D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Enrolment (ENROL)
Generated On: 2025 Nov 20 12:23 (GMT)

(Version: AZ2003 2020-03-31)	
What is the enrolment code?	2
What is the study code?	D702NC00001 3
Study part code	A 4

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Enrolment (ENROL)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	SUBJECT	$8	What is the enrolment code?	$8	Enrolment Code	
3	STUDY	$11	What is the study code?	$11	Study Code	D702NC00001
4	PART	$1	Study part code	$1	Study Part Code	A

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:23 (GMT)

(Version: AZ2305 2023-05-29)

Visit not done	Yes ☐	2
What is the date of the visit?	Fixed Unit: yyyy mon dd _____	3
What was the contact mode?	Remote-audio ☐ Remote-video ☐ On-site visit ☐ Other ☐	4
If Other, specify	_____	5
Visit was impacted by global/country situation	Yes ☐	6
IVRS Date	_____	7

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Visit Date (VISIT)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	VISITND	$6	Visit not done	$6	Visit Not Done	C49488 = Yes
3	VIS_DAT	yyyy MMM dd	What is the date of the visit?		Visit Date	
4	VECNTMOD	$2	What was the contact mode?	$2	Contact Mode	1 = Remote-audio 2 = Remote-video 3 = On-site visit 99 = Other
5	VECNMODO	$200	If Other, specify	$200	Contact Mode, Other	
6	VESPCHGI	$6	Visit was impacted by global/country situation	$6	Global/Country Situation Relat Indicator	C49488 = Yes
7	Z_VISTDT	yyyy MMM dd	IVRS Date			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Unscheduled Visit (UNS_VIS)
Generated On: 2025 Nov 20 12:23 (GMT)

Please choose the form(s) required for this unscheduled visit		
Physical Examination (PE)		2
Vital Signs (VS4)		3
ECOG Performance Status (ECOG)		4
ECG Test Results (EG)		5
Additional ECG (EG1)		6
Additional ECG (EG2)		7
Echocardiography (ECHOC)		8
Pregnancy Test (PREG1)		9
Non-central Laboratory Test Results - Chemistry (LB)		10
Non-central Laboratory Test Results - Hematology (LB1)		11
Non-central Laboratory Test Results - Coagulation (LB2)		12
Non-central Laboratory Test Results - Thyroid function test (LB3)		13
Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)		14
Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)		15
Non-central Laboratory Test Results - Urinalysis (LB6)		16
Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)		17
Non-central Laboratory Test Results - Hy’s Law (LB8)		18
Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)		19
Non-central Laboratory Test Results - Tuberculosis testing (LB10)		20
Non-central Laboratory Test Results - HIV testing (LB11)		21
Non-central Laboratory Test Results - Additional Chemistry (LB12)		22
Sample Collection, Predose_ADA Sample (SPCBEDB)		23
Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)		24
PBMC for immune profiling_Pre dose (SPCBEDB2)		25
Whole blood for RNA analysis_Pre-dose (SPCBEDB3)		26
Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)		27
Sample Collection, ADA Sample (SPCBEDB5)		28
Blood sample for plasma ctDNA (SPCBEDB6)		29
Genomics Initiative (optional), exploratory genetic sample (SPCGB)		30
Optional on study tumor sample (SPCBEDT)		31
Biological Sample Collection, PK (SPCPKB2)		32

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Unscheduled Visit (UNS_VIS)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	UNS_FRM1	1	Physical Examination (PE)			
3	UNS_FRM2	1	Vital Signs (VS4)			
4	UNS_FRM3	1	ECOG Performance Status (ECOG)			
5	UNS_FRM4	1	ECG Test Results (EG)			
6	UNS_FRM31	1	Additional ECG (EG1)			
7	UNS_FRM32	1	Additional ECG (EG2)			
8	UNS_FRM5	1	Echocardiography (ECHOC)			
9	UNS_FRM6	1	Pregnancy Test (PREG1)			
10	UNS_FRM7	1	Non-central Laboratory Test Results - Chemistry (LB)			
11	UNS_FRM8	1	Non-central Laboratory Test Results - Hematology (LB1)			
12	UNS_FRM9	1	Non-central Laboratory Test Results - Coagulation (LB2)			
13	UNS_FRM10	1	Non-central Laboratory Test Results - Thyroid function test (LB3)			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Unscheduled Visit (UNS_VIS)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
14	UNS_FRM11	1	Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)			
15	UNS_FRM12	1	Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)			
16	UNS_FRM13	1	Non-central Laboratory Test Results - Urinalysis (LB6)			
17	UNS_FRM14	1	Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)			
18	UNS_FRM15	1	Non-central Laboratory Test Results - Hy’s Law (LB8)			
19	UNS_FRM16	1	Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)			
20	UNS_FRM26	1	Non-central Laboratory Test Results - Tuberculosis testing (LB10)			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Unscheduled Visit (UNS_VIS)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
21	UNS_FRM27	1	Non-central Laboratory Test Results - HIV testing (LB11)			
22	UNS_FRM28	1	Non-central Laboratory Test Results - Additional Chemistry (LB12)			
23	UNS_FRM17	1	Sample Collection, Predose_ADA Sample (SPCBEDB)			
24	UNS_FRM18	1	Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)			
25	UNS_FRM19	1	PBMC for immune profiling_Pre dose (SPCBEDB2)			
26	UNS_FRM20	1	Whole blood for RNA analysis_Pre-d ose (SPCBEDB3)			
27	UNS_FRM21	1	Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)			
28	UNS_FRM22	1	Sample Collection, ADA Sample (SPCBEDB5)			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Unscheduled Visit (UNS_VIS)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
29	UNS_FRM23	1	Blood sample for plasma ctDNA (SPCBEDB6)			
30	UNS_FRM29	1	Genomics Initiative (optional), exploratory genetic sample (SPCGB)			
31	UNS_FRM30	1	Optional on study tumor sample (SPCBEDT)			
32	UNS_FRM24	1	Biological Sample Collection, PK (SPCPKB2)			

(Version: AZ2309 2023-09-14)

What was the Protocol milestone?	Main Informed Consent (2)
What was the main informed consent date?	Fixed Unit: yyyy mon dd (3)

What was the Protocol milestone?	Optional Consent (4)
Optional consent category	Participation to Optional Blood Tests (5) ■ 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 ☐ (6) Yes ☐ Not applicable ☐
Optional consent date	Fixed Unit: yyyy mon dd (7)

Optional consent category	Participation to Optional Blood Tests ☐ (5) 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 ☐ (6) Yes ☐

	Not applicable ☐
Optional consent date	Fixed Unit: yyyy mon dd (7)
Optional consent category	Participation to Optional Blood Tests ☐ (5) 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 ☐ (6) Yes ☐ Not applicable ☐
Optional consent date	Fixed Unit: yyyy mon dd (7)
Optional consent category	Participation to Optional Blood Tests ☐ (5) 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 ☐ (6) Yes ☐ Not applicable ☐

Optional consent date	Fixed Unit: yyyy mon dd (7)
Optional consent category	Participation to Optional Blood Tests (5) 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 (6) Yes Not applicable
Optional consent date	Fixed Unit: yyyy mon dd (7)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Informed Consent (CONSENT)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	DSTERM0	$40	What was the Protocol milestone?	$40	Disposition Event Reported Term	Main Informed Consent
3	DSSTDAT0	yyyy MMM dd	What was the main informed consent date?		Disposition Event Start Date	
4	DSTERM6	$40	What was the Protocol milestone?	$40	Disposition Event Reported Term	Optional Consent
5	DSODECOD	$2	Optional consent category	$2	Optional Consent	25 = Participation to Optional Blood Tests 31 = Optional services and the transfer of contact details to service providers 33 = Use of coded data (including images), biosamples and analysis of genetic information as required for future research 27 = Participation to Optional Biopsy at first day of Cycle 3 of study treatment

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Informed Consent (CONSENT)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						28 = Participation to Optional Biopsy at Cancer Progression
6	OCOCATNY	$6	Optional consent/assent obtained	$6	Optional Consent/Assent Obtained	C49487 = No C49488 = Yes C48660 = Not applicable
7	DSSTDAT6	yyyy MMM dd	Optional consent date		Disposition Event Start Date	

(Version: AZ2309 2023-09-14)

What was the Protocol version?		2
What was the Protocol milestone?	Main Informed Consent	3
What was the main informed consent date?	Fixed Unit: yyyy mon dd	4
What was the Protocol milestone?	Optional Consent	5
Optional consent category	Participation to Optional Blood Tests ■	6
	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 ☐	7
	Yes ☐	
	Not applicable ☐	
Optional consent date	Fixed Unit: yyyy mon dd	8
Optional consent category	Participation to Optional Blood Tests ☐	6
	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 ☐	7

	Yes ☐ Not applicable ☐
Optional consent date	Fixed Unit: yyyy mon dd 8
Optional consent category	Participation to Optional Blood Tests ☐ 6 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 ☐ 7 Yes ☐ Not applicable ☐
Optional consent date	Fixed Unit: yyyy mon dd 8
Optional consent category	Participation to Optional Blood Tests ☐ 6 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 ☐ 7 Yes ☐ Not applicable ☐

Optional consent date	Fixed Unit: yyyy mon dd (8)
Optional consent category	Participation to Optional Blood Tests ☐ (6) 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 ☐ (7) Yes ☐ Not applicable ☐
Optional consent date	Fixed Unit: yyyy mon dd (8)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Informed Consent- Reconsent (CONSENT1)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	DSASPID	3	What was the Protocol version?	8	Protocol Version	
3	DSTERM0	$40	What was the Protocol milestone?	$40	Disposition Event Reported Term	Main Informed Consent
4	DSSTDAT0	yyyy MMM dd	What was the main informed consent date?		Disposition Event Start Date	
5	DSTERM6	$40	What was the Protocol milestone?	$40	Disposition Event Reported Term	Optional Consent
6	DSODECOD	$2	Optional consent category	$2	Optional Consent	25 = Participation to Optional Blood Tests 31 = Optional services and the transfer of contact details to service providers 33 = Use of coded data (including images), biosamples and analysis of genetic information as required for future research 27 = Participation to Optional Biopsy at first day of Cycle 3 of study treatment

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Informed Consent- Reconsent (CONSENT1)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						28 = Participation to Optional Biopsy at Cancer Progression
7	OCOCATNY	$6	Optional consent/assent obtained	$6	Optional Consent/Assent Obtained	C49487 = No C49488 = Yes C48660 = Not applicable
8	DSSTDAT6	yyyy MMM dd	Optional consent date		Disposition Event Start Date	

(Version: AZ2203 2023-11-02)

What is the Subject's date of birth?	Fixed Unit: yyyy mon dd	2
What is the Subject's age?		3
What is the age unit used?	Years	4
What is the sex of the Subject?	Female	5
	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	7
	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	9
Which racial designation best describes you - Native Hawaiian or other Pacific Islander?	Native Hawaiian or other Pacific Islander	10
Which racial designation best describes you - American Indian or Alaska Native?	American Indian or Alaska Native	11
Which racial designation best describes you - Asian?	Asian	12
Which racial designation best describes you - White?	White	13
Which racial designation best describes you? (Not reported)	Not reported	14
Which racial designation best describes you - Other?	Other	15
What was the Other race?		16
RSG Field for Ethnic origin		17

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Demographics (DM)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	BRTHDAT	yyyy MMM-dd-	What is the Subject's date of birth?		Date of Birth	
3	AGE	3	What is the Subject's age?	8	Age	
4	AGEU	$6	What is the age unit used?	$6	Age Unit	C29848 = Years
5	SEX	$6	What is the sex of the Subject?	$6	Sex	C16576 = Female C20197 = Male
7	ETHNIC	$6	Do you consider yourself Hispanic/Latino or not Hispanic/Latino?	$6	Ethnicity	C17459 = Hispanic or Latino C41222 = Not Hispanic or Latino C43234 = Not reported
9	RACE1	$6	Which racial designation best describes you - Black or African American?	$6	Race	C16352 = Black or African American
10	RACE2	$6	Which racial designation best describes you - Native Hawaiian or other Pacific Islander?	$6	Race	C41219 = Native Hawaiian or other Pacific Islander
11	RACE3	$6	Which racial designation best describes you - American Indian or Alaska Native?	$6	Race	C41259 = American Indian or Alaska Native

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Demographics (DM)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
12	RACE4	$6	Which racial designation best describes you - Asian?	$6	Race	C41260 = Asian
13	RACE5	$6	Which racial designation best describes you - White?	$6	Race	C41261 = White
14	RACE7	$6	Which racial designation best describes you? (Not reported)	$6	Race	C43234 = Not reported
15	RACE6	$6	Which racial designation best describes you - Other?	$6	Race	C17649 = Other
16	RACEOTH	$200	What was the Other race?	$200	Race Other	
17	Z_RACETH	$1999	RSG Field for Ethnic origin			

(Version: AZ2310 2023-10-06)

What was the Protocol milestone?	Genomics Initiative Informed Consent	2
What was the genomics initiative informed consent date?	Fixed Unit: yyyy mon dd	3
Optional genomics initiative consent	Use of coded data and biosamples for optional multi-omics research including the analyses of genomic information	4
Optional consent/assent obtained	No Yes Not applicable	5

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Informed Consent - Genomics Initiative (ICFGEN)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	DSTERM7	$40	What was the Protocol milestone?	$40	Disposition Event Reported Term	Genomics Initiative Informed Consent
3	DSSTDAT7	yyyy MMM dd	What was the genomics initiative informed consent date?		Disposition Event Start Date	
4	DSGDECOD	$2	Optional genomics initiative consent	$2	Optional Genomics Initiative Consent	2 = Use of coded data and biosamples for optional multi-omics research including the analyses of genomic information
5	OCOCATNY	$6	Optional consent/assent obtained	$6	Optional Consent/Assent Obtained	C49487 = No C49488 = Yes C48660 = Not applicable

(Version: AZ2506 2025-06-30)

Were all eligibility criteria met?	No ☐	2
	Yes ☐	
	Not applicable ☐	

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

Criterion type	Exclusion ☐	4
	Inclusion ☐	
Exception criterion identifier	_____	5
Exception criterion identifier	_____	6
What was the Protocol version?	_____	7

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Inclusion/Exclusion Criteria Not Met (IE)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	IEYN	$6	Were all eligibility criteria met?	$6	Met Criteria	C49487 = No C49488 = Yes C48660 = Not applicable
4	IECAT	$6	Criterion type	$6	Category of Inclusion/Exclusion Criteria	C25370 = Exclusion C25532 = Inclusion
5	Z_IETESTCD	$6	Exception criterion identifier			
6	IETESTCD	$6	Exception criterion identifier	$6	Inclusion/Exclusion Criterion	
7	DSASPID	3	What was the Protocol version?	8	Protocol Version	

(Version: AZ2506 2025-06-30)

Were all eligibility criteria met? (2)
- 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 (4)
- Exclusion ☐
- Inclusion ☐

Exception criterion identifier _____ (5)

Exception criterion identifier _____ (6)

What was the Protocol version? _____ (7)

Was Subject allocated a randomization code? (8)
- No ☐
- Yes ☐

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

If Yes, randomization code _____ (10)

What was the randomization date? Fixed Unit: yyyy mon dd (11)

_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Inclusion/Exclusion Criteria Not Met - Randomization (IE1)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	IEYN	$6	Were all eligibility criteria met?	$6	Met Criteria	C49487 = No C49488 = Yes C48660 = Not applicable
4	IECAT	$6	Criterion type	$6	Category of Inclusion/Exclusion Criteria	C25370 = Exclusion C25532 = Inclusion
5	Z_IETESTCD	$6	Exception criterion identifier			
6	IETESTCD	$6	Exception criterion identifier	$6	Inclusion/Exclusion Criterion	
7	DSASPID	3	What was the Protocol version?	8	Protocol Version	
8	DSCTERM	$6	Was Subject allocated a randomization code?	$6	Randomization Code Allocated	C49487 = No C49488 = Yes
10	PATIENT	7	If Yes, randomization code	8	Randomization Code	
11	DSCSTDAT	yyyy MMM dd	What was the randomization date?		Date of Randomization	

(Version: AZ2008 2020-08-05)

What was the group allocation?	Experimental arm (Rilvegostomig) ☐ 2 Control arm (Durvalumab) ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Group (GROUP)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	ASMGRPN	$2	What was the group allocation?	$2	Group	1 = Experimental arm (Rilvegostomig) 2 = Control arm (Durvalumab)

(Version: ON2503 2025-05-05)

Metastatic/locally advanced

- [ ] Locally advanced (2)
- [ ] Metastatic

Anatomical location

- [ ] Adrenal gland (3)
- [ ] 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 _____ (4)

Other metastatic site, specify _____ 5

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 ☐ 7
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 9

_____

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	LOCADMET	$7	Metastatic/locally advanced	$7	Metastatic/Locally Advanced	C124451 = Locally advanced C124452 = Metastatic
3	FALOC	$7	Anatomical location	$7	Location	C12666 = Adrenal gland 1 = Ascites C12678 = Biliary tract C12414 = Bladder C12366 = Bone C12439 = Brain C106042 = Distant lymph node C12389 = Esophagus C12377 = Gallbladder C12810 = Genitourinary system C12415 = Kidney C12379 = Large intestine C12392 = Liver C12468 = Lung C12748 = Mediastinum C33209 = Omentum C12393 = Pancreas 2 = Pericardial effusion C12770 = Peritoneum

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						C12469 = Pleura 3 = Pleural effusion C12390 = Rectum C49018 = Regional lymph node C12470 = Skin C12386 = Small intestine C12464 = Spinal cord C12432 = Spleen C12391 = Stomach 6 = Other locally advanced sites 7 = Other metastatic sites
4	LOSITEO	$200	Other locally advanced site, specify	$200	Other Locally Advanced Sites	
5	MSOTHJO	$200	Other metastatic site, specify	$200	Other Metastatic Sites	
7	RECCURCA	$6	Was there recurrence after curative intent resection of BTC?	$6	Recurrence of Earlier Cancer	C49487 = No C49488 = Yes
9	REC_DAT	yyyy MMM-dd-	Date of recurrence		First Local or Dist Diseas Recurren Date	

(Version: AZ2309 2024-02-15)

Has the Subject experienced any past and/or concomitant diseases?	No ☐ Yes ☐	2
Medical history term		3
Ongoing (at the time of enrollment)	No ☐ Yes ☐	4
Start date	Fixed Unit: yyyy mon dd	5
End date	Fixed Unit: yyyy mon dd	6
Any current medication	No ☐ Yes ☐	7

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: General Medical History (1MH)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	MHYN	$6	Has the Subject experienced any past and/or concomitant diseases?	$6	Any Medical History Event	C49487 = No C49488 = Yes
3	MHTERM	$200	Medical history term	$200	Medical History Event Reported Term	
4	MHONGO	$6	Ongoing (at the time of enrollment)	$6	Ongoing Medical History Event	C49487 = No C49488 = Yes
5	MHSTDAT	yyyy MMM-dd-	Start date		Medical History Event Start Date	
6	MHENDAT	yyyy MMM-dd-	End date		Medical History Event End Date	
7	MHCURM	$6	Any current medication	$6	Current Medication	C49487 = No C49488 = Yes

(Version: AZ2309 2024-02-15)

Medical history term	Hepatic cirrhosis (2)
[Medical condition/event]	No ☐ (3)
	Yes ☐
	Unknown ☐
Medical history event prespecified	Yes ■ (4)
Medical history term	Hepatitis B (2)
[Medical condition/event]	No ☐ (3)
	Yes ☐
	Unknown ☐
Medical history event prespecified	Yes ■ (4)
Medical history term	Hepatitis C (2)
[Medical condition/event]	No ☐ (3)
	Yes ☐
	Unknown ☐
Medical history event prespecified	Yes ■ (4)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Pre-specified medical conditions or events (2MH)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	MHTERM	$200	Medical history term	$200	Medical History Event Reported Term	Hepatic cirrhosis|Hepatitis B|Hepatitis C|
3	MHOCCUR	$6	[Medical condition/event]	$6	Medical History Occurrence	C49487 = No C49488 = Yes C17998 = Unknown
4	MHPRESP	$6	Medical history event prespecified	$6	Medical History Event Prespecified	C49488 = Yes

(Version: AZ2310 2023-10-16)

What was the category of the procedure?	SURGICAL PROCEDURE	2
Were any surgical procedures performed? (prior to enrollment)	No ☐	3
	Yes ☐	
Procedure name		4
Start date	Fixed Unit: yyyy mon dd	5
Current medication	No ☐	6
	Yes ☐	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Surgical History (HISS)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	PRCAT	$40	What was the category of the procedure?	$40	Procedure Category	SURGICAL PROCEDURE
3	PRYN	$6	Were any surgical procedures performed? (prior to enrollment)	$6	Any Procedures Performed	C49487 = No C49488 = Yes
4	PRTRT	$200	Procedure name	$200	Reported Name of Procedure	
5	PRSTDAT	yyyy MMM-dd-	Start date		Procedure Start Date	
6	CURMED	$6	Current medication	$6	Current Medication	C49487 = No C49488 = Yes

(Version: AZ2402 2024-02-16)

Select 'Yes' if all assessment forms are to be triggered	Yes ☐ 2

Assessment(s) type	Extent of Disease Upon Entry to Study (DISEXT) ☐ 3
	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 ☐ 4
	Yes ☐
Reason assessment form is not to be triggered	Assessment not performed ☐ 5
	Assessment not required ☐
	Subject discontinuation ☐
	Screen failure ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Assessment(s) Performed Triggering Form (ASMTRIG)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	ASMLEAD	$6	Select 'Yes' if all assessment forms are to be triggered	$6	All Assessments Triggered	C49488 = Yes
3	ASMTYP	$11	Assessment(s) type	$11	Assessment(s) Type	DISEXT = Extent of Disease Upon Entry to Study (DISEXT) PATHGOM = Pathology: at Screening (PATHGOM) 1MH = General Medical History (1MH) 2MH = Pre-specified medical conditions or events (2MH) HISS = Surgical History (HISS) PE = Physical Examination (PE) VS = Vital Signs - Weight, Height (VS) VS1 = Vital Signs - Before Infusion (VS1) VS2 = Vital Signs - End of Infusion (VS2)

Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
					VS3 = Vital Signs - Excluding Weight (VS3) VS4 = Vital Signs (VS4) ECOG = ECOG Performance Status (ECOG) EG = ECG Test Results (EG) EG1 = Additional ECG (EG1) EG2 = Additional ECG (EG2) ECHOC = Echocardiography (ECHOC) LB = Non-central Laboratory Test Results - Chemistry (LB) LB1 = Non-central Laboratory Test Results - Hematology (LB1) LB2 = Non-central Laboratory Test Results - Coagulation (LB2)

Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
					LB3 = Non-central Laboratory Test Results - Thyroid function test (LB3) LB4 = Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4) LB5 = Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5) LB6 = Non-central Laboratory Test Results - Urinalysis (LB6) LB7 = Non-central Laboratory Test Results - Hepatitis B and C testing (LB7) LB8 = Non-central Laboratory Test Results - Hy's Law (LB8)

Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
					LB9 = Non-central Laboratory Test Results - Interstitial Lung Disease (LB9) LB10 = Non-central Laboratory Test Results - Tuberculosis testing (LB10) LB11 = Non-central Laboratory Test Results - HIV testing (LB11) LB12 = Non-central Laboratory Test Results - Additional Chemistry (LB12) SPCBEDB = Sample Collection, Predose_ADA Sample (SPCBEDB) SPCBEDB1 = Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1) SPCBEDB2 = PBMC for immune profiling_Pre dose (SPCBEDB2)

Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
					SPCBEDB3 = Whole blood for RNA analysis_Pre-dose (SPCBEDB3) SPCBEDB4 = Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4) SPCBEDB5 = Sample Collection, ADA Sample (SPCBEDB5) SPCBEDB6 = Blood sample for plasma ctDNA (SPCBEDB6) SPCBEDT = Optional on study tumor sample at recurrence (SPCBEDT) SPCBEDT1 = Mandatory tumor sample from surgical resection for PDL1 analysis (SPCBEDT1) SPCPKB = Biological Sample Collection, Pre-dose PK (SPCPKB)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						SPCPKB1 = Biological Sample Collection, Post-dose PK (SPCPKB1) SPCPKB2 = Biological Sample Collection, PK (SPCPKB2) SU_NIC = Substance Use - Nicotine (SU_NIC) SU_ALC = Substance Use - Alcohol (SU_ALC) CAPRX = Prior Cancer Therapy (CAPRX) CAPRXR = Prior Radiotherapy (CAPRXR) SURVIVE = Survival Status (SURVIVE)
4	ASMTRIG	$6	Assessment form to be triggered	$6	Assessment(s) Triggered	C49487 = No C49488 = Yes
5	ASMREAST	$2	Reason assessment form is not to be triggered	$2	Reason Assessment Not Triggered	1 = Assessment not performed 2 = Assessment not required 3 = Subject discontinuation

Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
					4 = Screen failure

(Version: ON2407 2025-07-15)

Original diagnosis date	Fixed Unit: yyyy mon dd	2
Primary tumor location	Extrahepatic bile duct (distal) ☐	3
	Extrahepatic bile duct (perhilar) ☐	
	Gallbladder ☐	
	Intrahepatic bile duct ☐	
	Other ☐	
If Other, specify		4
Histology type	Adenosquamous carcinoma ☐	5
	Adenocarcinoma ☐	
	Other ☐	
If Other, specify		6
Indicate TNM classification for each section	TX ☐	7
Primary tumor	T1 ☐	
	T1a ☐	
	T1b ☐	
	T2 ☐	
	T2a ☐	
	T2b ☐	
	T3 ☐	
	T4 ☐	
Regional lymph nodes	N0 ☐	8
	N1 ☐	
	N2 ☐	
	NX ☐	
Distant metastases	M0 ☐	9
	Mx ☐	
	M1 ☐	
Tumor grade	Well differentiated (G1) ☐	10
	Moderately differentiated (G2) ☐	
	Poorly differentiated (G3) ☐	
	Unassessable (GX) ☐	

Stage/AJCC stage	Stage I ☐ 11
	Stage IA ☐
	Stage IB ☐
	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: Uniques
Form: Pathology at time of initial diagnosis of early stage BTC (PATHGEN)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	MHSTDAT	yyyy MMM-dd-	Original diagnosis date		Original Diagnosis Date	
3	PTUMLOC	$6	Primary tumor location	$6	Primary Tumor Location	C32573 = Extrahepatic bile duct (distal) 4 = Extrahepatic bile duct (perhilar) C12377 = Gallbladder C12677 = Intrahepatic bile duct 99 = Other
4	S_PTUML	$200	If Other, specify	$200	Specify Primary Tumor Location	
5	HSTLTYP	$3	Histology type	$3	Histology Type	204 = Adenosquamous carcinoma 501 = Adenocarcinoma 99 = Other
6	S_HSTLTY	$200	If Other, specify	$200	Histology Type Details	
7	TNM_T	$2	**Indicate TNM classification for each section** Primary tumor	$2	Primary Tumor	9 = TX 10 = T1 11 = T1a 12 = T1b 20 = T2 21 = T2a 22 = T2b 30 = T3 40 = T4
8	TNM_N	$2	Regional lymph nodes	$2	Regional Lymph Nodes	0 = N0 1 = N1 2 = N2 9 = NX

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Pathology at time of initial diagnosis of early stage BTC (PATHGEN)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
9	TNM_M	$2	Distant metastases	$2	Distant Metastases	0 = M0 1 = Mx 2 = M1
10	TUMGRADE	$2	Tumor grade	$2	Tumor Grade	1 = Well differentiated (G1) 2 = Moderately differentiated (G2) 3 = Poorly differentiated (G3) 5 = Unassessable (GX)
11	AJCC_STG	$2	Stage/AJCC stage	$2	Stage/AJCC Stage	10 = Stage I 11 = Stage IA 12 = Stage IB 20 = Stage II 21 = Stage IIA 22 = Stage IIB 30 = Stage III 31 = Stage IIIA 32 = Stage IIIB 33 = Stage IIIC 40 = Stage IV 41 = Stage IVA 42 = Stage IVB

(Version: ON2311 2025-03-12)

Date of Diagnosis of unresectable locally advanced or metastatic BTC	Fixed Unit: yyyy mon dd	2
Primary tumor location	Extrahepatic bile duct (distal) ☐ Extrahepatic bile duct (perhilar) ☐ Gallbladder ☐ Intrahepatic bile duct ☐ Other ☐	3
If 'Primary Tumor location' is 'Other' then provide the specification If Other, specify		4
Histology type	Adenosquamous carcinoma ☐ Adenocarcinoma ☐ Other ☐	5
If "Histology type" is 'Other' then provide the details. Histology type details		6
Indicate TNM classification for each section Primary tumor	TX ☐ T1 ☐ T1a ☐ T1b ☐ T2 ☐ T2a ☐ T2b ☐ T3 ☐ T4 ☐	7
Regional lymph nodes	N0 ☐ N1 ☐ N2 ☐ NX ☐	8
Distant metastases	M0 ☐ Mx ☐ M1 ☐	9
Tumor grade	Well differentiated (G1) ☐	10

	Moderately differentiated (G2) ☐
	Poorly differentiated (G3) ☐
	Unassessable (GX) ☐
Stage/AJCC stage	Stage II ☐ 11
	Stage IIA ☐
	Stage IIB ☐
	Stage III ☐
	Stage IIIA ☐
	Stage IIIB ☐
	Stage IIIC ☐
	Stage IV ☐
	Stage IVA ☐
	Stage IVB ☐

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	FADAT	yyyy MMM dd	Date of Diagnosis of unresectable locally advanced or metastatic BTC		Date of Collection	
3	PTUMLOC	$6	Primary tumor location	$6	Primary Tumor Location	C32573 = Extrahepatic bile duct (distal) 4 = Extrahepatic bile duct (perhilar) C12377 = Gallbladder C12677 = Intrahepatic bile duct 99 = Other
4	S_PTUML	$200	**If 'Primary Tumor location' is 'Other' then provide the specification** If Other, specify	$200	Specify Primary Tumor Location	
5	HSTLTYP	$3	Histology type	$3	Histology Type	204 = Adenosquamous carcinoma 501 = Adenocarcinoma 99 = Other
6	S_HSTLTY	$200	**If "Histology type" is 'Other' then provide the details.** Histology type details	$200	Histology Type Details	

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
7	TNM_T	$2	**Indicate TNM classification for each section** Primary tumor	$2	Primary Tumor	9 = TX 10 = T1 11 = T1a 12 = T1b 20 = T2 21 = T2a 22 = T2b 30 = T3 40 = T4
8	TNM_N	$2	Regional lymph nodes	$2	Regional Lymph Nodes	0 = N0 1 = N1 2 = N2 9 = NX
9	TNM_M	$2	Distant metastases	$2	Distant Metastases	0 = M0 1 = Mx 2 = M1
10	TUMGRADE	$2	Tumor grade	$2	Tumor Grade	1 = Well differentiated (G1) 2 = Moderately differentiated (G2) 3 = Poorly differentiated (G3) 5 = Unassessable (GX)
11	AJCC_STG	$2	Stage/AJCC stage	$2	Stage/AJCC Stage	20 = Stage II 21 = Stage IIA 22 = Stage IIB 30 = Stage III 31 = Stage IIIA 32 = Stage IIIB 33 = Stage IIIC 40 = Stage IV 41 = Stage IVA 42 = Stage IVB

(Version: ON2502 2025-06-27)

Was Pulmonary Function Test performed?	No ☐ Yes ☐	2
Date of collection	Fixed Unit: yyyy mon dd	3
Peripheral oxygen saturation	Fixed Unit: %	4
PaO2		5
PaO2 unit	kPa	6
FiO2 (Fraction of inspired oxygen)		7
Subject been prescribed oxygen therapy	No ☐ Yes ☐	8
Oxygen treatment start date	Fixed Unit: yyyy mon dd	9
Oxygen treatment stop date	Fixed Unit: yyyy mon dd	10
Oxygen treatment prior to study start	Yes ☐	11
Oxygen treatment continues	Yes ☐	12
Method oxygen provided	Nasal cannula ☐ Mask ☐ Other ☐	13

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Pulmonary Function Test (PULMOA)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	PFYN	$6	Was Pulmonary Function Test performed?	$6	Pulmonary Function Test Performed	C49487 = No C49488 = Yes
3	REDAT	yyyy MMM dd	Date of collection		Date of Collection	
4	SPO2	3	Peripheral oxygen saturation	8	Peripheral Oxygen Saturation (%)	
5	PAO_VAL	3.1	PaO2	8	PaO2	
6	PAOUNIT	$6	PaO2 unit	$6	PaO2 Unit	C67284 = kPa
7	FIO2	3.2	FiO2 (Fraction of inspired oxygen)	8	FiO2 (Fraction of Inspired Oxygen)	
8	OXYTH	$6	Subject been prescribed oxygen therapy	$6	Subject Been Prescribed Oxygen Therapy	C49487 = No C49488 = Yes
9	OXSDAT	yyyy MMM dd	Oxygen treatment start date		Oxygen Treatment Start Date	
10	OXEDAT	yyyy MMM dd	Oxygen treatment stop date		Oxygen Treatment Stop Date	
11	OXYTHP	$6	Oxygen treatment prior to study start	$6	Oxygen Treatment Prior to Study Start	C49488 = Yes
12	OXYTHC	$6	Oxygen treatment continues	$6	Oxygen Treatment Continues	C49488 = Yes
13	RECMETHD	$2	Method oxygen provided	$2	Method Oxygen Provided	1 = Nasal cannula 2 = Mask 99 = Other

(Version: AZ2409 2024-10-24)

What was the category of substance used?	Nicotine ■ (2)
Has the Subject ever smoked tobacco?	Current ☐ (3) Former ☐ Never ☐
Number of pack years	_____ (4)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Substance Use - Nicotine (SU_NIC)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	SUCAT	$2	What was the category of substance used?	$2	Category for Substance Use	1 = Nicotine
3	SUNCF	$6	Has the Subject ever smoked tobacco?	$6	Never Current Former Usage	C25471 = Current C25627 = Former C70543 = Never
4	SUCDOSE	3	Number of pack years	8	Number of Pack Years	

(Version: AZ1906 2024-11-19)

What was the category of the substance used?	Alcohol	2
Has the Subject ever used the substance?	Current	3
	Former	
	Never	

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

Type of substance	Wine	5
	Wine, fortified	
	Beer	
	Cider	
	Liquor/Spirits	
	Alcopop	
	Other	
If Other, specify		6
Alcohol consumption (units)		7
Frequency	Daily	8
	Per week	
	Per month	

Type of substance	Wine	5
	Wine, fortified	
	Beer	
	Cider	
	Liquor/Spirits	
	Alcopop	
	Other	
If Other, specify		6
Alcohol consumption (units)		7
Frequency	Daily	8
	Per week	
	Per month	

Type of substance	Wine	5
	Wine, fortified	
	Beer	

	Cider ☐
	Liquor/Spirits ☐
	Alcopop ☐
	Other ☐
If Other, specify	_____ (6)
Alcohol consumption (units)	_____ (7)
Frequency	Daily ☐ (8)
	Per week ☐
	Per month ☐
Type of substance	Wine ☐ (5)
	Wine, fortified ☐
	Beer ☐
	Cider ■
	Liquor/Spirits ☐
	Alcopop ☐
	Other ☐
If Other, specify	_____ (6)
Alcohol consumption (units)	_____ (7)
Frequency	Daily ☐ (8)
	Per week ☐
	Per month ☐
Type of substance	Wine ☐ (5)
	Wine, fortified ☐
	Beer ☐
	Cider ☐
	Liquor/Spirits ■
	Alcopop ☐
	Other ☐
If Other, specify	_____ (6)
Alcohol consumption (units)	_____ (7)
Frequency	Daily ☐ (8)
	Per week ☐
	Per month ☐

Type of substance	Wine ☐	5
	Wine, fortified ☐	
	Beer ☐	
	Cider ☐	
	Liquor/Spirits ☐	
	Alcopop ■	
	Other ☐	
If Other, specify	_____	6
Alcohol consumption (units)	_____	7
Frequency	Daily ☐	8
	Per week ☐	
	Per month ☐	

Type of substance	Wine ☐	5
	Wine, fortified ☐	
	Beer ☐	
	Cider ☐	
	Liquor/Spirits ☐	
	Alcopop ☐	
	Other ■	
If Other, specify	_____	6
Alcohol consumption (units)	_____	7
Frequency	Daily ☐	8
	Per week ☐	
	Per month ☐	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Substance Use - Alcohol (SU_ALC)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	SUCAT	$2	What was the category of the substance used?	$2	Category for Substance Use	2 = Alcohol
3	SUNCF	$6	Has the Subject ever used the substance?	$6	Never Current Former Usage	C25471 = Current C25627 = Former C70543 = Never
5	SUTRT	$2	Type of substance	$2	Substance Use Name	1 = Wine 2 = Wine, fortified 3 = Beer 4 = Cider 5 = Liquor/Spirits 6 = Alcopop 99 = Other
6	SUTRTOTH	$200	If Other, specify	$200	Other Substance Type Specification	
7	SUDOSE	4.1	Alcohol consumption (units)	8	Substance Consumption (Units)	
8	SUDOSFRQ	$6	Frequency	$6	Frequency	C25473 = Daily C67069 = Per week C64498 = Per month

(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 ☐ 4
Yes ☐

What was the date of the physical examination? Fixed Unit: yyyy mon dd 5

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Physical Examination (PE)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
4	PEPERF	$6	Was the physical examination performed?	$6	Physical Examination Performed	C49487 = No C49488 = Yes
5	PEDAT	yyyy MMM dd	What was the date of the physical examination?		Date of Physical Examination	

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐	2
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd	3
Time	Fixed Unit: 24-hour clock	4
Pulse	Fixed Unit: beats/min	5
SBP	Fixed Unit: mmHg	6
DBP	Fixed Unit: mmHg	7
Respiration rate	Fixed Unit: breaths/min	8
Temperature		9
Temperature unit	C	10
Peripheral oxygen saturation	Fixed Unit: %	11
Weight		12
Weight unit	kg	13
Height		14
Height unit	cm	15
EHRID		16

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Vital Signs - Weight, Height (VS)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	VSPERF	$6	Were vital signs collected?	$6	Vital Signs Performed	C49487 = No C49488 = Yes
3	VSDAT	yyyy MMM dd	What was the date of the vital signs measurement?		Vital Signs Date	
4	VSTIM	HH:nn	Time		Vital Signs Time	
5	PULSE	3	Pulse	8	Pulse (beats/min)	
6	SBP	3	SBP	8	SBP (mmHg)	
7	DBP	3	DBP	8	DBP (mmHg)	
8	RRATE	3	Respiration rate	8	Respiration Rate (breaths/min)	
9	TEMP	4.1	Temperature	8	Temperature	
10	TEMPU	$6	Temperature unit	$6	Temperature Unit	C42559 = C
11	SPO2	3	Peripheral oxygen saturation	8	Peripheral Oxygen Saturation (%)	
12	WEIGHT	6.1	Weight	8	Weight	
13	WEIGHTU	$6	Weight unit	$6	Weight Unit	C28252 = kg
14	HEIGHT	4.1	Height	8	Height	
15	HEIGHTU	$6	Height unit	$6	Height Unit	C49668 = cm
16	Z_EHR_ID	$200	EHRID			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Vital Signs - Before Infusion (VS1)
Generated On: 2025 Nov 20 12:23 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐	2
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd	3
Protocol schedule	Prior to Infusion	4
Time	Fixed Unit: 24-hour clock	5
Pulse	Fixed Unit: beats/min	6
SBP	Fixed Unit: mmHg	7
DBP	Fixed Unit: mmHg	8
Respiration rate	Fixed Unit: breaths/min	9
Temperature		10
Temperature unit	C	11
Peripheral oxygen saturation	Fixed Unit: %	12
Weight		13
Weight unit	kg	14
EHRID		15

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Vital Signs - Before Infusion (VS1)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	VSPERF	$6	Were vital signs collected?	$6	Vital Signs Performed	C49487 = No C49488 = Yes
3	VSDAT	yyyy MMM dd	What was the date of the vital signs measurement?		Vital Signs Date	
4	PROTSCHD	$20	Protocol schedule	$20	Protocol Schedule	Prior to Infusion|
5	VSTIM	HH:nn	Time		Vital Signs Time	
6	PULSE	3	Pulse	8	Pulse (beats/min)	
7	SBP	3	SBP	8	SBP (mmHg)	
8	DBP	3	DBP	8	DBP (mmHg)	
9	RRATE	3	Respiration rate	8	Respiration Rate (breaths/min)	
10	TEMP	4.1	Temperature	8	Temperature	
11	TEMPU	$6	Temperature unit	$6	Temperature Unit	C42559 = C
12	SPO2	3	Peripheral oxygen saturation	8	Peripheral Oxygen Saturation (%)	
13	WEIGHT	6.1	Weight	8	Weight	
14	WEIGHTU	$6	Weight unit	$6	Weight Unit	C28252 = kg
15	Z_EHR_ID	$200	EHRID			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Vital Signs - End of Infusion (VS2)
Generated On: 2025 Nov 20 12:23 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐	2
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd	3
Protocol schedule	End of Infusion	4
Time	Fixed Unit: 24-hour clock	5
Pulse	Fixed Unit: beats/min	6
SBP	Fixed Unit: mmHg	7
DBP	Fixed Unit: mmHg	8
Respiration rate	Fixed Unit: breaths/min	9
Temperature		10
Temperature unit	C ■	11
Peripheral oxygen saturation	Fixed Unit: %	12
EHRID		13

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Vital Signs - End of Infusion (VS2)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	VSPERF	$6	Were vital signs collected?	$6	Vital Signs Performed	C49487 = No C49488 = Yes
3	VSDAT	yyyy MMM dd	What was the date of the vital signs measurement?		Vital Signs Date	
4	PROTSCHD	$20	Protocol schedule	$20	Protocol Schedule	End of Infusion|
5	VSTIM	HH:nn	Time		Vital Signs Time	
6	PULSE	3	Pulse	8	Pulse (beats/min)	
7	SBP	3	SBP	8	SBP (mmHg)	
8	DBP	3	DBP	8	DBP (mmHg)	
9	RRATE	3	Respiration rate	8	Respiration Rate (breaths/min)	
10	TEMP	4.1	Temperature	8	Temperature	
11	TEMPU	$6	Temperature unit	$6	Temperature Unit	C42559 = C
12	SPO2	3	Peripheral oxygen saturation	8	Peripheral Oxygen Saturation (%)	
13	Z_EHR_ID	$200	EHRID			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Vital Signs - Excluding Weight (VS3)
Generated On: 2025 Nov 20 12:23 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐	2
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd	3
Time	Fixed Unit: 24-hour clock	4
Pulse	Fixed Unit: beats/min	5
SBP	Fixed Unit: mmHg	6
DBP	Fixed Unit: mmHg	7
Respiration rate	Fixed Unit: breaths/min	8
Temperature		9
Temperature unit	C ■	10
Peripheral oxygen saturation	Fixed Unit: %	11
EHRID		12

