eCRF COMPLETION GUIDELINES

Study Code	D702NC00001
Version	03
EDC Platform	RAVE
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General eCRF Completion Guidelines

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TABLE OF CONTENTS

1 INTRODUCTION 9
2 EDC SPECIFIC INSTRUCTIONS 9
2.1 Getting Started 9
2.2 Icon Key 9
2.3 Editing data 10
2.4 Answering queries 10
2.4.1 System Queries (triggered by pre-configurated checks) 11
2.4.2 Manual Queries (user created queries, response required) 11
2.4.3 Non-Conformant Queries 11
3 GENERAL COMPLETION GUIDELINES 12
3.1 Data Entry 12
3.2 Text 12
3.3 Valid Characters and Disallowed Characters 13
3.3.1 Valid Characters 13
3.3.2 Disallowed Characters 13
3.4 Date 14
3.5 Time 15
3.6 Data Entry Timeline 16
3.7 Query Response Timeline 16
3.8 Data Submission 16
3.9 Log Forms 16
3.10 Page Navigation 17
3.11 Data Corrections and Change Control 19
3.12 Inactivation in EDC 19
3.12.1 INACTIVATE FORM 19
3.12.2 INACTIVATE LOGLINE 21
3.13 Missing Data 23
3.13.1 Missing Visits 23
3.13.2 Missing Forms 23
3.13.3 Missing Fields 24
3.13.4 Blank log lines 24
4 SUBJECT CREATION 24
5 RANDOMIZATION AND TRIAL SUPPLY MANAGEMENT (RTSM) SYSTEM INTEGRATION WITH THE ECRF 25
6 SCREEN FAILURES 25
7 RESCREENING 27
8 WOMEN OF CHILDBEARING POTENTIAL: 27
9 RANDOMIZED SUBJECTS WITHOUT TREATMENT 27
10 POPULATING DYNAMIC FOLDERS/ FORMS 28

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11 ADD EVENT FUNCTION 34
12 UNSCHEDULED DATA 35
13 SAE REPORTING 37
14 ELECTRONIC SIGNATURE 39
15 FORM LEVEL ECRF INSTRUCTIONS 41
15.1 Form Level Instructions 41
15.1.1 ENROLMENT (ENROL) 42
15.1.2 GROUP (GROUP) 45
15.1.3 VISIT DATE (VISIT) 46
15.1.4 INFORMED CONSENT (CONSENT) 48
15.1.5 INFORMED CONSENT- RECONSENT (CONSENT1) 49
15.1.6 DEMOGRAPHICS (DM) 50
15.1.7 INFORMED CONSENT - GENOMICS INITIATIVE (ICFGEN) 52
15.1.8 INCLUSION/EXCLUSION CRITERIA NOT MET (IE) 53
15.1.9 INCLUSION/EXCLUSION CRITERIA NOT MET - RANDOMIZATION (IE1) 55
15.1.10 EXTENT OF DISEASE UPON ENTRY TO STUDY (DISEXT) 57
15.1.11 GENERAL MEDICAL HISTORY (1MH) 58
15.1.12 PRE-SPECIFIED MEDICAL CONDITIONS OR EVENTS (2MH) 60
15.1.13 ASSESSMENT(S) PERFORMED TRIGGERING FORM (ASMTRIG) 61
15.1.14 SURGICAL HISTORY (HISS) 63
15.1.15 PATHOLOGY AT TIME OF INITIAL DIAGNOSIS OF EARLY STAGE BTC (PATHGEN) 64
15.1.16 PATHOLOGY: AT SCREENING (PATHGOM) 67
15.1.17 SUBSTANCE USE - NICOTINE (SU_NIC) 70
15.1.18 SUBSTANCE USE - ALCOHOL (SU_ALC) 71
15.1.19 PHYSICAL EXAMINATION (PE) 72
15.1.20 VITAL SIGNS - WEIGHT, HEIGHT (VS) 73
15.1.21 VITAL SIGNS - BEFORE INFUSION (VS1) 75
15.1.22 VITAL SIGNS - END OF INFUSION (VS2) 77
15.1.23 VITAL SIGNS - EXCLUDING WEIGHT (VS3) 79
15.1.24 VITAL SIGNS (VS4) 81
15.1.25 ECOG PERFORMANCE STATUS (ECOG) 83
15.1.26 ECG TEST RESULTS (EG), ADDITIONAL ECG (EG1) and ADDITIONAL ECG (EG2) 84
15.1.27 ECHOCARDIOGRAPHY (ECHOC) 86
15.1.28 PREGNANCY TEST - SCREENING (PREG) 87
15.1.29 PREGNANCY TEST (PREG1) 88
15.1.30 PREGNANCY REPORT (PREGREP) 89
15.1.31 NON-CENTRAL LABORATORY TEST RESULTS - CHEMISTRY (LB) 90
15.1.32 NON-CENTRAL LABORATORY TEST RESULTS - HEMATOLOGY (LB1) 92
15.1.33 NON-CENTRAL LABORATORY TEST RESULTS - COAGULATION (LB2) 93
15.1.34 NON-CENTRAL LABORATORY TEST RESULTS - THYROID FUNCTION TEST (LB3) 94

Approved

Downloaded by Shu Zhang on 08 Jul 2026

15.1.35 NON-CENTRAL LABORATORY TEST RESULTS - TROPONIN AND CREATINE PHOSPHOKINASE (LB4) 95
15.1.36 NON-CENTRAL LABORATORY TEST RESULTS - CA-19-9 AND CEA (SERUM) (LB5) 96
15.1.37 NON-CENTRAL LABORATORY TEST RESULTS - URINALYSIS (LB6) 97
15.1.38 NON-CENTRAL LABORATORY TEST RESULTS - HEPATITIS B AND C TESTING (LB7) 99
15.1.39 NON-CENTRAL LABORATORY TEST RESULTS - HY'S LAW (LB8) 101
15.1.40 NON-CENTRAL LABORATORY TEST RESULTS - INTERSTITIAL LUNG DISEASE (LB9) 103
15.1.41 NON-CENTRAL LABORATORY TEST RESULTS - TUBERCULOSIS TESTING (LB10) 104
15.1.42 NON-CENTRAL LABORATORY TEST RESULTS - HIV TESTING (LB11) 105
15.1.43 NON-CENTRAL LABORATORY TEST RESULTS - ADDITIONAL CHEMISTRY (LB12) 106
15.1.44 NON-CENTRAL LABORATORY TEST RESULTS - HEPATITIS B AND C TESTING - POST SCREENING (LB13) 107
15.1.45 SAMPLE COLLECTION, PREDOSE_ADA SAMPLE (SPCBEDB) 109
15.1.46 BLOOD SAMPLE FOR PLASMA PRE-DOSE CTDNA (SPCBEDB1) 110
15.1.47 PBMC FOR IMMUNE PROFILING_PRE DOSE (SPCBEDB2) 111
15.1.48 WHOLE BLOOD FOR RNA ANALYSIS_PRE-DOSE (SPCBEDB3) 112
15.1.49 BLOOD SAMPLES FOR SERUM BIOMARKER ANALYSIS PRE-DOSE (SPCBEDB4) 113
15.1.50 SAMPLE COLLECTION, ADA SAMPLE (SPCBEDB5) 114
15.1.51 BLOOD SAMPLE FOR PLASMA CTDNA (SPCBEDB6) 115
15.1.52 OPTIONAL ON STUDY TUMOR SAMPLE (SPCBEDT) 116
15.1.53 MANDATORY SCREENING TUMOR SAMPLE (SPCBEDT1) 118
15.1.54 GENOMICS INITIATIVE (OPTIONAL), EXPLORATORY GENETIC SAMPLE (SPCGB) 120
15.1.55 BIOLOGICAL SAMPLE COLLECTION, PRE-DOSE PK (SPCPKB) 121
15.1.56 BIOLOGICAL SAMPLE COLLECTION, POST-DOSE PK (SPCPKB1) 123
15.1.57 BIOLOGICAL SAMPLE COLLECTION, PK (SPCPKB2) 125
15.1.58 TARGET LESIONS, BASELINE (1RECIST1) 126
15.1.59 NON-TARGET LESIONS, BASELINE (2RECIST1) 129
15.1.60 TARGET LESIONS, FOLLOW-UP (3RECIST1) 131
15.1.61 NON-TARGET LESIONS, FOLLOW-UP (4RECIST1) 135
15.1.62 NEW LESIONS AND INVESTIGATOR ASSESSMENT OF RESPONSE (RECIST2) 137
15.1.63 NEW LESIONS ADDITIONAL INFORMATION (NLESADD) 142
15.1.64 EXPOSURE AS COLLECTED - RILVEGOSTOMIG (EC) 144
15.1.65 EXPOSURE AS COLLECTED - DURVALUMAB (EC3) 149
15.1.66 EXPOSURE AS COLLECTED - GEMCITABINE (EC1) 153
15.1.67 EXPOSURE AS COLLECTED - CISPLATIN (EC2) 159
15.1.68 END OF STUDY TREATMENT - RILVEGOSTOMIG (ETRT) 165
15.1.69 END OF STUDY TREATMENT - DURVALUMAB (ETRT3) 168
15.1.70 END OF STUDY TREATMENT - GEMCITABINE (ETRT1) 171
15.1.71 END OF STUDY TREATMENT - CISPLATIN (ETRT2) 174
15.1.72 PRIOR CANCER THERAPY (CAPRX) 177

Approved

Downloaded by Shu Zhang on 08 Jul 2026

15.1.73 PRIOR RADIOTHERAPY (CAPRXR) 179
15.1.74 SUBSEQUENT CANCER THERAPY (CAPRX1) 181
15.1.75 PALLIATIVE ON-STUDY RADIOTHERAPY (CAPRXR1) 183
15.1.76 POST TREATMENT RADIOTHERAPY (CAPRXR2) 185
15.1.77 PRIOR AND CONCOMITANT MEDICATIONS LOG (CMLOG) 187
15.1.78 PRIOR AND CONCOMITANT MEDICATIONS (CM) 188
15.1.79 PROCEDURES (1PR) 193
15.1.80 SURGERY FOR SUBSEQUENT ANTICANCER THERAPY (1PR1) 195
15.1.81 ADVERSE EVENTS LOG (AELOG) 196
15.1.82 ADVERSE EVENTS (AE) 197
15.1.83 AE OF SPECIAL INTEREST (AESI) 209
15.1.84 AE OF SPECIAL INTEREST ADDENDUM (AESIA) 248
15.1.85 ADDITIONAL LABORATORY EVALUATIONS (LABADD) 250
15.1.86 SERIOUS ADVERSE EVENT REPORT (SERAE) 251
15.1.87 INTERSTITIAL LUNG DISEASE (ILDIS) 256
15.1.88 PULMONARY FUNCTION TEST (PULMOA) 263
15.1.89 CRS SIGNS AND SYMPTOMS (CRSSS) 264
15.1.90 CRS ASTCT CRITERIA (CRASTCT) 266
15.1.91 INFUSION RELATED REACTION TQS (IRRTQS) 268
15.1.92 HOSPITAL ADMISSIONS DETAILS (HOSPAD) 274
15.1.93 DEVICE EVENTS LOG (DELOG) 277
15.1.94 DEVICE EVENTS (DE) 278
15.1.95 LIVER DIAGNOSTIC INVESTIGATIONS (LIVERDI) 282
15.1.96 LIVER RISK FACTORS/LIFE STYLE EVENTS (LIVERRF) 285
15.1.97 LIVER SIGNS AND SYMPTOMS (LIVERSS) 288
15.1.98 MEDICATION ERROR REPORT (MER) 290
15.1.99 OVERDOSE REPORT (OVERDOSE) 293
15.1.100 CONTACT (CONTACT) 295
15.1.101 SECOND TIME OF PROGRESSION (PFS2) 296
15.1.102 PARTICIPANT FOLLOW UP CHECKLIST (PFU) 297
15.1.103 SURVIVAL STATUS (SURVIVE) 299
15.1.104 REVIEW OF PRO/QUESTIONNAIRE/DIARY (REVPRDI) 300
15.1.105 WITHDRAWAL OF INFORMED CONSENT (CONSWD) 302
15.1.106 DEATH DETAILS (DD) 304
15.1.107 DISPOSITION (DS) 307
15.1.108 SUBJECT CONTINUATION (CONT) 309
15.1.109 INVESTIGATOR REVIEW (INVRE) 310
15.1.110 UNSCHEDULED VISIT (UNS_VIS) 311

16 REVISION HISTORY 313

17 TEMPLATE REVISION HISTORY 315

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LIST OF TABLES:

Table 1: PARTIAL DATES ALLOWED IN EDC 14
Table 2 FORMS TO BE INTEGRATED 24
Table 3: CRF FORMS REQUIRED FOR SCREEN FAILURES 26
Table 4: Additional Forms Required if Subject Has Experienced an SAE 26
Table 5 Randomized Without Treatment CRF Forms 27
Table 6 Additional Forms and Visits Triggered 28
Table 7 Forms Activated by ASMTRIG 32
Table 8 Evaluation of Target Lesions 139
Table 9 Evaluation of Non-target Lesions 140
Table 10 Overall visit response 141
Table 11: Reason for Study treatment discontinuation - Rilvegostomig 165
Table 12 Reason for study treatment discontinuation - Durvalumab 168
Table 13 Reason for study treatment discontinuation - Gemcitabine 171
Table 14 Reason for study treatment discontinuation - Cisplatin 174
Table 15 Reason for medication/treatment taken 189
Table 16: Outcome Instructions 201
Table 17: Description for corresponding Action Taken 203
Table 18 Description for corresponding Action Taken – Specific for Chemotherapy 205

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APPROVAL

Each authorization indicates review and approval of the study-specific eCRF Completion Guidelines. Authorization is obtained using validated electronic signatures.

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ABBREVIATIONS

AE	Adverse Event
CSP	Clinical Study Protocol
CRA	Clinical Research Associate
DES	Patient Safety Data Entry Site
DMP	Data Management Plan
ECG	Electrocardiogram
eCRF	electronic Case Report Form
EDC	Electronic Data Capture
IA	Interim Analysis
ID	Identification
IxRS	Interactive Voice/Web Response System
MedDRA	Medical Dictionary for Regulatory Activities
PA	Primary Analysis
PIN	Personal Identification Numbers
RAVE	Medidata EDC System
RTSM	Randomization and Trial Supply Management System
SAE	Serious Adverse Event
SDV	Source Data Verification
SERAE	Serious Adverse Event Report

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1 INTRODUCTION

This Case Report Form (CRF) Completion Guideline has been designed to assist site staff to complete electronic Case Report Form (eCRF) and support Clinical Research Associate (CRA) to ensure consistent data collection.

Information in this guide has been drawn from Clinical Study Protocol V.1.0 D702NC00001 and is not intended to be a comprehensive handbook. If there is a need for an additional assistance or clarification while completing Case Report Form, contact your CRA for clarification.

While logged into RAVE system, you can use the *Help* button for general help about the tool:



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2 EDC SPECIFIC INSTRUCTIONS

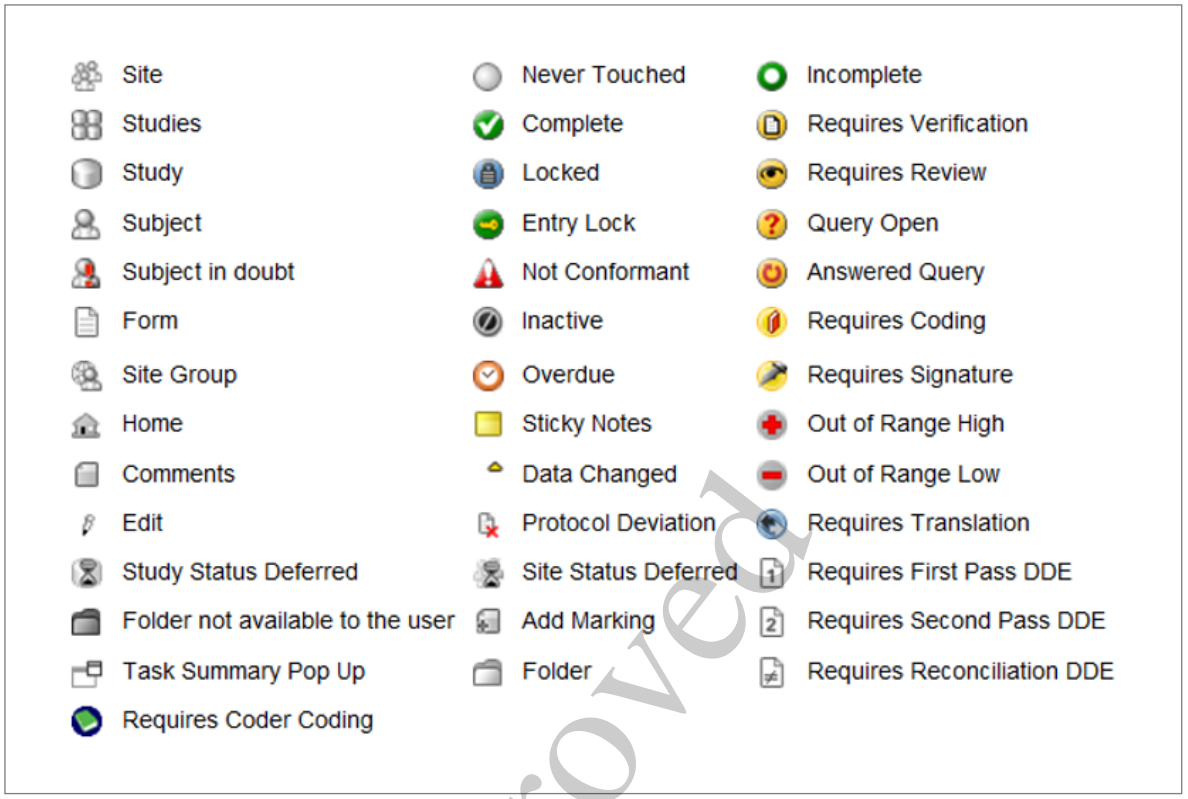
2.1 GETTING STARTED

To access RAVE, log on to the website: https://www.imedidata.com,
RAVE Technical Support can be accessed by the following means:
Email to helpdesk@mdsol.com.
By telephone, using the worldwide toll-free numbers: https://www.mdsol.com/contact.

2.2 ICON KEY

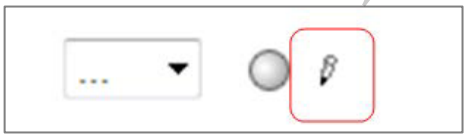
Graphical icons are used throughout the RAVE system to visually denote the status of subjects, folders, forms, or fields. On the bottom of each form, an Icon Key is accessible which contains a description and picture of the commonly used icons.

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2.3 EDITING DATA

Data that has been saved can be changed or edited by clicking on the Edit Pencil, icon next to the field you want to edit. If you want to reopen all data points in one page at once the Edit Pencil, of the page needs to be ticked. However, for AE and SERAE eCRFs, will be only allowed to be edited with the top pencil (page level), refer to AE and SERAE individual eCRF instructions for more details.



Please make sure not to enter any Sensitive Patient data in ECRF on form or in any query response.

2.4 ANSWERING QUERIES

There are two kinds of queries: **System Queries** and **Manual Queries**. Depending on the query, different types of responses may be required:

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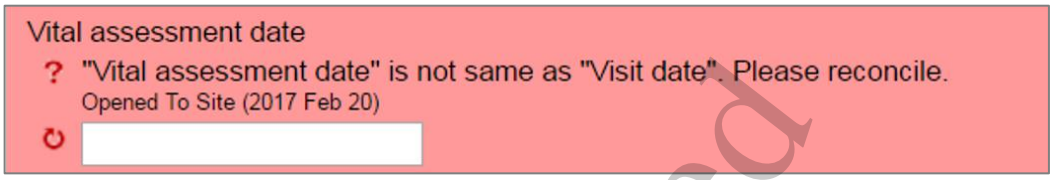
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2.4.1 SYSTEM QUERIES (TRIGGERED BY PRE-CONFIGURATED CHECKS)

- Data Change only (no additional response required)
- Additional Response Required

2.4.2 MANUAL QUERIES (USER CREATED QUERIES, RESPONSE REQUIRED)

To respond to a query, the form containing the query must be saved.



- If the query is triggered due to a data entry error, correct the data field and then click **Save**. No text response is required, and the query will be closed automatically.
- If the query remains open when the data field is corrected, check whether (other) data is incorrect and/or enter a text response.
- If all data is correctly entered but a query is present, enter a valid response and then click **Save**.
    - Valid responses: e.g., Date is correct (Date checks); Data correct as entered (Out of range checks) and then click **Save**
    - Non-valid responses: e.g., 'Done', 'Changed', 'Updated' (but data field is not updated)

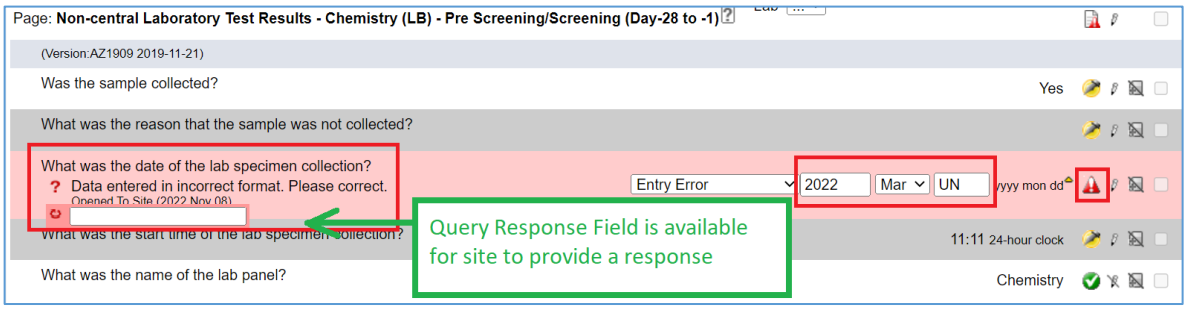
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2.4.3 NON-CONFORMANT QUERIES

Non-Conformant data queries will fire when data is entered in an unexpected format. For example, where partial dates are entered but a complete date is expected, where data is entered with too many decimal points, where text is entered in a field where numeric data is expected or where the entered data is too long.

Example of non-conformant query:

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These discrepancies to be addressed by updating the data to the expected type, format or length. The relevant form level instruction will outline the expected data type and format for each variable.

3 GENERAL COMPLETION GUIDELINES

3.1 DATA ENTRY

Any entry into the eCRF can only be done by the investigator, or designated authorized site staff.

Do **not** identify the subject by name or initials in the eCRF forms.

3.2 TEXT

- **English to be used** and abbreviations to be avoided. Both British and American spellings are acceptable.
- Use clear and consistent terminology. Use medical terminology when possible and avoid long descriptive text.
- Always refer to the study protocol before completing forms.
- Do not use single or double quotation marks when entering in free text fields (i.e., 'Hypertension' or 'Asthma').
- When an answer fits into the 'Other' category of a list, complete the 'specify' field if applicable.
- Entries in the eCRFs, including corrections, will be completed by the authorized site personnel that are listed on the Site Signature Log.
- All mandatory questions/ required items must be answered. If left blank, it will be queried. Check the appropriate responses throughout the entire eCRF. Enter only one response for each item, except for when it's specified that more than one response can be selected and in this case all responses that apply to be selected.

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- All project information must first appear in the source documentation records and then be transcribed to the applicable eCRF page.
- The case histories/ medical records/ research records/ laboratory/ etc. (source document records) require to contain sufficient information to explain and support all entries in the eCRF.
- Subject status is RAVE is derived based on the Data entry done. Hence, we would recommend to complete Data entry for these forms to have the subject status populated correctly.

3.3 VALID CHARACTERS AND DISALLOWED CHARACTERS

3.3.1 VALID CHARACTERS

Valid characters to be entered in EDC are ASCII 128 characters as below:

A b c d e f g h i j k l m n o p q r s t u v w x y z

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

0 1 2 3 4 5 6 7 8 9

[ ] { } ( ) ! ? , . % + - # @ $ & * : = ^ _ - ; < > ~ |

NOTE: If an auto-query is deployed for invalid characters, remove or re-enter those characters (e.g., if 90% is entered for LB result, remove the % symbol and retain 90 in the field. Contact your CRA for additional questions).

3.3.2 DISALLOWED CHARACTERS

To avoid additional queries there are some characters which may not be entered into RAVE database. Example, including but not limited to:

- Double quotes (“)
- Single quotes (‘)
- Apostrophe (’)
- \ or \\
- ©
- β

Avoid copying and pasting into text boxes and query text. Do not use the Enter / Return keys as these create leading space characters which cause validation issues.

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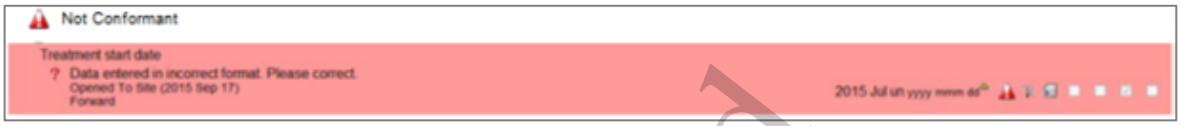
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3.4 DATE

Preferred date in the YYYY-MON-DD format, using standard English abbreviations for Month (JAN, FEB, MAR, APR, MAY, JUN, JUL, AUG, SEP, OCT, NOV, or DEC) and four digits for the year (e.g., 2014) or select the calendar icon if available.

Enter the complete date; use the drop down or Calendar icon to select the correct Month and enter the Year and Day into the fields.

If an incomplete date is entered in a field that requires a complete date, this will trigger a non-conformant data query. A complete date must be entered in these cases.



The Visit Date form must always be completed prior to any of the other forms of that visit, since it might trigger some data checks or forms. If the eCRF is not completed at the time of the visit, record the date of the visit, not the date of eCRF completion. Check that all visit dates are in chronological order. Ensure that all appropriate pages are present in the eCRF.

As a general rule ‘unknown’ not to be used for assessment dates and visit dates.

If a date is unknown, leave the field blank and confirm in a query answer.

The following fields will allow partial date entry:

Table 1: PARTIAL DATES ALLOWED IN EDC

FormOID	FieldOID	PreText/ Variable Label	Day or Day/ Month can be unknown?
DM	BRTHDAT	What is the Subject's date of birth?	Month and Day
AE	AESTDAT	Start Date	Month and Day
AE	AEENDAT	End Date	Month and Day
1MH	MHSTDAT	Start date	Month and Day
1MH	MHENDAT	End date	Month and Day
1PR	PRSTDAT	Start date	Month and Day
1PR	PRENDAT	End date	Month and Day
1PR1	PRSTDAT	Start date	Month and Day
1PR1	PRENDAT	End date	Month and Day
HISS	PRSTDAT	Start date	Month and Day
DISEXT	REC_DAT	Date of recurrence	Month and Day
PATHGEN	MHSTDAT	Original diagnosis date	Month and Day

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FormOID	FieldOID	PreText/ Variable Label	Day or Day/ Month can be unknown?
CAPRX	CMTSTDAT	Cancer therapy agent start date	Month and Day
CAPRX	CMTENDAT	Cancer therapy agent stop date	Month and Day
CAPRX1	CMTSTDAT	Cancer therapy agent start date	Month and Day
CAPRX1	CMTENDAT	Cancer therapy agent stop date	Month and Day
CAPRXR	CXRDSDAT	Radiotherapy start date	Month and Day
CAPRXR	CXRDEDAT	Radiotherapy stop date	Month and Day
CAPRXR1	CMCSTDAT	Radiotherapy start date	Month and Day
CAPRXR1	CMCENDAT	Radiotherapy stop date	Month and Day
CAPRXR2	CMCSTDAT	Radiotherapy start date	Month and Day
CAPRXR2	CMCSTDAT	Radiotherapy stop date	Month and Day
CM	CMSTDAT	Start date	Month and Day
CM	CMENDAT	End date	Month and Day
DE	DESTDAT	Device Event start date	Month and Day
DE	DEENDAT	Device Event end date	Month and Day
DE	DTSTDAT	Action taken date	Month and Day
DD	DTHDAT	What was the Subject's date of death?	Month and Day
DS	DSSTDAT	What was the completion or discontinuation date?	Month and Day
LIVERRF	LIVRSDAT	Liver risk factor start date	Month and Day
LIVERRF	LIVREDAT	Liver risk factor stop date	Month and Day
LIVERDI	FACDAT	Liver diagnostic investigation date	Day
LIVERSS	CESTDAT	Start date	Day
LIVERSS	CEENDAT	Stop date	Day

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3.5 TIME

- All time required to be entered using the 24-hour clock (HH:MM) unless otherwise indicated.
- Midnight required to be recorded as 00:00 as the start of a new day.
- Leading zero is required for both hour and minute (i.e., entry time as 04:09 instead of 4:9).

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3.6 DATA ENTRY TIMELINE

As a general rule, eCRF data required to be entered into the EDC system as soon as possible but no later than 5 business days (7 calendar days) after the subject's visit (except for SAE form, which is required to be reported within 24 hours after being aware of the event). The data entry timeline is reduced to 2 calendar days in preparation for major study milestones e.g., clinical data lock. Timely data entry will allow the data to progress appropriately through the data cleaning process and prevent a large number of queries.

3.7 QUERY RESPONSE TIMELINE

As a general rule, queries required to be answered within 5 business days (7 calendar days). This timeline is also reduced to 2 calendar days in preparation for major study milestones (e.g., Clinical Data Lock).

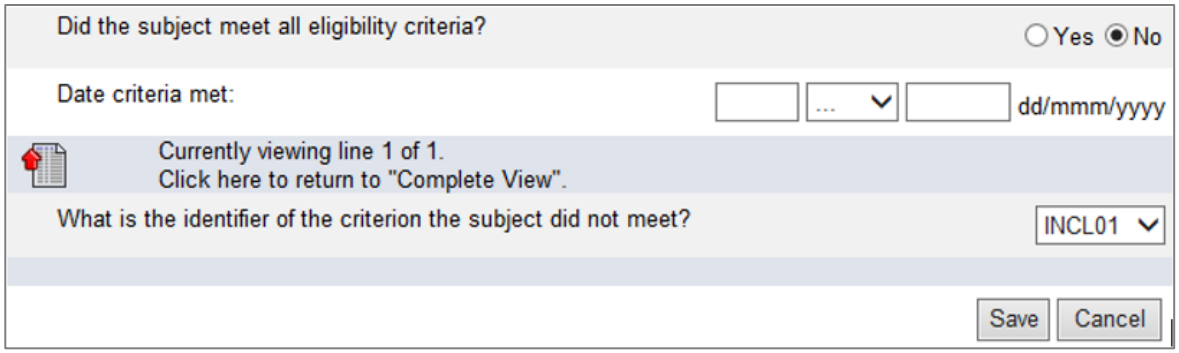
3.8 DATA SUBMISSION

To submit data entered in eCRF, or edits made to eCRF, ensure to 'Save' the page. If 'Save' button is not clicked, data will be lost.

3.9 LOG FORMS

The Log forms under this section refer to the database design for which forms are designed with loglines. Certain forms are set up as log forms (e.g., Inclusion/ Exclusion Criteria Not Met, Medical History, Adverse Events and Prior and Concomitant Medication). This allows you to enter as many records as you need on a form. Each entry on a log form is referred to as a log line.

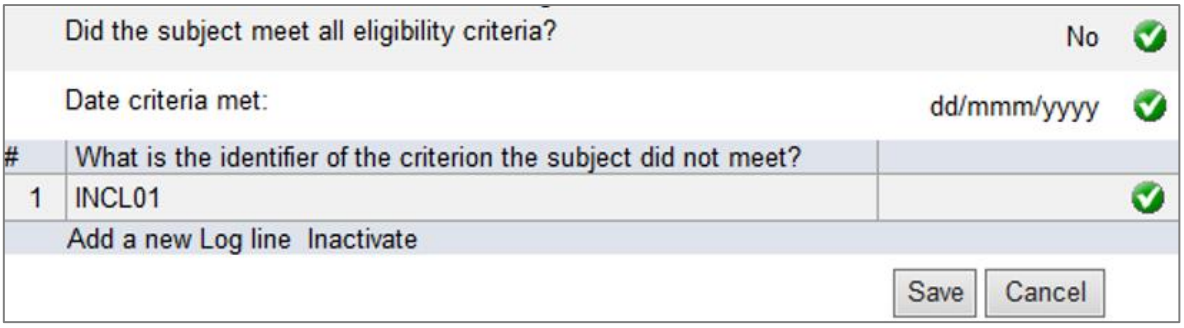
When these forms are opened for the first time, the first log line will open in a Portrait view:



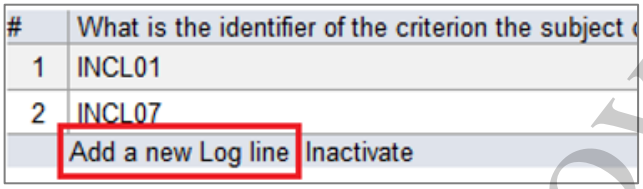
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Enter the required information into the form and click the 'Save' button. The form will be saved as a horizontal log line:



To enter additional records, click on the link for 'Add a new log line' at the bottom left of the log line table. This will open a new log line in 'Portrait' format.



For 'Prior and Concomitant Medications' form, the maximum log lines are 50. Use 'Add Event' function to add a new 'Prior and Concomitant Medications' form if more than 50 log lines are expected.

It is not possible to delete any of the log lines; if an entry was made in error the log line may be inactivated, see instructions below:

- To remove log line(s) that were added in error, use the 'Inactivate' link and select a log line number from the dropdown and provide reason for inactivating.
- Save all information on the current log line prior to adding a new log line; otherwise, all information will be erased and is non-retrievable.

3.10 PAGE NAVIGATION

For forms with multiple log lines, it may split into several pages. To view additional log lines, click the Page Number. On the lower right corner of the form, click Paginate and select Show All Lines from the dropdown list', as shown below:

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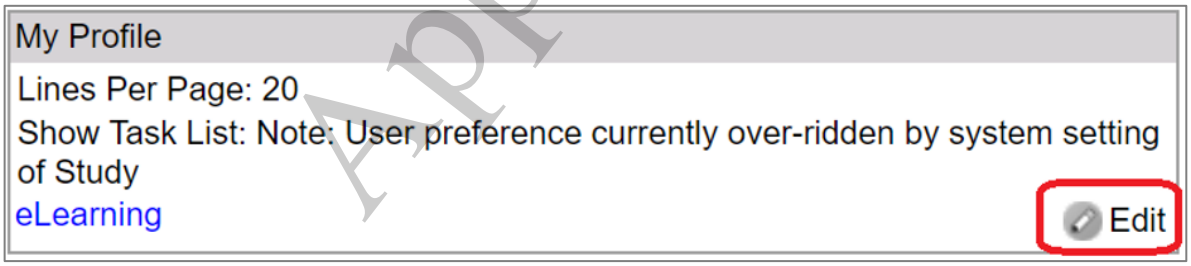


You can also follow the steps below to view more Lines or Sites per page in iMedidata RAVE

STEP 1 – Click 'My Profile' on the upper right corner of the RAVE screen



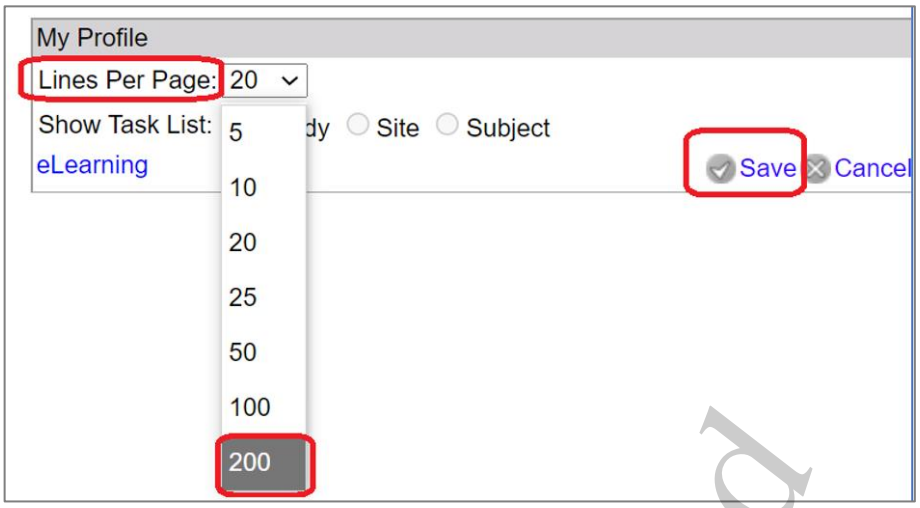
STEP 2 – Click 'Edit'



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STEP 3 – Select '200' from dropdown list, and click 'Save'



3.11 DATA CORRECTIONS AND CHANGE CONTROL

- Corrections can be made at any time to eCRF screens prior to submitting the form.
- If a form is saved and an update is made, the reason for change/ update must be selected.
- An audit trail is automatically initiated that tracks all changes.
- Changes cannot be made to frozen or locked forms here. Contact your study monitor if data changes are required.

3.12 INACTIVATION IN EDC

Site Personnel (Investigator/Site Co-ordinator) will have the access to inactivate complete eCRFs or individual loglines.

The inactivation can be done per following procedure:

3.12.1 INACTIVATE FORM

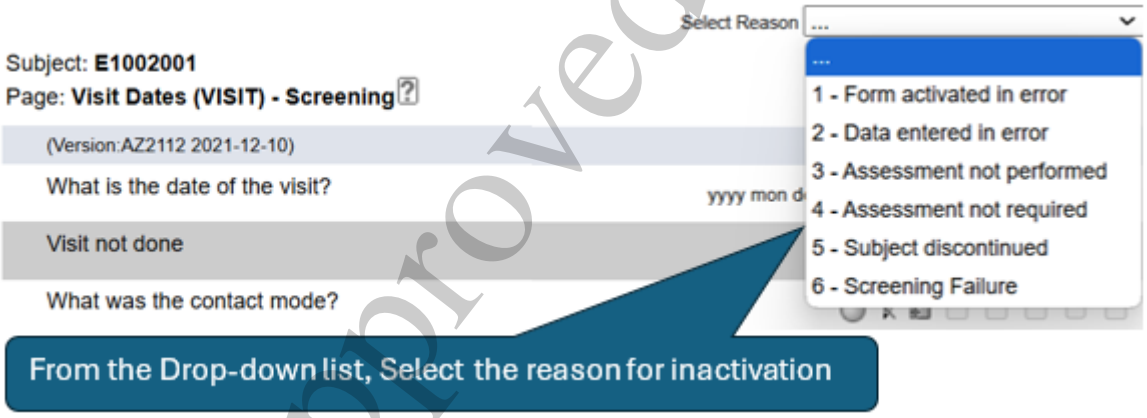
1. Click on "Inactivate Page" (located on the top right corner of your eCRF and a drop-down list for 'Reasons to Inactivate the eCRF will appear

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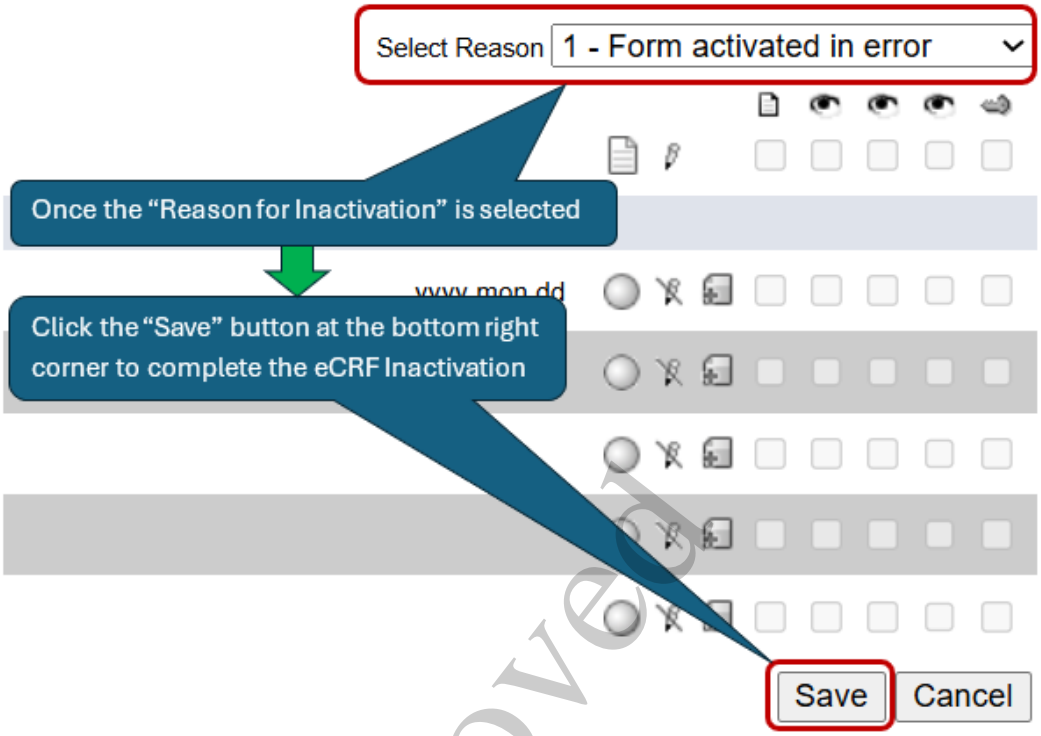
2. From the Drop-down list, Select the reason for inactivation.



3. Once the "Reason for Inactivation" is selected, Click the "Save" button at the bottom right corner to complete the eCRF Form Inactivation.

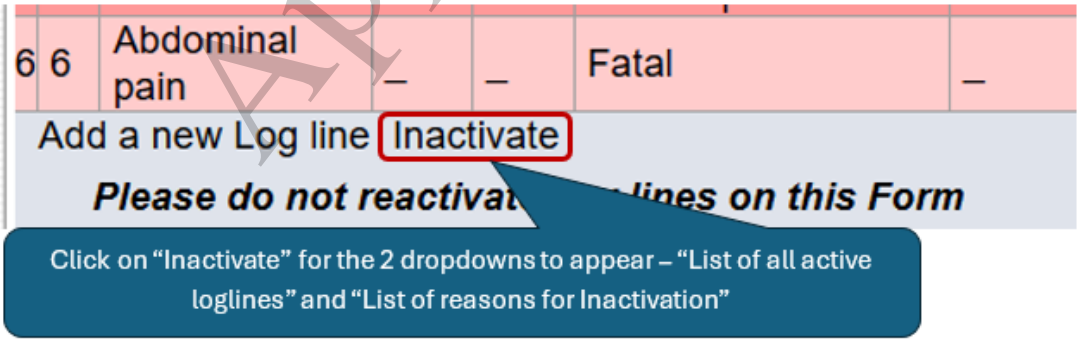
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3.12.2 INACTIVATE LOGLINE

1. Click on "Inactivate" for the 2 dropdowns to appear – "List of all active loglines" and "List of reasons for Inactivation".



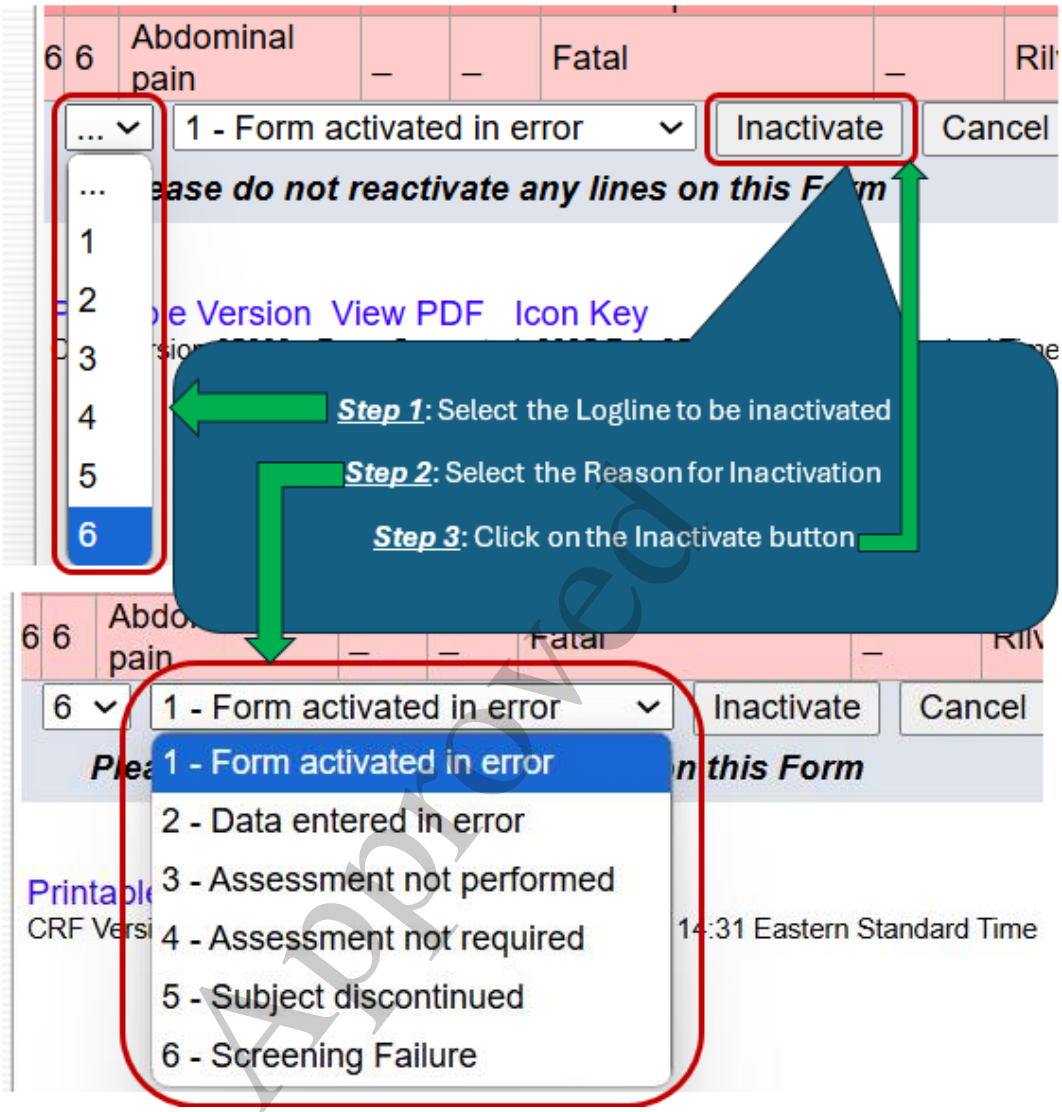
Step 1: Select the Logline to be inactivated

Step 2: Select the Reason for Inactivation

Step 3: Click on the Inactivate button

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Note:

- For Screen Failures: Only complete mandatory pages, there is no requirement to inactivate the remaining blank pages.
- Avoid inactivation of mandatory pages, apart from leading to missing data this would also interfere with the proper functioning of dynamic checks and/or other edit checks in the eCRF.
- If there is a Data Error, then it is advised to correct/delete as inactivating/re-activating the same form can cause the eCRF and the checks/dynamics associated to not function properly.
- If data was entered by mistake in form which is dynamically populated, then remove the erroneous data and inactivate the form.

