded Data (Including Images), Biosamples and Analysis of Genetic Information for Future Research ☐

	Optional Multi-omics Research and Analysis of Their Multi-omics Information, including Their Genetic Information
	Withdrawal from the Study, but the Patient Agrees for Data and Biosamples to be Used as Consented for the Current Study, Including the Samples and Data Collected During the Withdrawal Visit
	Withdrawal from the Study and any Use of Already Collected Biosamples (Including Data and Biosamples for Future Research and Multi-omics if Applicable)
	Patient Withdrew Informed Consent without Providing any Detailed Information
Consent withdrawn	No
	Yes
	Not applicable
Informed consent withdrawal date	Fixed Unit: yyyy mon dd
Consent withdrawal category	Optional Blood Tests
	Participation to Optional Biopsy at first day of Cycle 3 of study treatment
	Participation to Optional Biopsy at Cancer Progression
	Use of Optional Services and Transfer of Contact Details to Service Providers

	Use of Coded Data (Including Images), Biosamples and Analysis of Genetic Information for Future Research ☐
	Optional Multi-omics Research and Analysis of Their Multi-omics Information, including Their Genetic Information ☐
	Withdrawal from the Study, but the Patient Agrees for Data and Biosamples to be Used as Consented for the Current Study, Including the Samples and Data Collected During the Withdrawal Visit ☐
	Withdrawal from the Study and any Use of Already Collected Biosamples (Including Data and Biosamples for Future Research and Multi-omics if Applicable) ☐
	Patient Withdrew Informed Consent without Providing any Detailed Information ☐
Consent withdrawn	No ☐
	Yes ☐
	Not applicable ☐
Informed consent withdrawal date	Fixed Unit: yyyy mon dd
Consent withdrawal category	Optional Blood Tests ☐
	Participation to Optional Biopsy at first day of Cycle 3 of study treatment ☐
	Participation to Optional Biopsy at Cancer Progression ☐

	Use of Optional Services and Transfer of Contact Details to Service Providers ☐ Use of Coded Data (Including Images), Biosamples and Analysis of Genetic Information for Future Research ☐ Optional Multi-omics Research and Analysis of Their Multi-omics Information, including Their Genetic Information ☐ Withdrawal from the Study, but the Patient Agrees for Data and Biosamples to be Used as Consented for the Current Study, Including the Samples and Data Collected During the Withdrawal Visit ☐ Withdrawal from the Study and any Use of Already Collected Biosamples (Including Data and Biosamples for Future Research and Multi-omics if Applicable) ☐ Patient Withdrew Informed Consent without Providing any Detailed Information ☐
Consent withdrawn	No ☐ Yes ☐ Not applicable ☐
Informed consent withdrawal date	Fixed Unit: yyyy mon dd
Consent withdrawal category	Optional Blood Tests ☐ Participation to Optional Biopsy at first day of Cycle 3 of study treatment ☐

	Participation to Optional Biopsy at Cancer Progression ☐ Use of Optional Services and Transfer of Contact Details to Service Providers ☐ Use of Coded Data (Including Images), Biosamples and Analysis of Genetic Information for Future Research ☐ Optional Multi-omics Research and Analysis of Their Multi-omics Information, including Their Genetic Information ☐ Withdrawal from the Study, but the Patient Agrees for Data and Biosamples to be Used as Consented for the Current Study, Including the Samples and Data Collected During the Withdrawal Visit ☐ Withdrawal from the Study and any Use of Already Collected Biosamples (Including Data and Biosamples for Future Research and Multi-omics if Applicable) ☐ Patient Withdrew Informed Consent without Providing any Detailed Information ■
Consent withdrawn	No ☐ Yes ☐ Not applicable ☐
Informed consent withdrawal date	Fixed Unit: yyyy mon dd _____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Death
Form: Death Details (DD)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: ON2412 2024-12-03)

What was the Subject's date of death?	Fixed Unit: yyyy mon dd
Is death related to disease under investigation?	No ☐ Yes ☐
Is death related to adverse event?	No ☐ Yes ☐
What is the AE number?	
Was the autopsy performed?	No ☐ Yes ☐ Unknown ☐
What was the cause of death narrative?	
Death detail assessment name	Primary cause of death ■ Secondary cause of death ☐
Cause of death	
Death detail assessment name	Primary cause of death ☐ Secondary cause of death ■
Cause of death	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Study Disposition
Form: Disposition (DS)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2404 2024-09-12)

What was the completion or discontinuation date?	Fixed Unit: yyyy mon dd

What was the Subject's status?	Site Terminated by Sponsor ☐ Completed ☐ Death ☐ Lost to Follow-Up ☐ Physician Decision ☐ Screen Failure ☐ Study Terminated by Sponsor ☐ Withdrawal by Subject ☐ Other ☐

If the Subject's status is:

•Other

please make sure that the 'Status, specify' field is filled in.

Status, specify	

If the Subject's status is:

•Death

please make sure that appropriate corresponding forms have been filled in.