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Vital Signs - Excluding Weight (VS3)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	VSPERF	$6	Were vital signs collected?	$6	Vital Signs Performed	C49487 = No C49488 = Yes
3	VSDAT	yyyy MMM dd	What was the date of the vital signs measurement?		Vital Signs Date	
4	VSTIM	HH:nn	Time		Vital Signs Time	
5	PULSE	3	Pulse	8	Pulse (beats/min)	
6	SBP	3	SBP	8	SBP (mmHg)	
7	DBP	3	DBP	8	DBP (mmHg)	
8	RRATE	3	Respiration rate	8	Respiration Rate (breaths/min)	
9	TEMP	4.1	Temperature	8	Temperature	
10	TEMPU	$6	Temperature unit	$6	Temperature Unit	C42559 = C
11	SPO2	3	Peripheral oxygen saturation	8	Peripheral Oxygen Saturation (%)	
12	Z_EHR_ID	$200	EHRID			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Vital Signs (VS4)
Generated On: 2025 Nov 20 12:23 (GMT)

(Version: AZ2407 2024-07-05)

Were vital signs collected?	No ☐ Yes ☐	2
What was the date of the vital signs measurement?	Fixed Unit: yyyy mon dd	3
Time	Fixed Unit: 24-hour clock	4
Pulse	Fixed Unit: beats/min	5
SBP	Fixed Unit: mmHg	6
DBP	Fixed Unit: mmHg	7
Respiration rate	Fixed Unit: breaths/min	8
Temperature		9
Temperature unit	C	10
Peripheral oxygen saturation	Fixed Unit: %	11
Weight		12
Weight unit	kg	13
EHRID		14

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Vital Signs (VS4)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	VSPERF	$6	Were vital signs collected?	$6	Vital Signs Performed	C49487 = No C49488 = Yes
3	VSDAT	yyyy MMM dd	What was the date of the vital signs measurement?		Vital Signs Date	
4	VSTIM	HH:nn	Time		Vital Signs Time	
5	PULSE	3	Pulse	8	Pulse (beats/min)	
6	SBP	3	SBP	8	SBP (mmHg)	
7	DBP	3	DBP	8	DBP (mmHg)	
8	RRATE	3	Respiration rate	8	Respiration Rate (breaths/min)	
9	TEMP	4.1	Temperature	8	Temperature	
10	TEMPU	$6	Temperature unit	$6	Temperature Unit	C42559 = C
11	SPO2	3	Peripheral oxygen saturation	8	Peripheral Oxygen Saturation (%)	
12	WEIGHT	6.1	Weight	8	Weight	
13	WEIGHTU	$6	Weight unit	$6	Weight Unit	C28252 = kg
14	Z_EHR_ID	$200	EHRID			

(Version: ON2406 2024-06-04)

Clinical classification category	ECOG 2
What was the date the response or clinical classification was performed?	Fixed Unit: yyyy mon dd 3
Performance status	0-Fully active, able to carry on all pre-disease performance without restriction 4 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: Uniques
Form: ECOG Performance Status (ECOG)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	RSCAT	$7	Clinical classification category	$7	Category for Response or Clin Class	C102116 = ECOG
3	RSDAT	yyyy MMM dd	What was the date the response or clinical classification was performed?		Response or Clin Class Assessment Date	
4	ECOG101	$2	Performance status	$2	ECOG1-Performance Status	0 = 0-Fully active, able to carry on all pre-disease performance without restriction 1 = 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

Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
					2 = 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 = 3-Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours 4 = 4-Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair 5 = 5-Dead

(Version: AZ2112 2024-08-09)

Was the ECG performed?	No ☐ Yes ☐	2
What was the date of the ECG?	Fixed Unit: yyyy mon dd	3
ECG time	Fixed Unit: 24-hour clock	4
ECG mean heart rate	Fixed Unit: beats/min	5
QRS duration	Fixed Unit: ms	6
RR interval	Fixed Unit: ms	7
PR interval	Fixed Unit: ms	8
QT interval	Fixed Unit: ms	9
QTc interval Fridericia	Fixed Unit: ms	10
What was the interpretation of the ECG?	Normal ☐ Abnormal ☐	11
Reason, abnormal overall ECG evaluation		12
Was the ECG clinically significant?	No ☐ Yes ☐	13

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: ECG Test Results (EG)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	EGPERF	$6	Was the ECG performed?	$6	ECG Performed	C49487 = No C49488 = Yes
3	EGDAT	yyyy MMM dd	What was the date of the ECG?		Date of ECG	
4	EGTIM	HH:nn	ECG time		Time of ECG	
5	ECGHRMN	3	ECG mean heart rate	8	ECG Mean Heart Rate (beats/min)	
6	ECGQRS	3	QRS duration	8	QRS Duration (ms)	
7	ECGRR	4	RR interval	8	RR Interval (ms)	
8	ECGPR	3	PR interval	8	PR Interval (ms)	
9	ECGQT	3	QT interval	8	QT Interval (ms)	
10	ECGQTCF	3	QTc interval Fridericia	8	QTc Interval Fridericia (ms)	
11	INTP	$2	What was the interpretation of the ECG?	$2	ECG Interpretation	0 = Normal 1 = Abnormal
12	INTPR	$200	Reason, abnormal overall ECG evaluation	$200	Reason, Abnormal Overall ECG Evaluation	
13	EGCLSIG	$6	Was the ECG clinically significant?	$6	Clinical Significance	C49487 = No C49488 = Yes

(Version: AZ2112 2024-08-09)

Was the ECG performed?	No ☐ Yes ☐	2
What was the date of the ECG?	Fixed Unit: yyyy mon dd	3
ECG time	Fixed Unit: 24-hour clock	4
ECG mean heart rate	Fixed Unit: beats/min	5
QRS duration	Fixed Unit: ms	6
RR interval	Fixed Unit: ms	7
PR interval	Fixed Unit: ms	8
QT interval	Fixed Unit: ms	9
QTc interval Fridericia	Fixed Unit: ms	10
What was the interpretation of the ECG?	Normal ☐ Abnormal ☐	11
Reason, abnormal overall ECG evaluation		12
Was the ECG clinically significant?	No ☐ Yes ☐	13

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Additional ECG (EG1)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	EGPERF	$6	Was the ECG performed?	$6	ECG Performed	C49487 = No C49488 = Yes
3	EGDAT	yyyy MMM dd	What was the date of the ECG?		Date of ECG	
4	EGTIM	HH:nn	ECG time		Time of ECG	
5	ECGHRMN	3	ECG mean heart rate	8	ECG Mean Heart Rate (beats/min)	
6	ECGQRS	3	QRS duration	8	QRS Duration (ms)	
7	ECGRR	4	RR interval	8	RR Interval (ms)	
8	ECGPR	3	PR interval	8	PR Interval (ms)	
9	ECGQT	3	QT interval	8	QT Interval (ms)	
10	ECGQTCF	3	QTc interval Fridericia	8	QTc Interval Fridericia (ms)	
11	INTP	$2	What was the interpretation of the ECG?	$2	ECG Interpretation	0 = Normal 1 = Abnormal
12	INTPR	$200	Reason, abnormal overall ECG evaluation	$200	Reason, Abnormal Overall ECG Evaluation	
13	EGCLSIG	$6	Was the ECG clinically significant?	$6	Clinical Significance	C49487 = No C49488 = Yes

(Version: AZ2112 2024-08-09)

Was the ECG performed?	No ☐ Yes ☐	2
What was the date of the ECG?	Fixed Unit: yyyy mon dd	3
ECG time	Fixed Unit: 24-hour clock	4
ECG mean heart rate	Fixed Unit: beats/min	5
QRS duration	Fixed Unit: ms	6
RR interval	Fixed Unit: ms	7
PR interval	Fixed Unit: ms	8
QT interval	Fixed Unit: ms	9
QTc interval Fridericia	Fixed Unit: ms	10
What was the interpretation of the ECG?	Normal ☐ Abnormal ☐	11
Reason, abnormal overall ECG evaluation		12
Was the ECG clinically significant?	No ☐ Yes ☐	13

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Additional ECG (EG2)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	EGPERF	$6	Was the ECG performed?	$6	ECG Performed	C49487 = No C49488 = Yes
3	EGDAT	yyyy MMM dd	What was the date of the ECG?		Date of ECG	
4	EGTIM	HH:nn	ECG time		Time of ECG	
5	ECGHRMN	3	ECG mean heart rate	8	ECG Mean Heart Rate (beats/min)	
6	ECGQRS	3	QRS duration	8	QRS Duration (ms)	
7	ECGRR	4	RR interval	8	RR Interval (ms)	
8	ECGPR	3	PR interval	8	PR Interval (ms)	
9	ECGQT	3	QT interval	8	QT Interval (ms)	
10	ECGQTCF	3	QTc interval Fridericia	8	QTc Interval Fridericia (ms)	
11	INTP	$2	What was the interpretation of the ECG?	$2	ECG Interpretation	0 = Normal 1 = Abnormal
12	INTPR	$200	Reason, abnormal overall ECG evaluation	$200	Reason, Abnormal Overall ECG Evaluation	
13	EGCLSIG	$6	Was the ECG clinically significant?	$6	Clinical Significance	C49487 = No C49488 = Yes

(Version: AZ2201 2024-09-27)

What was the date of the echocardiography?	Fixed Unit: yyyy mon dd	2
What was the time of the echocardiography?	Fixed Unit: 24-hour clock	3
What was the method used for the examination?	Echocardiography ☐ Multiple Gated Acquisition (MUGA) ☐	4
Was the image quality sufficient?	No ☐ Yes ☐	5
What was the overall ECHOC evaluation?	Normal ☐ Abnormal ☐	6
What is the reason the overall ECHOC evaluation was abnormal?		7
What was the left ventricular ejection fraction?	Fixed Unit: %	8
What was the LV end diastolic volume?	Fixed Unit: mL	9
What was the LV end systolic volume?	Fixed Unit: mL	10

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Echocardiography (ECHOC)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	CVDAT	yyyy MMM dd	What was the date of the echocardiography?		Date of Collection	
3	CVTIM	HH:nn	What was the time of the echocardiography?		Time of Collection	
4	CVMETHOD	$6	What was the method used for the examination?	$6	Method of Test or Examination	C16525 = Echocardiography C38073 = Multiple Gated Acquisition (MUGA)
5	ECIMAGEQ	$6	Was the image quality sufficient?	$6	Image Quality Sufficient	C49487 = No C49488 = Yes
6	ECEVAL	$6	What was the overall ECHOC evaluation?	$6	Overall ECHOC Evaluation	C14165 = Normal C25401 = Abnormal
7	ECEVALR	$1000	What is the reason the overall ECHOC evaluation was abnormal?	$1000	Reason Evaluation Abnormal	
8	ECLVEF	3	What was the left ventricular ejection fraction?	8	Left Ventricular Ejection Fraction (%)	
9	ECLVEDV	3	What was the LV end diastolic volume?	8	LV End Diastolic Volume (mL)	
10	ECLVESV	3	What was the LV end systolic volume?	8	LV End Systolic Volume (mL)	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Pregnancy Test - Screening (PREG)
Generated On: 2025 Nov 20 12:23 (GMT)

(Version: AZ2008 2024-03-01)

Assessment applicable for Subject
No ☐ 2
Yes ☐

Sampling date
Fixed Unit: yyyy mon dd 3

Pregnancy test (serum)
Negative ☐ 4
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) 8

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Pregnancy Test - Screening (PREG)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	ASM_APP	$6	Assessment applicable for Subject	$6	Assessment Applicable	C49487 = No C49488 = Yes
3	SAMP_DAT	yyyy MMM dd	Sampling date		Sampling Date	
4	PREGTSTS	$6	Pregnancy test (serum)	$6	Pregnancy Test (Serum)	C38757 = Negative C38758 = Positive
8	Z_PREG	$2	Hidden Field (used for CF programming)			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Pregnancy Test (PREG1)
Generated On: 2025 Nov 20 12:23 (GMT)

(Version: AZ2008 2024-03-01)

Assessment applicable for Subject	No ☐	2
	Yes ☐	
Sampling date	Fixed Unit: yyyy mon dd _____	3
Pregnancy test (serum)	Negative ☐	4
	Positive ☐	
Pregnancy test (urine)	Negative ☐	5
	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)	_____	9

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Pregnancy Test (PREG1)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	ASM_APP	$6	Assessment applicable for Subject	$6	Assessment Applicable	C49487 = No C49488 = Yes
3	SAMP_DAT	yyyy MMM dd	Sampling date		Sampling Date	
4	PREGTSTS	$6	Pregnancy test (serum)	$6	Pregnancy Test (Serum)	C38757 = Negative C38758 = Positive
5	PREGTSTU	$6	Pregnancy test (urine)	$6	Pregnancy Test (Urine)	C38757 = Negative C38758 = Positive
9	Z_PREG	$2	Hidden Field (used for CF programming)			

(Version: AZ2307 2024-10-23)

What was the date the reproductive system question was collected?	Fixed Unit: yyyy mon dd	2
Date of last menstrual period	Fixed Unit: yyyy mon dd	3
Date of expected delivery	Fixed Unit: yyyy mon dd	4
Using hormonal contraception or IUD	No ☐ Yes ☐	5
Hormonal contraception/IUD specification		6
Number of previous pregnancies		7
Number of normal deliveries		8
Number of spontaneous abortions		9
Number of other previous pregnancies		10
Other previous pregnancies, specify		11
Relevant pregnancy risk factor		12
Relevant family history		13

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Pregnancy Report (PREGREP)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	RPDAT	yyyy MMM dd	What was the date the reproductive system question was collected?		Reproductive System Finding Date	
3	PRMP_DAT	yyyy MMM dd	Date of last menstrual period		Date of Last Menstrual Period	
4	PRED_DAT	yyyy MMM dd	Date of expected delivery		Date of Expected Delivery	
5	PRCNTR	$6	Using hormonal contraception or IUD	$6	Using Hormonal Contraception or IUD	C49487 = No C49488 = Yes
6	S_PRCNTR	$200	Hormonal contraception/ IUD specification	$200	Hormonal Contraception/ IUD Specification	
7	PRVPREGN	2	Number of previous pregnancies	8	Number of Previous Pregnancies	
8	PRNDNX	2	Number of normal deliveries	8	Number of Normal Deliveries	
9	SPABORTN	2	Number of spontaneous abortions	8	Number of Spontaneous Abortions	
10	PROTHNX	2	Number of other previous pregnancies	8	Number of Other Previous Pregnancies	
11	S_PROTH	$200	Other previous pregnancies, specify	$200	Other Previous Pregnancies, Specify	
12	PRRISK	$200	Relevant pregnancy risk factor	$200	Relevant Pregnancy Risk Factor	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Pregnancy Report (PREGREP)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
13	PRFAMHIS	$200	Relevant family history	$200	Relevant Family History	

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐	2
What was the reason that the sample was not collected?		3
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐	4
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd	5
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock	6
Liver Function Tests		7
Alanine Aminotransferase (Serum/Plasma)		
Alkaline Phosphatase (Serum/Plasma)		8
Aspartate Aminotransferase (Serum/Plasma)		9
Bilirubin, Total (Serum/Plasma)		10
Bilirubin, Direct, (Conj) (Serum/Plasma)		11
Bilirubin, Indirect (Unconj.) (Serum/Plasma)		12
Gamma-Glutamyltransferase (Serum/Plasma)		13
Lactate Dehydrogenase (LDH) (Serum/Plasma)		14
Protein, Total (Serum/Plasma)		15
Pancreatic Enzymes		16
Amylase (Serum/Plasma)		
Lipase (Serum/Plasma)		17
Renal Function Tests		18
Creatinine (Serum/Plasma)		
Creatinine Clearance, Calculated (Urine 24h)		19
Creatinine Clearance, Cockcroft-Gault (Plasma)		20
Creatinine Clearance, Cockcroft-Gault (Serum)		21
Glomerular Filtration Rate (51Cr-EDTA) (Plasma)		22
Glomerular Filtration Rate (51Cr-EDTA) (Serum)		23
Urea (Serum/Plasma)		24
Urea Nitrogen (BUN) (Serum/Plasma)		25

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

Electrolytes Calcium, Ionized (Serum)		26
Total Calcium (Serum/Plasma)		27
Chloride (Serum/Plasma)		28
Magnesium (Serum/Plasma)		29
Phosphate (Phosphorus) (Serum/Plasma)		30
Potassium (Serum/Plasma)		31
Sodium (Serum/Plasma)		32
Proteins Albumin (Serum/Plasma)		33
Glucose Metabolism Glucose, Fasting (Serum/Plasma)		34
Glucose,Random (Serum/Plasma)		35
Hidden for Bilirubin		36
Hidden for Aspartate		37
Hidden for Alanine		38
Hidden for Alanine Range		39
Hidden for Asparate Range		40
Hidden for Bilirubin Range		41
Derived field to call CF		42

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	LBPERF	$6	Was the sample collected?	$6	Lab Performed	C49487 = No C49488 = Yes
3	LBREASND	$200	What was the reason that the sample was not collected?	$200	Reason Not Done	
4	LBCAT	$2	What was the name of the lab panel?	$2	Category for Lab Test	1 = Hematology 2 = Chemistry 3 = Urinalysis 4 = Coagulation 7 = Serology/Immunology
5	LBDAT	yyyy MMM dd	What was the date of the lab specimen collection?		Date of Specimen Collection	
6	LBTIM	HH:nn	What was the start time of the lab specimen collection?		Time of Specimen Collection	
7	55101_ALANINEAMINOT_SERUMPLASMA	9.3	**Liver Function Tests** Alanine Aminotransferase (Serum/Plasma)			
8	55104_ALKALINE_PHOSPHATASE_SERUMPLASMA	9.3	Alkaline Phosphatase (Serum/Plasma)			

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
9	55102_ASPARTATE_AMINOT_SERUMPLASMA	9.3	Aspartate Aminotransferase (Serum/Plasma)			
10	55110_BILIRUBIN_TOTAL_SERUMPLASMA	9.3	Bilirubin, Total (Serum/Plasma)			
11	55111_BILIRUBIN_DIRECT_CONJ_SERUM_PLASMA	9.3	Bilirubin, Direct, (Conj) (Serum/Plasma)			
12	55483_BILI_UCONJ_SERUMPLASMA	9.3	Bilirubin, Indirect (Unconj.) (Serum/Plasma)			
13	55103_GAMMA_GLUTAMYLTRANSFERASE_SERUM_PLASMA	9.3	Gamma-Glutamyltransferase (Serum/Plasma)			
14	55105_LACTATE_DEHYDROGENASE_SERUMPLASMA	9.3	Lactate Dehydrogenase (LDH) (Serum/Plasma)			
15	55120_PROTEIN_TOTAL_SERUMPLASMA	9.3	Protein, Total (Serum/Plasma)			
16	55107_AMY_SERUMPLASMA	9.3	**Pancreatic Enzymes** Amylase (Serum/Plasma)			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
17	55643_LIPASE_SERUMPLASMA	9.3	Lipase (Serum/Plasma)			
18	55108_CREATININE_SERUMPLASMA	9.3	**Renal Function Tests** Creatinine (Serum/Plasma)			
19	54211_CREATININE_CC_SERUMURINE	9.3	Creatinine Clearance, Calculated (Urine 24h)			
20	01BY0_CREATININE_CLEARANCE_COCKCROFT_GAULT_PLASMA	9.3	Creatinine Clearance, Cockcroft-Gault (Plasma)			
21	02BY0_CRCL_COCKCROFT_GAULT_SERUM	9.3	Creatinine Clearance, Cockcroft-Gault (Serum)			
22	01D50_GLOMERULAR_FILTRATION_RATE_51CREDTA_PLASMA	9.3	Glomerular Filtration Rate (51Cr-EDTA) (Plasma)			
23	02D50_GLOMERULAR_FILTRATION_RATE_51CREDTA_SERUM	9.3	Glomerular Filtration Rate (51Cr-EDTA) (Serum)			
24	55127_UREA_SERUMPLASMA	9.3	Urea (Serum/Plasma)			

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
25	55229_BLOOD_UREA_NITROGEN_SERUMPLASMA	9.3	Urea Nitrogen (BUN) (Serum/Plasma)			
26	02152_CALCIUM_IONIZED_SERUM	9.3	**Electrolytes** Calcium, Ionized (Serum)			
27	55114_CALCIUM_SERUMPLASMA	9.3	Total Calcium (Serum/Plasma)			
28	55116_CHLORIDE_SERUM_PLASMA	9.3	Chloride (Serum/Plasma)			
29	55115_MAGNESIUM_SERUMPLASMA	9.3	Magnesium (Serum/Plasma)			
30	55117_INORGANIC_PHOSPHATE_SERUMPLASMA	9.3	Phosphate (Phosphorus) (Serum/Plasma)			
31	55113_POTASSIUM_SERUMPLASMA	9.3	Potassium (Serum/Plasma)			
32	55112_SODIUM_SERUMPLASMA	9.3	Sodium (Serum/Plasma)			
33	55118_ALBUMIN_SERUMPLASMA	9.3	**Proteins** Albumin (Serum/Plasma)			
34	55121_GLUCOSE_FASTING_SERUM_PLASMA	9.3	**Glucose Metabolism** Glucose, Fasting (Serum/Plasma)			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Chemistry (LB)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
35	55706_GLUCOSERANDOM_SERUMPLASMA	9.3	Glucose,Random (Serum/Plasma)			
36	Z_INITIAL5	9.3	Hidden for Bilirubin			
37	Z_INITIAL4	9.3	Hidden for Aspartate			
38	Z_INITIAL3	9.3	Hidden for Alanine			
39	Z_RANGEALT	$2	Hidden for Alanine Range			
40	Z_RANGEAST	$2	Hidden for Asparate Range			
41	Z_RANGEBILI	$2	Hidden for Bilirubin Range			
42	Z_TIME	dd MMM yyyy hh:nn:ss	Derived field to call CF			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Hematology (LB1)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐	2
What was the reason that the sample was not collected?		3
What was the name of the lab panel?	Hematology ■ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐	4
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd	5
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock	6
Hemoglobin (Blood)		7
Hematocrit (Blood)		8
Leucocytes, Absolute Count (WBC) (Blood)		9
Platelet count (Blood)		10
Mean corpuscular volume (Blood)		11
Absolute Neutrophil Count (Blood)		12
Absolute Lymphocytes Count (Blood)		13
Absolute Monocytes Count (Blood)		14
Absolute Eosinophils,Count (Blood)		15
Neutrophils, %/Ratio (Blood)		16
Lymphocytes, %/Ratio (Blood)		17
Monocytes, %/Ratio (Blood)		18
Eosinophils, % /Ratio (Blood)		19

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Hematology (LB1)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	LBPERF	$6	Was the sample collected?	$6	Lab Performed	C49487 = No C49488 = Yes
3	LBREASND	$200	What was the reason that the sample was not collected?	$200	Reason Not Done	
4	LBCAT	$2	What was the name of the lab panel?	$2	Category for Lab Test	1 = Hematology 2 = Chemistry 3 = Urinalysis 4 = Coagulation 7 = Serology/Immunology
5	LBDAT	yyyy MMM dd	What was the date of the lab specimen collection?		Date of Specimen Collection	
6	LBTIM	HH:nn	What was the start time of the lab specimen collection?		Time of Specimen Collection	
7	04004_HAEMOGLOBIN_BLOOD	9.3	Hemoglobin (Blood)			
8	04002_HAEMATOCRIT_BLOOD	9.3	Hematocrit (Blood)			
9	04005_LEUCOCYTES_WBC_BLOOD	9.3	Leucocytes, Absolute Count (WBC) (Blood)			
10	04006_PLATELETS_BLOOD	9.3	Platelet count (Blood)			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Hematology (LB1)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
11	04045_MEAN_CELL_VOLUME_BLOOD	9.3	Mean corpuscular volume (Blood)			
12	04032_NEUTROPHILS_ABSOLUTE_COUNT_BLOOD	9.3	Absolute Neutrophil Count (Blood)			
13	04051_LYMPHOCYTES_ABSOLUTE_COUNT_BLOOD	9.3	Absolute Lymphocytes Count (Blood)			
14	04052_MONOCYTES_ABSOLUTE_COUNT_BLOOD	9.3	Absolute Monocytes Count (Blood)			
15	04042_EOSINOPHILS_ABSOLUTE_COUNT_BLOOD	9.3	Absolute Eosinophils,Count (Blood)			
16	04049_NEUTROPHILS_RATIO_BLOOD	9.3	Neutrophils, %/Ratio (Blood)			
17	04035_LYMPHOCYTES_RATIO_BLOOD	9.3	Lymphocytes, %/Ratio (Blood)			
18	04036_MONOCYTES_RATIO_BLOOD	9.3	Monocytes, %/Ratio (Blood)			
19	04033_EOSINOPHILS_RATIO_BLOOD	9.3	Eosinophils, % /Ratio (Blood)			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Coagulation (LB2)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐	2
What was the reason that the sample was not collected?		3
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ■ Serology/Immunology ☐	4
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd	5
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock	6
Activated Partial Thromboplastin Time (APTT) (sec) (Blood)		7
Activated Partial Thromboplast. Time,Rel (APTT relative) (%, ratio) (Blood)		8
Fibrinogen (Blood)		9
Partial Thromboplastin Time (PTT) (sec) (Blood)		10
Partial Thromboplastin Time, Rel (PTT Relative) (%, ratio) (Blood)		11
Prothrombin Complex INR (Blood) (%,ratio) (Blood)		12
Prothrombin Time (PT) (sec) (Blood)		13
Prothrombin Time, Relative (PT Relative) (%, ratio) (Blood)		14

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Coagulation (LB2)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	LBPERF	$6	Was the sample collected?	$6	Lab Performed	C49487 = No C49488 = Yes
3	LBREASND	$200	What was the reason that the sample was not collected?	$200	Reason Not Done	
4	LBCAT	$2	What was the name of the lab panel?	$2	Category for Lab Test	1 = Hematology 2 = Chemistry 3 = Urinalysis 4 = Coagulation 7 = Serology/Immunology
5	LBDAT	yyyy MMM dd	What was the date of the lab specimen collection?		Date of Specimen Collection	
6	LBTIM	HH:nn	What was the start time of the lab specimen collection?		Time of Specimen Collection	
7	04009_ACTIVATED_PARTIAL_THROMBOPLASTIN_	9.3	Activated Partial Thromboplastin Time (APTT) (sec) (Blood)			
8	04523_APTT_REL_BLOOD	9.3	Activated Partial Thromboplast. Time,Rel (APTT relative) (%, ratio) (Blood)			
9	04230_FIBRINOGEN_BLOOD	9.3	Fibrinogen (Blood)			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Coagulation (LB2)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
10	04Z77_PTT_BLOOD	9.3	Partial Thromboplastin Time (PTT) (sec) (Blood)			
11	04Z78_PTT_REL_BLOOD	9.3	Partial Thromboplastin Time, Rel (PTT Relative) (%, ratio) (Blood)			
12	04404_PROTHROMBIN_COMPLEX_INR_BLOOD	9.3	Prothrombin Complex INR (Blood) (%,ratio) (Blood)			
13	04061_PROTHROMBIN_TIME_BLOOD	9.3	Prothrombin Time (PT) (sec) (Blood)			
14	04395_PROTHROMBIN_TIME_RELATIVE_BLOOD	9.3	Prothrombin Time, Relative (PT Relative) (%, ratio) (Blood)			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Thyroid function test (LB3)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐	2
What was the reason that the sample was not collected?		3
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐	4
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd	5
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock	6
Thyroid Stimulating Hormone(Serum/Plasma)		7
T4 (Thyroxine), Free(Serum/Plasma)		8
T3 (Triiodothyronine), Free(Serum/Plasma)		9

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Thyroid function test (LB3)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	LBPERF	$6	Was the sample collected?	$6	Lab Performed	C49487 = No C49488 = Yes
3	LBREASND	$200	What was the reason that the sample was not collected?	$200	Reason Not Done	
4	LBCAT	$2	What was the name of the lab panel?	$2	Category for Lab Test	1 = Hematology 2 = Chemistry 3 = Urinalysis 4 = Coagulation 7 = Serology/Immunology
5	LBDAT	yyyy MMM dd	What was the date of the lab specimen collection?		Date of Specimen Collection	
6	LBTIM	HH:nn	What was the start time of the lab specimen collection?		Time of Specimen Collection	
7	55125_THYROID_STIMULATING_HORMONE_SERUM_PLASMA	9.3	Thyroid Stimulating Hormone(Serum/Plasma)			
8	55610_T4_FREE_SERUM_PLASMA	9.3	T4 (Thyroxine), Free(Serum/Plasma)			
9	55212_T3_FREE_SERUM_PLASMA	9.3	T3 (Triiodothyronine), Free(Serum/Plasma)			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐	2
What was the reason that the sample was not collected?		3
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐	4
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd	5
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock	6
Creatine Kinase (Serum/Plasma)		7
Troponin T (Serum/Plasma)		8
Troponin I (Serum/Plasma)		9
High- sensitivity Troponin T (Serum/Plasma)		10
High- sensitivity Troponin I (Serum/Plasma)		11

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	LBPERF	$6	Was the sample collected?	$6	Lab Performed	C49487 = No C49488 = Yes
3	LBREASND	$200	What was the reason that the sample was not collected?	$200	Reason Not Done	
4	LBCAT	$2	What was the name of the lab panel?	$2	Category for Lab Test	1 = Hematology 2 = Chemistry 3 = Urinalysis 4 = Coagulation 7 = Serology/Immunology
5	LBDAT	yyyy MMM dd	What was the date of the lab specimen collection?		Date of Specimen Collection	
6	LBTIM	HH:nn	What was the start time of the lab specimen collection?		Time of Specimen Collection	
7	55106_CREATINE_KINASE_SERUMPLASMA	9.3	Creatine Kinase (Serum/Plasma)			
8	55295_TROPONIN_T_SERUMPLASMA	10.4	Troponin T (Serum/Plasma)			
9	55336_TROPONIN_I_SERUMPLASMA	10.4	Troponin I (Serum/Plasma)			
10	55K11_TROPONIN_T_ULTRA_SENSITIVE_SERUMPLASMA	10.4	High-sensitivity Troponin T (Serum/Plasma)			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
11	55B13_HIGH_SENSITIVITY_TROPONIN_I_SERUM PLASMA	10.4	High-sensitivity Troponin I (Serum/Plasma)			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐	2
What was the reason that the sample was not collected?		3
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐	4
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd	5
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock	6
Carcinoembryonic Antigen (Serum/Plasma) (ng/mL)		7
Carbohydrate Antigen 19-9 (Serum) (U/mL)		8

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - CA-19-9 and CEA (serum) (LB5)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	LBPERF	$6	Was the sample collected?	$6	Lab Performed	C49487 = No C49488 = Yes
3	LBREASND	$200	What was the reason that the sample was not collected?	$200	Reason Not Done	
4	LBCAT	$2	What was the name of the lab panel?	$2	Category for Lab Test	1 = Hematology 2 = Chemistry 3 = Urinalysis 4 = Coagulation 7 = Serology/Immunology
5	LBDAT	yyyy MMM dd	What was the date of the lab specimen collection?		Date of Specimen Collection	
6	LBTIM	HH:nn	What was the start time of the lab specimen collection?		Time of Specimen Collection	
7	55647_CARCINOEMBRYONIC_A_SERUMPLASMA	9.3	Carcinoembryonic Antigen (Serum/Plasma) (ng/mL)			
8	02654_CARBOHYDRATE_ANTIGEN_19_9_SERUM	9.3	Carbohydrate Antigen 19-9 (Serum) (U/mL)			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Urinalysis (LB6)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

(Version: AZ2211 2025-08-05)

Was the sample collected? — No (2) / Yes

What was the reason that the sample was not collected? (3)

What was the name of the lab panel? (4) — Hematology / Chemistry / Urinalysis / Coagulation / Serology/Immunology

What was the date of the lab specimen collection? Fixed Unit: yyyy mon dd (5)

What was the start time of the lab specimen collection? Fixed Unit: 24-hour clock (6)

Albumin, Strip, Qual (Urine) (7) — Negative / Trace / Positive / + / ++ / +++ / >+++ / +-

Bilirubin, Strip, Qual (Urine) (8) — Negative / Trace / Positive / + / ++ / +++ / >+++ / +-

Blood, Qual (Urine) (9) — Negative / Trace / Positive

	+ ☐
	++ ☐
	+++ ☐
	>+++ ☐
	+- ☐
Glucose, Strip, Qual (Urine)	Negative ☐ 10
	Trace ☐
	Positive ☐
	+ ☐
	++ ☐
	+++ ☐
	>+++ ☐
	+- ☐
Ketone Bodies, Strip, Qual (Urine)	Negative ☐ 11
	Trace ☐
	Positive ☐
	+ ☐
	++ ☐
	+++ ☐
	>+++ ☐
	+- ☐
Protein, Strip, Qual (Urine)	Negative ☐ 12
	Trace ☐
	Positive ☐
	+ ☐
	++ ☐
	+++ ☐
	>+++ ☐
	+- ☐
Appearance (Qual) (Urine)	13
Color (Qual) (Urine)	14
Albumin, Quant (Urine)	15
Bilirubin, Quant(Urine)	16

Glucose, Random, Quant (Urine)		17
Ketone Bodies, Quant (Urine)		18
Protein, Total, Quant (Urine)		19
Urine-Blood, Quant (Urine)		20
pH (Urine)		21
Specific Gravity (Urine)		22
Sediment, Erythrocytes, Quant (no/vis fld) (Urine)		23
Sediment, Leucocytes, Quant (no/vis fld) (Urine)		24
Leucocytes, Quant (10**6/L) (Volume) (Urine)		25
Erythrocytes, Quant (1/uL) (Volume) (Urine)		26

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Urinalysis (LB6)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	LBPERF	$6	Was the sample collected?	$6	Lab Performed	C49487 = No C49488 = Yes
3	LBREASND	$200	What was the reason that the sample was not collected?	$200	Reason Not Done	
4	LBCAT	$2	What was the name of the lab panel?	$2	Category for Lab Test	1 = Hematology 2 = Chemistry 3 = Urinalysis 4 = Coagulation 7 = Serology/Immunology
5	LBDAT	yyyy MMM dd	What was the date of the lab specimen collection?		Date of Specimen Collection	
6	LBTIM	HH:nn	What was the start time of the lab specimen collection?		Time of Specimen Collection	
7	05119_ALBUMIN_STRIP_QUAL_URINE	$50	Albumin, Strip, Qual (Urine)			1 = Negative 2 = Trace 3 = Positive 5 = + 6 = ++ 7 = +++ 8 = >+++ 12 = +-
8	05175_BILIRUBIN_URINE	$50	Bilirubin, Strip, Qual (Urine)			1 = Negative 2 = Trace 3 = Positive 5 = + 6 = ++ 7 = +++ 8 = >+++ 12 = +-

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
9	05742_BLOOD_URINE	$50	Blood, Qual (Urine)			1 = Negative 2 = Trace 3 = Positive 5 = + 6 = ++ 7 = +++ 8 = >+++ 12 = +-
10	05122_GLUCOSE_URINE	$50	Glucose, Strip, Qual (Urine)			1 = Negative 2 = Trace 3 = Positive 5 = + 6 = ++ 7 = +++ 8 = >+++ 12 = +-
11	05512_KETONE_BODIES_URINE	$50	Ketone Bodies, Strip, Qual (Urine)			1 = Negative 2 = Trace 3 = Positive 5 = + 6 = ++ 7 = +++ 8 = >+++ 12 = +-
12	05149_PROTEIN_URINE	$50	Protein, Strip, Qual (Urine)			1 = Negative 2 = Trace 3 = Positive 5 = + 6 = ++ 7 = +++ 8 = >+++ 12 = +-
13	05563_APPEARANCE_URINE	$50	Appearance (Qual) (Urine)			
14	05U03_COLOR_URINE	$50	Color (Qual) (Urine)			
15	05403_ALBUMIN_QUANT_URINE	9.3	Albumin, Quant (Urine)			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Urinalysis (LB6)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
16	05D18_BILI_QUANT_URINE	9.3	Bilirubin, Quant(Urine)			
17	05706_GLU_RAND_URINE	9.3	Glucose, Random, Quant (Urine)			
18	05269_KETO_URINE	9.3	Ketone Bodies, Quant (Urine)			
19	05120_PROT_URINE	9.3	Protein, Total, Quant (Urine)			
20	05766_URINE_BLOOD_URINE	9.3	Urine-Blood, Quant (Urine)			
21	05135_PH_URINE	9.3	pH (Urine)			
22	05826_SPECIFIC_GRAVITY_URINE	9.3	Specific Gravity (Urine)			
23	05208_SEDIMENT_ERYTHROCYTES_Q_URINE	$10	Sediment, Erythrocytes, Quant (no/vis fld) (Urine)			
24	05209_SEDIMENT_LEUCOCYTES_Q_URINE	$10	Sediment, Leucocytes, Quant (no/vis fld) (Urine)			
25	05D10_LEUCOCYTES_QUANT_URINE	9.3	Leucocytes, Quant (10**6/L) (Volume) (Urine)			
26	05C55_ERYTHROCYTES_QUANT_URINE	9.3	Erythrocytes, Quant (1/uL) (Volume) (Urine)			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ 2 Yes ☐
What was the reason that the sample was not collected?	3
What was the name of the lab panel?	Hematology ☐ 4 Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ■
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd 5
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock 6
Hepatitis B Surface Antigen (Qual) (HBsAg) (Blood)	Negative ☐ 7 Positive ☐ +-borderline ☐
Hepatitis B Surface Antibody (HBsAb) (Blood)	Negative ☐ 8 Positive ☐ +-borderline ☐
Hepatitis B Core Antibody, Qual (anti-HBc) (Blood)	Negative ☐ 9 Positive ☐ +-borderline ☐
Hepatitis C Antibody (HCV ab) (Blood)	Negative ☐ 10 Positive ☐ +-borderline ☐
Hepatitis D Antibody (Blood)	Negative ☐ 11 Positive ☐ +-borderline ☐
Hepatitis B Viral Load, Quant (IU/mL) (Blood)	12
Hepatitis B Viral Load, Quant (DNA copies/mL) (Blood)	13
Hepatitis C Viral Load, Quant (IU/mL) (Blood)	14
Hepatitis C Viral Load, Quant (RNA copies/mL) (Blood)	15

Hepatitis D Virus RNA, Quant (Serum/Plasma) 16

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	LBPERF	$6	Was the sample collected?	$6	Lab Performed	C49487 = No C49488 = Yes
3	LBREASND	$200	What was the reason that the sample was not collected?	$200	Reason Not Done	
4	LBCAT	$2	What was the name of the lab panel?	$2	Category for Lab Test	1 = Hematology 2 = Chemistry 3 = Urinalysis 4 = Coagulation 7 = Serology/Immunology
5	LBDAT	yyyy MMM dd	What was the date of the lab specimen collection?		Date of Specimen Collection	
6	LBTIM	HH:nn	What was the start time of the lab specimen collection?		Time of Specimen Collection	
7	04265_HEP_B_SURFACE_ANTIGEN_BLOOD	$50	Hepatitis B Surface Antigen (Qual) (HBsAg) (Blood)			1 = Negative 3 = Positive 12 = +-borderline
8	04A63_HEP_B_SURFACE_ANTIBODY_QUAL_BLOOD	$50	Hepatitis B Surface Antibody (HBsAb) (Blood)			1 = Negative 3 = Positive 12 = +-borderline

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
9	04469_HEP_B_CORE_ANTIBODY_QUAL_BLOOD	$50	Hepatitis B Core Antibody, Qual (anti-HBc) (Blood)			1 = Negative 3 = Positive 12 = +-borderline
10	04400_HEP_C_ANTIBODY_BLOOD	$50	Hepatitis C Antibody (HCV ab) (Blood)			1 = Negative 3 = Positive 12 = +-borderline
11	04K67_HEP_D_ANTIBODY_QUAL_BLOOD	$50	Hepatitis D Antibody (Blood)			1 = Negative 3 = Positive 12 = +-borderline
12	04D16_HEPATITIS_B_VIRAL_LOAD_QIU_BLOOD	9.3	Hepatitis B Viral Load, Quant (IU/mL) (Blood)			
13	04D14_HEPATITIS_B_VIRAL_LOAD_QDNA_BLOOD	9.3	Hepatitis B Viral Load, Quant (DNA copies/mL) (Blood)			
14	04D17_HEPATITIS_C_VIRAL_LOAD_QIU_BLOOD	9.3	Hepatitis C Viral Load, Quant (IU/mL) (Blood)			
15	04A65_HEPATITIS_C_VIRAL_LOAD_Q_BLOOD	9.3	Hepatitis C Viral Load, Quant (RNA copies/mL) (Blood)			
16	55IK2_HEPATITIS_D_VIRUS_RNA_QUANT_SERUM_PLASMA	9.3	Hepatitis D Virus RNA, Quant (Serum/Plasma)			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Hepatitis B and C testing - Post Screening (LB13)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐	2
What was the reason that the sample was not collected?		3
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ■	4
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd	5
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock	6
Hepatitis B Viral Load, Quant (IU/mL) (Blood)		7
Hepatitis B Viral Load, Quant (DNA copies/mL) (Blood)		8
Hepatitis C Viral Load, Quant (IU/mL) (Blood)		9
Hepatitis C Viral Load, Quant (RNA copies/mL) (Blood)		10

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Hepatitis B and C testing - Post Screening (LB13)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	LBPERF	$6	Was the sample collected?	$6	Lab Performed	C49487 = No C49488 = Yes
3	LBREASND	$200	What was the reason that the sample was not collected?	$200	Reason Not Done	
4	LBCAT	$2	What was the name of the lab panel?	$2	Category for Lab Test	1 = Hematology 2 = Chemistry 3 = Urinalysis 4 = Coagulation 7 = Serology/Immunology
5	LBDAT	yyyy MMM dd	What was the date of the lab specimen collection?		Date of Specimen Collection	
6	LBTIM	HH:nn	What was the start time of the lab specimen collection?		Time of Specimen Collection	
7	04D16_HEPATITIS_B_VIRAL_LOAD_QIU_BLOOD	9.3	Hepatitis B Viral Load, Quant (IU/mL) (Blood)			
8	04D14_HEPATITIS_B_VIRAL_LOAD_QDNA_BLOOD	9.3	Hepatitis B Viral Load, Quant (DNA copies/mL) (Blood)			
9	04D17_HEPATITIS_C_VIRAL_LOAD_QIU_BLOOD	9.3	Hepatitis C Viral Load, Quant (IU/mL) (Blood)			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Hepatitis B and C testing - Post Screening (LB13)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
10	04A65_HEPATITIS_C_VIRAL_LOAD_Q_BLOOD	9.3	Hepatitis C Viral Load, Quant (RNA copies/mL) (Blood)			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Hy's Law (LB8)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐	2
What was the reason that the sample was not collected?		3
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐	4
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd	5
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock	6
Alanine Aminotransferase (Serum/Plasma)		7
Alkaline Phosphatase (Serum/Plasma)		8
Aspartate Aminotransferase (Serum/Plasma)		9
Bilirubin, Total (Serum/Plasma)		10
Hidden for Bilirubin		11
Hidden for Aspartate		12
Hidden for Alanine		13
Hidden for Alanine Range		14
Hidden for Aspartate Range		15
Hidden for Bilirubin Range		16
Derived field to call CF		17