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Missing pages:

- If the pages are for assessment post a DCO and would be conducted/entered later then inform CRA about the same rather than inactivating them.
- If the assessments are not performed, then check if there is a leading question which can be completed as No; for e.g. 'Assessments performed?'; then please complete this leading question rather than inactivating the eCRF.
- If an entire Visit is skipped in between due to any reason, then check if there is a "Visit Not Done" option on the VISIT eCRF and complete it instead of inactivating the entire Visit
- If additional forms are populated post the discontinuation of the subject, then no need to inactivate them unless specifically requested
- If an Adverse Event logline reported with serious 'Yes' is inactivated, it will result in the corresponding Serious Adverse Event form being permanently inactivated. In the event that the Adverse event is still needed a new logline should be completed and the old Adverse Event logline should not be reactivated.

3.13 MISSING DATA

Data that is expected may be unavailable (e.g., unknown, assessment not performed). If an assessment was not completed or not done at the required time point, record the assessment as not done on the eCRF, do not leave blank. If some information has been impossible to obtain, respond accordingly to associated queries.

3.13.1 MISSING VISITS

If an entire visit is missed, check the 'Visit not done' as 'Yes' on the VISIT form.

Ensure that Adverse Events and/or Serious Adverse Events are assessed at the next visit.

3.13.2 MISSING FORMS

3.13.2.1 Forms with partially unavailable data

For partially unavailable data, fill in as much of the form as possible and leave the remaining fields empty.

3.13.2.2 Forms with no data available

Forms with a leading question (e.g., 'ECG Performed?' (Y/N) on EG form) are completed at study completion. Enter 'No' if no data is expected.

Forms without a leading question are required to be inactivated. Refer to section 3.12 for CRF inactivation in EDC.

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3.13.3 MISSING FIELDS

If a value within a form is missing, e.g., pulse not measured, leave field blank, respond to the generated query that the data was not obtained and the reason why. Do NOT enter data as '0' for missing numeric values.

For missing dates, see Section 3.4 for detail guidance.

3.13.4 BLANK LOG LINES

Log lines with no data entered are required to be inactivated by site.

4 SUBJECT CREATION

RTSM Integrated Study

- The 'Add Subject' link is not available for this study.
- After screening a subject in the RTSM system, the subject ID will populate in the subject list in the Site's home screen.
- If an expected subject is not present in the subject list after the RTSM screening transaction, contact your Site Monitor.

Table 2 FORMS TO BE INTEGRATED

Folder Name	Form Name	Variable Label
	Enrolment (ENROL)	What is the enrolment code?
Screening (Day-28 to -1)	Visit Date (VISIT)	What is the date of the visit?
Screening (Day-28 to -1)	Demographics (DM)	What is the Subject's date of birth?
Screening (Day-28 to -1)	Demographics (DM)	What is the Subject's age?
Screening (Day-28 to -1)	Demographics (DM)	What is the sex of the Subject?
Screening (Day-28 to -1)	Informed Consent (CONSENT)	What was the main informed consent date?
Rescreening	Visit Date (VISIT)	What is the date of the visit?
Rescreening	Informed Consent (CONSENT)	What was the main informed consent date?
Cycle 01 Day 01	Inclusion/Exclusion Criteria Not Met - Randomization (IE1)	If yes, randomization code
Cycle 01 Day 01	Inclusion/Exclusion Criteria Not Met - Randomization (IE1)	What was the randomization date?
Cycle 01 Day 01	Group (GROUP)	What was the group allocation?

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- If updates are required to any of the items listed above the updates will need to be made in the RTSM system. Once the necessary updates are made within the RTSM system the updated data will integrate to the Rave database. Contact your Monitor for assistance.
- The subject number is allocated by the RTSM at screening, the subject is randomized and keeps the same patient number as the one allocated at screening throughout the entire study duration.
- **Note**: For DM, CONSENT, VISIT, and IE1 forms, please ensure all fields are accurately completed, as not all data is automatically populated from the RTSM system. A thorough review of each form is required to confirm completeness.

5 RANDOMIZATION AND TRIAL SUPPLY MANAGEMENT (RTSM) SYSTEM INTEGRATION WITH THE ECRF

RTSM information that is programmatically populated by RTSM system (e.g., Subject ID, Entry/Randomization Date) cannot be edited once transferred to the eCRF, in case of changes this required to be done in the RTSM system. All other integrated fields can be updated. An ongoing reconciliation will take place to ensure that the changes in the eCRF are correct.

Data will be transferred from the RTSM system to the eCRF in real time (within approximately 15 min. of completion) and each time a change is made in RTSM system a new file is transferred to the eCRF.

The RTSM data can transfer to the eCRF at separate time points for each subject:

Screening

- When the screening form is complete in RTSM the file will be transferred to the eCRF and will trigger subject creation and automatically populate the above variables.

Randomization

- When a subject is randomized in RTSM the file will be transferred to the eCRF and the Randomization date will trigger the creation of an eCRF to be created for the subjects.

6 SCREEN FAILURES

Screen failure subject data will be captured in EDC. For subjects in randomized studies that give consent but have not been assigned a randomization code, the following eCRF forms must be completed:

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Table 3: CRF FORMS REQUIRED FOR SCREEN FAILURES

Visit	Form
Subject Level	Enrolment (ENROL)
Screening (Day-28 to -1) / Rescreening	Visit Date (VISIT)
Screening (Day-28 to -1) / Rescreening	Informed Consent (CONSENT)
Screening (Day-28 to -1)	Demographics (DM)
Screening (Day-28 to -1) / Rescreening	Inclusion/ Exclusion Criteria Not Met (IE)
Adverse Event	Adverse Events Log (AELOG) Adverse Events (AE) (if applicable)
Device Events*	Device Events Log (DELOG) Device Events (DE) (if applicable)
Study Disposition	Disposition (DS)
Withdrawal of Informed Consent	Withdrawal of Informed Consent (CONSWD) (if applicable)
Death	Death Details (DD) (if applicable)

* Device Events are expected only if malfunctions occurred related to the collection of mandatory tumor tissue samples during screening visit. If Device events occurred along with AE/SAE, the AE/SAE forms are expected to be reported as well.
If the subject has experienced an SAE, all SAE related forms must also be completed.

Table 4: Additional Forms Required if Subject Has Experienced an SAE

Visit	Form
Serious Adverse Event	Serious Adverse Event Report (SERAE)
Adverse Event of Special Interest	AE of Special Interest (AESI) (if SAE is an AE of special interest)
Screening (Day-28 to -1)	General Medical History (1MH)
Screening (Day-28 to -1)	Surgical History (HISS)
Concomitant Medication	Prior and Concomitant Medications Log (CMLOG) Prior and Concomitant Medications (CM)
Concomitant Medication	Procedures (1PR) (if applicable for the SAE under report) **Note:** The 1PR form is dynamically added when "Were all eligibility criteria met?" is recorded as "Yes". For screen failure subjects who require a 1PR form due to an SAE, please follow the steps below: 1. Temporarily change "Were all eligibility criteria met?" to "Yes" to trigger the 1PR form and complete the required data entry.

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Visit	Form
	2. After the 1PR form has been completed, change "Were all eligibility criteria met?" back to "No" to accurately reflect the subject's screen failure status.

7 RESCREENING

Rescreened subjects to be assigned the SAME subject number as for the initial screening.

- As per protocol, subject may be rescreened a single time.
- Rescreened subjects to be assigned the SAME e-code for re-screening as for the initial screening.
- Rescreen folder will trigger as soon as rescreen transaction is completed in IRT system, enter all re-screening data into the rescreening folder.
- All assessments, with the exception of PD-L1 testing (if a valid result was obtained), must be repeated for rescreening unless they were carried out within 28 days of randomization.

For detailed information on rescreening, please refer to Section 5.4 of the CSP.

8 WOMEN OF CHILDBEARING POTENTIAL:

A woman is considered of childbearing potential (WOCBP), i.e. fertile, following menarche and until becoming post-menopausal unless permanently sterile. Permanent sterilisation methods include hysterectomy, bilateral salpingectomy and bilateral oophorectomy.

A postmenopausal state is defined as no menses for 12 months without an alternative medical cause. A high follicle stimulating hormone (FSH) level in the postmenopausal range may be used to confirm a postmenopausal state in women not using hormonal contraception or hormonal replacement therapy. However, in the absence of 12 months of amenorrhea, a single FSH measurement is insufficient.

Refer to CSP Appendix G for more details.

9 RANDOMIZED SUBJECTS WITHOUT TREATMENT

All randomized participants, regardless of whether they receive the study intervention, will follow the same follow-up process. Subjects randomized without receiving treatment will have the same data collection requirements as those who are treated.

Table 5 Randomized Without Treatment CRF Forms

Not applicable for this study.

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10 POPULATING DYNAMIC FOLDERS/ FORMS

Certain RAVE folders and forms are only made available if applicable. These 'triggered' folders and forms are described below.

The following folders are available in EDC as soon as the subject is enrolled:

- Screening (Day-28 to -1),
- Adverse Event,
- Study Disposition
- Device Events
- Investigator Review
- Baseline RECIST
- Follow Up RECIST (ONLY applicable when subject is randomized)

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Table 6 Additional Forms and Visits Triggered

Trigger Condition	Triggered Folders/ Forms	Notes
Enrolment code (SUBJECT) is integrated by IxRS in ENROL form	Folders/ forms below are added: • Screening folder: VISIT, CONSENT, DM, IE. • Adverse Event folder: AELOG • RECIST folder: Baseline and Follow up RECIST. • Study Disposition folder: DS. • Device Events folder: DELOG	**Device Events folder:** This folder is exclusively used to report malfunctions related to mandatory screening tumor tissue sample collection.
Adverse Events Log (AELOG) form: When 'Yes' is selected.	It will trigger AE form in the same Adverse Event folder.	
"What was the contact mode?" is entered in Screening folder.	Folders/ forms below are added: Concomitant Medications folder: CMLOG	
Prior and Concomitant Medications Log (CMLOG) form: When 'Yes' is selected.	It will trigger CM form in the same Concomitant Medications folder.	
'Were all eligibility criteria met?' is answered as 'Yes' in IE form at Screening or Rescreening.	Folders/ forms below are added: • Concomitant Medication folder: 1PR • Screening or Rescreening folder: ICFGEN	

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Trigger Condition	Triggered Folders/ Forms	Notes
"Was Subject allocated a randomization code?" is answered as 'Yes' in IE1 form at C1D1 folder.	Folders/ forms below are added: • C1D1 folder: VISIT, CONT • Administration and Discontinuation of IP folder: EC1, EC2	
"What was the group allocation?" is integrated in 'GROUP' form under C1D1 folder.	Either of below form will be added in Administration and Discontinuation of IP folder: • EC, or • EC3	
"Does Subject continue in next visit?" in CONT1 form is recorded as 'Yes' in current folder from C1D1 Visit and onwards.	Next cycle/visit folder is added.	
In routine visit folders, if on VISIT form "Visit date" is entered and "Visit not done" is empty.	Assessment(s) Performed Triggering Form (ASMTRIG) is added in current visit folder.	Refer to **Table 7** for the list of forms that can be triggered by ASMTRIG in each visit folder.
"Was there recurrence after curative intent resection of BTC?" is selected as "Yes" on DISEXT form.	PATHGEN (Pathology at time of initial diagnosis of early stage BTC) form is added at Screening folder.	
On ICFGEN form in Screening or Rescreening folder, if "What was the genomics initiative informed consent date?" is entered, and "Optional consent/assent obtained" is answered as 'Yes'	SPCGB form triggers in C1D1	Except for site in China, Brazil, Belgium, Netherlands, Taiwan, Turkey
Hepatitis B Surface Antigen (Qual) (HBsAg) (Blood) OR Hepatitis B Core Antibody, Qual (anti-HBc) (Blood) OR Hepatitis C Antibody (HCV ab) (Blood) is selected as "Positive" in LB7 form.	Non-central Laboratory Test Results - Hepatitis B and C testing (LB13) is triggered in C1D1 and onwards.	
"Was this the last dose of study drug given?" is "Yes" in EC/EC1/EC2/EC3 form.	ETRT/ERTR1/ETRT2/ETRT3 form in the Administration and Discontinuation of IP folder is triggered.	
"What was the date when the decision was made to permanently discontinue study treatment?" is not blank for ETRT / ETRT3 and ETRT1 and ETRT2	1) End of Treatment folder is added with VISIT form; 2) Post Cancer Therapies and Radiotherapies folder is added with below subfolders and forms:	

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Trigger Condition	Triggered Folders/ Forms	Notes
	• Post IP Discontinuation Cancer Therapies sub-folder: CAPRX1, • Post IP Discontinuation Radiotherapies sub-folder: CAPRXR2, • Surgery for Subsequent Anticancer Therapy sub-folder: 1PR1.	
"What is the date of the visit?" is entered and "Visit not done" is blank in the End of Treatment folder	Post-treatment 90 Days Safety follow-up (PTFU90) folder is triggered	
"What is the date of the visit?" is entered, and "Visit not done" is blank in the Post-treatment 90 Days Safety follow-up folder	Survival follow-up (SFUP) folder is triggered, which contains the following forms: • PFS following disease recurrence (PFS2) • Survival Status (SURVIVE)	
"What is the sex of the Subject?" is integrated from IxRS as 'Female' in Demographics (DM) form at Screening	PREG form will be triggered in Screening, Re-Screening, C1D1, C2D1, C3D1, C4D, C5D1, C6D1, C7D1, C8D1, CXD1, EOT, PTFU90 folders	
"Sex" is selected as 'Female' in DM form in the Screening folder	Pregnancy Test (PREG) forms at all corresponding folders are present	
"Pregnancy Test" is 'Positive' in any form	Pregnancy Report (PREGREP) folder is present	
"New equivocal lesion present?" is reported as "Yes" in RECIST2 form and VISIT form on RECISTFU folder is not blank.	NLESADD form triggers in RECISTFU folder	
'Serious' is selected as 'Yes' in AE form	Serious Adverse Event Report (SERAE) form with derived AE number and AE name are added to Serious Adverse Event folder on the left menu	
"Is this AE of Special Interest?" is selected as 'Yes' for the applicable AE and the corresponding "Adverse event of special interest category" is selected.	AE of special Interest (AESI) folder is added. AESI form is part of this folder with AE number reported in form name for each AE recorded as of special interest	
If "Is this an AE of Special Interest?" in AE form is recorded as Yes and	Interstitial Lung Disease folder is added with below forms: • Visit Date (VISIT)	

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Trigger Condition	Triggered Folders/ Forms	Notes
an “Adverse Event category” is **Potential pneumonitis**	• Pulmonary Function Test (PULMOA) • Non-central Laboratory Test Results - Interstitial Lung Disease (LB9) • Interstitial Lung Disease (ILDIS)	
If “Is this an AE of Special Interest?” in AE form is recorded as Yes and an “Adverse Event category” is **Cytokine release syndrome**	Cytokine release syndrome folder is added. A Cytokine release syndrome Assessment folder is part of this folder for each AE recorded as Cytokine release syndrome. Below forms are part of this folder: • CRS Signs and Symptoms (CRSSS) • CRS (Cytokine Release Syndrome) ASTCT Criteria (CRASTCT)	Cytokine release syndrome Assessment folder name is automatically updated with corresponding AE number to easily identify it. NOTE: for each Cytokine release syndrome event, AESI form must be filled in along with the forms part of CRS assessment
If “Adverse event of special interest category” is selected as “**Infusion Related Reaction Including Anaphylaxis”**	Infusion Related Reaction TQS (IRRTQS) form is added in AESI folder	
“Any additional laboratory investigations performed?” is selected as “Yes” in AESI form	Trigger corresponding AESIA form in AE of Special Interest folder	
If “Any additional laboratory investigations performed?” In AESI form is recorded as Yes	Additional Laboratory Evaluations (LABADD) form is added in AESI folder	One LABADD is added for all AESIs. Record a log line for each Lab test performed for AESIs
“Reason for study treatment discontinuation” on DS form is selected as “Death”, or “Outcome” on AE form is selected as “Death”, or “Death” is selected as “Yes” on SERAE form.	Death folder is added with Death Details form populated.	
Any item(s) is selected in Unscheduled Visit (UNS_VIS) form at Unscheduled Visit folder	Corresponding form(s) to be present under Unscheduled Visit folder accordingly.	Refer to section 12 for the list of forms available to be selected at Unscheduled Visit.

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NOTE: If data is changed from 'Yes' to 'No' for the primary field, the secondary fields/ forms/ folders is automatically set to hidden and not visible anymore to the site. However, if the data has been entered into the triggered form/folder, the form/folder will remain visible. Follow below steps to remove the previous entries:

- Change back the response from 'No' to 'Yes' on the primary field.
- Remove the data entered in the secondary fields as appropriate.
- Change the response from 'Yes' to 'No' on the primary filed, and the secondary filed will be blank and hidden again.

Table 7 Forms Activated by ASMTRIG

NOTE: Use this form to trigger CRFs for the assessments completed at the visit.

In order to populate the list of forms populated on this form, below data fields on VISIT form must be completed in the corresponding folder:

- "What is the date of the visit?" is entered
- "Visit not done" is empty

Please refer to section 15.1.13 for the detailed instructions of data entry for ASMTRIG forms.

Visit	Forms applicable in ASMTRIG list
Screening (Day-28 to -1)	• DISEXT, • 1MH, 2MH, • HISS, PATHGOM, • SU_NIC, SU_ALC, • PE, VS, ECOG, ECHOC • EG, EG1,EG2, • LB, LB1, LB2, LB3, LB4, LB6, LB7, LB10, LB11, • SPCBEDT1, • CAPRX, CAPRXR
Rescreening	• PE, VS, ECOG, ECHOC, • EG, EG1, EG2 • LB, LB1, LB2, LB3, LB4, LB6, LB7, LB10, LB11, • SPCBEDT1
C1D1	• PE, VS1, VS2, ECOG, EG • LB, LB1, LB2, LB3, LB4, LB5, • SPCBEDB1 • SPCBEDB, SPCPKB, SPCPKB1 (Rilvegostomig arm ONLY) • SPCBEDB2 (not available for Brazil sites) • SPCBEDB3, SPCBEDB4 (not available for China or Brazil sites)

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Visit	Forms applicable in ASMTRIG list
C1D8	• VS3, ECOG, • LB, LB1, • SPCBEDB2, SPCBEDB3, SPCBEDB4 (not available for China or Brazil sites)
C2D1	• PE, VS1, ECOG, • LB, LB1, LB3, LB4, LB5, • SPCBEDB, SPCPKB (Rilvegostomig arm ONLY) • SPCBEDB2 (not available for Brazil sites) • SPCBEDB3, SPCBEDB4 (not available for China or Brazil sites)
C2D8, C3D8, C4D8, C5D8, C6D8, C7D8, C8D8	• VS3, ECOG • LB, LB1
C3D1	• PE, VS1, ECOG, • LB, LB1, LB3, LB4, LB5, • SPCBEDB1, SPCBEDB2, SPCBEDB3, SPCBEDB4, SPCBEDT (not available for China or Brazil sites)
C4D1	• PE, VS1, ECOG, • LB, LB1, LB3, LB4, LB5 • SPCBEDB, SPCPKB, SPCPKB1 (Rilvegostomig arm ONLY)
C5D1	• PE, VS1, ECOG, • LB, LB1, LB3, LB5, • SPCBEDB2 (not available for China or Brazil sites)
C6D1	• PE, VS1, ECOG, • LB, LB1, LB3, LB5, • SPCBEDB, SPCPKB (Rilvegostomig arm ONLY) • SPCBEDB1 (not available for China or Brazil sites)
C7D1	• PE, VS1, ECOG, • LB, LB1, LB3, LB4, LB5
C8D1	• PE, VS1, ECOG, • LB, LB1, LB3, LB5
CXD1 (includes C10D1, C14D1)	• PE, VS1, ECOG, LB, LB1, LB3, LB5
C10D1, C14D1	• SPCBEDB, SPCPKB (Rilvegostomig arm ONLY)
End of Treatment	• PE, VS4, ECOG, ECHOC, • LB, LB1, LB3, LB6, • SPCBEDB6 (not available for Brazil sites) • SPCBEDB5, SPCPKB2 (Rilvegostomig arm ONLY) • SURVIVE
Post-treatment 90 Days Safety follow-up	• PE, VS4, ECOG, • LB, LB1, LB3,

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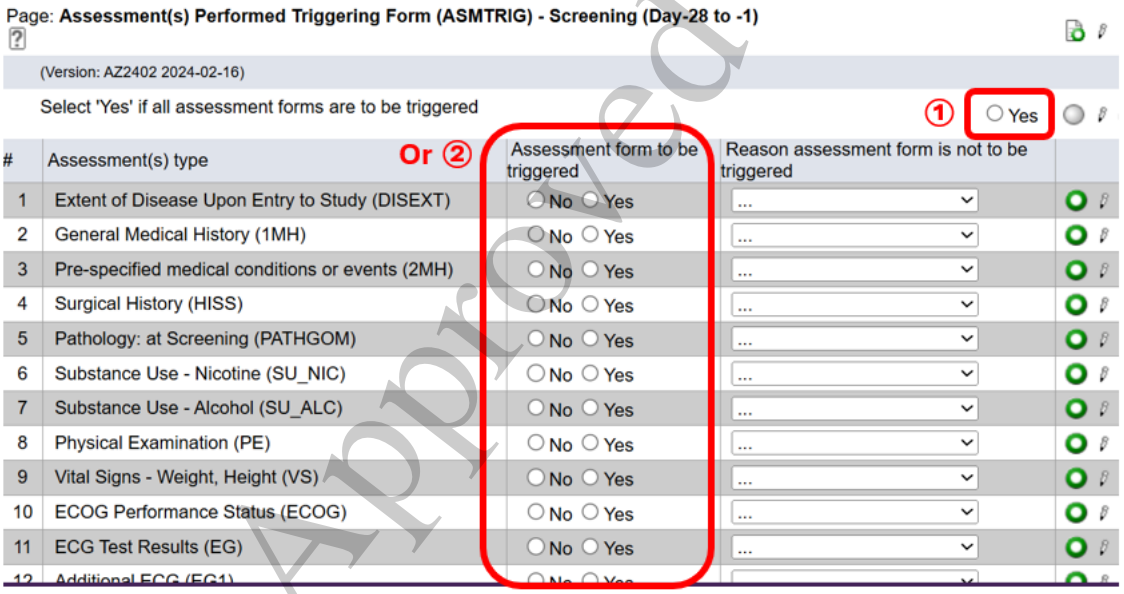
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Visit	Forms applicable in ASMTRIG list
	• SPCBEDB5, SPCPKB2 (Rilvegostomig arm ONLY) • SURVIVE

Example of ASMTRIG form:

Assessments on this form can be selected in two ways:

- ① **All at once**: Set “Select 'Yes' if all assessment forms are to be triggered” to ‘Yes’.
- ② Individually: Mark each assessment from the log form as ‘Yes’ one by one.



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11 ADD EVENT FUNCTION

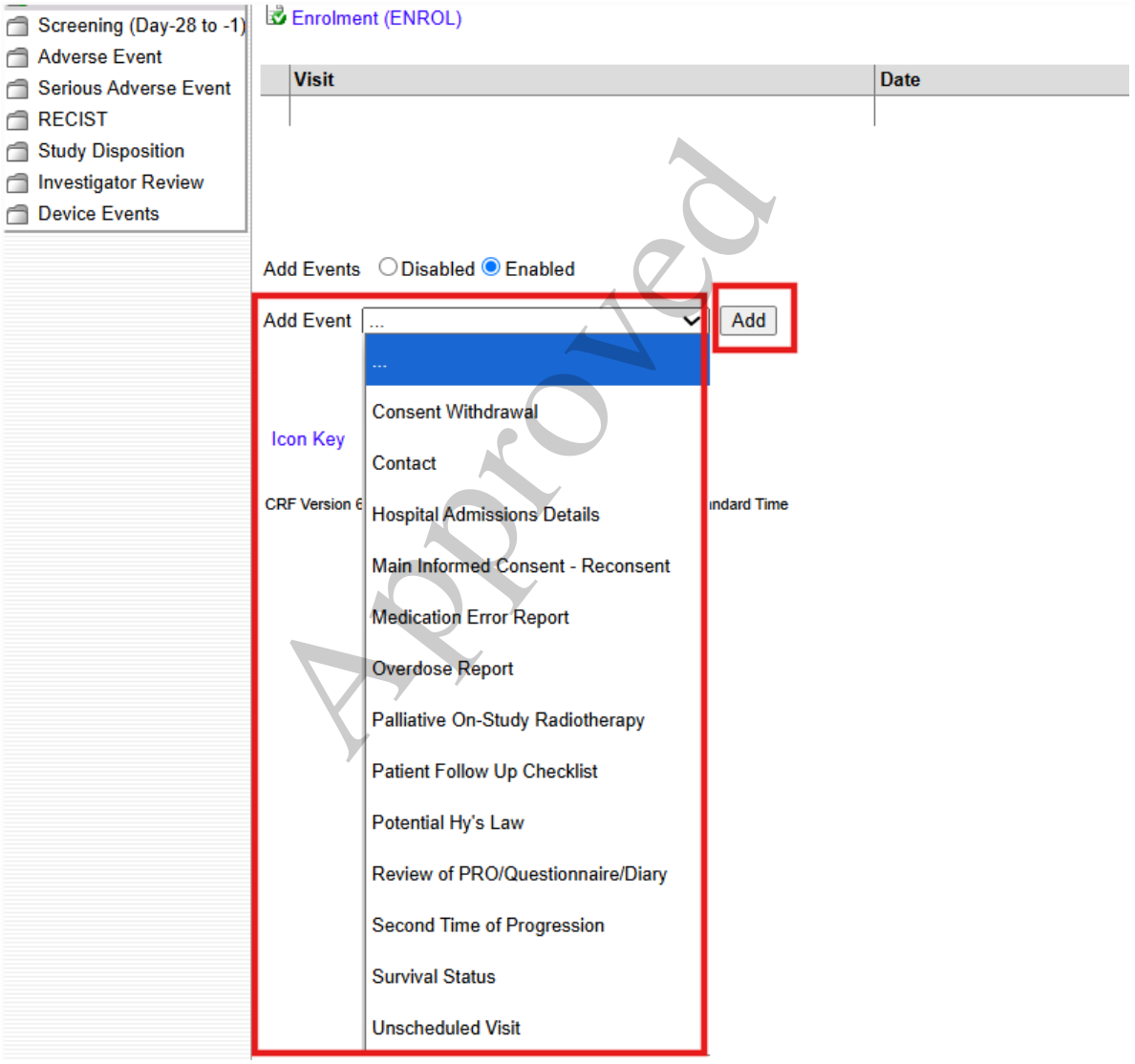
Several forms/ visits can be added manually in Rave. These include:

- Consent Withdrawal
- Contact
- Hospital Admissions Details
- Main Informed Consent – Reconsent
- Medication Error report
- Overdose Report
- Participant Follow Up Checklist (PFU)
- Palliative On-Study Radiotherapy
- Potential Hy's Law

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- Review of PRO/Questionnaire/Diary (REVPRDI)
- Second Time of Progression (PFS2)
- Survival Status (SURVIVE)
- Pregnancy Test
- Unscheduled Visits

These forms/ visits can be added to a subject by selecting the form/ visit from the 'Add Event' drop-down menu at the main area at Subject level:



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12 UNSCHEDULED DATA

Unscheduled data can only be added if specified in the Clinical Study Protocol (CSP).

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The following forms can be added for unscheduled data (refer to *UNS_VIS* form instructions for details):

- Physical Examination (PE)
- Vital Signs (VS4)
- ECOG Performance Status (ECOG)
- ECG Test Results (EG)
- Echocardiography (ECHOC)
- Pregnancy Test (PREG1)
- Non-central Laboratory Test Results - Chemistry (LB)
- Non-central Laboratory Test Results - Hematology (LB1)
- Non-central Laboratory Test Results - Coagulation (LB2)
- Non-central Laboratory Test Results - Thyroid function test (LB3)
- Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
- Non-central Laboratory Test Results - CA-19-9 and CEA (serum)(LB5)
- Non-central Laboratory Test Results - Urinalysis (LB6)
- Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
- Non-central Laboratory Test Results - Hy's Law (LB8)
- Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
- Non-central Laboratory Test Results - Tuberculosis testing (LB10)
- Non-central Laboratory Test Results - HIV testing (LB11)
- Non-central Laboratory Test Results - Additional Chemistry (LB12)
- Sample Collection, Predose_ADA Sample (SPCBEDB)*
- Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1) **
- PBMC for immune profiling_Pre dose (SPCBEDB2) **
- Whole blood for RNA analysis_Pre-dose (SPCBEDB3) **
- Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4) **
- Sample Collection, ADA Sample (SPCBEDB5)*
- Blood sample for plasma ctDNA (SPCBEDB6)
- Genomics Initiative (optional), exploratory genetic sample (SPCGB) ***
- Optional on study tumor sample (SPCBEDT) **
- Biological Sample Collection, PK (SPCPKB2)*

NOTE:

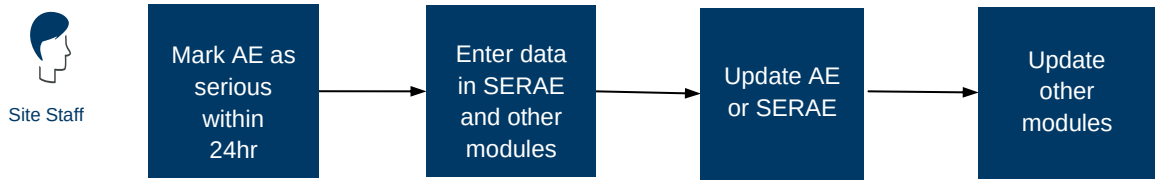
* PK/ ADA sample collection forms are available for Rilvegostomig arm ONLY;
** These sample collection forms are not available for sites in China or Brazil;
*** SPCGB form is not available for sites in China, Brazil, Taiwan, Denmark, Turkey, Belgium, Norway, Chile, The Netherlands.

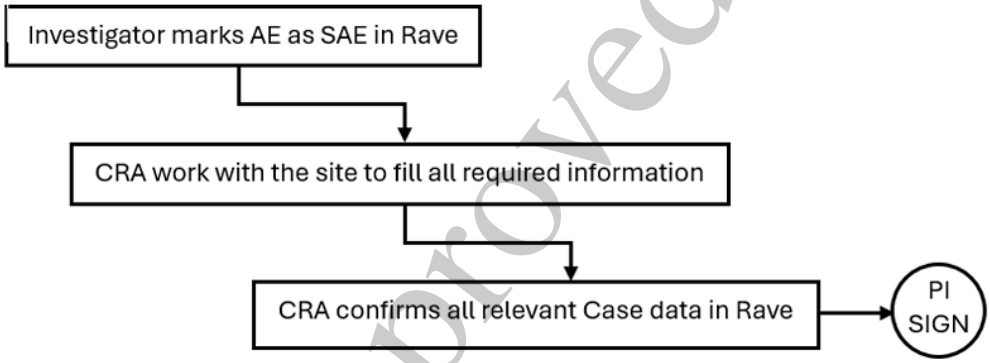
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13 SAE REPORTING

A serious adverse event that occurs during the study, whether or not it is considered related to the investigational product, must be reported by investigator to AstraZeneca or their designee no later than 24 hours from when site staff became aware of the serious adverse event (preferably immediately, but not later than 24 hours).





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For Site Staff

When an adverse event is entered into the eCRF on the Adverse Event (AE form), marked as serious='Yes' and the 'Save' button has been pressed, the following occurs:

- A Serious Adverse Event Report (SERAE) alert e-mail is automatically generated and sent to SAE Study Representative.
- A Serious Adverse Event Report form (SERAE form) is auto triggered into the Serious Adverse Events folder on the left menu.
- Site staff complete the SERAE form by entering all additional information regarding the SAE on this form. A completed SERAE form must be entered into the eCRF within 24 hours. This is then transmitted to the relevant Patient Safety Data Entry Site.

Make sure that the following supportive forms are up to date:

- Demographics (DM)

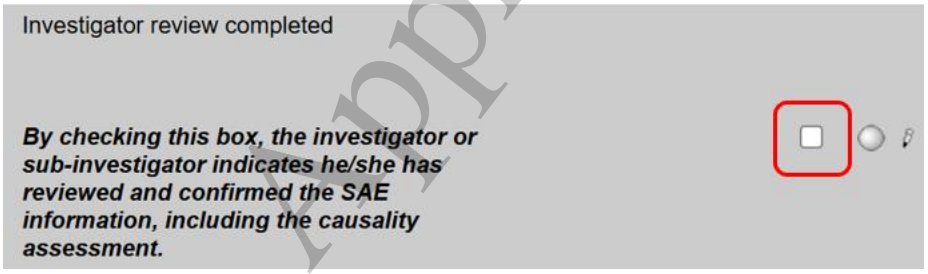
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- Medical History (MH)
- Surgical History (HISS)
- Adverse Events (AE)
- Exposure (EC) (for randomized/ dosed subjects)
- Hy's Law forms - if applicable
- Overdose Report (OVERDOSE) – if applicable
- Pregnancy Report (PREGREP) – if applicable
- Device Events (DE) – if applicable

If new or updated information is available site staff enters the information on the AE/SAE forms and save the forms. SAE term is triggered automatically by the AE form, hence update information on the AE form as applicable.

NOTE: Follow-up information must be entered immediately or no later than 24 hours from the time at which the site staff becomes aware of the new information.

NOTE: The checkbox "**Investigator review completed**" on SERAE form is required to be completed by the site investigator or sub-investigator. This checkbox indicates he/she has reviewed and confirmed the SAE information, including the causality assessment. Please make sure the review is completed, and box is checked within 10 days from SAE reporting date and/or within 10 days of any change on causality assessment.



NOTE: If the eCRF is not available (e.g., EDC system is down), contact the Sponsor Study Representative by telephone for guidance within one calendar day, AND provide a paper back-up Serious Adverse Event report (available in the Principal Investigator's Study File) to the Sponsor Study Representative immediately. The site is responsible for completing all appropriate forms as soon as the eCRF becomes available again.

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14 ELECTRONIC SIGNATURE

It is the Investigator's responsibility to have oversight of the study data by reviewing eCRF data on an ongoing basis. Electronic signatures are captured to attest that all data, including any changes or corrections, within the eCRF have been reviewed and are deemed accurate and complete in the EDC. Electronic signatures are legally binding and passwords or Personal Identification Numbers (PIN) and it must not be shared.

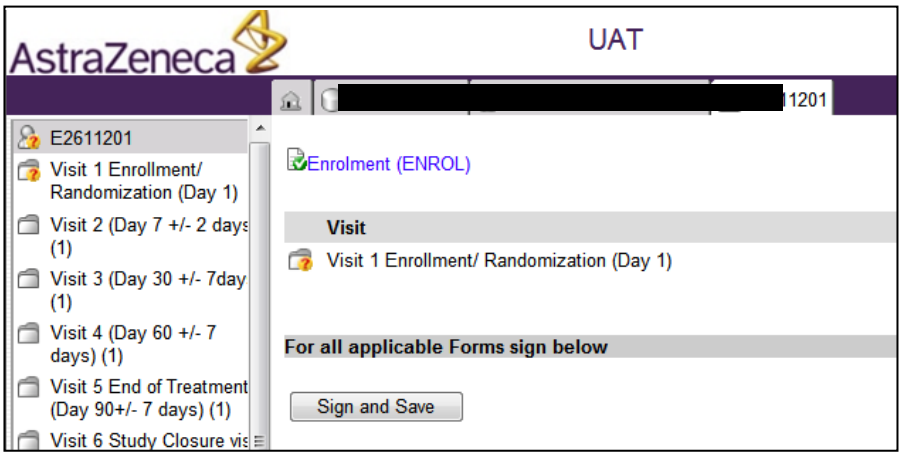
- *From the Study 'Home Page', expand the 'Requiring Signature' toggle.*
- *Navigate to the subject's home page and select the 'Sign and Save' button.*
- *Enter username and password credentials and select the 'Sign and Save' button.*
- *The Signature is applied successfully when 'Signature attempt was successful' message is displayed.*
- *One overall sign-off of the entire eCRF is required*.
- *For studies with interim clinical data locks for interim analysis/ primary analysis purposes, the data identified as required in the DMP must be signed prior to being used for any regulatory approval submission. (The DMP is updated and this section is added for each identified IA/PA.)*
- Any changes to a previously signed form will 'break' the signature and require the changed form to be re-signed. The signature is only broken on the specific form, thus only this form/subject requires re-signing.
- Investigators will sign off on each patient's entire eCRF at the end of the study (i.e., at the time of final database lock), before the eCRF for the patient is locked. The Investigator may be asked by the Study Team to sign eCRF pages during the study, on an interim basis (i.e., at the time of interim analysis) or if regular eCRF signature is required by local health authorities. Instructions on electronic signature will be provided from the Study Team.

Investigator can enter the Signature in RAVE as described below:

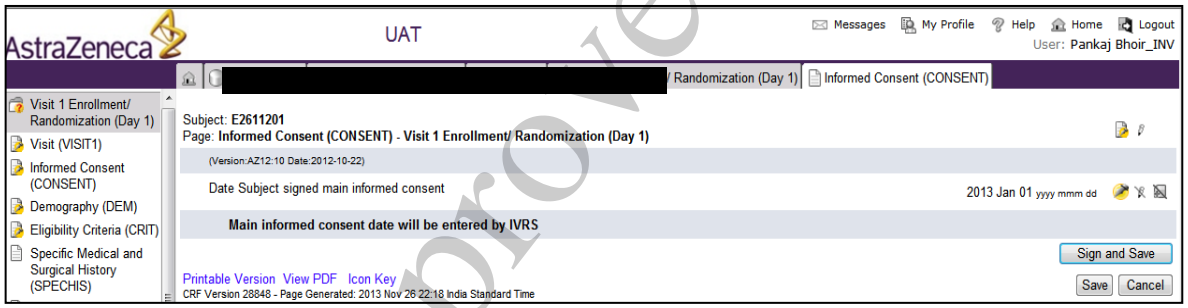
- **Subject Level** – If Signature is entered at this level, it will be applicable to all the entered forms.

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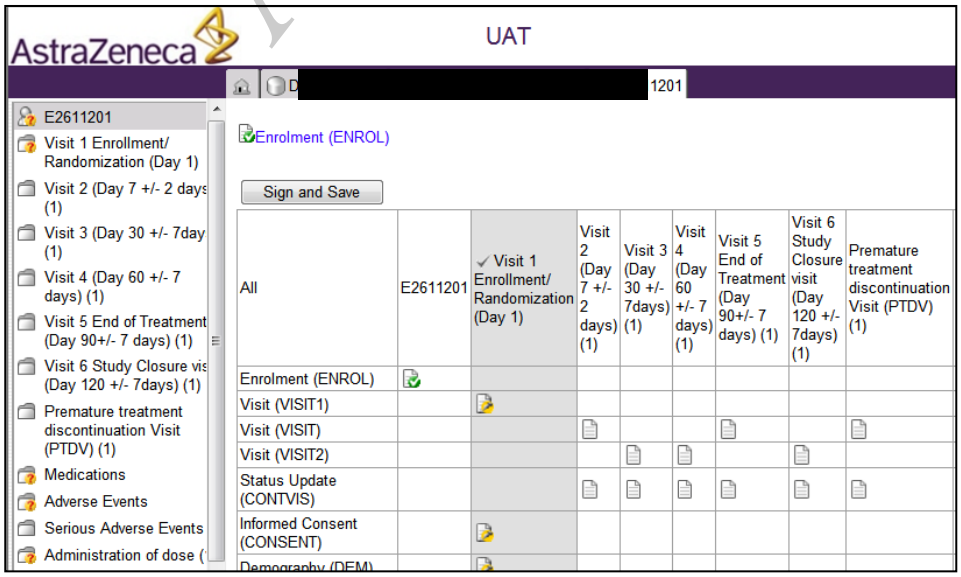
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- **Form Level –** If Signature is entered at this level, it will be applicable only to that form.



- **Grid View Level/ Batch Level functionality** – This level gives provision to select individual folder and enter the signature. In this case, the signature will be applicable to only those forms which are present under that folder.

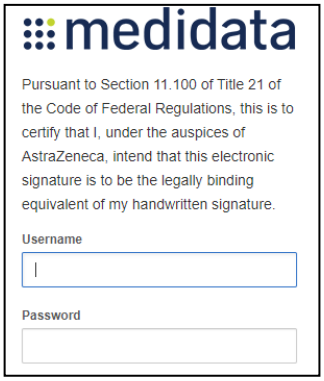


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Entering the Signature

Once ‘Sign and Save’ button is clicked, a pop-up window will appear displaying Investigator’s declaration before signing the data.



The Investigator enters the Password of his/her RAVE account to confirm the signature once. The ‘Sign and Save’ button is clicked, a pop-up window will close and the signature will become applicable to all the pages with data entered.

Once the Principal Investigator Signature is applied, the signature cannot be manually removed if signed in error. Therefore, it is very important that all information is confirmed correct before signature is applied.

15 FORM LEVEL ECRF INSTRUCTIONS

RAVE eCRF instructions are included below and can also be viewed by clicking the question mark icon beside the header of every RAVE form. Please refer to the Guidance doc for uploading this in RAVE.

15.1 FORM LEVEL INSTRUCTIONS

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15.1.1 ENROLMENT (ENROL)

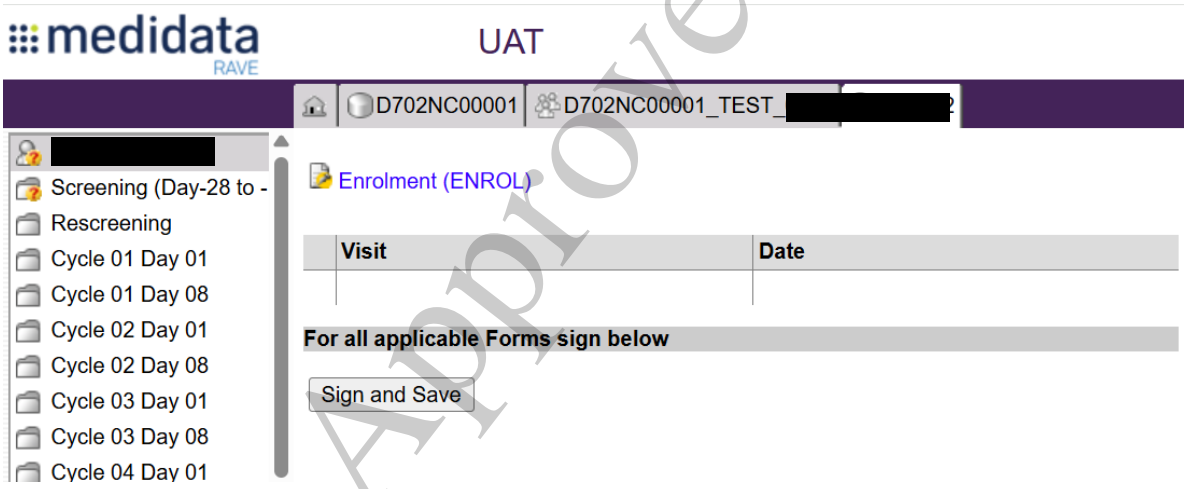
This field should be integrated from IxRS automatically into RAVE, therefore there is no need to record any data.

What is the enrolment code?
The enrolment code, assigned to this Subject, will be loaded into RAVE from the IxRS system.

What is the study code?
The study code, “D702NC00001” will be loaded into RAVE from the IRT system.

Sign and Save functionality
Investigators can enter the Signature in RAVE as mentioned below.