Subject's status was related to a global/country situation	Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Investigator Review
Form: Investigator Review (INVRE)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2308 2023-08-11)

Date(s) of ongoing eCRF review by investigator Fixed Unit: yyyy mon dd

Note to Investigator: By completing this form the investigator indicates he/she has conducted ongoing review of data on the case report forms for this study participant.

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Survival Status
Form: Survival Status (SURVIVE)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: ON2102 2022-03-07)

Date Subject confirmed to be alive	Fixed Unit: yyyy mon dd
Date of the latest unsuccessful contact attempt	Fixed Unit: yyyy mon dd

(Version: AZ2403 2024-03-25)

Were any Device Events reported during Mandatory screening tumor sample (SPCBEDT1) collection?	No ☐ Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Device Events
Form: Device Events (DE)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2403 2024-03-25)

Please include only device event related information and remember to keep chronological order.
Avoid duplicating non-relevant details recorded in eCRF fields (e. g. demographics, medical history, concomitant medications, etc.) and make sure that event text is consistent with data entered in fields.
Do not provide personal information, e.g., names, private aspects.

NOTE: Make sure device event description does not exceed 1999 characters due to reporting limitations and integration with the Safety database. Do not copy paste any text to avoid disallowed characters.

Device event description in chronological order:

•event description (circumstances leading to the event and detail of the event itself)

•when the event occurred (before, during, or after surgery/administration)

•procedure details

•date of surgical procedure (only if that info is not captured in another device eCRF field)

•how the product was administered

•how the product was used

•action or medical intervention taken

•availability of medical device for evaluation

•relevant follow-up information (events where there is potential for patient impact)

NOTE: Please make sure to report all medical treatment in forms as specified in the eCRF Instructions, including new medications and any changes in treatment due to the event.

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Device Events
Form: Device Events (DE)
Generated On: 2025 Nov 20 12:27 (GMT)

Keep free text formatting in readable manner by:

•start sentence/phrase with capital letter and end with full stop.

•provide date in standard format DD-MON-YYYY (where MON is represented by 3-letter English abbreviation).

•avoid merging word/number with special characters [e. g., in lab results], instead always separate each item with single space

•do not use whitespace characters, e. g. tab, instead always separate each item with single space;

•enter text continuously in the same line without using Enter key to move to the next line;

•do not use bullet points, hyphens etc.;

•do not use abbreviations/acronyms difficult to define;

Relationship to Subject	Study participant ■
Associated Person's Identifier	_____
Category of Device Event	Procedure ☐
Category of Device Event	In-vitro device deficiency ☐
Category of Device Event	Device deficiency ☐
Device Event number	_____
Standardized Device Event	AE related to biopsy ☐
	False positive (PD-L1) ☐
	False negative (PD-L1) ☐
	Other ☐
If other, specify Device Event	_____
Description of Device Event	_____
Device Event expected/unexpected	Expected ☐
	Unexpected (unanticipated) ☐
Device Event start date	Fixed Unit: yyyy mon dd
	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Device Events
Form: Device Events (DE)
Generated On: 2025 Nov 20 12:27 (GMT)

Device Event end date	Fixed Unit: yyyy mon dd
Any Adverse Event caused by this Device Event?	No ☐ Yes ☐
Serious Device Event	No ☐ Yes ☐
"If 'No', could the event have led to SAE?"	No ☐ Yes ☐
Outcome of Device Event	Recovered/resolved ☐ Recovered/resolved with sequelae ☐ Not recovered/not resolved ☐ Fatal ☐
Relationship to device	Not related ☐ Possible ☐ Probable ☐ Causal ☐
Relationship to procedure associated with the use of the device	Not related ☐ Possible ☐ Probable ☐ Causal ☐
Procedure name	
Device trade/brand name	
Device Identifier	
Current device location	Implanted ☐ Explanted ☐ Returned ☐ Installed ☐ Retained ☐ Discarded ☐ Unknown ☐ Other ■
Specify current device location	

Action taken date	Fixed Unit: yyyy mon dd
Party responsible for the device	Manufacturer

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Folder: Pregnancy Test
Form: Pregnancy Test (PREG1)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2008 2024-03-01)

Assessment applicable for Subject
No ☐
Yes ☐

Sampling date
Fixed Unit: yyyy mon dd

Pregnancy test (serum)
Negative ☐
Positive ☐

Pregnancy test (urine)
Negative ☐
Positive ☐

For a positive pregnancy test after first dose of study drug, fill in PREGREP (or the 'Pregnancy Outcome Report Form' [Part 1]) and send to the AstraZeneca Monitor.

If positive pregnancy test, the administration of study drug to that Subject must be discontinued immediately and the End of Study Treatment form (ETRT) filled in.

If Positive pregnancy test, and considered an AE, please fill in Adverse Event (AE) Form
(Pregnancy itself is not regarded as an adverse event unless there is a suspicion that AstraZeneca product may have interfered with the effectiveness of a contraceptive medication.)

Hidden Field (used for CF programming)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Annotated Trial Design
Form: Enrolment (ENROL)
Generated On: 2025 Nov 20 12:27 (GMT)

(Version: AZ2003 2020-03-31)	
What is the enrolment code?	
What is the study code?	D702NC00001
Study part code	A