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Hy's Law (LB8)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	LBPERF	$6	Was the sample collected?	$6	Lab Performed	C49487 = No C49488 = Yes
3	LBREASND	$200	What was the reason that the sample was not collected?	$200	Reason Not Done	
4	LBCAT	$2	What was the name of the lab panel?	$2	Category for Lab Test	1 = Hematology 2 = Chemistry 3 = Urinalysis 4 = Coagulation 7 = Serology/Immunology
5	LBDAT	yyyy MMM dd	What was the date of the lab specimen collection?		Date of Specimen Collection	
6	LBTIM	HH:nn	What was the start time of the lab specimen collection?		Time of Specimen Collection	
7	55101_ALANINEAMINOT_SERUMPLASMA	9.3	Alanine Aminotransferase (Serum/Plasma)			
8	55104_ALKALINE_PHOSPHATASE_SERUMPLASMA	9.3	Alkaline Phosphatase (Serum/Plasma)			
9	55102_ASPARTATE_AMINOT_SERUMPLASMA	9.3	Aspartate Aminotransferase (Serum/Plasma)			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Hy's Law (LB8)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
10	55110_BILIRUBIN_TOTAL_SERUMPLASMA	9.3	Bilirubin, Total (Serum/Plasma)			
11	Z_INITIAL5	9.3	Hidden for Bilirubin			
12	Z_INITIAL4	9.3	Hidden for Aspartate			
13	Z_INITIAL3	9.3	Hidden for Alanine			
14	Z_RANGEALT	$2	Hidden for Alanine Range			
15	Z_RANGEAST	$2	Hidden for Aspartate Range			
16	Z_RANGEBILI	$2	Hidden for Bilirubin Range			
17	Z_TIME	dd MMM yyyy hh:nn:ss	Derived field to call CF			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐	2
What was the reason that the sample was not collected?		3
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐	4
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd	5
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock	6
1,3-Beta-D-Glucan (Serum)		7
Carcinoembryonic Antigen (Serum/Plasma) (ng/mL)		8
Carcinoembryonic Antigen (Serum/Plasma) (in Units (IU/mL))		9
C-Reactive Protein (Blood)		10
C-Reactive Protein (Serum/Plasma)		11
Lactate Dehydrogenase (Serum/Plasma)		12
Sialylated Carbohydrate Antigen KL-6 (Serum)		13
Surfactant Protein A (Serum)		14
Surfactant Protein D (Serum/Plasma)		15
Surfactant Protein D (Sputum)		16

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	LBPERF	$6	Was the sample collected?	$6	Lab Performed	C49487 = No C49488 = Yes
3	LBREASND	$200	What was the reason that the sample was not collected?	$200	Reason Not Done	
4	LBCAT	$2	What was the name of the lab panel?	$2	Category for Lab Test	1 = Hematology 2 = Chemistry 3 = Urinalysis 4 = Coagulation 7 = Serology/Immunology
5	LBDAT	yyyy MMM dd	What was the date of the lab specimen collection?		Date of Specimen Collection	
6	LBTIM	HH:nn	What was the start time of the lab specimen collection?		Time of Specimen Collection	
7	02J94_BG_SERUM	9.3	1,3-Beta-D-Glucan (Serum)			
8	55647_CARCINOEMBRYONIC_A_SERUMPLASMA	9.3	Carcinoembryonic Antigen (Serum/Plasma) (ng/mL)			
9	55S61_CARCINOEMBRYONIC_ANTIGEN_SERUM_PLASMA	9.3	Carcinoembryonic Antigen (Serum/Plasma) (in Units (IU/mL))			
10	04128_C_REACTIVE_PROTEIN_BLOOD	9.3	C-Reactive Protein (Blood)			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
11	55128_C_REACTIVE_PROTEIN_SERUM_PLASMA	9.3	C-Reactive Protein (Serum/Plasma)			
12	55105_LACTATE_DEHYDROGENASE_SERUMPLASMA	9.3	Lactate Dehydrogenase (Serum/Plasma)			
13	02755_KL_6_SERUM	9.3	Sialylated Carbohydrate Antigen KL-6 (Serum)			
14	02C82_SP_A_SERUM	9.3	Surfactant Protein A (Serum)			
15	55C83_SURFACTANT_PROTEIN_D_SERUMPLASMA	9.3	Surfactant Protein D (Serum/Plasma)			
16	60C83_SURFACTANT_PROT_D_SPUTUM	9.3	Surfactant Protein D (Sputum)			

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐	2
	Yes ☐	
What was the reason that the sample was not collected?	_____	3
What was the name of the lab panel?	Hematology ☐	4
	Chemistry ☐	
	Urinalysis ☐	
	Coagulation ☐	
	Serology/Immunology ■	
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd _____	5
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock _____	6
Culture, Mycobacterium Tuberculosis(Sputum)	Negative ☐	7
	Positive ☐	
	+-borderline ☐	
Quantiferon Tuberculosis Gold (Plasma)	Negative ☐	8
	Positive ☐	
	+-borderline ☐	
Quantiferon Tuberculosis Gold (Blood)	Negative ☐	9
	Positive ☐	
	+-borderline ☐	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Tuberculosis testing (LB10)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	LBPERF	$6	Was the sample collected?	$6	Lab Performed	C49487 = No C49488 = Yes
3	LBREASND	$200	What was the reason that the sample was not collected?	$200	Reason Not Done	
4	LBCAT	$2	What was the name of the lab panel?	$2	Category for Lab Test	1 = Hematology 2 = Chemistry 3 = Urinalysis 4 = Coagulation 7 = Serology/Immunology
5	LBDAT	yyyy MMM dd	What was the date of the lab specimen collection?		Date of Specimen Collection	
6	LBTIM	HH:nn	What was the start time of the lab specimen collection?		Time of Specimen Collection	
7	18Q71_CULTURE_MYCOBACTERIUM_TUBERCULOSIS_SPUTUM	$50	Culture, Mycobacterium Tuberculosis(Sputum)			1 = Negative 3 = Positive 12 = +-borderline
8	01E12_QUANTIFERON_TUBERCULOSIS_GOLD_PLASMA	$50	Quantiferon Tuberculosis Gold (Plasma)			1 = Negative 3 = Positive 12 = +-borderline
9	04E12_QUANTIFERON_TUBERCULOSIS_GOLD_BLOOD	$50	Quantiferon Tuberculosis Gold (Blood)			1 = Negative 3 = Positive 12 = +-borderline

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - HIV testing (LB11)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐	2
What was the reason that the sample was not collected?		3
What was the name of the lab panel?	Hematology ☐ Chemistry ☐ Urinalysis ☐ Coagulation ☐ Serology/Immunology ■	4
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd	5
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock	6
HIV-1/2 Antibody Screen (Blood)	Negative ☐ Positive ☐ +-borderline ☐	7
HIV Viral Load, Quant, PCR (Blood)		8
CD4+, abs(cells/uL) (Blood)		9

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - HIV testing (LB11)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	LBPERF	$6	Was the sample collected?	$6	Lab Performed	C49487 = No C49488 = Yes
3	LBREASND	$200	What was the reason that the sample was not collected?	$200	Reason Not Done	
4	LBCAT	$2	What was the name of the lab panel?	$2	Category for Lab Test	1 = Hematology 2 = Chemistry 3 = Urinalysis 4 = Coagulation 7 = Serology/Immunology
5	LBDAT	yyyy MMM dd	What was the date of the lab specimen collection?		Date of Specimen Collection	
6	LBTIM	HH:nn	What was the start time of the lab specimen collection?		Time of Specimen Collection	
7	04N30_HIV_1_2_ANTIBODY_SCREEN_BLOOD	$50	HIV-1/2 Antibody Screen (Blood)			1 = Negative 3 = Positive 12 = +-borderline
8	04BR2_HIV_VIRAL_LOAD_QUANT_PCR_BLOOD	9.3	HIV Viral Load, Quant, PCR (Blood)			
9	04564_CD4_ABS_BLOOD	9.3	CD4+, abs(cells/uL) (Blood)			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Additional Chemistry (LB12)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

(Version: AZ2211 2025-08-05)

Was the sample collected?	No ☐ Yes ☐	2
What was the reason that the sample was not collected?		3
What was the name of the lab panel?	Hematology ☐ Chemistry ■ Urinalysis ☐ Coagulation ☐ Serology/Immunology ☐	4
What was the date of the lab specimen collection?	Fixed Unit: yyyy mon dd	5
What was the start time of the lab specimen collection?	Fixed Unit: 24-hour clock	6
Ferritin (Serum/Plasma)		7
Hba1c (IFCC-mmol/mol)		8
Hba1c(% ,Ratio)		9
Iron (Serum/Plasma)		10
Thyroglobulin Antibody (Serum)		11
Thyroid Peroxidase Antibody (Serum)		12
Thyrotropin Receptor Antibody (Serum)		13
Uric acid (Urate) (Serum/Plasma)		14

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Additional Chemistry (LB12)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	LBPERF	$6	Was the sample collected?	$6	Lab Performed	C49487 = No C49488 = Yes
3	LBREASND	$200	What was the reason that the sample was not collected?	$200	Reason Not Done	
4	LBCAT	$2	What was the name of the lab panel?	$2	Category for Lab Test	1 = Hematology 2 = Chemistry 3 = Urinalysis 4 = Coagulation 7 = Serology/Immunology
5	LBDAT	yyyy MMM dd	What was the date of the lab specimen collection?		Date of Specimen Collection	
6	LBTIM	HH:nn	What was the start time of the lab specimen collection?		Time of Specimen Collection	
7	55171_FERRITIN_SERUMPLASMA	9.3	Ferritin (Serum/Plasma)			
8	04D11_HBA1C_IFCC_BLOOD	9.3	Hba1c (IFCC-mmol/mol)			
9	04241_HBA1C_BLOOD	9.3	Hba1c(% ,Ratio)			
10	55170_IRON_SERUMPLASMA	9.3	Iron (Serum/Plasma)			
11	02L48_THYROGLOBULIN_ANTIBODY_SERUM	9.3	Thyroglobulin Antibody (Serum)			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-central Laboratory Test Results - Additional Chemistry (LB12)
Generated On: 2025 Nov 20 12:23 (GMT)
Lab Name:

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
12	02F33_THYROID_PEROXIDASE_ANTIBODY_SERUM	9.3	Thyroid Peroxidase Antibody (Serum)			
13	02BE9_THYROTROPIN_RECEPTOR_ANTIBODY_SERUM	9.3	Thyrotropin Receptor Antibody (Serum)			
14	55160_URATE_SERUMPLASMA	9.3	Uric acid (Urate) (Serum/Plasma)			

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid	2
Sample collected	No	3
	Yes	
Sample collection method	Blood draw	4
Biofluid collected (parent sample)	Blood Na heparin	5
	cfDNA-BCT	
	Blood	
Biofluid processed	PBMC	6
	Blood	
	Serum	
	Plasma	
Sample format	DNA	7
	Fresh	
	Frozen	
	RNA	
Date of collection	Fixed Unit: yyyy mon dd	8
Time of collection	Fixed Unit: 24-hour clock	9
Sample condition	Sample acceptable	10
	Hemolyzed	
	Clotted	
	Lipemic	
	Quantity less than expected	
	Sample discarded	
	Other	
If Other, specify		11
Protocol schedule	Pre Dose	12
Laboratory ID	Labcorp	13

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Sample Collection, Predose_ADA Sample (SPCBEDB)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	SPECCAT	$2	What was the sample category?	$2	Specimen Collection Category	7 = Biomarkers/exploratory research/diagnostic, biofluid
3	SPECCOL	$6	Sample collected	$6	Specimen Collected	C49487 = No C49488 = Yes
4	COLMTH	$7	Sample collection method	$7	Specimen Collection Method	8 = Blood draw
5	SPECCOLF	$7	Biofluid collected (parent sample)	$7	Biofluid Collected (Parent Sample)	10 = Blood Na heparin 35 = cfDNA-BCT C12434 = Blood
6	SPECPRCF	$6	Biofluid processed	$6	Biofluid Processed	19 = PBMC C12434 = Blood C13325 = Serum C13356 = Plasma
7	SPECFMT	$2	Sample format	$2	Specimen Format	9 = DNA 14 = Fresh 16 = Frozen 24 = RNA
8	SPECDAT	yyyy MMM dd	Date of collection		Date of Collection	
9	SPECTIM	HH:nn	Time of collection		Time of Collection	
10	SPECCND	$6	Sample condition	$6	Specimen Condition	0 = Sample acceptable C70720 = Hemolyzed C78724 = Clotted C70715 = Lipemic 50 = Quantity less than expected

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Sample Collection, Predose_ADA Sample (SPCBEDB)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						51 = Sample discarded 99 = Other
11	SPECCNDO	$200	If Other, specify	$200	Specimen Condition, Other	
12	PROTSCHD	$20	Protocol schedule	$20	Protocol Schedule	Pre Dose|
13	LABID	5	Laboratory ID	8	Laboratory ID	13 = Labcorp

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid	2
Sample collected	No	3
	Yes	
Sample collection method	Blood draw	4
Biofluid collected (parent sample)	Blood Na heparin	5
	cfDNA-BCT	
	Blood	
Biofluid processed	PBMC	6
	Blood	
	Serum	
	Plasma	
Sample format	DNA	7
	Fresh	
	Frozen	
	RNA	
Date of collection	Fixed Unit: yyyy mon dd	8
Time of collection	Fixed Unit: 24-hour clock	9
Sample condition	Sample acceptable	10
	Hemolyzed	
	Clotted	
	Lipemic	
	Quantity less than expected	
	Sample discarded	
	Other	
If Other, specify		11
Protocol schedule	Pre Dose	12
Laboratory ID	Labcorp	13

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	SPECCAT	$2	What was the sample category?	$2	Specimen Collection Category	7 = Biomarkers/exploratory research/diagnostic, biofluid
3	SPECCOL	$6	Sample collected	$6	Specimen Collected	C49487 = No C49488 = Yes
4	COLMTH	$7	Sample collection method	$7	Specimen Collection Method	8 = Blood draw
5	SPECCOLF	$7	Biofluid collected (parent sample)	$7	Biofluid Collected (Parent Sample)	10 = Blood Na heparin 35 = cfDNA-BCT C12434 = Blood
6	SPECPRCF	$6	Biofluid processed	$6	Biofluid Processed	19 = PBMC C12434 = Blood C13325 = Serum C13356 = Plasma
7	SPECFMT	$2	Sample format	$2	Specimen Format	9 = DNA 14 = Fresh 16 = Frozen 24 = RNA
8	SPECDAT	yyyy MMM dd	Date of collection		Date of Collection	
9	SPECTIM	HH:nn	Time of collection		Time of Collection	
10	SPECCND	$6	Sample condition	$6	Specimen Condition	0 = Sample acceptable C70720 = Hemolyzed C78724 = Clotted C70715 = Lipemic 50 = Quantity less than expected

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						51 = Sample discarded 99 = Other
11	SPECCNDO	$200	If Other, specify	$200	Specimen Condition, Other	
12	PROTSCHD	$20	Protocol schedule	$20	Protocol Schedule	Pre Dose|
13	LABID	5	Laboratory ID	8	Laboratory ID	13 = Labcorp

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid	2
Sample collected	No	3
	Yes	
Sample collection method	Blood draw	4
Biofluid collected (parent sample)	Blood Na heparin	5
	cfDNA-BCT	
	Blood	
Biofluid processed	PBMC	6
	Blood	
	Serum	
	Plasma	
Sample format	DNA	7
	Fresh	
	Frozen	
	RNA	
Date of collection	Fixed Unit: yyyy mon dd	8
Time of collection	Fixed Unit: 24-hour clock	9
Sample condition	Sample acceptable	10
	Hemolyzed	
	Clotted	
	Lipemic	
	Quantity less than expected	
	Sample discarded	
	Other	
If Other, specify		11
Protocol schedule	Pre Dose	12
Laboratory ID	Labcorp	13

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: PBMC for immune profiling_Pre dose (SPCBEDB2)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	SPECCAT	$2	What was the sample category?	$2	Specimen Collection Category	7 = Biomarkers/exploratory research/diagnostic, biofluid
3	SPECCOL	$6	Sample collected	$6	Specimen Collected	C49487 = No C49488 = Yes
4	COLMTH	$7	Sample collection method	$7	Specimen Collection Method	8 = Blood draw
5	SPECCOLF	$7	Biofluid collected (parent sample)	$7	Biofluid Collected (Parent Sample)	10 = Blood Na heparin 35 = cfDNA-BCT C12434 = Blood
6	SPECPRCF	$6	Biofluid processed	$6	Biofluid Processed	19 = PBMC C12434 = Blood C13325 = Serum C13356 = Plasma
7	SPECFMT	$2	Sample format	$2	Specimen Format	9 = DNA 14 = Fresh 16 = Frozen 24 = RNA
8	SPECDAT	yyyy MMM dd	Date of collection		Date of Collection	
9	SPECTIM	HH:nn	Time of collection		Time of Collection	
10	SPECCND	$6	Sample condition	$6	Specimen Condition	0 = Sample acceptable C70720 = Hemolyzed C78724 = Clotted C70715 = Lipemic 50 = Quantity less than expected

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: PBMC for immune profiling_Pre dose (SPCBEDB2)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						51 = Sample discarded 99 = Other
11	SPECCNDO	$200	If Other, specify	$200	Specimen Condition, Other	
12	PROTSCHD	$20	Protocol schedule	$20	Protocol Schedule	Pre Dose|
13	LABID	5	Laboratory ID	8	Laboratory ID	13 = Labcorp

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid	2
Sample collected	No	3
	Yes	
Sample collection method	Blood draw	4
Biofluid collected (parent sample)	Blood Na heparin	5
	cfDNA-BCT	
	Blood	
Biofluid processed	PBMC	6
	Blood	
	Serum	
	Plasma	
Sample format	DNA	7
	Fresh	
	Frozen	
	RNA	
Date of collection	Fixed Unit: yyyy mon dd	8
Time of collection	Fixed Unit: 24-hour clock	9
Sample condition	Sample acceptable	10
	Hemolyzed	
	Clotted	
	Lipemic	
	Quantity less than expected	
	Sample discarded	
	Other	
If Other, specify		11
Protocol schedule	Pre Dose	12
Laboratory ID	Labcorp	13

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Whole blood for RNA analysis_Pre-dose (SPCBEDB3)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	SPECCAT	$2	What was the sample category?	$2	Specimen Collection Category	7 = Biomarkers/exploratory research/diagnostic, biofluid
3	SPECCOL	$6	Sample collected	$6	Specimen Collected	C49487 = No C49488 = Yes
4	COLMTH	$7	Sample collection method	$7	Specimen Collection Method	8 = Blood draw
5	SPECCOLF	$7	Biofluid collected (parent sample)	$7	Biofluid Collected (Parent Sample)	10 = Blood Na heparin 35 = cfDNA-BCT C12434 = Blood
6	SPECPRCF	$6	Biofluid processed	$6	Biofluid Processed	19 = PBMC C12434 = Blood C13325 = Serum C13356 = Plasma
7	SPECFMT	$2	Sample format	$2	Specimen Format	9 = DNA 14 = Fresh 16 = Frozen 24 = RNA
8	SPECDAT	yyyy MMM dd	Date of collection		Date of Collection	
9	SPECTIM	HH:nn	Time of collection		Time of Collection	
10	SPECCND	$6	Sample condition	$6	Specimen Condition	0 = Sample acceptable C70720 = Hemolyzed C78724 = Clotted C70715 = Lipemic 50 = Quantity less than expected

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Whole blood for RNA analysis_Pre-dose (SPCBEDB3)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						51 = Sample discarded 99 = Other
11	SPECCNDO	$200	If Other, specify	$200	Specimen Condition, Other	
12	PROTSCHD	$20	Protocol schedule	$20	Protocol Schedule	Pre Dose|
13	LABID	5	Laboratory ID	8	Laboratory ID	13 = Labcorp

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid	2
Sample collected	No	3
	Yes	
Sample collection method	Blood draw	4
Biofluid collected (parent sample)	Blood Na heparin	5
	cfDNA-BCT	
	Blood	
Biofluid processed	PBMC	6
	Blood	
	Serum	
	Plasma	
Sample format	DNA	7
	Fresh	
	Frozen	
	RNA	
Date of collection	Fixed Unit: yyyy mon dd	8
Time of collection	Fixed Unit: 24-hour clock	9
Sample condition	Sample acceptable	10
	Hemolyzed	
	Clotted	
	Lipemic	
	Quantity less than expected	
	Sample discarded	
	Other	
If Other, specify		11
Protocol schedule	Pre Dose	12
Laboratory ID	Labcorp	13

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	SPECCAT	$2	What was the sample category?	$2	Specimen Collection Category	7 = Biomarkers/exploratory research/diagnostic, biofluid
3	SPECCOL	$6	Sample collected	$6	Specimen Collected	C49487 = No C49488 = Yes
4	COLMTH	$7	Sample collection method	$7	Specimen Collection Method	8 = Blood draw
5	SPECCOLF	$7	Biofluid collected (parent sample)	$7	Biofluid Collected (Parent Sample)	10 = Blood Na heparin 35 = cfDNA-BCT C12434 = Blood
6	SPECPRCF	$6	Biofluid processed	$6	Biofluid Processed	19 = PBMC C12434 = Blood C13325 = Serum C13356 = Plasma
7	SPECFMT	$2	Sample format	$2	Specimen Format	9 = DNA 14 = Fresh 16 = Frozen 24 = RNA
8	SPECDAT	yyyy MMM dd	Date of collection		Date of Collection	
9	SPECTIM	HH:nn	Time of collection		Time of Collection	
10	SPECCND	$6	Sample condition	$6	Specimen Condition	0 = Sample acceptable C70720 = Hemolyzed C78724 = Clotted C70715 = Lipemic 50 = Quantity less than expected

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						51 = Sample discarded 99 = Other
11	SPECCNDO	$200	If Other, specify	$200	Specimen Condition, Other	
12	PROTSCHD	$20	Protocol schedule	$20	Protocol Schedule	Pre Dose|
13	LABID	5	Laboratory ID	8	Laboratory ID	13 = Labcorp

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid	2
Sample collected	No	3
	Yes	
Sample collection method	Blood draw	4
Biofluid collected (parent sample)	Blood Na heparin	5
	cfDNA-BCT	
	Blood	
Biofluid processed	PBMC	6
	Blood	
	Serum	
	Plasma	
Sample format	DNA	7
	Fresh	
	Frozen	
	RNA	
Date of collection	Fixed Unit: yyyy mon dd	8
Time of collection	Fixed Unit: 24-hour clock	9
Sample condition	Sample acceptable	10
	Hemolyzed	
	Clotted	
	Lipemic	
	Quantity less than expected	
	Sample discarded	
	Other	
If Other, specify		11
Laboratory ID	Labcorp	12

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Sample Collection, ADA Sample (SPCBEDB5)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	SPECCAT	$2	What was the sample category?	$2	Specimen Collection Category	7 = Biomarkers/exploratory research/diagnostic, biofluid
3	SPECCOL	$6	Sample collected	$6	Specimen Collected	C49487 = No C49488 = Yes
4	COLMTH	$7	Sample collection method	$7	Specimen Collection Method	8 = Blood draw
5	SPECCOLF	$7	Biofluid collected (parent sample)	$7	Biofluid Collected (Parent Sample)	10 = Blood Na heparin 35 = cfDNA-BCT C12434 = Blood
6	SPECPRCF	$6	Biofluid processed	$6	Biofluid Processed	19 = PBMC C12434 = Blood C13325 = Serum C13356 = Plasma
7	SPECFMT	$2	Sample format	$2	Specimen Format	9 = DNA 14 = Fresh 16 = Frozen 24 = RNA
8	SPECDAT	yyyy MMM dd	Date of collection		Date of Collection	
9	SPECTIM	HH:nn	Time of collection		Time of Collection	
10	SPECCND	$6	Sample condition	$6	Specimen Condition	0 = Sample acceptable C70720 = Hemolyzed C78724 = Clotted C70715 = Lipemic 50 = Quantity less than expected

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Sample Collection, ADA Sample (SPCBEDB5)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						51 = Sample discarded 99 = Other
11	SPECCNDO	$200	If Other, specify	$200	Specimen Condition, Other	
12	LABID	5	Laboratory ID	8	Laboratory ID	13 = Labcorp

(Version: AZ2310 2023-10-26)

What was the sample category?	Biomarkers/exploratory research/diagnostic, biofluid	2
Sample collected	No	3
	Yes	
Sample collection method	Blood draw	4
Biofluid collected (parent sample)	Blood Na heparin	5
	cfDNA-BCT	
	Blood	
Biofluid processed	PBMC	6
	Blood	
	Serum	
	Plasma	
Sample format	DNA	7
	Fresh	
	Frozen	
	RNA	
Date of collection	Fixed Unit: yyyy mon dd	8
Sample condition	Sample acceptable	9
	Hemolyzed	
	Clotted	
	Lipemic	
	Quantity less than expected	
	Sample discarded	
	Other	
If Other, specify		10
Laboratory ID	Labcorp	11

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Blood sample for plasma ctDNA (SPCBEDB6)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	SPECCAT	$2	What was the sample category?	$2	Specimen Collection Category	7 = Biomarkers/exploratory research/diagnostic, biofluid
3	SPECCOL	$6	Sample collected	$6	Specimen Collected	C49487 = No C49488 = Yes
4	COLMTH	$7	Sample collection method	$7	Specimen Collection Method	8 = Blood draw
5	SPECCOLF	$7	Biofluid collected (parent sample)	$7	Biofluid Collected (Parent Sample)	10 = Blood Na heparin 35 = cfDNA-BCT C12434 = Blood
6	SPECPRCF	$6	Biofluid processed	$6	Biofluid Processed	19 = PBMC C12434 = Blood C13325 = Serum C13356 = Plasma
7	SPECFMT	$2	Sample format	$2	Specimen Format	9 = DNA 14 = Fresh 16 = Frozen 24 = RNA
8	SPECDAT	yyyy MMM dd	Date of collection		Date of Collection	
9	SPECCND	$6	Sample condition	$6	Specimen Condition	0 = Sample acceptable C70720 = Hemolyzed C78724 = Clotted C70715 = Lipemic 50 = Quantity less than expected 51 = Sample discarded

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Blood sample for plasma ctDNA (SPCBEDB6)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						99 = Other
10	SPECCNDO	$200	If Other, specify	$200	Specimen Condition, Other	
11	LABID	5	Laboratory ID	8	Laboratory ID	13 = Labcorp

(Version: AZ2310 2025-07-01)

What was the sample collection category?	Biomarkers/exploratory research/diagnostic, solid tissue (2)
Sample collected	No (3)
	Yes
Sample collection method	Core Needle Biopsy (4)
	Excisional Biopsy
	Incisional Biopsy
Biopsy tissue type	Primary tumor (5)
	Metastatic tumor
Organ	Abdomen (6)
	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 ☐	7
Unstained slides sectioning date	Fixed Unit: yyyy mon dd	8
Date of Biopsy	Fixed Unit: yyyy mon dd	9
Sample condition	Sample acceptable ☐ Quantity less than expected ☐ Sample discarded ☐ Other ☐	10
If Other, specify		11
Date of storage	Fixed Unit: yyyy mon dd	12
Time of storage	Fixed Unit: 24-hour clock	13
Laboratory ID	Labcorp	14

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Optional on study tumor sample (SPCBEDT)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	SPECCAT	$2	What was the sample collection category?	$2	Specimen Collection Category	8 = Biomarkers/exploratory research/diagnostic, solid tissue
3	SPECCOL	$6	Sample collected	$6	Specimen Collected	C49487 = No C49488 = Yes
4	COLMTH	$7	Sample collection method	$7	Specimen Collection Method	12 = Core Needle Biopsy 20 = Excisional Biopsy 27 = Incisional Biopsy
5	BIOPTTYP	$2	Biopsy tissue type	$2	Biopsy Tissue Type	1 = Primary tumor 2 = Metastatic tumor
6	ORGAN	$6	Organ	$6	Organ	1 = Abdomen 12 = Bronchus (Main Stem) 23 = Fat 48 = Oesophagus 56 = Pituitary 81 = Urinary Bladder 82 = Esophagogastric Junction C12246 = Hypopharynx C12263 = Duodenum C12311 = Cervix Uteri C12328 = Epididymis C12377 = Gallbladder

Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
					C12379 = Large Intestine C12380 = Appendix C12382 = Colon C12386 = Small Intestine C12387 = Ileum C12388 = Jejunum C12390 = Rectum C12391 = Stomach C12392 = Liver C12393 = Pancreas C12400 = Thyroid Gland C12403 = Fallopian Tube C12404 = Ovary C12405 = Uterus C12410 = Prostate Gland C12412 = Testis C12415 = Kidney C12416 = Ureter C12417 = Urethra C12420 = Larynx C12421 = Oral Cavity

Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
					C12422 = Tongue C12425 = Pharynx C12427 = Parotid Gland C12428 = Trachea C12432 = Spleen C12433 = Thymus Gland C12439 = Brain C12464 = Spinal Cord C12468 = Lung C12469 = Pleura C12470 = Skin C12471 = Soft Tissue C12664 = Abdominal Cavity C12666 = Adrenal Gland C12702 = Diaphragm C12727 = Heart C12745 = Lymph Node C12756 = Nose C12762 = Oropharynx C12765 = Parathyroid Gland C12768 = Peripheral Nerve

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						C12770 = Peritoneum C12802 = Tonsil C12971 = Breast C13044 = Joint C13056 = Muscle C32668 = Gastroesophageal Junction C33103 = Mesentery C33209 = Omentum C43362 = Anus C77608 = Abdominal Wall 99 = Other (Not Specified)
7	SPECFMT	$2	Sample format	$2	Specimen Format	31 = FFPE block 32 = FFPE unstained slides
8	SLSECDT	yyyy MMM dd	Unstained slides sectioning date		Unstained Slides Sectioning Date	
9	SPECDAT	yyyy MMM dd	Date of Biopsy		Date of Collection	
10	SPECCND	$6	Sample condition	$6	Specimen Condition	0 = Sample acceptable 50 = Quantity less than expected 51 = Sample discarded

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Optional on study tumor sample (SPCBEDT)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						99 = Other
11	SPECCNDO	$200	If Other, specify	$200	Specimen Condition, Other	
12	PRCSDAT	yyyy MMM dd	Date of storage		Date of Storage	
13	PRCSTIM	HH:nn	Time of storage		Time of Storage	
14	LABID	5	Laboratory ID	8	Laboratory ID	13 = Labcorp

(Version: AZ2310 2025-07-01)

What was the sample collection category?	Biomarkers/exploratory research/diagnostic, solid tissue (2)
Sample collected	No (3)
	Yes
Sample collection method	Core Needle Biopsy (4)
	Excisional Biopsy
	Incisional Biopsy
Biopsy tissue type	Primary tumor (5)
	Metastatic tumor
Organ	Abdomen (6)
	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 ☐	7
Unstained slides sectioning date	Fixed Unit: yyyy mon dd	8
Date of Biopsy	Fixed Unit: yyyy mon dd	9
Sample condition	Sample acceptable ☐ Quantity less than expected ☐ Sample discarded ☐ Other ☐	10
If Other, specify		11
Date of storage	Fixed Unit: yyyy mon dd	12
Time of storage	Fixed Unit: 24-hour clock	13
Laboratory ID	Labcorp	14

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Mandatory screening tumor sample (SPCBEDT1)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	SPECCAT	$2	What was the sample collection category?	$2	Specimen Collection Category	8 = Biomarkers/exploratory research/diagnostic, solid tissue
3	SPECCOL	$6	Sample collected	$6	Specimen Collected	C49487 = No C49488 = Yes
4	COLMTH	$7	Sample collection method	$7	Specimen Collection Method	12 = Core Needle Biopsy 20 = Excisional Biopsy 27 = Incisional Biopsy
5	BIOPTTYP	$2	Biopsy tissue type	$2	Biopsy Tissue Type	1 = Primary tumor 2 = Metastatic tumor
6	ORGAN	$6	Organ	$6	Organ	1 = Abdomen 12 = Bronchus (Main Stem) 23 = Fat 48 = Oesophagus 56 = Pituitary 81 = Urinary Bladder 82 = Esophagogastric Junction C12246 = Hypopharynx C12263 = Duodenum C12311 = Cervix Uteri C12328 = Epididymis C12377 = Gallbladder

Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
					C12379 = Large Intestine C12380 = Appendix C12382 = Colon C12386 = Small Intestine C12387 = Ileum C12388 = Jejunum C12390 = Rectum C12391 = Stomach C12392 = Liver C12393 = Pancreas C12400 = Thyroid Gland C12403 = Fallopian Tube C12404 = Ovary C12405 = Uterus C12410 = Prostate Gland C12412 = Testis C12415 = Kidney C12416 = Ureter C12417 = Urethra C12420 = Larynx C12421 = Oral Cavity

Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
					C12422 = Tongue C12425 = Pharynx C12427 = Parotid Gland C12428 = Trachea C12432 = Spleen C12433 = Thymus Gland C12439 = Brain C12464 = Spinal Cord C12468 = Lung C12469 = Pleura C12470 = Skin C12471 = Soft Tissue C12664 = Abdominal Cavity C12666 = Adrenal Gland C12702 = Diaphragm C12727 = Heart C12745 = Lymph Node C12756 = Nose C12762 = Oropharynx C12765 = Parathyroid Gland C12768 = Peripheral Nerve

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						C12770 = Peritoneum C12802 = Tonsil C12971 = Breast C13044 = Joint C13056 = Muscle C32668 = Gastroesophageal Junction C33103 = Mesentery C33209 = Omentum C43362 = Anus C77608 = Abdominal Wall 99 = Other (Not Specified)
7	SPECFMT	$2	Sample format	$2	Specimen Format	31 = FFPE block 32 = FFPE unstained slides
8	SLSECDT	yyyy MMM dd	Unstained slides sectioning date		Unstained Slides Sectioning Date	
9	SPECDAT	yyyy MMM dd	Date of Biopsy		Date of Collection	
10	SPECCND	$6	Sample condition	$6	Specimen Condition	0 = Sample acceptable 50 = Quantity less than expected 51 = Sample discarded

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Mandatory screening tumor sample (SPCBEDT1)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						99 = Other
11	SPECCNDO	$200	If Other, specify	$200	Specimen Condition, Other	
12	PRCSDAT	yyyy MMM dd	Date of storage		Date of Storage	
13	PRCSTIM	HH:nn	Time of storage		Time of Storage	
14	LABID	5	Laboratory ID	8	Laboratory ID	13 = Labcorp

(Version: AZ2310 2023-10-26)

Was assessment applicable?	No (2) Yes
What was the sample category?	Genetics Inherited, Biofluid (3)
Sample collected	No (4) Yes
Sample collection method	Blood draw (5)
Biofluid collected (parent sample)	Blood (6)
Sample format	Brushings (7) 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	8
Sample condition	Sample acceptable ☐	9
	Hemolyzed ☐	
	Clotted ☐	
	Lipemic ☐	
	Quantity less than expected ☐	
	Sample discarded ☐	
	Other ☐	
If Other, specify		10
Sample collection comment		11
Date of storage	Fixed Unit: yyyy mon dd	12
Time of storage	Fixed Unit: 24-hour clock	13
Laboratory ID	Labcorp	14

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Genomics Initiative (optional), exploratory genetic sample (SPCGB)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	ASM_APP	$6	Was assessment applicable?	$6	Assessment Applicable	C49487 = No C49488 = Yes
3	SPECCAT	$2	What was the sample category?	$2	Specimen Collection Category	1 = Genetics Inherited, Biofluid
4	SPECCOL	$6	Sample collected	$6	Specimen Collected	C49487 = No C49488 = Yes
5	COLMTH	$7	Sample collection method	$7	Specimen Collection Method	8 = Blood draw
6	SPECCOLF	$7	Biofluid collected (parent sample)	$7	Biofluid Collected (Parent Sample)	C12434 = Blood
7	SPECFMT	$2	Sample format	$2	Specimen Format	1 = Brushings 2 = cDNA 3 = Cell culture 4 = Cells 5 = Cells suspension 6 = Cells microarray 7 = cRNA 8 = Cytospin 9 = DNA 10 = DNA microarray 11 = FFPE 12 = FFPE shavings 13 = Formalin fixed 14 = Fresh 15 = Fresh frozen 16 = Frozen 17 = H&E stained slide 18 = IHC slide 19 = Microarray

Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
					20 = Microsomes 21 = OCT embedded 22 = Protein 23 = Protein microarray 24 = RNA 25 = RNA microarray 26 = Supernatant 27 = Tissue microarray (TMA) 28 = Unstained section 29 = Cells frozen 30 = Cells lysate 31 = FFPE Block 32 = FFPE Unstained slides
8 SPECDAT	yyyy MMM dd	Date of collection		Date of Collection	
9 SPECCND	$6	Sample condition	$6	Specimen Condition	0 = Sample acceptable C70720 = Hemolyzed C78724 = Clotted C70715 = Lipemic 50 = Quantity less than expected 51 = Sample discarded 99 = Other

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Genomics Initiative (optional), exploratory genetic sample (SPCGB)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
10	SPECCNDO	$200	If Other, specify	$200	Specimen Condition, Other	
11	SPECCOM	$200	Sample collection comment	$200	Specimen Collection Comment	
12	PRCSDAT	yyyy MMM dd	Date of storage		Date of Storage	
13	PRCSTIM	HH:nn	Time of storage		Time of Storage	
14	LABID	5	Laboratory ID 8		Laboratory ID 13 = Labcorp	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Biological Sample Collection, Pre-dose PK (SPCPKB)
Generated On: 2025 Nov 20 12:23 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample collection category?	PK, biofluid	2
Sample collected	No	3
	Yes	
Last investigational product date	Fixed Unit: yyyy mon dd	4
Last investigational product time	Fixed Unit: 24-hour clock	5
Biofluid collected (parent sample)	Blood	6
Biofluid processed	Serum	7
Date of collection	Fixed Unit: yyyy mon dd	8
Time of collection	Fixed Unit: 24-hour clock	9
Sample condition	Sample acceptable	10
	Hemolyzed	
	Clotted	
	Lipemic	
	Quantity less than expected	
	Sample discarded	
	Other	
If Other, specify		11
Date of storage	Fixed Unit: yyyy mon dd	12
Time of storage	Fixed Unit: 24-hour clock	13
Protocol schedule	Pre Dose	14
Protocol schedule day	1	15
Protocol schedule hour	-99	16
Protocol schedule minute	-99	17
Laboratory ID	Labcorp	18

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Biological Sample Collection, Pre-dose PK (SPCPKB)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	SPECCAT	$2	What was the sample collection category?	$2	Specimen Collection Category	5 = PK, biofluid
3	SPECCOL	$6	Sample collected	$6	Specimen Collected	C49487 = No C49488 = Yes
4	IP_LPDAT	yyyy MMM dd	Last investigational product date		Last Investigational Product Date	
5	IP_LPTIM	HH:nn	Last investigational product time		Last Investigational Product Time	
6	SPECCOLF	$7	Biofluid collected (parent sample)	$7	Biofluid Collected (Parent Sample)	C12434 = Blood
7	SPECPRCF	$6	Biofluid processed	$6	Biofluid Processed	C13325 = Serum
8	SPECDAT	yyyy MMM dd	Date of collection		Date of Collection	
9	SPECTIM	HH:nn	Time of collection		Time of Collection	
10	SPECCND	$6	Sample condition	$6	Specimen Condition	0 = Sample acceptable C70720 = Hemolyzed C78724 = Clotted C70715 = Lipemic 50 = Quantity less than expected 51 = Sample discarded 99 = Other
11	SPECCNDO	$200	If Other, specify	$200	Specimen Condition, Other	
12	PRCSDAT	yyyy MMM dd	Date of storage		Date of Storage	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Biological Sample Collection, Pre-dose PK (SPCPKB)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
13	PRCSTIM	HH:nn	Time of storage		Time of Storage	
14	PROTSCHD	$20	Protocol schedule	$20	Protocol Schedule	Pre Dose|
15	PSCHDAY	4	Protocol schedule day	8	Protocol Schedule Day	1
16	PSCHHOUR	4	Protocol schedule hour	8	Protocol Schedule Hour	-99
17	PSCHMIN	4	Protocol schedule minute	8	Protocol Schedule Minute	-99
18	LABID	5	Laboratory ID	8	Laboratory ID	13 = Labcorp

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Biological Sample Collection, Post-dose PK (SPCPKB1)
Generated On: 2025 Nov 20 12:23 (GMT)

(Version: AZ2310 2023-10-26)

What was the sample collection category?	PK, biofluid	2
Sample collected	No	3
	Yes	
Last investigational product date	Fixed Unit: yyyy mon dd	4
Last investigational product time	Fixed Unit: 24-hour clock	5
Biofluid collected (parent sample)	Blood	6
Biofluid processed	Serum	7
Date of collection	Fixed Unit: yyyy mon dd	8
Time of collection	Fixed Unit: 24-hour clock	9
Sample condition	Sample acceptable	10
	Hemolyzed	
	Clotted	
	Lipemic	
	Quantity less than expected	
	Sample discarded	
	Other	
If Other, specify		11
Date of storage	Fixed Unit: yyyy mon dd	12
Time of storage	Fixed Unit: 24-hour clock	13
Protocol schedule	15 mins Post Dose	14
Protocol schedule day	1	15
Protocol schedule hour	0	16
Protocol schedule minute	15	17
Laboratory ID	Labcorp	18

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Biological Sample Collection, Post-dose PK (SPCPKB1)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	SPECCAT	$2	What was the sample collection category?	$2	Specimen Collection Category	5 = PK, biofluid
3	SPECCOL	$6	Sample collected	$6	Specimen Collected	C49487 = No C49488 = Yes
4	IP_LPDAT	yyyy MMM dd	Last investigational product date		Last Investigational Product Date	
5	IP_LPTIM	HH:nn	Last investigational product time		Last Investigational Product Time	
6	SPECCOLF	$7	Biofluid collected (parent sample)	$7	Biofluid Collected (Parent Sample)	C12434 = Blood
7	SPECPRCF	$6	Biofluid processed	$6	Biofluid Processed	C13325 = Serum
8	SPECDAT	yyyy MMM dd	Date of collection		Date of Collection	
9	SPECTIM	HH:nn	Time of collection		Time of Collection	
10	SPECCND	$6	Sample condition	$6	Specimen Condition	0 = Sample acceptable C70720 = Hemolyzed C78724 = Clotted C70715 = Lipemic 50 = Quantity less than expected 51 = Sample discarded 99 = Other
11	SPECCNDO	$200	If Other, specify	$200	Specimen Condition, Other	
12	PRCSDAT	yyyy MMM dd	Date of storage		Date of Storage	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Biological Sample Collection, Post-dose PK (SPCPKB1)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
13	PRCSTIM	HH:nn	Time of storage		Time of Storage	
14	PROTSCHD	$20	Protocol schedule	$20	Protocol Schedule	15 mins Post Dose|
15	PSCHDAY	4	Protocol schedule day	8	Protocol Schedule Day	1
16	PSCHHOUR	4	Protocol schedule hour	8	Protocol Schedule Hour	0
17	PSCHMIN	4	Protocol schedule minute	8	Protocol Schedule Minute	15
18	LABID	5	Laboratory ID	8	Laboratory ID	13 = Labcorp

(Version: AZ2310 2023-10-26)

What was the sample collection category?	PK, biofluid	2
Sample collected	No	3
	Yes	
Last investigational product date	Fixed Unit: yyyy mon dd	4
Last investigational product time	Fixed Unit: 24-hour clock	5
Biofluid collected (parent sample)	Blood	6
Biofluid processed	Serum	7
Date of collection	Fixed Unit: yyyy mon dd	8
Time of collection	Fixed Unit: 24-hour clock	9
Sample condition	Sample acceptable	10
	Hemolyzed	
	Clotted	
	Lipemic	
	Quantity less than expected	
	Sample discarded	
	Other	
If Other, specify		11
Date of storage	Fixed Unit: yyyy mon dd	12
Time of storage	Fixed Unit: 24-hour clock	13
Protocol schedule day	9999	14
Protocol schedule hour	-999	15
Protocol schedule minute	-99	16
Laboratory ID	Labcorp	17