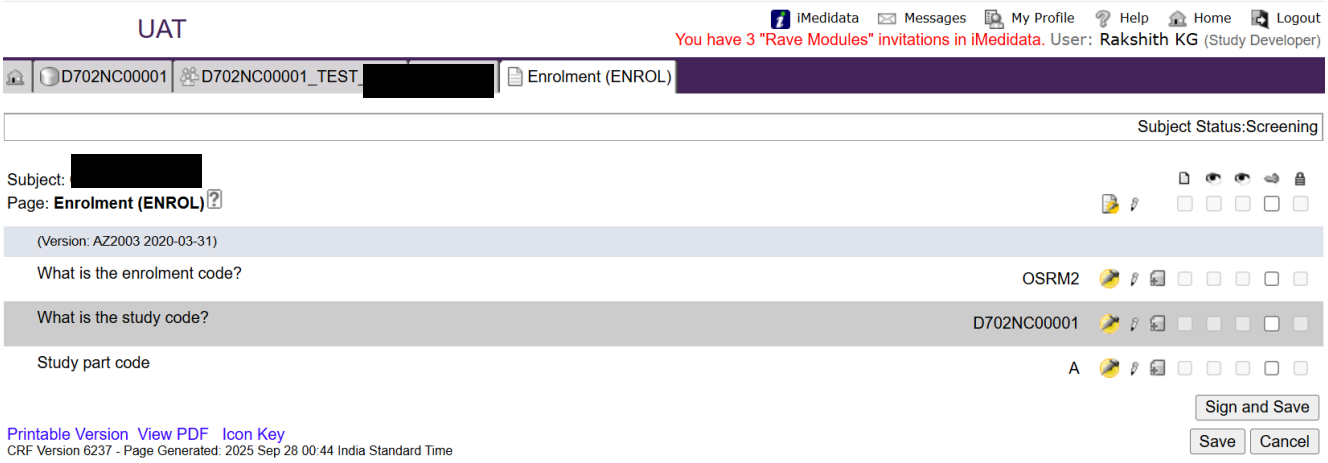
Subject level: If Signature is entered at this level it will be applicable to all the entered forms



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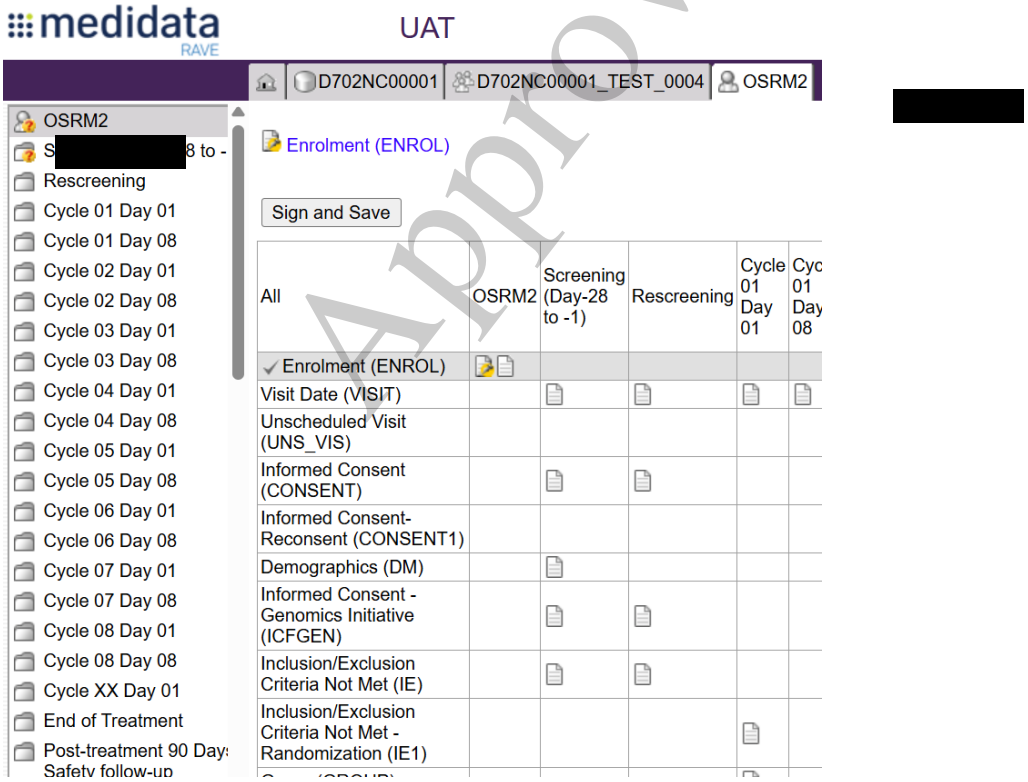
Form level: If Signature is entered at this level, it will be applicable only to that particular form.

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Grid View level/ Batch level functionality:

This level gives provision to select individual folder and enter signature. In this case signature will be applicable to only those forms which are present under that particular folder.



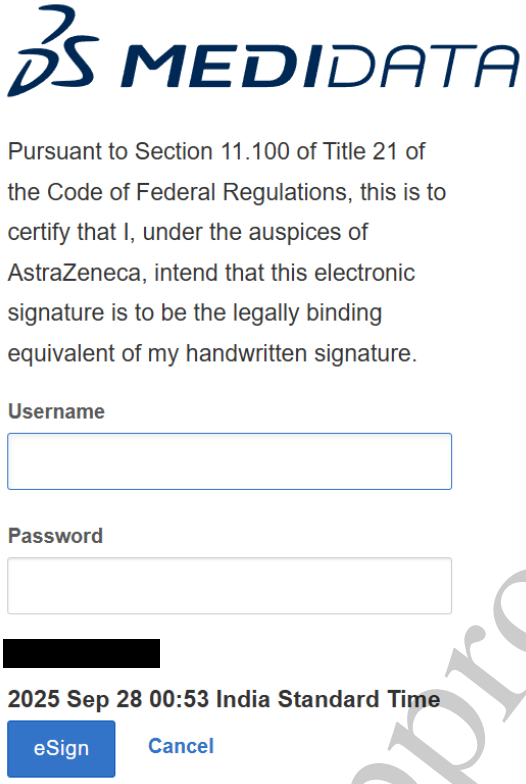
Entering the signature:

Once Sign and Save button is clicked Pop-up window will appear displaying Investigator's declaration before signing the data.

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The investigator should enter the Password of his/her RAVE account to confirm the Signature once Sign and Save button is clicked Pop up window will get closed and signature will become applicable to all the pages with data entered.



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15.1.2 GROUP (GROUP)

This form is automatically entered by IxRS.

What was the group allocation?
Automatically integrated by IxRS with one of the available options (*Experimental arm (Rilvegostomig); Control arm (Durvalumab)*). No data entry required.

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15.1.3 VISIT DATE (VISIT)

Adverse event should be reviewed at every visit, every day during a multiple day visit. All Adverse events previously reported must be followed up and updated if applicable.

Note for C1D1 folder:

- Please complete **IE** form first, when **'Yes'** is selected for 'Were all eligibility criteria met?' and the form is saved, the **VISIT** form will automatically appear in the **C1D1** folder.
- After entering the **Visit Date** in the Visit folder (and leaving **'Visit not done'** blank), the **ASMTRIG** form will then be generated in C1D1 folder.

Note: If the visit was not done due to global/country situation "**Visit was impacted by global/country situation**" should be recorded.

What is the date of the visit?
Record the [date/start date] of the visit using YYYY-MON-DD format (for example 2000-JAN-01).

Note*: the date of visit of below visits are derived from IVRS integration. The dates are not editable in EDC. If the date is incorrect, please contact IVRS (Signant Health) helpdesk for correction:*

- Screening
- Re-screening

Note:

- For Treatment Cycles, please enter Dosing date as visit date if dosing is performed.
- For RECIST visits where multiple scans were done, then site should enter earlier scan date as visit date in eCRF. *E.g.: For Follow-up 1 (Week 6) RECIST, 2 Scans were done on 1st Jan 2020 and 2nd Jan 2020 respectively, then please record Follow-up 1 RECIST visit date as 01 JAN 2020 (earliest scan date).*

What was the contact mode?
Indicate how the visit was performed by selecting an appropriate option: *Remote-audio* (phone call with subject)*; Remote-video* (video call with subject); *On-site visit* (on-site visit with subject)*; Other.*

If Other, specify
Record the appropriate response if Contact mode is selected as '**Other'**.

Visit was impacted by global/country situation
If visit was impacted by global/country situation (i.e. epidemic/pandemic, healthcare crisis, natural disaster etc.) record '*Yes*'. Otherwise leave this field blank.

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Visit not done
Record '*Yes'* if the visit was not performed.

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15.1.4 INFORMED CONSENT (CONSENT)

What was the Protocol milestone?
This is a pre-populated field with a default value of "*Main Informed Consent*". No data entry required.

What was the main informed consent date?
The date signed main informed consent will be integrated through IRT.

What was the Protocol milestone?
This is a pre-populated field with a default value of "*Optional Consent*". No data entry required. The protocol version must be entered as an integer (whole number) without decimal notation (e.g., enter 1 instead of 1.0).

Ensure that the Subject Written Information and Consent for the Main Study is dated and signed off by Subject before any study specific procedures are started.

Optional consent category
This is a pre-populated field with pre-defined default values mentioned below. No data entry required.

1. Participation to Optional Blood Tests;
2. Participation to Optional Biopsy at first day of Cycle 3 of study treatment;
3. Participation to Optional Biopsy at Cancer Progression;
4. Optional services and the transfer of contact details to service providers;
5. Use of coded data (including images), biosamples and analysis of genetic information as required for future research.

Optional consent/assent obtained
Record the appropriate option (*No; Yes; Not applicable*) indicating whether optional consent was signed by Subject. Record 'Not Applicable' for each consent category for which due to country regulation or law restriction consent cannot be obtained by the Subject.

Optional consent date
If applicable, record the date of Optional consent/assent obtained using this format YYYY-MON-DD (for example 2000-JAN-01).

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15.1.5 INFORMED CONSENT- RECONSENT (CONSENT1)

This form can be accessed through the *ADD EVENT* menu. It should be completed whenever a subject is re-consented upon randomized in the study.

What was the Protocol version?
Record the version of main protocol for which Subject signed main informed consent. The protocol version must be entered as an integer (whole number) without decimal notation (e.g., enter 1 instead of 1.0).

What was the Protocol milestone?
This is a pre-populated field with a default value of "*Main Informed Consent*". No data entry required.

What was the main informed consent date?
Record the date of Informed Consent for the reconsent using this format *YYYY-MON-DD* (for example 2000-JAN-01).

What was the Protocol milestone?
This is a pre-populated field with a default value of "*Optional Consent*". No data entry required.

Ensure that the Subject Written Information and Consent for the Main Study is dated and signed off by Subject before any study specific procedures are started.

Optional consent category
This is a pre-populated field with pre-defined default values mentioned below. No data entry required.

1. Participation to Optional Blood Tests
2. Participation to Optional Biopsy at first day of Cycle 3 of study treatment
3. Participation to Optional Biopsy at Cancer Progression
4. Optional services and the transfer of contact details to service providers
5. Use of coded data (including images), biosamples and analysis of genetic information as required for future research

Optional consent/assent obtained
Record the appropriate option (*No; Yes; Not applicable*) indicating whether optional consent was signed by Subject. Record 'Not Applicable' for each consent category for which due to country regulation or law restriction consent cannot be obtained by the Subject.

Optional consent date
If applicable, record the date of Optional consent/assent obtained using this format YYYY-MON-DD (for example 2000-JAN-01).

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15.1.6 DEMOGRAPHICS (DM)

Demographics form must be filled in for all enrolled Subjects.

What is the Subject's date of birth?
Value will be populated from the IRT system.

What is the Subject's age?
Value will be populated from the IRT system.

What is the age unit used?
Value is pre-populated as *Years*

What is the sex of the Subject?
Value will be populated from the IRT system.

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?
Record the appropriate option *(Hispanic or Latino; Not Hispanic or Latino; Not reported).*

Race - select all that apply:

Which racial designation best describes you?

Record the appropriate option(s) *(Black or African American; Native Hawaiian or other Pacific Islander; American Indian or Alaska Native; Asian; White; Not reported; Other).*
More than one choice is acceptable.

Geographical origin does not necessarily refer to the individual Subject’s place of birth but to the geographical origin of his/her group. A Japanese person, even if second or third generation American, still belongs to the Asian race category.

NB: FDA definitions of above races can be found below:

Black or African American
A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."

Native Hawaiian or other Pacific Islander
Denotes a person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands. The term covers particularly people who identify themselves as part-Hawaiian, Native Hawaiian, Guamanian or Chamorro, Carolinian, Samoan, Chuu.

American Indian or Alaska Native
A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.

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Asian
A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.

White
Denotes a person with European, Middle Eastern, or North African ancestral origin who identifies, or is identified, as White.

Other
Different than the one(s) previously specified or mentioned.

What was the Other race?
If 'Other' was recorded, a specification must be given.

NB: If any change(s) in this form after an SAE has been reported, please ensure that the updated information has been made available immediately to AstraZeneca (contact Monitor).

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15.1.7 INFORMED CONSENT - GENOMICS INITIATIVE (ICFGEN)

What was the Protocol milestone?
This field is pre populated “Genomics Initiative Informed Consent”

What was the genomics initiative informed consent date?
Record the date of Genomics Initiative Informed Consent as defined in the protocol using this format YYYY-MON-DD (for example 2000-JAN-01).

Optional genomic initiative consent
This is pre populated “Use of coded data and biosamples for optional multi-omics research including the analyses of genomic information”

Optional consent/assent obtained
Record the appropriate option *(No; Yes; Not applicable).*

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15.1.8 INCLUSION/EXCLUSION CRITERIA NOT MET (IE)

This form populates in Screening (Day-28 to -1) or Rescreening folder.

Were all eligibility criteria met?
Record "*Yes*", "*No*" or "*Not Applicable*" as appropriate.

Record 'Yes' if all eligibility criteria were met at the time the Subject was enrolled.

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

If 'No', if the Subject was not eligible, record **Exception criterion identifier** for each **Criterion type** that was an exception *(Exclusion; Inclusion).*

Inclusion criteria identifier
Refer to section 5.1 of the protocol for addition details on Inclusion Criteria for Screening.
Select data from the dropdown list: *1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14.*

Exclusion criteria identifier
Refer to section 5.2 of the protocol for addition details on Exclusion Criteria. Select data from the dropdown list: *1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11a, 11b, 11c, 11d, 11e, 11f, 11g, 11h, 12a, 12b, 12c, 12d, 12e, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28.*

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

Scenario 1: If Subject complied with all inclusion/exclusion criteria, please complete Randomization form.

Scenario 2: If Subject completed inclusion/exclusion criteria assessment and before randomization decided to withdrawn consent or died, then record:

- On Inclusion/Exclusion Criteria Not Met (IE) form: Report "***Were all eligibility criteria met?"*** with '***Yes'***
- Disposition (DS) form: Update "***What was the Subject's status?"*** *as* '***Withdrawal by Subject***' or '***Death'*** (which applicable)

Scenario 3: If the Subject was in the middle of the screening assessment when the Subject decided to withdraw from the study, record:

- On Inclusion/Exclusion Criteria Not Met (IE) form: Report "***Were all eligibility criteria met?"*** as '***Not applicable'***, with no log line reported.
- Disposition (DS) form: Update "***What was the Subject's status?"*** as ***'Withdrawal by Subject'***.
- Withdrawal of Informed Consent (CONSWD) form: details are expected to be reported.

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Scenario 4: If the Subject was in the middle of the screening assessment when the Subject died, record:

- On Inclusion/Exclusion Criteria Not Met (IE) form: Report "***Were all eligibility criteria met?"*** as '***Not applicable'***, with no log line reported.
- Disposition (DS) form: Update "***What was the Subject's status?"*** as ***'Death'.***
- Death Details (DD) form: details are expected to be reported.

Scenario 5: If subject was randomized by mistake, record:

- On Inclusion/Exclusion Criteria Not Met (IE) form: Report "***Were all eligibility criteria met?"*** should be answered as '***No***'. System query may pop up. Please explain in the query answer as appropriate.
- If subject is still being followed up in the study, then Disposition (DS) form doesn't need to be updated.

What was the Protocol version?
Record the version of the main protocol applicable for assessed eligibility criteria. The protocol version must be entered as an integer (whole number) without decimal notation (e.g., enter 1 instead of 1.0).

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15.1.9 INCLUSION/EXCLUSION CRITERIA NOT MET - RANDOMIZATION (IE1)

This form populates in Cycle 1 Day 1 folder.

Complete the Inclusion/Exclusion Criteria Not Met form for all enrolled Subjects.

Were all eligibility criteria met?
Record "*Yes*", "*No*" or "*Not Applicable*" as appropriate.

- Record '*Yes'* if all eligibility criteria were met at the time the Subject was enrolled. **Note**: When **'Yes'** is selected for 'Were all eligibility criteria met?' and the form is saved, the **VISIT** form will automatically appear in the **C1D1** folder. After entering the **Visit Date** in the Visit folder (and leaving **'Visit not done'** blank), the **ASMTRIG** form will then be generated in this folder.
- Record '*No'* if Subject did *not* meet all criteria at the time the Subject was enrolled.

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

If 'No', if the Subject was not eligible, record **Exception criterion identifier** for each **Criterion type** that was an exception *(Exclusion; Inclusion).*

Inclusion criteria
Refer to section 5.1 of the protocol for addition details on Inclusion Criteria for Screening. Select data from the dropdown list: *1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14.*

Exclusion criteria
Refer to section 5.2 of the protocol for addition details on Exclusion Criteria. Select data from the dropdown list: *1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11a, 11b, 11c, 11d, 11e, 11f, 11g, 11h, 12a, 12b, 12c, 12d, 12e, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28.*

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

Scenario 1: If Subject complied with all inclusion/exclusion criteria, please complete Randomization form.

Scenario 2: If Subject completed inclusion/exclusion criteria assessment and before randomization decided to withdrawn consent or died, then record:

- On Inclusion/Exclusion Criteria Not Met (IE) form: Report "**Were all eligibility criteria met?**" with '***Yes'***
- Disposition (DS) form: Update "*What was the Subject's status?" as* 'Withdrawal by Subject' or 'Death' (which applicable)

Scenario 3: If the Subject was in the middle of the screening assessment when the Subject decided to withdraw from the study, or death occurred, record:

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- On Inclusion/Exclusion Criteria Not Met (IE) form: Report "*Were all eligibility criteria met?"* as '*Not applicable'*, with no log line reported.
- Disposition (DS) form: Update "*What was the Subject's status?"* as *'Withdrawal by Subject'.*
- Withdrawal of Informed Consent (CONSWD) form: details are expected to be reported.

Scenario 4: If subject was randomized by mistake

- "Were all eligibility criteria met?" should be answered as 'No'. System query may pop up. Please explain in the query answer as appropriate.
- If subject is still being followed up in the study, then Disposition (DS) form doesn't need to be updated.

Was Subject allocated a randomization code?
Record the appropriate option (*No; Yes*).

The following items will be integrated from IxRS system if the subject is registered as randomized:

- If Yes, randomization code
- What was the randomization date?

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15.1.10 EXTENT OF DISEASE UPON ENTRY TO STUDY (DISEXT)

This eCRF should be completed at the time of screening. The eCRF should not be updated with information from post-screening assessments of disease extent.

Metastatic/locally advanced
Record the appropriate option *(Locally advanced, Metastatic).*

Note: Make sure the value is consistent with the stage of BTC at screening reported on **PATHGOM** eCRF and **RECIST baseline** eCRFs.

Anatomical location
Please choose the most appropriate option (Adrenal gland, Ascites, Biliary tract, Bladder, Bone, Brain, Distant lymph node, Esophagus, Gallbladder, Genitourinary system, Kidney, Large intestine, Liver, Lung, Mediastinum, Omentum, Pancreas, Pericardial effusion, Peritoneum, Pleura, Pleural effusion, Rectum, Regional lymph node, Skin, Small intestine, Spinal cord, Spleen, Stomach, Other locally advanced sites, Other metastatic sites.)

NOTE: Make sure all anatomical locations of lesions reported on RECIST baseline eCRF are documented. Initiate a new logline to include all the applicable anatomical locations.

Please initiate a new log line to include all the applicable anatomical locations.

Other locally advanced site, specify
If '**Other locally advanced sites'** is recorded in Anatomical location, provide details.

Other metastatic site, specify
If '**Other metastatic sites'** is recorded in Anatomical location, provide details.

Was there recurrence after curative intent resection of BTC?
Answer "Yes" if BTC was initially diagnosed in an early setting, treated with curative intent resection, and subsequently developed recurrence. Answer "No" if BTC was initially diagnosed as unresectable; including those with previous resections that were not performed with curative intent.

NOTE: If "Yes" is selected, the form *Pathology at Time of Initial Diagnosis of Early Stage BTC (PATHGEN)* will be added to Screening (Day-28 to -1) folder. Please ensure the PATHGEN form is completed accordingly.

Date of recurrence
Record the date of recurrence of early biliary tract cancer.
This field should *only* be entered if "Was there recurrence after curative intent resection of BTC?" is selected as 'Yes'.

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15.1.11 GENERAL MEDICAL HISTORY (1MH)

Has the Subject experienced any past and/or concomitant diseases?
Indicate if the Subject experienced any medical conditions or events. If 'Yes', include the appropriate details where indicated on the CRF.

This excludes lesser conditions with no obvious importance for the purposes of this study, such as:

- common diseases of childhood

- accidental fractures unless resulting in sequel

- minor symptomatic conditions.

Medical history term
Use English standard medical terminology. Do not record any extra information e.g. year: "Myocardial infarction 1986".

Record all relevant medical conditions or events, as defined in the protocol. Record only one medical condition or event per line.

Compare recorded diagnosis with exclusion criteria in **section 5.2 of protocol.**

Ongoing (at the time of enrollment)

Note: Please reflect the status at the time when subjects sign off the main informed consent.

Record the medical condition or event as ongoing ('Yes') if it has not ended at the time of enrollment and the "**End date**" should be left blank.

If answer is 'Yes' (current): conditions are not cured, but the Subject may be symptom-free at the time of the visit, e.g. rhinitis, migraine, hypertension.

If answer is 'No' (past): a condition, which the Subject had in the past and declared cured, e.g. pneumonia.

Past and current condition: if Subject has a new instance of this condition (pneumonia in this example) at the time of the visit. Record instances of ongoing conditions as 'No' (past) and as 'Yes' (current) on separate lines.

Start date
Record the start date of the medical event or condition at the level of precision known using YYYY-MON-DD format (for example 2001-JAN-01). If the exact start date is unknown (for example Subject doesn't remember it), at least year should be recorded.

Note: Partial dates can be captured as unknown in system as YYYY-UNK-UN or YYYY-MON-UN.

If the start date of the event is after ICF date, please move the event to AE form and do not report them as Medical History.

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End date
Record the end date of the medical event or condition at the level of precision known using YYYY-MON-DD format (for example 2001-JAN-01). If the exact end date is unknown (for example Subject doesn't remember it), at least year should be recorded.

Note: Partial dates can be captured as unknown in system as YYYY-UNK-UN or YYYY-MON-UN.

Any current medication
Record the most appropriate response *(No; Yes).*
Save this page before adding a new Log line (in other case information already entered will be lost).

NB: If any change(s) in this form after an SAE was reported, ensure that the updated information has been made available immediately to AstraZeneca (contact the Monitor).

NB: If medication is currently being taken for any of the above conditions, fill in the Prior and Concomitant Medications (CM) Form. Note that PRN (= Pro Re Nata: medication to be taken when needed) is also to be considered.

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15.1.12 PRE-SPECIFIED MEDICAL CONDITIONS OR EVENTS (2MH)

Pre-specified medical conditions or events
Medical history term
Below Medical conditions or events are prespecified in each logline respectively:

- *Hepatic cirrhosis*
- *Hepatitis B*
- *Hepatitis C*

Medical condition/event
Indicate if the Medical conditions prespecified in each logline has occurred/is occurring respectively. Record the appropriate response *(No; Yes; Unknown).*

Medical history event prespecified
This field is defaulted to “Yes”.

NOTE: If medication is currently being taken for any of the above conditions, fill in the Prior and Concomitant Medications (CM) Form. Note that PRN (= Pro Re Nata: medication to be taken when needed) is also to be considered.

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15.1.13 ASSESSMENT(S) PERFORMED TRIGGERING FORM (ASMTRIG)

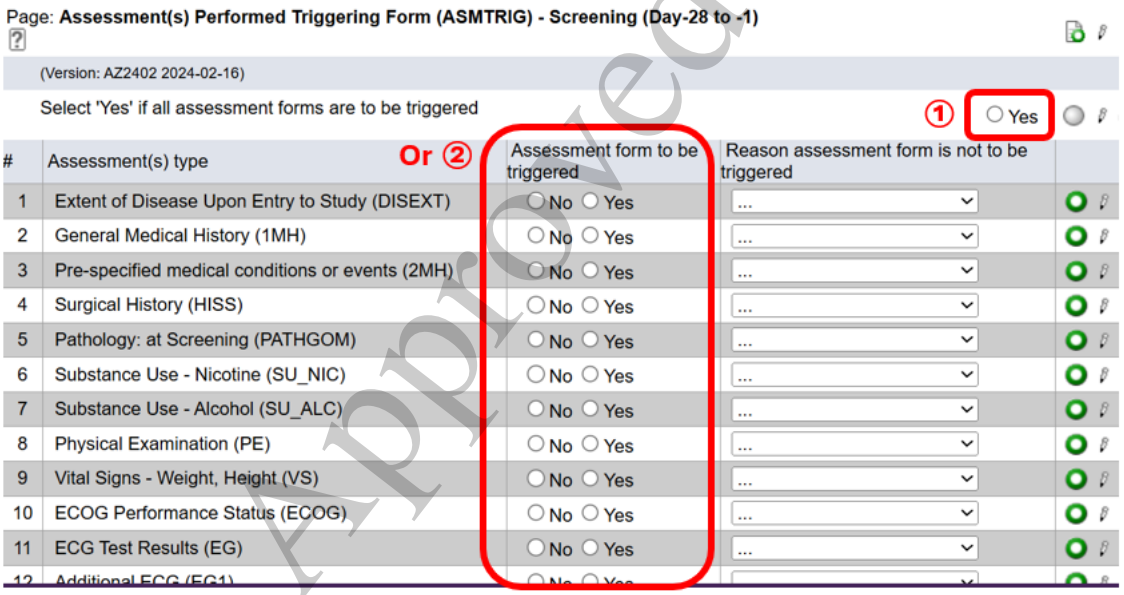
This operational CRF is created in a visit folder when the **Visit Date is saved and "Visit not done" is empty on VISIT form of the current folder.**

Use this form to trigger CRFs for the assessments completed at this visit.

Please refer to **Section 10 - Table 7** for the list of forms applicable to each visit respectively.

Assessments on this form can be selected in two ways:

- ① **All at once**: Set "Select 'Yes' if all assessment forms are to be triggered" to 'Yes'.
- ② **Individually:** Mark each assessment from the log form as 'Yes' one by one.



Note for C1D1 folder:

- Please complete **IE** form first, when **'Yes'** is selected for 'Were all eligibility criteria met?' and the form is saved, the **VISIT** form will automatically appear in the **C1D1** folder.
- After entering the **Visit Date** in the Visit folder (and leaving **'Visit not done'** blank), the **ASMTRIG** form will then be generated in C1D1 folder.

Select 'Yes' if all assessment forms are to be triggered
Record 'Yes' if all assessments are performed at this visit. Refer to **Section 10 - Table 7** for assessments of each visit.

This checkbox will work only once. If unmarked and marked again, it will not re-trigger all the CRFs.

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Assessment(s) type
The field is pre-specified. Please refer to **Section 10 - Table 7** for the list of forms applicable to each visit respectively.

Assessment form to be triggered
Record the appropriate option *(No; Yes).*
If 'Yes' is selected, then that form will be added to the same visit folder.

Reason assessment form is not to be triggered
Record the appropriate option when Assessment form to be triggered is 'No' (Assessment not performed; Assessment not required; Subject discontinuation; Screen failure;).

NOTE:
1. If a response to "Select 'Yes' if all assessment forms are to be triggered" is marked as 'Yes' and the Assessment form to be triggered is marked as 'No' for any of the log lines then the corresponding CRF with entry 'No' for field Assessment form to be triggered will not be added.

2. If 'Assessment form to be triggered' is marked as 'Yes', then that form will be added to the same visit.

3. If Assessment form to be triggered is marked back again to 'No' from 'Yes', then that form will be inactivated at the same visit if the form is blank.

4. If Assessment form to be triggered is marked as 'Yes', data entered on the form and Assessment form to be triggered is marked back to 'No' from 'Yes', then form will not be inactivated, because there is data entry in the form.

5. If the form is submitted and Assessment form to be triggered is marked as 'No' from 'Yes', then the form will not be inactivated.

6. Other forms may be defaulted in the visit folder and not listed on the Assessment(s) Performed Triggering Form. These pages are expected to be entered and thus are not given as options on this form. Examples include:

· Visit Date (VISIT)
· Informed Consent (CONSENT)
· Demographics (DM)
· Eligibility forms (IE/ IE1)
· Subject Continuation (CONT)

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15.1.14 SURGICAL HISTORY (HISS)

What was the category of the procedure?
The value is defaulted as “SURGICAL PROCEDURE”.

Were any surgical procedures performed? (prior to enrollment)
Indicate if the Subject had any surgical procedures. If ‘Yes’, include the appropriate details where indicated on the CRF.
Record the appropriate option *(No; Yes).*

Procedure name
Record the appropriate details. Record only one procedure per line.

Start date
Record the complete date using YYYY-MON-DD format (for example 2000-JAN-01). Every effort should be made to obtain complete start date of surgery.
Partial dates are allowed in a study, then day can be captured as unknown (YYYY-MON-UN).
Partial dates are allowed in a study, then day and month can be captured as unknown (YYYY-UNK-UN)

Current medication
Record the appropriate option *(No; Yes).*

If medication is currently being taken for any of the above surgeries/procedures, please fill in the Prior and Concomitant Medications (CM) Form.

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15.1.15 PATHOLOGY AT TIME OF INITIAL DIAGNOSIS OF EARLY STAGE BTC (PATHGEN)

This form only populates when data on DISEXT form is completed with “Was there recurrence after curative intent resection of BTC?” selected as “Yes”.

Original diagnosis date

This is a date when the diagnosis of early stage biliary tract cancer was made. Record a complete date in YYYY-MON-DD format (for example 2000-JAN-01). Every effort should be made to obtain complete date.

As partial dates are allowed in a study, day and month can be captured as unknown (YYYY-UNK-UN).

Primary tumor location
This is a location of the primary tumor diagnosed in early stage.
Record the appropriate option *(Extrahepatic bile duct (distal), Extrahepatic bile duct (perhilar), Gallbladder, Intrahepatic bile duct, Other).*
NOTE: Please cross check Primary tumor location reported in PATHGOM form. The Primary tumor location is expected to be the same between PATHGOM and PATHGEN forms.

If Other, specify
If Primary tumor location is ‘Other’, then provide the details.

Histology type
This is histology type of the early stage biliary tract cancer. Record the appropriate option *(Adenosquamous carcinoma, Adenocarcinoma or Other).*

If Other, specify
If Histology type is ‘Other’, then provide the details.

Indicate TNM classification for early stage biliary tract cancer in each section
Primary tumor,
Record the appropriate option *(TX, T1, T1a, T1b, T2,T2a, T2b, T3, T4).*

Regional lymph nodes
Record the appropriate option *(N0; N1; N2; NX).*

Distant metastases
Record the appropriate option *(M0; Mx; M1)*

Tumor grade
This is tumor grade of the early stage biliary tract cancer. Record the appropriate option *(Well differentiated (G1); Moderately differentiated (G2); Poorly differentiated (G3); Unassessable (GX)).*

Note: Unassessable to be selected only when the tumor type grading cannot be assessed.

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Stage/AJCC stage
This is the stage of the early stage biliary tract cancer.

NOTE: Please follow the 8th edition of AJCC staging. Record the appropriate option (Stage I, Stage IA , Stage IB, Stage II, Stage IIA, Stage IIB, Stage III, Stage IIIA, Stage IIIB, Stage IIIC, Stage IV, Stage IVA, Stage IVB).

The AJCC stage groupings are as below:
(source https://meridian.allenpress.com/aplm/article/145/5/543/442292/The-8th-Edition-American-Joint-Committee-on-Cancer).

Intrahepatic Bile Ducts

AJCC stage groupings	
IA	**T1a N0 M0**
IB	**T1b N0 M0**
I	
II	T2 N0 M0
IIIA	T3 N0 M0
IIIB	**T4 N0 M0; any T N1 M0**
III	
IV	Any T any N M1
IVA	
IVB	

Extrahepatic Perihilar Bile Ducts

AJCC stage groupings	
I	T1 N0 M0
II	T2a–b N0 M0
IIIA	T3 N0 M0
IIIB	**T4 N0 M0**
IIIC	**Any T N1 M0**
IVA	**Any T N2 M0**
IVB	**Any T any N M1**

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Distal Extrahepatic Bile Ducts

AJCC stage groupings

I	T1 N0 M0
IA	
IB	
IIA	**T1 N1 M0; T2 N0 M0**
IIB	**T2 N1 M0; T3 N0–1 M0**
IIIA	**T1–3 N2 M0**
IIIB	**T4 any N M0**
III	
IV	Any T any N M1

Gallbladder

AJCC stage groupings

I	T1 N0 M0
IIA	**T2a N0 M0**
II	
IIB	**T2b N0 M0**
IIIA	T3 N0 M0
IIIB	T1–3 N1 M0
IVA	T4 N0–1 M0
IVB	Any T N2 M0; any T any N M1

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15.1.16 PATHOLOGY: AT SCREENING (PATHGOM)

Date of Diagnosis of unresectable locally advanced or metastatic BTC
Record the complete date in *YYYY-MON-DD* format *(for example 2000-JAN-01).*
NOTE: In a scenario of recurrent tumor diagnosed initially in early stage, please note that the date of diagnosis of unresectable locally advanced or metastatic BTC data filled in this form usually refers to the “Date of recurrence” of early biliary tract cancer and should be the same as recorded in DISEXT form.
EXCEPTION: If first recurrence was local and resectable, these dates might be different.

Primary tumor location
Record the appropriate option (*Extrahepatic bile duct (distal); Extrahepatic bile duct (perhilar); Gallbladder; Intrahepatic bile duct; Other*).

NOTE: In a scenario of recurrent tumor diagnosed initially in early stage, please note that the primary tumor location data filed in this form refers to the location of the primary tumor in early stage and should be the same as recorded in *PATHGEN* form.

If Other, specify
If **Primary tumor location** is *'Other'* then provide details.

Histology type
Record the appropriate option (*Adenosquamous carcinoma, Adenocarcinoma, Other)*

NOTE: In a scenario of recurrent tumor diagnosed initially in early stage, please note that the histology type here refers to histology type assessed in screening. If there was no assessment of histology for the recurrent tumor, please leave this data field as blank and ensure histology type is entered in *PATHGEN* form (Pathology: at time of initial diagnosis).

Histology type details
If **Histology type** is ‘*Other’*, provide the details.

Indicate TNM classification for locally advanced or metastatic biliary tract cancer assessed in screening in each section

Primary tumor
Record the appropriate option (*TTX; T1 ;T1a ;T1b ;T2 ;T2a ;T2b ;T3 ;T4)*

Regional lymph nodes
Record the appropriate option (*N0; N1 ;N2; NX*).

Distant metastases
Record the appropriate option (M0; Mx ;M1)
Tumor grade

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Record the appropriate option (*Well differentiated (G1); Moderately differentiated (G2); Poorly differentiated (G3); Unassessable (GX)*).
NOTE: In a scenario of recurrent tumor diagnosed initially in early stage, please note that the tumor grade here refers to tumor grade assessed in screening. If there was no assessment of histology for the recurrent tumor, please select *Unassessable (GX)*.

Stage/AJCC stage
This is the **clinical stage** of the unresectable locally advanced or metastatic biliary tract cancer assessed in screening.

NOTE: Please follow the 8th edition of AJCC staging.
Record the appropriate option (*Stage II; Stage IIA; Stage IIB; Stage III; Stage IIIA; Stage IIIB; Stage IIIC; Stage IV; Stage IVA; Stage IVB*).

The AJCC stage groupings are as below:
(source https://meridian.allenpress.com/aplm/article/145/5/543/442292/The-8th-Edition-American-Joint-Committee-on-Cancer).

Intrahepatic Bile Ducts

AJCC stage groupings	
IA	**T1a N0 M0**
IB	**T1b N0 M0**
I	
II	T2 N0 M0
IIIA	T3 N0 M0
IIIB	**T4 N0 M0; any T N1 M0**
III	
IV	Any T any N M1
IVA	
IVB	

Extrahepatic Perihilar Bile Ducts

AJCC stage groupings	
I	T1 N0 M0
II	T2a–b N0 M0
IIIA	T3 N0 M0
IIIB	**T4 N0 M0**
IIIC	**Any T N1 M0**
IVA	**Any T N2 M0**
IVB	**Any T any N M1**

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Distal Extrahepatic Bile Ducts

AJCC stage groupings

I	T1 N0 M0
IA	
IB	
IIA	**T1 N1 M0; T2 N0 M0**
IIB	**T2 N1 M0; T3 N0–1 M0**
IIIA	**T1–3 N2 M0**
IIIB	**T4 any N M0**
III	
IV	Any T any N M1

Gallbladder

AJCC stage groupings

I	T1 N0 M0
IIA	**T2a N0 M0**
II	
IIB	**T2b N0 M0**
IIIA	T3 N0 M0
IIIB	T1–3 N1 M0
IVA	T4 N0–1 M0
IVB	Any T N2 M0; any T any N M1

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15.1.17 SUBSTANCE USE - NICOTINE (SU_NIC)

Has the Subject ever smoked tobacco?
Record if the Subject has ever smoked tobacco, currently smokes tobacco, or formerly smoked tobacco *(Current; Former; Never).*

Number of pack years
Record calculated number of total pack years for cigarettes currently and formerly consumed, **except when Subject never smoked.**
One pack year = 1 pack (20 cigarettes) per day for 1 year.

Record only whole pack years.

Examples of 10 pack years:

- 1 pack (20 cigarettes) per day for 10 years
- 2 packs (40 cigarettes) per day for 5 years
- ½ pack (10 cigarettes) per day for 20 years

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15.1.18 SUBSTANCE USE - ALCOHOL (SU_ALC)

What was the category of the substance used?
Pre-specified in the eCRF (*Alcohol*).

Has the Subject ever used substance?
Record if the Subject has ever used/consumed alcohol, currently consumes alcohol, or formerly used/consumed alcohol *(Current; Former; Never).*

Type of substance
Pre-specified field.

- Wine;
- Wine, fortified
- Beer
- Cider
- Liquor/Spirits
- Alcopop
- Other

If Other, specify

Alcohol consumption (units)
Record the appropriate value for substance consumption. The quantity should be recorded in relation to the category chosen in **Frequency**.
NB. Units of measure

1-unit equals
- half a pint of beer, cider or 'alcopop' (285 mL)
- 1 glass of wine (125 mL)
- 1 small glass of fortified wine (50 mL)
- 1 measure of liquor/spirits (25 mL)

Frequency
Record the appropriate option *(Daily; Per week; Per month*) for recorded **Alcohol consumption (units).**

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15.1.19 PHYSICAL EXAMINATION (PE)

Was the physical examination performed?
Record an appropriate option *(No; Yes).*

What was the date of the physical examination?
Record the complete date of examination using this format (YYYY-MON-DD) (for example 2000-JAN-01.

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15.1.20 VITAL SIGNS - WEIGHT, HEIGHT (VS)

This form populates in Screening (Day-28 to -1) and Rescreening (if applicable) folders.

Please refer to section 8.3.2 of CSP on how vital signs should be measured.

Were vital signs collected?
Indicate if the vital signs were collected. Record the appropriate option *(No; Yes).*
If 'Yes', include the appropriate details where indicated on the CRF.

What was the date of the vital signs measurement?
Record the appropriate date of collection in YYYY-MON-DD format (for example 2001-JAN-01).

Time
Record time of measurement (as complete as possible) in 24-hours clock format.

Pulse
Let Subject rest.
- measure pulse before blood pressure
- assess the pulse by palpation at beats/min.

SBP and **DBP**
As per CSP section 8.3.2, the average of the 3 blood pressure readings will be recorded in the eCRF.

Use a manometer and measure the blood pressure to the nearest mmHg.

- use the same size of cuff (suitable for the individual Subject) on the arm throughout the study

- derive Pulse Pressure (PP) from Systemic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) measurements

- if any item is considered to be a serious adverse event (SAE) or the abnormality causes the Subject to discontinue from the Study, or the Investigator insists to report the abnormality, then report as an adverse event on the Adverse Event form and, if appropriate, on the SERAE form.

Respiration rate
Measurement should be done according to instructions in the Clinical Study Protocol (CSP).

Temperature
Temperature applies to Subject's body temperature

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Temperature unit
Pre-specified as °C.

Peripheral oxygen saturation
- if percentage value is calculated then the definition of oxygen saturation is percentage of oxygen binding sites on hemoglobin that are actually binding oxygen
- if any item is considered to be a serious adverse event (SAE) or the abnormality causes the Subject to discontinue from the Study, or the Investigator insists to report the abnormality, then report as an adverse event on the Adverse Event form and, if appropriate, on the SERAE form.

Weight
Subject should wear light-weight clothing and no shoes during the weight and height assessment
- enter the rounded value without decimals unless otherwise specified in the Clinical Study Protocol, e.g. decimals 1-4 should be rounded down and 5-9 should be rounded up: Weight=67.4 should be entered as 67.

Weight unit
Pre-specified as kg.

Height
Record the hight. Height=164.5 should be entered as 165.

Height unit
Pre-specified as cm.

If any finding:

- that is abnormal and of clinical relevance for the purpose of the stud y started prior to enrolment, it must be recorded as Medical History (MH form)
- started or worsened after enrolment and fulfils SAE criteria or causes Subject to discontinue treatment with investigational product, it must be recorded as an Adverse Event (AE form)
- violates the eligibility criteria withdraw Subject and fill in Disposition (DS) form. Make sure that Inclusion/Exclusion Criteria Not Met (IE) form reflects this information (only applicable during screening).

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15.1.21 VITAL SIGNS - BEFORE INFUSION (VS1)

This form populates in Day 1 folders of each Cycle to record the Vital Signs obtained within 30 minutes prior to start of iv administration of study intervention.

Were vital signs collected?
Indicate if the vital signs were collected. Record the appropriate option (No; Yes).
If 'Yes', include the appropriate details where indicated on the CRF.

What was the date of the vital signs measurement?
Record the appropriate date of collection in YYYY-MON-DD format (for example 2001-JAN-01).

Protocol schedule
Prespecified as Prior to Infusion

Time
Record time of measurement (as complete as possible) in 24-hours clock format.

Pulse
let Subject rest.
- measure pulse before blood pressure
- assess the pulse by palpation at beats/min.

SBP and **DBP**
As per CSP section 8.3.2, the average of the 3 blood pressure readings will be recorded in the eCRF.

use a manometer and measure the blood pressure to the nearest mmHg.
- use the same size of cuff (suitable for the individual Subject) on the arm throughout the study
- derive Pulse Pressure (PP) from Systemic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) measurements
- if any item is considered to be a serious adverse event (SAE) or the abnormality causes the Subject to discontinue from the Study, or the Investigator insists to report the abnormality, then report as an adverse event on the Adverse Event form and, if appropriate, on the SERAE form.

Respiration rate
measurement should be done according to instructions in the Clinical Study Protocol (CSP)

Temperature
temperature applies to Subject's body temperature

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Temperature unit
Pre-specified as °C.

Peripheral oxygen saturation
- if percentage value is calculated then the definition of oxygen saturation is percentage of oxygen binding sites on hemoglobin that are actually binding oxygen
- if any item is considered to be a serious adverse event (SAE) or the abnormality causes the Subject to discontinue from the Study, or the Investigator insists to report the abnormality, then report as an adverse event on the Adverse Event form and, if appropriate, on the SERAE form.

Weight
Subject should wear light-weight clothing and no shoes during the weight assessment
- enter the rounded value without decimals unless otherwise specified in the Clinical Study Protocol, e.g. decimals 1-4 should be rounded down and 5-9 should be rounded up: Weight=67.4 should be entered as 67

Weight unit
Pre-specified as kg.

If any finding:

- that is abnormal and of clinical relevance for the purpose of the study started prior to enrolment, it must be recorded as Medical History (MH form)
- started or worsened after enrolment and fulfils SAE criteria or causes Subject to discontinue treatment with investigational product, it must be recorded as an Adverse Event (AE form)
- violates the eligibility criteria withdraw Subject and fill in Disposition (DS) form. Make sure that Inclusion/Exclusion Criteria Not Met (IE) form reflects this information (only applicable during screening).

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15.1.22 VITAL SIGNS - END OF INFUSION (VS2)

This form only populates at Cycle 1 Day 1 to record post-dose vital signs for rilvegostomig or durvalumab within 30 minutes from the end of the infusion.

Were vital signs collected?
Indicate if the vital signs were collected. Record the appropriate option (No; Yes).
If 'Yes', include the appropriate details where indicated on the CRF.

What was the date of the vital signs measurement?
Record the appropriate date of collection in YYYY-MON-DD format (for example 2001-JAN-01).

Protocol schedule
Prespecified as End of Infusion

Time
Record time of measurement (as complete as possible) in 24-hours clock format.

Pulse
let Subject rest.
- measure pulse before blood pressure
- assess the pulse by palpation at beats/min.

SBP and **DBP**
As per CSP section 8.3.2, the average of the 3 blood pressure readings will be recorded in the eCRF.

use a manometer and measure the blood pressure to the nearest mmHg

- use the same size of cuff (suitable for the individual Subject) on the arm throughout the study
- derive Pulse Pressure (PP) from Systemic Blood Pressure (SBP) and Diastolic Blood Pressure(DBP) measurements
- if any item is considered to be a serious adverse event (SAE) or the abnormality causes the Subject to discontinue from the Study, or the Investigator insists to report the abnormality, then report as an adverse event on the Adverse Event form and, if appropriate, on the SERAE form.