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Biological Sample Collection, PK (SPCPKB2)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	SPECCAT	$2	What was the sample collection category?	$2	Specimen Collection Category	5 = PK, biofluid
3	SPECCOL	$6	Sample collected	$6	Specimen Collected	C49487 = No C49488 = Yes
4	IP_LPDAT	yyyy MMM dd	Last investigational product date		Last Investigational Product Date	
5	IP_LPTIM	HH:nn	Last investigational product time		Last Investigational Product Time	
6	SPECCOLF	$7	Biofluid collected (parent sample)	$7	Biofluid Collected (Parent Sample)	C12434 = Blood
7	SPECPRCF	$6	Biofluid processed	$6	Biofluid Processed	C13325 = Serum
8	SPECDAT	yyyy MMM dd	Date of collection		Date of Collection	
9	SPECTIM	HH:nn	Time of collection		Time of Collection	
10	SPECCND	$6	Sample condition	$6	Specimen Condition	0 = Sample acceptable C70720 = Hemolyzed C78724 = Clotted C70715 = Lipemic 50 = Quantity less than expected 51 = Sample discarded 99 = Other
11	SPECCNDO	$200	If Other, specify	$200	Specimen Condition, Other	
12	PRCSDAT	yyyy MMM dd	Date of storage		Date of Storage	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Biological Sample Collection, PK (SPCPKB2)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
13	PRCSTIM	HH:nn	Time of storage		Time of Storage	
14	PSCHDAY	4	Protocol schedule day	8	Protocol Schedule Day	9999
15	PSCHHOUR	4	Protocol schedule hour	8	Protocol Schedule Hour	-999
16	PSCHMIN	4	Protocol schedule minute	8	Protocol Schedule Minute	-99
17	LABID	5	Laboratory ID	8	Laboratory ID	13 = Labcorp

(Version: ON2212 2025-03-26)

Target lesions, Baseline

Were there any target lesions present?	No ☐ 3 Yes ☐
What was the date of last scan?	Fixed Unit: yyyy mon dd 4

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 5
Anatomical location	Esophagus, Upper Thoracic ☐ 6 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 ☐	7
	Right ☐	
	Left ☐	
	Not applicable ☐	
Specify location within site	_____	8
Specify liver location	Liver-caudate lobe, segment I ☐	9
	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	_____	10
Method	MRI ☐	11
	CT scan ☐	
	Not done ☐	
Longest diameter	Fixed Unit: mm	12
	_____	
Lesion number	2	5
Anatomical location	Esophagus, Upper Thoracic ☐	6
	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 ☐ (7)
	Right ☐
	Left ☐
	Not applicable ☐
Specify location within site	_____ (8)
Specify liver location	Liver-caudate lobe, segment I ☐ (9)
	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	_____ (10)
Method	MRI ☐ (11)
	CT scan ☐

	Not done ☐
Longest diameter	Fixed Unit: mm (12)
Lesion number	3 (5)
Anatomical location	Esophagus, Upper Thoracic ☐ (6)
	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 ☐ (7)
	Right ☐
	Left ☐
	Not applicable ☐
Specify location within site	(8)

Specify liver location	Liver-caudate lobe, segment I	9
	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		10
Method	MRI	11
	CT scan	
	Not done	
Longest diameter	Fixed Unit: mm	12
Lesion number	4	5
Anatomical location	Esophagus, Upper Thoracic	6
	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 ☐ 7
	Right ☐
	Left ☐
	Not applicable ☐
Specify location within site	_____ 8
Specify liver location	Liver-caudate lobe, segment I ☐ 9
	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	_____ 10
Method	MRI ☐ 11
	CT scan ☐
	Not done ☐
Longest diameter	Fixed Unit: mm 12
	_____
Lesion number	5 5
Anatomical location	Esophagus, Upper Thoracic ☐ 6

	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 ☐ (7)
	Right ☐
	Left ☐
	Not applicable ☐
Specify location within site	_____ (8)
Specify liver location	Liver-caudate lobe, segment I ☐ (9)
	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	_____ 10
Method	MRI ☐ 11
	CT scan ☐
	Not done ☐
Longest diameter	Fixed Unit: mm 12
	_____

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Target lesions, Baseline (1RECIST1)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
3	TRCYN	$6	Were there any target lesions present?	$6	Any Target Lesion Present	C49487 = No C49488 = Yes
4	TRCDAT1	yyyy MMM dd	What was the date of last scan?		Date of Last Scan	
5	TUCLNKID	2	Lesion number	8	Lesion Number	1|2|3|4|5|
6	TULOC1	$7	Anatomical location	$7	Location 1	1 = Esophagus, Upper Thoracic 2 = Esophagus, Middle Thoracic 3 = Esophagus, Lower Thoracic C12298 = Retroperitoneum C12392 = Liver C12469 = Pleura C12666 = Adrenal gland C33020 = Lung, Left Lower Lobe C33021 = Lung, Left Upper Lobe C33022 = Lung, Right Lower Lobe C12286 = Lung, Right Middle Lobe

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						C33023 = Lung, Right Upper Lobe C49018 = Regional lymph node C106042 = Distant lymph node C12366 = Bone C12391 = Stomach C12404 = Ovary C12432 = Spleen C12393 = Pancreas C12677 = Intrahepatic Bile Duct C32573 = Extrahepatic Bile Duct C12748 = Mediastinum C12377 = Gallbladder C12770 = Peritoneum 99 = Other
7	TUCLAT1	$6	Tumor laterality	$6	Tumor Laterality 1	C13332 = Bilateral C25228 = Right C25229 = Left 98 = Not applicable
8	S_R1SIT	$200	Specify location within site	$200	Location Within Site Specification	

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
9	SL_R1SIT	$6	Specify liver location	$6	Specific Liver Location	1 = Liver-caudate lobe, segment I 2 = Liver-left lobe, segment II 3 = Liver-left lobe, segment III 4 = Liver-left lobe, segment IV 5 = Liver-right lobe, segment V 6 = Liver-right lobe, segment VI 7 = Liver-right lobe, segment VII 8 = Liver-right lobe, segment VIII C32965 = Liver, left lobe C33481 = Liver, right lobe 9 = Liver, specify
10	SSLR1SIT	$200	Location within liver specification	$200	Location Within Liver Specification	
11	TRMETHD1	$7	Method	$7	Method of Test or Examination	C16809 = MRI C17204 = CT scan C49484 = Not done
12	LDIAM	5.1	Longest diameter	8	Longest Diameter	

(Version: ON2212 2025-03-26)

Non-target lesions, Baseline

Was any non-target lesion present?	No	3
	Yes	
What was the date of the last scan?	Fixed Unit: yyyy mon dd	4
Anatomical location	Brain Frontal Lobe	5
	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	6
	Right	
	Left	
	Not applicable	
Method	MRI	7
	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: Uniques
Form: Non-target lesions, Baseline (2RECIST1)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
3	R2PRES	$6	Was any non-target lesion present?	$6	Any Non-Target Lesion Present	C49487 = No C49488 = Yes
4	TRCDAT2	yyyy MMM dd	What was the date of the last scan?		Date of Last Scan/Clinical Examination	
5	TULOC2	$7	Anatomical location	$7	Location 2	C12352 = Brain Frontal Lobe C12354 = Brain Parietal Lobe C12355 = Brain Occipital Lobe C12441 = Brain stem C12510 = Brain Midbrain C12827 = Brain, third ventricle C12366 = Bone C12392 = Liver C12464 = Spinal cord C12469 = Pleura C12666 = Adrenal gland C33020 = Lung, Left Lower Lobe C33021 = Lung, Left Upper Lobe C33022 = Lung, Right Lower Lobe

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						C12286 = Lung, Right Middle Lobe C33023 = Lung, Right Upper Lobe C49018 = Regional lymph node C106042 = Distant lymph node C12748 = Mediastinum 5 = Pericardial Effusion 6 = Pleural Effusion 99 = Other
6	TUCLAT2	$6	Tumor laterality	$6	Tumor Laterality 2	C13332 = Bilateral C25228 = Right C25229 = Left 98 = Not applicable
7	TRMETHD2	$7	Method	$7	Method of Test or Examination	C16809 = MRI C17204 = CT scan C38101 = X-ray C62667 = Scintigraphy C103400 = FDGPET

(Version: ON2212 2025-03-26)

Have target lesions been assessed?	No ☐ 2 Yes ☐ Not applicable ☐
What was the date of last scan?	Fixed Unit: yyyy mon dd 3

For lymph nodes, the shortest axis must be recorded.

Lesion number	1 4
Anatomical location	Esophagus, Upper Thoracic ☐ 5 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 ☐ 6

	Right ☐
	Left ☐
	Not applicable ☐
Specify location within site	7
Specify liver location	Liver-caudate lobe, segment I ☐ 8
	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	9
Method	MRI ☐ 10
	CT scan ☐
	Not done ☐
Longest diameter	Fixed Unit: mm 11
If no longer measurable, reason	Tumor too large to accurately measure ☐ 12
	Tumor too small to accurately measure ☐
	Not evaluable ☐
Lesion intervention	Yes ☐ 13
Lesion number	2 4
Anatomical location	Esophagus, Upper Thoracic ☐ 5
	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 ☐ (6)
	Right ☐
	Left ☐
	Not applicable ☐
Specify location within site	(7)
Specify liver location	Liver-caudate lobe, segment I ☐ (8)
	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	_____ 9
Method	MRI ☐ 10
	CT scan ☐
	Not done ☐
Longest diameter	Fixed Unit: mm 11
	_____
If no longer measurable, reason	Tumor too large to accurately measure ☐ 12
	Tumor too small to accurately measure ☐
	Not evaluable ☐
Lesion intervention	Yes ☐ 13
Lesion number	3 4
Anatomical location	Esophagus, Upper Thoracic ☐ 5
	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 ☐	6
	Right ☐	
	Left ☐	
	Not applicable ☐	
Specify location within site	_____	7
Specify liver location	Liver-caudate lobe, segment I ☐	8
	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	_____	9
Method	MRI ☐	10
	CT scan ☐	
	Not done ☐	
Longest diameter	Fixed Unit: mm _____	11
If no longer measurable, reason	Tumor too large to accurately measure ☐	12
	Tumor too small to accurately measure ☐	
	Not evaluable ☐	
Lesion intervention	Yes ☐	13
Lesion number	4	4

Anatomical location	Esophagus, Upper Thoracic ☐	5
	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 ☐	6
	Right ☐	
	Left ☐	
	Not applicable ☐	
Specify location within site	_____	7
Specify liver location	Liver-caudate lobe, segment I ☐	8
	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	_____	9
Method	MRI ☐	10
	CT scan ☐	
	Not done ☐	
Longest diameter	Fixed Unit: mm 11	
	_____	
If no longer measurable, reason	Tumor too large to accurately measure ☐	12
	Tumor too small to accurately measure ☐	
	Not evaluable ☐	
Lesion intervention	Yes ☐	13
Lesion number	5	4
Anatomical location	Esophagus, Upper Thoracic ☐	5
	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 ☐	6
	Right ☐	
	Left ☐	
	Not applicable ☐	
Specify location within site	_____	7
Specify liver location	Liver-caudate lobe, segment I ☐	8
	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	_____	9
Method	MRI ☐	10
	CT scan ☐	
	Not done ☐	
Longest diameter	Fixed Unit: mm	11
	_____	

If no longer measurable, reason	Tumor too large to accurately measure	☐ 12
	Tumor too small to accurately measure	☐
	Not evaluable	☐
Lesion intervention	Yes	☐ 13

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Target lesions, Follow-up (3RECIST1)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	R1TLASS	$6	Have target lesions been assessed?	$6	Target Lesions Assessed	C49487 = No C49488 = Yes C48660 = Not applicable
3	TRCDAT1	yyyy MMM dd	What was the date of last scan?		Date of Last Scan	
4	TUCLNKID	2	Lesion number	8	Lesion Number	1|2|3|4|5|
5	TULOC1	$7	Anatomical location	$7	Location 1	1 = Esophagus, Upper Thoracic 2 = Esophagus, Middle Thoracic 3 = Esophagus, Lower Thoracic C12298 = Retroperitoneum C12392 = Liver C12469 = Pleura C12666 = Adrenal gland C33020 = Lung, Left Lower Lobe C33021 = Lung, Left Upper Lobe C33022 = Lung, Right Lower Lobe C12286 = Lung, Right Middle Lobe

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						C33023 = Lung, Right Upper Lobe C49018 = Regional lymph node C106042 = Distant lymph node C12366 = Bone C12391 = Stomach C12404 = Ovary C12432 = Spleen C12393 = Pancreas C12677 = Intrahepatic Bile Duct C32573 = Extrahepatic Bile Duct C12748 = Mediastinum C12377 = Gallbladder C12770 = Peritoneum 99 = Other
6	TUCLAT1	$6	Tumor laterality	$6	Tumor Laterality 1	C13332 = Bilateral C25228 = Right C25229 = Left 98 = Not applicable
7	S_R1SIT	$200	Specify location within site	$200	Location Within Site Specification	

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
8	SL_R1SIT	$6	Specify liver location	$6	Specific Liver Location	1 = Liver-caudate lobe, segment I 2 = Liver-left lobe, segment II 3 = Liver-left lobe, segment III 4 = Liver-left lobe, segment IV 5 = Liver-right lobe, segment V 6 = Liver-right lobe, segment VI 7 = Liver-right lobe, segment VII 8 = Liver-right lobe, segment VIII C32965 = Liver, left lobe C33481 = Liver, right lobe 9 = Liver, specify
9	SSLR1SIT	$200	Location within liver specification	$200	Location Within Liver Specification	
10	TRMETHD1	$7	Method	$7	Method of Test or Examination	C16809 = MRI C17204 = CT scan C49484 = Not done
11	LDIAM	5.1	Longest diameter	8	Longest Diameter	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Target lesions, Follow-up (3RECIST1)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
12	R1NLM	$2	If no longer measurable, reason	$2	Lesion No Longer Measurable	14 = Tumor too large to accurately measure 15 = Tumor too small to accurately measure 91 = Not evaluable
13	R1LESINT	$6	Lesion intervention	$6	Lesion Intervention	C49488 = Yes

(Version: ON2212 2025-03-26)

Have non-target lesions been assessed?	No	2
	Yes	
	Not applicable	
What was the date of last scan?	Fixed Unit: yyyy mon dd	3
What was the response of non-target lesions at this assessment?	Complete response	4
	Progressive disease	
	Non-complete response/non-progressive disease	
	Not evaluable	
Anatomical location	Brain Frontal Lobe	5
	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	6

CT scan ☐
X-ray ☐
Scintigraphy ☐
FDGPET ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Non-target lesions, Follow-up (4RECIST1)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	R1NTLASS	$6	Have non-target lesions been assessed?	$6	Non-Target Lesions Assessed	C49487 = No C49488 = Yes C48660 = Not applicable
3	TRCDAT2	yyyy MMM dd	What was the date of last scan?		Date of Last Scan/Clinical Examination	
4	NTRGRESP	$6	What was the response of non-target lesions at this assessment?	$6	Non-target Response	C4870 = Complete response C35571 = Progressive disease C96700 = Non-complete response/non-progressive disease C62222 = Not evaluable
5	TULOC2	$7	Anatomical location	$7	Location 2	C12352 = Brain Frontal Lobe C12354 = Brain Parietal Lobe C12355 = Brain Occipital Lobe C12441 = Brain stem C12510 = Brain Midbrain C12827 = Brain, third ventricle C12366 = Bone C12392 = Liver C12464 = Spinal cord

Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
					C12469 = Pleura C12666 = Adrenal gland C33020 = Lung, Left Lower Lobe C33021 = Lung, Left Upper Lobe C33022 = Lung, Right Lower Lobe C12286 = Lung, Right Middle Lobe C33023 = Lung, Right Upper Lobe C49018 = Regional lymph node C106042 = Distant lymph node C12748 = Mediastinum 5 = Pericardial Effusion 6 = Pleural Effusion 99 = Other
6 TRMETHD2	$7	Method	$7	Method of Test or Examination	C16809 = MRI C17204 = CT scan C38101 = X-ray C62667 = Scintigraphy C103400 = FDGPET

(Version: ON2310 2025-03-26)

New lesions

Are there any new lesions since baseline?	No Yes	3
What was the date of earliest scan/clinical examination detecting new lesions?	Fixed Unit: yyyy mon dd	4
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	5
If Other, specify		6
Method	FDGPET MRI CT scan X-ray Scintigraphy	7
New equivocal lesion present	No	8

	Yes ☐
Equivocal lesion converted to unequivocal	No ☐ 9
	Yes ☐
	Not applicable ☐
Date of scan equivocal lesion first detected	Fixed Unit: yyyy mon dd 10

Overall visit response

What is the RECIST response?	Complete response ☐ 12
	Partial response ☐
	Stable disease ☐
	Progressive disease ☐
	Not evaluable ☐
Criteria type	RECIST 1.1 13

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
3	TRCYN1	$6	Are there any new lesions since baseline?	$6	Any New Lesions Since Baseline	C49487 = No C49488 = Yes
4	TRCDAT3	yyyy MMM dd	What was the date of earliest scan/clinical examination detecting new lesions?		Date Earliest Scan/Clin Exam New Lesion	
5	TULOC	$7	Anatomical location	$7	Location	5 = Pericardial effusion 6 = Pleural effusion C12366 = Bone C12392 = Liver C12439 = Brain C12464 = Spinal cord C12469 = Pleura C12470 = Skin C12666 = Adrenal gland C49018 = Regional lymph node C106042 = Distant lymph node 30 = Ascites C32573 = Extrahepatic Bile Duct C12677 = Intrahepatic Bile Duct C12377 = Gallbladder

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						C12468 = Lung C12393 = Pancreas C12770 = Peritoneum C12432 = Spleen 99 = Other
6	TULOCO	$200	If Other, specify	$200	New Lesion Site, Specify	
7	TRMETHD	$7	Method	$7	Method of Test or Examination	C103400 = FDGPET C16809 = MRI C17204 = CT scan C38101 = X-ray C62667 = Scintigraphy
8	EQLSCN	$6	New equivocal lesion present	$6	New Equivocal Lesion Present	C49487 = No C49488 = Yes
9	LESCON	$6	Equivocal lesion converted to unequivocal	$6	Equivocal Lesion Convert to Unequivocal	C49487 = No C49488 = Yes C48660 = Not applicable
10	LESEQDAT	yyyy MMM dd	Date of scan equivocal lesion first detected		Date of Scan Equivocal Lesion Detected	
12	R3IORESP	$6	What is the RECIST response?	$6	RECIST Response	C4870 = Complete response C18058 = Partial response C18213 = Stable disease C35571 = Progressive disease

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						C62222 = Not evaluable
13	CRITYPE	$7	Criteria type	$7	Criteria Type	C124415 = RECIST 1.1

(Version: OM20407 2024-07-18)

Assessment date	Fixed Unit: yyyy mon dd	2
New lesion number		3
Has biopsy been performed?	No ☐ Yes ☐	4
Date of biopsy	Fixed Unit: yyyy mon dd	5
Did the pathology results of the biopsy confirm a new primary malignancy?	No ☐ Yes ☐	6
Did the pathology results of the biopsy confirm metastasis from the primary disease?	No ☐ Yes ☐	7
Did the pathology results of the biopsy confirm the metastasis from a new primary malignancy?	No ☐ Yes ☐	8
Enter details of pathology results e.g. infection, inflammation, cytology or details of new cancer, Pathology results, specify		9

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: New Lesions Additional Information (NLESADD)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	ASM_DAT	yyyy MMM dd	Assessment date		Assessment Date	
3	NEWLESNO	2	New lesion number	8	New Lesion Number	
4	BIOPYN	$6	Has biopsy been performed?	$6	Biopsy Performed	C49487 = No C49488 = Yes
5	BIOPDAT	yyyy MMM dd	Date of biopsy		Date of Biopsy	
6	NEWPRMAL	$6	Did the pathology results of the biopsy confirm a new primary malignancy?	$6	Pathology Conf New Primary Malignancy	C49487 = No C49488 = Yes
7	METPRIMS	$6	Did the pathology results of the biopsy confirm metastasis from the primary disease?	$6	Pathology Conf Met from Primary Disease	C49487 = No C49488 = Yes
8	METNEWPM	$6	Did the pathology results of the biopsy confirm the metastasis from a new primary malignancy?	$6	Pathology Conf Met from New Primary Mal	C49487 = No C49488 = Yes

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: New Lesions Additional Information (NLESADD)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
9	PATHRES	$200	Enter details of pathology results e.g. infection, inflammation, cytology or details of new cancer, Pathology results, specify	$200	Pathology Results, Specify	

(Version: AZ2403 2025-05-05)

Were any study drugs taken?	No ☐ 2 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 3
Cycle number	C1D1 ☐ 4 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	_____	5
Start date	Fixed Unit: yyyy mon dd _____	6
Start time	Fixed Unit: 24-hour clock _____	7
End date	Fixed Unit: yyyy mon dd _____	8
End time	Fixed Unit: 24-hour clock _____	9
Planned study drug dose for this cycle	_____	10
Planned dose units	mg ☐	11
	mg/m2 ☐	
Actual study drug dose for this cycle	_____	12
Actual study drug dose unit	mg ☐	13
	mg/m2 ☐	
Action taken with study drug	Dose Not Changed ☐	14
	Drug Interrupted ☐	
	Not Applicable ☐	
Was this the last dose of study drug given?	Yes ☐	15
Reason adjusted	Adverse event ☐	16
	Technical issue ☐	
	Subject decision ☐	
	Other ☐	
If reason adjusted is equal to 'Other', specify Reason adjusted, specify	_____	17

AE number 1	_____	18
AE number 2	_____	19
AE number 3	_____	20
AE number 4	_____	21
Volume of infusion before administration	_____	22
Volume of infusion after administration	_____	23
Infusion volume unit	mL	24
Treatment cycle delayed	No	25
	Yes	
Reason treatment cycle delayed	Adverse event	26
	Subject decision	
	Lab abnormality not reported as an AE	
	Other	
Treatment delayed AE number 1	_____	27
Treatment delayed AE number 2	_____	28
Treatment delayed AE number 3	_____	29
Treatment delayed AE number 4	_____	30
If Reason treatment cycle delayed is equal to 'Other', specify Reason treatment cycle delayed, Specify	_____	31
Study drug administration/location impacted by global/country situation	Yes	32
Study drug location status - global/country situation	Site	33
	Other	
If Other, specify	_____	34
Administration performed by - global/country situation	Health care professional	35
	Other	
If Other, specify	_____	36

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Exposure as Collected - Rilvegostomig (EC)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	ECYN	$6	Were any study drugs taken?	$6	Any Study Treatment Taken	C49487 = No C49488 = Yes
3	ECTRT	$200	Study drug	$200	Treatment Name	Rilvegostomig
4	Z_CYCNUM	$5	Cycle number			1 = C1D1 2 = C2D1 3 = C3D1 4 = C4D1 5 = C5D1 6 = C6D1 7 = C7D1 8 = C8D1 9 = C9D1 10 = C10D1 11 = C11D1 12 = C12D1 13 = C13D1 14 = C14D1 15 = C15D1 16 = C16D1 17 = C17D1 18 = C18D1 19 = C19D1 20 = C20D1 21 = C21D1 22 = C22D1 23 = C23D1 24 = C24D1 25 = C25D1 26 = C26D1 27 = C27D1 28 = C28D1 29 = C29D1 30 = C30D1 31 = C31D1 32 = C32D1 33 = C33D1 34 = C34D1 35 = C35D1 36 = C36D1 37 = C37D1 38 = C38D1 39 = C39D1

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						40 = C40D1 41 = C41D1 42 = C42D1 43 = C43D1 44 = C44D1 45 = C45D1 46 = C46D1 47 = C47D1 48 = C48D1 49 = C49D1 50 = C50D1 51 = C51D1 52 = C52D1 53 = C53D1 54 = C54D1 55 = C55D1 56 = C56D1 57 = C57D1 58 = C58D1 59 = C59D1 60 = C60D1 61 = C61D1 62 = C62D1 63 = C63D1 64 = C64D1 65 = C65D1 66 = C66D1 67 = C67D1 68 = C68D1 69 = C69D1 70 = C70D1
5	CYCNUM	$8	Cycle number	$8	Cycle Number	
6	ECSTDAT	yyyy MMM dd	Start date		Exposure Start Date	
7	ECSTTIM	HH:nn	Start time		Exposure Start Time	
8	ECENDAT	yyyy MMM dd	End date		Exposure End Date	
9	ECENTIM	HH:nn	End time		Exposure End Time	
10	ECPDOSE	4.1	Planned study drug dose for this cycle	8	Planned Dose	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Exposure as Collected - Rilvegostomig (EC)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
11	ECPDOSEU	$7	Planned dose units	$7	Planned Dose Units	C28253 = mg C67402 = mg/m2
12	ECDSTXT	4.1	Actual study drug dose for this cycle	8	Dose	
13	ECDOSU	$7	Actual study drug dose unit	$7	Exposure Dose Unit	C28253 = mg C67402 = mg/m2
14	ECACN	$2	Action taken with study drug	$2	Action Taken, Study Drug	0 = Dose Not Changed 3 = Drug Interrupted 98 = Not Applicable
15	ECDISC	$6	Was this the last dose of study drug given?	$6	Last Dose of Study Drug Given	C49488 = Yes
16	ECADJ	$2	Reason adjusted	$2	Reason for Dose Adjustment	1 = Adverse event 12 = Technical issue 18 = Subject decision 99 = Other
17	ECADJS	$200	**If reason adjusted is equal to 'Other', specify** Reason adjusted, specify	$200	Reason Adjusted Specification	
18	ECAENO1	3	AE number 1	8	AE Number 1	
19	ECAENO2	3	AE number 2	8	AE Number 2	
20	ECAENO3	3	AE number 3	8	AE Number 3	
21	ECAENO4	3	AE number 4	8	AE Number 4	

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
22	ECVIBEF	3	Volume of infusion before administration	8	Volume of Infusion Before Administration	
23	ECVIAFT	3	Volume of infusion after administration	8	Volume of Infusion After Administration	
24	ECSDVIU	$6	Infusion volume unit	$6	Infusion Volume Unit	C28254 = mL
25	ECDEL	$6	Treatment cycle delayed	$6	Treatment Cycle Delayed	C49487 = No C49488 = Yes
26	ECDELR	$2	Reason treatment cycle delayed	$2	Reason Treatment Cycle Delayed	2 = Adverse event 5 = Subject decision 6 = Lab abnormality not reported as an AE 99 = Other
27	ECDAENO1	3	Treatment delayed AE number 1	8	Treatment Delayed AE Number 1	
28	ECDAENO2	3	Treatment delayed AE number 2	8	Treatment Delayed AE Number 2	
29	ECDAENO3	3	Treatment delayed AE number 3	8	Treatment Delayed AE Number 3	
30	ECDAENO4	3	Treatment delayed AE number 4	8	Treatment Delayed AE Number 4	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Exposure as Collected - Rilvegostomig (EC)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
31	ECDELRO	$200	**If Reason treatment cycle delayed is equal to 'Other', specify** Reason treatment cycle delayed, Specify	$200	Reason Treatment Cycle Delayed, Other	
32	ECLPRELI	$6	Study drug administration /location impacted by global/country situation	$6	Glob/Countr Sit Relat Indicat, Loc/Admin	C49488 = Yes
33	ECSLOCST	$2	Study drug location status - global/country situation	$2	SD Locatio Status, Global/Countr y Situat	1 = Site 99 = Other
34	ECSLOSTO	$200	If Other, specify	$200	Other, Specify	
35	ECSADPER	$6	Administratio n performed by - global/country situation	$6	Admin. Perfr. by, Global/Countr y Situat	C53287 = Health care professional 99 = Other
36	ECSADPEO	$200	If Other, specify	$200	Other, Specify	

(Version: AZ2403 2025-05-05)

Were any study drugs taken?	No	2
	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	3
Cycle number	C1D1	4
	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	_____	5
Start date	Fixed Unit: yyyy mon dd _____	6
Start time	Fixed Unit: 24-hour clock _____	7
End date	Fixed Unit: yyyy mon dd _____	8
End time	Fixed Unit: 24-hour clock _____	9
Planned study drug dose for this cycle	_____	10
Planned dose units	mg ☐	11
	mg/m2 ☐	
Actual study drug dose for this cycle	_____	12
Actual study drug dose unit	mg ☐	13
	mg/m2 ☐	
Action taken with study drug	Dose Not Changed ☐	14
	Drug Interrupted ☐	
	Not Applicable ☐	
Was this the last dose of study drug given?	Yes ☐	15
Reason adjusted	Adverse event ☐	16
	Technical issue ☐	
	Subject decision ☐	
	Other ☐	
If reason adjusted is equal to 'Other', specify Reason adjusted, specify	_____	17

AE number 1	_____	18
AE number 2	_____	19
AE number 3	_____	20
AE number 4	_____	21
Volume of infusion before administration	_____	22
Volume of infusion after administration	_____	23
Infusion volume unit	mL	24
Treatment cycle delayed	No	25
	Yes	
Reason treatment cycle delayed	Adverse event	26
	Subject decision	
	Lab abnormality not reported as an AE	
	Other	
Treatment delayed AE number 1	_____	27
Treatment delayed AE number 2	_____	28
Treatment delayed AE number 3	_____	29
Treatment delayed AE number 4	_____	30
If Reason treatment cycle delayed is equal to 'Other', specify Reason treatment cycle delayed, Specify	_____	31
Study drug administration/location impacted by global/country situation	Yes	32
Study drug location status - global/country situation	Site	33
	Other	
If Other, specify	_____	34
Administration performed by - global/country situation	Health care professional	35
	Other	
If Other, specify	_____	36

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Exposure as Collected - Durvalumab (EC3)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	ECYN	$6	Were any study drugs taken?	$6	Any Study Treatment Taken	C49487 = No C49488 = Yes
3	ECTRT	$200	Study drug	$200	Treatment Name	Durvalumab
4	Z_CYCNUM	$5	Cycle number			1 = C1D1 2 = C2D1 3 = C3D1 4 = C4D1 5 = C5D1 6 = C6D1 7 = C7D1 8 = C8D1 9 = C9D1 10 = C10D1 11 = C11D1 12 = C12D1 13 = C13D1 14 = C14D1 15 = C15D1 16 = C16D1 17 = C17D1 18 = C18D1 19 = C19D1 20 = C20D1 21 = C21D1 22 = C22D1 23 = C23D1 24 = C24D1 25 = C25D1 26 = C26D1 27 = C27D1 28 = C28D1 29 = C29D1 30 = C30D1 31 = C31D1 32 = C32D1 33 = C33D1 34 = C34D1 35 = C35D1 36 = C36D1 37 = C37D1 38 = C38D1 39 = C39D1

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						40 = C40D1 41 = C41D1 42 = C42D1 43 = C43D1 44 = C44D1 45 = C45D1 46 = C46D1 47 = C47D1 48 = C48D1 49 = C49D1 50 = C50D1 51 = C51D1 52 = C52D1 53 = C53D1 54 = C54D1 55 = C55D1 56 = C56D1 57 = C57D1 58 = C58D1 59 = C59D1 60 = C60D1 61 = C61D1 62 = C62D1 63 = C63D1 64 = C64D1 65 = C65D1 66 = C66D1 67 = C67D1 68 = C68D1 69 = C69D1 70 = C70D1
5	CYCNUM	$8	Cycle number	$8	Cycle Number	
6	ECSTDAT	yyyy MMM dd	Start date		Exposure Start Date	
7	ECSTTIM	HH:nn	Start time		Exposure Start Time	
8	ECENDAT	yyyy MMM dd	End date		Exposure End Date	
9	ECENTIM	HH:nn	End time		Exposure End Time	
10	ECPDOSE	4	Planned study drug dose for this cycle	8	Planned Dose	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Exposure as Collected - Durvalumab (EC3)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
11	ECPDOSEU	$7	Planned dose units	$7	Planned Dose Units	C28253 = mg C67402 = mg/m2
12	ECDSTXT	4	Actual study drug dose for this cycle	8	Dose	
13	ECDOSU	$7	Actual study drug dose unit	$7	Exposure Dose Unit	C28253 = mg C67402 = mg/m2
14	ECACN	$2	Action taken with study drug	$2	Action Taken, Study Drug	0 = Dose Not Changed 3 = Drug Interrupted 98 = Not Applicable
15	ECDISC	$6	Was this the last dose of study drug given?	$6	Last Dose of Study Drug Given	C49488 = Yes
16	ECADJ	$2	Reason adjusted	$2	Reason for Dose Adjustment	1 = Adverse event 12 = Technical issue 18 = Subject decision 99 = Other
17	ECADJS	$200	**If reason adjusted is equal to 'Other', specify** Reason adjusted, specify	$200	Reason Adjusted Specification	
18	ECAENO1	3	AE number 1	8	AE Number 1	
19	ECAENO2	3	AE number 2	8	AE Number 2	
20	ECAENO3	3	AE number 3	8	AE Number 3	
21	ECAENO4	3	AE number 4	8	AE Number 4	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Exposure as Collected - Durvalumab (EC3)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
22	ECVIBEF	4	Volume of infusion before administration	8	Volume of Infusion Before Administration	
23	ECVIAFT	4	Volume of infusion after administration	8	Volume of Infusion After Administration	
24	ECSDVIU	$6	Infusion volume unit	$6	Infusion Volume Unit	C28254 = mL
25	ECDEL	$6	Treatment cycle delayed	$6	Treatment Cycle Delayed	C49487 = No C49488 = Yes
26	ECDELR	$2	Reason treatment cycle delayed	$2	Reason Treatment Cycle Delayed	2 = Adverse event 5 = Subject decision 6 = Lab abnormality not reported as an AE 99 = Other
27	ECDAENO1	3	Treatment delayed AE number 1	8	Treatment Delayed AE Number 1	
28	ECDAENO2	3	Treatment delayed AE number 2	8	Treatment Delayed AE Number 2	
29	ECDAENO3	3	Treatment delayed AE number 3	8	Treatment Delayed AE Number 3	
30	ECDAENO4	3	Treatment delayed AE number 4	8	Treatment Delayed AE Number 4	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Exposure as Collected - Durvalumab (EC3)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
31	ECDELRO	$200	**If Reason treatment cycle delayed is equal to 'Other', specify** Reason treatment cycle delayed, Specify	$200	Reason Treatment Cycle Delayed, Other	
32	ECLPRELI	$6	Study drug administration /location impacted by global/country situation	$6	Glob/Countr Sit Relat Indicat, Loc/Admin	C49488 = Yes
33	ECSLOCST	$2	Study drug location status - global/country situation	$2	SD Locatio Status, Global/Countr y Situat	1 = Site 99 = Other
34	ECSLOSTO	$200	If Other, specify	$200	Other, Specify	
35	ECSADPER	$6	Administratio n performed by - global/country situation	$6	Admin. Perfr. by, Global/Countr y Situat	C53287 = Health care professional 99 = Other
36	ECSADPEO	$200	If Other, specify	$200	Other, Specify	

(Version: AZ2403 2025-05-05)

Were any study drugs taken?	No ☐	2
	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	3
Cycle number	C1D1 ☐	4
	C1D8 ☐	
	C2D1 ☐	
	C2D8 ☐	
	C3D1 ☐	
	C3D8 ☐	
	C4D1 ☐	
	C4D8 ☐	
	C5D1 ☐	
	C5D8 ☐	
	C6D1 ☐	
	C6D8 ☐	
	C7D1 ☐	
	C7D8 ☐	
	C8D1 ☐	
	C8D8 ☐	
Cycle number		5
Start date	Fixed Unit: yyyy mon dd	6
Start time	Fixed Unit: 24-hour clock	7
End date	Fixed Unit: yyyy mon dd	8
End time	Fixed Unit: 24-hour clock	9
Planned study drug dose for this cycle		10
Planned dose units	mg ☐	11
	mg/m2 ■	

Actual study drug dose for this cycle		12
Actual study drug dose unit	mg	13
	mg/m2	
Action taken with study drug	Dose not changed	14
	Dose increased	
	Dose reduced	
	Drug interrupted	
	Not applicable	
Was this the last dose of study drug given?	Yes	15
Reason adjusted	Adverse event	16
	Technical issue	
	Subject decision	
	Other	
If reason adjusted is equal to 'Other', specify Reason adjusted, specify		17
AE number 1		18
AE number 2		19
AE number 3		20
AE number 4		21
Volume of infusion before administration		22
Volume of infusion after administration		23
Infusion volume unit	mL	24
Treatment cycle delayed	No	25
	Yes	
Reason treatment cycle delayed	Adverse event	26
	Subject decision	
	Lab abnormality not reported as an AE	
	Other	
Treatment delayed AE number 1		27
Treatment delayed AE number 2		28
Treatment delayed AE number 3		29
Treatment delayed AE number 4		30
If Reason treatment cycle delayed is equal to 'Other', specify Reason treatment cycle delayed, Specify		31

Study drug administration/location impacted by global/country situation	Yes ☐	32
Study drug location status - global/country situation	Site ☐	33
	Other ☐	
If Other, specify	_____	34
Administration performed by - global/country situation	Health care professional ☐	35
	Other ☐	
If Other, specify	_____	36

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Exposure as Collected - Gemcitabine (EC1)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	ECYN	$6	Were any study drugs taken?	$6	Any Study Treatment Taken	C49487 = No C49488 = Yes
3	ECTRT	$200	Study drug	$200	Treatment Name	Gemcitabine
4	Z_CYCNUM	$5	Cycle number			1 = C1D1 1a = C1D8 2 = C2D1 2a = C2D8 3 = C3D1 3a = C3D8 4 = C4D1 4a = C4D8 5 = C5D1 5a = C5D8 6 = C6D1 6a = C6D8 7 = C7D1 7a = C7D8 8 = C8D1 8a = C8D8
5	CYCNUM	$8	Cycle number	$8	Cycle Number	
6	ECSTDAT	yyyy MMM dd	Start date		Exposure Start Date	
7	ECSTTIM	HH:nn	Start time		Exposure Start Time	
8	ECENDAT	yyyy MMM dd	End date		Exposure End Date	
9	ECENTIM	HH:nn	End time		Exposure End Time	
10	ECPDOSE	4	Planned study drug dose for this cycle	8	Planned Dose	
11	ECPDOSEU	$7	Planned dose units	$7	Planned Dose Units	C28253 = mg C67402 = mg/m2
12	ECDSTXT	4	Actual study drug dose for this cycle	8	Dose	
13	ECDOSU	$7	Actual study drug dose unit	$7	Exposure Dose Unit	C28253 = mg C67402 = mg/m2

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Exposure as Collected - Gemcitabine (EC1)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
14	ECACN	$2	Action taken with study drug	$2	Action Taken, Study Drug	0 = Dose not changed 1 = Dose increased 2 = Dose reduced 3 = Drug interrupted 98 = Not applicable
15	ECDISC	$6	Was this the last dose of study drug given?	$6	Last Dose of Study Drug Given	C49488 = Yes
16	ECADJ	$2	Reason adjusted	$2	Reason for Dose Adjustment	1 = Adverse event 12 = Technical issue 18 = Subject decision 99 = Other
17	ECADJS	$200	**If reason adjusted is equal to 'Other', specify** Reason adjusted, specify	$200	Reason Adjusted Specification	
18	ECAENO1	3	AE number 1	8	AE Number 1	
19	ECAENO2	3	AE number 2	8	AE Number 2	
20	ECAENO3	3	AE number 3	8	AE Number 3	
21	ECAENO4	3	AE number 4	8	AE Number 4	
22	ECVIBEF	4	Volume of infusion before administration	8	Volume of Infusion Before Administration	

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
23	ECVIAFT	4	Volume of infusion after administration	8	Volume of Infusion After Administration	
24	ECSDVIU	$6	Infusion volume unit	$6	Infusion Volume Unit	C28254 = mL
25	ECDEL	$6	Treatment cycle delayed	$6	Treatment Cycle Delayed	C49487 = No C49488 = Yes
26	ECDELR	$2	Reason treatment cycle delayed	$2	Reason Treatment Cycle Delayed	2 = Adverse event 5 = Subject decision 6 = Lab abnormality not reported as an AE 99 = Other
27	ECDAENO1	3	Treatment delayed AE number 1	8	Treatment Delayed AE Number 1	
28	ECDAENO2	3	Treatment delayed AE number 2	8	Treatment Delayed AE Number 2	
29	ECDAENO3	3	Treatment delayed AE number 3	8	Treatment Delayed AE Number 3	
30	ECDAENO4	3	Treatment delayed AE number 4	8	Treatment Delayed AE Number 4	
31	ECDELRO	$200	**If Reason treatment cycle delayed is equal to 'Other', specify** Reason treatment cycle delayed, Specify	$200	Reason Treatment Cycle Delayed, Other	

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
32	ECLPRELI	$6	Study drug administration /location impacted by global/country situation	$6	Glob/Countr Sit Relat Indicat, Loc/Admin	C49488 = Yes
33	ECSLOCST	$2	Study drug location status - global/country situation	$2	SD Locatio Status, Global/Countr y Situat	1 = Site 99 = Other
34	ECSLOSTO	$200	If Other, specify	$200	Other, Specify	
35	ECSADPER	$6	Administratio n performed by - global/country situation	$6	Admin. Perfr. by, Global/Countr y Situat	C53287 = Health care professional 99 = Other
36	ECSADPEO	$200	If Other, specify	$200	Other, Specify	

(Version: AZ2403 2025-05-05)

Were any study drugs taken?	No ☐	2
	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	3
Cycle number	C1D1 ☐	4
	C1D8 ☐	
	C2D1 ☐	
	C2D8 ☐	
	C3D1 ☐	
	C3D8 ☐	
	C4D1 ☐	
	C4D8 ☐	
	C5D1 ☐	
	C5D8 ☐	
	C6D1 ☐	
	C6D8 ☐	
	C7D1 ☐	
	C7D8 ☐	
	C8D1 ☐	
	C8D8 ☐	
Cycle number	_____	5
Start date	Fixed Unit: yyyy mon dd	6
	_____	
Start time	Fixed Unit: 24-hour clock	7
	_____	
End date	Fixed Unit: yyyy mon dd	8
	_____	
End time	Fixed Unit: 24-hour clock	9
	_____	
Planned study drug dose for this cycle	_____	10
Planned dose units	mg ☐	11
	mg/m2 ■	

Actual study drug dose for this cycle		12
Actual study drug dose unit	mg	13
	mg/m2	
Action taken with study drug	Dose not changed	14
	Dose increased	
	Dose reduced	
	Drug interrupted	
	Not applicable	
Was this the last dose of study drug given?	Yes	15
Reason adjusted	Adverse event	16
	Technical issue	
	Subject decision	
	Other	
If reason adjusted is equal to 'Other', specify Reason adjusted, specify		17
AE number 1		18
AE number 2		19
AE number 3		20
AE number 4		21
Volume of infusion before administration		22
Volume of infusion after administration		23
Infusion volume unit	mL	24
Treatment cycle delayed	No	25
	Yes	
Reason treatment cycle delayed	Adverse event	26
	Subject decision	
	Lab abnormality not reported as an AE	
	Other	
Treatment delayed AE number 1		27
Treatment delayed AE number 2		28
Treatment delayed AE number 3		29
Treatment delayed AE number 4		30
If Reason treatment cycle delayed is equal to 'Other', specify Reason treatment cycle delayed, Specify		31