Respiration rate
measurement should be done according to instructions in the Clinical Study Protocol (CSP).

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Temperature
temperature applies to Subject's body temperature

Temperature unit
Pre-specified as °C.

Peripheral oxygen saturation
- if percentage value is calculated then the definition of oxygen saturation is: percentage of oxygen binding sites on hemoglobin that are actually binding oxygen
- if any item is considered to be a serious adverse event (SAE) or the abnormality causes the Subject to discontinue from the Study, or the Investigator insists to report the abnormality, then report as an adverse event on the Adverse Event form and, if appropriate, on the SERAE form.

If any finding:

- that is abnormal and of clinical relevance for the purpose of the study started prior to enrolment, it must be recorded as Medical History (MH form)
- started or worsened after enrolment and fulfils SAE criteria or causes Subject to discontinue treatment with investigational product, it must be recorded as an Adverse Event (AE form)
- violates the eligibility criteria withdraw Subject and fill in Disposition (DS) form. Make sure that Inclusion/Exclusion Criteria Not Met (IE) form reflects this information (only applicable during screening).

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15.1.23 VITAL SIGNS - EXCLUDING WEIGHT (VS3)

This form populated in C1D8, C2D8, C3D8, C4D8, C5D8, C6D8, C7D8, C8D8 folders, to record vital signs only whilst the participant is receiving gemcitabine/cisplatin.

Were vital signs collected?
Indicate if the vital signs were collected. Record the appropriate option (No; Yes).
If 'Yes', include the appropriate details where indicated on the CRF.

What was the date of the vital signs measurement?
Record the appropriate date of collection in YYYY-MON-DD format (for example 2001-JAN-01).

Time
Record time of measurement (as complete as possible) in 24-hours clock format.

Pulse
let Subject rest.
- measure pulse before blood pressure
- assess the pulse by palpation at beats/min.

SBP and **DBP**
As per CSP section 8.3.2, the average of the 3 blood pressure readings will be recorded in the eCRF.

use a manometer and measure the blood pressure to the nearest mmHg

- use the same size of cuff (suitable for the individual Subject) on the arm throughout the study
- derive Pulse Pressure (PP) from Systemic Blood Pressure(SBP) and Diastolic Blood Pressure(DBP) measurements
- if any item is considered to be a serious adverse event (SAE) or the abnormality causes the Subject to discontinue from the Study, or the Investigator insists to report the abnormality, then report as an adverse event on the Adverse Event form and, if appropriate, on the SERAE form.

Respiration rate
measurement should be done according to instructions in the Clinical Study Protocol (CSP).

Temperature
temperature applies to Subject's body temperature.

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Temperature unit
Pre-specified as °C.

Peripheral oxygen saturation
- if percentage value is calculated then the definition of oxygen saturation is: percentage of oxygen binding sites on hemoglobin that are actually binding oxygen
- if any item is considered to be a serious adverse event (SAE) or the abnormality causes the Subject to discontinue from the Study, or the Investigator insists to report the abnormality, then report as an adverse event on the Adverse Event form and, if appropriate, on the SERAE form.

If any finding:

- that is abnormal and of clinical relevance for the purpose of the study started prior to enrolment, it must be recorded as Medical History (MH form)
- started or worsened after enrolment and fulfils SAE criteria or causes Subject to discontinue treatment with investigational product, it must be recorded as an Adverse Event (AE form)
- violates the eligibility criteria withdraw Subject and fill in Disposition (DS) form. Make sure that Inclusion/Exclusion Criteria Not Met (IE) form reflects this information (only applicable during screening).

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15.1.24 VITAL SIGNS (VS4)

This form populated in ***End of Treatment*** visit and ***Post-treatment 90 Days Safety follow-up*** visit folders. This form can also be added in ***Unscheduled Visit*** folders.

Were vital signs collected?
Indicate if the vital signs were collected. Record the appropriate option (No; Yes).
If 'Yes', include the appropriate details where indicated on the CRF.

What was the date of the vital signs measurement?
Record the appropriate date of collection in YYYY-MON-DD format (for example 2001-JAN-01).

Time
Record time of measurement (as complete as possible) in 24-hours clock format.

Pulse
let Subject rest.
- measure pulse before blood pressure
- assess the pulse by palpation at beats/min.

SBP and **DBP**
As per CSP section 8.3.2, the average of the 3 blood pressure readings will be recorded in the eCRF.

use a manometer and measure the blood pressure to the nearest mmHg
- use the same size of cuff (suitable for the individual Subject) on the arm throughout the study
- derive Pulse Pressure (PP) from Systemic Blood Pressure(SBP) and Diastolic Blood Pressure(DBP) measurements
- if any item is considered to be a serious adverse event (SAE) or the abnormality causes the Subject to discontinue from the Study, or the Investigator insists to report the abnormality, then report as an adverse event on the Adverse Event form and, if appropriate, on the SERAE form.

Respiration rate
measurement should be done according to instructions in the Clinical Study Protocol (CSP)

Temperature
temperature applies to Subject's body temperature.

Temperature unit
Pre-specified as °C.

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Peripheral oxygen saturation

- if percentage value is calculated then the definition of oxygen saturation is: percentage of oxygen binding sites on hemoglobin that are actually binding oxygen
- if any item is considered to be a serious adverse event (SAE) or the abnormality causes the Subject to discontinue from the Study, or the Investigator insists to report the abnormality, then report as an adverse event on the Adverse Event form and, if appropriate, on the SERAE form.

Weight

Subject should wear light-weight clothing and no shoes during the weight assessment
- enter the rounded value without decimals unless otherwise specified in the Clinical Study Protocol, e.g. decimals 1-4 should be rounded down and 5-9 should be rounded up: Weight=67.4 should be entered as 67

Weight unit

Pre-specified as kg;

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15.1.25 ECOG PERFORMANCE STATUS (ECOG)

Clinical classification category
This value is defaulted to ECOG.

What was the date the response or clinical classification was performed?
Record a complete date of assessment using YYYY-MON-DD format (for example 2000-JAN-01)

Performance status
Record the appropriate option
(Fully active, able to carry on all pre-disease performance without restriction;
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;
Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours;
Capable of only limited selfcare, confined to bed or chair more than 50% of; waking hours;
Completely disabled. Cannot carry on any selfcare. Totally confined to bed or; chair;
Dead).

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15.1.26 ECG TEST RESULTS (EG), ADDITIONAL ECG (EG1) AND ADDITIONAL ECG (EG2)

The ECG forms are located in below folders:

- **Screening/ Rescreening visit folders**: ALL EG, EG1 and EG2 forms are required to be recorded as per CSP Schedule of Activities.
- **Cycle 1 Day 1 folder**: Only EG form is available in C1D1 folder. In case of clinically significant ECG abnormalities, two additional 12-lead ECGs must be obtained over a brief period (no more than 2 minutes apart as per CSP section 8.3.3) to confirm the finding and results recorded in EG1 and EG2 forms in Unscheduled Visit.
- **Unscheduled Visit folder**: EG, EG1 and EG2 are available to be added in Unscheduled Visit folder if ECG (or triplicated ECGs) is performed as clinically indicated.

Was the ECG performed?
Record whether ECG or specific ECG test was done *(No/Yes).*

What was the date of the ECG?
Record the date the ECG was done using *YYYY-MON-DD* format (for example 2000-JAN-01).

ECG time
Record the time the ECG was done (as complete as possible).

ECG mean heart rate
Record the mean heart rate in beats/min.

QRS duration
Record the QRS duration in ms.

RR interval
Record the RR interval in ms

PR interval
Record the PR interval in ms.

QT interval
Record QT interval in ms.

QTc interval Fridericia
Record QTc interval Fridericia in ms.

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What was the interpretation of the ECG?
Record the appropriate option *(Normal; Abnormal).*

Reason, abnormal overall ECG evaluation
Record reason, abnormal overall ECG evaluation.

Was the ECG clinically significant?
Record whether ECG results were clinically significant *(No/Yes).*

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15.1.27 ECHOCARDIOGRAPHY (ECHOC)

What was the date of the echocardiography?
Record the complete date in YYYY-MON-DD format (for example 2000-Jan-01).

What was the time of the echocardiography?
Record the complete time of in 24-hour clock format.

What was the method used for the examination?
Record the appropriate option (Echocardiography; Multiple Gated Acquisition (MUGA)).

Was the image quality sufficient?
Record the appropriate option (No; Yes).

What was the overall ECHOC evaluation?
Record the appropriate option (Normal; Abnormal).

What is the reason the overall ECHOC evaluation was abnormal?
If 'Abnormal' is recorded, specify the abnormality.

What was the left ventricular ejection fraction?
Record the appropriate data in %.

What was the LV end diastolic volume?
Record the appropriate data in ml.
Note: Leave this field as empty if it is not applicable.

What was the LV end systolic volume?
Record the appropriate data in ml.
Note: Leave this field as empty if it is not applicable.

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15.1.28 PREGNANCY TEST - SCREENING (PREG)

This form populates in Screening/ Rescreening folders if the participant is female:

Assessment applicable for Subject
Record the appropriate option (No; Yes).
Select Yes for female of childbearing potential (FOCBP). Refer to Appendix G of CSP for definition of FOCB.

Sampling date
Record the complete date in YYYY-MON-DD format (for example 2000-JAN-01).

Pregnancy test (serum)
Record the appropriate option (Negative; Positive).

Note:

- 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.)

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15.1.29 PREGNANCY TEST (PREG1)

PREG1 form is available in below folders if the participant is female:

- **Day 1 visit of each cycle folders:** To record either the serum or urine pregnancy result at each cycle.
- **Unscheduled Visit folder:** To record any unscheduled pregnancy test results when clinically necessary.
- **End of Treatment:** To record the result on D30 post last dose of ALL study treatment.
- **Post-treatment 90 Days Safety follow-up:** To record the result on D90 post last dose of ALL study treatment.
- **ADD EVENT:** Add “Pregnancy Test” from ADD EVENT option list to document the monthly pregnancy test for 60 days after last dose of Rilvegostomig, or 90 days after the last dose of Durvalumab, or for 6 months after the last dose of chemotherapy (unless local Prescribing Information requires a longer duration), whichever is longer.

  Note: If the monthly pregnancy test result is overlapping with Day 1 of each cycle (when chemotherapy discontinued prior to Rilvestomig or Durvalumab), the results should be reported in Day 1 folders instead.

Assessment applicable for Subject
Record the appropriate option (No; Yes).
Select Yes for female of childbearing potential (FOCBP). Refer to Appendix G of CSP for definition of FOCB
Sampling date
Record the complete date in YYYY-MON-DD format (for example 2000-JAN-01).

Pregnancy test (serum)
Record the appropriate option (Negative; Positive).

Pregnancy test (urine)
Record the appropriate option (Negative; Positive).

Note:
- 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.)

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15.1.30 PREGNANCY REPORT (PREGREP)

All pertinent information must be obtained and PREGREP must be completed with all available information as soon as possible after the pregnancy has been identified. Inform the AstraZeneca representative immediately, no later than 24 hours.

What was the date the reproductive system question was collected?
Record the date when the reproductive system information was collected from the Subject. Record the complete date in YYYY-MON-DD format (for example 2000-JAN-01).

Date of last menstrual period
Record the complete date in YYYY-MON-DD format (for example 2000-JAN-01).

Date of expected delivery
Record the complete date in YYYY-MON-DD format (for example 2000-JAN-01).

Using hormonal contraception or IUD
Record the appropriate option (No; Yes).

Hormonal contraception/IUD specification
If Subject is using hormonal contraception (oral or implant) or an IUD at time of conception, provide specification.

Number of previous pregnancies
If no previous pregnancy, please enter ‘0’.
Provided overall number of previous pregnancies should be consistent with number of pregnancies detailed below:

Number of normal deliveries
Provide number of previous normal deliveries; if none, please enter ‘0’.

Number of spontaneous abortions
Provide number of spontaneous miscarriages; if none, please enter ‘0’.

Number of other previous pregnancies
Provide number of other previous pregnancies; if none, please enter ‘0’.

Other previous pregnancies, specify
If number of other previous pregnancies is different than ‘0’, please provide specification of these pregnancies.

Relevant pregnancy risk factor
Enter relevant information in the text fields, Eg smoking, alcohol etc.

Relevant family history
Enter relevant information in the text fields.

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15.1.31 NON-CENTRAL LABORATORY TEST RESULTS - CHEMISTRY (LB)

Was the sample collected?
Indicate whether or not lab specimen was collected, or measurement performed.
If 'No', specify the reason.

What was the reason that the sample was not collected?
If "Was the sample collected?" is 'No', specify the reason.

What was the name of the lab panel?
This is pre-printed on the CRF *Chemistry*.

What was the date of the lab specimen collection?
Record the date when specimen collection was done using YYYY-MON-DD format (for example 2000-JAN-01).

What was the start time of the lab specimen collection?
Record time of collection (as complete as possible) in 24-hour format.

The following tests are applicable:

Liver Function Tests
- Alanine Aminotransferase (Serum/Plasma)
- Alkaline Phosphatase (Serum/Plasma)
- Aspartate Aminotransferase (Serum/Plasma)
- Bilirubin, Total (Serum/Plasma)
- Bilirubin, Direct, (Conj) (Serum/Plasma)
- Bilirubin, Indirect (Unconj.) (Serum/Plasma)
- Gamma-Glutamyltransferase (Serum/Plasma)
- Lactate Dehydrogenase (LDH) (Serum/Plasma)
- Protein, Total (Serum/Plasma)

Pancreatic Enzymes
- Amylase (Serum/Plasma)
- Lipase (Serum/Plasma)

Renal Function Tests
- Creatinine (Serum/Plasma)
- Creatinine Clearance, Calculated (Urine 24h)
- Creatinine Clearance, Cockcroft-Gault (Plasma)
- Creatinine Clearance, Cockcroft-Gault (Serum)
- Glomerular Filtration Rate (51Cr-EDTA) (Plasma)
- Glomerular Filtration Rate (51Cr-EDTA) (Serum)
- Urea (Serum/Plasma)
- Urea Nitrogen (BUN) (Serum/Plasma)

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Electrolytes

- Calcium, Ionized (Serum)
- Total Calcium (Serum/Plasma)
- Chloride (Serum/Plasma)
- Magnesium (Serum/Plasma)
- Phosphate (Phosphorus) (Serum/Plasma)
- Potassium (Serum/Plasma)
- Sodium (Serum/Plasma)

Proteins

- Albumin (Serum/Plasma)

Glucose Metabolism

- Glucose, Fasting (Serum/Plasma)
- Glucose, Random (Serum/Plasma)

Data

Record laboratory test result.

Range Status, Unit and Range

Range Status, Unit and Range will be imported when local lab name is selected from the drop-down list at the top of the page.

NOTE: If the following tests are performed as clinically indicated, record the results in the *Non-central Laboratory Test Results – Additional Chemistry (LB12)* form under the UNSCHEDULED visit:

- Ferritin and iron studies
- Glycated hemoglobin (HbA1c)
- Uric acid
- Anti-thyroid antibodies (anti-TPOAb, TRAb, and TgAb)

For further information about LB12 form, please refer to section 15.1.44.

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15.1.32 NON-CENTRAL LABORATORY TEST RESULTS - HEMATOLOGY (LB1)

Was the sample collected?
Indicate whether or not lab specimen was collected, or measurement performed.
If 'No', specify the reason.

What was the reason that the sample was not collected?
If "Was the sample collected?" is 'No', specify the reason.

What was the name of the lab panel?
This is pre-printed on the CRF *Hematology*.

What was the date of the lab specimen collection?
Record the date when specimen collection was done using YYYY-MON-DD format (for example 2000-JAN-01).

What was the start time of the lab specimen collection?
Record time of collection (as complete as possible) in 24-hour format.

The following tests are available

- Hemoglobin (Blood)
- Hematocrit (Blood)
- Leucocytes, Absolute Count (WBC) (Blood)
- Platelet count (Blood)
- Mean corpuscular volume (Blood)
- Absolute Neutrophil Count (Blood)
- Absolute Lymphocytes Count (Blood)
- Absolute MonocytesCount (Blood)
- Absolute Eosinophils,Count (Blood)
- Neutrophils, %/Ratio (Blood)
- Lymphocytes, %/Ratio (Blood)
- Monocytes, %/Ratio (Blood)
- Eosinophils, % /Ratio (Blood)

Data
Record laboratory test result.

Range Status, Unit and Range
Range Status, Unit and Range will be imported when local lab name is selected from the drop-down list at the top of the page.

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15.1.33 NON-CENTRAL LABORATORY TEST RESULTS - COAGULATION (LB2)

Was the sample collected?
Indicate whether or not lab specimen was collected, or measurement performed.
If 'No', specify the reason.

What was the reason that the sample was not collected?
If" Was the sample collected?" is 'No', specify the reason.

What was the name of the lab panel?
This is pre-printed on the CRF as *Coagulation*.

What was the date of the lab specimen collection?
Record the date when specimen collection was done using YYYY-MON-DD format (for example 2000-JAN-01).

What was the start time of the lab specimen collection?
Record time of collection (as complete as possible) in 24-hour format.

The following tests are available

- **Activated Partial Thromboplastin Time (APTT) (sec) (Blood)**
- **Activated Partial Thromboplast. Time,Rel (APTT relative) (%, ratio) (Blood)**
- **Fibrinogen (Blood)**
- **Partial Thromboplastin Time (PTT) (sec) (Blood)**
- **Partial Thromboplastin Time, Rel (PTT Relative) (%, ratio) (Blood)**
- **Prothrombin Complex INR (Blood) (%,ratio) (Blood)**
- **Prothrombin Time (PT) (sec) (Blood)**
- **Prothrombin Time, Relative (PT Relative) (%, ratio) (Blood**)

Data
Record laboratory test result.

Range Status, Unit and Range
Range Status, Unit and Range will be imported when local lab name is selected from the drop-down list at the top of the page.

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15.1.34 NON-CENTRAL LABORATORY TEST RESULTS - THYROID FUNCTION TEST (LB3)

Was the sample collected?
Indicate whether or not lab specimen was collected, or measurement performed.
If 'No', specify the reason.

What was the reason that the sample was not collected?
If" Was the sample collected?" is 'No', specify the reason.

What was the name of the lab panel?
This is pre-printed on the CRF *Chemistry*.

What was the date of the lab specimen collection?
Record the date when specimen collection was done using YYYY-MON-DD format (for example 2000-JAN-01).

What was the start time of the lab specimen collection?
Record time of collection (as complete as possible) in 24-hour format.

The following tests are available

- **Thyroid Stimulating Hormone(Serum/Plasma)**
- **T4 (Thyroxine), Free(Serum/Plasma)**
- **T3 (Triiodothyronine), Free(Serum/Plasma)**

Data
Record laboratory test result.

Range Status, Unit and Range
Range Status, Unit and Range will be imported when local lab name is selected from the drop-down list at the top of the page.

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15.1.35 NON-CENTRAL LABORATORY TEST RESULTS - TROPONIN AND CREATINE PHOSPHOKINASE (LB4)

Was the sample collected?
Indicate whether or not lab specimen was collected, or measurement performed.
If 'No', specify the reason.

What was the reason that the sample was not collected?
If" Was the sample collected?" is 'No', specify the reason.

What was the name of the lab panel?
This is pre-printed on the CRF- Chemistry.

What was the date of the lab specimen collection?
Record the date when specimen collection was done using YYYY-MON-DD format (for example 2000-JAN-01).

What was the start time of the lab specimen collection?
Record time of collection (as complete as possible) in 24-hour format.

The following tests are available

- **Creatine Kinase (Serum/Plasma)**
- **Troponin T (Serum/Plasma)**
- **Troponin I (Serum/Plasma)**
- **High- sensitivity Troponin T (Serum/Plasma)**
- **High- sensitivity Troponin I (Serum/Plasma)**

Data
Record laboratory test result.

Range Status, Unit and Range
Range Status, Unit and Range will be imported when local lab name is selected from the drop-down list at the top of the page.

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15.1.36 NON-CENTRAL LABORATORY TEST RESULTS - CA-19-9 AND CEA (SERUM) (LB5)

Was the sample collected?
Indicate whether or not lab specimen was collected, or measurement performed.
If 'No', specify the reason.

What was the reason that the sample was not collected?
If" Was the sample collected?" is 'No', specify the reason.

What was the name of the lab panel?
This is pre-printed on the CRF Chemistry.

What was the date of the lab specimen collection?
Record the date when specimen collection was done using YYYY-MON-DD format (for example 2000-JAN-01).

What was the start time of the lab specimen collection?
Record time of collection (as complete as possible) in 24-hour format.

The following tests are available

- **Carcinoembryonic Antigen (Serum/Plasma) (ng/mL)**
- **Carbohydrate Antigen 19-9 (Serum) (U/mL)**

Data
Record laboratory test result.

Range Status, Unit and Range
Range Status, Unit and Range will be imported when local lab name is selected from the drop-down list at the top of the page.

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15.1.37 NON-CENTRAL LABORATORY TEST RESULTS - URINALYSIS (LB6)

Was the sample collected?
Indicate whether or not lab specimen was collected, or measurement performed.
If 'No', specify the reason.

What was the reason that the sample was not collected?
If" Was the sample collected?" is 'No', specify the reason.

What was the name of the lab panel?
This is pre-printed on the CRF Urinalysis.

What was the date of the lab specimen collection?
Record the date when specimen collection was done using YYYY-MON-DD format (for example 2000-JAN-01).

What was the start time of the lab specimen collection?
Record time of collection (as complete as possible) in 24-hour format.

Albumin, Strip, Qual (Urine)
Select the appropriate option (Negative; Trace; Positive; +; ++; +++; >+++; +-)

Bilirubin, Strip, Qual (Urine)
Select the appropriate option (Negative; Trace; Positive; +; ++; +++; >+++; +-)

Blood, Qual (Urine)
Select the appropriate option (Negative; Trace; Positive; +; ++; +++; >+++; +-)

Glucose, Strip, Qual (Urine)
Select the appropriate option (Negative; Trace; Positive; +; ++; +++; >+++; +-)

Ketone Bodies, Strip, Qual (Urine)
Select the appropriate option (Negative; Trace; Positive; +; ++; +++; >+++; +-)

Protein, Strip, Qual (Urine)
Select the appropriate option (Negative; Trace; Positive; +; ++; +++; >+++; +-)

The following tests are available

- **Appearance (Qual) (Urine)**
- **Color (Qual) (Urine)**
- **Albumin, Quant (Urine)**
- **Bilirubin, Quant(Urine)**
- **Glucose, Random, Quant (Urine)**
- **Ketone Bodies, Quant (Urine)**
- **Protein, Total, Quant (Urine)**
- **Urine-Blood, Quant (Urine)**
- **pH (Urine)**

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- **Specific Gravity (Urine)**
- **Sediment, Erythrocytes, Quant (no/vis fld) (Urine)**
- **Sediment, Leucocytes, Quant (no/vis fld) (Urine)**
- **Leucocytes, Quant (10**6/L) (Volume) (Urine)**
- **Erythrocytes, Quant (1/uL) (Volume) (Urine)**

Data
Record laboratory test result.

Range Status, Unit and Range
Range Status, Unit and Range will be imported when local lab name is selected from the drop-down list at the top of the page.

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15.1.38 NON-CENTRAL LABORATORY TEST RESULTS - HEPATITIS B AND C TESTING (LB7)

For all subjects: This form is located in the *Screening or Rescreening* folder and is also available in the *Unscheduled* Visit folder.

For subjects with positive hepatitis B or C findings at the Screening/Rescreening visit, or those with a history of hepatitis B or C reported in the 2MH form: The form will appear in the Day 1 folder for each cycle.

Was the sample collected?
Indicate whether or not lab specimen was collected, or measurement performed.
If 'No', specify the reason.

What was the reason that the sample was not collected?
If "Was the sample collected?" is 'No', specify the reason.

What was the name of the lab panel?
Pre-specified on CRF as Serology/Immunology.

What was the date of the lab specimen collection?
Record the date when specimen collection was done using YYYY-MON-DD format (for example 2000-JAN-01).

What was the start time of the lab specimen collection?
Record time of collection (as complete as possible) in 24-hour format.

At the Screening/Rescreening visit, please ensure that the following mandatory qualitative analyte results are recorded in the CRF:

- *Hepatitis B Surface Antigen (HBsAg, Qual)*
- *Hepatitis B Core Antibody (anti-HBc, Qual)*
- *Hepatitis B Surface Antibody (HBsAb, Qual)*
- *Hepatitis C Antibody (HCV Ab, Qual)*

Hepatitis B Surface Antigen (Qual) (HBsAg) (Blood)
Select the appropriate option (Negative; Positive; +-borderline).

NOTE: If HBsAg result is positive, please record the test result for **qualitative Hepatitis D Antibody (Blood)**. If the result is +-borderline the test should be repeated, and results to be reported in UNSCHEDULED visit.

Hepatitis B Surface Antibody (HBsAb) (Blood)
Select the appropriate option (Negative; Positive; +-borderline).

NOTE: If the result is +-borderline the test should be repeated, and results to be reported in UNSCHEDULED visit.

Hepatitis B Core Antibody, Qual (anti-HBc) (Blood)
Select the appropriate option (Negative; Positive; +-borderline).

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NOTE: If anti-HBc result is positive, please record the test result for **qualitative Hepatitis D Antibody (Blood)**. If the result is +-borderline the test should be repeated, and results to be reported in UNSCHEDULED visit.

Hepatitis C Antibody (HCV ab) (Blood)
Select the appropriate option (Negative; Positive; +-borderline).

NOTE: If the result is +-borderline the test should be repeated, and results to be reported in UNSCHEDULED visit.

Hepatitis D Antibody (Blood)
Select the appropriate option (Negative; Positive; +-borderline).

NOTE: This result should be provided if either of HBsAg or anti-HBc values above is positive. If the result is +-borderline the test should be repeated, and results to be reported in UNSCHEDULED visit.

The following tests are available if the qualitative values above are positive:

- If Hepatitis B Surface Antigen (Qual) (HBsAg) (Blood) or Hepatitis B Core Antibody, Qual (anti-HBc) (Blood) is positive, either of below results should be provided:
  - **Hepatitis B Viral Load, Quant (IU/mL) (Blood)**
  - **Hepatitis B Viral Load, Quant (DNA copies/mL) (Blood)**
- If Hepatitis C Antibody (HCV ab) (Blood) is positive, either of below results should be provided:
  - **Hepatitis C Viral Load, Quant (IU/mL) (Blood)**
  - **Hepatitis C Viral Load, Quant (RNA copies/mL) (Blood)**
- If Hepatitis D Antibody (Blood) above is positive, please provide result for:
  - **Hepatitis D Virus RNA, Quant (Serum/Plasma)**

Note: If the site local lab report shows a result of "**Not Detected**", the result should be entered as "**0**" in the EDC.

Data
Record laboratory test results.

Range Status, Unit and Range
Range Status, Unit and Range will be imported when local lab name is selected from the drop-down list at the top of the page.

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15.1.39 NON-CENTRAL LABORATORY TEST RESULTS - HY'S LAW (LB8)

LB8 is used to report laboratory data for any subject who meets potential Hy's criteria – see Appendix E in the protocol for additional details.

This form is available to be added from ADD EVENT with either of below folders:

- ***Potential Hy's Law Folder:*** *Use this folder to report potential Hy's Law cases.*
- ***Unscheduled Visits Folder****: Report any additional laboratory results performed to confirm potential Hy's Law cases.*
  Note*: Do not include duplicate results that have already been reported in the LB8 form under the Hy's Law folder.*

Note: If liver function test results are already reported in LB (chemistry) form under scheduled visits those results shouldn't be duplicated in LB8 form as already recorded elsewhere.

Note: If criteria for potential Hy's Law has not been met (e.g., elevations of AST or ALT in isolation; no elevation in TBL), this eCRF does not need to be completed.

Was the sample collected?
Indicate whether or not lab specimen was collected, or measurement performed.
If 'No', specify the reason.

What was the reason that the sample was not collected?
If "Was the sample collected?" is 'No', specify the reason.

What was the name of the lab panel?
Pre-printed on the CRF Chemistry.

What was the date of the lab specimen collection?
Record the date when specimen collection was done using YYYY-MON-DD format (for example 2000-JAN-01).

What was the start time of the lab specimen collection?
Record time of collection (as complete as possible) in 24-hour format.

The following tests are available

- **Alanine Aminotransferase (Serum/Plasma)**
- **Alkaline Phosphatase (Serum/Plasma)**
- **Aspartate Aminotransferase (Serum/Plasma)**
- **Bilirubin, Total (Serum/Plasma)**

Data
Record laboratory test results.

Range Status, Unit and Range

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Range Status, Unit and Range will be imported when local lab name is selected from the drop-down list at the top of the page.

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15.1.40 NON-CENTRAL LABORATORY TEST RESULTS - INTERSTITIAL LUNG DISEASE (LB9)

Was the sample collected?
Indicate whether or not lab specimen was collected, or measurement performed.
If 'No', specify the reason.

What was the reason that the sample was not collected?
If "Was the sample collected?" is 'No', specify the reason.

What was the name of the lab panel?
Pre-printed on the CRF Chemistry.

What was the date of the lab specimen collection?
Record the date when specimen collection was done using YYYY-MON-DD format (for example 2000-JAN-01).

What was the start time of the lab specimen collection?
Record time of collection (as complete as possible) in 24-hour format.

The following tests are available:

- **1,3-Beta-D-Glucan (Serum)**
- **Carcinoembryonic Antigen (Serum/Plasma) (ng/mL)**
- **Carcinoembryonic Antigen (Serum/Plasma) (in Units (IU/mL))**
- **C-Reactive Protein (Blood)**
- **C-Reactive Protein (Serum/Plasma)**
- **Lactate Dehydrogenase (Serum/Plasma)**
- **Sialylated Carbohydrate Antigen KL-6 (Serum)**
- **Surfactant Protein A (Serum)**
- **Surfactant Protein D (Serum/Plasma)**
- **Surfactant Protein D (Sputum)**

Data
Record laboratory test results.

Range Status, Unit and Range
Range Status, Unit and Range will be imported when local lab name is selected from the drop-down list at the top of the page.

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15.1.41 NON-CENTRAL LABORATORY TEST RESULTS - TUBERCULOSIS TESTING (LB10)

Was the sample collected?
Indicate whether or not lab specimen was collected, or measurement performed.
If 'No', specify the reason.

What was the reason that the sample was not collected?
If "Was the sample collected?" is 'No', specify the reason.

What was the name of the lab panel?
Pre-printed on the CRF Serology/Immunology

What was the date of the lab specimen collection?
Record the date when specimen collection was done using YYYY-MON-DD format (for example 2000-JAN-01).

What was the start time of the lab specimen collection?
Record time of collection (as complete as possible) in 24-hour format.

Culture, Mycobacterium Tuberculosis(Sputum)
Select the appropriate option (Negative; Positive; +-borderline). If the result is +-borderline the test should be repeated, and results to be reported in UNSCHEDULED visit.

Quantiferon Tuberculosis Gold (Plasma)
Select the appropriate option (Negative; Positive; +-borderline). If the result is +-borderline the test should be repeated, and results to be reported in UNSCHEDULED visit.

Quantiferon Tuberculosis Gold (Blood)
Select the appropriate option (Negative; Positive; +-borderline). If the result is +-borderline the test should be repeated, and results to be reported in UNSCHEDULED visit.

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15.1.42 NON-CENTRAL LABORATORY TEST RESULTS - HIV TESTING (LB11)

Was the sample collected?
Indicate whether or not lab specimen was collected, or measurement performed.
If 'No', specify the reason.

What was the reason that the sample was not collected?
If "Was the sample collected?" is 'No', specify the reason.

What was the name of the lab panel?
Pre-printed on the CRF Serology/Immunology.

What was the date of the lab specimen collection?
Record the date when specimen collection was done using YYYY-MON-DD format (for example 2000-JAN-01).

What was the start time of the lab specimen collection?
Record time of collection (as complete as possible) in 24-hour format.

HIV-1/2 Antibody Screen (Blood)
Select the appropriate option (Negative; Positive; +-borderline). If the result is +-borderline the test should be repeated, and results to be reported in UNSCHEDULED visit.

The following tests are available:

- **HIV Viral Load, Quant, PCR (Blood)**
- **CD4+, abs(cells/uL) (Blood)**

Data
Record laboratory test results.

Range Status, Unit and Range
Range Status, Unit and Range will be imported when local lab name is selected from the drop-down list at the top of the page.

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15.1.43 NON-CENTRAL LABORATORY TEST RESULTS - ADDITIONAL CHEMISTRY (LB12)

NOTE: This form should be manually added to the **UNSCHEDULED visit** folder for tests that need to be performed as clinically indicated, in accordance with *Clinical Study Protocol Table 9*.

Was the sample collected?
Indicate whether or not lab specimen was collected, or measurement performed.
If 'No', specify the reason.

What was the reason that the sample was not collected?
If "Was the sample collected?" is 'No', specify the reason.

What was the name of the lab panel?
Pre-printed on the CRF as Chemistry.

What was the date of the lab specimen collection?
Record the date when specimen collection was done using YYYY-MON-DD format (for example 2000-JAN-01).

What was the start time of the lab specimen collection?
Record time of collection (as complete as possible) in 24-hour format.
The following tests are available:

Ferritin (Serum/Plasma)
Hba1c (IFCC-mmol/mol)
Hba1c (% ,Ratio)
Iron (Serum/Plasma)
Thyroglobulin Antibody (Serum)
Thyroid Peroxidase Antibody (Serum)
Thyrotropin Receptor Antibody (Serum)
Uric acid (Urate) (Serum/Plasma)

Data
Record laboratory test results.

Range Status, Unit and Range
Range Status, Unit and Range will be imported when local lab name is selected from the drop-down list at the top of the page.

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15.1.44 NON-CENTRAL LABORATORY TEST RESULTS - HEPATITIS B AND C TESTING - POST SCREENING (LB13)

This form is populated in the post-screening folders under the following conditions at Screening or Rescreening Visit:

- 2MH form: The subject has Hepatitis B or Hepatitis C history marked as “Yes” on the 2MH form located in the Screening Visit folder;

and/or

- LB7 form: The subject has one or more positive results for any of the following analytes on the LB7 form from the Screening or Rescreening Visit folders:
  - Hepatitis B Surface Antigen (Qual) (HBsAg) (Blood),
  - Hepatitis B Core Antibody, Qual (anti-HBc) (Blood),
  - Hepatitis C Antibody (HCV ab) (Blood)

Was the sample collected?
Indicate whether or not lab specimen was collected, or measurement performed.
If ‘No’, specify the reason.

What was the reason that the sample was not collected?
If ”Was the sample collected?” is ’No’, specify the reason.

What was the name of the lab panel?
Pre-printed on the CRF as Serology/Immunology.

What was the date of the lab specimen collection?
Record the date when specimen collection was done using YYYY-MON-DD format (for example 2000-JAN-01).

What was the start time of the lab specimen collection?
Record time of collection (as complete as possible) in 24-hour format.

The following tests are available:

- If subject has Hepatitis B history confirmed on 2MH form (Screening), or positive results of Hepatitis B tests from LB7 form (Screening or Rescreening), provide either of below results:
  - **Hepatitis B Viral Load, Quant (IU/mL) (Blood)**
  - **Hepatitis B Viral Load, Quant (DNA copies/mL) (Blood)**
- If subject has Hepatitis C history confirmed on 2MH form (Screening), or positive results of Hepatitis C tests from LB7 form (Screening or Rescreening), provide either of below results:
  - **Hepatitis C Viral Load, Quant (IU/mL) (Blood)**
  - **Hepatitis C Viral Load, Quant (RNA copies/mL) (Blood)**

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Note: If the site local lab report shows a result of "**Not Detected**", the result should be entered as "**0**" in the EDC.

Data
Record laboratory test results.

Range Status, Unit and Range
Range Status, Unit and Range will be imported when local lab name is selected from the drop-down list at the top of the page.

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15.1.45 SAMPLE COLLECTION, PREDOSE_ADA SAMPLE (SPCBEDB)

What was the sample category?
This will be pre-specified as 'Biomarkers/exploratory research/diagnostic, biofluid' in RAVE.

Sample collected
Record the appropriate option *(No; Yes).*

Sample collection method
This is defaulted to "Blood draw". Data entry not required.

Biofluid collected (parent sample)
This is defaulted to "Blood". Data entry not required.

Biofluid processed
This is defaulted to "Serum". Data entry not required.

Sample format
This is defaulted to "Frozen". Data entry not required.

Date of collection
Record a complete date using YYYY-MON-DD format (for example 2000-JAN-01).

Time of collection
Record a complete time in 24-hour clock format.

Sample condition
Record the appropriate option (Sample acceptable; Hemolyzed; Clotted; Lipemic; Quantity less than expected; Sample discarded; Other).

If Other, specify
If 'Other' was recorded for Sample condition, record details in this field.

Protocol schedule
The value is defaulted as "Pre Dose".

Laboratory ID
The value is defaulted as "LabCorp".

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15.1.46 BLOOD SAMPLE FOR PLASMA PRE-DOSE CTDNA (SPCBEDB1)

What was the sample category?
This will be pre-specified as 'Biomarkers/exploratory research/diagnostic, biofluid' in RAVE.

Sample collected
Record the appropriate option *(No; Yes).*

Sample collection method
This is defaulted to "Blood draw". Data entry not required.

Biofluid collected (parent sample)
This is defaulted to "cfDNA-BCT". Data entry not required.

Biofluid processed
This is defaulted to "Plasma". Data entry not required.

Sample format
This is defaulted to "DNA ". Data entry not required.

Date of collection
Record a complete date using *YYYY-MON-DD* format (for example 2000-JAN-01).

Time of collection
Record a complete time in 24-hour clock format.

Sample condition
Record the appropriate option *(Sample acceptable; Hemolyzed; Clotted; Lipemic; Quantity less than expected; Sample discarded; Other).*

If Other, specify
If 'Other' was recorded for Sample condition, record details in this field.

Protocol schedule
The value is defaulted as "Pre Dose".

Laboratory ID
The value is defaulted as "LabCorp".

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15.1.47 PBMC FOR IMMUNE PROFILING_PRE DOSE (SPCBEDB2)

What was the sample category?
This will be pre-specified as 'Biomarkers/exploratory research/diagnostic, biofluid' in RAVE.

Sample collected
Record the appropriate option *(No; Yes).*

Sample collection method
This is defaulted to "Blood draw". Data entry not required.

Biofluid collected (parent sample)
This is defaulted to "Blood Na heparin". Data entry not required.

Biofluid processed
This is defaulted to "PBMC". Data entry not required.

Sample format
This is defaulted to "Fresh". Data entry not required.

Date of collection
Record a complete date using YYYY-MON-DD format (for example 2000-JAN-01).

Time of collection
Record a complete time in 24-hour clock format.

Sample condition
Record the appropriate option *(Sample acceptable; Hemolyzed; Clotted; Lipemic; Quantity less than expected; Sample discarded; Other).*

If Other, specify
If 'Other' was recorded for Sample condition, record details in this field.

Protocol schedule
The value is defaulted as "Pre Dose".

Laboratory ID
The value is defaulted as "LabCorp".

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15.1.48 WHOLE BLOOD FOR RNA ANALYSIS_PRE-DOSE (SPCBEDB3)

What was the sample category?
This will be pre-specified as 'Biomarkers/exploratory research/diagnostic, biofluid' in RAVE.

Sample collected
Record the appropriate option *(No; Yes).*

Sample collection method
This is defaulted to " Blood draw". Data entry not required.

Biofluid collected (parent sample)
This is defaulted to "Blood". Data entry not required.

Biofluid processed
This is defaulted to "Blood". Data entry not required.

Sample format
This is defaulted to "RNA". Data entry not required.

Date of collection
Record a complete date using YYYY-MON-DD format (for example 2000-JAN-01).

Time of collection
Record a complete time in 24-hour clock format.

Sample condition
Record the appropriate option *(Sample acceptable; Hemolyzed; Clotted; Lipemic; Quantity less than expected; Sample discarded; Other).*

If Other, specify
If 'Other' was recorded for Sample condition, record details in this field.

Protocol schedule
The value is defaulted as "Pre Dose".

Laboratory ID
The value is defaulted as "LabCorp".

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15.1.49 BLOOD SAMPLES FOR SERUM BIOMARKER ANALYSIS PRE-DOSE (SPCBEDB4)

What was the sample category?
This will be pre-specified as ‘Biomarkers/exploratory research/diagnostic, biofluid’ in RAVE.

Sample collected
Record the appropriate option (No; Yes).

Sample collection method
This is defaulted to " Blood draw". Data entry not required.

Biofluid collected (parent sample)
This is defaulted to "Blood". Data entry not required.

Biofluid processed
This is defaulted to "Serum". Data entry not required.

Sample format
This is defaulted to "Frozen". Data entry not required.

Date of collection
Record a complete date using YYYY-MON-DD format (for example 2000-JAN-01).

Time of collection
Record a complete time in 24-hour clock format.

Sample condition
Record the appropriate option *(Sample acceptable; Hemolyzed; Clotted; Lipemic; Quantity less than expected; Sample discarded; Other).*

If Other, specify
If ‘Other’ was recorded for Sample condition, record details in this field.

Protocol schedule
The value is defaulted as "Pre Dose".

Laboratory ID
The value is defaulted as "LabCorp".

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15.1.50 SAMPLE COLLECTION, ADA SAMPLE (SPCBEDB5)

What was the sample category?
This will be pre-specified as 'Biomarkers/exploratory research/diagnostic, biofluid' in RAVE.

Sample collected
Record the appropriate option (No; Yes).

Sample collection method
This is defaulted to " Blood draw". Data entry not required.

Biofluid collected (parent sample)
This is defaulted to "Blood". Data entry not required.

Biofluid processed
This is defaulted to "Serum". Data entry not required.

Sample format
This is defaulted to "Frozen". Data entry not required.

Date of collection
Record a complete date using YYYY-MON-DD format (for example 2000-JAN-01).

Time of collection
Record a complete time in 24-hour clock format.

Sample condition
Record the appropriate option (Sample acceptable; Hemolyzed; Clotted; Lipemic; Quantity less than expected; Sample discarded; Other).

If Other, specify
If 'Other' was recorded for Sample condition, record details in this field.

Laboratory ID
The value is defaulted as "LabCorp".

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15.1.51 BLOOD SAMPLE FOR PLASMA CTDNA (SPCBEDB6)

What was the sample category?
This will be pre-specified as 'Biomarkers/exploratory research/diagnostic, biofluid' in RAVE.

Sample collected
Record the appropriate option (No; Yes).

Sample collection method
This is defaulted to " Blood draw". Data entry not required.

Biofluid collected (parent sample)
This is defaulted to "cfDNA-BCT". Data entry not required.

Biofluid processed
This is defaulted to "Plasma". Data entry not required.

Sample format
This is defaulted to "DNA". Data entry not required.

Date of collection
Record a complete date using YYYY-MON-DD format (for example 2000-JAN-01).

Sample condition
Record the appropriate option (Sample acceptable; Hemolyzed; Clotted; Lipemic; Quantity less than expected; Sample discarded; Other).

If Other, specify
If 'Other' was recorded for Sample condition, record details in this field.

Laboratory ID
The value is defaulted as "LabCorp".

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15.1.52 OPTIONAL ON STUDY TUMOR SAMPLE (SPCBEDT)

This form is available in below folders:

- Cycle 03 Day 01
- Unscheduled Visit

If Optional tumor sample is collected at disease progression, please record in Unscheduled Visit folder.

What was the sample collection category?
This will be pre-specified as 'Biomarkers/exploratory research/diagnostic, solid tissue'

Sample collected
Record the appropriate option *(No; Yes).*

Sample collection method
Record the appropriate option *(Core Needle Biopsy; Excisional Biopsy; Incisional Biopsy*)

Biopsy tissue type
Record the appropriate option *(Primary tumor; Metastatic tumor).*

Organ
Record the appropriate option *(Abdomen; Bronchus (Main Stem); Fat; Oesophagus; Pituitary; Urinary Bladder; Esophagogastric Junction; Other (Not Specified); 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)*

Sample format
Record the appropriate option *(FFPE block, FFPE unstained slides)*

Unstained slides sectioning date
Record a complete date using YYYY-MON-DD format (for example 2000-JAN-01).

Date of biopsy
Record a complete date using YYYY-MON-DD format (for example 2000-JAN-01).

Sample condition
Record the appropriate *option (Sample acceptable; Quantity less than expected; Sample discarded; Other)*.
If "Sample condition" is 'Other', record the "If Other, specify" field.

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If Other, specify
Record response if 'Other' is selected for Sample condition.

Date of storage
Record a complete date using YYYY-MON-DD format (for example 2000-JAN-01).

Time of storage
Record the complete time in 24-hour clock format.

Laboratory ID
This will be Study specific and will be pre-specified in RAVE as 'Labcorp'.

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15.1.53 MANDATORY SCREENING TUMOR SAMPLE (SPCBEDT1)

Refer to Device Events (DE) module guidelines if any related events *(AE related to biopsy, False positive PD-L1 results, False negative PD-L1 results, or Other events)* observed during tumor sample collection process.