Study drug administration/location impacted by global/country situation	Yes ☐	32
Study drug location status - global/country situation	Site ☐	33
	Other ☐	
If Other, specify	_____	34
Administration performed by - global/country situation	Health care professional ☐	35
	Other ☐	
If Other, specify	_____	36

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Exposure as Collected - Cisplatin (EC2)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	ECYN	$6	Were any study drugs taken?	$6	Any Study Treatment Taken	C49487 = No C49488 = Yes
3	ECTRT	$200	Study drug	$200	Treatment Name	Cisplatin
4	Z_CYCNUM	$5	Cycle number			1 = C1D1 1a = C1D8 2 = C2D1 2a = C2D8 3 = C3D1 3a = C3D8 4 = C4D1 4a = C4D8 5 = C5D1 5a = C5D8 6 = C6D1 6a = C6D8 7 = C7D1 7a = C7D8 8 = C8D1 8a = C8D8
5	CYCNUM	$8	Cycle number	$8	Cycle Number	
6	ECSTDAT	yyyy MMM dd	Start date		Exposure Start Date	
7	ECSTTIM	HH:nn	Start time		Exposure Start Time	
8	ECENDAT	yyyy MMM dd	End date		Exposure End Date	
9	ECENTIM	HH:nn	End time		Exposure End Time	
10	ECPDOSE	4.1	Planned study drug dose for this cycle	8	Planned Dose	
11	ECPDOSEU	$7	Planned dose units	$7	Planned Dose Units	C28253 = mg C67402 = mg/m2
12	ECDSTXT	4.1	Actual study drug dose for this cycle	8	Dose	
13	ECDOSU	$7	Actual study drug dose unit	$7	Exposure Dose Unit	C28253 = mg C67402 = mg/m2

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Exposure as Collected - Cisplatin (EC2)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
14	ECACN	$2	Action taken with study drug	$2	Action Taken, Study Drug	0 = Dose not changed 1 = Dose increased 2 = Dose reduced 3 = Drug interrupted 98 = Not applicable
15	ECDISC	$6	Was this the last dose of study drug given?	$6	Last Dose of Study Drug Given	C49488 = Yes
16	ECADJ	$2	Reason adjusted	$2	Reason for Dose Adjustment	1 = Adverse event 12 = Technical issue 18 = Subject decision 99 = Other
17	ECADJS	$200	**If reason adjusted is equal to 'Other', specify** Reason adjusted, specify	$200	Reason Adjusted Specification	
18	ECAENO1	3	AE number 1	8	AE Number 1	
19	ECAENO2	3	AE number 2	8	AE Number 2	
20	ECAENO3	3	AE number 3	8	AE Number 3	
21	ECAENO4	3	AE number 4	8	AE Number 4	
22	ECVIBEF	4	Volume of infusion before administration	8	Volume of Infusion Before Administration	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Exposure as Collected - Cisplatin (EC2)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
23	ECVIAFT	4	Volume of infusion after administration	8	Volume of Infusion After Administration	
24	ECSDVIU	$6	Infusion volume unit	$6	Infusion Volume Unit	C28254 = mL
25	ECDEL	$6	Treatment cycle delayed	$6	Treatment Cycle Delayed	C49487 = No C49488 = Yes
26	ECDELR	$2	Reason treatment cycle delayed	$2	Reason Treatment Cycle Delayed	2 = Adverse event 5 = Subject decision 6 = Lab abnormality not reported as an AE 99 = Other
27	ECDAENO1	3	Treatment delayed AE number 1	8	Treatment Delayed AE Number 1	
28	ECDAENO2	3	Treatment delayed AE number 2	8	Treatment Delayed AE Number 2	
29	ECDAENO3	3	Treatment delayed AE number 3	8	Treatment Delayed AE Number 3	
30	ECDAENO4	3	Treatment delayed AE number 4	8	Treatment Delayed AE Number 4	
31	ECDELRO	$200	**If Reason treatment cycle delayed is equal to 'Other', specify** Reason treatment cycle delayed, Specify	$200	Reason Treatment Cycle Delayed, Other	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Exposure as Collected - Cisplatin (EC2)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
32	ECLPRELI	$6	Study drug administration /location impacted by global/country situation	$6	Glob/Countr Sit Relat Indicat, Loc/Admin	C49488 = Yes
33	ECSLOCST	$2	Study drug location status - global/country situation	$2	SD Locatio Status, Global/Countr y Situat	1 = Site 99 = Other
34	ECSLOSTO	$200	If Other, specify	$200	Other, Specify	
35	ECSADPER	$6	Administratio n performed by - global/country situation	$6	Admin. Perfr. by, Global/Countr y Situat	C53287 = Health care professional 99 = Other
36	ECSADPEO	$200	If Other, specify	$200	Other, Specify	

(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 (3)
What was the subcategory for disposition event?	Rilvegostomig (4)
What was the study treatment discontinuation date?	Fixed Unit: yyyy mon dd (5)
What was the date when the decision was made to permanently discontinue study treatment?	Fixed Unit: yyyy mon dd (6)
Reason for study treatment discontinuation	Subject Decision ☐ (7) 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'	(8)

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 ☐ (11) 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	(12)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: End of Study Treatment - Rilvegostomig (ETRT)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
3	DSCAT	$40	What was the category of the disposition?	$40	Category for Disposition Event	DISPOSITION EVENT
4	DSSCAT	$200	What was the subcategory for disposition event?	$200	Subcategory for Disposition Event	Rilvegostomig
5	DSTSTDAT	yyyy MMM dd	What was the study treatment discontinuation date?		Date of Trt Compl or Discontinuation	
6	TRDCDDAT	yyyy MMM dd	What was the date when the decision was made to permanently discontinue study treatment?		Date of Decision to Permanent Trt Discon	
7	DSDECOD	$7	Reason for study treatment discontinuation	$7	Standardized Disposition Term	1 = Subject Decision C41331 = Adverse Event 3 = Severe Non-Compliance to Protocol 22 = Objective Disease Progression C48227 = Lost to Follow-Up 10 = Subjective Disease Progression 16 = Investigator Decision C191656 = Pregnancy

Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
					C49632 = Study Terminated by Sponsor C28554 = Death C17649 = Other
8 TRDSPEC	$200	Specify, if main reason is 'Other' or 'Severe non-compliance to protocol'	$200	Treatment Discontinuation Specification	
11 TRDSJDS	$2	Specify, if main reason is 'Subject decision'	$2	Subject Decision Specification	1 = Subject Perceives the Study Treatment to be Ineffective 2 = Subject is Unable to Comply with Protocol-specified Visits and/or Procedures Due to Conflicts Not Related to Clinical Trial 3 = Subject Perceives Logistics to be Unacceptable 4 = Subject Wishes to Participate in Another Clinical Trial

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						5 = Subject Wishes to Take a Treatment That is Not Allowed in This Study 6 = An AE or Laboratory Abnormality is of Concern to the Subject, but Not Clinically Significant to Physician 99 = Other
12	TRDCDSPC	$200	If Other, specify	$200	Other Subject Decision Specification	

(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 (3)
What was the subcategory for disposition event?	Durvalumab (4)
What was the study treatment discontinuation date?	Fixed Unit: yyyy mon dd (5)
What was the date when the decision was made to permanently discontinue study treatment?	Fixed Unit: yyyy mon dd (6)

Reason for study treatment discontinuation (7)

- ☐ 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' (8)

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' (11)

- ☐ 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	(12)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: End of Study Treatment - Durvalumab (ETRT3)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
3	DSCAT	$40	What was the category of the disposition?	$40	Category for Disposition Event	DISPOSITION EVENT
4	DSSCAT	$200	What was the subcategory for disposition event?	$200	Subcategory for Disposition Event	Durvalumab
5	DSTSTDAT	yyyy MMM dd	What was the study treatment discontinuation date?		Date of Trt Compl or Discontinuation	
6	TRDCDDAT	yyyy MMM dd	What was the date when the decision was made to permanently discontinue study treatment?		Date of Decision to Permanent Trt Discon	
7	DSDECOD	$7	Reason for study treatment discontinuation	$7	Standardized Disposition Term	1 = Subject Decision C41331 = Adverse Event 3 = Severe Non-Compliance to Protocol 22 = Objective Disease Progression C48227 = Lost to Follow-Up 10 = Subjective Disease Progression 16 = Investigator Decision C191656 = Pregnancy

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						C49632 = Study Terminated by Sponsor C28554 = Death C17649 = Other
8	TRDSPEC	$200	Specify, if main reason is 'Other' or 'Severe non-compliance to protocol'	$200	Treatment Discontinuation Specification	
11	TRDSJDS	$2	Specify, if main reason is 'Subject decision'	$2	Subject Decision Specification	1 = Subject Perceives the Study Treatment to be Ineffective 2 = Subject is Unable to Comply with Protocol-specified Visits and/or Procedures Due to Conflicts Not Related to Clinical Trial 3 = Subject Perceives Logistics to be Unacceptable 4 = Subject Wishes to Participate in Another Clinical Trial

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						5 = Subject Wishes to Take a Treatment That is Not Allowed in This Study 6 = An AE or Laboratory Abnormality is of Concern to the Subject, but Not Clinically Significant to Physician 99 = Other
12	TRDCDSPC	$200	If Other, specify	$200	Other Subject Decision Specification	

(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 (3)
What was the subcategory for disposition event?	Gemcitabine (4)
What was the study treatment completion or discontinuation date?	Fixed Unit: yyyy mon dd (5)
What was the date when the decision was made to permanently discontinue study treatment?	Fixed Unit: yyyy mon dd (6)
Completion or reason for study treatment discontinuation	Subject decision ☐ (7) 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'	(8)

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 ☐ (11) 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	_____ (12)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: End of Study Treatment - Gemcitabine (ETRT1)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
3	DSCAT	$40	What was the category of the disposition?	$40	Category for Disposition Event	DISPOSITION EVENT
4	DSSCAT	$200	What was the subcategory for disposition event?	$200	Subcategory for Disposition Event	Gemcitabine
5	DSTSTDAT	yyyy MMM dd	What was the study treatment completion or discontinuation date?		Date of Trt Compl or Discontinuation	
6	TRDCDDAT	yyyy MMM dd	What was the date when the decision was made to permanently discontinue study treatment?		Date of Decision to Permanent Trt Discon	
7	DSDECOD	$7	Completion or reason for study treatment discontinuation	$7	Standardized Disposition Term	1 = Subject decision C41331 = Adverse event 3 = Severe non-compliance to protocol 22 = Objective disease progression C48227 = Lost to follow-up 10 = Subjective disease progression C25250 = Completed 16 = Investigator decision

Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
					C191656 = Pregnancy C49632 = Study terminated by sponsor C28554 = Death C17649 = Other
8 TRDSPEC	$200	Specify, if main reason is 'Other' or 'Severe non-compliance to protocol'	$200	Treatment Discontinuation Specification	
11 TRDSJDS	$2	Specify, if main reason is 'Subject decision'	$2	Subject Decision Specification	2 = Subject is unable to comply with Protocol-specified visits and/or procedures due to conflicts not related to clinical trial 3 = Subject perceives logistics to be unacceptable 5 = Subject wishes to take a treatment that is not allowed in this study

Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
					6 = An AE or laboratory abnormality is of concern to the subject, but not clinically significant to physician 99 = Other
12 TRDCDSPC	$200	If Other, specify	$200	Other Subject Decision Specification	

(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 (3)
What was the subcategory for disposition event?	Cisplatin (4)
What was the study treatment completion or discontinuation date?	Fixed Unit: yyyy mon dd (5)
What was the date when the decision was made to permanently discontinue study treatment?	Fixed Unit: yyyy mon dd (6)

Completion or reason for study treatment discontinuation (7)

- ☐ 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' (8)

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' (11)

- ☐ 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	_____ (12)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: End of Study Treatment - Cisplatin (ETRT2)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
3	DSCAT	$40	What was the category of the disposition?	$40	Category for Disposition Event	DISPOSITION EVENT
4	DSSCAT	$200	What was the subcategory for disposition event?	$200	Subcategory for Disposition Event	Cisplatin
5	DSTSTDAT	yyyy MMM dd	What was the study treatment completion or discontinuation date?		Date of Trt Compl or Discontinuation	
6	TRDCDDAT	yyyy MMM dd	What was the date when the decision was made to permanently discontinue study treatment?		Date of Decision to Permanent Trt Discon	
7	DSDECOD	$7	Completion or reason for study treatment discontinuation	$7	Standardized Disposition Term	1 = Subject decision C41331 = Adverse event 3 = Severe non-compliance to protocol 22 = Objective disease progression C48227 = Lost to follow-up 10 = Subjective disease progression C25250 = Completed 16 = Investigator decision

Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
					C191656 = Pregnancy C49632 = Study terminated by sponsor C28554 = Death C17649 = Other
(8) TRDSPEC	$200	Specify, if main reason is 'Other' or 'Severe non-compliance to protocol'	$200	Treatment Discontinuation Specification	
(11) TRDSJDS	$2	Specify, if main reason is 'Subject decision'	$2	Subject Decision Specification	2 = Subject is unable to comply with Protocol-specified visits and/or procedures due to conflicts not related to clinical trial 3 = Subject perceives logistics to be unacceptable 5 = Subject wishes to take a treatment that is not allowed in this study

Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
					6 = An AE or laboratory abnormality is of concern to the subject, but not clinically significant to physician 99 = Other
12 TRDCDSPC	$200	If Other, specify	$200	Other Subject Decision Specification	

Were any concomitant medications taken?	No (1) Yes

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Prior and Concomitant Medications Log (CMLOG)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
1	CMYN	$6	Were any concomitant medications taken?	$6	Any Meds	C49487 = No C49488 = Yes

(Version: AZ2409 2024-11-25)

Medication number	_____	2
Medication verbatim name	_____	3
Indication	_____	4
Therapy reason	Adverse event ☐	5
	Medical history ☐	
	Prophylaxis ☐	
	Disease under study ☐	
	Protocol specified pre-medication ☐	
	Other ☐	
If Other, specify	_____	6
AE number(s) for which medication taken	_____	7
AE number(s) for which medication taken 1	_____	8
AE number(s) for which medication taken 2	_____	9
AE number(s) for which medication taken 3	_____	10
AE number(s) for which medication taken 4	_____	11
Medical history condition(s) number for which medication taken	_____	12
Medical history condition(s) number for which medication taken 1	_____	13
Medical history condition(s) number for which medication taken 2	_____	14
Dose per administration	_____	15
Frequency	Daily ☐	16
	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	_____ 17
Dose unit	% ☐ 18
	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	_____ 19

Route	Respiratory (inhalation) ☐	20
	Intravenous ☐	
	Oral ☐	
	Rectal ☐	
	Subcutaneous ☐	
	Topical ☐	
	Cutaneous ☐	
	Other ☐	
If Other, specify	_____	21
Start date	Fixed Unit: yyyy mon dd	22
	_____	
Taken prior to Study Treatment Start	Yes ☐	23
Ongoing	No ☐	24
	Yes ☐	
If No, complete section below End date	Fixed Unit: yyyy mon dd	25
	_____	
Stopped prior to Study Treatment Start	Yes ☐	26

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Prior and Concomitant Medications (CM)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	CMSPID	3	Medication number	8	Medication Number	
3	CMTRT	$200	Medication verbatim name	$200	Reported Name of Drug, Med or Therapy	
4	CMINDC	$200	Indication	$200	CM Indication	
5	CMTREAS	$2	Therapy reason	$2	Therapy Reason	1 = Adverse event 2 = Medical history 3 = Prophylaxis 4 = Disease under study 5 = Protocol specified pre-medication 99 = Other
6	CMTREASO	$200	If Other, specify	$200	Therapy Reason, Specify	
7	CMAENO	3	AE number(s) for which medication taken	8	Related Adverse Event ID	
8	CMAENO1	3	AE number(s) for which medication taken 1	8	Related Adverse Event ID 1	
9	CMAENO2	3	AE number(s) for which medication taken 2	8	Related Adverse Event ID 2	
10	CMAENO3	3	AE number(s) for which medication taken 3	8	Related Adverse Event ID 3	

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
11	CMAENO4	3	AE number(s) for which medication taken 4	8	Related Adverse Event ID 4	
12	CMMHNO	3	Medical history condition(s) number for which medication taken	8	Related Medical History Event ID	
13	CMMHNO1	3	Medical history condition(s) number for which medication taken 1	8	Related Medical History Event ID 1	
14	CMMHNO2	3	Medical history condition(s) number for which medication taken 2	8	Related Medical History Event ID 2	
15	CMDOSE	6.1	Dose per administration	8	CM Dose per Administration	
16	CMDOSFRQ	$6	Frequency	$6	CM Dosing Frequency per Interval	C25473 = Daily C64496 = Twice per day C64498 = Per month C64499 = As needed C64510 = Every hour C64516 = Every 2 hours C64518 = Every 4 hours

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						C64525 = Every other day C64526 = 1 time per week C64527 = 3 times per day C64530 = 4 times per day C64576 = Once C64497 = 2 times per week C64528 = 3 times per week C64531 = 4 times per week C67069 = Every week C71127 = Every 2 weeks C64535 = Every 3 weeks C64529 = Every 4 weeks 99 = Other C17998 = Unknown
17	CMDOSFO	$200	If Other, specify	$200	CM Dosing Frequency per Interval, Other	
18	CMDOSU	$6	Dose unit	$6	CM Dose Unit	C25613 = % C28253 = mg C28254 = mL C48152 = ug C48155 = g C48480 = CAPSULE C48505 = L C48509 = umol

Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
					C48511 = mCi C48512 = mEq C48513 = mmol C48516 = ng C48542 = TABLET C48579 = IU C65060 = PUFF C67312 = ug/m2 C67379 = IU/kg C67396 = ug/kg C67401 = mg/kg C67402 = mg/m2 C48491 = gtt C70492 = kIU C70512 = MBq 92 = UNKNOWN 93 = OTHER
19 CMDOSUO	$200	If Other, specify	$200	CM Dose Unit, Other	
20 CMROUTE	$6	Route	$6	CM Route	C38216 = Respiratory (inhalation) C38276 = Intravenous C38288 = Oral C38295 = Rectal C38299 = Subcutaneous C38304 = Topical

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						C38675 = Cutaneous 99 = Other
21	CMROUTEO	$200	If Other, specify	$200	CM Route, Other	
22	CMSTDAT	yyyy MMM-dd-	Start date		Concomitant Meds Start Date	
23	CMPRIOR	$6	Taken prior to Study Treatment Start	$6	Prior Concomitant Meds	C49488 = Yes
24	CMONGO	$6	Ongoing	$6	Ongoing Concomitant Meds	C49487 = No C49488 = Yes
25	CMENDAT	yyyy MMM-dd-	**If No, complete section below** End date		Concomitant Meds End Date	
26	CMENPRIO	$6	Stopped prior to Study Treatment Start	$6	Stopped Prior to Study	C49488 = Yes

(Version: AZ2311 2023-11-24)

Any procedures performed?	No ☐	2
	Yes ☐	
Procedure name		3
Start date	Fixed Unit: yyyy mon dd	4
End date	Fixed Unit: yyyy mon dd	5
Ongoing	Yes ☐	6
Indication	Adverse event ☐	7
	Medical history ☐	
	Disease Under Study ☐	
	Other ☐	
Adverse event number		8
Medical history event identifier		9
If Other, specify		10

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Procedures (1PR)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	PRYN	$6	Any procedures performed?	$6	Any Procedures Performed	C49487 = No C49488 = Yes
3	PRTRT	$200	Procedure name	$200	Procedure Name	
4	PRSTDAT	yyyy MMM-dd-	Start date		Procedure Start Date	
5	PRENDAT	yyyy MMM-dd-	End date		Procedure End Date	
6	PRONGO	$6	Ongoing	$6	Ongoing Procedure	C49488 = Yes
7	PRINDC	$2	Indication	$2	Procedure Indication	1 = Adverse event 2 = Medical history 3 = Disease Under Study 99 = Other
8	PRAENO1	3	Adverse event number	8	Adverse Event Number	
9	PRMHNO1	4	Medical history event identifier	8	Related Medical History Event ID	
10	PRINDCS	$200	If Other, specify	$200	Other Procedure Indication, Specify	

(Version: AZ2311 2023-11-24)

Any procedures performed?	No ☐ Yes ☐	2
Procedure name		3
Start date	Fixed Unit: yyyy mon dd	4
End date	Fixed Unit: yyyy mon dd	5
Ongoing	Yes ☐	6
Indication	Disease Under Study ■	7

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Surgery for Subsequent Anticancer Therapy (1PR1)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	PRYN	$6	Any procedures performed?	$6	Any Procedures Performed	C49487 = No C49488 = Yes
3	PRTRT	$200	Procedure name	$200	Procedure Name	
4	PRSTDAT	yyyy MMM-dd-	Start date		Procedure Start Date	
5	PRENDAT	yyyy MMM-dd-	End date		Procedure End Date	
6	PRONGO	$6	Ongoing	$6	Ongoing Procedure	C49488 = Yes
7	PRINDC	$2	Indication	$2	Procedure Indication	3 = Disease Under Study

Were any adverse events experienced?	No ☐ 1 Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Adverse Events Log (AELOG)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
1	AEYN	$6	Were any adverse events experienced?	$6	Any Adverse Event	C49487 = No C49488 = Yes

(Version: AZ2504 2025-04-09)

Now Derivation(This field required for CF approach)		49
AE No.		2
Adverse Event		3
Start date	Fixed Unit: yyyy mon dd	4
End date	Fixed Unit: yyyy mon dd	5
Outcome	Recovered/Resolved ☐ Recovering/Resolving ☐ Recovered/Resolved with sequelae ☐ Not recovered/Not resolved ☐ Fatal ☐	6
Serious	No ☐ Yes ☐	7
Investigational product	Rilvegostomig	8
Action taken due to AE, Rilvegostomig	Dose not changed ☐ Drug interrupted ☐ Drug permanently discontinued ☐ Not applicable ☐	9
Reasonable possibility AE caused by Rilvegostomig	No ☐ Yes ☐	10
Investigational product 1	Durvalumab	11
Action taken due to AE, Durvalumab	Dose not changed ☐ Drug interrupted ☐ Drug permanently discontinued ☐ Not applicable ☐	12
Reasonable possibility AE caused by Durvalumab	No ☐ Yes ☐	13
Investigational product 2	Gemcitabine	14
Action taken due to AE, Gemcitabine	Dose Not Changed ☐ Dose Increased ☐ Dose Reduced ☐	15

	Drug Interrupted ☐	
	Drug Permanently Discontinued ☐	
	Not Applicable ☐	
Reasonable possibility AE caused by Gemcitabine	No ☐	16
	Yes ☐	
Investigational product 3	Cisplatin	17
Action taken due to AE, Cisplatin	Dose Not Changed ☐	18
	Dose Increased ☐	
	Dose Reduced ☐	
	Drug Interrupted ☐	
	Drug Permanently Discontinued ☐	
	Not Applicable ☐	
Reasonable possibility AE caused by Cisplatin	No ☐	19
	Yes ☐	
Reasonable possibility AE caused by Device Event	No ☐	20
	Yes ☐	
Device Event	_____	21
Device Event number	_____	22
CTCAE grade at start of AE	Grade 1 Mild AE ☐	23
	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 ☐	24
	Yes ☐	
Adverse event of special interest category	Potential Endocrinopathies ☐	25
	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 ☐ (26) Yes ☐
1. Date AE CTCAE grade changed	Fixed Unit: yyyy mon dd (27)
1. CTCAE grade	Grade 1 Mild AE ☐ (28)
	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 (29)
2. CTCAE grade	Grade 1 Mild AE ☐ (30)
	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 (31)
3. CTCAE grade	Grade 1 Mild AE ☐ (32)
	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 33
4. CTCAE grade	Grade 1 Mild AE ☐ 34 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 35
5. CTCAE grade	Grade 1 Mild AE ☐ 36 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 37
6. CTCAE grade	Grade 1 Mild AE ☐ 38 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 39
7. CTCAE grade	Grade 1 Mild AE ☐ 40 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	41
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	42
9. Date AE CTCAE grade changed	Fixed Unit: yyyy mon dd	43
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	44
CTCAE Version	5.0	45
Immune-mediated AE	No Yes	46
Infusion reaction AE	No Yes	47
Generated CASEID		48
Initial email sent(This field required for CF approach)		50
Downgrade Mail Sent(This field required for CF approach)		51
Hidden field for DE Alert		52

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Adverse Events (AE)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	AENO	3	AE No.	8	AE Number	
3	AETERM	$200	Adverse Event	$200	Adverse Event Reported Term	
4	AESTDAT	yyyy MMM-dd-	Start date		Adverse Event Start Date	
5	AEENDAT	yyyy MMM-dd-	End date		Adverse Event End Date	
6	AEOUT	$6	Outcome	$6	Outcome of Adverse Event	C49498 = Recovered/Resolved C49496 = Recovering/Resolving C49495 = Recovered/Resolved with sequelae C49494 = Not recovered/Not resolved C48275 = Fatal
7	AESER	$6	Serious	$6	Serious Adverse Event	C49487 = No C49488 = Yes
8	IP	$20	Investigational product	$20	Investigational Product	Rilvegostomig
9	AEACN	$2	Action taken due to AE, Rilvegostomig	$2	Action Taken, Investigational Product	0 = Dose not changed 3 = Drug interrupted 4 = Drug permanently discontinued 98 = Not applicable
10	AEREL	$6	Reasonable possibility AE caused by Rilvegostomig	$6	Reasonable Possibility AE Caused by IP	C49487 = No C49488 = Yes
11	IP1	$20	Investigational product 1	$20	Investigational Product 1	Durvalumab

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Adverse Events (AE)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
12	AEACN1	$2	Action taken due to AE, Durvalumab	$2	Action Taken, Investigational Product 1	0 = Dose not changed 3 = Drug interrupted 4 = Drug permanently discontinued 98 = Not applicable
13	AEREL1	$6	Reasonable possibility AE caused by Durvalumab	$6	Reasonable Possibility AE Caused by IP1	C49487 = No C49488 = Yes
14	IP2	$20	Investigational product 2	$20	Investigational Product 2	Gemcitabine
15	AEACN2	$2	Action taken due to AE, Gemcitabine	$2	Action Taken, Investigational Product 2	0 = Dose Not Changed 1 = Dose Increased 2 = Dose Reduced 3 = Drug Interrupted 4 = Drug Permanently Discontinued 98 = Not Applicable
16	AEREL2	$6	Reasonable possibility AE caused by Gemcitabine	$6	Reasonable Possibility AE Caused by IP2	C49487 = No C49488 = Yes
17	IP3	$20	Investigational product 3	$20	Investigational Product 3	Cisplatin
18	AEACN3	$2	Action taken due to AE, Cisplatin	$2	Action Taken, Investigational Product 3	0 = Dose Not Changed 1 = Dose Increased 2 = Dose Reduced 3 = Drug Interrupted

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						4 = Drug Permanently Discontinued 98 = Not Applicable
19	AEREL3	$6	Reasonable possibility AE caused by Cisplatin	$6	Reasonable Possibility AE Caused by IP3	C49487 = No C49488 = Yes
20	AEDREL	$6	Reasonable possibility AE caused by Device Event	$6	Reasonable Possibility AE Caus by Device	C49487 = No C49488 = Yes
21	Z_DENO	$200	Device Event			
22	DENO	3	Device Event number	8	Device Event Number	
23	AETOXGR	$2	CTCAE grade at start of AE	$2	CTCAE Grade	1 = Grade 1 Mild AE 2 = Grade 2 Moderate AE 3 = Grade 3 Severe AE 4 = Grade 4 Life-threatening or disabling AE 5 = Grade 5 Death related to AE
24	AECATOCC	$6	Is this an Adverse Event of Special Interest?	$6	AE Category Occurrence	C49487 = No C49488 = Yes
25	AECAT	$2	Adverse event of special interest category	$200	Category for Adverse Events	2 = Potential Endocrinopathies 3 = Potential Hepatic Events 4 = Potential Nephritis or Renal Dysfunction

Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
					5 = Potential Neuropathy/Neuro-muscular Toxicity 6 = Potential Pancreatitis 7 = Potential Rash or Dermatitis 9 = Potential GI Toxicity 10 = Potential Myositis/Polymyositis 11 = Potential Myocarditis 12 = Potential Pneumonitis 17 = Infusion Related Reaction Including Anaphylaxis 18 = Combined Elevations of Aminotransferases and Bilirubin 22 = Cytokine Release Syndrome 31 = Encephalitis 99 = Other

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
26	AECONTRT	$6	Concomitant or additional treatment given *If 'Yes', ensure corresponding AE number is reported on the [Prior and Concomitant Medications (CM), Procedures (1PR)]*	$6	Concomitant or Additional Trtmnt Given	C49487 = No C49488 = Yes
27	AEC01DAT	yyyy MMM dd	1. Date AE CTCAE grade changed		AE Change Date	
28	AEC01TOX	$2	1. CTCAE grade	$2	CTCAE Grade	1 = Grade 1 Mild AE 2 = Grade 2 Moderate AE 3 = Grade 3 Severe AE 4 = Grade 4 Life-threatening or disabling AE 5 = Grade 5 Death related to AE
29	AEC02DAT	yyyy MMM dd	2. Date AE CTCAE grade changed		AE Change Date	
30	AEC02TOX	$2	2. CTCAE grade	$2	CTCAE Grade	1 = Grade 1 Mild AE 2 = Grade 2 Moderate AE 3 = Grade 3 Severe AE 4 = Grade 4 Life-threatening or disabling AE

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						5 = Grade 5 Death related to AE
31	AEC03DAT	yyyy MMM dd	3. Date AE CTCAE grade changed		AE Change Date	
32	AEC03TOX	$2	3. CTCAE grade	$2	CTCAE Grade	1 = Grade 1 Mild AE 2 = Grade 2 Moderate AE 3 = Grade 3 Severe AE 4 = Grade 4 Life-threatening or disabling AE 5 = Grade 5 Death related to AE
33	AEC04DAT	yyyy MMM dd	4. Date AE CTCAE grade changed		AE Change Date	
34	AEC04TOX	$2	4. CTCAE grade	$2	CTCAE Grade	1 = Grade 1 Mild AE 2 = Grade 2 Moderate AE 3 = Grade 3 Severe AE 4 = Grade 4 Life-threatening or disabling AE 5 = Grade 5 Death related to AE
35	AEC05DAT	yyyy MMM dd	5. Date AE CTCAE grade changed		AE Change Date	
36	AEC05TOX	$2	5. CTCAE grade	$2	CTCAE Grade	1 = Grade 1 Mild AE 2 = Grade 2 Moderate AE

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						3 = Grade 3 Severe AE 4 = Grade 4 Life-threatening or disabling AE 5 = Grade 5 Death related to AE
37	AEC06DAT	yyyy MMM dd	6. Date AE CTCAE grade changed		AE Change Date	
38	AEC06TOX	$2	6. CTCAE grade	$2	CTCAE Grade	1 = Grade 1 Mild AE 2 = Grade 2 Moderate AE 3 = Grade 3 Severe AE 4 = Grade 4 Life-threatening or disabling AE 5 = Grade 5 Death related to AE
39	AEC07DAT	yyyy MMM dd	7. Date AE CTCAE grade changed		AE Change Date	
40	AEC07TOX	$2	7. CTCAE grade	$2	CTCAE Grade	1 = Grade 1 Mild AE 2 = Grade 2 Moderate AE 3 = Grade 3 Severe AE 4 = Grade 4 Life-threatening or disabling AE 5 = Grade 5 Death related to AE

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Adverse Events (AE)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
41	AEC08DAT	yyyy MMM dd	8. Date AE CTCAE grade changed		AE Change Date	
42	AEC08TOX	$2	8. CTCAE grade	$2	CTCAE Grade	1 = Grade 1 Mild AE 2 = Grade 2 Moderate AE 3 = Grade 3 Severe AE 4 = Grade 4 Life-threatening or disabling AE 5 = Grade 5 Death related to AE
43	AEC09DAT	yyyy MMM dd	9. Date AE CTCAE grade changed		AE Change Date	
44	AEC09TOX	$2	9. CTCAE grade	$2	CTCAE Grade	1 = Grade 1 Mild AE 2 = Grade 2 Moderate AE 3 = Grade 3 Severe AE 4 = Grade 4 Life-threatening or disabling AE 5 = Grade 5 Death related to AE
45	CTCAE_V	$5	CTCAE Version	$5	CTCAE Version	5.0
46	AEADD1	$6	Immune-mediated AE	$6	Immune-mediated AE	C49487 = No C49488 = Yes
47	AEADD2	$6	Infusion reaction AE	$6	Infusion Reaction AE	C49487 = No C49488 = Yes
48	CASEID	$100	Generated CASEID			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Adverse Events (AE)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
49	Z_AENOW	yyyy MMM dd hh:nn:ss	Now Derivation(This field required for CF approach)			
50	Z_SAEALERT	$2	Initial email sent(This field required for CF approach)			
51	Z_DOGRADE	$2	Downgrade Mail Sent(This field required for CF approach)			
52	Z_DE	$2	Hidden field for DE Alert			

(Version: OM2107 2024-07-23)

AE number	_____	2
Adverse event	_____	3
AE of special interest	Potential endocrinopathies ☐	4
	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	_____	5
Number of bowel movements at baseline	_____	6
Current bowel movements CTCAE grade	Mild AE (increase of <4 stools/day over baseline) ☐	7
	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% ☐	8
	10-30% ☐	
	>30% ☐	
Anatomical site 01	Lower leg ☐	9
	Abdominal cavity ☐	

	Inguinal region ☐
	Back ☐
	Neck ☐
	Face ☐
	Chest ☐
	Arm ☐
	Foot ☐
	Hand ☐
	Buttock ☐
	Scalp ☐
	Eye ☐
	Not applicable ☐
	Other ☐
Anatomical site 02	Lower leg ☐ 10
	Abdominal cavity ☐
	Inguinal region ☐
	Back ☐
	Neck ☐
	Face ☐
	Chest ☐
	Arm ☐
	Foot ☐
	Hand ☐
	Buttock ☐
	Scalp ☐
	Eye ☐
	Not applicable ☐
	Other ☐
Anatomical site 03	Lower leg ☐ 11
	Abdominal cavity ☐
	Inguinal region ☐
	Back ☐
	Neck ☐
	Face ☐

Chest ☐
Arm ☐
Foot ☐
Hand ☐
Buttock ☐
Scalp ☐
Eye ☐
Not applicable ☐
Other ☐

Anatomical site 04

Lower leg ☐ 12
Abdominal cavity ☐
Inguinal region ☐
Back ☐
Neck ☐
Face ☐
Chest ☐
Arm ☐
Foot ☐
Hand ☐
Buttock ☐
Scalp ☐
Eye ☐
Not applicable ☐
Other ☐

Anatomical site 05

Lower leg ☐ 13
Abdominal cavity ☐
Inguinal region ☐
Back ☐
Neck ☐
Face ☐
Chest ☐
Arm ☐
Foot ☐
Hand ☐

	Buttock ☐ Scalp ☐ Eye ☐ Not applicable ☐ Other ☐	
Signs and symptoms		14
Signs and symptoms, other		15
Was a specialist consulted?	No ☐ Yes ☐	16
Services and result description		17
Any additional laboratory investigations performed?	No ☐ Yes ☐	18
If Yes, complete LABADD module		
Any significant medical or surgical history relevant to this event?	No ☐ Yes ☐	20
If Yes, specify the Medical/Surgical History number and text		
Medical history number/text 1		22
Medical history number 1		23
Medical history text 1		24
Surgical history number/text 1		25
Surgical history number 1		26
Surgical history text 1		27
Any concomitant medication that triggered the event?	No ☐ Yes ☐	28
If Yes, please specify the medication number and name		
Concomitant medication number/name 1		30
Concomitant medication number 1		31
Concomitant medication name 1		32
Could disease progression have triggered the event?	No ☐ Yes ☐	33
If Yes, specify below		
Can the event be attributed to disease/metastasis?	No ☐ Yes ☐	35
Anatomic location	Distant Lymph Nodes ☐	36

	Stomach ☐
	Liver ☐
	Pancreas ☐
	Ovary ☐
	Spleen ☐
	Brain ☐
	Lung ☐
	Pleura ☐
	Skin ☐
	Adrenal Gland ☐
	Regional Lymph Node ☐
	Other ☐
Any potential alternate etiology excluding disease progression?	No ☐ 37
	Yes ☐
If Yes, specify	_____ 38
Additional comments	_____ 39

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: AE of Special Interest (AESI)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	AENO	3	AE number	8	AE Number	
3	AETERM	$200	Adverse event	$200	Adverse Event	
4	AESI	$2	AE of special interest	$2	AE of Special Interest	2 = Potential endocrinopathies 3 = Potential hepatic events 4 = Potential nephritis or renal dysfunction 5 = Potential neuropathy/neuro-muscular toxicity 6 = Potential pancreatitis 7 = Potential rash or dermatitis 9 = Potential GI Toxicity 10 = Potential myositis/polymyositis 11 = Potential myocarditis 12 = Potential pneumonitis 17 = Infusion related reaction including anaphylaxis 18 = Combined elevations of aminotransferases and bilirubin

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						22 = Cytokine release syndrome 31 = Encephalitis 99 = Other
5	AESIS	$200	If Other, specify	$200	AE of Special Interest, Specify	
6	BMNBAS	8	Number of bowel movements at baseline	8	Bowel Movements Num Baseline	
7	BMNCUR	8	Current bowel movements CTCAE grade	8	Current Bowel Movements CTCAE Grade	1 = Mild AE (increase of <4 stools/day over baseline) 2 = Moderate AE (increase of 4-6 stools/day over baseline) 3 = Severe AE (increase of ≥ 7 stools/day over baseline) 4 = Life-threatening or disabling AE 5 = Death related to AE
8	SIGBSUR	$2	Body surface area covered	$2	Body Surface Area Covered	1 = <10% 2 = 10-30% 3 = >30%
9	SIGANS01	$6	Anatomical site 01	$6	Anatomical site 01	1 = Lower leg C12664 = Abdominal cavity C12726 = Inguinal region

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						C13062 = Back C13063 = Neck C13071 = Face C25389 = Chest C32141 = Arm C32622 = Foot C32712 = Hand C89806 = Buttock C89807 = Scalp C12401 = Eye 98 = Not applicable 99 = Other
10	SIGANS02	$6	Anatomical site 02	$6	Anatomical site 02	1 = Lower leg C12664 = Abdominal cavity C12726 = Inguinal region C13062 = Back C13063 = Neck C13071 = Face C25389 = Chest C32141 = Arm C32622 = Foot C32712 = Hand

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						C89806 = Buttock C89807 = Scalp C12401 = Eye 98 = Not applicable 99 = Other
11	SIGANS03	$6	Anatomical site 03	$6	Anatomical site 03	1 = Lower leg C12664 = Abdominal cavity C12726 = Inguinal region C13062 = Back C13063 = Neck C13071 = Face C25389 = Chest C32141 = Arm C32622 = Foot C32712 = Hand C89806 = Buttock C89807 = Scalp C12401 = Eye 98 = Not applicable 99 = Other
12	SIGANS04	$6	Anatomical site 04	$6	Anatomical site 04	1 = Lower leg C12664 = Abdominal cavity C12726 = Inguinal region

Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
					C13062 = Back C13063 = Neck C13071 = Face C25389 = Chest C32141 = Arm C32622 = Foot C32712 = Hand C89806 = Buttock C89807 = Scalp C12401 = Eye 98 = Not applicable 99 = Other
13 SIGANS05	$6	Anatomical site 05	$6	Anatomical site 05	1 = Lower leg C12664 = Abdominal cavity C12726 = Inguinal region C13062 = Back C13063 = Neck C13071 = Face C25389 = Chest C32141 = Arm C32622 = Foot C32712 = Hand

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						C89806 = Buttock C89807 = Scalp C12401 = Eye 98 = Not applicable 99 = Other
14	SIGSYM	$70	Signs and symptoms	$70	Signs and Symptoms	
15	SIGSYMO	$200	Signs and symptoms, other	$200	Signs and Symptoms, Other	
16	SPECON	$6	Was a specialist consulted?	$6	Specialist Consulted or Additional Inv	C49487 = No C49488 = Yes
17	SREDES0	$200	Services and result description	$200	Services and Result Description	
18	ADDINV	$6	Any additional laboratory investigations performed?	$6	Any Additional Laboratory Investigations	C49487 = No C49488 = Yes
20	SIGMH	$6	Any significant medical or surgical history relevant to this event?	$6	Any Significant Medic or Surgic History	C49487 = No C49488 = Yes
22	Z_SIGMH1	$70	Medical history number/text 1			
23	SIGMHO1	8	Medical history number 1	8	MH Number 1	
24	SIGMHT1	$200	Medical history text 1	$200	Specify MH Text 1	
25	Z_SURGH1	$70	Surgical history number/text 1			

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
26	SURGHO1	8	Surgical history number 1	8	Surgical History Number 1	
27	SURGHT1	$200	Surgical history text 1	$200	Surgical History Text 1	
28	CMEVENT	$6	Any concomitant medication that triggered the event?	$6	Concomitant Medication Event	C49487 = No C49488 = Yes
30	Z_CMEVT1	$70	Concomitant medication number/name 1			
31	CMEVTN1	8	Concomitant medication number 1	8	Concomitant Medication Number 1	
32	CMEVTR1	$200	Concomitant medication name 1	$200	Concomitant Medication Name 1	
33	EVENTR	$6	Could disease progression have triggered the event?	$6	Event Triggered by Disease Progression	C49487 = No C49488 = Yes
35	METEVEN	$6	Can the event be attributed to disease/metastasis?	$6	Event Attributed to Disease/Metastasis	C49487 = No C49488 = Yes
36	METANAS	$6	Anatomic location	$6	Anatomic Location	1 = Distant Lymph Nodes C12391 = Stomach C12392 = Liver C12393 = Pancreas C12404 = Ovary C12432 = Spleen C12439 = Brain

Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
					C12468 = Lung C12469 = Pleura C12470 = Skin C12666 = Adrenal Gland C49018 = Regional Lymph Node 99 = Other
37 POTALET	$6	Any potential alternate etiology excluding disease progression?	$6	Potential Altern Etiology Excl Dise Prog	C49487 = No C49488 = Yes
38 POTALETS	$200	If Yes, specify	$200	Potential Alternate Etiology, Specify	
39 AESICOM	$200	Additional comments	$200	Additional Comments	

(Version: OM2208 2022-08-04)

AE number	2
Adverse event	3
AE of special interest	4
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	5
Investigation	6
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	7
Please specify Procedure number and text	8
Procedure number/text 1	
Procedure number 1	9
Procedure text 1	10
Procedure number/text 2	11
Procedure number 2	12
Procedure text 2	13
Procedure number/text 3	14
Procedure number 3	15
Procedure text 3	16
Procedure number/text 4	17
Procedure number 4	18
Procedure text 4	19
Procedure number/text 5	20
Procedure number 5	21
Procedure text 5	22
Result description	23
Result description 1	24
Result description 2	25
Result description 3	26
Result description 4	27
Result description 5	28
Result description 6	29
Result description 7	30
Result description 8	31
Result description 9	32

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: AE of Special Interest Addendum (AESIA)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	AENO	3	AE number	8	AE Number	
3	AETERM	$200	Adverse event	$200	Adverse Event	
4	AESI	$2	AE of special interest	$2	AE of Special Interest	2 = Potential endocrinopathies 3 = Potential hepatic events 4 = Potential nephritis or renal dysfunction 5 = Potential neuropathy/neuro-muscular toxicity 6 = Potential pancreatitis 7 = Potential rash or dermatitis 9 = Potential GI toxicity 10 = Potential myositis/polymyositis 11 = Potential myocarditis 12 = Potential Pneumonitis 17 = Infusion Related Reaction Including Anaphylaxis 18 = Combined Elevations of Aminotransferases and Bilirubin

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						22 = Cytokine Release Syndrome 31 = Encephalitis 99 = Other
5	AESIS	$200	If Other, specify	$200	AE of Special Interest, Specify	
6	ADDINP	$6	Investigation	$6	Additional Investigation Performed	1 = MRCP 2 = Colonoscopy 3 = ERCP 4 = Electromyogram 5 = Nerve conduction investigations 6 = Repetitive stimulation 7 = Cultures 8 = ECG 9 = Eye exam 10 = ACTH (Cosyntropin) stimulation test C15189 = Biopsy C16546 = Endoscopy C16809 = MRI C17204 = CT Scan C17230 = Ultrasound C38101 = X-Ray 99 = Other

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
7	ADDINPO	$200	If other, specify	$200	Additional Investigation Perform, Other	
8	Z_CONPS1	$70	**Please specify Procedure number and text** Procedure number/text 1			
9	LICONPS1	5	Procedure number 1	8	Line From PR 1	
10	LICONPT1	$200	Procedure text 1	$200	Specify PR Text 1	
11	Z_CONPS2	$70	Procedure number/text 2			
12	LICONPS2	5	Procedure number 2	8	Line From PR 2	
13	LICONPT2	$200	Procedure text 2	$200	Specify PR Text 2	
14	Z_CONPS3	$70	Procedure number/text 3			
15	LICONPS3	5	Procedure number 3	8	Line From PR 3	
16	LICONPT3	$200	Procedure text 3	$200	Specify PR Text 3	
17	Z_CONPS4	$70	Procedure number/text 4			
18	LICONPS4	5	Procedure number 4	8	Line From PR 4	
19	LICONPT4	$200	Procedure text 4	$200	Specify PR Text 4	
20	Z_CONPS5	$70	Procedure number/text 5			
21	LICONPS5	5	Procedure number 5	8	Line From PR 5	
22	LICONPT5	$200	Procedure text 5	$200	Specify PR Text 5	

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
23	SRDES0	$200	Result description	$200	Services and Result Description	
24	SRDES1	$200	Result description 1	$200	Services and Result Description 1	
25	SRDES2	$200	Result description 2	$200	Services and Result Description 2	
26	SRDES3	$200	Result description 3	$200	Services and Result Description 3	
27	SRDES4	$200	Result description 4	$200	Services and Result Description 4	
28	SRDES5	$200	Result description 5	$200	Services and Result Description 5	
29	SRDES6	$200	Result description 6	$200	Services and Result Description 6	
30	SRDES7	$200	Result description 7	$200	Services and Result Description 7	
31	SRDES8	$200	Result description 8	$200	Services and Result Description 8	
32	SRDES9	$200	Result description 9	$200	Services and Result Description 9	

(Version: OM1907 2022-11-09)

AE number		2
AE number *(derived, no entry required)*		3
Adverse event *(derived, no entry required)*		4
AE of special interest *(derived, no entry required)*		5
If Other, specify		6
Collection date	Fixed Unit: yyyy mon dd	7
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 ☐	8
If Other, specify		9
Result		10
Laboratory value comment		11
Low normal		12
High normal		13
Units		14
Clinically significant	No ☐ Yes ☐	15

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Additional Laboratory Evaluations (LABADD)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	Z_AENO	$156	AE number			
3	AENO	3	AE number *(derived, no entry required)*	8	AE Number	
4	AETERM	$200	Adverse event *(derived, no entry required)*	$200	Adverse Event	
5	AESI	$200	AE of special interest *(derived, no entry required)*	$200	AE of Special Interest	
6	AESIS	$200	If Other, specify	$200	AE of Special Interest, Specify	
7	LBDAT	yyyy MMM dd	Collection date		Collection Date	
8	LBTEST	$6	Test name	$6	Lab Test or Examination Name	04241 = Hba1c (Blood) 02BE9 = Thyrotropin Receptor Antibody (Serum) 02F33 = Thyroid Peroxidase Antibody (Serum) 02L48 = Thyroglobulin Antibody (Serum) 02B78 = Glutamic Acid Decarboxylase Antibody, Quant

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						02BP9 = Islet Cell Autoantibodies, Qual 02BQ0 = Islet Cell Autoantibodies, Quant 99 = Other
9	LBTESTOT	$200	If Other, specify	$200	Test Name, Other	
10	LBORRES	$50	Result	$50	Result	
11	LBCOVAL	$200	Laboratory value comment	$200	Laboratory Value Comment	
12	LBORNRLO	$25	Low normal	$25	Low Normal	
13	LBORNRHI	$25	High normal	$25	High Normal	
14	LBORRESU	$20	Units	$20	Units	
15	LBCLSIG	$6	Clinically significant	$6	Clinically Significant	C49487 = No C49488 = Yes

(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 (3)

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? (4)

What is the adverse event term? (5)

What was the date AE met criteria for serious AE? Fixed Unit: yyyy mon dd (6)

What was the date investigator became aware of serious AE? Fixed Unit: yyyy mon dd (7)

AE is serious due to:

Death	No ☐ Yes ☐	(9)
Inpatient hospitalization or prolongation of existing inpatient hospitalization	No ☐ Yes ☐	(10)
Congenital anomaly or birth defect	No ☐ Yes ☐	(11)
Life threatening	No ☐ Yes ☐	(12)
Persistent or significant disability/incapacity	No ☐ Yes ☐	(13)
Important medical event	No ☐ Yes ☐	(14)
Foetal distress, foetal death or congenital physical or mental or birth defect	No ☐ Yes ☐	(15)

Permanent impairment/Chronic disease	No ☐ Yes ☐	16
Medical or surgical intervention	No ☐ Yes ☐	17

If Hospitalization is selected as Yes, complete below:

Date of hospitalization	Fixed Unit: yyyy mon dd	19
Date of discharge	Fixed Unit: yyyy mon dd	20
Reasonable possibility SAE caused by other medication	No ☐ Yes ☐	21
If Yes, specify trade name(s)		22
Reasonable possibility SAE caused by study procedure(s)	No ☐ Yes ☐	23
If Yes, specify procedure(s)		24
Description of AE		25

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		27
Date AZ aware of serious AE		28

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
3	Z_INVREV	1	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.***			
4	AENO	3	What is the AE number?	8	AE Number	
5	AETERM	$200	What is the adverse event term?	$200	Adverse Event Reported Term	
6	AESDAT	yyyy MMM dd	What was the date AE met criteria for serious AE?		Date AE Met Criteria for Serious AE	
7	AESIADAT	yyyy MMM dd	What was the date investigator became aware of serious AE?		Date Investigator Aware of Serious AE	
9	AESDTH	$6	Death	$6	Results in Death	C49487 = No C49488 = Yes
10	AESHOSP	$6	Inpatient hospitalization or prolongation of existing inpatient hospitalization	$6	Requires or Prolongs Hospitalization	C49487 = No C49488 = Yes

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Serious Adverse Event Report (SERAE)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
11	AESCONG	$6	Congenital anomaly or birth defect	$6	Congenital Anomaly or Birth Defect	C49487 = No C49488 = Yes
12	AESLIFE	$6	Life threatening	$6	Is Life Threatening	C49487 = No C49488 = Yes
13	AESDISAB	$6	Persistent or significant disability/incapacity	$6	Persist. or Sign. Disability/Incapacity	C49487 = No C49488 = Yes
14	AESMIE	$6	Important medical event	$6	Other Medically Important Serious Event	C49487 = No C49488 = Yes
15	DESCONG	$6	Foetal distress, foetal death or congenital physical or mental or birth defect	$6	Foetal Dis Death/Con Phys Ment/Birth Def	C49487 = No C49488 = Yes
16	DESDISAB	$6	Permanent impairment/Chronic disease	$6	Permanent Impairment/Chronic Disease	C49487 = No C49488 = Yes
17	DESMSI	$6	Medical or surgical intervention	$6	Medical or Surgical Intervention	C49487 = No C49488 = Yes
19	AESHODAT	yyyy MMM dd	Date of hospitalization		Date of Hospitalization	
20	AESDIDAT	yyyy MMM dd	Date of discharge		Date of Discharge	
21	AESMEDCA	$6	Reasonable possibility SAE caused by other medication	$6	Reason Possib AE Caused by Oth Medicat	C49487 = No C49488 = Yes
22	AESMED	$200	If Yes, specify trade name(s)	$200	Other Medication	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Serious Adverse Event Report (SERAE)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
23	AECAUSSP	$6	Reasonable possibility SAE caused by study procedure(s)	$6	Reason Possib AE Caused by Study Proced	C49487 = No C49488 = Yes
24	AESP	$200	If Yes, specify procedure(s)	$200	Study Procedure(s)	
25	AEDESC01	$1999	Description of AE	$1999	AE Description	
27	CASEID	$100	CaseID			
28	SAEAZDAT	yyyy MMM dd	Date AZ aware of serious AE		Date AZ aware of serious AE	

(Version: ON2206 2024-06-05)

What was the AE number? ____ 2

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

Symptoms associated with Interstitial Lung Disease

Did the Subject have a fever? 5
- No ☐
- Yes ☐

Did the Subject have dyspnea? 6
- No ☐
- Yes ☐

Did the Subject have a cough? 7
- No ☐
- Yes ☐

Was cough productive? 8
- No ☐
- Yes ☐

Did the Subject have any other symptoms? 9
- No ☐
- Yes ☐

If Other, specify ____ 10

What was the method used for the diagnosis? 11
- Bronchoalveolar lavage ☐
- Lung biopsy ☐
- ILD markers ☐
- MRI ☐
- CT scan ☐
- High resolution CT ☐
- X-ray ☐
- Other ☐

If Other, specify ____ 12

What was the axial distribution of lung findings?	Central lung predominant Peripheral lung predominant Both	13
What was the zonal distribution of lung findings?	Upper lung predominant Middle lung predominant Lower lung predominant Not applicable	14
What was distribution pattern of findings?	Focal pattern Multifocal pattern Diffuse pattern Mixed pattern	15
Was there lobar involvement in the right upper lobe?	No Yes	16
Was there lobar involvement in the right middle lobe?	No Yes	17
Was there lobar involvement in the right lower lobe?	No Yes	18
Was there lobar involvement in the left upper lobe?	No Yes	19
Was there lobar involvement in the left lower lobe?	No Yes	20
Were ground glass opacities found in CT?	No Yes	21
Were reticular opacities found in CT?	No Yes	22
Was consolidation found in CT?	No Yes	23
Was traction bronchiectasis found in CT?	No Yes	24
Was centrilobular nodularity found in CT?	No Yes	25
Was honeycombing found in CT?	No	26

	Yes ☐	
Were there any further findings?	_____	27

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 ☐	29
What was the description of cancer progression within the thorax?	_____	30
At the time of diagnosis of the pulmonary event, was there any evidence of bacterial infection?	No ☐ Yes ☐	31
At the time of diagnosis of the pulmonary event, was there any evidence of viral infection?	No ☐ Yes ☐	32
At the time of diagnosis of the pulmonary event, was there any evidence of fungal infection?	No ☐ Yes ☐	33
At the time of diagnosis of the pulmonary event, was there any other type of evidence of infection?	No ☐ Yes ☐	34
Was the lung biopsy performed?	No ☐ Yes ☐	40
Type of biopsy	Transbronchial ☐ Bronchial biopsy ☐ Cryobiopsy ☐ Other ☐	41
If Other biopsy, specify	_____	42
What was the date the biopsy was performed?	Fixed Unit: yyyy mon dd _____	43
What were the biopsy findings, specify	_____	44
Was bronchoalveolar lavage (BAL) performed?	No ☐ Yes ☐	45
What was the date of examination of BAL?	Fixed Unit: yyyy mon dd _____	46

Specify results of this examination

What was the total cells count?		48
What was the unit of total cells count?	10^8/L	49
What was the lymphocyte cell count?		50
What was the unit of lymphocyte cell count?	%	51
What was the neutrophil count?		52
What was the unit of neutrophil count?	%	53
What was the macrophage count?		54
What was the unit of macrophage count?	%	55
What was the eosinophil count?		56
What was the unit of eosinophil count?	%	57
What was the basophil count?		58
What was the unit of basophil count?	%	59
What was the CD4/CD8 count?		60
What was the unit of CD4/CD8 count?	RATIO	61
If there are any pathological findings in BAL, specify		62
Were there malignant cells in cytology?	No / Yes	63
If there were malignant cells on cytology, specify results		64
Did pleural effusion co-exist with the event?	No / Yes	65
Was cytology of pleural fluid done?	No / Yes	66
Were malignant cells present in cytology of pleural fluid?	No / Yes	67
If malignant cells were present in cytology of pleural fluid, specify results		68
Were blood gases performed at the time of the suspected pulmonary event?	No / Yes	69

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	71

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

Has the Subject ever had pleurodesis performed?	No	73

	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 ☐	75
If Other, specify	_____	76
At the time of the event, was there any evidence of an inflammatory reaction?	No ☐ Yes ☐	77
If not captured on AE / LB, then add details here	_____	78
At the time of the event, was there any evidence of allergic reaction?	No ☐ Yes ☐	79
If not captured on AE / LB, then add details here	_____	80
Was prior radiation administered to the chest?	No ☐ Yes ☐	81
What were the radiological findings?	Confined to radiation field only ☐ Outside of radiation field only ☐ Both ☐ No radiological findings ☐	82
What was the pneumonitis type?	Radiation pneumonitis ☐ Drug-induced pneumonitis/Interstitial lung disease ☐ Other ☐	83
If Other, specify	_____	84
Analytes	Common bacteria ☐ Acid fast bacillus ☐ Tubercle bacillus ☐ Legionnaire ☐ Pneumocystis ☐ Cytomegalovirus ☐ COVID-19 ☐ Influenza ☐	35

	Mycoplasma ☐	
	Aspergillus ☐	
	Cryptococcus ☐	
	Candida ☐	
	Other ☐	
Test method	Sputum culture ☐	36
	Blood culture ☐	
	Serum antibody titer ☐	
	Broncho-alveolar lavage ☐	
	Other fungal ☐	
	Other ☐	
Date of examination	Fixed Unit: yyyy mon dd _____	37
Result	Negative ☐	38
	Positive ☐	
Other, specify	_____	39
Analytes	Common bacteria ☐	35
	Acid fast bacillus ■	
	Tubercle bacillus ☐	
	Legionnaire ☐	
	Pneumocystis ☐	
	Cytomegalovirus ☐	
	COVID-19 ☐	
	Influenza ☐	
	Mycoplasma ☐	
	Aspergillus ☐	
	Cryptococcus ☐	
	Candida ☐	
	Other ☐	
Test method	Sputum culture ☐	36
	Blood culture ☐	
	Serum antibody titer ☐	
	Broncho-alveolar lavage ☐	

	Other fungal ☐ Other ☐
Date of examination	Fixed Unit: yyyy mon dd 37
Result	Negative ☐ 38 Positive ☐
Other, specify	39
Analytes	Common bacteria ☐ 35 Acid fast bacillus ☐ Tubercle bacillus ■ Legionnaire ☐ Pneumocystis ☐ Cytomegalovirus ☐ COVID-19 ☐ Influenza ☐ Mycoplasma ☐ Aspergillus ☐ Cryptococcus ☐ Candida ☐ Other ☐
Test method	Sputum culture ☐ 36 Blood culture ☐ Serum antibody titer ☐ Broncho-alveolar lavage ☐ Other fungal ☐ Other ☐
Date of examination	Fixed Unit: yyyy mon dd 37
Result	Negative ☐ 38 Positive ☐
Other, specify	39
Analytes	Common bacteria ☐ 35 Acid fast bacillus ☐

	Tubercle bacillus ☐ Legionnaire ■ Pneumocystis ☐ Cytomegalovirus ☐ COVID-19 ☐ Influenza ☐ Mycoplasma ☐ Aspergillus ☐ Cryptococcus ☐ Candida ☐ Other ☐
Test method	Sputum culture ☐ 36 Blood culture ☐ Serum antibody titer ☐ Broncho-alveolar lavage ☐ Other fungal ☐ Other ☐
Date of examination	Fixed Unit: yyyy mon dd 37
Result	Negative ☐ 38 Positive ☐
Other, specify	39
Analytes	Common bacteria ☐ 35 Acid fast bacillus ☐ Tubercle bacillus ☐ Legionnaire ☐ Pneumocystis ■ Cytomegalovirus ☐ COVID-19 ☐ Influenza ☐ Mycoplasma ☐ Aspergillus ☐ Cryptococcus ☐

	Candida ☐
	Other ☐
Test method	Sputum culture ☐ 36
	Blood culture ☐
	Serum antibody titer ☐
	Broncho-alveolar lavage ☐
	Other fungal ☐
	Other ☐
Date of examination	Fixed Unit: yyyy mon dd 37
Result	Negative ☐ 38
	Positive ☐
Other, specify	39
Analytes	Common bacteria ☐ 35
	Acid fast bacillus ☐
	Tubercle bacillus ☐
	Legionnaire ☐
	Pneumocystis ☐
	Cytomegalovirus ■
	COVID-19 ☐
	Influenza ☐
	Mycoplasma ☐
	Aspergillus ☐
	Cryptococcus ☐
	Candida ☐
	Other ☐
Test method	Sputum culture ☐ 36
	Blood culture ☐
	Serum antibody titer ☐
	Broncho-alveolar lavage ☐
	Other fungal ☐
	Other ☐

Date of examination	Fixed Unit: yyyy mon dd (37)
Result	Negative ☐ (38) Positive ☐
Other, specify	(39)
Analytes	Common bacteria ☐ (35) Acid fast bacillus ☐ Tubercle bacillus ☐ Legionnaire ☐ Pneumocystis ☐ Cytomegalovirus ☐ COVID-19 ■ Influenza ☐ Mycoplasma ☐ Aspergillus ☐ Cryptococcus ☐ Candida ☐ Other ☐
Test method	Sputum culture ☐ (36) Blood culture ☐ Serum antibody titer ☐ Broncho-alveolar lavage ☐ Other fungal ☐ Other ☐
Date of examination	Fixed Unit: yyyy mon dd (37)
Result	Negative ☐ (38) Positive ☐
Other, specify	(39)
Analytes	Common bacteria ☐ (35) Acid fast bacillus ☐ Tubercle bacillus ☐ Legionnaire ☐

	Pneumocystis ☐	
	Cytomegalovirus ☐	
	COVID-19 ☐	
	Influenza ■	
	Mycoplasma ☐	
	Aspergillus ☐	
	Cryptococcus ☐	
	Candida ☐	
	Other ☐	
Test method	Sputum culture ☐	36
	Blood culture ☐	
	Serum antibody titer ☐	
	Broncho-alveolar lavage ☐	
	Other fungal ☐	
	Other ☐	
Date of examination	Fixed Unit: yyyy mon dd _____	37
Result	Negative ☐	38
	Positive ☐	
Other, specify	_____	39
Analytes	Common bacteria ☐	35
	Acid fast bacillus ☐	
	Tubercle bacillus ☐	
	Legionnaire ☐	
	Pneumocystis ☐	
	Cytomegalovirus ☐	
	COVID-19 ☐	
	Influenza ☐	
	Mycoplasma ■	
	Aspergillus ☐	
	Cryptococcus ☐	
	Candida ☐	
	Other ☐	

Test method	Sputum culture ☐ 36 Blood culture ☐ Serum antibody titer ☐ Broncho-alveolar lavage ☐ Other fungal ☐ Other ☐
Date of examination	Fixed Unit: yyyy mon dd 37
Result	Negative ☐ 38 Positive ☐
Other, specify	39
Analytes	Common bacteria ☐ 35 Acid fast bacillus ☐ Tubercle bacillus ☐ Legionnaire ☐ Pneumocystis ☐ Cytomegalovirus ☐ COVID-19 ☐ Influenza ☐ Mycoplasma ☐ Aspergillus ■ Cryptococcus ☐ Candida ☐ Other ☐
Test method	Sputum culture ☐ 36 Blood culture ☐ Serum antibody titer ☐ Broncho-alveolar lavage ☐ Other fungal ☐ Other ☐
Date of examination	Fixed Unit: yyyy mon dd 37
Result	Negative ☐ 38

	Positive	
Other, specify		39
Analytes	Common bacteria	35
	Acid fast bacillus	
	Tubercle bacillus	
	Legionnaire	
	Pneumocystis	
	Cytomegalovirus	
	COVID-19	
	Influenza	
	Mycoplasma	
	Aspergillus	
	Cryptococcus	
	Candida	
	Other	
Test method	Sputum culture	36
	Blood culture	
	Serum antibody titer	
	Broncho-alveolar lavage	
	Other fungal	
	Other	
Date of examination	Fixed Unit: yyyy mon dd	37
Result	Negative	38
	Positive	
Other, specify		39
Analytes	Common bacteria	35
	Acid fast bacillus	
	Tubercle bacillus	
	Legionnaire	
	Pneumocystis	
	Cytomegalovirus	
	COVID-19	

	Influenza ☐ Mycoplasma ☐ Aspergillus ☐ Cryptococcus ☐ Candida ■ Other ☐
Test method	Sputum culture ☐ 36 Blood culture ☐ Serum antibody titer ☐ Broncho-alveolar lavage ☐ Other fungal ☐ Other ☐
Date of examination	Fixed Unit: yyyy mon dd 37
Result	Negative ☐ 38 Positive ☐
Other, specify	39
Analytes	Common bacteria ☐ 35 Acid fast bacillus ☐ Tubercle bacillus ☐ Legionnaire ☐ Pneumocystis ☐ Cytomegalovirus ☐ COVID-19 ☐ Influenza ☐ Mycoplasma ☐ Aspergillus ☐ Cryptococcus ☐ Candida ☐ Other ■
Test method	Sputum culture ☐ 36 Blood culture ☐ Serum antibody titer ☐

	Broncho-alveolar lavage ☐ Other fungal ☐ Other ☐
Date of examination	Fixed Unit: yyyy mon dd 37
Result	Negative ☐ 38 Positive ☐
Other, specify	39

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Interstitial Lung Disease (ILDIS)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	AENO	3	What was the AE number?	8	AE Number	
3	AETOXCH	$2	What was the AE grade change number?	$2	AE Grade Change Number	0 = 0 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9
5	ILDFEV	$6	Did the Subject have a fever?	$6	Symptom: Fever	C49487 = No C49488 = Yes
6	ILDDYSP	$6	Did the Subject have dyspnea?	$6	Symptom: Dyspnea	C49487 = No C49488 = Yes
7	ILDCOUG	$6	Did the Subject have a cough?	$6	Symptom: Cough	C49487 = No C49488 = Yes
8	ILDCOUGP	$6	Was cough productive?	$6	Symptom: Productive Cough	C49487 = No C49488 = Yes
9	ILDSYMO	$6	Did the Subject have any other symptoms?	$6	Symptom: Other	C49487 = No C49488 = Yes
10	ILDSYMOS	$200	If Other, specify	$200	Other Symptom, Specify	
11	ILDMD	$6	What was the method used for the diagnosis?	$6	Method of Diagnosis	2 = Bronchoalveolar lavage 3 = Lung biopsy 4 = ILD markers C16809 = MRI C17204 = CT scan

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						C20644 = High resolution CT C38101 = X-ray 99 = Other
12	ILDOMD	$200	If Other, specify	$200	Other Method, Specify	
13	ILDADLFD	$6	What was the axial distribution of lung findings?	$6	Axial Distribution of Lung Findings	1 = Central lung predominant 2 = Peripheral lung predominant 3 = Both
14	ILDZDLFD	$6	What was the zonal distribution of lung findings?	$6	Zonal Distribution of Lung Findings	1 = Upper lung predominant 2 = Middle lung predominant 3 = Lower lung predominant 4 = Not applicable
15	ILDPTFD	$6	What was distribution pattern of findings?	$6	Distribution Pattern of Findings	1 = Focal pattern 2 = Multifocal pattern 3 = Diffuse pattern 4 = Mixed pattern
16	ILDINRUL	$6	Was there lobar involvement in the right upper lobe?	$6	Lobar Involvement - Right Upper Lobe	C49487 = No C49488 = Yes

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Interstitial Lung Disease (ILDIS)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
17	ILDINRML	$6	Was there lobar involvement in the right middle lobe?	$6	Lobar Involvement - Right Middle Lobe	C49487 = No C49488 = Yes
18	ILDINRLL	$6	Was there lobar involvement in the right lower lobe?	$6	Lobar Involvement - Right Lower Lobe	C49487 = No C49488 = Yes
19	ILDINLUL	$6	Was there lobar involvement in the left upper lobe?	$6	Lobar Involvement - Left Upper Lobe	C49487 = No C49488 = Yes
20	ILDINLLL	$6	Was there lobar involvement in the left lower lobe?	$6	Lobar Involvement - Left Lower Lobe	C49487 = No C49488 = Yes
21	ILDCTGGO	$6	Were ground glass opacities found in CT?	$6	Sp CT Findings - Ground Glass Opacities	C49487 = No C49488 = Yes
22	ILDCTRO	$6	Were reticular opacities found in CT?	$6	Sp CT Findings - Reticular Opacities	C49487 = No C49488 = Yes
23	ILDCTCON	$6	Was consolidation found in CT?	$6	Sp CT Findings - Consolidation	C49487 = No C49488 = Yes
24	ILDCTTB	$6	Was traction bronchiectasis found in CT?	$6	Sp CT Findings- Traction Bronchiectasis	C49487 = No C49488 = Yes
25	ILDCTCN	$6	Was centrilobular nodularity found in CT?	$6	Sp CT Findings-Centrilobular Nodularity	C49487 = No C49488 = Yes

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
26	ILDCTHC	$6	Was honeycombing found in CT?	$6	Sp CT Findings - Honeycombing	C49487 = No C49488 = Yes
27	ILDSCHF	$200	Were there any further findings?	$200	Sp Any Further Findings	
29	ILDCPT	$6	At the time of diagnosis of the pulmonary event was there any sign of cancer progression within the thorax?	$6	Sign of Cancer Progr. Within the Thorax	C49487 = No C49488 = Yes
30	ILDDCPT	$200	What was the description of cancer progression within the thorax?	$200	Desc. of Cancer Progr. Within the Thorax	
31	ILDEBI	$6	At the time of diagnosis of the pulmonary event, was there any evidence of bacterial infection?	$6	Any Evidence of Bacterial Infection	C49487 = No C49488 = Yes
32	ILDEVI	$6	At the time of diagnosis of the pulmonary event, was there any evidence of viral infection?	$6	Any Evidence of Viral Infection	C49487 = No C49488 = Yes

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
33	ILDEFI	$6	At the time of diagnosis of the pulmonary event, was there any evidence of fungal infection?	$6	Any Evidence of Fungal Infection	C49487 = No C49488 = Yes
34	ILDEOI	$6	At the time of diagnosis of the pulmonary event, was there any other type of evidence of infection?	$6	Any Other Type of Evidence of Infection	C49487 = No C49488 = Yes
35	ILDANAL	$6	Analytes	$6	Analytes	1 = Common bacteria 2 = Acid fast bacillus 3 = Tubercle bacillus 4 = Legionnaire 5 = Pneumocystis 6 = Cytomegalovirus 7 = COVID-19 8 = Influenza C73540 = Mycoplasma C77180 = Aspergillus C77184 = Cryptococcus C77163 = Candida 99 = Other
36	ILDTM	$2	Test method	$2	Test Method	1 = Sputum culture

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						2 = Blood culture 3 = Serum antibody titer 4 = Broncho-alveolar lavage 5 = Other fungal 99 = Other
37	ILDEXDAT	yyyy MMM dd	Date of examination		Date of Examination	
38	ILDRES	$6	Result	$6	Result	0 = Negative 1 = Positive
39	ILDCOM	$200	Other, specify	$200	Other, Specify	
40	ILDLBP	$6	Was the lung biopsy performed?	$6	Lung Biopsy Performed	C49487 = No C49488 = Yes
41	ILDLBPT	$6	Type of biopsy	$6	Type of Biospy	1 = Transbronchial 2 = Bronchial biopsy 3 = Cryobiopsy 99 = Other
42	ILDLBPTO	$200	If Other biopsy, specify	$200	Other Biopsy, Specify	
43	ILDDBP	yyyy MMM dd	What was the date the biopsy was performed?		Date the Biopsy Performed	
44	ILDBPF	$200	What were the biopsy findings, specify	$200	Biopsy Performed, Findings	
45	ILDBLP	$6	Was bronchoalveolar lavage (BAL) performed?	$6	Broncho-alveolar Lavage (BAL) Performed	C49487 = No C49488 = Yes

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
46	ILDEDATB	yyyy MMM dd	What was the date of examination of BAL?		Date of Examination of BAL	
48	ILDCNR	2.1	What was the total cells count?	8	Result of Cell Numbers	
49	ILDCNRU	$7	What was the unit of total cells count?	$7	Result of Cell Numbers, Unit	C105489 = 10^8/L
50	ILDLR	4.2	What was the lymphocyte cell count?	8	Result of Lymphocyte	
51	ILDLRU	$6	What was the unit of lymphocyte cell count?	$6	Result of Lymphocyte, Unit	C25613 = %
52	ILDNR	4.2	What was the neutrophil count?	8	Result of Neutrophil	
53	ILDNRU	$6	What was the unit of neutrophil count?	$6	Result of Neutrophil, Unit	C25613 = %
54	ILDMR	4.2	What was the macrophage count?	8	Result of Macrophage	
55	ILDMRU	$6	What was the unit of macrophage count?	$6	Result of Macrophage, Unit	C25613 = %
56	ILDER	4.2	What was the eosinophil count?	8	Result of Eosinophil	
57	ILDERU	$6	What was the unit of eosinophil count?	$6	Result of Eosinophil, Unit	C25613 = %
58	ILDBR	4.2	What was the basophil count?	8	Result of Basophil	

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
59	ILDBRU	$6	What was the unit of basophil count?	$6	Result of Basophil, Unit	C25613 = %
60	ILDCDR	2.1	What was the CD4/CD8 count?	8	Result of CD4/CD8	
61	ILDCDRU	$6	What was the unit of CD4/CD8 count?	$6	Result of CD4/CD8, Unit	C44256 = RATIO
62	ILDPFB	$200	If there are any pathological findings in BAL, specify	$200	Any Pathological Findings in BAL	
63	ILDMCYT	$6	Were there malignant cells in cytology?	$6	Malignant Cells on Cytology	C49487 = No C49488 = Yes
64	ILDMCYTR	$200	If there were malignant cells on cytology, specify results	$200	Malignant Cells on Cytology Result Spec.	
65	ILDPLEFF	$6	Did pleural effusion co-exist with the event?	$6	Pleural Eff. Co-exist with Event	C49487 = No C49488 = Yes
66	ILDPLCYT	$6	Was cytology of pleural fluid done?	$6	Cytology of Pleural Fluid Done	C49487 = No C49488 = Yes
67	ILDMCELL	$6	Were malignant cells present in cytology of pleural fluid?	$6	Malignant Cells Presence in Cytology	C49487 = No C49488 = Yes

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
68	ILDMCECR	$200	If malignant cells were present in cytology of pleural fluid, specify results	$200	Malignant Cells Pres. in Cytol Res. Spec	
69	ILDBGP	$6	Were blood gases performed at the time of the suspected pulmonary event?	$6	Blood Gases Performed	C49487 = No C49488 = Yes
71	ILDHRT	$6	Is there a history of radiotherapy to the thorax prior to entering the study?	$6	History of Radiotherapy to the Thorax	C49487 = No C49488 = Yes
73	ILDPP	$6	Has the Subject ever had pleurodesis performed?	$6	Pleurodesis Performed	C49487 = No C49488 = Yes
75	ILDPT	$2	What was the type of pleurodesis?	$2	Type of Pleurodesis	1 = Talc 2 = Picibanil (ok-432) 3 = Tetracycline 4 = Bleomycine 99 = Other
76	ILDOT	$200	If Other, specify	$200	Other Type, Specify	
77	ILDEIR	$6	At the time of the event, was there any evidence of an inflammatory reaction?	$6	Any Evidence of an Inflammatory Reaction	C49487 = No C49488 = Yes

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
78	ILDIRD	$200	If not captured on AE / LB, then add details here	$200	Inflammatory Reaction Details	
79	ILDEAR	$6	At the time of the event, was there any evidence of allergic reaction?	$6	Any Evidence of Allergic Reaction	C49487 = No C49488 = Yes
80	ILDARD	$200	If not captured on AE / LB, then add details here	$200	Allergic Reaction Details	
81	ILDCRAD	$6	Was prior radiation administered to the chest?	$6	Prior Radiation Adm. to the Chest	C49487 = No C49488 = Yes
82	RADFIN	$2	What were the radiological findings?	$2	Radiological Findings	1 = Confined to radiation field only 2 = Outside of radiation field only 3 = Both 4 = No radiological findings
83	PNUTYP	$2	What was the pneumonitis type?	$2	Pneumonitis Type	1 = Radiation pneumonitis 2 = Drug-induced pneumonitis/Interstitial lung disease 99 = Other
84	PNUTPOTH	$200	If Other, specify	$200	Pneumonitic Type, Other	

(Version: ON2410 2024-10-03)

AE No.	_____	2
Adverse Event	_____	3
CTCAE Version	5	4

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	_____	6
CTCAE grade	Grade 1 Mild AE ☐	7
	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 _____	8
Sign/symptom end date	Fixed Unit: yyyy mon dd _____	9
Sign/symptom ongoing	Yes ☐	10
Description of Cytokine Release Syndrome	_____	11
Were any medication given prior to study drug infusion for prophylaxis of CRS?	No ☐	12
	Yes ☐	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: CRS Signs and Symptoms (CRSSS)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	AENO	3	AE No.	8	AE Number	
3	AETERM	$200	Adverse Event	$200	Adverse Event Reported Term	
4	CTCAE_V	$5	CTCAE Version	$5	CTCAE Version	5
6	CRSTERM	$200	Sign/symptom reported term	$200	Sign/Symptom Reported Term	
7	CRSTOXGR	$2	CTCAE grade	$2	CTCAE Grade	1 = Grade 1 Mild AE 2 = Grade 2 Moderate AE 3 = Grade 3 Severe AE 4 = Grade 4 Life-threatening or disabling AE 5 = Grade 5 Death related to AE
8	CRSSTDAT	yyyy MMM dd	Sign/symptom start date		Sign/Symptom Start Date	
9	CRSENDAT	yyyy MMM dd	Sign/symptom end date		Sign/Symptom End Date	
10	CRSONGO	$6	Sign/symptom ongoing	$6	Sign/Symptom Ongoing	C49488 = Yes
11	CRSDES01	$1999	Description of Cytokine Release Syndrome	$1999	CRS Description	
12	CRSPMED	$6	Were any medication given prior to study drug infusion for prophylaxis of CRS?	$6	Any Prohylac Med. Prior Study Drug Infus	C49487 = No C49488 = Yes

(Version: ON2211 2025-03-12)

AE No.		2
Adverse Event		3
ASTCT CRS Criteria Version	LEE ASTCT 2019	4

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)	6
	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	7
	Not requiring vasopressor	
	Requiring vasopressor with or without vasopressin	
	Requiring multiple vasopressors (excluding vasopressin)	
Hypoxia	None	8
	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	9
	Grade 2	
	Grade 3	
	Grade 4	
	Grade 5	
Start date	Fixed Unit: yyyy mon dd	10
End date	Fixed Unit: yyyy mon dd	11

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: CRS ASTCT Criteria (CRASTCT)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	AENO	3	AE No.	8	AE Number	
3	AETERM	$200	Adverse Event	$200	Adverse Event Reported Term	
4	CRSASTCV	$2	ASTCT CRS Criteria Version	$2	ASTCT CRS Criteria Version	1 = LEE ASTCT 2019
6	BTEMP	$2	Body temperature	$2	Body Temperature	1 = <38.0C (100.4F) 2 = 38.0-39.0C (100.4-102.2F) 3 = >39.0-40.0C (102.3-104.0F) 4 = >40C (>104.0F) for =<24 hours 5 = >40C (>104.0F) for >24 hours
7	PULSEPL	$2	Hypotension	$2	Hypotension	1 = None 2 = Not requiring vasopressor 3 = Requiring vasopressor with or without vasopressin 4 = Requiring multiple vasopressors (excluding vasopressin)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: CRS ASTCT Criteria (CRASTCT)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
8	HYPOX	$2	Hypoxia	$2	Hypoxia	1 = None 2 = Requiring low flow nasal cannula or blow-by 3 = Requiring high flow nasal cannula, facemask, non-rebreather mask or venturi mask 4 = Requiring positive pressure (e.g. CPAP, BiPAP) 5 = Requiring intubation & mechanical ventilation
9	CRSASTCT	$2	ASTCT CRS grade	$2	ASTCT CRS Grade	1 = Grade 1 2 = Grade 2 3 = Grade 3 4 = Grade 4 5 = Grade 5
10	ASTSTDAT	yyyy MMM dd	Start date		Start Date	
11	ASTENDAT	yyyy MMM dd	End date		End Date	

(Version:DK2303 2023-07-25)

AE number _____ 2

Adverse event _____ 3

AE of special interest _____ 4

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 6

Suspect drug name +/- additives / excipients (trade name) _____

Timing between suspect drug administration and AE onset Fixed Unit: 24-hours clock 7

_____

Was premedication given? No ☐ 8
Yes ☐

Acetaminophen No ☐ 9
Yes ☐

Antihistamines No ☐ 10
Yes ☐

Glucocorticoids No ☐ 11
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 ☐ 14
Yes ☐

Hives/urticaria No ☐ 15
Yes ☐

Macular rash No ☐ 16
Yes ☐

Papular rash No ☐ 17
Yes ☐

Vesicular rash No ☐ 18
Yes ☐

Skin exfoliation No ☐ 19
Yes ☐

Vasculitic rash	No Yes	20
Eczematoid rash	No Yes	21
Bullous lesions	No Yes	22
Acute generalized exanthemous pustulosis (AGEP)	No Yes	23
Only Pruritus	No Yes	24
Angioedema	No Yes	25
Respiratory symptoms:		
Cough	No Yes	27
Dyspnea	No Yes	28
Bronchospasm/wheezing	No Yes	29
Sensation of throat tightening or closing / dysphonia / change in voice quality	No Yes	30
Hyperventilation	No Yes	31
Cardiovascular signs / symptoms:		
Palpitations/tachycardia	No Yes	33
Hypotension	No Yes	34
Chest discomfort/tightness/pain	No Yes	35
Arrythmia	No Yes	36

Gastrointestinal symptoms:

Nausea	No ☐	38
	Yes ☐	
Vomiting	No ☐	39
	Yes ☐	
Diarrhea	No ☐	40
	Yes ☐	
Abdominal pain/GI cramps	No ☐	41
	Yes ☐	
Dysphagia (difficulty of swallowing)	No ☐	42
	Yes ☐	

Psychological symptoms (before or during infusion; please specify in narrative):

Fear/panic reaction	No ☐	44
	Yes ☐	

Other associated signs / symptoms :

Fever	No ☐	46
	Yes ☐	
Flushing	No ☐	47
	Yes ☐	
Erythema	No ☐	48
	Yes ☐	
Headache	No ☐	49
	Yes ☐	
Chills/rigors (shivering)	No ☐	50
	Yes ☐	
Cold, clammy sensation/extremities	No ☐	51
	Yes ☐	
Injection site pain, burn, extravasation	No ☐	52
	Yes ☐	
Paresthesia (abnormal sensation)	No ☐	53
	Yes ☐	
Lightheadedness	No ☐	54

	Yes ☐	
Edema	No ☐	55
	Yes ☐	
Back pain	No ☐	56
	Yes ☐	
Arthralgia/myalgia (joint/muscle pain)	No ☐	57
	Yes ☐	
Pre-syncope/dizziness	No ☐	58
	Yes ☐	
Syncope	No ☐	59
	Yes ☐	
Blurred vision	No ☐	60
	Yes ☐	
Seizure/convulsions	No ☐	61
	Yes ☐	
Cardiac arrest	No ☐	62
	Yes ☐	
Other	No ☐	63
	Yes ☐	
Other, specify _____		64
Was non-drug treatment given for management of the adverse event?	No ☐	65
	Yes ☐	
Infusion speed reduction	No ☐	66
	Yes ☐	
Supine positioning	No ☐	67
	Yes ☐	
Cardiopulmonary resuscitation (CPR)	No ☐	68
	Yes ☐	
Oxygen therapy	No ☐	69
	Yes ☐	
Airway management (bag-mask ventilation, etc.)	No ☐	70

	Yes ☐	
Was treatment given in consultation with a specialist?	No ☐	71
	Yes ☐	
Specialist consulted for treatment, specify	_____	72
If a specialist (e.g., allergist) was consulted, indicate any concluding interpretations if applicable:		
Specialist concluding interpretation	Type 1 reaction (ige mediated; anaphylactic response) ☐	74
	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	_____	75

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Infusion Related Reaction TQS (IRRTQS)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	AENO	3	AE number	8	AE Number	
3	AETERM	$200	Adverse event	$200	Adverse event	
4	AESI	$200	AE of special interest	$200	AE of Special Interest	
6	IRCMTRT	$200	**Provide formulation if applicable** Suspect drug name +/- additives / excipients (trade name)	$200	Medication or Therapy	
7	IRCMTIM	HH:nn	Timing between suspect drug administration and AE onset		Timing Between CM and AE	
8	IRPCM	$6	Was premedication given?	$6	Premedication Given	C49487 = No C49488 = Yes
9	IRPACCM	$6	Acetaminophen	$6	Acetaminophen Given	C49487 = No C49488 = Yes
10	IRPAHCM	$6	Antihistamines	$6	Antihistamines Given	C49487 = No C49488 = Yes
11	IRPGLCM	$6	Glucocorticoids	$6	Glucocorticoids Given	C49487 = No C49488 = Yes
14	IRRMR	$6	Maculopapular rash	$6	Maculopapular Rash	C49487 = No C49488 = Yes
15	IRRHU	$6	Hives/urticaria	$6	Hives/Urticaria	C49487 = No C49488 = Yes
16	IRRMRS	$6	Macular rash	$6	Macular Rash	C49487 = No C49488 = Yes
17	IRRPR	$6	Papular rash	$6	Papular Rash	C49487 = No C49488 = Yes
18	IRRVR	$6	Vesicular rash	$6	Vesicular Rash	C49487 = No C49488 = Yes
19	IRRSE	$6	Skin exfoliation	$6	Skin Exfoliation	C49487 = No C49488 = Yes
20	IRRVR1	$6	Vasculitic rash	$6	Vasculitic Rash	C49487 = No C49488 = Yes