What was the sample collection category?
This will be pre-specified as 'Biomarkers/exploratory research/diagnostic, solid tissue'

Sample collected
Record the appropriate option *(No; Yes).*

Sample collection method
Record the appropriate option *(Core Needle Biopsy; Excisional Biopsy; Incisional Biopsy)*

Biopsy tissue type
Record the appropriate option *(Primary tumor; Metastatic tumor).*

Organ
Record the appropriate option *(Abdomen; Bronchus (Main Stem); Fat; Oesophagus; Pituitary; Urinary Bladder; Esophagogastric Junction; Other (Not Specified); 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)*

Sample format
Record the appropriate option (FFPE block, FFPE unstained slides)

Unstained slides sectioning date
Record a complete date using YYYY-MON-DD format (for example 2000-JAN-01).

Date of biopsy
Record a complete date using YYYY-MON-DD format (for example 2000-JAN-01).

Sample condition
Record the appropriate option (Sample acceptable; Quantity less than expected; Sample discarded; Other). If "Sample condition" is 'Other', record the "If Other, specify" field.

If Other, specify
Record response if 'Other' is selected for Sample condition.

Date of storage
Record a complete date using YYYY-MON-DD format (for example 2000-JAN-01).

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Time of storage
Record the complete time in 24-hour clock format.

Laboratory ID
This will be Study specific and will be pre-specified in RAVE as ‘Labcorp’.

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15.1.54 GENOMICS INITIATIVE (OPTIONAL), EXPLORATORY GENETIC SAMPLE (SPCGB)

Was assessment applicable?
Record the appropriate option (No; Yes).

What was the sample category?
The value is defaulted as ‘Genetics somatic, biofluid’.

Sample collected
Record the appropriate option (No; Yes).

Sample collection method
This is defaulted to " Blood draw". Data entry not required.

Biofluid collected (parent sample)
This is defaulted to "Blood". Data entry not required.

Sample format
This is defaulted to "Frozen". Data entry not required.

Date of collection
Record a complete date using YYYY-MON-DD format (for example 2000-JAN-01).

Sample condition
Record the appropriate option (Sample acceptable; Hemolyzed; Clotted; Lipemic; Quantity less than expected; Sample discarded; Other).

If Other, specify
If ‘Other’ was recorded for Sample condition, record details in this field.

Sample collection comment
Record the sample collection comments

Date of storage
Record a complete date using YYYY-MON-DD format (for example 2000-JAN-01).

Time of storage
Record the complete time in 24-hour clock format.

Laboratory ID
This will be Study specific and will be pre-specified in RAVE as ‘Labcorp’.

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15.1.55 BIOLOGICAL SAMPLE COLLECTION, PRE-DOSE PK (SPCPKB)

What was the sample collection category?
Pre-specified as 'PK, biofluid'.

Sample collected
Record the appropriate option (No; Yes)

Biofluid collected (parent sample)
This is defaulted to "Blood". Data entry not required.

Biofluid processed
This is defaulted to "Serum". Data entry not required.

Date of collection
Record the appropriate date of collection in YYYY-MON-DD format (for example 2001-JAN-01).

Time of collection
Record the appropriate time of collection in 24-hours clock format.

Sample condition
Record the appropriate option (Sample acceptable; Hemolyzed; Clotted; Lipemic; Quantity less than expected; Sample discarded; Other).
If Other, specify
If 'Other' was recorded for Sample condition, record details in this field

Date of storage
Record a complete date using YYYY-MON-DD format (for example 2000-JAN-01).

Time of storage
Record the complete time in 24-hour clock format.

Protocol schedule
Pre-specified on eCRF as 'Pre Dose'.

Protocol schedule day
Pre-specified on eCRF

Protocol schedule hour
Pre-specified on eCRF

Protocol schedule minute
Pre-specified on eCRF

Approved

Downloaded by Shu Zhang on 08 Jul 2026

Laboratory ID

This will be Study specific and will be pre-specified in RAVE as ‘Labcorp’.

Approved

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15.1.56 BIOLOGICAL SAMPLE COLLECTION, POST-DOSE PK (SPCPKB1)

What was the sample collection category?
Pre-specified as ‘PK, biofluid’.

Sample collected
Record the appropriate option (No; Yes)

Biofluid collected (parent sample)
This is defaulted to "Blood". Data entry not required.

Biofluid processed
This is defaulted to "Serum". Data entry not required.

Date of collection
Record the appropriate date of collection in YYYY-MON-DD format (for example 2001-JAN-01).

Time of collection
Record the appropriate time of collection in 24-hours clock format.

Sample condition
Record the appropriate option (Sample acceptable; Hemolyzed; Clotted; Lipemic; Quantity less than expected; Sample discarded; Other).
If Other, specify
If ‘Other’ was recorded for Sample condition, record details in this field

Date of storage
Record a complete date using YYYY-MON-DD format (for example 2000-JAN-01).

Time of storage
Record the complete time in 24-hour clock format.

Protocol schedule
Pre-specified on eCRF as '15 mins Post Dose'.

Protocol schedule day
Pre-specified on eCRF as 1

Protocol schedule hour
Pre-specified on eCRF as 0

Protocol schedule minute
Pre-specified on eCRF as 15

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Downloaded by Shu Zhang on 08 Jul 2026

Laboratory ID

This will be Study specific and will be pre-specified in RAVE as ‘Labcorp’.

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15.1.57 BIOLOGICAL SAMPLE COLLECTION, PK (SPCPKB2)

What was the sample collection category?
Pre-specified as ‘PK, biofluid’.

Sample collected
Record the appropriate option (No; Yes)

Biofluid collected (parent sample)
This is defaulted to "Blood". Data entry not required.

Biofluid processed
This is defaulted to "Serum". Data entry not required.

Date of collection
Record the appropriate date of collection in YYYY-MON-DD format (for example 2001-JAN-01).

Time of collection
Record the appropriate time of collection in 24-hours clock format.

Sample condition
Record the appropriate option (Sample acceptable; Hemolyzed; Clotted; Lipemic; Quantity less than expected; Sample discarded; Other).

If Other, specify
If ‘Other’ was recorded for Sample condition, record details in this field

Date of storage
Record a complete date using YYYY-MON-DD format (for example 2000-JAN-01).

Time of storage
Record the complete time in 24-hour clock format.

Protocol schedule day
Pre-specified on eCRF as 9999

Protocol schedule hour
Pre-specified on eCRF as -999

Protocol schedule minute
Pre-specified on eCRF as -99

Laboratory ID
This will be Study specific and will be pre-specified in RAVE as ‘Labcorp’.

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15.1.58 TARGET LESIONS, BASELINE (1RECIST1)

General Guidance: Target lesions at Baseline:

The following Target lesion details recorded at baseline will be automatically copied to all target lesion follow up forms:

- Lesion number
- Anatomical location
- Specify location within site
- Tumor laterality
- Specify liver location
  - Location within liver specification (if applicable)
- Method

Target lesion details should be recorded on the 5 provided log lines. No new log line can be added and no logline can be inactivated. If data entered in error it should be corrected within logline.

No more than 2 lesions per organ (including lymph nodes collectively considered as a single organ) are to be recorded.

Definition of target lesion

A (not previously irradiated) lesion that can be accurately measured at baseline (as ≥ 10 mm in the longest diameter for non-nodal lesions or as ≥ 15 mm in the short axis diameter of for lymph node lesions) with computed tomography (CT) or magnetic resonance imaging (MRI) and which is suitable for accurate repeated measurements.

If the CT/MRI image slice thickness used is >5 mm, the minimum size of measurable disease at baseline should be at least twice the slice thickness of the baseline scan.

Target lesions should be selected on the basis of their size (lesions with the longest diameter or short axis for lymph nodes), be representative of all involved organs, and be those that lend themselves to reproducible repeated measurements.

It may be the case that, on occasion, the largest lesion does not lend itself to reproducible measurement in which circumstance the next largest lesion which can be measured reproducibly should be selected.

Approved

Note: If there is only one potential Target lesion that fulfils the target lesion size criteria per RECIST 1.1, but had been previously irradiated (external beam radiotherapy only), the lesion must show radiographic evidence of subsequent growth to qualify as a measurable TL at baseline.

Were there any target lesions present?
Record the appropriate option *(No; Yes).*

If *'Yes'*, record up to a maximum of 2 target lesions per site (organ) and 5 target lesions in total. Lymph nodes, in any location (local/regional and distant), are collectively considered as a single organ, with a maximum of 2 lymph nodes as target lesions. A bilateral organ

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(e.g., adrenal glands), a segmented organ (e.g., liver), or a multilobed organ (e.g., lung) is each considered as a single organ.

Excess target lesions should be recorded as non-target lesions.

Note:

- All lesions of disease under study detected at baseline should be identified as either target lesion or non-target lesion.
- Lytic bone lesions or mixed lytic-blastic lesions, with identifiable soft tissue components, can be considered measurable if the soft tissue component meets the definition of measurability.
- Blastic lesions are considered non-measurable.
- Cystic lesions thought to represent cystic metastases can be considered measurable lesions if they meet the criteria for measurability from a radiological point of view, but if non-cystic lesions are present in the same participant, these should be selected over cystic lesions as TLs.

What was the date of last scan?
Record the date using YYYY-MON-DD format *(for example 2000-JAN-01)* on which the last scan was performed where target lesions were identified within the screening period (baseline visit) even if no target lesions are identified. If more than one scan was performed, record the date of the last scan within the screening period (baseline visit).

All baseline scans must have been performed within 28 days prior to the date of randomization.

Lesion number
Pre-printed on eCRF. The maximum lesion is fixed to 5 Target lesions.

Anatomical location
Record the site (organ) for each target lesion *(Esophagus, Upper Thoracic; Esophagus, Middle Thoracic; Esophagus, Lower Thoracic; Retroperitoneum; Liver; Pleura; Adrenal gland; Lung, Left Lower Lobe; Lung, Left Upper Lobe; Lung, Right Lower Lobe; Lung, Right Middle Lobe; Lung, Right Upper Lobe; Regional lymph node; Distant lymph node; Bone; Stomach; Ovary; Spleen; Pancreas; Intrahepatic Bile Duct; Extrahepatic Bile Duct; Mediastinum; Gallbladder; Peritoneum; Other)*

Record up to a maximum of 2 target lesions per site. Lymph nodes, in any location (local/regional and distant), are collectively considered as a single organ, with a maximum of 2 lymph nodes as target lesions. A bilateral organ (e.g., adrenal glands), a segmented organ (e.g., liver), or a multilobed organ (e.g., lung) is each considered as a single organ.

All lymph nodes must be recorded using the codes *'regional lymph node'* or '*distant Lymph node'* (site like mediastinum or other should not be used to document lymph nodes).

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The code *'Other'* is reserved exclusively for locations not provided in the Anatomical location and should not be used to record a third location from a single organ (as defined above).

NOTE: Cross check the Anatomical location answer with the answer from module Extent of Disease (DISEXT).

Specify location within site
Record the location within site for each documented lesion. Be specific with location e.g. for the site code 'lung', the location within site might be 'upper right lobe'.

Field should be also used to specify location, when Anatomical location code of '*Other'* has been used.

Tumor laterality
Record the appropriate option *(Bilateral; Right; Left; Not applicable).*

Specify liver location
Record the appropriate option *(Liver-caudate lobe, segment I; Liver-left lobe, segment II; Liver-left lobe, segment III; Liver-left lobe, segment IV; Liver-right lobe, segment V; Liver-right lobe, segment VI; Liver-right lobe, segment VII; Liver-right lobe, segment VIII; Liver, left lobe; Liver, right lobe; Liver, specify).*

NOTE: This information should be entered only once in the Baseline RECIST folder and will automatically carry forward to all subsequent follow-up RECIST visits.

If "**Specify liver location**" is selected as *'Liver, Specify'*, please complete "**Location within liver specification".**
Location within liver specification
Record the location within liver if 'Liver" is selected in the 'Anatomical location' data field.

NOTE: This information should be entered only once in the Baseline RECIST folder and will automatically carry forward to all subsequent follow-up RECIST visits.

Method
Record the method of assessment *(MRI; CT scan; Not Done)* for each documented target lesion.

The same method of assessment for an individual lesion should be used throughout the duration of the study, unless the participant develops an adverse reaction to CT contrast.

Longest diameter
The longest diameter for each documented lesion refers to the long axis diameter for non-nodal lesions or the short axis diameter for lymph nodes (the short axis is defined as the longest axis perpendicular to the long axis). Diameter should be recorded in mm, with one decimal point precision. A non-nodal long axis diameter must be >= 10 mm, and a pathological lymph node short axis diameter must be >= 15 mm at baseline. If the CT/MRI image slice thickness used is >5 mm, the minimum size of measurable disease at baseline should be at least twice the slice thickness of the baseline scan.

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15.1.59 NON-TARGET LESIONS, BASELINE (2RECIST1)

Was any non-target lesion present?

Record the appropriate option *(No; Yes).*

If 'Yes', record the locations of non-target lesions.

NOTE: Multiple non-target lesions involving the same site should be recorded on a single line.

Definition of Non-Target Lesion (Refer to Appendix F of the Clinical Study Protocol)

Non-target lesions are selected at baseline and include all existing lesions other than those selected as target lesions:

- All measurable lesions not recorded as a target lesion
- Small lesions (longest diameter <10 mm or pathological lymph nodes with short axis > 10 mm and < 15 mm short axis)
- Truly non-measurable lesions including: bone, leptomeningeal disease, ascites, pleural or pericardial effusion, inflammatory breast disease, lymphangitic involvement of skin or lung.
- Previously irradiated lesions
- Brain metastasis

Note: Measurements of these lesions are not required, but the presence or absence of each should be noted throughout follow up.

What was the date of the last scan?
Record the date using YYYY-MON-DD format *(for example 2000-JAN-01)* on which the last scan/clinical examination was performed where non-target lesions were identified within this visit. If more than one scan/clinical examination was performed where non-target lesions were identified, record the date of the last scan/clinical examination.
All baseline scans must have been performed within 28 days, prior to the date of randomization.

Note: If Participant doesn't have any non-target lesions, please record the date on which the last scan was performed where no non-target lesion was identified within the screening period (baseline visit).

Anatomical location
Record the sites of all non-target lesions *(Brain Frontal Lobe; Brain Parietal Lobe; Brain Occipital Lobe; Brain stem; Brain Midbrain; Brain, third ventricle; Bone; Liver; Spinal cord; Pleura; Adrenal gland; Lung, Left Lower Lobe; Lung, Left Upper Lobe; Lung, Right Lower Lobe; Lung, Right Middle Lobe; Lung, Right Upper Lobe; Regional lymph node; Distant lymph node; Mediastinum; Pericardial Effusion; Pleural Effusion; Other).*

NOTE: Cross check the Anatomical location answer with the answer from module Extent of Disease (DISEXT).

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Multiple non-target lesions involving the same Anatomical location should be recorded on a single line when the same method of assessment (Method) has been used.

Specify location
If 'Other' is recorded for **Anatomical location**, record the details in this field.

Tumor laterality
Record the appropriate option *(Bilateral; Right; Left; Not applicable).*

Method
Record the method of assessment *(MRI; CT scan; X-ray; Scintigraphy; FDGPET;).*
The same method of assessment for an individual lesion should be used throughout the duration of the study.

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15.1.60 TARGET LESIONS, FOLLOW-UP (3RECIST1)

General Guidance: Target lesions at Follow-up

The following Target lesion details recorded at baseline will be copied across to the follow up forms:

- Lesion Number
- Anatomical location
- Specify location within site
- Tumor laterality
- Specify liver location
  - Location within liver specification (if applicable)
- Method

The Method (imaging modality, e.g., CT scan) is editable, in case a different method of assessment was used in the follow-up assessment as compared to baseline.

No additional target lesions (log lines) can be added during the study. If any target lesions that are not new lesions are required to be added during the study, then these must be recorded on the baseline form, and not on the follow-up forms. Any target lesions recorded at baseline will be automatically copied to all the follow up forms.

If a target lesion has been recorded in error, then the corresponding log line should be corrected on the baseline form. This will then be carried forward to each follow up form.

Note for **Unscheduled RECIST assessments**:
All unscheduled RECIST (tumor assessment) scans, even if no metastases are observed, must be added to the **Follow Up RECIST folder**. All relevant RECIST pages should be completed, including Target Lesion (3RECIST1) and Non-Target Lesion (4RECIST1) assessments. The overall response assessment must also be entered in RECIST2.

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Have target lesions been assessed?
Record the appropriate option *(No; Yes; Not applicable).*

Select 'No' if there was Target lesion documented at baseline but none of them were assessed at this visit (i.e. the scan from this visit covers a different anatomy). All remaining editable fields for target lesion(s) details should be left blank.

Select 'Yes', if at least one of the target lesion have been assessed at this visit, the **Lesion number, Anatomical location, Tumor laterality, Specify location within site, Specify liver location (Location within liver specification)** within site and **Method** details will be populated from baseline. The Longest diameter (mm) should be recorded (see below).

Select *'Not applicable'* only if there were no target lesions recorded at baseline.

What was the date of last scan?
Record the date of the last scan within the current RECIST visit, using YYYY-MON-DD format *(for example 2000-JAN-01)* on which the last scan was performed within this visit

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even if no target lesions identified. If more than one scan was performed, record the date of the last scan.

If the target lesion were identified at baseline and were not assessed at this visit (i.e. because the relevant anatomy was not scanned) or **if no target lesions was identified** at baseline the date of the latest scan performed should still be documented.

For lymph nodes, the shortest axis must be recorded.

Lesion number
Pre-printed on eCRF from the 1RECIST1 form.

Anatomical location
Location will be populated from baseline if there were target lesions recorded at baseline.
Pre-printed on eCRF from the 1RECIST1 form (*Esophagus, Upper Thoracic; Esophagus, Middle Thoracic; Esophagus, Lower Thoracic; Retroperitoneum; Liver; Pleura; Adrenal gland; Lung, Left Lower Lobe; Lung, Left Upper Lobe; Lung, Right Lower Lobe; Lung, Right Middle Lobe; Lung, Right Upper Lobe; Regional lymph node; Distant lymph node; Bone; Stomach; Ovary; Spleen; Pancreas; Intrahepatic Bile Duct; Extrahepatic Bile Duct; Mediastinum; Gallbladder; Peritoneum; Other).*

Specify location within site
It will be populated from baseline if there were target lesions recorded at baseline.
Pre-printed on eCRF from the 1RECIST1 form.

Tumor laterality
Pre-printed on eCRF from the 1RECIST1 form.
Laterality will be populated from baseline if there were target lesions recorded at baseline.
Record the appropriate option *(Bilateral; Right; Left; Not applicable).*

Specify liver location
Pre-printed on eCRF from the 1RECIST1 form.

Specify liver location will be populated from baseline if there were target lesions recorded at baseline. Record the appropriate option *(Liver-caudate lobe, segment I; Liver-left lobe, segment II; Liver-left lobe, segment III; Liver-left lobe, segment IV; Liver-right lobe, segment V; Liver-right lobe, segment VI; Liver-right lobe, segment VII; Liver-right lobe, segment VIII; Liver, specify; Liver, left lobe; Liver, right lobe.)*

If "Specify liver location" is selected as 'Liver, Specify', please complete "Location within liver specification"
Location within liver specification
Pre-printed on eCRF from the 1RECIST1 form.

Location within liver specification will be populated from baseline if there were target lesions recorded at baseline.

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Method
Method will be populated from baseline if there were target lesions recorded at baseline. The same method of assessment for an individual lesion should be used throughout the duration of the study. If the method of assessment for each site of a target lesion is different from that used at baseline, update the new method of assessment.

Longest diameter
The longest diameter for each documented lesion refers to the long axis diameter for non-nodal lesions or the short axis diameter for lymph nodes (the short axis is defined as the longest axis perpendicular to the long axis). Diameter should be recorded in mm, with one decimal point precision.

Lymph nodes with a short axis diameter of <10 mm are considered non-pathological; however, the short axis diameter measurements of lymph node lesions should continue to be recorded.

If no longer measurable, reason
Select *'Tumor too large to accurately measure' if* a target lesion increases in size significantly compared to the previous visit and is too large to accurately measure (e.g. partially outside the field of view of covered anatomy), the longest diameter measurable should still be entered as an estimate (assessment of target lesions will become progressive disease with this scenario).

Select '*Tumor too small to accurately measure' if* a target lesion is too faint or too small to accurately measure but believed to be present and is faintly seen, record a default longest diameter value of 5 mm. However, if an accurate measurement can be provided even if it is below 5 mm, then this measurement should be recorded and the lesion should not be recorded as 'too small to measure'.

Select '*Not Evaluable'* if the target lesion is not suitable for measurement (e.g. technical issues such as poor image quality, or missing anatomy), then the "**Longest diameter"** should be left blank.

If a target lesion has completely disappeared, then the "**Longest diameter"** should be recorded as 0 mm at this visit and at all subsequent visits, and the "**If no longer measurable**" code should be left blank. If a lesion appears in the same location on a subsequent scan, it will be recorded as a new lesion (New unequivocal lesions must be recorded in the "Tumor Evaluation (RECIST 1.1 Guidelines) New Lesions and Investigator Assessment of Overall Visit Response (RECIST2)" form).

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Special cases:

- If a target lesion has split into 2 or more parts, record the sum of the longest diameters (long axis diameters for non-lymph nodes or short axis diameters for lymph nodes) of those parts.
- If 2 or more target lesions have merged, record the longest diameter (long axis diameters for non-lymph nodes or short axis diameter for lymph nodes) of the merged lesion under one lesion and 0 mm for the other(s).
- If a target lesion has merged with a non-target lesion, try to find an image plane where the lesions are still separated, or, if not possible, use the full size as target lesion diameter.
- For target lesions measurable in 2 or 3 dimensions, always report the longest diameter (long axis diameter for non-lymph nodes or short axis diameter for lymph nodes).

Lesion intervention

Record "**Lesion intervention"** as '*Yes'* if there has been any intervention to a target lesion, e.g. irradiation, surgical excision, embolization, etc. If no intervention, leave blank.

When a target lesion has had any intervention during the study, "**Lesion intervention"** should be recorded as '*Yes'* and the size of the target lesion (longest diameter for non-nodal lesions or the short axis diameter for lymph nodes) should still be provided where possible. If a target lesion is completely missing due to an intervention, record 0 mm as longest diameter (regardless of whether the lesion was a lymph node or non-lymph node at baseline). When a target lesion has had any intervention during the study, "**Lesion intervention"** should be recorded as '*Yes'* at all subsequent visits, because once a lesion has had an intervention then it should be treated as having had an intervention for the remainder of the study. Ensure the lesion size is recorded at all subsequent visits for lesions with previous intervention.

Biopsies should not be included as an intervention unless in the Investigator's opinion there is a significant impact on the lesion size, e.g. from excisional biopsy.

NOTE: Once the RECIST outcome is determined to indicate Progressive Disease (PD), an additional scan (the follow-up scan) is expected to be conducted at least 4 weeks later and no later than the next scheduled imaging visit to provide additional information to mitigate potential informative censoring events by BICR-associated study endpoints.

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15.1.61 NON-TARGET LESIONS, FOLLOW-UP (4RECIST1)

Have non-target lesions been assessed?
Record the appropriate option *(No; Yes; Not applicable).*

Select ***'Yes'*** if there were non-target lesion at baseline and they have been assessed at this visit record "What was the date of the last scan?" and "What was the response of non-target lesions at this assessment?".

Select ***'No'*** if there were non-target lesion at baseline and they were not assessed at this visit, date of last scan should still be recorded and response of non-target lesions at this assessment should be recorded as 'Not evaluable'.

Select ***'Not applicable'*** only if there were no non-target lesions recorded at baseline (date of last scan and response of non-target lesions at this assessment should not be completed if 'Not applicable' is recorded).

What was the date of the last scan?
Record the date of the last scan within the current RECIST visit, using YYYY-MON-DD format *(for example 2000-JAN-01)* on which the last scan/clinical examination was performed where non-target lesions were identified within this visit. If more than one scan/clinical examination was performed where non-target lesions were identified, record the date of the last scan/clinical examination. All baseline scans must have been performed within 28 days prior to the date of randomization.

What was the response of non-target lesions at this assessment?
Record an overall non-target lesion response *(Complete response; Progressive disease; Non complete response/non-progressive disease; Not evaluable).*
If there were no non-target lesions recorded at baseline, the response of non-target lesions at this assessment should not be completed.

Response of Non-Target lesions:

- **Complete response (CR)**

  Disappearance of all non-target lesions since baseline. All lymph nodes must be non-pathological in size (< 10 mm short axis).

- **Non complete response/Non-progressive disease (Non-CR/Non-PD)**

  Persistence of one or more non-target lesion(s).

- **Progressive disease (PD)**

  Unequivocal progression of existing non-target lesions. To achieve 'unequivocal progression' on the basis of non-target lesions, there must be an overall level of substantial worsening in non-target disease such that, even in presence of stable disease or partial response in target lesions, the overall tumor burden has increased sufficiently to merit a determination of disease progression. A modest 'increase' in the

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size of one or more NTLs is usually not sufficient to qualify for unequivocal progression status.

- **Not evaluable (NE)**

  Only relevant when no non-target lesions qualify for unequivocal progression, when any of the non-target lesions were not assessed, or when the Investigator is not able to provide an evaluable overall non-target lesion assessment at this visit.

<u>If progressive disease (PD), provide details below for all progressed lesion sites.</u>

Anatomical location
Record the sites of all non-target lesions *(Brain Frontal Lobe; Brain Parietal Lobe; Brain Occipital Lobe; Brain stem; Brain Midbrain; Brain, third ventricle; Bone; Liver; Spinal cord; Pleura; Adrenal gland; Lung, Left Lower Lobe; Lung, Left Upper Lobe Lung, Right Lower Lobe; Lung, Right Middle Lobe; Lung, Right Upper Lobe; Regional lymph node; Distant lymph node; Mediastinum; Pericardial Effusion; Pleural Effusion; Other).*

Note: Multiple non-target lesions involving the same Anatomical location should be recorded on a single line when the same method of assessment (**Method**) has been used.

Specify location
If 'Other' is recorded for **Anatomical location**, record the details in this field.

Tumor laterality
Record the appropriate option *(Bilateral; Right; Left; Not applicable).*

Method
Record the method of assessment *(MRI; CT scan; X-ray; Scintigraphy; FDGPET;).* The same method of assessment for an individual lesion should be used throughout the duration of the study. If the method of assessment for each site of a non-target lesion is different from that used at baseline, provide the new method of assessment.

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15.1.62 NEW LESIONS AND INVESTIGATOR ASSESSMENT OF RESPONSE (RECIST2)

The appearance of brand-new unequivocal lesions as an indicator of RECIST 1.1 progression is only relevant for the overall visit response evaluation. New lesion assessment is distinct from the assessment of either target lesions or non-target lesions.

A new lesion is considered new only at the visit it was first identified—in all subsequent visits, it will be considered a pre-existing 'new' lesion. For follow-up scans after a RECIST 1.1-defined radiological progression (PD), both brand new lesions and pre-existing 'new' lesions are evaluated to determine the overall visit response. And the follow-up scans are expected to be reported in **Follow up RECIST folder**.

The finding of a New Lesion should be unequivocal, ie, not attributable to differences in scanning technique, change in imaging modality, or findings thought to represent something other than tumour.

A lesion identified at a follow-up assessment in an anatomical location that was not scanned at baseline is considered a new lesion and will indicate PD.

Note for **Unscheduled RECIST assessments**:
All unscheduled RECIST (tumor assessment) scans, even if no metastases are observed, must be added to the **Follow Up RECIST folder**.

All relevant RECIST pages should be completed, including Target Lesion (3RECIST1) and Non-Target Lesion (4RECIST1) assessments. The overall response assessment must also be entered in RECIST2.

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New lesions

Are there any new lesions since baseline?

Record either 'No' or 'Yes' to indicate if there are any new lesions since baseline. A new lesion is compared to the baseline assessment, once it appeared, it must be recorded in this page for all subsequent visits when it's visible. Record 'Yes' to indicate either/both the appearance of a brand, new lesion or the repeat observation of a pre-existing lesion at this visit.

What was the date of earliest scan/clinical examination detecting new lesions?

Record the corresponding date within the current RECIST visit, using this format *(YYYY-MON-DD)* on which the earliest scan was performed where new lesions were assessed within this visit. If more than one scan was performed where new lesions were assessed, record the date of the earliest scan. Record a date only if at least one new lesion is documented.

Anatomical location

Record the location (organ) for each documented brand new lesion (*Pericardial effusion; Pleural effusion; Bone; Liver; Brain; Spinal cord; Pleura; Skin; Adrenal gland; Regional*

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lymph node; Distant lymph node; Ascites; Extrahepatic Bile Duct; Intrahepatic Bile Duct; Gallbladder; Lung; Pancreas; Peritoneum; Spleen; Other)

If Other, specify

Record the appropriate information.

Method

Record the appropriate option *(FDGPET; MRI; CT scan; X-ray; Scintigraphy).*
Method of assessment (imaging modality, e.g. CT scan) must be recorded for each documented new lesion. If the new lesion is a pre-existing lesion (first observed at a previous visit), populate the Method of assessment that is used at the current visit, but it is editable, in case a different method of assessment was used.

New equivocal lesion present

Record either *'Yes', 'No'* to clarify if the new lesion recorded is equivocal or unequivocal.
Record ***'Yes'*** if the new lesion is equivocal and is not significant enough or too faint to trigger progressive disease.
Record ***'No'*** if the lesion is unequivocal and should trigger the progressive disease. Also record 'No' if a previous equivocal lesion is becoming unequivocal at this visit (do not modify the previous record when the lesion was equivocal).

Equivocal lesion converted to unequivocal

Record the appropriate option *(No; Yes; Not applicable).*
Record ***'Yes'*** if the lesion was recorded as equivocal at a previous visit and is now confirmed as unequivocal.
Record ***'No'*** if the lesion was previously equivocal and is still equivocal at this visit.
Record ***'Not applicable'*** if the lesion was unequivocal since the first time it appeared.

Date of scan equivocal lesion first detected

Record the appropriate date *(YYYY-MON-DD)* on which the equivocal lesion first appeared. The date should be the date from a previous visit.

Add a new Log line

Record 'Add a new Log line' to add details on brand new or pre-existing new lesions. A new lesion is considered new only at the visit it was first identified - in all subsequent visits, it will be considered a pre-existing 'new' lesion. If the new lesion is a pre-existing lesion (first observed at a previous visit), populate the new lesion number with the number that was used at the previous visit when the new lesion was first observed.

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OVERALL VISIT RESPONSE

Overall visit response is derived algorithmically from responses of target lesions, non-target lesions, and the presence of new unequivocal lesions. Responses of target lesions and non-target lesions are described in the tables below:

Table 8 Evaluation of Target Lesions

(refer to Clinical Study Protocol Table 15)

Complete response (CR)	Disappearance of all target lesions since baseline. Any pathological lymph nodes recorded as target lesions must have a reduction in short axis diameter to <10 mm.
Partial response (PR)	At least a 30% decrease in the sum of the diameters of target lesion, taking as reference the baseline sum of diameters
Stable disease (SD)	Neither sufficient decrease in sum of diameters to qualify for PR nor sufficient increase to qualify for PD
Progressive disease (PD)	At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest previous sum of diameters (nadir) – this includes the baseline sum if that is the smallest on study. In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm from nadir.
Not evaluable (NE)	Only relevant if any of the target lesions at follow-up were not assessed or not evaluable (e.g. poor image quality, missing anatomy, etc.) or had a lesion intervention at this or prior visits. Note: If the sum of diameters meets the progressive disease criteria, progressive disease overrides 'Not evaluable' as a target lesion response. Note: If any of the target lesions at follow-up were 'Not evaluable', the sum of diameters at that visit cannot be considered as the smallest sum of diameters (nadir) for comparison with sum of diameters at future visits for determination of progressive disease.
Not Applicable (NA)	Only relevant if no target lesions were present at baseline

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Table 9 Evaluation of Non-target Lesions

(refer to Clinical Study Protocol Table 16)

Complete response (CR)	Disappearance of all non-target lesions since baseline. All lymph nodes must be non-pathological in size (<10 mm short axis diameter).
Non-CR/non-PD	Persistence of one or more non-target lesion.
Progressive Disease (PD)	Unequivocal progression of existing non-target lesions. Unequivocal progression may be due to an important progression in one lesion only or in several lesions. In all cases the progression MUST be clinically significant for the physician to consider changing (or stopping) therapy.
Not evaluable (NE)	Only relevant when no non-target lesions qualify for unequivocal progression, when any of the non-target lesions were not assessed, or when the Investigator is not able to provide an evaluable overall non-target lesion assessment at this visit. Note: for patients without target lesions at baseline, this is relevant if any of the non-target lesions were not assessed at this visit and the progression criteria have not been met.
Not Applicable (NA)	Only relevant if no non-target lesions were present at baseline

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What is the RECIST response?

Record *'Complete response', 'Partial response', 'Progressive disease', 'Stable disease', 'Not evaluable', or 'No evidence of disease (NED)'* for Overall visit response.

Note: If the overall response is assessed as Progressive Disease, an additional follow-up scan should be done at least 4 weeks later, and no later than the next scheduled imaging visit even if the participant discontinues or delays study intervention. This follow-up scan will be reported in Follow-up RECIST folder accordingly.

Overall visit response is determined from assessments of target lesions, non-target lesions, and new unequivocal lesions according to the following table:

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Table 10 Overall visit response
(refer to Clinical Study Protocol Table 17)

Target lesions	Non-target lesions	New unequivocal lesions	Overall response
CR	CR	No	CR
CR	NA	No	CR
CR	Non-CR/Non-PD	No	PR
CR	NE	No	PR
PR	Non-PD or NE	No	PR
SD	Non-PD or NE	No	SD
NE	Non-PD or NE	No	NE
PD	Any	Yes or No	PD
Any	PD	Yes or No	PD
Any	Any	Yes	PD

Non-CR/Non-PD for overall response if only NTL (no TLs) are present at baseline.

NOTE: An overall assessment of CR (all other disease disappears/reverts to normal) would be changed to PR if ascites remains present radiologically.

Criteria type
Defaulted as 'RECIST 1.1'

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15.1.63 NEW LESIONS ADDITIONAL INFORMATION (NLESADD)

The NLESADD (new lesions additional information) form is used to record details of lesions identified on imaging that have been sampled. It is important to collect this data so that any biopsy/ cytology results if available may be shared for BICR analysis (blinded independent central review). Investigators may choose to sample a lesion that is equivocal or if the etiology is unclear. It is not required to sample every new lesion. Cytology findings may also be recorded on this form.

NLESADD form is triggered upon the addition of a new lesion in the follow up RECIST form when the question 'New equivocal lesion present?' is selected as '*yes'*. An NLESADD form should be completed for each equivocal new lesion entered.

In RECIST2 form, for an equivocal lesion, the question 'new equivocal lesion present?' should be answered "yes" at the time point when first detected, even if the lesion is later considered unequivocal after biopsy.

Assessment date
Record the assessment date of new lesion in YYYY-MON-DD format *(for example 2001-JAN-01).*

New lesion number
Record the new lesion number.

The 'New lesion number' field is manually entered and must match the corresponding lesion number in the RECIST 2 new lesion form where the "New equivocal lesion present?" is selected as "*Yes*".

Has biopsy been performed?
Record either '*No'* or '*Yes'* as appropriate.
If biopsy performed then record as '*Yes'*, or if not performed record as '*No'*.

Date of biopsy
Record a complete date using *YYYY-MMM-DD* format (for example *2000-JAN-01*). Please enter the actual biopsy date.

Did the pathology results of the biopsy confirm a new primary malignancy?
Select the appropriate option *(No; Yes).*

Did the pathology results of the biopsy confirm metastasis from the primary disease?
Select the appropriate option *(No; Yes).*

Did the pathology results of the biopsy confirm the metastasis from a new primary malignancy?
Select the appropriate option *(No; Yes).*

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Enter details of pathology results e.g. infection, inflammation, cytology or details of new cancer, Pathology results, specify
Record the pathology result details. This is a Free text field.

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15.1.64 EXPOSURE AS COLLECTED - RILVEGOSTOMIG (EC)

Important Notes:

- Skipped doses will **NOT** be applicable to Rilvegostomig.
- Cycle numbers for chemotherapy and immunotherapy can differ in timing because of treatment delays in one drug but not the other.

Note on Rounding Rules for Numeric Values

- The **Volume of infusion before/after administration** fields only allow 3-digit whole numbers (integers) to be entered in the EDC.
- The **Planned/Actual study drug dose for this cycle** fields only allow one decimal place.
- Please apply the following **rounding rules** where applicable:
    - If the digit to be rounded is 5 or greater, round up to the next higher value.
    - If the digit to be rounded is less than 5, round down to the nearest lower value.

Were any study drugs taken?
Record an appropriate option *(No; Yes).*

Study drug
Pre-populated as: Rilvegostomig.

Cycle number
Select appropriate cycle number from the drop-down list: e.g. C1D1, C2D1, C3D1…C70D1

Cycle number (Derived) This field is a derived value, No Data entry required.

Start date
Record the date in *YYYY-MON-DD* (for example 2000-Jan-01) format when subject started infusion of the study drug.

Start time
Record the time 24-hour clock format when subject started infusion of the study drug.

End date
Record the date in *YYYY-MON-DD* (for example 2000-Jan-01) format when subject stopped the intake.

End time
Record the time 24-hour clock format when subject stopped the intake.

N.B. If the Subject is lost to follow-up during a treatment period; please fill in the date of last study-related contact with the Subject as end date of administration.

Planned study drug dose for this cycle
Record the planned study drug dose for this cycle. For Rilvegostomig this is 750 mg.

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Planned dose units
Defaulted to mg

Actual study drug dose for this cycle
Record the actual study drug dose for this cycle.

NOTE: If the dose was **partially infused** because of an infusion reaction or otherwise, estimate the dose that was infused and record the dose, with an action taken as Drug Interrupted *(see Example at the end of this section).*
Actual study drug dose unit
Defaulted to mg

Action taken with study drug
Record an appropriate option; at least one value is compulsory (Dose not changed; Drug interrupted; Not applicable).

- **Not applicable**: For the first log line the response for Action taken with study drug is always 'Not applicable' unless there is an infusion interruption in which case it would be 'drug interrupted'.
- **Drug interrupted:** Select the response for Action taken with study drug when the study drug infusion is interrupted. Do not use this option when the planned dose is delayed.
- **Dose not changed:** Select the response for Action taken with study drug as 'Dose not changed'; when the '**Planned study drug dose for this cycle'** and '**Actual study drug dose for this cycle'** values entered in the current log line are same as in the previous log line.

Was this the last dose of study drug given?
If the dose was the actual last dose given to the Subject prior to completion or permanent discontinuation from the study treatment, select YES.

Reason adjusted
Record an appropriate option *(Adverse event; Technical issue; Subject decision; Other).*

Reason adjusted, specify
Record if Reason adjusted is equal to *'Other'.*

AE number 1, AE number 2, AE number 3, AE number 4
Record if Reason adjusted is 'Adverse event'.
Provide numbers of corresponding Adverse Events recorded on AE module (every AE number in separate AE number field).

Volume of infusion before administration
Record volume of infusion before administration.

Volume of infusion after administration
Record volume of remaining infusion that was not administered.

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As an example, if the volume of infusion before administration is 20 mL, and all 20mL were received by the Patient, the amount left in the Bag after infusion is 0 mL. The Volume of infusion after administration should be then recorded as 0 mL.

Infusion volume unit
The unit is defaulted to mL.

Treatment cycle delayed
Record an appropriate option *(No; Yes).* Treatment delays should be marked on the first resumed dose only.

Reason treatment cycle delayed
Record an appropriate option *(Adverse event; Subject decision; Lab abnormality not reported as an AE; Other).*

> ***Note****: If multiple reasons are applicable, please enter the PRIMARY reason the treatment cycle was delayed.*

If Reason treatment cycle delayed is equal to '*Adverse event'*, record Treatment cycle delayed AE number 1/2/3/4 (as applicable) by providing AE number that caused delay.

Treatment delayed AE number 1
Treatment delayed AE number 2
Treatment delayed AE number 3
Treatment delayed AE number 4

If *'Other'* is selected for "Reason treatment cycle delayed", record *Reason treatment cycle delayed, Specify.*

Reason treatment cycle delayed, Specify
Specify the reason for cycle delay.

Study drug administration/location impacted by global/country situation
If study drug administration or location was impacted by global/country situation (i.e. epidemic/pandemic, healthcare crisis, natural disaster etc.) record 'Yes'. Otherwise leave this field blank.

Study drug location status - global/country situation
If Study drug administration/location impacted by global/country situation was selected as 'Yes', indicate where study drug was administrated by selecting appropriate option *(Site; Other).*

If Other, specify
Record the appropriate response if Study drug location status - global/country situation is selected as 'Other'.

Administration performed by - global/country situation
If Study drug administration/location impacted by global/country situation was selected as 'Yes', indicate who performed study drug administration by selecting an appropriate option *(Health care professional; Other).*

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If Other, specify
Record the appropriate response if Administration performed by - global/country situation is selected as 'Other'.

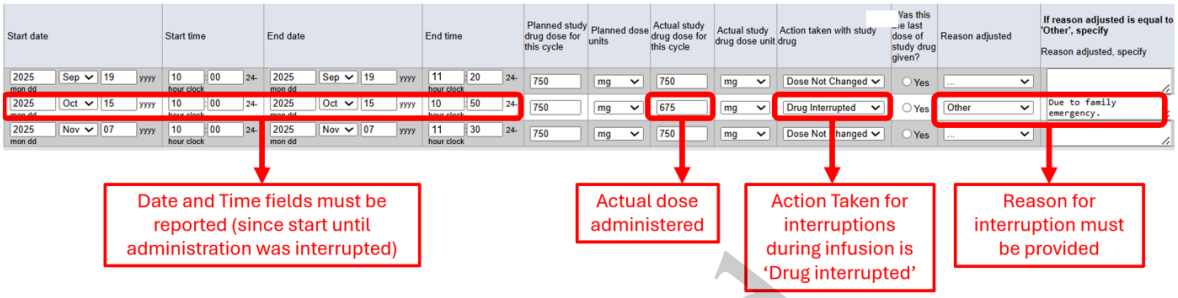
NOTE: If any changes in administration of investigational product were made because of an adverse event or disease progression, please fill in AE or RECIST2.

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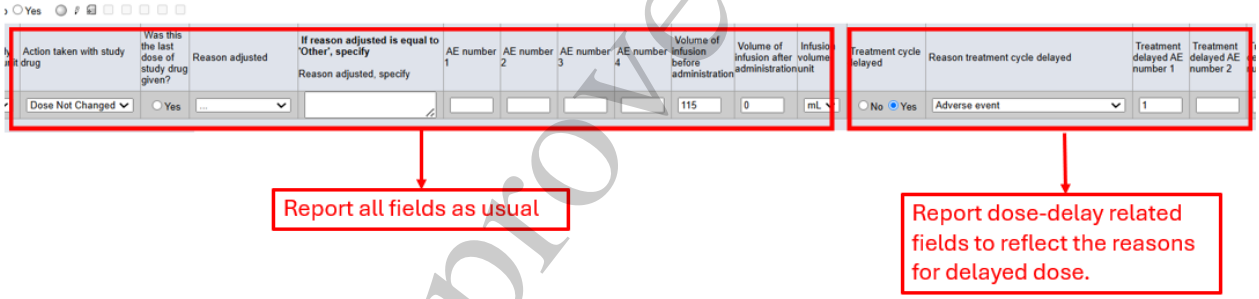
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- **Example# 1: Interruption during infusion**

Logline 2: interruption during infusion due to AE



- **Example# 2: Dose delay**



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15.1.65 EXPOSURE AS COLLECTED - DURVALUMAB (EC3)

Important Notes:

- Skipped doses will **NOT** be applicable to Durvalumab.
- Cycle numbers for chemotherapy and immunotherapy can differ in timing because of treatment delays in one drug but not the other.

Note on Rounding Rules for Numeric Values

- The **Volume of infusion before/after administration** fields only allow 4-digit whole numbers (integers) to be entered in the EDC.
- The **Planned/Actual study drug dose for this cycle** fields only allow 4-digit whole numbers (integers) for EC3 form.
- Please apply the following **rounding rules** where applicable:
    - If the digit to be rounded is 5 or greater, round up to the next higher value.
    - If the digit to be rounded is less than 5, round down to the nearest lower value.

Were any study drugs taken?
Record an appropriate option (No; Yes).

Study drug
Pre-populated as: Durvalumab

Cycle number
Record appropriate cycle number e.g. C1D1, etc.

Cycle number (Derived)
This field is a derived value, No Data entry required.

Start date
Record the date in *YYYY-MON-DD* (for example 2000-Jan-01) format when subject started infusion of the study drug.

Start time
Record the time 24-hour clock format when subject started infusion of the study drug..

End date
Record the date in *YYYY-MON-DD* (for example 2000-Jan-01) format when subject stopped the intake.

End time
Record the time 24-hour clock format when subject stopped the intake.

N.B. If the Subject is lost to follow-up during a treatment period; please fill in the date of last study-related contact with the Subject as end date of administration.

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Planned study drug dose for this cycle
Record the planned study drug dose for this cycle.

For Durvalumab this is usually 1500 mg. If the patient's weight drops ≤ 30 kg, the planned dose is calculated based on the rule of 20 mg/kg or per country Prescribing Information. For participants in Europe and UK, Durvalumab dose is 20 mg/kg for participants who weigh ≤ 36 kg until weight increases to > 36 kg.

Planned dose units
Defaulted to mg

Actual study drug dose for this cycle
Record the actual study drug dose for this cycle.

NOTE: If the dose was **partially infused** because of an infusion reaction or otherwise, estimate the dose that was infused and record the dose, with an action taken as Drug Interrupted *(see Example at the end of this section).*

Actual study drug dose unit
Defaulted to mg

Action taken with study drug
Record an appropriate option; at least one value is compulsory (Dose not changed; Drug interrupted; Not applicable).

- **Not applicable**: For the first log line the response for Action taken with study drug is always 'Not applicable' unless there is an infusion interruption in which case it would be 'drug interrupted'.
- **Drug interrupted**: Select the response for Action taken with study drug when the study drug infusion is interrupted. Do not use this option when the planned dose is delayed.
- **Dose not changed**: Select the response for Action taken with study drug as 'Dose not changed'; when the '**Planned study drug dose for this cycle'** and '**Actual study drug dose for this cycle**' values entered in the current log line are same as in the previous log line.

Was this the last dose of study drug given?
If the dose was the actual last dose given to the Subject prior to completion or permanent discontinuation from the study treatment, select YES.

Reason adjusted
Record an appropriate option *(Adverse event; Technical issue; Subject decision; Other).*

Reason adjusted, specify
Record if Reason adjusted is equal to '*Other'*.

AE number 1, AE number 2, AE number 3, AE number 4
Record if Reason adjusted is 'Adverse event'.

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Provide numbers of corresponding Adverse Events recorded on AE module (every AE number in separate AE number field).

Volume of infusion before administration
Record volume of infusion before administration.

Volume of infusion after administration
Record volume of remaining infusion that was not administered.
As an example, if the volume of infusion before administration is 20 mL, and all 20mL were received by the Patient, the amount left in the Bag after infusion is 0 mL. The Volume of infusion after administration should be then recorded as 0 mL.

Infusion volume unit
The unit is defaulted to mL.
Treatment cycle delayed
Record an appropriate option *(No; Yes).* Treatment delays should be marked on the first resumed dose only.

Reason treatment cycle delayed
Record an appropriate option *(Adverse event; Subject decision; Lab abnormality not reported as an AE; Other).*
Note: If multiple reasons are applicable, please enter the PRIMARY reason the treatment cycle was delayed.

If Reason treatment cycle delayed is equal to '*Adverse event'*, record Treatment cycle delayed AE number 1/2/3/4 (as applicable) by providing AE number that caused delay.

Treatment delayed AE number 1
Treatment delayed AE number 2
Treatment delayed AE number 3
Treatment delayed AE number 4

If *'Other'* is selected for "Reason treatment cycle delayed", record *Reason treatment cycle delayed, Specify.*

Reason treatment cycle delayed, Specify
Specify the reason for cycle delay.

Study drug administration/location impacted by global/country situation
If study drug administration or location was impacted by global/country situation (i.e. epidemic/pandemic, healthcare crisis, natural disaster etc.) record 'Yes'. Otherwise leave this field blank.

Study drug location status - global/country situation
If Study drug administration/location impacted by global/country situation was selected as 'Yes', indicate where study drug was administrated by selecting appropriate option (Site; Other).

If Other, specify

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Record the appropriate response if Study drug location status - global/country situation is selected as 'Other'.

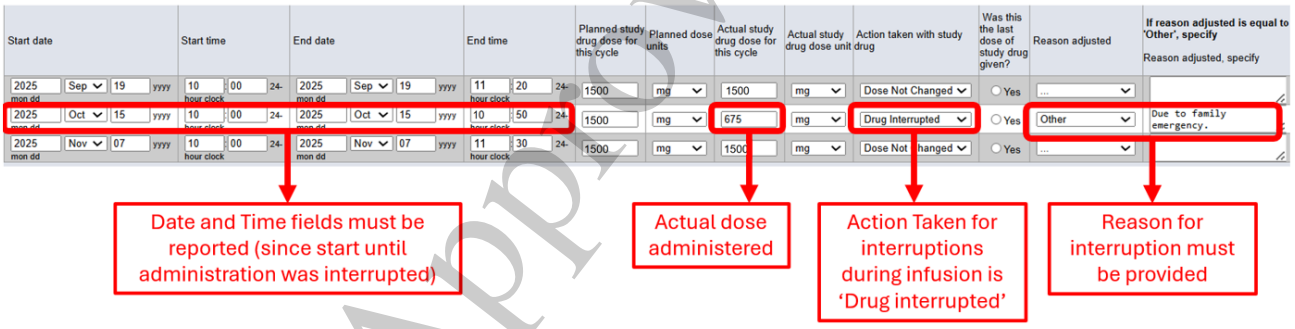
Administration performed by - global/country situation
If Study drug administration/location impacted by global/country situation was selected as 'Yes', indicate who performed study drug administration by selecting an appropriate option (Health care professional; Other).

If **Other, specify**
Record the appropriate response if Administration performed by - global/country situation is selected as 'Other'.

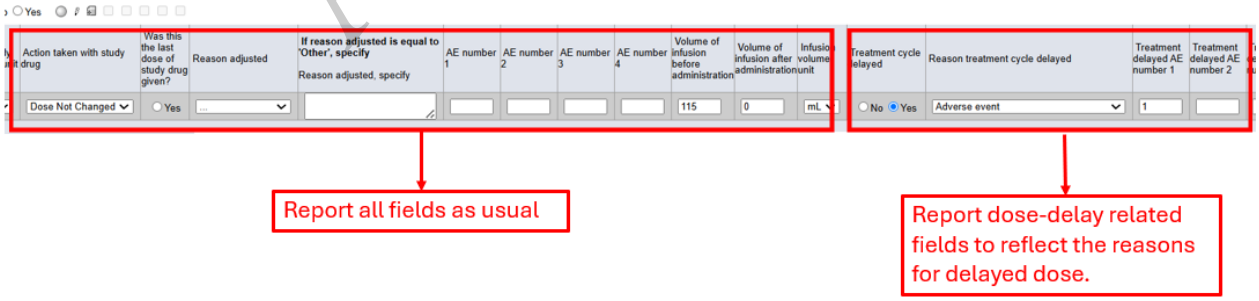
NOTE: If any changes in administration of investigational product were made because of an adverse event or disease progression, please fill in AE or RECIST2.

- **Example #1: Interruption during infusion**

Logline 2: interruption during infusion due to AE



- **Example# 2: Dose delay**



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15.1.66 EXPOSURE AS COLLECTED - GEMCITABINE (EC1)

Important Notes:

- Skipped dose instructions will **Only** be applicable to chemotherapy.

Cycle numbers for chemotherapy and immunotherapy can differ in timing because of treatment delays in one drug but not the other.

Note on Rounding Rules for Numeric Values

- The **Volume of infusion before/after administration** fields only allow 4-digit whole numbers (integers) to be entered in the EDC.
- The **Planned/Actual study drug dose for this cycle** fields only allow 4-digit whole numbers (integers) for EC3 form.
- Please apply the following **rounding rules** where applicable:
  - If the digit to be rounded is 5 or greater, round up to the next higher value.
  - If the digit to be rounded is less than 5, round down to the nearest lower value.

Were any study drugs taken?
Record an appropriate option (No; Yes).

Study drug
Pre-populated as: Gemcitabine

Cycle number
Record appropriate cycle number e.g. C1D1, C1D8.

Cycle number (Derived)
This field is a derived value, No Data entry required.

Start date
Record the date in *YYYY-MON-DD* (for example 2000-Jan-01) format when subject received started infusion of the study drug.

Start time
Record the time 24-hour clock format when subject started infusion of the study drug.

End date
Record the date in *YYYY-MON-DD* (for example 2000-Jan-01) format when subject stopped the intake.

End time
Record the time 24-hour clock format when subject stopped the intake.

N.B. If the Subject is lost to follow-up during a treatment period; please fill in the date of last study-related contact with the Subject as end date of administration.

Planned study drug dose for this cycle

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Record the planned study drug dose for this cycle.

Planned dose units
Defaulted to mg/m2

Actual study drug dose for this cycle
Record the actual study drug dose for this cycle.

NOTE:

- If a dose was **skipped** (see Example #1 at the end of this section):
    - Enter '0 mg' as the actual dose amount.
    - Use the planned dosing date for both the Start Date and End Date fields for that cycle.
    - All other fields in this log entry can be left blank.

  For the cycle immediately following the skipped dose, set 'Treatment Cycle Delayed' to 'Yes' and provide the reason for the delay.
- If the dose was **partially infused** because of an infusion reaction or otherwise, estimate the dose that was infused and record the dose, with an action taken as Drug Interrupted *(see Example #2 at the end of this section).*

Actual study drug dose unit
Defaulted to mg

Action taken with study drug
Record an appropriate option; at least one value is compulsory (Dose not changed; Drug interrupted; Not applicable; Dose increased; Dose reduced).

- **Not applicable**: For the first log line the response for Action taken with study drug is always 'Not applicable' unless there is an infusion interruption in which case it would be 'drug interrupted'.
- **Drug interrupted**: Select the response for Action taken with study drug when the study drug infusion is interrupted. Do not use this option when the planned dose is delayed.
- **Dose not changed**: Select the response for Action taken with study drug as 'Dose not changed' when the '**Planned study drug dose for this cycle' and** '**Actual study drug dose for this cycle'** values entered in the current log line are same as in the previous log line. Also, use 'Dose not changed' when actual dose of Gemcitabine in mg is adjusted due to weight drop but the planned dose in mg/m2 is not changed.
- **Dose increased/ Dose reduced**: Select the response for Action taken with study drug as '*Dose increased*' or '*Dose reduced*' according to the increase or decrease in **mg/m2** for the '**Planned study drug dose for this cycle'.**

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- **Blank:** When the D1 of a cycle is skipped but D8 of this cycle is administered, OR when the D8 of a cycle is skipped but D1 of this cycle is administered, leave the Action taken 'blank' and the dose should be '0'.

Was this the last dose of study drug given?
If the dose was the actual last dose given to the Subject prior to completion or permanent discontinuation from the study treatment, select YES.

Reason adjusted
Record an appropriate option (Adverse event; Technical issue; Subject decision; Other).

Reason adjusted, specify
Record if Reason adjusted is equal to 'Other'.

AE number 1, AE number 2, AE number 3, AE number 4
Record if Reason adjusted is 'Adverse event'.
Provide numbers of corresponding Adverse Events recorded on AE module (every AE number in separate AE number field).

Volume of infusion before administration
Record volume of infusion before administration.

Volume of infusion after administration
Record volume of remaining infusion that was not administered.
As an example, if the volume of infusion before administration is 20 mL, and all 20mL were received by the Patient, the amount left in the Bag after infusion is 0 mL. The Volume of infusion after administration should be then recorded as 0 mL.

Infusion volume unit
The unit is defaulted to mL.

Treatment cycle delayed
Record an appropriate option *(No; Yes).*

NOTE: if a dose is completely skipped in a cycle instead of being delayed,

- In current logline where dose skipped, leave 'Treatment cycle delayed' as blank;
- In the cycle immediately following the skipped dose, answer 'Treatment Cycle Delayed' to 'Yes' and provide the reason for the delay *(Refer to Example#1 at the end of this section).*

Reason treatment cycle delayed
Record an appropriate option *(Adverse event; Subject decision; Lab abnormality not reported as an AE; Other).*

Note: If multiple reasons are applicable, please enter the PRIMARY reason the treatment cycle was delayed.

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If Reason treatment cycle delayed is equal to '*Adverse event'*, record Treatment cycle delayed AE number 1/2/3/4 (as applicable) by providing AE number that caused delay.

Treatment delayed AE number 1
Treatment delayed AE number 2
Treatment delayed AE number 3
Treatment delayed AE number 4

If *'Other'* is selected for "Reason treatment cycle delayed", record *Reason treatment cycle delayed, Specify.*

Reason treatment cycle delayed, Specify
Specify the reason for cycle delay.

Study drug administration/location impacted by global/country situation
If study drug administration or location was impacted by global/country situation (i.e. epidemic/pandemic, healthcare crisis, natural disaster etc.) record 'Yes'. Otherwise leave this field blank.

Study drug location status - global/country situation
If Study drug administration/location impacted by global/country situation was selected as 'Yes', indicate where study drug was administrated by selecting appropriate option *(Site; Other).*

If Other, specify
Record the appropriate response if Study drug location status - global/country situation is selected as 'Other'.

Administration performed by - global/country situation
If Study drug administration/location impacted by global/country situation was selected as 'Yes', indicate who performed study drug administration by selecting an appropriate option *(Health care professional; Other).*

If Other, specify
Record the appropriate response if Administration performed by - global/country situation is selected as 'Other'.

NOTE: If any changes in administration of investigational product were made because of an adverse event or disease progression, please fill in AE or RECIST2.

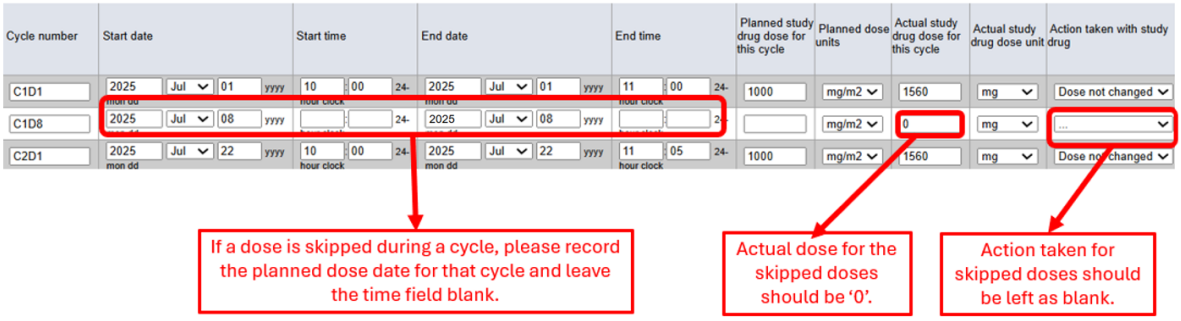
Examples:

- **Example#1: Skipped dose**

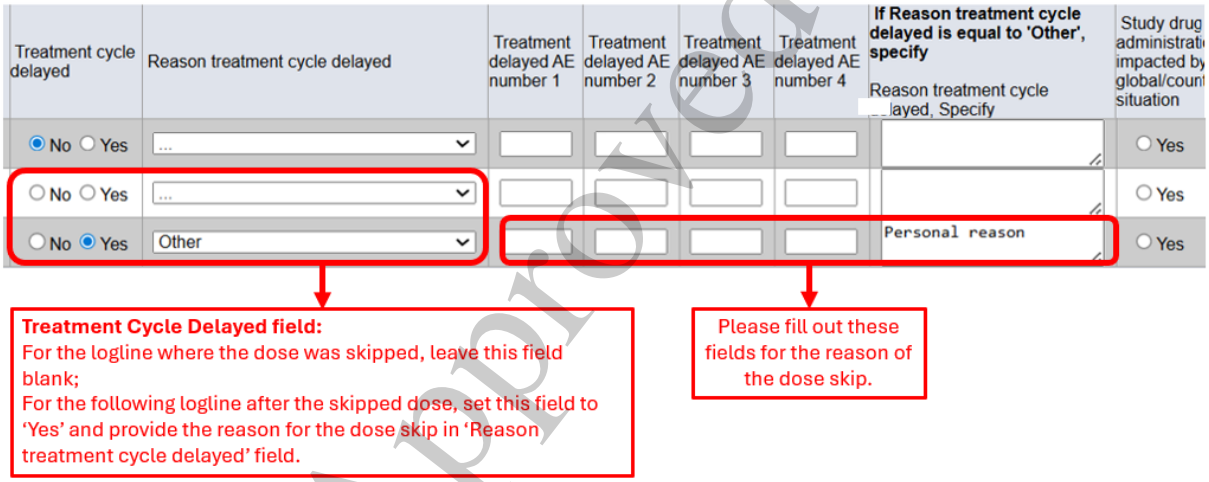
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Logline 2: skipped dose (if dose is skipped in a cycle)



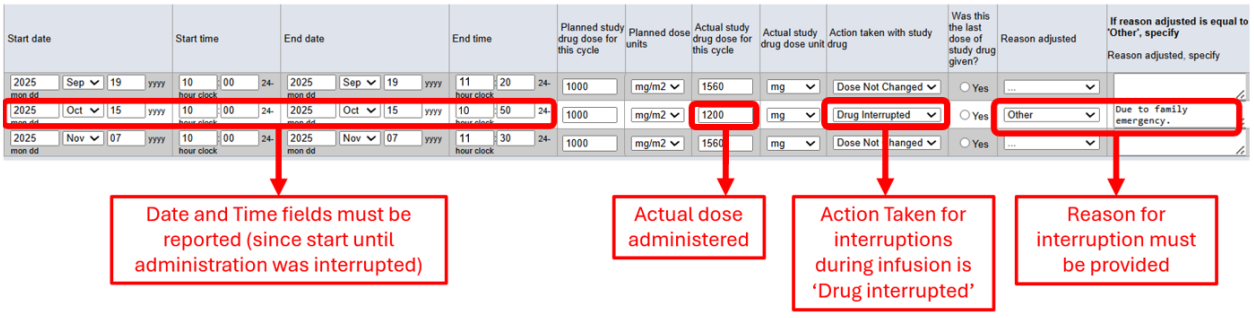
Logline 2: skipped dose (continue)



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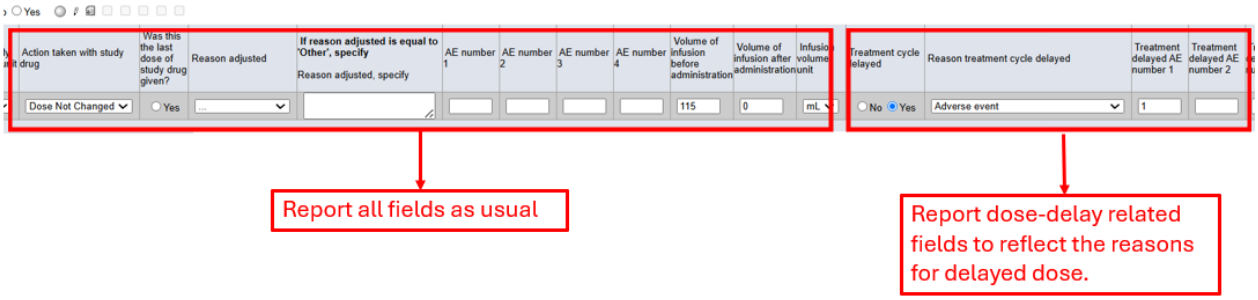
- **Example# 2: Interruption during infusion**

Logline 2: interruption during infusion due to AE



- **Example# 3: Dose delay**

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15.1.67 EXPOSURE AS COLLECTED - CISPLATIN (EC2)

Important Notes:

- Skipped dose instructions will **Only** be applicable to chemotherapy when the D1 of a cycle is skipped but D8 of this cycle is administered on time OR when the D8 of a cycle is skipped but D1 of this cycle is administered on time.
- Cycle numbers for chemotherapy and immunotherapy can differ in timing because of treatment delays in one drug but not the other.

Note on Rounding Rules for Numeric Values

- The **Volume of infusion before/after administration** fields only allow 4-digit whole numbers (integers) to be entered in the EDC.
- The **Planned/Actual study drug dose for this cycle** fields only allow one decimal place.
- Please apply the following **rounding rules** where applicable:
    - If the digit to be rounded is 5 or greater, round up to the next higher value.
    - If the digit to be rounded is less than 5, round down to the nearest lower value.

Were any study drugs taken?
Record an appropriate option *(No; Yes)*.

Study drug
Pre-populated as: Cisplatin

Cycle number
Record appropriate cycle number e.g. C1D1, C1D8.

Cycle number (Derived)
This field is a derived value, No Data entry required.

Start date
Record the date in *YYYY-MON-DD* (for example 2000-Jan-01) format when subject started infusion of the study drug.

Start time
Record the time 24-hour clock format when subject started infusion of the study drug.

End date
Record the date in *YYYY-MON-DD* (for example 2000-Jan-01) format when subject stopped the intake.

End time
Record the time 24-hour clock format when subject stopped the intake.

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N.B. If the Subject is lost to follow-up during a treatment period; please fill in the date of last study-related contact with the Subject as end date of administration.

Planned study drug dose for this cycle
Record the planned study drug dose for this cycle.

Planned dose units
Defaulted to mg

Actual study drug dose for this cycle
Record the actual study drug dose for this cycle.
NOTE:

- If a dose was **skipped** (see Example #1 at the end of this section):
    - Enter '0 mg' as the actual dose amount.
    - Use the planned dosing date for both the Start Date and End Date fields for that cycle.
    - All other fields in this log entry can be left blank.

  For the cycle immediately following the skipped dose, set 'Treatment Cycle Delayed' to 'Yes' and provide the reason for the delay.
- If the dose was **partially infused** because of an infusion reaction or otherwise, estimate the dose that was infused and record the dose, with an action taken as Drug Interrupted *(see Example #2 at the end of this section).*

Actual study drug dose unit
Defaulted to mg

Action taken with study drug
Record an appropriate option; at least one value is compulsory *(Dose not changed; Drug interrupted; Not applicable; Dose increased; Dose reduced).*

- **Not applicable**: For the first log line the response for Action taken with study drug is always 'Not applicable' unless there is an infusion interruption in which case it would be 'drug interrupted'.
- **Drug interrupted**: Select the response for Action taken with study drug when the study drug infusion is interrupted. Do not use this option when the planned dose is delayed.
- **Dose not changed**: Select the response for Action taken with study drug as 'Dose not changed' when the '**Planned study drug dose for this cycle' and** '**Actual study drug dose for this cycle'** values entered in the current log line are same as in the previous log line. Also, use 'Dose not changed' when actual dose of Gemcitabine in mg is adjusted due to weight drop but the planned dose in mg/m2 is not changed.

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- **Dose increased/ Dose reduced**: Select the response for Action taken with study drug as '*Dose increased*' or '*Dose reduced*' according to the increase or decrease in **mg/m2** for the '**Planned study drug dose for this cycle'.**
- **Blank**: When the D1 of a cycle is skipped but D8 of this cycle is administered OR when the D8 of a cycle is skipped but D1 of this cycle is administered, leave the Action taken 'blank' and the dose should be '0'.

Was this the last dose of study drug given?
If the dose was the actual last dose given to the Subject prior to completion or permanent discontinuation from the study treatment, select *YES*.

Reason adjusted
Record an appropriate option (*Adverse event; Technical issue; Subject decision; Other).*

Reason adjusted, specify
Record if Reason adjusted is equal to 'Other'.

AE number 1, AE number 2, AE number 3, AE number 4
Record if Reason adjusted is 'Adverse event'.
Provide numbers of corresponding Adverse Events recorded on AE module (every AE number in separate AE number field).

Volume of infusion before administration
Record volume of infusion before administration.

Volume of infusion after administration
Record volume of remaining infusion that was not administered.
As an example, if the volume of infusion before administration is 20 mL, and all 20mL were received by the Patient, the amount left in the Bag after infusion is 0 mL. The Volume of infusion after administration should be then recorded as 0 mL.

Infusion volume unit
The unit is defaulted to mL.

Treatment cycle delayed
Record an appropriate option *(No; Yes).* Treatment delays should be marked on the first resumed dose only.

NOTE: if a dose is completely skipped in a cycle instead of being delayed,
- In current logline where dose skipped, leave 'Treatment cycle delayed' as blank;
- In the cycle immediately following the skipped dose, answer 'Treatment Cycle Delayed' to 'Yes' and provide the reason for the delay *(Refer to Example#1 at the end of this section).*

Reason treatment cycle delayed
Record an appropriate option *(Adverse event; Subject decision; Lab abnormality not reported as an AE; Other).*

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Note: If multiple reasons are applicable, please enter the PRIMARY reason the treatment cycle was delayed.

If Reason treatment cycle delayed is equal to '*Adverse event'*, record Treatment cycle delayed AE number 1/2/3/4 (as applicable) by providing AE number that caused delay.

Treatment delayed AE number 1
Treatment delayed AE number 2
Treatment delayed AE number 3
Treatment delayed AE number 4

If *'Other'* is selected for "Reason treatment cycle delayed", record *Reason treatment cycle delayed, Specify.*

Reason treatment cycle delayed, Specify
Specify the reason for cycle delay.

Study drug administration/location impacted by global/country situation
If study drug administration or location was impacted by global/country situation (i.e. epidemic/pandemic, healthcare crisis, natural disaster etc.) record 'Yes'. Otherwise leave this field blank.

Study drug location status - global/country situation
If Study drug administration/location impacted by global/country situation was selected as 'Yes', indicate where study drug was administrated by selecting appropriate option *(Site; Other).*

If Other, specify
Record the appropriate response if Study drug location status - global/country situation is selected as 'Other'.

Administration performed by - global/country situation
If Study drug administration/location impacted by global/country situation was selected as 'Yes', indicate who performed study drug administration by selecting an appropriate option *(Health care professional; Other).*

If Other, specify
Record the appropriate response if Administration performed by - global/country situation is selected as 'Other'.

NOTE: If any changes in administration of investigational product were made because of an adverse event or disease progression, please fill in AE or RECIST2.

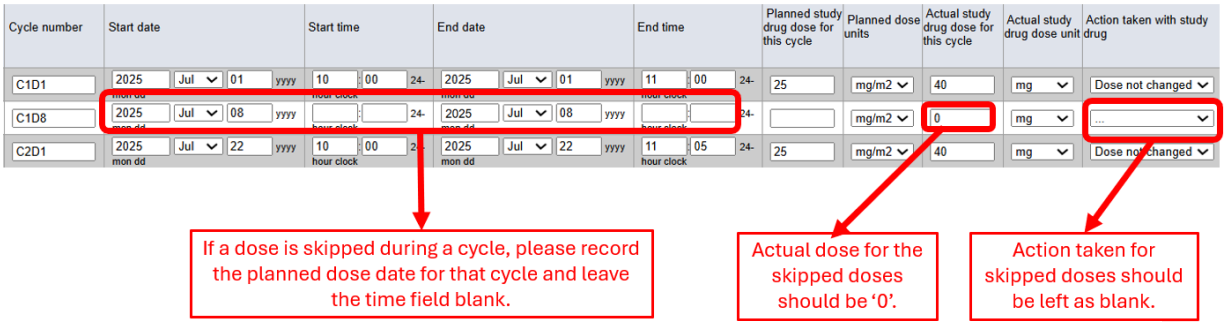
Examples:

- **Example #1: Skipped dose**

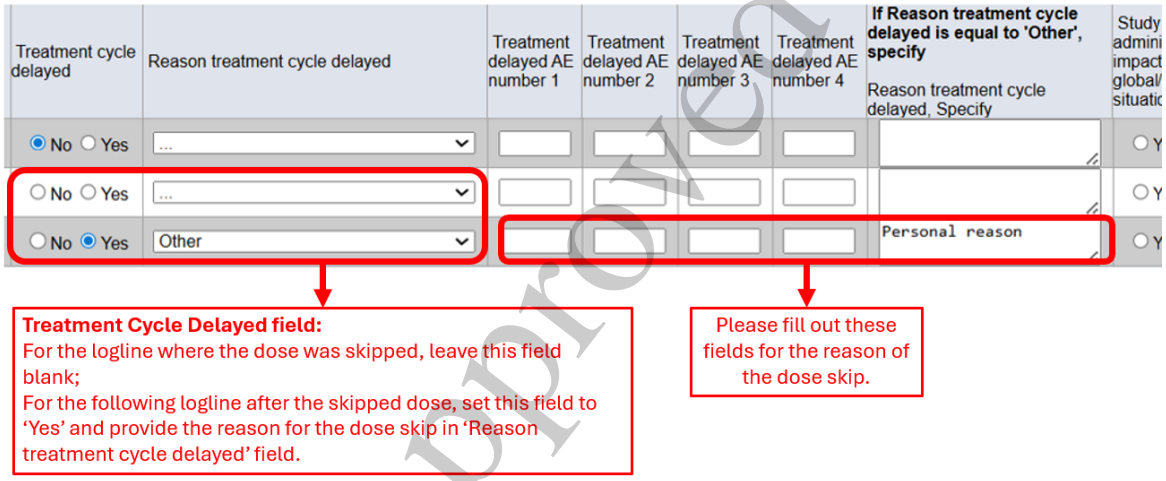
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Logline 2: skipped dose (if dose is skipped in a cycle)



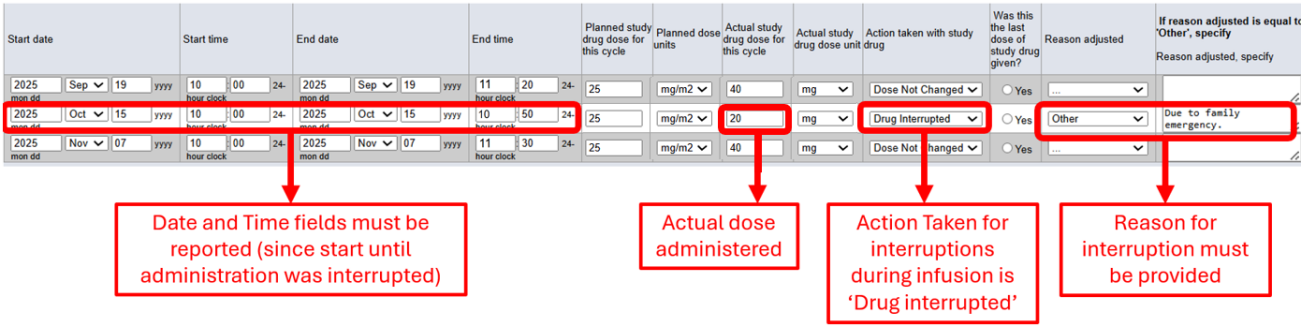
Logline 2: skipped dose (continue)



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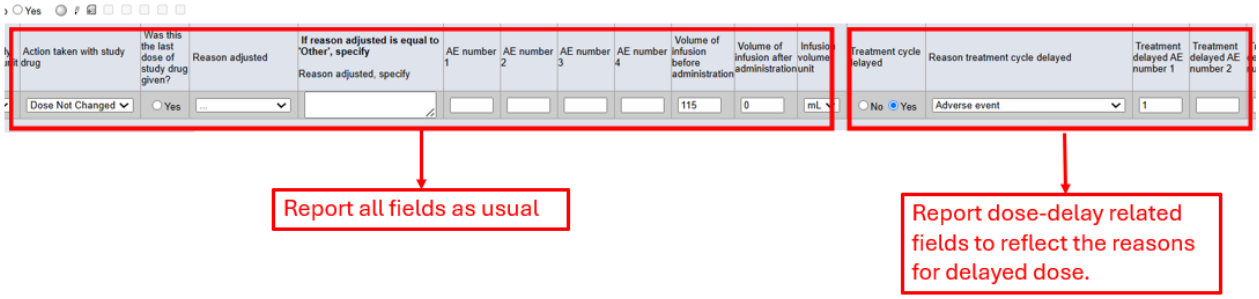
- **Example# 2: Interruption during infusion**

Logline 2: interruption during infusion due to AE



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- **Example# 2: Dose delay**



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15.1.68 END OF STUDY TREATMENT - RILVEGOSTOMIG (ETRT)

The End of Study Treatment (ETRT) form should be completed for all Subjects receiving study treatment (who received at least one study treatment dose). If Subject did not have the study treatment initiated or Subject continues study treatment after final clinical data lock, this form should be left untouched.
The End of Study Treatment form should be completed at the time of completion or discontinuation of study treatment.

NOTE: Discontinuation from study treatment is not equal to discontinuation/withdrawal from the study.

If study treatment is permanently discontinued, Subject should be followed up according to the Clinical Study Protocol.

What was the category of the disposition?
Defaulted to: DISPOSITION EVENT.

What was the subcategory for disposition event?
Defaulted as Rilvegostomig.

What was the study treatment discontinuation date?
This field is automatically derived from the EC form when the field *"Was this the last dose of study drug given?"* is marked as '*Yes*'. This is a system-generated field and does not require manual data entry.

Note: Please ensure the date is correctly recorded on EC form.

What was the date when the decision was made to permanently discontinue study treatment?
A complete date must be entered when the Investigator or Subject decided to discontinue Subject from the study treatment. Record the date using YYYY-MON-DD format (for example 2000-JAN-01).

Note: If there was no Investigator or Subject decision of study treatment discontinuation e.g. reason for study treatment discontinuation is selected as *Death; Lost to follow up*, this field should be left blank.

Reason for study treatment discontinuation
Record the appropriate option

Table 11: Reason for Study treatment discontinuation - Rilvegostomig

Subject decision	This option is applicable when Subject/Legal Representative decided to discontinue study treatment. Subject Decision is also applicable when the preliminary reason for study treatment discontinuation was consent withdrawal.

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Adverse event	This option is applicable when the study treatment was actively discontinued due to Adverse Event as per Investigator's judgment. Adverse event (AE) Form needs to be completed. Cross-check with the AE page to ensure "*Action taken due to AE, Rilvegostomig"* is aligned.
Severe non-compliance to protocol	This option is applicable in case of severe non-compliance with the clinical study protocol as judged by Investigator or AstraZeneca.
Objective disease progression	Participants will receive IP on D1 of each cycle starting on C1D1 until disease progression or unacceptable toxicity.
Lost to follow up	A participant will be considered lost to follow-up if the participant repeatedly fails to return for scheduled visits and no contact has been established by the time the study is completed, such that there is insufficient information to determine the participant's status at that time. • Before a participant is deemed lost to follow-up, the Investigator or designee must make every effort to regain contact with the participant (where possible, 3 telephone calls, texts, emails, and if necessary, a certified letter to the participant's last known mailing address or local equivalent methods). These contact attempts should be documented in the participant's medical record.
Subjective disease progression	This option is applicable when there was an Investigator decision of study treatment discontinuation based on clinical observations of disease progression but without RECIST1.1 defined radiological progression
Investigator decision	This option is applicable when the Investigator made the decision to discontinue study treatment for any reason other than those already covered within other available options.
Pregnancy	This option is applicable when a study treatment was discontinued due to pregnancy.
Study terminated by sponsor	This option is applicable when the study was terminated by a sponsor for any reason.
Death	This option is applicable when Subject died while on study treatment and there was no active decision made by Investigator to discontinue study treatment prior to death. Death is also applicable when if Subject died while on temporary interruption of study treatment and there was no decision made

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	by Investigator to permanently discontinue study treatment prior to death.
Other	This option is applicable if study treatment discontinuation was caused by any other reason not listed on the value list.

Specify, if main reason is 'Other' or 'Severe non-compliance to protocol'
If reason for treatment discontinuation is '*Other'* or '*Severe non-compliance to protocol'*, provide details.

NB:

- If main reason is "***Adverse event***" make sure that **Adverse event (AE)** form has been filled in for conditions leading to discontinuation.
- If main reason is "***Death***" make sure that **Death Details (DD)** form has been filled in.

Specify, if main reason is 'Subject decision'
Record the appropriate option (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
Record the appropriate information

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15.1.69 END OF STUDY TREATMENT - DURVALUMAB (ETRT3)

The End of Study Treatment (ETRT) form should be completed for all Subjects receiving study treatment (who received at least one study treatment dose). If Subject did not have the study treatment initiated or Subject continues study treatment after final clinical data lock, this form should be left untouched.

The End of Study Treatment form should be completed at the time of completion or discontinuation of study treatment.

NOTE: Discontinuation from study treatment is not equal to discontinuation/withdrawal from the study.

If study treatment is permanently discontinued, Subject should be followed up according to the Clinical Study Protocol.

What was the category of the disposition?
Defaulted to DISPOSITION EVENT.

What was the subcategory for disposition event?
Defaulted as Durvalumab.

What was the study treatment discontinuation date?
This field is automatically derived from the EC3 form when the field *"Was this the last dose of study drug given?"* is marked as '*Yes*'. This is a system-generated field and does not require manual data entry.

Note: Please ensure the date is correctly recorded on EC3 form.

What was the date when the decision was made to permanently discontinue study treatment?
A complete date must be entered when the Investigator or Subject decided to discontinue Subject from the study treatment. Record the date using YYYY-MON-DD format (for example 2000-JAN-01).

Note: If there was no Investigator or Subject decision of study treatment discontinuation e.g. reason for study treatment discontinuation is selected as *Death; Lost to follow up*, this field should be left blank.

Reason for study treatment discontinuation
Record the appropriate option

Table 12 Reason for study treatment discontinuation - Durvalumab

Subject decision	This option is applicable when Subject/Legal Representative decided to discontinue study treatment. Subject Decision is also applicable when

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	the preliminary reason for study treatment discontinuation was consent withdrawal.
Adverse event	This option is applicable when the study treatment was actively discontinued due to Adverse Event as per Investigator's judgment. Adverse event (AE) Form needs to be completed. Cross-check with the AE page to ensure *"Action taken due to AE, Durvalumab"* is aligned.
Severe non-compliance to protocol	This option is applicable in case of severe non-compliance with the clinical study protocol as judged by Investigator or AstraZeneca.
Objective disease progression	Participants will receive IP on D1 of each cycle starting on C1D1 until disease progression or unacceptable toxicity.
Lost to follow up	A participant will be considered lost to follow-up if the participant repeatedly fails to return for scheduled visits and no contact has been established by the time the study is completed, such that there is insufficient information to determine the participant's status at that time. • Before a participant is deemed lost to follow-up, the Investigator or designee must make every effort to regain contact with the participant (where possible, 3 telephone calls, texts, emails, and if necessary, a certified letter to the participant's last known mailing address or local equivalent methods). These contact attempts should be documented in the participant's medical record.
Subjective disease progression	This option is applicable when there was an Investigator decision of study treatment discontinuation based on clinical observations of disease progression but without RECIST1.1 defined radiological progression
Investigator decision	This option is applicable when the Investigator made the decision to discontinue study treatment for any reason other than those already covered within other available options.

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Pregnancy	This option is applicable when a study treatment was discontinued due to pregnancy.
Study terminated by sponsor	This option is applicable when the study was terminated by a sponsor for any reason.
Death	This option is applicable when Subject died while on study treatment and there was no active decision made by Investigator to discontinue study treatment prior to death. Death is also applicable when if Subject died while on temporary interruption of study treatment and there was no decision made by Investigator to permanently discontinue study treatment prior to death.
Other	This option is applicable if study treatment discontinuation was caused by any other reason not listed on the value list.

Specify, if main reason is 'Other' or 'Severe non-compliance to protocol'
If reason for treatment discontinuation is 'Other' or 'Severe non-compliance to protocol', provide details.

NB:
- If main reason is "***Adverse event***" make sure that **Adverse event (AE)** form has been filled in for conditions leading to discontinuation.
- If main reason is "***Death***" make sure that **Death Details (DD)** form has been filled in.

Specify, if main reason is 'Subject decision'
Record the appropriate option (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
Record the appropriate information

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15.1.70 END OF STUDY TREATMENT - GEMCITABINE (ETRT1)

The End of Study Treatment (ETRT) form should be completed for all Subjects receiving study treatment (who received at least one study treatment dose). If Subject did not have the study treatment initiated or Subject continues study treatment after final clinical data lock, this form should be left untouched.
The End of Study Treatment form should be completed at the time of completion or discontinuation of study treatment.

NOTE: Discontinuation from study treatment is not equal to discontinuation/withdrawal from the study.
If study treatment is permanently discontinued, Subject should be followed up according to the Clinical Study Protocol.

What was the category of the disposition?
Defaulted to DISPOSITION EVENT.

What was the subcategory for disposition event?
Defaulted as Gemcitabine.

What was the study treatment completion or discontinuation date?
This field is automatically derived from the EC1 form when the field *"Was this the last dose of study drug given?"* is marked as '*Yes'*. This is a system-generated field and does not require manual data entry.

Note: Please ensure the date is correctly recorded on EC1 form.

What was the date when the decision was made to permanently discontinue study treatment?
A complete date must be entered when the Investigator or Subject decided to discontinue Subject from the study treatment. Record the date using YYYY-MON-DD format (for example 2000-JAN-01).

Note: If there was no Investigator or Subject decision of study treatment discontinuation e.g. reason for study treatment discontinuation is selected as Completed; Death; Lost to follow up, this field should be left blank.

Completion or reason for study treatment discontinuation
Record the appropriate option

Table 13 Reason for study treatment discontinuation - Gemcitabine

Subject decision	This option is applicable when Subject/Legal Representative decided to discontinue study treatment. Subject Decision is also applicable when the preliminary reason for study treatment discontinuation was consent withdrawal.

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Adverse event	This option is applicable when the study treatment was actively discontinued due to Adverse Event as per Investigator's judgment. Adverse event (AE) Form needs to be completed. Cross-check with the AE page to ensure *"Action taken due to AE, Gemcitabine"* is aligned.
Severe non-compliance to protocol	This option is applicable in case of severe non-compliance with the clinical study protocol as judged by Investigator or AstraZeneca.
Objective disease progression	Participants will receive IP on D1 of each cycle starting on C1D1 until disease progression or unacceptable toxicity.
Lost to follow up	A participant will be considered lost to follow-up if the participant repeatedly fails to return for scheduled visits and no contact has been established by the time the study is completed, such that there is insufficient information to determine the participant's status at that time. • Before a participant is deemed lost to follow-up, the Investigator or designee must make every effort to regain contact with the participant (where possible, 3 telephone calls, texts, emails, and if necessary, a certified letter to the participant's last known mailing address or local equivalent methods). These contact attempts should be documented in the participant's medical record.
Subjective disease progression	This option is applicable when there was an Investigator decision of study treatment discontinuation based on clinical observations of disease progression but without RECIST1.1 defined radiological progression
Completed	This option is applicable when Subject continued Gemcitabine treatment for 8 cycles Q3W, on Day 1 and Day 8 of each cycle, as tolerated and per local guidelines.
Investigator decision	This option is applicable when the Investigator made the decision to discontinue study treatment for any

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	reason other than those already covered within other available options.
Pregnancy	This option is applicable when a study treatment was discontinued due to pregnancy.
Study terminated by sponsor	This option is applicable when the study was terminated by a sponsor for any reason.
Death	This option is applicable when Subject died while on study treatment and there was no active decision made by Investigator to discontinue study treatment prior to death. Death is also applicable when if Subject died while on temporary interruption of study treatment and there was no decision made by Investigator to permanently discontinue study treatment prior to death.
Other	This option is applicable if study treatment discontinuation was caused by any other reason not listed on the value list.

Specify, if main reason is 'Other' or 'Severe non-compliance to protocol'
If reason for treatment discontinuation is 'Other' or 'Severe non-compliance to protocol', provide details.

NB:

- If main reason is "***Adverse event***" make sure that **Adverse event (AE)** form has been filled in for conditions leading to discontinuation.
- If main reason is "***Death***" make sure that **Death Details (DD)** form has been filled in.

Specify, if main reason is 'Subject decision'
Record the appropriate option (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
Record the appropriate information

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15.1.71 END OF STUDY TREATMENT - CISPLATIN (ETRT2)

The End of Study Treatment (ETRT) form should be completed for all Subjects receiving study treatment (who received at least one study treatment dose). If Subject did not have the study treatment initiated or Subject continues study treatment after final clinical data lock, this form should be left untouched.
The End of Study Treatment form should be completed at the time of completion or discontinuation of study treatment.

NOTE: Discontinuation from study treatment is not equal to discontinuation/withdrawal from the study.
If study treatment is permanently discontinued, Subject should be followed up according to the Clinical Study Protocol.

What was the category of the disposition?
Defaulted to DISPOSITION EVENT.

What was the subcategory for disposition event?
Defaulted as **Cisplatin**.

What was the study treatment completion or discontinuation date?
This field is automatically derived from the EC2 form when the field *"Was this the last dose of study drug given?"* is marked as '*Yes'*. This is a system-generated field and does not require manual data entry.

Note: Please ensure the date is correctly recorded on EC2 form.

What was the date when the decision was made to permanently discontinue study treatment?
A complete date must be entered when the Investigator or Subject decided to discontinue Subject from the study treatment. Record the date using YYYY-MON-DD format (for example 2000-JAN-01).

Note: If there was no Investigator or Subject decision of study treatment discontinuation e.g. reason for study treatment discontinuation is selected as Completed; Death; Lost to follow up, this field should be left blank.

Completion or reason for study treatment discontinuation
Record the appropriate option

Table 14 Reason for study treatment discontinuation - Cisplatin

Subject decision	This option is applicable when Subject/Legal Representative decided to discontinue study treatment. Subject Decision is also applicable when the preliminary reason for study treatment discontinuation was consent withdrawal.

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Adverse event	This option is applicable when the study treatment was actively discontinued due to Adverse Event as per Investigator's judgment. Adverse event (AE) Form needs to be completed. Cross-check with the AE page to ensure "*Action taken due to AE, Cisplatin"* is aligned.
Severe non-compliance to protocol	This option is applicable in case of severe non-compliance with the clinical study protocol as judged by Investigator or AstraZeneca.
Objective disease progression	Participants will receive IP on D1 of each cycle starting on C1D1 until disease progression or unacceptable toxicity.
Lost to follow up	A participant will be considered lost to follow-up if the participant repeatedly fails to return for scheduled visits and no contact has been established by the time the study is completed, such that there is insufficient information to determine the participant's status at that time. • Before a participant is deemed lost to follow-up, the Investigator or designee must make every effort to regain contact with the participant (where possible, 3 telephone calls, texts, emails, and if necessary, a certified letter to the participant's last known mailing address or local equivalent methods). These contact attempts should be documented in the participant's medical record.
Subjective disease progression	This option is applicable when there was an Investigator decision of study treatment discontinuation based on clinical observations of disease progression but without RECIST1.1 defined radiological progression
Completed	This option is applicable when Subject continued Cisplatin treatment for 8 cycles Q3W, on Day 1 and Day 8 of each cycle, as tolerated and per local guidelines.
Investigator decision	This option is applicable when the Investigator made the decision to discontinue study treatment for any

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	reason other than those already covered within other available options.
Pregnancy	This option is applicable when a study treatment was discontinued due to pregnancy.
Study terminated by sponsor	This option is applicable when the study was terminated by a sponsor for any reason.
Death	This option is applicable when Subject died while on study treatment and there was no active decision made by Investigator to discontinue study treatment prior to death. Death is also applicable when if Subject died while on temporary interruption of study treatment and there was no decision made by Investigator to permanently discontinue study treatment prior to death.
Other	This option is applicable if study treatment discontinuation was caused by any other reason not listed on the value list.