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
21	IRRER	$6	Eczematoid rash		Eczematoid Rash	C49487 = No C49488 = Yes
22	IRRBL	$6	Bullous lesions	$6	Bullous Lesions	C49487 = No C49488 = Yes
23	IRRAGEP	$6	Acute generalized exanthemous pustulosis (AGEP)	$6	Acute Generalized Exanthemous Pustulosis	C49487 = No C49488 = Yes
24	IRRPUR	$6	Only Pruritus	$6	Only Pruritus	C49487 = No C49488 = Yes
25	IRRANG	$6	Angioedema	$6	Angioedema	C49487 = No C49488 = Yes
27	IRRCGH	$6	Cough	$6	Cough	C49487 = No C49488 = Yes
28	IRRDYSP	$6	Dyspnea	$6	Dyspnea	C49487 = No C49488 = Yes
29	IRRBRON	$6	Bronchospasm /wheezing	$6	Bronchospasm /Wheezing	C49487 = No C49488 = Yes
30	IRRTIGH	$6	Sensation of throat tightening or closing / dysphonia / change in voice quality	$6	Throat Tightning, Dysphonia, Voice Chang	C49487 = No C49488 = Yes
31	IRRHYPV	$6	Hyperventilation	$6	Hyperventilation	C49487 = No C49488 = Yes
33	IRRTACH	$6	Palpitations/tachycardia	$6	Palpitations/Tachycardia	C49487 = No C49488 = Yes
34	IRRHYPT	$6	Hypotension	$6	Hypotension	C49487 = No C49488 = Yes
35	IRRCHP	$6	Chest discomfort/tightness/pain	$6	Chest Discomfort/Tightness/Pain	C49487 = No C49488 = Yes
36	IRRARR	$6	Arrythmia	$6	Arrythmia	C49487 = No C49488 = Yes
38	IRRNAU	$6	Nausea	$6	Nausea	C49487 = No C49488 = Yes
39	IRRVOM	$6	Vomiting	$6	Vomiting	C49487 = No C49488 = Yes

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
40	IRRDIA	$6	Diarrhea	$6	Diarrhea	C49487 = No C49488 = Yes
41	IRRABD	$6	Abdominal pain/GI cramps	$6	Abdominal Pain/GI Cramps	C49487 = No C49488 = Yes
42	IRRDYSP1	$6	Dysphagia (difficulty of swallowing)	$6	Dysphagia (Difficulty of Swallowing)	C49487 = No C49488 = Yes
44	IRRFEAR	$6	Fear/panic reaction	$6	Fear/Panic Reaction	C49487 = No C49488 = Yes
46	IRRFEV	$6	Fever	$6	Fever	C49487 = No C49488 = Yes
47	IRRFLUSH	$6	Flushing	$6	Flushing	C49487 = No C49488 = Yes
48	IRRERY	$6	Erythema	$6	Erythema	C49487 = No C49488 = Yes
49	IRRHACH	$6	Headache	$6	Headache	C49487 = No C49488 = Yes
50	IRRCHIL	$6	Chills/rigors (shivering)	$6	Chills/Rigors (Shivering)	C49487 = No C49488 = Yes
51	IRRCOLD	$6	Cold, clammy sensation/extremities	$6	Cold, Clammy Sensation/Extremities	C49487 = No C49488 = Yes
52	IRRBURN	$6	Injection site pain, burn, extravasation	$6	Injection Site Pain, Burn, Extravasation	C49487 = No C49488 = Yes
53	IRRPAR	$6	Paresthesia (abnormal sensation)	$6	Paresthesia (Abnormal Sensation)	C49487 = No C49488 = Yes
54	IRRLIGH	$6	Lightheadedness	$6	Lightheadedness	C49487 = No C49488 = Yes
55	IRREDM	$6	Edema	$6	Edema	C49487 = No C49488 = Yes
56	IRRBCK	$6	Back pain	$6	Back pain	C49487 = No C49488 = Yes
57	IRRMYAL	$6	Arthralgia/myalgia (joint/muscle pain)	$6	Arthralgia/Myalgia (Joint/Muscle Pain)	C49487 = No C49488 = Yes

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
58	IRRDIZ	$6	Pre-syncope/dizziness	$6	Pre-Syncope/ Dizziness	C49487 = No C49488 = Yes
59	IRRSYNC	$6	Syncope	$6	Syncope	C49487 = No C49488 = Yes
60	IRRBLR	$6	Blurred vision	$6	Blurred Vision	C49487 = No C49488 = Yes
61	IRRCONV	$6	Seizure/convulsions	$6	Seizure/Convulsions	C49487 = No C49488 = Yes
62	IRRCRD	$6	Cardiac arrest	$6	Cardiac Arrest	C49487 = No C49488 = Yes
63	IRROTH	$6	Other	$6	Other	C49487 = No C49488 = Yes
64	IRROTHS	$200	Other, specify	$200	Other, Specify	
65	IRRTRT	$6	Was non-drug treatment given for management of the adverse event?	$6	Non-Drug Treatment Given for AE	C49487 = No C49488 = Yes
66	IRRIVSR	$6	Infusion speed reduction	$6	Infusion Speed Reduction	C49487 = No C49488 = Yes
67	IRRSUP	$6	Supine positioning	$6	Supine Positioning	C49487 = No C49488 = Yes
68	IRRCPR	$6	Cardiopulmonary resuscitation (CPR)	$6	Cardiopulmonary Resuscitation (CPR)	C49487 = No C49488 = Yes
69	IRROXY	$6	Oxygen therapy	$6	Oxygen Therapy	C49487 = No C49488 = Yes
70	IRRAIR	$6	Airway management (bag-mask ventilation, etc.)	$6	Airway Management (Bag-Mask Ventilation)	C49487 = No C49488 = Yes
71	IRRNDS	$6	Was treatment given in consultation with a specialist?	$6	Specialist Consulted for Treatment	C49487 = No C49488 = Yes

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
72	IRRNDSS1	$999	Specialist consulted for treatment, specify	$999	Specialist Consulted for Treat, Specif	
74	IRRCIS	$2	Specialist concluding interpretation	$2	Specialist Concluding Interpretation	1 = Type 1 reaction (ige mediated; anaphylactic response) 2 = Type II reaction (cytotoxic-mediated) 3 = Type III reaction (immune complex-mediated) 4 = Type IV reaction (cell-mediated, late- or delayed-type reaction) 5 = Pseudoallergic reaction 6 = Pharmacological reaction 7 = Psychophysiological reaction 99 = Other
75	IRRCISS	$200	Specialist concluding interpretation, specify	$200	Specialist Concluding Interpret, Specify	

(Version: ON2310 2023-10-19)

Any hospital/ inpatient/ emergency room visit	No ☐	2
	Yes ☐	
Type of attendance	Outpatient/physician office attendance ☐	3
	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	4
Stop date of admission or attendance	Fixed Unit: yyyy mon dd	5
Admission or attendance continues	Yes ☐	6
ICU/HDU stay during hospital admission	No ☐	7
	Yes ☐	
Start date of ICU/HDU stay	Fixed Unit: yyyy mon dd	8
End date of ICU/HDU stay	Fixed Unit: yyyy mon dd	9
ICU/HDU stay continues	Yes ☐	10
Primary symptom for hospital /inpatient/ emergency room visit	Pain ☐	11
	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 _____ (12)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	HOCYN	$6	Any hospital/ inpatient/ emergency room visit	$6	Any Hosp/Inpnt/ER Visit	C49487 = No C49488 = Yes
3	HADTYPE	$2	Type of attendance	$2	Type of Attendance	1 = Outpatient/physician office attendance 2 = Planned hospital admission with no emergency room visit 3 = Unplanned hospital admission with no emergency room visit 4 = Emergency room attendance only (Patient was discharged direct from the emergency room) 5 = Emergency room attendance resulting in a hospital admission at the same time (Further hospital care outside the emergency room)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
4	HOASTDAT	yyyy MMM dd	Start date of admission or attendance		Start Date of Admission or Attendance	
5	HOAENDAT	yyyy MMM dd	Stop date of admission or attendance		Stop Date of Admission or Attendance	
6	HOAONGO	$6	Admission or attendance continues	$6	Admission or Attendance Continues	C49488 = Yes
7	HADIH	$6	ICU/HDU stay during hospital admission	$6	ICU/HDU Stay During Hospital Admission	C49487 = No C49488 = Yes
8	HOISTDAT	yyyy MMM dd	Start date of ICU/HDU stay		Start Date of ICU/HDU Stay	
9	HOIENDAT	yyyy MMM dd	End date of ICU/HDU stay		End Date of ICU/HDU Stay	
10	HOIONGO	$6	ICU/HDU stay continues	$6	ICU/HDU Stay Continues	C49488 = Yes
11	HOCREAS	$3	Primary symptom for hospital /inpatient/ emergency room visit	$3	Primary Symptom for Hosp/Inpnt/ER Visit	1 = Pain 2 = Fatigue 6 = Diarrhea 9 = Swelling 10 = Fever 12 = Numbness/tingling 14 = Dehydration 60 = Stomach or abdominal cramps/pain 61 = Stomach or abdominal bloating/swelling 62 = Difficulty in eating/feeling full quickly

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						100 = Jaundice 131 = Rash 151 = Other (disease related) 152 = Other (non disease related)
12	HOCREASO	$200	If Other, specify	$200	Other, Please Specify	

(Version: AZ21:10 Date:2021-10-13)

AE Number(from AE)		2
Events Linked for the Case		3
Serious (from AE)	No ☐	4
	Yes ☐	
Date AE started (from AE)	Fixed Unit: yyyy mmm dd	5
Date AE stopped (from AE)	Fixed Unit: yyyy mmm dd	6
Outcome (from AE)	Recovered/Resolved ☐	7
	Recovering/Resolving ☐	
	Recovered/Resolved with sequelae ☐	
	Not recovered/Not resolved ☐	
	Fatal ☐	
Reasonable possibility AE caused by Rilvegostomig	No ☐	8
	Yes ☐	
Reasonable possibility AE caused by Durvalumab	No ☐	9
	Yes ☐	
Reasonable possibility AE caused by Gemcitabine	No ☐	10
	Yes ☐	
Reasonable possibility AE caused by Cisplatin	No ☐	11
	Yes ☐	
Maximum CTCAE grade (from AE)	Grade 1 ☐	12
	Grade 2 ☐	
	Grade 3 ☐	
	Grade 4 ☐	
	Grade 5 ☐	
Date AZ aware of serious AE	Fixed Unit: yyyy mmm dd	13
Date AE met criteria for serious AE	Fixed Unit: yyyy mmm dd	14
Death	No ☐	15

	Yes ☐	
Life threatening	No ☐	16
	Yes ☐	
In-patient hospitalization or prolongation of existing	No ☐	17
	Yes ☐	
Persistent or significant disability/incapacity	No ☐	18
	Yes ☐	
A congenital abnormality/birth defect	No ☐	19
	Yes ☐	
Important medical event	No ☐	20
	Yes ☐	
Date of hospitalization	Fixed Unit: yyyy mmm dd	21
Date of discharge	Fixed Unit: yyyy mmm dd	22
SAE caused by other medication trade name(s)		23
SAE caused by study procedure(s)		24
SAE Comments		25
Details of Narrative:		26
Formatted CASEID		27
E2B File Sent		28
E2B Initial Date		29
E2B Change Date		30
CASEID (Populated from AE)		31
Is Previous SAE ?	No ☐	32
	Yes ☐	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: AZ Safety Report Form (AZSRF)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	AENO	3	AE Number (from AE)			
3	EVTTEXT	$200	Events Linked for the Case			
4	AESER	$6	Serious (from AE)			C49487 = No C49488 = Yes
5	AESTDAT	yyyy MMM-dd-	Date AE started (from AE)			
6	AEENDAT	yyyy MMM-dd-	Date AE stopped (from AE)			
7	AEOUT	$6	Outcome (from AE)			C49498 = Recovered/Resolved C49496 = Recovering/Resolving C49495 = Recovered/Resolved with sequelae C49494 = Not recovered/Not resolved C48275 = Fatal
8	AEREL	$6	Reasonable possibility AE caused by Rilvegostomig			C49487 = No C49488 = Yes
9	AEREL1	$6	Reasonable possibility AE caused by Durvalumab			C49487 = No C49488 = Yes
10	AEREL2	$6	Reasonable possibility AE caused by Gemcitabine			C49487 = No C49488 = Yes

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
11	AEREL3	$6	Reasonable possibility AE caused by Cisplatin			C49487 = No C49488 = Yes
12	AETOXGR	$2	Maximum CTCAE grade (from AE)			1 = Grade 1 2 = Grade 2 3 = Grade 3 4 = Grade 4 5 = Grade 5
13	SAEAZDAT	yyyy MMM dd	Date AZ aware of serious AE			
14	AESDAT	yyyy MMM dd	Date AE met criteria for serious AE			
15	AESDTH	$6	Death			C49487 = No C49488 = Yes
16	AESLIFE	$6	Life threatening			C49487 = No C49488 = Yes
17	AESHOSP	$6	In-patient hospitalization or prolongation of existing			C49487 = No C49488 = Yes
18	AESDISAB	$6	Persistent or significant disability/incapacity			C49487 = No C49488 = Yes
19	AESCONG	$6	A congenital abnormality/birth defect			C49487 = No C49488 = Yes
20	AESMIE	$6	Important medical event			C49487 = No C49488 = Yes
21	AESHODAT	yyyy MMM dd	Date of hospitalization			
22	AESDIDAT	yyyy MMM dd	Date of discharge			
23	AESMED	$200	SAE caused by other medication trade name(s)			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: AZ Safety Report Form (AZSRF)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
24	AESP	$200	SAE caused by study procedure(s)			
25	AESCOMNT	$1999	SAE Comments			
26	AENARRAT	$1999	Details of Narrative:			
27	SECASEID	$100	Formatted CASEID			
28	E2BALERT	$3	E2B File Sent			
29	E2BINDAT	yyyy MMM dd HH:nn:ss	E2B Initial Date			
30	E2BCHDAT	yyyy MMM dd HH:nn:ss	E2B Change Date			
31	CASEID1	$100	CASEID (Populated from AE)			
32	AEPRESAE	$2	Is Previous SAE ?			0 = No 1 = Yes

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: AZ Rave Safety Gateway Form (AZRSGF)
Generated On: 2025 Nov 20 12:23 (GMT)

(Version:AZ2103 2021-06-25)

Field created for RSG to calculate weight		2
Field created for RSG to calculate height		3
RSG Field for Date of Death		4
RSG Field for Autopsy performed	No ☐ Yes ☐ Unknown ☐	5
RSG Field for Primary Cause of Death		6
RSG Field for Secondary Cause of death		7
RSG Field for Country Code		8
RSG Field for Pregnancy Date		9

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: AZ Rave Safety Gateway Form (AZRSGF)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	Z_WEIGHT	8	Field created for RSG to calculate weight			
3	Z_HEIGHT	8	Field created for RSG to calculate height			
4	Z_AESDDAT	yyyy MMM-dd-	RSG Field for Date of Death			
5	Z_AESAUTOP	$6	RSG Field for Autopsy performed			C49487 = No C49488 = Yes C17998 = Unknown
6	Z_PRICAUSE	$200	RSG Field for Primary Cause of Death			
7	Z_SECCAUSE	$200	RSG Field for Secondary Cause of death			
8	Z_COUNTRY	$5	RSG Field for Country Code			
9	Z_PREGDAT	yyyy MMM dd	RSG Field for Pregnancy Date			

(Version: AZ2403 2024-03-25)

Were any Device Events reported during Mandatory screening tumor sample (SPCBEDT1) collection?	No ☐ 2 Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Device Events Log (DELOG)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	DEYN	$6	Were any Device Events reported during Mandatory screening tumor sample (SPCBEDT1) collection?	$6	Any Device Events	C49487 = No C49488 = Yes

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Device Events (DE)
Generated On: 2025 Nov 20 12:23 (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.

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 ■	2
Associated Person's Identifier	_____	3
Category of Device Event	Procedure ☐	4
Category of Device Event	In-vitro device deficiency ☐	5
Category of Device Event	Device deficiency ☐	6
Device Event number	_____	7
Standardized Device Event	AE related to biopsy ☐	8
	False positive (PD-L1) ☐	
	False negative (PD-L1) ☐	
	Other ☐	
If other, specify Device Event	_____	9
Description of Device Event	_____	10
Device Event expected/unexpected	Expected ☐	11
	Unexpected (unanticipated) ☐	
Device Event start date	Fixed Unit: yyyy mon dd	12
	_____	
Device Event end date	Fixed Unit: yyyy mon dd	13
	_____	
Any Adverse Event caused by this Device Event?	No ☐	14

	Yes ☐	
Serious Device Event	No ☐	15
	Yes ☐	
"If 'No', could the event have led to SAE?"	No ☐	16
	Yes ☐	
Outcome of Device Event	Recovered/resolved ☐	17
	Recovered/resolved with sequelae ☐	
	Not recovered/not resolved ☐	
	Fatal ☐	
Relationship to device	Not related ☐	18
	Possible ☐	
	Probable ☐	
	Causal ☐	
Relationship to procedure associated with the use of the device	Not related ☐	19
	Possible ☐	
	Probable ☐	
	Causal ☐	
Procedure name		20
Device trade/brand name		21
Device Identifier		22
Current device location	Implanted ☐	23
	Explanted ☐	
	Returned ☐	
	Installed ☐	
	Retained ☐	
	Discarded ☐	
	Unknown ☐	
	Other ☐	
Specify current device location		24
Action taken date	Fixed Unit: yyyy mon dd	25
Party responsible for the device	Manufacturer ☐	26

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Device Events (DE)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	SREL	$6	Relationship to Subject	$6	Subject, Device or Study Relationship	1 = Study participant
3	APID	3	Associated Person's Identifier	8	Associated Persons Identifier	
4	DECAT1	$2	Category of Device Event	$2	Category of Device Event	1 = Procedure
5	DECAT2	$2	Category of Device Event	$2	Category of Device Event	1 = In-vitro device deficiency
6	DECAT3	$2	Category of Device Event	$2	Category of Device Event	1 = Device deficiency
7	DESPID	3	Device Event number	8	Device Event Number	
8	DEDECOD	$2	Standardized Device Event	$2	Device Events Dictionary-Derived Term	1 = AE related to biopsy 2 = False positive (PD-L1) 4 = False negative (PD-L1) 99 = Other
9	DETERM	$200	If other, specify Device Event	$200	Reported Term for Device Event	
10	DEDESC01	$1999	Description of Device Event	$1999	DE Description	
11	EXPCAT	$2	Device Event expected/unexpected	$2	Event Expected / Unexpected	1 = Expected 2 = Unexpected (unanticipated)
12	DESTDAT	yyyy MMM-dd-	Device Event start date		Device Event Start Date	
13	DEENDAT	yyyy MMM-dd-	Device Event end date		Device Event End Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Device Events (DE)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
14	AECAUSFL	$6	Any Adverse Event caused by this Device Event?	$6	Any AE Caused by Device Event	C49487 = No C49488 = Yes
15	DESER	$6	Serious Device Event	$6	Serious Device Event	C49487 = No C49488 = Yes
16	POTDESER	$6	"If 'No', could the event have led to SAE?"	$6	Potential Seriousness	C49487 = No C49488 = Yes
17	DEOUT	$6	Outcome of Device Event	$6	Outcome of Device Event	C49498 = Recovered/resolved C49495 = Recovered/resolved with sequelae C49494 = Not recovered/not resolved C48275 = Fatal
18	DEREL	$2	Relationship to device	$2	Relationship to Device	1 = Not related 2 = Possible 3 = Probable 4 = Causal
19	DEPRREL	$2	Relationship to procedure associated with the use of the device	$2	Relationship to Procedure	1 = Not related 2 = Possible 3 = Probable 4 = Causal
20	PRTRT	$200	Procedure name	$200	Procedure Name	
21	TRADENAM	$200	Device trade/brand name	$200	Device Trade/Brand Name	
22	SPDEVID	$50	Device Identifier	$50	Sponsor Device Identifier	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Device Events (DE)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
23	DTTERM	$2	Current device location	$2	Reported Term for the Tracking Event	1 = Implanted 2 = Explanted 3 = Returned 4 = Installed 5 = Retained 6 = Discarded 97 = Unknown 99 = Other
24	DTTERMO	$200	Specify current device location	$200	Reported Term for Tracking Event Specify	
25	DTSTDAT	yyyy MMM-dd-	Action taken date		Start Date of Device Tracking Event	
26	DTPARTY	$2	Party responsible for the device	$2	Party Responsible for the Device	4 = Manufacturer

(Version: ON2406 2024-08-20)

Has cancer therapy been previous/current/post withdrawn of IP?	Previous ■	2
	Post ☐	
Has the Subject had any cancer therapy?	No ☐	3
	Yes ☐	
	Not applicable ☐	
If Not applicable, specify	_____	4
Cancer therapy agent	_____	5
Cancer therapy agent start date	Fixed Unit: yyyy mon dd _____	6
Cancer therapy agent stop date	Fixed Unit: yyyy mon dd _____	7
Best overall response	Complete response ☐	8
	Partial response ☐	
	Stable disease ☐	
	Progressive disease ☐	
	Not evaluable ☐	
	Not applicable ☐	
Treatment status	Adjuvant ☐	9
	Neo-adjuvant ☐	
	Not applicable ☐	
Concomitant chemoradiotherapy **If Yes, Radiotherapy must be recorded on the Prior Radiotherapy (CAPRXR) page**	No ☐	10
	Yes ☐	
Indication	Biliary Tract Cancer ☐	11
	Other anticancer indication ☐	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Prior Cancer Therapy (CAPRX)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	CXCANCER	$2	Has cancer therapy been previous/current/post withdrawn of IP?	$2	Previous/Current/Post Withdrawal of IP	0 = Previous 2 = Post
3	CMYN	$6	Has the Subject had any cancer therapy?	$6	Any Cancer Therapy	C49487 = No C49488 = Yes C48660 = Not applicable
4	CMYNSP	$200	If Not applicable, specify	$200	Not Applicable, Specify	
5	CMCTATRT	$200	Cancer therapy agent	$200	Cancer Therapy Agent	
6	CMTSTDAT	yyyy MMM-dd-	Cancer therapy agent start date		Cancer Therapy Agent Start Date	
7	CMTENDAT	yyyy MMM-dd-	Cancer therapy agent stop date		Cancer Therapy Agent Stop Date	
8	ONCRSR	$7	Best overall response	$7	Best Overall Response	C4870 = Complete response C18058 = Partial response C18213 = Stable disease C35571 = Progressive disease C62222 = Not evaluable 98 = Not applicable
9	TREATSTS	$7	Treatment status	$7	Treatment Status	C124450 = Adjuvant C124453 = Neo-adjuvant

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						98 = Not applicable
10	CXCHERAD	$6	Concomitant chemoradiotherapy **If Yes, Radiotherapy must be recorded on the Prior Radiotherapy (CAPRXR) page**	$6	Concomitant Chemoradiotherapy	C49487 = No C49488 = Yes
11	CXINDC	$2	Indication	$200	Indication	1 = Biliary Tract Cancer 2 = Other anticancer indication

(Version: ON2505 2025-05-07)

Has cancer therapy been previous/current/post withdrawn of IP?	Previous	2
	Current (non-study intervention)	
	Post	
Was radiotherapy performed?	No	3
	Yes	

If Yes, specify below

Concomitant chemoradiotherapy	No	5
	Yes	
Treatment setting	Adjuvant	6
	Neo-Adjuvant	
	Palliative	
	Other	
If Other, specify		7
Number of sites/regions treated simultaneously		8
Radiotherapy site/region treated location	Lung - Lower Lobe	9
	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		10
Radiotherapy site/region laterality	Right	11

	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 ☐	12
If Other, specify	_____	13
Radiotherapy start date	Fixed Unit: yyyy mon dd _____	14
Radiotherapy stop date	Fixed Unit: yyyy mon dd _____	15
Dose per fraction	_____	16
Dose per fraction unit	Gy ☐ Other ☐	17
If Other, specify	_____	18
Number of fraction doses	_____	19

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Prior Radiotherapy (CAPRXR)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	CXCANCER	$2	Has cancer therapy been previous/current/post withdrawn of IP?	$2	Previous/Current/Post Withdrawal of IP	0 = Previous 4 = Current (non-study intervention) 2 = Post
3	CXRD	$6	Was radiotherapy performed?	$6	Radiotherapy	C49487 = No C49488 = Yes
5	CXCHERAD	$6	Concomitant chemoradiotherapy	$6	Concomitant Chemoradiotherapy	C49487 = No C49488 = Yes
6	TRTSET	$7	Treatment setting	$7	Treatment Setting	C124450 = Adjuvant C124453 = Neo-Adjuvant C101516 = Palliative 99 = Other
7	TRTSETO	$200	If Other, specify	$200	Treatment Setting, Other	
8	REGSIM	3	Number of sites/regions treated simultaneously	8	Sites/Regions Treated Simultaneously Num	
9	RSTRLOC	$7	Radiotherapy site/region treated location	$7	Radiotherapy Site/Region Treated Locatio	6 = Lung - Lower Lobe 7 = Lung - Middle Lobe 8 = Lung - Upper Lobe C12366 = Bone C12392 = Liver C12439 = Brain C12464 = Spinal Cord C12469 = Pleura

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						C12470 = Skin C12666 = Adrenal Gland C33287 = Pelvic Bone C49018 = Regional Lymph Node C106042 = Distant Lymph Node C12377 = Gallbladder C12678 = Biliary Tract 99 = Other
10	CXRDREGO	$200	If Other, specify	$200	Radiotherapy Site/Region Location Other	
11	CXLATEAL	$6	Radiotherapy site/region laterality	$6	Radiotherapy Site/Region Laterality	C25228 = Right C25229 = Left C13332 = Bilateral 98 = Not applicable
12	CXRATEC	$2	Radiotherapy technique	$2	Radiotherapy Technique	1 = 3-D conformal 2 = Intensity modulated radiotherapy (IMRT) 3 = Stereotactic intracranial radiotherapy 4 = Stereotactic body radiotherapy (SBRT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						5 = Stereotactic radiosurgery (SRS) 6 = Whole brain radiotherapy (WBRT) 7 = Selective Internal Radiotherapy (SIRT) 99 = Other
13	CXRATECO	$200	If Other, specify	$200	Radiotherapy Technique, Other	
14	CMCSTDAT	yyyy MMM-dd-	Radiotherapy start date		Radiotherapy Start Date	
15	CMCENDAT	yyyy MMM-dd-	Radiotherapy stop date		Radiotherapy Stop Date	
16	CMPFDOS	4.1	Dose per fraction	8	Dose per Fraction	
17	CMPFDOSU	$6	Dose per fraction unit	$6	Dose per Fraction Unit	C18063 = Gy 99 = Other
18	CMPFUO	$200	If Other, specify	$200	Dose per Fraction Unit, Other	
19	NOFRACRY	4	Number of fraction doses	8	Number of Fraction Doses	

(Version: ON2406 2024-08-20)

Has cancer therapy been previous/current/post withdrawn of IP?	Previous ☐ Post ■	2
Has the Subject had any cancer therapy?	No ☐ Yes ☐ Not applicable ☐	3
If Not applicable, specify	_____	4
If Yes, specify below		
Cancer therapy agent	_____	6
Cancer therapy agent start date	Fixed Unit: yyyy mon dd _____	7
Cancer therapy agent stop date	Fixed Unit: yyyy mon dd _____	8
Best overall response	Complete response ☐ Partial response ☐ Stable disease ☐ Progressive disease ☐ Not evaluable ☐ Not applicable ☐	9
Treatment status	First Line ☐ Second Line ☐ Third Line ☐ > Third Line ☐ Not Applicable ☐	10
Reason for therapy failure	Toxicity ☐ Progression on therapy ☐ Progression following completion of therapy ☐ Unknown ☐ Not applicable ☐	11
Concomitant chemoradiotherapy **If Yes, Radiotherapy must be recorded on the Post Treatment Radiotherapy (CAPRXR2) page**	No ☐ Yes ☐	12
Indication	Biliary Tract Cancer ☐	13

Other anticancer indication ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Subsequent Cancer Therapy (CAPRX1)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	CXCANCER	$2	Has cancer therapy been previous/current/post withdrawn of IP?	$2	Previous/Current/Post Withdrawal of IP	0 = Previous 2 = Post
3	CMYN	$6	Has the Subject had any cancer therapy?	$6	Any Cancer Therapy	C49487 = No C49488 = Yes C48660 = Not applicable
4	CMYNSP	$200	If Not applicable, specify	$200	Not Applicable, Specify	
6	CMCTATRT	$200	Cancer therapy agent	$200	Cancer Therapy Agent	
7	CMTSTDAT	yyyy MMM-dd-	Cancer therapy agent start date		Cancer Therapy Agent Start Date	
8	CMTENDAT	yyyy MMM-dd-	Cancer therapy agent stop date		Cancer Therapy Agent Stop Date	
9	ONCRSR	$7	Best overall response	$7	Best Overall Response	C4870 = Complete response C18058 = Partial response C18213 = Stable disease C35571 = Progressive disease C62222 = Not evaluable 98 = Not applicable
10	TREATSTS	$7	Treatment status	$7	Treatment Status	1 = First Line 2 = Second Line

Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
					3 = Third Line 8 = > Third Line 98 = Not Applicable
11 FAILREAS	$2	Reason for therapy failure	$2	Reason for Therapy Failure	1 = Toxicity 2 = Progression on therapy 3 = Progression following completion of therapy 97 = Unknown 98 = Not applicable
12 CXCHERAD	$6	Concomitant chemoradiotherapy **If Yes, Radiotherapy must be recorded on the Post Treatment Radiotherapy (CAPRXR2) page**	$6	Concomitant Chemoradiotherapy	C49487 = No C49488 = Yes
13 CXINDC	$2	Indication	$200	Indication	1 = Biliary Tract Cancer 2 = Other anticancer indication

(Version: ON2505 2025-05-07)

Has cancer therapy been previous/current/post withdrawn of IP?	Previous ☐	2
	Current (non-study intervention) ■	
	Post ☐	
Was radiotherapy performed?	No ☐	3
	Yes ☐	
Concomitant chemoradiotherapy	No ☐	4
	Yes ☐	
Treatment setting	Palliative ■	5
Number of sites/regions treated simultaneously	_____	6
Radiotherapy site/region treated location	Bone ☐	7
	Liver ☐	
	Brain ☐	
	Spinal Cord ☐	
	Pleura ☐	
	Skin ☐	
	Adrenal Gland ☐	
	Pelvic Bone ☐	
	Regional Lymph Node ☐	
	Distant Lymph Node ☐	
	Gallbladder ☐	
	Lung ☐	
	Biliary Tract ☐	
	Other ☐	
If Other, specify	_____	8
Radiotherapy site/region laterality	Right ☐	9
	Left ☐	
	Bilateral ☐	
	Not applicable ☐	
Radiotherapy technique	3-D Conformal ☐	10
	Intensity Modulated Radiotherapy (IMRT) ☐	
	Stereotactic Intracranial Radiotherapy ☐	

	Stereotactic Body Radiotherapy (SBRT) ☐ Stereotactic Radiosurgery (SRS) ☐ Selective Internal Radiotherapy (SIRT) ☐ Other ☐	
If Other, specify	_____	11
Radiotherapy start date	Fixed Unit: yyyy mon dd _____	12
Radiotherapy stop date	Fixed Unit: yyyy mon dd _____	13
Dose per fraction	_____	14
Dose per fraction unit	Gy ☐ Other ☐	15
If Other, specify	_____	16
Number of fraction doses	_____	17

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Palliative On-Study Radiotherapy (CAPRXR1)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	CXCANCER	$2	Has cancer therapy been previous/current/post withdrawn of IP?	$2	Previous/Current/Post Withdrawal of IP	0 = Previous 4 = Current (non-study intervention) 2 = Post
3	CXRD	$6	Was radiotherapy performed?	$6	Radiotherapy	C49487 = No C49488 = Yes
4	CXCHERAD	$6	Concomitant chemoradiotherapy	$6	Concomitant Chemoradiotherapy	C49487 = No C49488 = Yes
5	TRTSET	$7	Treatment setting	$7	Treatment Setting	C101516 = Palliative
6	REGSIM	3	Number of sites/regions treated simultaneously	8	Sites/Regions Treated Simultaneously Num	
7	RSTRLOC	$7	Radiotherapy site/region treated location	$7	Radiotherapy Site/Region Treated Locatio	C12366 = Bone C12392 = Liver C12439 = Brain C12464 = Spinal Cord C12469 = Pleura C12470 = Skin C12666 = Adrenal Gland C33287 = Pelvic Bone C49018 = Regional Lymph Node C106042 = Distant Lymph Node

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						C12377 = Gallbladder C12468 = Lung C12678 = Biliary Tract 99 = Other
8	CXRDREGO	$200	If Other, specify	$200	Radiotherapy Site/Region Location Other	
9	CXLATEAL	$6	Radiotherapy site/region laterality	$6	Radiotherapy Site/Region Laterality	C25228 = Right C25229 = Left C13332 = Bilateral 98 = Not applicable
10	CXRATEC	$2	Radiotherapy technique	$2	Radiotherapy Technique	1 = 3-D Conformal 2 = Intensity Modulated Radiotherapy (IMRT) 3 = Stereotactic Intracranial Radiotherapy 4 = Stereotactic Body Radiotherapy (SBRT) 5 = Stereotactic Radiosurgery (SRS) 7 = Selective Internal Radiotherapy (SIRT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						99 = Other
11	CXRATECO	$200	If Other, specify	$200	Radiotherapy Technique, Other	
12	CMCSTDAT	yyyy MMM-dd-	Radiotherapy start date		Radiotherapy Start Date	
13	CMCENDAT	yyyy MMM-dd-	Radiotherapy stop date		Radiotherapy Stop Date	
14	CMPFDOS	4.1	Dose per fraction	8	Dose per Fraction	
15	CMPFDOSU	$6	Dose per fraction unit	$6	Dose per Fraction Unit	C18063 = Gy 99 = Other
16	CMPFUO	$200	If Other, specify	$200	Dose per Fraction Unit, Other	
17	NOFRACRY	4	Number of fraction doses	8	Number of Fraction Doses	

(Version: ON2505 2025-05-07)

Has cancer therapy been previous/current/post withdrawn of IP?	Previous ☐	2
	Current (non-study intervention) ☐	
	Post ■	
Was radiotherapy performed?	No ☐	3
	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 ☐	7
	Yes ☐	
Treatment setting	Definitive ☐	8
	Palliative ☐	
	Other ☐	
If Other, specify	_____	9
If Definitive, specify Line of Treatment	1 ☐	10
	2 ☐	
	3 ☐	
	>3 ☐	
Number of sites/regions treated simultaneously	_____	11
Radiotherapy site/region treated location	Bone ☐	12
	Liver ☐	
	Brain ☐	
	Spinal Cord ☐	
	Pleura ☐	
	Skin ☐	
	Adrenal Gland ☐	
	Pelvic Bone ☐	
	Regional Lymph Node ☐	
	Distant Lymph Node ☐	
	Gallbladder ☐	
	Lung ☐	
	Biliary Tract ☐	
	Other ☐	

If Other, specify	_____	13
Radiotherapy site/region laterality	Right ☐ Left ☐ Bilateral ☐ Not applicable ☐	14
Radiotherapy technique	3-D Conformal ☐ Intensity Modulated Radiotherapy (IMRT) ☐ Stereotactic Intracranial Radiotherapy ☐ Stereotactic Body Radiotherapy (SBRT) ☐ Stereotactic Radiosurgery (SRS) ☐ Selective Internal Radiotherapy (SIRT) ☐ Other ☐	15
If Other, specify	_____	16
Radiotherapy start date	Fixed Unit: yyyy mon dd _____	17
Radiotherapy stop date	Fixed Unit: yyyy mon dd _____	18
Dose per fraction	_____	19
Dose per fraction unit	Gy ☐ Other ☐	20
If Other, specify	_____	21
Number of fraction doses	_____	22

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Post Treatment Radiotherapy (CAPRXR2)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	CXCANCER	$2	Has cancer therapy been previous/current/post withdrawn of IP?	$2	Previous/Current/Post Withdrawal of IP	0 = Previous 4 = Current (non-study intervention) 2 = Post
3	CXRD	$6	Was radiotherapy performed?	$6	Radiotherapy	C49487 = No C49488 = Yes
7	CXCHERAD	$6	Concomitant chemoradiotherapy	$6	Concomitant Chemoradiotherapy	C49487 = No C49488 = Yes
8	TRTSET	$7	Treatment setting	$7	Treatment Setting	5 = Definitive C101516 = Palliative 99 = Other
9	TRTSETO	$200	If Other, specify	$200	Treatment Setting, Other	
10	THLINE	$2	If Definitive, specify Line of Treatment	$2	Line of Therapy	1 = 1 2 = 2 3 = 3 11 = >3
11	REGSIM	3	Number of sites/regions treated simultaneously	8	Sites/Regions Treated Simultaneously Num	
12	RSTRLOC	$7	Radiotherapy site/region treated location	$7	Radiotherapy Site/Region Treated Locatio	C12366 = Bone C12392 = Liver C12439 = Brain C12464 = Spinal Cord C12469 = Pleura C12470 = Skin C12666 = Adrenal Gland C33287 = Pelvic Bone

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						C49018 = Regional Lymph Node C106042 = Distant Lymph Node C12377 = Gallbladder C12468 = Lung C12678 = Biliary Tract 99 = Other
13	CXRDREGO	$200	If Other, specify	$200	Radiotherapy Site/Region Location Other	
14	CXLATEAL	$6	Radiotherapy site/region laterality	$6	Radiotherapy Site/Region Laterality	C25228 = Right C25229 = Left C13332 = Bilateral 98 = Not applicable
15	CXRATEC	$2	Radiotherapy technique	$2	Radiotherapy Technique	1 = 3-D Conformal 2 = Intensity Modulated Radiotherapy (IMRT) 3 = Stereotactic Intracranial Radiotherapy 4 = Stereotactic Body Radiotherapy (SBRT) 5 = Stereotactic Radiosurgery (SRS)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						7 = Selective Internal Radiotherapy (SIRT) 99 = Other
16	CXRATECO	$200	If Other, specify	$200	Radiotherapy Technique, Other	
17	CMCSTDAT	yyyy MMM-dd-	Radiotherapy start date		Radiotherapy Start Date	
18	CMCENDAT	yyyy MMM-dd-	Radiotherapy stop date		Radiotherapy Stop Date	
19	CMPFDOS	4.1	Dose per fraction	8	Dose per Fraction	
20	CMPFDOSU	$6	Dose per fraction unit	$6	Dose per Fraction Unit	C18063 = Gy 99 = Other
21	CMPFUO	$200	If Other, specify	$200	Dose per Fraction Unit, Other	
22	NOFRACRY	4	Number of fraction doses	8	Number of Fraction Doses	

(Version: AZ2411 2024-11-08)

What is the category of the liver event?	POTENTIAL HY'S LAW (2)
What is the subcategory of the liver event?	DIAGNOSTIC INVESTIGATION (3)
What is the potential Hy's law case number?	(4)
AE number	(5)
Now Derivation(This field required for CF approach)	(11)
[Hidden Dummy] Previous Potential Hy's law case number	(12)

Liver diagnostic investigation

- [x] Ultrasound (6)
- [ ] 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 ☐	7
	Yes ☐	
Liver diagnostic investigation specification	_____	8
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd _____	9
Liver diagnostic investigation results	_____	10
Liver diagnostic investigation	Ultrasound ☐	6
	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 ☐ 7
	Yes ☐
Liver diagnostic investigation specification	8
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd 9
Liver diagnostic investigation results	10
Liver diagnostic investigation	Ultrasound ☐ 6
	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 ☐	7
	Yes ☐	
Liver diagnostic investigation specification	_____	8
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd _____	9
Liver diagnostic investigation results	_____	10
Liver diagnostic investigation	Ultrasound ☐	6
	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 ☐	7
	Yes ☐	
Liver diagnostic investigation specification		8
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd	9
Liver diagnostic investigation results		10
Liver diagnostic investigation	Ultrasound ☐	6
	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 ☐ (7)
	Yes ☐
Liver diagnostic investigation specification	(8)
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd (9)
Liver diagnostic investigation results	(10)
Liver diagnostic investigation	Ultrasound ☐ (6)
	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	☐ 7
	Yes	☐
Liver diagnostic investigation specification		8
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd	9
Liver diagnostic investigation results		10
Liver diagnostic investigation	Ultrasound	☐ 6
	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 ☐	7
	Yes ☐	
Liver diagnostic investigation specification	_____	8
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd _____	9
Liver diagnostic investigation results	_____	10
Liver diagnostic investigation	Ultrasound ☐	6
	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	☐ 7
	Yes	☐
Liver diagnostic investigation specification		8
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd	9
Liver diagnostic investigation results		10
Liver diagnostic investigation	Ultrasound	☐ 6
	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	☐ (7)
	Yes	☐
Liver diagnostic investigation specification		(8)
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd	(9)
Liver diagnostic investigation results		(10)
Liver diagnostic investigation	Ultrasound	☐ (6)
	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	7
	Yes	
Liver diagnostic investigation specification		8
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd	9
Liver diagnostic investigation results		10
Liver diagnostic investigation	Ultrasound	6
	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 ☐ 7
	Yes ☐
Liver diagnostic investigation specification	_____ 8
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd 9
Liver diagnostic investigation results	_____ 10
Liver diagnostic investigation	Ultrasound ☐ 6
	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 ☐ (7)
	Yes ☐
Liver diagnostic investigation specification	_____ (8)
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd (9)
Liver diagnostic investigation results	_____ (10)
Liver diagnostic investigation	Ultrasound ☐ (6)
	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	☐ 7
	Yes	☐
Liver diagnostic investigation specification		8
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd	9
Liver diagnostic investigation results		10
Liver diagnostic investigation	Ultrasound	☐ 6
	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 ☐	7
	Yes ☐	
Liver diagnostic investigation specification		8
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd	9
Liver diagnostic investigation results		10
Liver diagnostic investigation	Ultrasound ☐	6

	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 ☐ (7)
	Yes ☐
Liver diagnostic investigation specification	_____ (8)
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd (9)
	_____

Liver diagnostic investigation results 10

Liver diagnostic investigation 6
- 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 7
- No
- Yes

Liver diagnostic investigation specification 8

Liver diagnostic investigation date	Fixed Unit: yyyy mon dd (9)
Liver diagnostic investigation results	(10)
Liver diagnostic investigation	Ultrasound ☐ (6)
	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 ☐ (7)

	Yes ☐
Liver diagnostic investigation specification	_____ 8
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd _____ 9
Liver diagnostic investigation results	_____ 10
Liver diagnostic investigation	Ultrasound ☐ 6
	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 ☐	7
Liver diagnostic investigation specification		8
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd	9
Liver diagnostic investigation results		10
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 ☐	6

	Other 4 ☐ Other 5 ☐ Other 6 ☐	
Examination(s) performed	No ☐ Yes ☐	7
Liver diagnostic investigation specification	_____	8
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd _____	9
Liver diagnostic investigation results	_____	10
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 ☐	6