Specify, if main reason is 'Other' or 'Severe non-compliance to protocol'
If reason for treatment discontinuation is 'Other' or 'Severe non-compliance to protocol', provide details.

NB:
- If main reason is "***Adverse event***" make sure that **Adverse event (AE)** form has been filled in for conditions leading to discontinuation.
- If main reason is "***Death***" make sure that **Death Details (DD)** form has been filled in.

Specify, if main reason is 'Subject decision'
Record the appropriate option (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
Record the appropriate information

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15.1.72 PRIOR CANCER THERAPY (CAPRX)

Has cancer therapy been previous/current/post withdrawn of IP?
Defaulted to *'Previous'* for previous cancer therapy.
Has the Subject had any cancer therapy?
Record the appropriate option *(No; Yes; Not applicable).*

> **If Not applicable, specify**
> Record the appropriate details if **Has the Subject had any cancer therapy?** is recorded as *' Not applicable '.*

Cancer therapy agent
Record a single agent per logline. Enter the full generic or trade name, without abbreviations.

Cancer therapy agent start date
Record the complete date in *YYYY-MON-DD* format (for example *2000-Jan-01*).

NOTE: For previous therapy only: Dates should be as complete as possible. If exact start date is not known, date can be modified to record only year (YYYY-UNK-UN), or year and month only (e.g. YYYY-MON-UN).

Cancer therapy agent stop date
Record the complete date in *YYYY-MON-DD* format (for example *2000-Jan-01*).

NOTE: For previous therapy only: Dates should be as complete as possible. If exact start date is not known, date can be modified to record only year (YYYY-UNK-UN), or year and month only (e.g. YYYY-MON-UN).

Best overall response
Record the appropriate option (*Complete response; Partial response; Stable disease; Progressive disease; Not evaluable; Not applicable*).
NOTE: The "**Best overall response**" should be the same on all lines that are components of the same regimen.

Treatment status
Record the appropriate option *(Adjuvant; Neo-adjuvant; Not applicable).*
NOTE: If neo-adjuvant or adjuvant is selected, please ensure the associated surgery is recorded*.*

Concomitant chemoradiotherapy
Record the appropriate option *(No; Yes).*
NB*: If 'Yes', Radiotherapy must be recorded on the Prior Radiotherapy (CAPRXR) page.*

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Indication

Record the appropriate details (Biliary Tract Cancer; Other).

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15.1.73 PRIOR RADIOTHERAPY (CAPRXR)

Has cancer therapy been previous/current/post withdrawn of IP?
Defaulted to *Previous* for Prior Radiotherapy.

Was radiotherapy performed?
Record the appropriate option (*No; Yes).*

If "Was radiotherapy performed?" is recorded as 'Yes', specify below:
Concomitant chemoradiotherapy
Record the appropriate option (*No; Yes).*

Treatment setting
Record the appropriate option (*Adjuvant; Neo-adjuvant; Palliative; Other*).

If Other, specify
If '*Other*' was recorded for **Treatment setting**, provide details.

Number of sites/regions treated simultaneously
Record the appropriate number.

Radiotherapy site/region treated location
Record the appropriate option (*Lung - Lower Lobe; Lung - Middle Lobe; Lung - Upper Lobe; Bone; Liver; Brain; Spinal Cord; Pleura; Skin; Adrenal Gland; Pelvic Bone; Regional Lymph Node; Distant Lymph Node; Gallbladder; Biliary Tract; Other*).

If Other, specify
If '*Other*' was recorded for **Radiotherapy site/region treated location**, provide details.

Radiotherapy site/region laterality
Record the appropriate option (*Left; Right; Bilateral; Not applicable*).

Radiotherapy technique
Record the appropriate option (*3-D conformal; Intensity modulated radiotherapy (IMRT); Stereotactic intracranial radiotherapy; Stereotactic body radiotherapy (SBRT); Stereotactic radiosurgery (SRS); Whole brain radiotherapy (WBRT); Selective Internal Radiotherapy (SIRT); Other*).

If Other, specify
If '*Other*' was recorded for **Radiotherapy technique,** provide details.

Radiotherapy start date
Record a complete date using *YYYY-MON-DD* format (*for example 2000-JAN-01*).

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Radiotherapy stop date
Record a complete date in *YYYY-MON-DD* format (*for example 2000-JAN-01*).

Dose per fraction
Record the appropriate data.

Dose per fraction unit
Record the appropriate option (*Gy; Other*).

If Other, specify
If '*Other*' was recorded for **Dose per fraction unit** provide the unit.

Number of fraction doses
Record the number of fraction doses given.

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15.1.74 SUBSEQUENT CANCER THERAPY (CAPRX1)

Subsequent Cancer Therapy form must be reviewed at the time of every follow-up contact with the patient and this information should be updated on the ongoing basis.

Has cancer therapy been previous/current/post withdrawn of IP?
Text is pre-specified as '*Post'* for post IP discontinuation cancer therapy.

Has the patient had any cancer therapy?
Select an appropriate option. *(No; Yes; Not Applicable)*

If Not applicable, specify

Record the appropriate details if **Has the Subject had any cancer therapy?** is recorded as *' Not applicable '.*

- **If Yes, please complete the remaining sections of this form:**

Cancer therapy agent
Record a single agent per logline. Enter the full generic or trade name, without abbreviations.

Cancer therapy agent start date
Enter the date in *YYYY-MMM-DD* format.
Dates should be as complete as possible. If exact start date is not known enter as a minimum, the year, for Month select UNK and Day enter UN.

Cancer therapy agent stop date
Enter the date in *YYYY-MMM-DD* format.
Please leave as blank if post-IP discontinuation anticancer treatment still ongoing. Please update when patient has completed therapy or when patient is terminated from study.
Dates should be as complete as possible. If exact start date is not known enter as a minimum, the year, for Month select UNK and Day enter UN.

Best overall response
Select an appropriate option. (*Complete response; Partial response; Stable disease; Progression; Non-evaluable; Not applicable*)
The Best response should be the same on all lines that are components of the same regimen
Please leave as blank if post-IP discontinuation anticancer treatment still ongoing. Please update when patient has completed therapy or when patient is terminated from study.

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Treatment status
Select an appropriate option. *(First line; Second line; Third line; >Third line; Not applicable)*

The first line therapy is the initial treatment given for advanced disease. If the first line therapy fails due to disease progression patients may be moved to second line therapy, which means a different drug, or combination or schedule of drugs. Subsequent changes in treatment due to disease progression (third line, fourth line, etc.) are defined similarly, representing each new regimen or approach used after the previous one is discontinued.

Note: In most cases “First line” is not applicable in this study because Artemide-Biliary02 study treatment counts as a first line of therapy unless discontinued due to reason other than progressive disease. In the absence of progression, retain the same line number for the next therapy administered.

Reason for therapy failure
Select an appropriate option. *(Toxicity; Progression on therapy; Progression following completion of therapy; Not applicable)*

Concomitant chemoradiotherapy
Select an appropriate option. (*No; Yes*).

NB*: If ‘Yes’*, Radiotherapy must be recorded on the Post Treatment Radiotherapy (CAPRXR2) page

Indication
Select appropriate option (Biliary Tract Cancer or Other)

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15.1.75 PALLIATIVE ON-STUDY RADIOTHERAPY (CAPRXR1)

This form is used as an 'Add Event' to record Palliative radiotherapy that are used while the participant is on study intervention.

Has cancer therapy been previous/current/post withdrawn of IP?
Field can be pre-specified in eCRF *(Current (non-study intervention)).*

Was radiotherapy performed?
Record the appropriate option (*No; Yes).*

If "Was radiotherapy performed?" is recorded as 'Yes', specify below:
Concomitant chemoradiotherapy
Record the appropriate option (*No; Yes).*

Treatment setting
Prespecified as *Palliative*

Number of sites/regions treated simultaneously
Record the appropriate number.

Radiotherapy site/region treated location
Record the appropriate option (*Lung - Lower Lobe; Lung - Middle Lobe; Lung - Upper Lobe; Bone; Liver; Brain; Spinal Cord; Pleura; Skin; Adrenal Gland; Pelvic Bone; Regional Lymph Node; Distant Lymph Node; Gallbladder; Biliary Tract; Other*).

If Other, specify
If '*Other*' was recorded for **Radiotherapy site/region treated location**, provide details.

Radiotherapy site/region laterality
Record the appropriate option (*Left; Right; Bilateral; Not applicable*).

Radiotherapy technique
Record the appropriate option (*3-D conformal; Intensity modulated radiotherapy (IMRT); Stereotactic intracranial radiotherapy; Stereotactic body radiotherapy (SBRT); Stereotactic radiosurgery (SRS); Whole brain radiotherapy (WBRT); Selective Internal Radiotherapy (SIRT); Other*).

If Other, specify
If '*Other*' was recorded for **Radiotherapy technique,** provide details.
Radiotherapy start date
Record a complete date using *YYYY-MON-DD* format (*for example 2000-JAN-01*).

Radiotherapy stop date
Record a complete date in *YYYY-MON-DD* format (*for example 2000-JAN-01*).

Dose per fraction
Record the appropriate data.

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Dose per fraction unit
Record the appropriate option (*Gy; Rad; cGy; GBq; Other*).

If Other, specify
If '*Other*' was recorded for **Dose per fraction unit** provide the unit.

Number of fraction doses
Record the number of fraction doses given.

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15.1.76 POST TREATMENT RADIOTHERAPY (CAPRXR2)

Has cancer therapy been previous/current/post withdrawn of IP?
Field can be pre-specified in eCRF *(Post).*

Was radiotherapy performed?
Record the appropriate option (*No; Yes).*

If "Was radiotherapy performed?" is recorded as **'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
Record the appropriate option (*No; Yes).*

Treatment setting
Record the appropriate option (Definitive; *Palliative; Other)*
*Select **Palliative** when radiotherapy is used primarily to **manage symptoms**;*
*Select **Definitive** when radiotherapy is delivered as a **distinct line of anti-cancer treatment** (see definition of line of therapy in CAPRX1 section),*

If Other, specify
Record the appropriate data.

If Definitive, specify Line of Treatment
Record the appropriate option (1,2,3,>3)

Number of sites/regions treated simultaneously
Record the appropriate number.

Radiotherapy site/region treated location
Record the appropriate option (*Bone; Liver; Brain; Spinal Cord; Pleura; Skin; Adrenal Gland; Pelvic Bone; Regional Lymph Node; Distant Lymph Node; Gallbladder; Lung; Biliary Tract*).

If Other, specify
If '*Other*' was recorded for **Radiotherapy site/region treated location**, provide details.

Radiotherapy site/region laterality
Record the appropriate option (*Left; Right; Bilateral; Not applicable*).

Radiotherapy technique
Record the appropriate option (*3-D conformal; Intensity modulated radiotherapy (IMRT); Stereotactic intracranial radiotherapy; Stereotactic body radiotherapy (SBRT); Stereotactic radiosurgery (SRS); Selective Internal Radiotherapy (SIRT); Other*).
If Other, specify
If '*Other*' was recorded for **Radiotherapy technique,** provide details.

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Radiotherapy start date
Record a complete date using *YYYY-MON-DD* format (*for example 2000-JAN-01*).

Radiotherapy stop date
Record a complete date in *YYYY-MON-DD* format (*for example 2000-JAN-01*).

Dose per fraction
Record the appropriate data.

Dose per fraction unit
Record the appropriate option (*Gy; Other*).

If Other, specify
If '*Other*' was recorded for **Dose per fraction unit** provide the unit.

Number of fraction doses
Record the number of fraction doses given.

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15.1.77 PRIOR AND CONCOMITANT MEDICATIONS LOG (CMLOG)

Were any concomitant medications taken?
Indicate if the Subject took any concomitant medications by checking ‘Yes’ or ‘No’. When answered ’Yes’, CM eCRF for recording medication is triggered.

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15.1.78 PRIOR AND CONCOMITANT MEDICATIONS (CM)

- Please record all prescription and Over-The-Counter medication taken by Subject at entry and during the proceeding days prior to visit as well as new and changed concomitant medication during the Study.
- This should include hormones (including contraceptives), dietary supplements, vitamins and herbal medication infusion fluids, vaccines, parenteral nutrition products oxygen therapy, transfusions and blood products if not collected in other dedicated forms. If known, the generic substance(s) should be entered within brackets into the Medication verbatim name field.
- Please note that the maintenance and additional study drugs, for example rescue medication given during the study also must be recorded in this form if not collected on another form.
- **Exception**: Investigational product should NOT be recorded in this form.
- Use English only while entering the data and avoid the use of special characters like å, ö, Æ etc.

Medication number
This is automatically populated.

Medication verbatim name
Record only one medication per line. Provide the full trade or proprietary name of the medication; otherwise the generic name may be recorded.

Indication
Record the reason the medication was taken based on clinical investigator's evaluation. If taken to treat a condition, and a diagnosis was made, the indication should be the diagnosis. If taken to treat a condition, and no diagnosis was made, the indication should be the signs and symptoms. If taken as prophylaxis, report as "Prophylaxis for " and include a description of the condition(s).

- Record the diagnoses/symptoms as well as any worsening of disease.

- **NB**: Use consistent terminology, e.g., as recorded on Medical History or Surgical History

forms, respectively.

Therapy reason

Select the reason for medication/treatment taken (*Adverse Event, Medical History, Prophylaxis, Disease Under Study, Protocol specified Pre-medication, Other).*

NOTE:

If the therapy reason for a concomitant medication (CM) **changes**:

1. Provide the end date for the existing logline that reflects the previous therapy reason.

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2. Start a new logline to record the medication under the new therapy reason.

Examples of situations:

- A medication initially administered for Medical History (MH) and later for Adverse Event (AE).
- A medication first given as prophylaxis and then used for AE treatment.
- A medication initially used for AE treatment and subsequently as prophylaxis.

If Other, specify
If for Therapy reason, response 'Other' is selected, record the appropriate response.

Table 15 Reason for medication/treatment taken

Category	Notes
Adverse event	Any medication administered for an AE. If selected, please ensure AE ID is entered and cross-reference with information entered in AE eCRF.
Medical History	Any medication the subject was receiving at time of enrolment for a medical history event. If selected, please ensure MH ID is entered and cross-reference with information entered in MH and HISS eCRFs.
Prophylaxis	Used for any prophylactic medications, **except** for medication taken prior to chemotherapy (see below)
Disease under study	Related to the subject's signs and symptoms of disease (for example, pain related to subject's cancer)
Protocol specified Pre-medication	Any medication administered to mitigate or prevent side-effects from chemotherapy as per protocol. Pre-medication administered prior to study treatments should be recorded as a single log line with a frequency of Every 3 weeks. For **Gemcitabine or Cisplatin** chemotherapy, pre-medication may be recorded as **one log line for Cycle Day 1** and **one log line for Cycle Day 8**, as applicable. **NOTE**: If any dose is **not administered** or is **modified**, the site must enter a stop date for the current log line and create a new log line to reflect the change.
Other	Please specify. **Note:** *Please record use of multi-vitamins or nutritional supplements that are not administered/prescribed for an adverse event or medical history event* or *used for pre-medication for chemotherapy fall under "Other" with the specified indication of "General Use".*

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AE number(s) for which medication taken (up to 5 available fields)
Select the number(s) of the Adverse Event for which this medication was taken.

Medical history condition(s) number for which medication taken (up to 3 available fields)
Select the number of the medical history event for which this medication was taken.

Dose per administration
Record the dose of medication taken per administration (e.g., 200).
Additionally, record Frequency.
NB: Only a figure should be recorded. E.g., enter 600 if the prescription is 2 tablets of 300 mg.
NB: Record each dose change on a new logline.
Note:
For the Frequency selected as 'Highly variable dosing' the Dose per administration should be left blank. The average daily dose should be provided as 'CM Total daily dose'.

Frequency
Record how often the medication was taken (*Daily; Twice per day; Per month; As needed; Every hour; Every 2 hours; Every 4 hours; Every other day; 1 time per week; 3 times per day; 4 times per day; Once; 2 times per Week; 3 times per week; 4 times per week; Every week; Every 2 weeks; Every 3 weeks; Every 4 weeks; Other; Unknown; Highly variable dosing).*

Note:
'1 time per week' – medication used 1 time every week.
'Every week' – medication used weekly, could be 1 time, 3 times or any number of times per week, frequency unspecified

If Other, specify
If for Frequency response 'Other' is selected, record the appropriate response.

Dose unit
Record the dose unit of the dose of concomitant medication taken (%; 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
If for Dose unit response "Other" is selected, record the appropriate response.

Route
Record the route of administration for the medication (Intramuscular; Auricular (OTIC); Buccal; Dental; Intrathoracic; Enteral; Epidural; Respiratory (Inhalation); Intra-arterial; Intra-articular; Intracaudal; Intradermal; Intraocular; Intraperitoneal; Intraspinal; Intrathecal; Urethral; Intravenous; Intraventricular; Nasal; Ophthalmic; Oral; Parenteral; Rectal; Subcutaneous; Sublingual; Topical; Transdermal; Oromucosal; Vaginal; Cutaneous; Unknown; Other)

If Other, specify

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If for Route response 'Other' is selected, record the appropriate response.

Start date
Record the date the concomitant medication was first taken using this format (YYYY-MON-DD) (for example 2001-JAN-01). If the Subject has been taking the medication for a longer period of time prior to the start of the study and does not remember the exact start date, it is acceptable to have an incomplete date. Medication taken during the study are expected to have a complete start date. Prior medication that meets exclusion criteria should have both a start and end date.

- For medications at entry, record the date of first dose.
- For new and changed medications during the study, record the complete date of first dose.
- For 'As needed' or 'Rescue medication', the start date should be the day the medication was first taken by Subject, not the prescription date.
- Efforts should be made to enter the complete date, if unknown month and year OR year should be entered.
- **Note:** Medication, which is given/prescribed as the Subject completes/discontinues the study, is not to be recorded.

Taken prior to Study Treatment Start
Check only if the medication started before any of study treatment start.

Ongoing
(No; Yes)
Select 'Yes' if the Subject has not stopped taking the concomitant medication at the time of data collection. If Yes, the end date should be left blank
Select 'No' if the medication is stopped – in such case the end date should be completed.

If No, complete section below
End date
Record the complete date the medication was stopped using this format (YYYY-MON-DD) (for example 2001-JAN-01). It is always advised to enter the complete end date, in cases where the medication was stopped prior to the start of the study and Subject does not remember the exact end date, it is acceptable to have an incomplete date

NB: If the CM is taken for an AE, CM end date does not have to match with AE end date. A medication can be continued after AE resolution, if medically justified (e.g. antibiotic continued for short period after infection resolved).

Stopped prior to Study Treatment Start
Record 'Yes' only if the medication was stopped prior to study treatment start and complete end date is unknown.

NB: If any change(s) in this form after an SAE has been reported please ensure that the updated information has been made available immediately to AstraZeneca (contact Monitor).

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Note: Within CM form only 50 Loglines are allowed consisting of both Active & Inactive, if additional CM details must be included then it has to be recorded in next available CM form.

If you would like to add another medication when you have pressed the ‘Save’ button and a new window appears, you must move the cursor to “Add a new Log line” and you will get a new window, which allows you to enter a new medication. If you want to delete an entered medication you must, in the ‘Complete View’ select ‘Inactivate’.

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15.1.79 PROCEDURES (1PR)

NOTE: Do not report Surgery for *Subsequent Anticancer Surgery* on this form. Surgery for Subsequent Anticancer Surgery should be reported into *1PR1 form.*

Note: The 1PR form is dynamically added when "Were all eligibility criteria met?" is recorded as "Yes". For screen failure subjects who require a 1PR form due to an SAE, please follow the steps below:

1. Temporarily change "Were all eligibility criteria met?" to "Yes" to trigger the 1PR form and complete the required data entry.
2. After the 1PR form has been completed, change "Were all eligibility criteria met?" back to "No" to accurately reflect the subject's screen failure status.

Any procedures performed?
Record the appropriate option *(No; Yes).*

Procedure name
Record the procedure name. Record only one procedure per line.

Start date
Record the date the procedure was started or performed using *YYYY-MON-DD* format (for example *2000-JAN-01*). Procedures performed during the study are expected to have a complete start date. Prior procedures that are exclusionary should have both a start and end date.

End date
Record the end date of the procedure using *YYYY-MON-DD* format (for example *2000-JAN-01*). If the procedure has not ended, leave this field blank and record **Ongoing** field as 'Yes'.

Ongoing
Record the appropriate option (*Yes*) if the procedure has not ended at the time of data collection the **End date** and **End time** should be left blank.

Indication
Record the reason the procedure was performed (*Adverse event; Medical history; Disease under study; Other*).

Adverse event number
Record the appropriate AE number if **Indication** is selected as '*Adverse event*'.
Note: If a procedure is performed for the diagnosis or examination of an adverse event (AE) OR for its treatment, the indication in the 1PR form should be recorded as

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"Adverse Event", and the corresponding "Adverse Event Number" field must be completed.

Medical history event identifier
Record the appropriate AE number if **Indication** is selected as '*Medical history*'.

If Other, specify
Record the appropriate details if **Indication** is selected as *'Other'.*

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15.1.80 SURGERY FOR SUBSEQUENT ANTICANCER THERAPY (1PR1)

This form is used to collect post study treatment discontinuation biliary tract cancer surgeries, if any.

Any procedures performed?
Record the appropriate option *(No; Yes).*

Procedure name
Record the surgery name. Record only one procedure per line.

Start date
Record the date the surgery was started or performed using YYYY-MON-DD format (for example *2000-JAN-01*). If the exact start date is unknown (for example Subject doesn't remember it), at least year should be recorded.
Note: Partial dates can be captured as unknown in system as YYYY-UNK-UN or YYYY-MON-UN.

End date
Record the end date of the surgery using YYYY-MON-DD format (for example *2000-JAN-01*). If the exact start date is unknown (for example Subject doesn't remember it), at least year should be recorded.
Note: Partial dates can be captured as unknown in system as YYYY-UNK-UN or YYYY-MON-UN.
If the procedure has not ended, leave this field blank and record **Ongoing** field as 'Yes'.

Ongoing
Record the appropriate option (*Yes*) if the procedure has not ended at the time of data collection the **End date** and **End time** should be left blank.

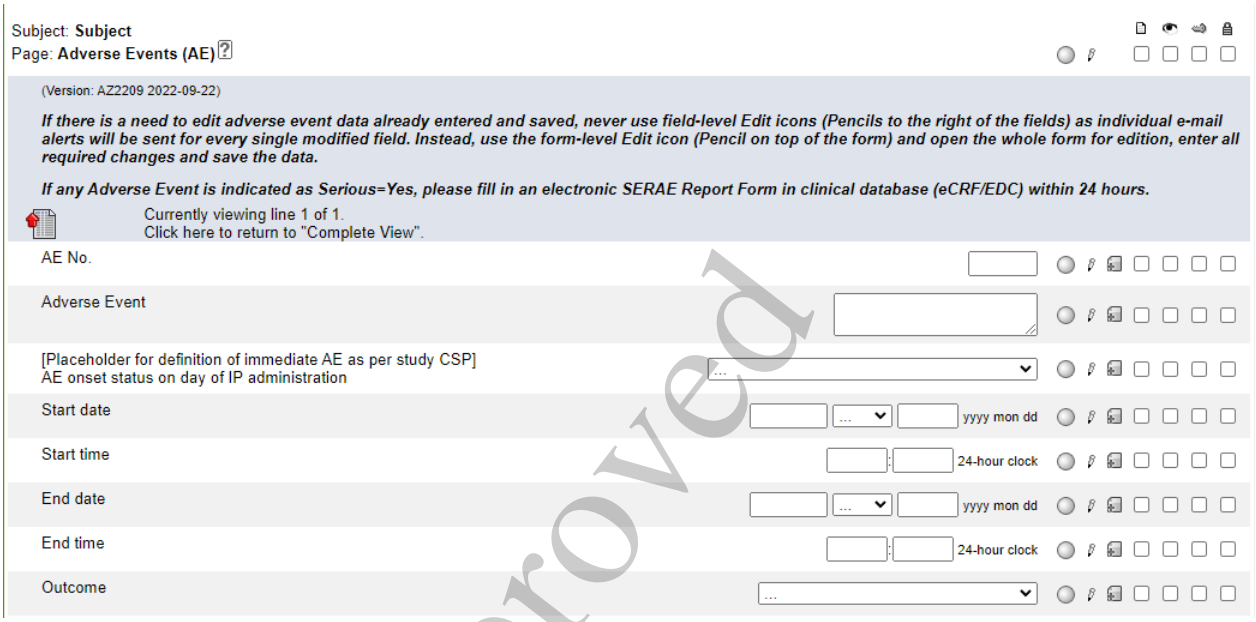
Indication
Disease under study is defaulted value.

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15.1.81 ADVERSE EVENTS LOG (AELOG)

Were any adverse events experienced?
Provide *Yes* or *No* answer.
When answered *'Yes'*, AE eCRF for recording events details is triggered as shown in the screenshot below:



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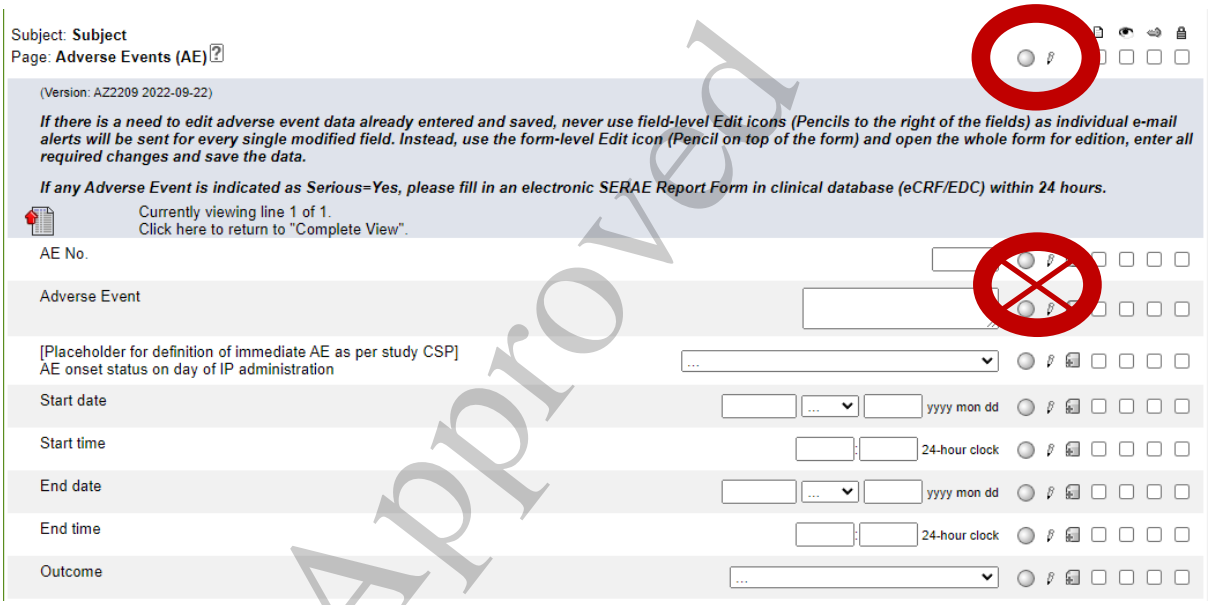
15.1.82 ADVERSE EVENTS (AE)

AE No.

AE number is automatically generated by the system.

Adverse Event

IMPORTANT NOTE: 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.



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Adverse event reporting

AE and SAE reporting are explained in CSP section 9.4.3.1. *Rules of SAE reporting and SAE alert process can be found in General eCRF Completion Guideline* ***Section 13****.*

Time period and frequency for collecting AE and SAE information

Adverse events will be collected from time of signature of the Informed Consent Form and throughout the treatment period until the safety follow-up period is completed.
For disease progression reporting please refer to section 8.4.7 of CSP.

Record the Adverse Event term. Only one Adverse Event (diagnosis, sign or symptom) should be recorded on each line.

Full guidance on AE/SAE reporting can be found in CSP section 9.4.3.1. Below guidance can be used as a reminder:

- If a diagnosis is known, record the diagnosis.

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- If a diagnosis is known and there are other signs/symptoms, which are not generally part of the main diagnosis, record the diagnosis and each sign/symptom on a separate line.
- If a diagnosis is not known, record each sign/symptom on a separate line. Update AE term whenever more specific/final diagnosis becomes available.
- Terms containing more than one diagnosis or multiple symptoms will be queried. Examples of disallowed entries**:**

Verbatim	**Action**
Vomiting and Diarrhea	Query will be issued to list these as separate events or to provide a single diagnosis based on symptoms.
Pneumonia and Bronchitis	Query will be issued to list these as separate events

- Provide a concise, complete and correctly spelled English event term
- Avoid abbreviations as most of them might be subject to interpretation, and if unclear they will be queried for clarification. Examples of disallowed abbreviations that will be queried:

Verbatim	**Different meanings**
DM	Diabetes mellitus, Diastolic murmur
CHF	Congestive heart failure, Chronic heart failure

- Avoid ambiguous and imprecise terms. When possible specify anatomical location (body part/organ/tissue) and site (left/right/bilateral/upper/lower). Some terms are incomplete or require more specificity. The following examples would require a query for clarification:

Verbatim	**Different meanings**
Angina	Angina pectoris, Intestinal angina
Respiratory tract infection	Upper respiratory tract infection, Lower respiratory tract infection

- Make sure reported term has no typos or special characters e.g. ; “ / ‘ # ^ & entered. Bear in mind that punctuation such as quotation marks, periods, and commas cause the terms to fail auto-encoding. Examples:

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Fails Dictionary Auto-coding	Dictionary Auto-codes
Abdominal pain, lower	Abdominal pain lower
“Headache”	Headache

- Specify causes of injuries (when known) as well as the injury itself (when known), e.g. in case of broken leg due to fall, report two events ‘**Accidental fall’** and **‘Broken leg’**.
- Worsening of medical history terms: If condition listed on the medical history form deteriorates, then it must be reported as an adverse event. The term should indicate the worsening of pre-existing condition (e.g., ‘worsening of asthma’, ‘acute on chronic heart failure’, ‘worsening of chronic kidney disease’).
- For AEs requiring procedure treatment, report solely the condition requiring the procedure as AE and then record the procedure in Procedure form.
- If the resolved AE is recurring at different time point, use consistent terminology while entering following AEs.
- Wherever possible, use clinical, rather than the laboratory term (e.g., anemia vs. low hemoglobin value).
- Deterioration in protocol-mandated laboratory as compared to baseline values/vital signs should only be reported as AEs if they fulfil any of the SAE criteria or are the reason for discontinuation of treatment with the investigational product, or are considered to be clinically relevant as judged by the Investigator. For full guidance refer to CSP section 8.4.4.
- In the absence of clinical signs or symptoms, clinically relevant deteriorations in non-mandated parameters should be reported as AEs. The AE must indicate if the result is, e.g. increased, decreased.

Verbatim	Action
Hemoglobin 6.0	Query will be issued to clarify this entry, a term of Decreased hemoglobin or Anemia may be more appropriate
Blood pressure 180/100	Query will be issued to specify, e.g., Blood pressure increased or clinical term.

- Avoid including information within AE term that does not contribute to the medical diagnosis. Examples:

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Verbatim with extraneous information	Verbatim Properly reported
Headache at 2 a. m.	Headache
Cholecystectomy on 15 Jan	Cholecystectomy

- Distinguishing a finding from a diagnosis makes a difference - The MedDRA dictionary treats ‘decreased’ and ‘increased’ as findings, which code to Investigations. The MedDRA dictionary treats ‘high and ‘low’ as diagnoses, in general, and codes to the appropriate System Organ Class. See the examples below:

Verbatim	MedDRA Dictionary Hierarchy
Decreased blood pressure	Preferred Term - Blood Pressure Decreased System Organ Class - Investigations
Blood pressure low	Preferred Term - Hypotension System Organ Class - Vascular Disorders

NOTE: Per CSP section 8.4.8: Events which are unequivocally due to disease under study should not be reported as AEs during the study unless they meet SAE criteria or lead to discontinuation of IMP (CSP section 8.4.8).

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Start date

Record the complete date using *YYYY-MON-DD* format *(for example 2000-JAN-01)*. Every effort should be made to obtain complete start date of AE.

Start date is the date of the first observations relevant to the event (such as symptoms, signs, investigational findings or diagnosis) e.g., except for new cancer occurrences for which the date of confirmed diagnosis should be entered.

NOTE: The recurring AE should be entered as a new event (when previous AE has resolved with end date completed).

End date

Record the complete date using *YYYY-MON-DD* format *(for example 2000-JAN-01)*.
Every effort should be made to obtain complete end date of AE (if applicable for AE outcome).
End date should be entered when Outcome of AE (see below) is entered as *Recovered/Resolved* or *Recovered/Resolved with Sequelae*.

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NOTE: In the event there is death, ongoing events are not considered as resolved as a result of the death (**End date** is expected only for events that were actually resolved on the date of death or prior to the death)

Please refer to Outcome instructions (*Table 16*) for further guidance
Any AEs that are unresolved at the participant's last AE assessment or other assessment/visit as appropriate in the study are followed up by the Investigator for as long as medically indicated, but without further recording in the eCRF as per section 8.4.2 of CSP.

Outcome

Record an appropriate option following guidance in Table 16.

NOTE: The Outcome of ongoing AEs should be followed up on every visit and updated if applicable. If Subject completes the study/ dies/ is withdrawn from the study/ lost to follow-up and there are ongoing AEs, the 'Outcome' should reflect the status at study completion/ time of death/ last visit/ last confirmed contact, respectively.

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Table 16: Outcome Instructions

OUTCOME	Description	End date (YYYY-MON-DD)
Recovered/Resolved	The event has improved or recuperated, with no reported sequelae.	Date when the AE has been resolved/ Subject recovered
Recovered/Resolved with sequelae	The event has resolved, but residual effects remain.(e.g. Primary AE: limb fracture, Sequalae symptoms: limping)	Date when the AE has been resolved/ Subject recovered, while sequelae symptoms may still be present.
Recovering/Resolving	The event is improving but has not yet stabilized or resolved.	Blank = AE is ongoing
Not recovered/Not resolved	The event is ongoing (has not improved or recuperated or is worsening/worsened). This option is to be selected when the AE is ongoing and has not improved (i.e., is not recovering/resolving) as suggested by a decrease in CTCAE grade.	Blank = AE is ongoing

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Fatal	The event led to the Subject's death. When AE with outcome Fatal is reported, death to be recorded in DEATH DETAILS; SERAE It is expected that only one Adverse Event has an outcome of 'Fatal' reflecting the primary cause of death in alignment with the SERAE/DD form. For detailed information on primary cause of death, please see SERAE/DD eCRF instructions. For any other events that are occurring, or ongoing, at the time of the fatality, Outcome field should reflect the outcome at the time of death.	Blank Date of death recorded in DEATH DETAILS; SERAE.

Serious

'Serious' should be marked '*Yes*' if Adverse Event meets any of the criteria for Serious Adverse Event.

Serious Adverse Event form is dynamically triggered and must be filled in for every AE marked as serious. See separate instructions for Serious Adverse Event form.

IMPORTANT NOTE: If any Adverse Event is indicated as Serious = *Yes* please fill in an electronic SERAE Report Form in clinical database (eCRF/EDC) within 24 hours. When clinical database is facing downtime, contact the Sponsor Study Representative by telephone for guidance within one calendar day, **AND** provide a paper back-up Serious Adverse Event report (available in the Principal Investigator's Study File) to the Sponsor Study Representative immediately. The site is responsible for completing all appropriate forms as soon as the eCRF becomes available again.

In case of error: Do not inactivate Adverse Events with 'Serious' question responded as '*Yes*' on AELOG form. If Serious Adverse Event was triggered in error, it should be first downgraded by updating 'Serious' question as '*No*' in respective Adverse Event logline. After 'Serious' is corrected as '*No*' and Adverse Event form saved, the SAE is automatically inactivated in the system and downgraded SAE alert is sent via mail. Only thereafter, if applicable, Adverse Event can be inactivated on AE log form.

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Investigational product

This is pre-populated as “Rilvegostomig”

Action taken due to AE, Rilvegostomig

Record actions made to the study treatment **resulting from the adverse event as per Investigator’s judgement**, following guidance in Table 17.

Table 17: Description for corresponding Action Taken

Action taken	Description	Supporting data entry
Dose not changed	No change in dosing of IP in relation to the AE (medication schedule/dosing maintained as per CSP). Includes AEs that resulted in death, when IP dosing was not actively changed prior to the death.	Study drug administered in cycles: Dose not changed if AE starts and ends between the study drug administration cycles, with no changes in the cycle interval and dose amounts.
Drug interrupted	IP administration temporarily stopped due to the AE with the intention that the IP dosing will continue as per study treatment plan. Includes scenarios when IP administration is shifted outside of Visit Window (IP dose was delayed). **Important:** Verify data against information in ‘Exposure as collected’ form (EC). For infusion IPs, this option covers Infusion interruption and/or cycle delays.	If IP administration is delayed for other reason than AE (documented delay) with no decision to permanently discontinue IP administration, while there is also AE to be reported at the same time, ‘**Dose not changed’** in Action taken should be selected for this AE on AE form. If IP administration was delayed for other reason than the AE before the AE start date, and later on IP was discontinued for a reason other than the AE, ‘**Dose not changed’** should be selected as Action taken. It refers to an infusion interruption and a treatment cycle delay Action taken due to AE

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Drug permanently discontinued	IP permanently discontinued due to AE (AE directly caused this decision as per **Investigator's judgement**). The option is only applicable to the Subjects who received at least one IP dose. **Important:** Verify data against information in 'Exposure as collected' form (EC) and End of Study Treatment (ETRT).	If AE Start date is the same as the date of last IP dose administration/Date of decision on IP discontinuation select: "Drug permanently discontinued" if AE caused IP discontinuation "Not Applicable" if AE started after IP was already stopped due to other reason "Dose not changed" if AE started with no impact on IP dosing, while later IP was stopped for other reason
Not Applicable	Option to be used when AE occurred before 1st IP dose or after Date of decision to discontinue IP/date of completion of 8 cycles of chemotherapy	If AE Start date is the same as the /Date of decision on IP discontinuation/Date of completion of 8 cycles of chemotherapy,select: "Drug permanently discontinued" if AE caused IP discontinuation "Not Applicable" if AE started after IP was already stopped due to other reason "Dose not changed" if AE started with no impact on IP dosing, while later IP was stopped for other reason

Only one Action taken is collected for particular AE/AE intensity grade change/CTCAE grade change, and the worst action taken should be reported for particular AE/AE intensity grade change/CTCAE grade change,

The hierarchy of action taken should be as follows: Dose not changed/Not applicable/Drug interrupted /Drug Permanently Discontinued.

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For a scenario when an AE caused drug interruption and later on drug was discontinued, the action taken on AE page shall be reported as 'Drug Permanently Discontinued' since discontinuation is worse than dose interruption.

For a scenario when an AE caused drug interruption and later on drug was restarted, the action taken on AE page shall be reported as 'Drug interrupted'

For a scenario when an AE caused drug interruption with intention to restart eventually, but it is not restarted before study completion/withdrawal, the action taken on AE page shall be reported as 'Drug interrupted'.

Reasonable possibility AE caused by, Rilvegostomig
Consider whether there is a reasonable possibility that the event may have been caused by the investigational product and refer to appropriate appendix 8.4.3 in CSP for guidance on interpreting this question

Investigational product 1
Prepopulated as "Durvalumab"

Action taken due to AE, Durvalumab
Record an appropriate option following guidance in Table 17 (the same rules apply to action taken for additional study drug as in case of IP).

Reasonable possibility AE caused by, Durvalumab
Consider whether there is a reasonable possibility that the event may have been caused by the investigational product and refer to appropriate appendix 8.4.3 in CSP for guidance on interpreting this question. Please note that dose modification of Durvalumab due to change in patients's weight is not considered dose reduction.

Investigational product 2
Prepopulated as "Gemcitabine"

Action taken due to AE, Gemcitabine
Record an appropriate option following guidance in Table 17 (the same rules apply to action taken for additional study drug as in case of IP), and also with 2 additional options shown in Table 18 below.

Table 18 Description for corresponding Action Taken – Specific for Chemotherapy

Action taken	Description	Supporting data entry
Dose Increased	IP dose value increased in relation to AE (a medication schedule modified by addition in relation to Study Protocol IP dosing schedule).	**Note**: Dose modifications due to change(s) in Subject's weight are not

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	Important: Verify data against information in 'Exposure as collected' form (EC1 or EC2).	considered "dose increased".
Dose Reduced	IP dose value decreased in relation to AE (a medication schedule modified by subtraction in relation to Study Protocol IP dosing schedule). **Important:** Verify data against information in 'Exposure as collected' form (EC1 or EC2).	**Note**: Study with IP dose adjusted to Subject's weight: Dose modifications due to change(s) in Subject's weight are not considered "dose reduced".

Reasonable possibility AE caused by, Gemcitabine
Consider whether there is a reasonable possibility that the event may have been caused by the investigational product and refer to appropriate appendix 8.4.3 in CSP for guidance on interpreting this question

Investigational product 3
Prepopulated as "Cisplatin"

Action taken due to AE, Cisplatin
Record an appropriate option following guidance in Table 17 (the same rules apply to action taken for additional study drug as in case of IP) and Table 18.

Reasonable possibility AE caused by, Cisplatin
Consider whether there is a reasonable possibility that the event may have been caused by the investigational product and refer to appropriate appendix 8.4.3 in CSP for guidance on interpreting this question

Reasonable possibility AE caused by Device Event
Consider whether there is a reasonable possibility that the event may have been caused by the Device Event during mandatory tumor sample collection at Screening Visit. Cross check Device Event form for data entry.

Device Event
If **Reasonable possibility AE caused by device** is selected as '*Yes*', record the Device Event provided on the dropdown list derived from the Device Events (DE) eCRF.

Device Event Number
This field is auto-populated with the Device Event number based on the selection for **Device Event**.

CTCAE grade at start of AE

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Record an appropriate option (*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*) using the Common Terminology Criteria for Adverse Events Version 5.0
For events without specific categories in CTCAE, use general guidance in CTCAE version 5.0.

Is this an Adverse Event of Special Interest?
Select *Yes* or *No*

Adverse event of special interest category (See instruction of AESI)

Record an appropriate option *(Potential Endocrinopathies; Potential Hepatic Events; Potential Nephritis or Renal Dysfunction; Potential Neuropathy/Neuro-muscular Toxicity; Potential Pancreatitis; Potential Rash or Dermatitis; Potential GI Toxicity; Potential Myositis/Polymyositis; Potential Myocarditis; Potential Pneumonitis; Infusion Related Reaction Including Anaphylaxis; Combined Elevations of Aminotransferases and Bilirubin; Cytokine Release Syndrome; Encephalitis; Other.)*

Concomitant or additional treatment given
If 'Yes', ensure corresponding AE number entry is reported on the Prior and Concomitant Medications (CM) or Procedures (1PR) corresponding to the required medication or procedure.

Note: In cases where no medication was administered for the adverse event (AE) and only an examination was conducted without any treatment procedure being performed, record the examination in the **1PR** form. However, the "**Concomitant or Additional Treatment Given**" field should be marked as "***No***".

Date AE CTCAE grade changed
Record the complete date when the AE CTCAE grade changed for a given AE using YYYY-MON-DD format (e.g., 2000-JAN-01).
Each time there is a new AE CTCAE grade recorded, related information within AE form should be verified and edited accordingly, to reflect most current status of AE.

CTCAE grade
Record an appropriate option (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) using the Common Terminology Criteria for Adverse Events Version
For events without specific categories in CTCAE, use general guidance in CTCAE version 5.0.

Immune-mediated AE
Record an appropriate option (Yes; No)

Infusion reaction AE
Automatically derived as '*Yes'* when "Adverse event of special interest category" is selected as 'Infusion Related Reaction Including Anaphylaxis'. Otherwise, the answer is derived as '*No'*. No data entry is required in this field.

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Derived Maximum CTCAE Grade

Automatically derived maximum CTCAE grade refers to the complete course of the Adverse Event - since Adverse Event started and over duration of Adverse Event in case of deterioration. No data entry is required in this field.

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15.1.83 AE OF SPECIAL INTEREST (AESI)

AESI form will be triggered when the site selects “AE of special interest category” on the Adverse Event CRF.

The following variables will be populated automatically based on the information entered in the Adverse Event form.

AE number, Adverse event and **AE of special interest**

If the AE information that has been auto-populated is incorrect, return to the Adverse Event page and update the information there.

If “Other Potential AESIs” has been selected on the AE form, provide additional information here in the AESI form

The AESI category that has been selected will determine the subsequent data that will be entered into this module:

The AESI category selected from AE form will determine the **subsequent data** that will be entered. The following hyperlinks will lead you to the specific instructions for each AESI category:

- Section 15.1.79.1: Potential endocrinopathies
- Section 15.1.79.2: Potential hepatic events
- Section 15.1.79.3: Potential nephritis or renal dysfunction
- Section 15.1.79.4: Potential neuropathy/neuro-muscular toxicity
- Section 15.1.79.5: Potential pancreatitis
- Section 15.1.79.6: Potential rash or dermatitis
- Section 15.1.79.7: Potential GI Toxicity
- Section 15.1.79.8: Potential myositis/polymyositis
- Section 15.1.79.9: Potential myocarditis (other form: LB4)
- Section 15.1.79.10: Potential pneumonitis (Interstitial Lung Disease folder: VISIT, ILDIS, PULMOA, LB9)
- Section 15.1.79.11: Infusion related reaction including anaphylaxis (other form: IRRTQS)
- Section 15.1.79.12: Cytokine release syndrome (CRS Signs and Symptoms folder: CRSSS, CRASTCT)
- Section 15.1.79.13: Other potential AESIs
    - Combined elevations of aminotransferases and bilirubin
    - Encephalitis

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- Other

GENERAL GUIDANCE:

AE of special interest
This field is derived from AE form.
The options are: (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
Please update if "Other" was selected.