	Other 2 ☐
	Other 3 ☐
	Other 4 ☐
	Other 5 ☐
	Other 6 ☐
Examination(s) performed	No ☐ (7)
	Yes ☐
Liver diagnostic investigation specification	_____ (8)
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd (9)
	_____
Liver diagnostic investigation results	_____ (10)
Liver diagnostic investigation	Ultrasound ☐ (6)
	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 ☐ 7
	Yes ☐
Liver diagnostic investigation specification	_____ 8
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd 9
	_____
Liver diagnostic investigation results	_____ 10
Liver diagnostic investigation	Ultrasound ☐ 6
	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	☐ 7
	Yes	☐
Liver diagnostic investigation specification		8
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd	9
Liver diagnostic investigation results		10
Liver diagnostic investigation	Ultrasound	☐ 6
	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 ☐ (7)
	Yes ☐
Liver diagnostic investigation specification	_____ (8)
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd (9)
Liver diagnostic investigation results	_____ (10)
Liver diagnostic investigation	Ultrasound ☐ (6)
	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	☐ 7
	Yes	☐
Liver diagnostic investigation specification		8
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd	9
Liver diagnostic investigation results		10
Liver diagnostic investigation	Ultrasound	☐ 6
	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	☐ 7
	Yes	☐
Liver diagnostic investigation specification		8
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd	9
Liver diagnostic investigation results		10
Liver diagnostic investigation	Ultrasound	☐ 6
	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 ☐ 7
	Yes ☐
Liver diagnostic investigation specification	_____ 8
Liver diagnostic investigation date	Fixed Unit: yyyy mon dd 9
	_____
Liver diagnostic investigation results	_____ 10

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Liver Diagnostic Investigations (LIVERDI)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	FACAT	$2	What is the category of the liver event?	$2	Category for Findings About	1 = POTENTIAL HY'S LAW
3	FASCAT	$2	What is the subcategory of the liver event?	$2	Subcategory for Findings About	1 = DIAGNOSTIC INVESTIGATION
4	FACSPID	2	What is the potential Hy's law case number?	8	Potential Hy's Law Case Number	
5	AENO	3	AE number	8	AE Number	
6	FACMETHD	$7	Liver diagnostic investigation	$7	Liver Diagnostic Investigation	C17230 = Ultrasound C17204 = CT scan C16809 = MRI C113775 = Magnetic resonance cholangiopancreatography C16430 = Endoscopic retrograde cholangiopancreatography C15189 = Biopsy C38101 = X-ray 7 = Tox screening for acetaminophen/paracetamol 8 = Tox screening for ethanol 9 = Tox screening, other

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						10 = Specialist (e.g. hepatologist) consulted 11 = Serology for hepatitis A 12 = Serology for hepatitis B 13 = Serology for hepatitis C 14 = Serology for hepatitis D 15 = Serology for hepatitis E 16 = Serology for cytomegalovirus (CMV) 17 = Serology for Epstein Barr Virus (EBV) 19 = Serology for Herpes Simplex Virus (HSV) 18 = Autoimmune serology 51 = Other 1 52 = Other 2 53 = Other 3 54 = Other 4 55 = Other 5 56 = Other 6
7	FAPERF	$6	Examination(s) performed	$6	Findings About Performed	C49487 = No C49488 = Yes
8	LIVDSPEC	$150	Liver diagnostic investigation specification	$150	Liver Diagnostic Invest. Specification	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Liver Diagnostic Investigations (LIVERDI)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
9	FACDAT	yyyy MMM dd-	Liver diagnostic investigation date		Liver Diagnostic Investigation Date	
10	LIVDIRES	$200	Liver diagnostic investigation results	$200	Liver Diagnostic Investigation Results	
11	Z_LIVERDINOW	yyyy MMM dd hh:nn:ss	Now Derivation(This field required for CF approach)			
12	Z_LIVCASE	$2	[Hidden Dummy] Previous Potential Hy's law case number			

(Version: AZ2411 2024-11-06)

What is the assessment date?	Fixed Unit: yyyy mon dd (2)
What is the Potential Hy's Law case number?	(3)
AE number	(4)
Now Derivation(This field required for CF approach)	(12)
[Hidden Dummy] Previous Potential Hy's law case number	(13)

Liver risk factor (5)

- [ ] 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 ☐	6
	Yes ☐	
Liver risk factor reference period (in reference to assessment date)	Before ☐	7
	Ongoing ☐	
Liver risk factor details	_____	8
Liver risk factor start date	Fixed Unit: yyyy mon dd _____	9
Liver risk factor stop date	Fixed Unit: yyyy mon dd _____	10
Liver risk factor comment	_____	11
Liver risk factor	Alcohol abuse ☐	5
	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	☐ 6
	Yes	☐
Liver risk factor reference period (in reference to assessment date)	Before	☐ 7
	Ongoing	☐
Liver risk factor details		8
Liver risk factor start date	Fixed Unit: yyyy mon dd	9
Liver risk factor stop date	Fixed Unit: yyyy mon dd	10
Liver risk factor comment		11
Liver risk factor	Alcohol abuse	☐ 5
	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 ☐	6
	Yes ☐	
Liver risk factor reference period (in reference to assessment date)	Before ☐	7
	Ongoing ☐	
Liver risk factor details	_____	8
Liver risk factor start date	Fixed Unit: yyyy mon dd _____	9
Liver risk factor stop date	Fixed Unit: yyyy mon dd _____	10
Liver risk factor comment	_____	11
Liver risk factor	Alcohol abuse ☐	5
	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 ☐ (6)
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐ (7)
	Ongoing ☐
Liver risk factor details	_____ (8)
Liver risk factor start date	Fixed Unit: yyyy mon dd (9)
	_____
Liver risk factor stop date	Fixed Unit: yyyy mon dd (10)
	_____
Liver risk factor comment	_____ (11)
Liver risk factor	Alcohol abuse ☐ (5)

	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 ☐ 6
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐ 7
	Ongoing ☐
Liver risk factor details	_____ 8

Liver risk factor start date — Fixed Unit: yyyy mon dd (9)

Liver risk factor stop date — Fixed Unit: yyyy mon dd (10)

Liver risk factor comment (11)

Liver risk factor (5)

- [ ] 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 ☐ 6
- Yes ☐

Liver risk factor reference period (in reference to assessment date)
- Before ☐ 7
- Ongoing ☐

Liver risk factor details _____ 8

Liver risk factor start date Fixed Unit: yyyy mon dd 9

_____

Liver risk factor stop date Fixed Unit: yyyy mon dd 10

_____

Liver risk factor comment _____ 11

Liver risk factor
- Alcohol abuse ☐ 5
- 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 ☐ 6
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐ 7
	Ongoing ☐
Liver risk factor details	_____ 8
Liver risk factor start date	Fixed Unit: yyyy mon dd 9
	_____
Liver risk factor stop date	Fixed Unit: yyyy mon dd 10
	_____
Liver risk factor comment	_____ 11
Liver risk factor	Alcohol abuse ☐ 5
	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	☐ 6
	Yes	☐
Liver risk factor reference period (in reference to assessment date)	Before	☐ 7
	Ongoing	☐
Liver risk factor details		8
Liver risk factor start date	Fixed Unit: yyyy mon dd	9
Liver risk factor stop date	Fixed Unit: yyyy mon dd	10
Liver risk factor comment		11
Liver risk factor	Alcohol abuse	☐ 5
	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 ☐	6
Liver risk factor reference period (in reference to assessment date)	Before ☐ Ongoing ☐	7
Liver risk factor details		8
Liver risk factor start date	Fixed Unit: yyyy mon dd	9
Liver risk factor stop date	Fixed Unit: yyyy mon dd	10
Liver risk factor comment		11
Liver risk factor	Alcohol abuse ☐ Increased alcohol consumption in the 4 weeks prior to reported event ☐ IV drug abuse ☐ Tattoo ☐ Acupuncture ☐	5

	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 ☐ (6)
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐ (7)
	Ongoing ☐
Liver risk factor details	(8)
Liver risk factor start date	Fixed Unit: yyyy mon dd (9)
Liver risk factor stop date	Fixed Unit: yyyy mon dd (10)
Liver risk factor comment	(11)

Liver risk factor	Alcohol abuse	5
	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	6
	Yes	
Liver risk factor reference period (in reference to assessment date)	Before	7
	Ongoing	
Liver risk factor details	_____	8

Liver risk factor start date — Fixed Unit: yyyy mon dd (9)

Liver risk factor stop date — Fixed Unit: yyyy mon dd (10)

Liver risk factor comment (11)

Liver risk factor (5)

- [ ] 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
- [x] 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 ☐ 6
Yes ☐

Liver risk factor reference period (in reference to assessment date)
Before ☐ 7
Ongoing ☐

Liver risk factor details
_____ 8

Liver risk factor start date
Fixed Unit: yyyy mon dd 9
_____

Liver risk factor stop date
Fixed Unit: yyyy mon dd 10
_____

Liver risk factor comment
_____ 11

Liver risk factor
Alcohol abuse ☐ 5
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 ☐	6
Liver risk factor reference period (in reference to assessment date)	Before ☐ Ongoing ☐	7
Liver risk factor details	_____	8
Liver risk factor start date	Fixed Unit: yyyy mon dd _____	9
Liver risk factor stop date	Fixed Unit: yyyy mon dd _____	10
Liver risk factor comment	_____	11
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 ■	5

	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 ☐	6
	Yes ☐	
Liver risk factor reference period (in reference to assessment date)	Before ☐	7
	Ongoing ☐	
Liver risk factor details	_____	8
Liver risk factor start date	Fixed Unit: yyyy mon dd _____	9
Liver risk factor stop date	Fixed Unit: yyyy mon dd _____	10
Liver risk factor comment	_____	11
Liver risk factor	Alcohol abuse ☐	5
	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 ☐	6
Liver risk factor reference period (in reference to assessment date)	Before ☐ Ongoing ☐	7
Liver risk factor details		8
Liver risk factor start date	Fixed Unit: yyyy mon dd	9
Liver risk factor stop date	Fixed Unit: yyyy mon dd	10
Liver risk factor comment		11
Liver risk factor	Alcohol abuse ☐ Increased alcohol consumption in the 4 weeks prior to reported event ☐ IV drug abuse ☐ Tattoo ☐ Acupuncture ☐	5

	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 ☐ (6)
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐ (7)
	Ongoing ☐
Liver risk factor details	(8)
Liver risk factor start date	Fixed Unit: yyyy mon dd (9)
Liver risk factor stop date	Fixed Unit: yyyy mon dd (10)
Liver risk factor comment	(11)

Liver risk factor	Alcohol abuse	5
	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	6
	Yes	
Liver risk factor reference period (in reference to assessment date)	Before	7
	Ongoing	
Liver risk factor details	_____	8

Liver risk factor start date — Fixed Unit: yyyy mon dd (9)

Liver risk factor stop date — Fixed Unit: yyyy mon dd (10)

Liver risk factor comment (11)

Liver risk factor (5)

- 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 ☐ 6
- Yes ☐

Liver risk factor reference period (in reference to assessment date)
- Before ☐ 7
- Ongoing ☐

Liver risk factor details _____ 8

Liver risk factor start date — Fixed Unit: yyyy mon dd _____ 9

Liver risk factor stop date — Fixed Unit: yyyy mon dd _____ 10

Liver risk factor comment _____ 11

Liver risk factor
- Alcohol abuse ☐ 5
- 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 ☐	6
	Yes ☐	
Liver risk factor reference period (in reference to assessment date)	Before ☐	7
	Ongoing ☐	
Liver risk factor details	_____	8
Liver risk factor start date	Fixed Unit: yyyy mon dd _____	9
Liver risk factor stop date	Fixed Unit: yyyy mon dd _____	10
Liver risk factor comment	_____	11
Liver risk factor	Alcohol abuse ☐	5
	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	☐ 6
	Yes	☐
Liver risk factor reference period (in reference to assessment date)	Before	☐ 7
	Ongoing	☐
Liver risk factor details		8
Liver risk factor start date	Fixed Unit: yyyy mon dd	9
Liver risk factor stop date	Fixed Unit: yyyy mon dd	10
Liver risk factor comment		11
Liver risk factor	Alcohol abuse	☐ 5
	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 ☐	6
Liver risk factor reference period (in reference to assessment date)	Before ☐ Ongoing ☐	7
Liver risk factor details	_____	8
Liver risk factor start date	Fixed Unit: yyyy mon dd _____	9
Liver risk factor stop date	Fixed Unit: yyyy mon dd _____	10
Liver risk factor comment	_____	11
Liver risk factor	Alcohol abuse ☐ Increased alcohol consumption in the 4 weeks prior to reported event ☐ IV drug abuse ☐ Tattoo ☐ Acupuncture ☐	5

	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 ☐ (6)
	Yes ☐
Liver risk factor reference period (in reference to assessment date)	Before ☐ (7)
	Ongoing ☐
Liver risk factor details	(8)
Liver risk factor start date	Fixed Unit: yyyy mon dd (9)
Liver risk factor stop date	Fixed Unit: yyyy mon dd (10)
Liver risk factor comment	(11)

Liver risk factor	Alcohol abuse ☐	5
	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 ☐	6
	Yes ☐	
Liver risk factor reference period (in reference to assessment date)	Before ☐	7
	Ongoing ☐	
Liver risk factor details	_____	8

Liver risk factor start date — Fixed Unit: yyyy mon dd (9)

Liver risk factor stop date — Fixed Unit: yyyy mon dd (10)

Liver risk factor comment (11)

Liver risk factor (5)

- ☐ 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 ☐	6
Liver risk factor reference period (in reference to assessment date)	Before ☐ Ongoing ☐	7
Liver risk factor details	_____	8
Liver risk factor start date	Fixed Unit: yyyy mon dd _____	9
Liver risk factor stop date	Fixed Unit: yyyy mon dd _____	10
Liver risk factor comment	_____	11

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Liver Risk Factors/Life Style Events (LIVERRF)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	LIVDAT	yyyy MMM dd	What is the assessment date?		Assessment Date	
3	MHCSPID	2	What is the Potential Hy's Law case number?	8	Potential Hy's Law Case Number	
4	AENO	3	AE number	8	AE Number	
5	LIVRF	$2	Liver risk factor	$2	Liver Risk Factor	1 = Alcohol abuse 2 = Increased alcohol consumption in the 4 weeks prior to reported event 3 = IV drug abuse 4 = Tattoo 5 = Acupuncture 6 = Sexually transmitted diseases 7 = Toxic/Chemical agent exposure 8 = Travel (areas at risk in the last year) 9 = Pregnancy 10 = Parenteral nutrition 11 = Excessive physical exercise 12 = Changes diet/fasting episodes/weight loss diet

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						13 = Previous drug reaction (associated with an elevation of liver tests) 14 = Blood transfusion 15 = Patient exposed to anyone with jaundice in the 4 weeks 16 = History of hypotension 17 = Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value 18 = History of liver disease 51 = Other 1 52 = Other 2 53 = Other 3 54 = Other 4 55 = Other 5 56 = Other 6
6	LIVRFOCC	$6	Liver risk factor occurrence	$6	Liver Risk Factor Occurrence	C49487 = No C49488 = Yes
7	LIVREFP	$6	Liver risk factor reference period (in reference to assessment date)	$6	Liver Risk Factor Reference Period	C25629 = Before C53279 = Ongoing
8	LIVRSPEC	$200	Liver risk factor details	$200	Liver Risk Factor Details	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Liver Risk Factors/Life Style Events (LIVERRF)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
9	LIVRSDAT	yyyy MMM-dd-	Liver risk factor start date		Liver Risk Factor Start Date	
10	LIVREDAT	yyyy MMM-dd-	Liver risk factor stop date		Liver Risk Factor Stop Date	
11	LVRCOM1	$1999	Liver risk factor comment	$1999	Liver Risk Factor Comment	
12	Z_LIVERRFNOW	yyyy MMM dd hh:nn:ss	Now Derivation(This field required for CF approach)			
13	Z_LIVCASE	$2	[Hidden Dummy] Previous Potential Hy's law case number			

(Version: AZ2411 2024-11-08)

What is the category of the clinical event?	POTENTIAL HY'S LAW (2)
AE number	(3)
What is the Potential Hy's Law case number?	(4)
Now Derivation(This field required for CF approach)	(13)
[Hidden Dummy] Previous Potential Hy's law case number	(14)

Sign or symptom	Anorexia (5)
	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 (6)
	Yes

Start date	Fixed Unit: yyyy mon dd (7)
Ongoing	Yes ☐ (8)
Stop date	Fixed Unit: yyyy mon dd (9)
Intermittent	No ☐ (10) Yes ☐
Liver sign/symptom specification	(11)
Liver sign/symptom text	(12)
Sign or symptom	Anorexia ☐ (5) 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 ☐ 6
- Yes ☐

Start date — Fixed Unit: yyyy mon dd 7

Ongoing — Yes ☐ 8

Stop date — Fixed Unit: yyyy mon dd 9

Intermittent
- No ☐ 10
- Yes ☐

Liver sign/symptom specification 11

Liver sign/symptom text 12

Sign or symptom 5
- 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 ☐ 6
	Yes ☐
Start date	Fixed Unit: yyyy mon dd 7
Ongoing	Yes ☐ 8
Stop date	Fixed Unit: yyyy mon dd 9
Intermittent	No ☐ 10
	Yes ☐
Liver sign/symptom specification	11
Liver sign/symptom text	12
Sign or symptom	Anorexia ☐ 5
	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 ☐ 6
	Yes ☐
Start date	Fixed Unit: yyyy mon dd 7
Ongoing	Yes ☐ 8
Stop date	Fixed Unit: yyyy mon dd 9
Intermittent	No ☐ 10
	Yes ☐
Liver sign/symptom specification	11
Liver sign/symptom text	12
Sign or symptom	Anorexia ☐ 5
	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	6
	Yes	
Start date	Fixed Unit: yyyy mon dd	7
Ongoing	Yes	8
Stop date	Fixed Unit: yyyy mon dd	9
Intermittent	No	10
	Yes	
Liver sign/symptom specification		11
Liver sign/symptom text		12
Sign or symptom	Anorexia	5
	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	6
	Yes	
Start date	Fixed Unit: yyyy mon dd	7
Ongoing	Yes	8
Stop date	Fixed Unit: yyyy mon dd	9
Intermittent	No	10
	Yes	
Liver sign/symptom specification		11
Liver sign/symptom text		12
Sign or symptom	Anorexia	5
	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 ☐	6
	Yes ☐	
Start date	Fixed Unit: yyyy mon dd	7
Ongoing	Yes ☐	8
Stop date	Fixed Unit: yyyy mon dd	9
Intermittent	No ☐	10
	Yes ☐	
Liver sign/symptom specification		11
Liver sign/symptom text		12
Sign or symptom	Anorexia ☐	5
	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	6
	Yes	
Start date	Fixed Unit: yyyy mon dd	7
Ongoing	Yes	8
Stop date	Fixed Unit: yyyy mon dd	9
Intermittent	No	10
	Yes	
Liver sign/symptom specification		11
Liver sign/symptom text		12
Sign or symptom	Anorexia	5
	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 ☐ (6)
	Yes ☐
Start date	Fixed Unit: yyyy mon dd (7)
	_____
Ongoing	Yes ☐ (8)
Stop date	Fixed Unit: yyyy mon dd (9)
	_____
Intermittent	No ☐ (10)
	Yes ☐
Liver sign/symptom specification	_____ (11)
Liver sign/symptom text	_____ (12)
Sign or symptom	Anorexia ☐ (5)

	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 ☐ (6)
	Yes ☐
Start date	Fixed Unit: yyyy mon dd (7)
	_____
Ongoing	Yes ☐ (8)
Stop date	Fixed Unit: yyyy mon dd (9)
	_____
Intermittent	No ☐ (10)
	Yes ☐

Liver sign/symptom specification		11
Liver sign/symptom text		12
Sign or symptom	Anorexia ☐	5
	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 ☐	6
	Yes ☐	
Start date	Fixed Unit: yyyy mon dd	7
Ongoing	Yes ☐	8
Stop date	Fixed Unit: yyyy mon dd	9

Intermittent
- No ☐ 10
- Yes ☐

Liver sign/symptom specification _____ 11

Liver sign/symptom text _____ 12

Sign or symptom
- Anorexia ☐ 5
- 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 ☐ 6
- Yes ☐

Start date — Fixed Unit: yyyy mon dd 7

_____

Ongoing	Yes ☐ 8
Stop date	Fixed Unit: yyyy mon dd 9
Intermittent	No ☐ 10 Yes ☐
Liver sign/symptom specification	11
Liver sign/symptom text	12
Sign or symptom	Anorexia ☐ 5 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 ☐ 6

	Yes ☐
Start date	Fixed Unit: yyyy mon dd 7
Ongoing	Yes ☐ 8
Stop date	Fixed Unit: yyyy mon dd 9
Intermittent	No ☐ 10
	Yes ☐
Liver sign/symptom specification	11
Liver sign/symptom text	12
Sign or symptom	Anorexia ☐ 5
	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	6
	Yes	
Start date	Fixed Unit: yyyy mon dd	7
Ongoing	Yes	8
Stop date	Fixed Unit: yyyy mon dd	9
Intermittent	No	10
	Yes	
Liver sign/symptom specification		11
Liver sign/symptom text		12
Sign or symptom	Anorexia	5
	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 ☐ 6
	Yes ☐
Start date	Fixed Unit: yyyy mon dd 7
Ongoing	Yes ☐ 8
Stop date	Fixed Unit: yyyy mon dd 9
Intermittent	No ☐ 10
	Yes ☐
Liver sign/symptom specification	11
Liver sign/symptom text	12
Sign or symptom	Anorexia ☐ 5
	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 ☐	6
	Yes ☐	
Start date	Fixed Unit: yyyy mon dd	7
Ongoing	Yes ☐	8
Stop date	Fixed Unit: yyyy mon dd	9
Intermittent	No ☐	10
	Yes ☐	
Liver sign/symptom specification		11
Liver sign/symptom text		12
Sign or symptom	Anorexia ☐	5
	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 ☐	6
	Yes ☐	
Start date	Fixed Unit: yyyy mon dd _____	7
Ongoing	Yes ☐	8
Stop date	Fixed Unit: yyyy mon dd _____	9
Intermittent	No ☐	10
	Yes ☐	
Liver sign/symptom specification	_____	11
Liver sign/symptom text	_____	12
Sign or symptom	Anorexia ☐	5
	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 ☐ 6
	Yes ☐
Start date	Fixed Unit: yyyy mon dd 7
Ongoing	Yes ☐ 8
Stop date	Fixed Unit: yyyy mon dd 9
Intermittent	No ☐ 10
	Yes ☐
Liver sign/symptom specification	11
Liver sign/symptom text	12
Sign or symptom	Anorexia ☐ 5
	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	6
	Yes	
Start date	Fixed Unit: yyyy mon dd	7
Ongoing	Yes	8
Stop date	Fixed Unit: yyyy mon dd	9
Intermittent	No	10
	Yes	
Liver sign/symptom specification		11
Liver sign/symptom text		12
Sign or symptom	Anorexia	5
	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 ☐ 6
	Yes ☐
Start date	Fixed Unit: yyyy mon dd 7
Ongoing	Yes ☐ 8
Stop date	Fixed Unit: yyyy mon dd 9
Intermittent	No ☐ 10
	Yes ☐
Liver sign/symptom specification	11
Liver sign/symptom text	12
Sign or symptom	Anorexia ☐ 5
	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 ☐ (6)
	Yes ☐
Start date	Fixed Unit: yyyy mon dd (7)
	_____
Ongoing	Yes ☐ (8)
Stop date	Fixed Unit: yyyy mon dd (9)
	_____
Intermittent	No ☐ (10)
	Yes ☐
Liver sign/symptom specification	_____ (11)

Liver sign/symptom text	12
Sign or symptom	5
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	6
No	☐
Yes	☐
Start date	7
Fixed Unit: yyyy mon dd	
Ongoing	8
Yes	☐
Stop date	9
Fixed Unit: yyyy mon dd	

Intermittent
- No ☐ 10
- Yes ☐

Liver sign/symptom specification _____ 11

Liver sign/symptom text _____ 12

Sign or symptom 5
- 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 ☐ 6
- Yes ☐

Start date — Fixed Unit: yyyy mon dd 7

_____

Ongoing	Yes ☐ 8
Stop date	Fixed Unit: yyyy mon dd 9
Intermittent	No ☐ 10 Yes ☐
Liver sign/symptom specification	11
Liver sign/symptom text	12
Sign or symptom	Anorexia ☐ 5 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 ☐ 6

	Yes ☐
Start date	Fixed Unit: yyyy mon dd 7
Ongoing	Yes ☐ 8
Stop date	Fixed Unit: yyyy mon dd 9
Intermittent	No ☐ 10
	Yes ☐
Liver sign/symptom specification	11
Liver sign/symptom text	12
Sign or symptom	Anorexia ☐ 5
	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 ☐	6
Start date	Fixed Unit: yyyy mon dd _____	7
Ongoing	Yes ☐	8
Stop date	Fixed Unit: yyyy mon dd _____	9
Intermittent	No ☐ Yes ☐	10
Liver sign/symptom specification	_____	11
Liver sign/symptom text	_____	12

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Liver Signs and Symptoms (LIVERSS)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	CECAT	$2	What is the category of the clinical event?	$2	Category for Clinical Events	1 = POTENTIAL HY'S LAW
3	AENO	3	AE number	8	AE Number	
4	CECSPID	2	What is the Potential Hy's Law case number?	8	Potential Hy's Law Case Number	
5	CECTERM	$2	Sign or symptom	$2	Liver Sign/Symptom	1 = Anorexia 2 = Asthenia 3 = Pyrexia 4 = Pruritus 5 = Jaundice 6 = Arthralgia 7 = Abdominal pain 8 = Abdominal tenderness 9 = Nausea 10 = Vomiting 11 = Rash 12 = Mucosal inflammation 13 = Purpura 14 = Hepatomegaly 15 = Splenomegaly 16 = Lymphadenopathy 17 = Ascites 18 = Confusional state 19 = Coma 20 = Upper quadrant tenderness 21 = Biliary obstruction

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						22 = Eosinophilia 23 = Dark urine 51 = Other 1 52 = Other 2
6	CEOCCUR	$6	Sign or symptom occurrence	$6	Clinical Event Occurrence	C49487 = No C49488 = Yes
7	CESTDAT	yyyy MMM dd-	Start date		Clinical Event Start Date	
8	CEONGO	$6	Ongoing	$6	Ongoing Clinical Event	C49488 = Yes
9	CEENDAT	yyyy MMM dd-	Stop date		Clinical Event End Date	
10	CECPATT	$6	Intermittent	$6	Intermittent	C49487 = No C49488 = Yes
11	CETERMO	$175	Liver sign/symptom specification	$175	Liver Sign/Symptom Specification	
12	LIVSSTXT	$200	Liver sign/symptom text	$200	Liver Sign/Symptom Text	
13	Z_LIVERSSNOW	yyyy MMM dd hh:nn:ss	Now Derivation(This field required for CF approach)			
14	Z_LIVCASE	$2	[Hidden Dummy] Previous Potential Hy's law case number			

(Version: AZ2006 2023-07-27)

IMP and/or suspect device associated with Medication Error	IMP ☐	2
Date of medication error	Fixed Unit: yyyy mon dd	3
Medication error occurrence	Actual error ☐	4
	Intercepted error ☐	
	Potential error ☐	
Stage of error occur (storage)	No ☐	5
	Yes ☐	
Stage of error occur (dispensing)	No ☐	6
	Yes ☐	
Stage of error occur (preparation for administration)	No ☐	7
	Yes ☐	
Stage of error occur (administration)	No ☐	8
	Yes ☐	
AE on medication error	Medication error without any associated AE ☐	9
	Medication error with non-serious AE ☐	
	Medication error with SAE ☐	
AE number		10
AE number		11
Adverse Event		12
Error associated to product defect	No ☐	13
	Yes ☐	
Error associated to product defect, specify		14
Description of error occurrence, action taken		15
Description of potential error and possible harm		16
Derived field to call CF		17
[Hidden Dummy] Used for email alert		18

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Medication Error Report (MER)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	MEDEV	$2	IMP and/or suspect device associated with Medication Error	$2	IMP and or Susp Dev Assoc with ME	1 = IMP
3	FACMDAT	yyyy MMM dd	Date of medication error		Date of Medication Error	
4	MEOCCUR	$2	Medication error occurrence	$2	Medication Error Occurrence	1 = Actual error 2 = Intercepted error 3 = Potential error
5	SEOSTOR	$6	Stage of error occur (storage)	$6	Stage of Error Occur (Storage)	C49487 = No C49488 = Yes
6	SEODISP	$6	Stage of error occur (dispensing)	$6	Stage of Error Occur (Dispensing)	C49487 = No C49488 = Yes
7	SEOPADM	$6	Stage of error occur (preparation for administration)	$6	Stage of Error Occur (Prep for Admin)	C49487 = No C49488 = Yes
8	SEOADM	$6	Stage of error occur (administration)	$6	Stage of Error Occur (Administration)	C49487 = No C49488 = Yes
9	MEAE	$2	AE on medication error	$2	AE on Medication Error	1 = Medication error without any associated AE 2 = Medication error with non-serious AE

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Medication Error Report (MER)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						3 = Medication error with SAE
10	Z_AENO	$70	AE number			
11	AENO	3	AE number	8	AE Number	
12	AETERM	$200	Adverse Event	$200	Adverse Event	
13	MEDEF	$6	Error associated to product defect	$6	Error Associated to Product Defect	C49487 = No C49488 = Yes
14	DEFSPEC	$200	Error associated to product defect, specify	$200	Error Assoc. to Product Defect, Specify	
15	DESCAT	$200	Description of error occurrence, action taken	$200	Desc of Error Occurrence, Action Taken	
16	DESCPE	$200	Description of potential error and possible harm	$200	Desc of Potent Error and Possible Harm	
17	Z_TIME	dd MMM yyyy hh:nn:ss	Derived field to call CF			
18	Z_MEDEV	$2	[Hidden Dummy] Used for email alert			

(Version: AZ2311 2023-11-22)

Study drug	Rilvegostomig ☐	2
	Durvalumab ☐	
	Gemcitabine ☐	
	Cisplatin ☐	
Route	Intravenous ■	3
Total dose		4
Unit	mg ☐	5
	mg/m2 ☐	
Date overdose started	Fixed Unit: yyyy mon dd	6
Date overdose stopped	Fixed Unit: yyyy mon dd	7
Intentional overdose	No ☐	8
	Yes ☐	
Overdose associated with AE	No ☐	9
	Yes ☐	
AE number associated with overdose		10
AE number associated with overdose		11
CRF text for AE associated with overdose		12
CRF text for AE associated with overdose		13
Further information (for non SAE)		14
Hidden Trade name Field		15
Hidden Number for AE Field		16

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Overdose Report (OVERDOSE)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	ECTRT	$200	Study drug	$200	Treatment Name	1 = Rilvegostomig 2 = Durvalumab 3 = Gemcitabine 4 = Cisplatin
3	ECROUTE	$6	Route	$6	Exposure Route of Administration	C38276 = Intravenous
4	ODTDOS	5.1	Total dose	8	Total Dose	
5	ECDOSU	$7	Unit	$7	Exposure Dose Unit	C28253 = mg C67402 = mg/m2
6	ECOSTDAT	yyyy MMM dd	Date overdose started		Overdose Start Date	
7	ECOENDAT	yyyy MMM dd	Date overdose stopped		Overdose Stop Date	
8	ODINTENT	$6	Intentional overdose	$6	Intentional Overdose	C49487 = No C49488 = Yes
9	ODAE	$6	Overdose associated with AE	$6	Overdose Associated with AE	C49487 = No C49488 = Yes
10	ODAENO1	3	AE number associated with overdose	8	AE Number Associated with Overdose	
11	ODAENO2	3	AE number associated with overdose	8	AE Number Associated with Overdose	
12	ODAETXT1	$200	CRF text for AE associated with overdose	$200	CRF Text for AE Associated with Overdose	
13	ODAETXT2	$200	CRF text for AE associated with overdose	$200	CRF Text for AE Associated with Overdose	
14	COCCOVAL	$200	Further information (for non SAE)	$200	Further Information (for non SAE)	
15	Z_ALERT	$200	Hidden Trade name Field			

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Overdose Report (OVERDOSE)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
16	Z_ALERT1	$2	Hidden Number for AE Field			

(Version: AZ1211 2020-04-24)

Was any contact made?	No ☐	2
	Yes ☐	
If 'No', specify reason	_____	3
If 'Yes', specify below		
What was the contact date?	Fixed Unit: yyyy mon dd _____	5
Who was the contact respondent?	Study subject ☐	6
	Caregiver ☐	
What was the type of contact?	Telephone ☐	7
	Home visit ☐	
	Letter ☐	
	e-mail ☐	
	Other ☐	
If 'Other', specify	_____	8

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Contact (CONTACT)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	CONTACT	$6	Was any contact made?	$6	Contact Made	C49487 = No C49488 = Yes
3	REASNOC	$200	If 'No', specify reason	$200	Reason Contact Not Made	
5	CON_DAT	yyyy MMM dd	What was the contact date?		Contact Date	
6	CONRESP	$6	Who was the contact respondent?	$6	Contact Respondent	C41189 = Study subject C17445 = Caregiver
7	CONTYPE	$2	What was the type of contact?	$2	Type of Contact	1 = Telephone 2 = Home visit 3 = Letter 4 = e-mail 99 = Other
8	CONOTH	$200	If 'Other', specify	$200	Other Type of Contact	

(Version: ON2007 2021-04-27)

Assessment performed	No ☐ Yes ☐	2
Date of scan/assessment for second progression	Fixed Unit: yyyy mon dd _____	3
Investigator assessment of Subject's response	Progressive disease ☐ Non progressive disease ☐ Not evaluable ☐	4
If progression, specify the type of progression	Symptomatic Progression ☐ Objective radiological progression ☐ Other ☐	5
If Other, specify	_____	6

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Second Time of Progression (PFS2)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	ASMPERF	$6	Assessment performed	$6	Assessment(s) Performed	C49487 = No C49488 = Yes
3	PFSXDAT	yyyy MMM dd	Date of scan/assessment for second progression		Assessment Date	
4	PFSRESP	$7	Investigator assessment of Subject's response	$7	Investigator Asmt of Patients Response	C35571 = Progressive disease C123599 = Non progressive disease C62222 = Not evaluable
5	PFSTYPE	$2	If progression, specify the type of progression	$2	Type of Progression	3 = Symptomatic Progression 6 = Objective radiological progression 99 = Other
6	PFSOTH	$200	If Other, specify	$200	Other, Specify	

(Version: AZ2502 2025-02-13)

Has the drug been permanently discontinued?	No	2
	Yes	
Patient follow up options	Agrees to continue according to the current CSP visit plan/schedule	3
	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	4
Decision date	Fixed Unit: yyyy mon dd	5

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Participant Follow Up Checklist (PFU)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	DSDPPSYN	$6	Has the drug been permanently discontinued?	$6	Drug Permanently Discontin.	C49487 = No C49488 = Yes
3	DSPTERM	$2	Patient follow up options	$2	Patient Follow Up Options	1 = Agrees to continue according to the current CSP visit plan/schedule 13 = Agrees to continue in the study with a modified visit plan 3 = 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 4 = 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

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						5 = 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 6 = Does not want to be contacted but agrees that personal and medical information about him or her can be collected from medical records 14 = Agrees to be contacted by phone when needed but will not come to the site for visits 15 = Agrees for contact to be made with a treating physician or relative but will not come to the site for visits
4	DSPTERMS	$6	Patient follow up option selection	$6	Patient Follow Up Option Selection	C49488 = Yes

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Participant Follow Up Checklist (PFU)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
5	DSDSTDAT	yyyy MMM dd	Decision date		Decision Date	

(Version: ON2102 2022-03-07)

Date Subject confirmed to be alive	Fixed Unit: yyyy mon dd (2)
Date of the latest unsuccessful contact attempt	Fixed Unit: yyyy mon dd (3)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Survival Status (SURVIVE)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	SUR_DAT	yyyy MMM dd	Date Subject confirmed to be alive		Date Subject Last Known to be Alive	
3	CON_DAT	yyyy MMM dd	Date of the latest unsuccessful contact attempt		Date of Latest Unsuccess Contact Attempt	

(Version: AZ2010 2021-10-01)

Questionnaire Name	REVIEW OF PRO/QUESTIONNAIRE/DIARY (2)
If No, specify the reason below Reason Subject did not complete questionnaire	Unwilling ☐ (3) 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	(4)
Questionnaire Expected Completion Date	Fixed Unit: yyyy mon dd (5)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Review of PRO/Questionnaire/Diary (REVPRDI)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	QSCAT	$40	Questionnaire Name	$40	Questionnaire Name	REVIEW OF PRO/QUESTIONNAIRE/DIARY
3	QSREASND	$2	**If No, specify the reason below** Reason Subject did not complete questionnaire	$2	Reason Not Performed	1 = Unwilling 2 = Cannot understand instructions 3 = Technical problems with device 4 = Too sick, other than disease under investigation 5 = Cannot use device due to physical limitations 6 = Too affected by symptoms of disease under investigation 7 = Relevant language version not available 8 = Administrative failure distribute questionnaire to Subject 9 = Illiterate 10 = Patient forgot 11 = Unsolvable patient device training issues

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						99 = Other
4	QREASNDO	$200	If Other, specify	$200	Other Reason Questionnaire Not Completed	
5	QSCDAT	yyyy MMM dd	Questionnaire Expected Completion Date		Questionnaire Completion Date	

(Version: AZ2309 2024-07-03)

Consent withdrawal category	Optional Blood Tests ☑ 2
	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 ☐ 3
	Yes ☐
	Not applicable ☐
Informed consent withdrawal date	Fixed Unit: yyyy mon dd 4
Consent withdrawal category	Optional Blood Tests ☐ 2

	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 ☐ (3)
	Yes ☐
	Not applicable ☐
Informed consent withdrawal date	Fixed Unit: yyyy mon dd (4)
Consent withdrawal category	Optional Blood Tests ☐ (2)
	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 ☐ (3) Yes ☐ Not applicable ☐
Informed consent withdrawal date	Fixed Unit: yyyy mon dd (4)
Consent withdrawal category	Optional Blood Tests ☐ (2) 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 ☐ 3 Yes ☐ Not applicable ☐
Informed consent withdrawal date	Fixed Unit: yyyy mon dd 4
Consent withdrawal category	Optional Blood Tests ☐ 2 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 ☐ 3
	Yes ☐
	Not applicable ☐
Informed consent withdrawal date	Fixed Unit: yyyy mon dd 4
Consent withdrawal category	Optional Blood Tests ☐ 2
	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 ☐ 3
	Yes ☐
	Not applicable ☐
Informed consent withdrawal date	Fixed Unit: yyyy mon dd 4
Consent withdrawal category	Optional Blood Tests ☐ 2
	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 (3)
	Yes
	Not applicable
Informed consent withdrawal date	Fixed Unit: yyyy mon dd (4)
Consent withdrawal category	Optional Blood Tests (2)
	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 ☐ 3
	Yes ☐
	Not applicable ☐
Informed consent withdrawal date	Fixed Unit: yyyy mon dd 4
Consent withdrawal category	Optional Blood Tests ☐ 2
	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 ☐ 3 Yes ☐ Not applicable ☐
Informed consent withdrawal date	Fixed Unit: yyyy mon dd 4

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Withdrawal of Informed Consent (CONSWD)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	DSWDECOD	$2	Consent withdrawal category	$2	Consent Withdrawal Category	1 = Optional Blood Tests 27 = Participation to Optional Biopsy at first day of Cycle 3 of study treatment 28 = Participation to Optional Biopsy at Cancer Progression 12 = Use of Optional Services and Transfer of Contact Details to Service Providers 13 = Use of Coded Data (Including Images), Biosamples and Analysis of Genetic Information for Future Research 15 = Optional Multi-omics Research and Analysis of Their Multi-omics Information, including Their Genetic Information

Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
					16 = 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 18 = Withdrawal from the Study and any Use of Already Collected Biosamples (Including Data and Biosamples for Future Research and Multi-omics if Applicable)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
						9 = Patient Withdrew Informed Consent without Providing any Detailed Information
3	OCONWD	$6	Consent withdrawn	$6	Consent Withdrawn	C49487 = No C49488 = Yes C48660 = Not applicable
4	DSTDAT13	yyyy MMM dd	Informed consent withdrawal date		Disposition Event Start Date	

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Death Details (DD)
Generated On: 2025 Nov 20 12:23 (GMT)

(Version: ON2412 2024-12-03)

What was the Subject's date of death? Fixed Unit: yyyy mon dd (2)

Is death related to disease under investigation? (3)
- [ ] No
- [ ] Yes

Is death related to adverse event? (4)
- [ ] No
- [ ] Yes

What is the AE number? (5)

Was the autopsy performed? (6)
- [ ] No
- [ ] Yes
- [ ] Unknown

What was the cause of death narrative? (9)

Death detail assessment name (7)
- [x] Primary cause of death
- [ ] Secondary cause of death

Cause of death (8)

Death detail assessment name (7)
- [ ] Primary cause of death
- [x] Secondary cause of death

Cause of death (8)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Death Details (DD)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	DTHDAT	yyyy MMM-dd-	What was the Subject's date of death?		Date of Death	
3	DDCCAT	$6	Is death related to disease under investigation?	$6	Death Related to Disease Under Investig.	C49487 = No C49488 = Yes
4	DDCCAT1	$6	Is death related to adverse event?	$6	Death Related to Adverse Event	C49487 = No C49488 = Yes
5	AENO	3	What is the AE number?	8	AE Number	
6	DTHAUTOP	$6	Was the autopsy performed?	$6	Autopsy Performed	C49487 = No C49488 = Yes C17998 = Unknown
7	DDTEST	$7	Death detail assessment name	$7	Death Detail Assessment Name	C99531 = Primary cause of death C116142 = Secondary cause of death
8	DDCORRES	$200	Cause of death	$200	Cause of Death	
9	DTHNAR01	$1999	What was the cause of death narrative?	$1999	Cause of Death Narrative	

(Version: AZ2404 2024-09-12)

What was the completion or discontinuation date? Fixed Unit: yyyy mon dd (2)

What was the Subject's status? (3)

- 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 (5)

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 ☐ (7)

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Disposition (DS)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	DSSTDAT	yyyy MMM-dd-	What was the completion or discontinuation date?		Disposition Event Start Date	
3	DSDECOD	$7	What was the Subject's status?	$7	Standardized Disposition Term	C106576 = Site Terminated by Sponsor C25250 = Completed C28554 = Death C48227 = Lost to Follow-Up C48250 = Physician Decision C49628 = Screen Failure C49632 = Study Terminated by Sponsor C49634 = Withdrawal by Subject C17649 = Other
5	DSTERM	$200	Status, specify	$200	Disposition Event Reported Term	
7	DSSPRELI	$6	Subject's status was related to a global/country situation	$6	Global/Country Situation Relat Indicator	C49488 = Yes

Subject Continues to the Next Visit?	No ☐ 1 Yes ☐

D702NC00001_UAT_V0.300_20NOV2025_GJ: Uniques
Form: Subject Continuation (CONT)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
1	Z_CONT	$6	Subject Continues to the Next Visit?			C49487 = No C49488 = Yes

(Version: AZ2308 2023-08-11)

Date(s) of ongoing eCRF review by investigator Fixed Unit: yyyy mon dd (2)

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: Uniques
Form: Investigator Review (INVRE)
Generated On: 2025 Nov 20 12:23 (GMT)

	Field Name	Data Type	Field Label	SAS Format	SAS Label	Values
2	INVDAT	yyyy MMM dd	Date(s) of ongoing eCRF review by investigator		Date of Ongoing eCRF Review Investigator	