Number of bowel movements at baseline
Provide the appropriate data.

Current bowel movements CTCAE
Select the appropriate option from the below list.
Mild AE (increase of <4 stools/day over baseline)
Moderate AE (increase of 4-6 stools/day over baseline)
Severe AE (increase of ≥7 stools/day over baseline)
Life-threatening or Disabling AE
Death related to AE

Body surface area covered
Select the appropriate option *(<10%; 10-30%; >30%)*

Anatomical site (up to 5)
Select the appropriate option *(Lower leg; Abdominal cavity; Inguinal region; Back; Neck; Face; Chest; Arm; Foot; Hand; Buttock; Scalp; Eye; Not Applicable; Other*).

Anatomical site 02, Anatomical site 03 etc.

Note: Complete this field only when the AESI type is identified as ***potential rash or dermatitis****.*

Signs and symptoms
Update the appropriate Signs and Symptoms as per the available dropdown.
If 'Other' is selected, please enter information in the free text field **Signs and symptoms, other**

Was a specialist consulted?
Select the appropriate option *(No; Yes).*

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Services and result description
If Yes was selected, describe what type of consultation and/or additional procedure(s) was conducted.
For example: dermatology consult, skin biopsy and histological findings, skin photos, etc.
If additional space is needed, please enter the text on a new log line.
Additional information can also be added in the AESIA form.

Any additional laboratory investigations performed?
Select the appropriate option *(No; Yes).*

If Yes was selected, complete the LabADD form and enter more complete information regarding the additional specialized lab tests (such as viral tests, and/or auto-antibody results).

Laboratory results that are part of the regularly assessed laboratory panel should be entered in the LB page.

NOTE: If Yes, complete LABADD module

Any significant medical or surgical history relevant to this event?
Select the appropriate option *(No; Yes).*

If Yes, specify the Medical/Surgical History number and text

Medical history number/text 1
Select the appropriate option from the dropdown.

The data in the drop-down menu is based on the data entered in the 1MH Form.

The medical history name and number will automatically be populated based on this selection.

Multiple medical history events can be selected.

If the appropriate medical history is not found in the drop-down menu, go back to the 1MH form and enter the appropriate information.

Medical history number 1
Medical history text 1

Surgical history number/text 1
Select the appropriate option from the dropdown.

The data in the drop-down menu is based on the data entered in the HISS Form.

The surgical history name and number will automatically be populated based on this selection.

Multiple surgical history events can be selected.

If the appropriate surgical history is not found in the drop-down menu, go back to the HISS form and enter the appropriate information.

Surgical history number 1
Surgical history text 1

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Any concomitant medication that triggered the event?
If Yes, please specify the medication number and name.
NOTE: This field refers to medication that could have caused AE, not to medication that used to treat AE.

Concomitant medication number/name 1
Select the appropriate option form the dropdown.
Concomitant medication number 1
Concomitant medication name 1

Could disease progression have triggered the event?
Select the appropriate option *(No; Yes).*

If Yes, specify below
Can the event be attributed to disease/metastasis?
Select the appropriate option *(No; Yes).*

Anatomic location
Select the appropriate option (Distant Lymph Nodes; Stomach; Liver; Pancreas; Ovary; Spleen; Brain; Lung; Pleura; Skin; Adrenal Gland; Regional Lymph Node; Other)

Any potential alternate etiology excluding disease progression?
Select the appropriate option *(No; Yes).*
NOTE: Causality to any study Study Intervention (Rilvegostomig, Durvalumab, or Chemotherapy) should not be captured here.

Additional comments
Provide any additional comments for this AESI (e.g., family history)

GUIDENCE as per the AESI selected:

15.1.83.1 POTENTIAL ENDOCRINOPATHIES

Immune-mediated endocrinopathies may include:

- Hypophysitis/hypopituitarism
- Adrenal insufficiency
- Hyperthyroidism
- Hypothyroidism
- Type I diabetes mellitus

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Immune mediated endocrinopathy may present with non-specific symptoms which can easily be ascribed to other causes.

Endocrine toxicities can become highly symptomatic if left untreated

Patients should be encouraged to report symptoms as early as possible

Review adverse events that may have initially been considered non-specific, as they may be early indictors of an immune mediated endocrine toxicity

- **Signs and symptoms**
  Select all appropriate options
  (Abdominal pain; Fatigue; Vomiting; Pyrexia; Headache; Malaise; Myalgia; Visual changes; Polyuria; Thirst, Behaviour changes; Changes to mental status; Vertigo; Unusual bowel habits; Weakness; Hypotension; No symptoms; Other)
  Note: As the list of options is very long, please click on 'Next' to move to the next page of the options if needed.

- **Signs and symptoms, other**
  If 'Other' is selected, please firstly save the form by clicking the 'Save' button, then the free text field will appear. Please enter information in the free text field.
  If there is more than 1 sign and symptom that will be entered/selected, add each additional sign and symptom using the add new logline option.

- NOTE: Some endocrinopathies can be asymptomatic and found by laboratory findings. Report all relevant details below, even if there are no signs and symptoms.
- NOTE: More severe endocrinopathies may manifest in highly specific signs and symptoms. If relevant, enter these in the "other" category

➢ **Was a specialist consulted?**
Select the appropriate option *(No; Yes).*

➢ **Services and result description**

If '*Yes*' was selected, describe what type of consultation and/or additional procedure(s) were conducted.
For example: endocrine consult, radiologic imaging, etc
If additional space is needed, enter the text on a new log line
Additional information can also be added in the AESIA form

➢ **Any additional laboratory investigations performed?**
Select the appropriate option *(No; Yes).*

If '*Yes*' was selected, complete the LABADD form and enter more complete information regarding the additional specialized lab tests, such as ACTH, cortisol, aldosterone, prolactin, calcitonin, GH, LH, FSH, HgA1c, and/or

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serum auto-antibody results (for those events that may have an autoimmune component).

For patients with potential auto-immune diabetes, examples of specialized lab tests include specialized auto-antibody tests for Islet cell cytoplasmic autoantibodies (ICA), Glutamic acid decarboxylase autoantibodies (GADA), Islet Antigen 2 (IA-2) Antibody (IA-2A), Insulin autoantibodies (IAA), Zinc transporter ZnT8 autoantibodies (ZnT8A)

Laboratory results (such as TSH, T3, Free T4, Total T4, metabolic panel, etc), that are part of the regularly assessed laboratory panel should be entered in the LB page

- **Any significant medical or surgical history relevant to this event?**
  Select the appropriate option *(No; Yes*

  - **If Yes was selected due to a relevant <u>Medical History</u>,**
    Enter a letter to trigger a drop-down menu and select appropriate medical history even
    The data in the drop-down menu is based on the data entered in the MH Form.
    The medical history name and number will automatically be populated based on this selection.
    Multiple medical history events can be selected.
    If the appropriate medical history is not found in the drop-down menu, go back to the MH form and enter the appropriate information.

  - **If Yes was selected due to a relevant <u>Surgical History</u>,**
    Enter a letter to trigger a drop-down menu and select appropriate surgical history event.
    The data in the drop-down menu is based on the data entered in the HISS Form.
    The surgical history name and number will automatically be populated based on this selection.
    Multiple surgical history events can be selected.
    If the appropriate surgical history is not found in the drop-down menu, go back to the HISS form and enter the appropriate information.

- **Any concomitant medication that triggered the event?**
  Select the appropriate option *(No; Yes).*
  . NOTE: Do not enter medications used for treatment/management of the event, only that which caused the event, if any

  - **If Yes, specify the medication number and name**
    Enter a letter to trigger a drop-down menu and select appropriate concomitant medication.
    The data in the drop-down menu is based on the data entered in the CM Form.
    The concomitant medication name and number will automatically be populated based on this selection.
    Multiple concomitant medications can be selected.

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If the appropriate concomitant medications is not found in the drop-down menu, go back to the CM form and enter the appropriate information.

- **Could disease progression have triggered the event?**
  Select the appropriate option *(No; Yes).*
  NOTE if the event is unequivocally due to disease progression, it should not be recorded as an AE (only PD) as per protocol section 8.4.7
  - **If Yes, specify below**

  - **Can the event be attributed to disease/metastasis?**
    Select the appropriate option *(No; Yes).*

  - **Anatomic location**
    Select the appropriate option *(Distant lymph nodes; Supraglottis; Hypopharynx; Subglottis; Cervix uteri; Colon; Small intestine; Esophagus; Rectum; Stomach; Liver; Pancreas; Thyroid Gland; Parathyroid, Pituitary, Fallopian tube; Ovary; Uterus; Prostate gland; Testis; Bladder; Kidney; Head and neck; Larynx; Oral cavity; Nasopharynx; Trachea; Spleen; Central nervous system; Brain; Lung; Pleura; Skin; Adrenal gland; Biliary tract; Glottis; Oropharynx; Peritoneum; Uvea; Breast; Muscle; Mucosa; Regional lymph node; Other).*

    If the anatomic location is the spinal cord, select central nervous system.

- **Any potential alternate etiology excluding disease progression?**
  Select the appropriate option *(No; Yes).*

  - **If Yes, specify**
    Examples of alternative etiologies could include:
    - Brain metastases
    - Primary tumor
    - History of endocrine dysfunction
    - Prior intracranial therapies (ie surgery of radiotherapy)
    - Prior radiotherapy (please enter the data in the radiotherapy page)

    Examples of alternative etiologies for Diabetes Mellitus could include:
    - Obesity
    - Alcohol abuse
    - Long term steroid usage
    - Prior medical history of hyperglycemia/diabetes

- **Additional comments**
  Provide any additional comments for this AESI (e.g., family history).
  Note: When responding to a query, directly enter appropriate data that is consistent with query response in the Additional comments field within the EDC database itself. Responses that are captured only in the query response are not sufficient to meet the query requirements for closure and query will remain open until appropriate data field is updated.

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15.1.83.2 POTENTIAL HEPATIC EVENTs (Hepatitis/Transaminase increases)

NOTE: Please add **Hy's Law folder** from *ADD EVENT* only if the lab results meet potential Hy's Law criteria. Please refer to Appendix E in Clinical Study Protocol for details.

- **Signs and symptoms**
  Select all appropriate options
  (Abdominal pain; Pruritis; Tenderness; Vomiting; Pyrexia; Icteric sclera; No symptoms; Other).
  If 'Other' is selected, please enter information in the free text field.
  If there is more than 1 sign and symptom that will be entered/selected, please add each additional sign and symptom using the add new logline option.

➢ NOTE: Almost all immune related hepatitis events will present with asymptomatic abnormal levels of liver enzymes. Report all relevant details below, even if there are no signs and symptoms.

- **Was a specialist consulted?**
  Select the appropriate option *(No; Yes).*

  Services and result description
  If Yes was selected, describe what type of consultation and/or additional procedure(s) were conducted.
  For example: radiologic imaging (CT scan and/or abdominal ultrasound, MRCP, ERCP, histologic findings, liver biopsy etc).
  If additional space is needed, enter the text on a new log line.
  Additional information can also be added in the AESIA form.

  - **Any additional laboratory investigations performed?**
    Select the appropriate option *(No; Yes).*

    If Yes was selected, complete the LabADD form and enter more complete information regarding the additional specialized lab tests such as viral tests, tox screen, and/or auto-antibody results.

    Liver enzyme laboratory results (such as AST. ALT, ALP, total bilirubin, metabolic panel, etc), that are part of the regularly assessed laboratory panel should be entered in the LB page.

- **Any significant medical or surgical history relevant to this event?**
  Select the appropriate option *(No; Yes).*

  - **If Yes was selected due to a relevant Medical History,**
    Enter a letter to trigger a drop-down menu and select appropriate medical history event.

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The data in the drop-down menu is based on the data entered in the MH Form.
The medical history name and number will automatically be populated based on this selection.
Multiple medical history events can be selected.
If the appropriate medical history is not found in the drop-down menu, go back to the MH form and enter the appropriate information.

- **If Yes was selected due to a relevant <u>Surgical History</u>,**
  Enter a letter to trigger a drop-down menu and select appropriate surgical history event.
  The data in the drop-down menu is based on the data entered in the HISS Form.
  The surgical history name and number will automatically be populated based on this selection.
  Multiple surgical history events can be selected.
  If the appropriate surgical history is not found in the drop-down menu, go back to the HISS form and enter the appropriate information.

- **Any concomitant medication that triggered the event?**
  Select the appropriate option *(No; Yes).*
  NOTE: Do not enter medications used for treatment/management of the event, only that which caused the event, if any

  - **If Yes, specify the medication number and name**
    Enter a letter to trigger a drop-down menu and select appropriate concomitant medication.
    The data in the drop-down menu is based on the data entered in the CM Form.
    The concomitant medication name and number will automatically be populated based on this selection.
    Multiple concomitant medications can be selected.
    If the appropriate concomitant medications is not found in the drop-down menu, go back to the CM form and enter the appropriate information.

- **Could disease progression have triggered the event?**
  Select the appropriate option *(No; Yes).*
  NOTE if the event is unequivocally due to disease progression, it should not be recorded as an AE (only PD) as per protocol section 8.4.7
  - **If Yes, specify below**

  - **Can the event be attributed to disease / metastasis?**
    Select the appropriate option *(No; Yes).*

  - **Anatomic location**
    Select the appropriate option *(Distant lymph nodes; Supraglottis; Hypopharynx; Subglottis; Cervix uteri; Colon; Small intestine; Esophagus; Rectum; Stomach; Liver; Pancreas; Thyroid Gland; Parathyroid; Pituitary; Fallopian tube; Ovary; Uterus; Prostate gland; Testis; Bladder; Kidney; Head and neck; Larynx; Oral*

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cavity; Nasopharynx; Trachea; Spleen; Central nervous system; Brain; Lung; Pleura; Skin; Adrenal gland; Biliary tract; Glottis; Oropharynx; Peritoneum; Uvea; Breast; Muscle; Mucosa; Regional lymph node; Other).

If the anatomic location is the spinal cord, select central nervous system.

- **Any potential alternate etiology excluding disease progression?**
  Select the appropriate option *(No; Yes).*

  - **If Yes, specify**
    Examples of alternative etiologies could include:
    - Tumor progression in the liver and/or metastatic disease
    - Hypoperfusion or ischemic injury of the liver
    - Alternative medications (OTC, herbal medications)
    - Alcohol abuse
    - Liver abscess
    - Idiopathic autoimmune hepatitis
    - Viral infections (eg hepatitis A, B or C, CMV, EBV)
    - Biliary obstructions (such as gallstones)
    - Chronic heart failure

- **Additional comments**
  Provide any additional comments for this AESI (e.g., family history).
  Note: When responding to a query, directly enter appropriate data that is consistent with query response in the Additional comments field within the EDC database itself. Responses that are captured only in the query response are not sufficient to meet the query requirements for closure and query will remain open until appropriate data field is updated.

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- NOTE: Evaluate liver function tests for Hy's law to rule out potential drug-induced liver injury

Early intervention is critical to limit the risk of more severe hepato-toxicities

15.1.83.3 **POTENTIAL NEPHRITIS OR RENAL DYSFUNCTION**

- **Signs and symptoms**
  Select all appropriate options
  (Abdominal pain; Pain; Fatigue; Vomiting; Pyrexia; Oedema; Nausea; Changes in urine output; Rash; Proteinuria; Dehydration; Other; No symptoms)
  If 'Other' is selected, enter information in the free text field

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If there is more than 1 sign and symptom that will be entered/selected, please add each additional sign and symptom using the add new logline option

> ➢ NOTE: Many cases will present with asymptomatic, gradual increases in serum creatinine levels. Report all relevant details below, even if there are no signs and symptoms.

- **Was a specialist consulted?**
  Select the appropriate option *(No; Yes).*

  - **Services and result description**
    If Yes was selected, describe what type of consultation and/or additional procedure(s) were conducted.
    For example: renal consult, radiologic imaging (CT scan, MRI, and/or renal ultrasound), histologic findings, renal biopsy, etc).
    If additional space is needed, please enter the text on a new log line.
    Additional information can also be added in the AESIA form.

  - **Any additional laboratory investigations performed?**
    Select the appropriate option *(No; Yes).*

    If Yes was selected, complete the LabADD form and enter more complete information regarding the additional specialized lab tests, such as additional urinalysis results including urine osmolality, amorphous sediment, casts, crystals or glomerulonephritis lab values which may include ANA, Ds-DN, ANCA, C50, C4, Anti-GBM, cryoglobulins, LDH, haptoglobin, schistocytes.

    Laboratory results (such as creatinine, BUN, urinalysis, metabolic panel, etc), that are part of the regularly assessed laboratory panel should be entered in the LB page.

- **Any significant medical or surgical history relevant to this event?**
  Select the appropriate option *(No; Yes).*

  - **If Yes was selected due to a relevant <u>Medical History</u>,**
    Enter a letter to trigger a drop-down menu and select appropriate medical history event.
    The data in the drop-down menu is based on the data entered in the MH Form.
    The medical history name and number will automatically be populated based on this selection.
    Multiple medical history events can be selected.
    If the appropriate medical history is not found in the drop-down menu, go back to the MH form and enter the appropriate information.

  - **If Yes was selected due to a relevant <u>Surgical History</u>,**
    Enter a letter to trigger a drop-down menu and select appropriate surgical history event.

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The data in the drop-down menu is based on the data entered in the HISS Form.
The surgical history name and number will automatically be populated based on this selection.
Multiple surgical history events can be selected.
If the appropriate surgical history is not found in the drop-down menu, go back to the HISS form and enter the appropriate information.

- **Any concomitant medication that triggered the event?**
  Select the appropriate option *(No; Yes).*
  Recent medications such as anti-bacterials, anti-fungals, anti-inflammatories, ACE inhibitors/ARBs, diuretics and/or herbal medications should be noted.
  NOTE: Do not enter medications used for treatment/management of the event, only that which caused the event, if any

  - **If Yes, specify the medication number and name**
    Enter a letter to trigger a drop-down menu and select appropriate concomitant medication.
    The data in the drop-down menu is based on the data entered in the CM Form.
    The concomitant medication name and number will automatically be populated based on this selection.
    Multiple concomitant medications can be selected.
    If the appropriate concomitant medications is not found in the drop-down menu, go back to the CM form and enter the appropriate information.

- **Could disease progression have triggered the event?**
  Select the appropriate option *(No; Yes).*
  NOTE if the event is unequivocally due to disease progression, it should not be recorded as an AE (only PD) as per protocol section 8.4.7

  - **If Yes, specify below**

  - **Can the event be attributed to disease / metastasis?**
    Select the appropriate option *(No; Yes).*

  - **Anatomic location**
    Select the appropriate option *(Distant lymph nodes; Supraglottis; Hypopharynx; Subglottis; Cervix uteri; Colon; Small intestine; Esophagus; Rectum; Stomach; Liver; Pancreas; Thyroid Gland; Parathyroid; Pituitary; Fallopian tube; Ovary; Uterus; Prostate gland; Testis; Bladder; Kidney; Head and neck; Larynx; Oral cavity; Nasopharynx; Trachea; Spleen; Central nervous system; Brain; Lung; Pleura; Skin; Adrenal gland; Biliary tract; Glottis; Oropharynx; Peritoneum; Uvea; Breast; Muscle; Mucosa; Regional lymph node; Other).*

    If the anatomic location is the spinal cord, select central nervous system.

- **Any potential alternate etiology excluding disease progression?**
  Select the appropriate option *(No; Yes).*

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- **If Yes, specify**
  Examples of alternative etiologies could include:
  - Prior nephrectomy
  - Acute dehydration due to immune-mediated diarrhea, chemotherapy induced nausea/vomiting
  - Infections (systemic or localized; viral, bacterial or fungal)
  - Physical obstructions
    - Extra renal – such as prostate hypertrophy
    - Intrarenal – such as kidney stones
  - Tumor progression in the kidney and/or metastatic disease
  - Acute kidney injury induced by alternatives medications, cheapy or herbal supplements
  - Autoimmune disease (eg diabetes, systemic lupus erythematosus, sarcoiditis)
  - Vascular etiologies (eg renal atheroembolic disease, malignant hypertension)
  - Metabolic abnormalities
  - Chronic Kidney disease
  - Recent medications (anti-bacterials, anti-fungals, anti-inflammatories, ACE inhibitors/ARBs, diuretics, herbal medications, etc)

- **Additional comments**
  Provide any additional comments for this AESI (e.g., family history).
  Note: When responding to a query, directly enter appropriate data that is consistent with query response in the Additional comments field within the EDC database itself. Responses that are captured only in the query response are not sufficient to meet the query requirements for closure and query will remain open until appropriate data field is updated.

Early intervention is critical to limit the risk of more severe renal injury

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15.1.83.4 **POTENTIAL NEUROPATHY/NEUROMUSCULAR TOXICITY**

- **Signs and symptoms**
  Select all appropriate options
  (Paresthesia; Loss of deep tendon reflexes; Rapid progressive weakness; Respiratory insufficiency; Autonomic instability; Appearance; Headache; Nausea; Visual changes; Behaviour changes; Vertigo; Dyspnea; Seizure; Confusion; Dysphagia; Other; No symptoms)
  If 'Other' is selected, enter information in the free text field

  If there is more than 1 sign and symptom that will be entered/selected, add each additional sign and symptom using the add new logline option

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NOTE: Presenting symptoms of immune-related neurotoxicity can often be vague and non-specific.

- **Was a specialist consulted?**
  Select the appropriate option *(No; Yes).*

  Services and result description
  If Yes was selected, describe what type of consultation and/or additional procedure(s) were conducted.
  For example: neurologic consult, radiologic imaging (brain MRI), electrophysiologic exams, EEG, etc.
  If additional space is needed, enter the text on a new log line.
  Additional information can also be added in the AESIA form.

  - **Any additional laboratory investigations performed?**
    Select the appropriate option *(No; Yes).*

    If Yes was selected, complete the LabADD form and enter more complete information regarding the additional specialized lab tests (such as viral tests, CSF analysis and/or auto-antibody results).

    Laboratory results that are part of the regularly assessed laboratory panel should be entered in the LB page.

- **Any significant medical or surgical history relevant to this event?**
  Select the appropriate option *(No; Yes).*

  - **If Yes was selected due to a relevant <u>Medical History</u>,**
    Enter a letter to trigger a drop-down menu and select appropriate medical history event.
    The data in the drop-down menu is based on the data entered in the MH Form.
    The medical history name and number will automatically be populated based on this selection.
    Multiple medical history events can be selected.
    If the appropriate medical history is not found in the drop-down menu, go back to the MH form and enter the appropriate information.

  - **If Yes was selected due to a relevant <u>Surgical History</u>,**
    Enter a letter to trigger a drop-down menu and select appropriate surgical history event.
    The data in the drop-down menu is based on the data entered in the HISS Form.
    The surgical history name and number will automatically be populated based on this selection.
    Multiple surgical history events can be selected.

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If the appropriate surgical history is not found in the drop-down menu, go back to the HISS form and enter the appropriate information.

- **Any concomitant medication that triggered the event?**
  Select the appropriate option *(No; Yes).*
  . NOTE: Do not enter medications used for treatment/management of the event, only that which caused the event, if any

  - **If Yes, specify the medication number and name**
    Enter a letter to trigger a drop-down menu and select appropriate concomitant medication.
    The data in the drop-down menu is based on the data entered in the CM Form.
    The concomitant medication name and number will automatically be populated based on this selection.
    Multiple concomitant medications can be selected.
    If the appropriate concomitant medications is not found in the drop-down menu, go back to the CM form and enter the appropriate information.

- **Could disease progression have triggered the event?**
  Select the appropriate option *(No; Yes).*
  NOTE if the event is unequivocally due to disease progression, it should not be recorded as an AE (only PD) as per protocol section 8.4.7

  - **If Yes, specify below**

  - **Can the event be attributed to disease / metastasis?**
    Select the appropriate option *(No; Yes).*

  - **Anatomic location**
    Select the appropriate option *(Distant lymph nodes; Supraglottis; Hypopharynx; Subglottis; Cervix uteri; Colon; Small intestine; Esophagus; Rectum; Stomach; Liver; Pancreas; Thyroid Gland; Parathyroid; Pituitary; Fallopian tube; Ovary; Uterus; Prostate gland; Testis; Bladder; Kidney; Head and neck; Larynx; Oral cavity; Nasopharynx; Trachea; Spleen; Central nervous system; Brain; Lung; Pleura; Skin; Adrenal gland; Biliary tract; Glottis; Oropharynx; Peritoneum; Uvea; Breast; Muscle; Mucosa; Regional lymph node; Other).*

    If the anatomic location is the spinal cord, select central nervous system.

- **Any potential alternate etiology excluding disease progression?**
  Select the appropriate option *(No; Yes).*

  - **If Yes, specify**
    Examples of alternative etiologies could include:
    - Immune related endocrinopathy can present with similar general symptoms
    - Infections
      - Viral – (eg, herpes zoster, cytomegalovirus, EBV4)

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  - Bacterial – (e.g., Lyme disease, *Campylobacter jejuni*)
  - Fungal
- Tumor progression and/or metastatic disease
- Exposure to toxic agents
- Acute vascular events (eg stroke, transient ischemic attack)
- Metabolic or hepatic encephalopathy

➢ **Additional comments**
Provide any additional comments for this AESI (e.g., family history).
Note: When responding to a query, directly enter appropriate data that is consistent with query response in the Additional comments field within the EDC database itself. Responses that are captured only in the query response are not sufficient to meet the query requirements for closure and query will remain open until appropriate data field is updated.

Early diagnosis and appropriate intervention is critical

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15.1.83.5 **POTENTIAL PANCREATITIS**

- **Signs and symptoms**
Select all appropriate options
(Abdominal pain; Tenderness; Fatigue; Vomiting; Pyrexia; Nausea; Anorexia; Back pain Other; No symptoms)
If 'Other' is selected, enter information in the free text field
If there is more than 1 sign and symptom that will be entered/selected, add each additional sign and symptom using the add new logline option

➢ NOTE: Pancreatitis can be asymptomatic and found by abnormal amylase and lipase laboratory results. Report all relevant details below, even if there are no signs and symptoms.

➢ **Was a specialist consulted?**
Select an appropriate option *(No; Yes).*

Services and result description
If Yes was selected, describe what type of consultation and/or additional procedure(s) were conducted.
For example: endocrine consult, radiologic imaging, abdominal CT/ultrasound, etc.
If additional space is needed, please enter the text on a new log line.
Additional information can also be added in the AESIA form.

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- **Any additional laboratory investigations performed?**
  Select the appropriate option *(No; Yes).*
  If Yes was selected, complete the LabADD form and enter more complete information regarding the additional specialized lab tests and/or serum auto-antibody results.

  Laboratory results (such as amylase, lipase, etc), that are part of the regularly assessed laboratory panel should be entered in the LB page.

- **Any significant medical or surgical history relevant to this event?**
  Select the appropriate option *(No; Yes).*

  - **If Yes was selected due to a relevant <u>Medical History</u>,**
    Enter a letter to trigger a drop-down menu and select appropriate medical history event.
    The data in the drop-down menu is based on the data entered in the MH Form.
    The medical history name and number will automatically be populated based on this selection.

    Multiple medical history events can be selected.
    If the appropriate medical history is not found in the drop-down menu, go back to the MH form and enter the appropriate information.
  - **If Yes was selected due to a relevant <u>Surgical History</u>,**
    Enter a letter to trigger a drop-down menu and select appropriate surgical history event.
    The data in the drop-down menu is based on the data entered in the HISS Form.
    The surgical history name and number will automatically be populated based on this selection.
    Multiple surgical history events can be selected.
    If the appropriate surgical history is not found in the drop-down menu, go back to the HISS form and enter the appropriate information.

- **Any concomitant medication that triggered the event?**
  Select the appropriate option *(No; Yes).*
  NOTE: Do not enter medications used for treatment/management of the event, only that which caused the event, if any

  - **If Yes, specify the medication number and name**
    Enter a letter to trigger a drop-down menu and select appropriate concomitant medication.
    The data in the drop-down menu is based on the data entered in the CM Form.
    The concomitant medication name and number will automatically be populated based on this selection.
    Multiple concomitant medications can be selected.
    If the appropriate concomitant medications is not found in the drop-down menu, go back to the CM form and enter the appropriate information.

- **Could disease progression have triggered the event?**

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Select the appropriate option *(No; Yes).*
NOTE if the event is unequivocally due to disease progression, it should not be recorded as an AE (only PD) as per protocol section 8.4.7

- **If Yes, specify below**
- **Can the event be attributed to disease / metastasis?**
  Select the appropriate option *(No; Yes).*

- **Anatomic location**
  Select the appropriate option *(Distant lymph nodes; Supraglottis; Hypopharynx; Subglottis; Cervix uteri; Colon; Small intestine; Esophagus; Rectum; Stomach; Liver; Pancreas; Thyroid Gland; Parathyroid; Pituitar;: Fallopian tube; Ovary; Uterus; Prostate gland; Testis; Bladder; Kidney; Head and neck; Larynx; Oral cavity; Nasopharynx; Trachea; Spleen; Central nervous system; Brain; Lung; Pleura; Skin; Adrenal gland; Biliary tract; Glottis; Oropharynx; Peritoneum; Uvea; Breast; Muscle; Mucosa; Regional lymph node; Other).*

  If the anatomic location is the spinal cord, select central nervous system.

- **Any potential alternate etiology excluding disease progression?**
  Select the appropriate option *(No; Yes).*

  - **If Yes, please specify**
    Examples of alternative etiologies could include:
    - Infections
    - Obstructions (eg, Gallstones)
    - Use of opioids

15.1.83.6 **POTENTIAL RASH OR DERMATITIS**

- **Body surface area covered**
  Select the appropriate option
  (<10%; 10-30%; >30%)

- **Anatomical site**
  Select the appropriate option
  (Lower leg; Abdominal cavity; Inguinal region; Back; Neck; Face; Chest; Arm; Foot; Hand; Buttock; Scalp; Not Applicable; Other).

- **Signs and symptoms**
  Select the appropriate options
  (Infection; Pruritis; Tenderness; Burning; Tightness; Pain; Blistering; Ulceration; Striae; Superinfection – local; Superinfection – extensive; Hyperkeratosis; Hyperpigmentation; Telangiectasia; Fissures; Macules; Papules; Folliculitis; Bullous eruptions, Vitiligo, Erythema; Other; No symptoms).
  If 'Other' is selected, please enter information in the free text field.
  If there is more than 1 sign and symptom that will be entered/selected, please add each additional sign and symptom using the add new logline option.

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> ➢ NOTE: Skin reactions and rashes are the most common adverse event associated with checkpoint inhibitor drugs.

- **Was a specialist consulted?**
  Select the appropriate option *(No; Yes).*

  - **Services and result description**
    If Yes was selected, describe what type of consultation and/or additional procedure(s) was conducted.
    For example: dermatology consult, skin biopsy and histological findings, skin photos, etc.
    If additional space is needed, please enter the text on a new log line.
    Additional information can also be added in the AESIA form.

  - **Any additional laboratory investigations performed?**
    Select the appropriate option *(No; Yes).*

    If Yes was selected, complete the LabADD form and enter more complete information regarding the additional specialized lab tests (such as viral tests, and/or auto-antibody results).

    Laboratory results that are part of the regularly assessed laboratory panel should be entered in the LB page.

- **Any significant medical or surgical history relevant to this event?**
  Select the appropriate option *(No; Yes).*

  - **If Yes was selected due to a relevant <u>Medical History</u>,**
    Enter a letter to trigger a drop-down menu and select appropriate medical history event.
    The data in the drop-down menu is based on the data entered in the MH Form.
    The medical history name and number will automatically be populated based on this selection.
    Multiple medical history events can be selected.
    If the appropriate medical history is not found in the drop-down menu, go back to the MH form and enter the appropriate information.

  - **If YES was selected due to a relevant <u>Surgical History</u>,**
    Enter a letter to trigger a drop-down menu and select appropriate surgical history event.
    The data in the drop-down menu is based on the data entered in the HISS Form.
    The surgical history name and number will automatically be populated based on this selection.
    Multiple surgical history events can be selected.
    If the appropriate surgical history is not found in the drop-down menu, go back to the HISS form and enter the appropriate information.

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- **Any concomitant medication that triggered the event?**
  Select the appropriate option *(No; Yes).*
  NOTE: Do not enter medications used for treatment/management of the event, only that which caused the event, if any

  - **If Yes, specify the medication number and name**
    Enter a letter to trigger a drop-down menu and select appropriate concomitant medication.
    The data in the drop-down menu is based on the data entered in the CM Form.
    The concomitant medication name and number will automatically be populated based on this selection.
    Multiple concomitant medications can be selected.
    If the appropriate concomitant medications is not found in the drop-down menu, go back to the CM form and enter the appropriate information.

- **Could disease progression have triggered the event?**
  Select the appropriate option *(No; Yes).*
  NOTE if the event is unequivocally due to disease progression, it should not be recorded as an AE (only PD) as per protocol section 8.4.7

  - **If Yes, specify below**
  - **Can the event be attributed to disease / metastasis?**
    Select the appropriate option *(No; Yes).*

  - **Anatomic location**
    Select the appropriate option *(Distant lymph nodes; Supraglottis; Hypopharynx; Subglottis; Cervix uteri; Colon; Small intestine; Esophagus; Rectum; Stomach; Liver; Pancreas; Thyroid Gland; Parathyroid; Pituitary; Fallopian tube; Ovary; Uterus; Prostate gland; Testis; Bladder; Kidney; Head and neck; Larynx; Oral cavity; Nasopharynx; Trachea; Spleen; Central nervous system; Brain; Lung; Pleura; Skin; Adrenal gland; Biliary tract; Glottis; Oropharynx; Peritoneum; Uvea; Breast; Muscle; Mucosa; Regional lymph node; Other).*

    If the anatomic location is the spinal cord, select central nervous system.

- **Any potential alternate etiology excluding disease progression?**
  Select the appropriate option *(No; Yes).*

  - **If Yes, specify**
    Examples of alternative etiologies could include:
    - Contact dermatitis
    - Rashes induced by alternative meds, food or other substances
    - Acute infections (viral or bacterial)
    - Vasculitis
    - Cutaneous metastases

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- **Additional comments**

  Provide any additional comments for this AESI (e.g., family history).
  Note: When responding to a query, directly enter appropriate data that is consistent with query response in the Additional comments field within the EDC database itself. Responses that are captured only in the query response are not sufficient to meet the query requirements for closure and query will remain open until appropriate data field is updated.

Early intervention is critical to effective management of skin reactions

15.1.83.7 POTENTIAL GI TOXICITY (Colitis/Diarrhea/Intestinal Perforation)

- **Number of bowel movements at baseline**
  Provide the appropriate data (should be expressed in terms of stools per day).

- **Current bowel movements CTCAE**
  Select the appropriate option.
  Mild AE (increase of <4 stools/day over baseline)
  Moderate AE (increase of 4-6 stools/day over baseline)
  Severe AE (increase of ≥7 stools/day over baseline)
  Life-threatening or Disabling AE
  Death related to AE

- **Signs and symptoms**
  Select all appropriate options
  (Abdominal pain; Vomiting; Pyrexia; Cramping; Incontinence Chills; Bloody stool; Rectal discomfort; Nausea; Ileus; Sepsis; Peritoneal signs; Other; No symptoms).
  If 'Other' is selected, enter information in the free text field.
  If there is more than 1 sign and symptom that will be entered/selected, add each additional sign and symptom using the add new logline option.

- **Was a specialist consulted?**
  Select the appropriate option *(No; Yes).*

  - **Services and result description**

    If Yes was selected, describe what type of consultation and/or additional procedure(s) were conducted.
    For example: gastroenterologist consult, colonoscopy, sigmoidoscopy, radiologic imaging, biopsy, surgery, etc.
    If additional space is needed, enter the text on a new log line.
    Additional information can also be added in the AESIA form.

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- **Any additional laboratory investigations performed?**
  Select the appropriate option *(No; Yes).*

  If Yes was selected, complete the LabADD form and enter more complete information regarding the additional specialized lab tests, such as fecal blood, fecal calprotein, *C. difficile* toxin/culture, enteric pathogens.

  Laboratory results that are part of the regularly assessed laboratory panel should be entered in the LB page.

- **Any significant medical or surgical history relevant to this event?**
  Select the appropriate option *(No; Yes).*

  - **If Yes was selected due to a relevant <u>Medical History</u>,**
    Enter a letter to trigger a drop-down menu and select appropriate medical history event.
    The data in the drop-down menu is based on the data entered in the MH Form.
    The medical history name and number will automatically be populated based on this selection.
    Multiple medical history events can be selected.
    If the appropriate medical history is not found in the drop-down menu, go back to the MH form and enter the appropriate information.

  - **If Yes was selected due to a relevant <u>Surgical History</u>,**
    Enter a letter to trigger a drop-down menu and select appropriate surgical history event.
    The data in the drop-down menu is based on the data entered in the HISS Form.
    The surgical history name and number will automatically be populated based on this selection.
    Multiple surgical history events can be selected.
    If the appropriate surgical history is not found in the drop-down menu, go back to the HISS form and enter the appropriate information.

- **Any concomitant medication that triggered the event?**
  Select the appropriate option *(No; Yes).*
  NOTE: Do not enter medications used for treatment/management of the event, only that which caused the event, if any

  - **If Yes, specify the medication number and name**
    Enter a letter to trigger a drop-down menu and select appropriate concomitant medication.
    The data in the drop-down menu is based on the data entered in the CM Form.
    The concomitant medication name and number will automatically be populated based on this selection.
    Multiple concomitant medications can be selected.
    If the appropriate concomitant medications are not found in the drop-down menu, go back to the CM form and enter the appropriate information.

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- **Could disease progression have triggered the event?**
  Select the appropriate option *(No; Yes).*
  NOTE if the event is unequivocally due to disease progression, it should not be recorded as an AE (only PD) as per protocol section 8.4.7

  - **If Yes, specify below**

  - **Can the event be attributed to disease / metastasis?**
    Select an appropriate option *(No; Yes).*
  - **Anatomic location**
    Select the appropriate option *(Distant lymph nodes; Supraglottis; Hypopharynx; Subglottis; Cervix uteri; Colon; Small intestine; Esophagus; Rectum; Stomach; Liver; Pancreas; Thyroid Gland; Parathyroid; Pituitary; Fallopian tube; Ovary; Uterus; Prostate gland; Testis; Bladder; Kidney; Head and neck; Larynx; Oral cavity; Nasopharynx; Trachea; Spleen; fagi system; Brain; Lung; Pleura; Skin; Adrenal gland; Biliary tract; Glottis; Oropharynx; Peritoneum; Uvea; Breast; Muscle; Mucosa; Regional lymph node; Other).*

    If the anatomic location is the spinal cord, select central nervous system.

- **Any potential alternate etiology excluding disease progression?**
  Select the appropriate option *(No; Yes).*

  - **If Yes, specify**
    Examples of alternative etiologies for diarrhea/colitis could include:
    - Infectious colitis - bacterial, viral or parasitic pathogens (ie cytomegalovirus, Clostridium difficile)
    - Chemotherapy or radiation induced diarrhoea in patients recently exposed to those therapies
    - Ischemic colitis
    - History of inflammatory bowel disease, Crohn's disease, ulcerative colitis, celiac disease
    - Concomitant medications
    - Diet

    Examples of alternative etiologies for Intestinal perforation could include:
    - Appendicitis
    - Diverticulitis
    - Stomach ulcers
    - Prolonged use of Aspirin or other NSAIDs
    - Infections
    - Inflammatory bowel disease
    - Trauma to abdomen
    - Bowel obstruction/bowel injury
    - Colon Cancer
    - Abdominal surgery/abdominal procedures

  - **Additional comments**

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Provide any additional comments for this AESI (e.g., family history).
Note: When responding to a query, directly enter appropriate data that is consistent with query response in the Additional comments field within the EDC database itself. Responses that are captured only in the query response are not sufficient to meet the query requirements for closure and query will remain open until appropriate data field is updated.

Early intervention is critical to limit the risk of more severe toxicities such as sepsis and bowel perforation

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15.1.83.8 POTENTIAL MYOSITIS/POLYMYOSITIS

- **Signs and symptoms**
  Select all appropriate options
  (Pyrexia; Myalgia; Visual changes; Weakness; Dysphagia; Articular pain; Gait disturbances; Arthralgia; Drowsiness; Symmetrical muscle fatigue; Other; No symptoms).
  If 'Other' is selected, enter information in the free text field.
  If there is more than 1 sign and symptom that will be entered/selected, add each additional sign and symptom using the add new logline option.

- **Was a specialist consulted?**
  Select the appropriate option *(No; Yes).*

  Services and result description
  If Yes was selected, describe what type of consultation and/or additional procedures(s) were conducted.
  For example: electromyographic procedure, biopsies, magnetic resonance imaging, etc.
  If additional space is needed, please enter the text on a new log line.
  Additional information can also be added in the AESIA form.

  - **Any additional laboratory investigations performed?**
    Select the appropriate option *(No; Yes).*

    If Yes was selected, complete the LabADD form and enter more complete information regarding the additional specialized lab tests such as creatine kinase, aldolase, erythrocyte sedimentation rate, etc and/or serum auto-antibody results such as Anti-Jo-1, Anti-PL-7, Anti-PL-12.

    Laboratory results that are part of the regularly assessed laboratory panel (e.g., liver transaminases) should be entered in the LB page.

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- **Any significant medical or surgical history relevant to this event?**
  Select the appropriate option *(No; Yes).*

  - **If Yes was selected due to a relevant <u>Medical History</u>,**
    Enter a letter to trigger a drop-down menu and select appropriate medical history event .
    The data in the drop-down menu is based on the data entered in the MH Form.
    The medical history name and number will automatically be populated based on this selection.
    Multiple medical history events can be selected.
    If the appropriate medical history is not found in the drop-down menu, go back to the MH form and enter the appropriate information.

  - **If Yes was selected due to a relevant <u>Surgical History</u>,**
    Enter a letter to trigger a drop-down menu and select appropriate surgical history event.
    The data in the drop-down menu is based on the data entered in the HISS Form.
    The surgical history name and number will automatically be populated based on this selection.
    Multiple surgical history events can be selected.
    If the appropriate surgical history is not found in the drop-down menu, go back to the HISS form and enter the appropriate information.

- **Any concomitant medication that triggered the event?**
  Select the appropriate option *(No; Yes).*
  NOTE: Do not enter medications used for treatment/management of the event, only that which caused the event, if any

  - **If Yes, specify the medication number and name**
    Enter a letter to trigger a drop-down menu and select appropriate concomitant medication.
    The data in the drop-down menu is based on the data entered in the CM Form.
    The concomitant medication name and number will automatically be populated based on this selection.
    Multiple concomitant medications can be selected.
    If the appropriate concomitant medications is not found in the drop-down menu, go back to the CM form and enter the appropriate information.

- **Could disease progression have triggered the event?**
  Select the appropriate option *(No; Yes).*
  NOTE if the event is unequivocally due to disease progression, it should not be recorded as an AE (only PD) as per protocol section 8.4.7
  - **If Yes, specify below**

  - **Can the event be attributed to disease / metastasis?**
    Select the appropriate option *(No; Yes).*

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- **Anatomic location**
  Select the appropriate option *(Distant lymph nodes; Supraglottis; Hypopharynx; Subglottis; Cervix uteri; Colon; Small intestine; Esophagus; Rectum; Stomach; Liver; Pancreas; Thyroid Gland; Parathyroid; Pituitary; Fallopian tube; Ovary; Uterus; Prostate gland; Testis; Bladder; Kidney; Head and neck; Larynx; Oral cavity; Nasopharynx; Trachea; Spleen; Central nervous system; Brain; Lung; Pleura; Skin; Adrenal gland; Biliary tract; Glottis; Oropharynx; Peritoneum; Uvea; Breast; Muscle; Mucosa; Regional lymph node; Other).*

  If the anatomic location is the spinal cord, select central nervous system.

- **Any potential alternate etiology excluding disease progression?**
  Select the appropriate option *(No; Yes).*

  - **If Yes, specify**

    Examples of alternative etiologies could include:
    - Bacterial, viral, parasitic or fungal infections
    - Autoimmune diseases
    - Concomitant medications such as statins, penicillamine

- **Additional comments**
  Provide any additional comments for this AESI (e.g., family history).
  Note: When responding to a query, directly enter appropriate data that is consistent with query response in the Additional comments field within the EDC database itself. Responses that are captured only in the query response are not sufficient to meet the query requirements for closure and query will remain open until appropriate data field is updated.

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15.1.83.9 **POTENTIAL MYOCARDITIS**

- **Signs and symptoms**
  Select all appropriate options
  (Tenderness; Fatigue; Pyrexia; Myalgia; Hypotension; Weakness; Back pain; Chest pain; Dyspnea; Abnormal heart beat; Syncope; Skeletal-muscular symptoms; Pulmonary edema; Pulmonary rales; Shock; Peripheral Edema; Cardiac arrhythmias; Cardiac arrest; Sudden Cardiac Death; Other; No symptoms).
  If 'Other' is selected, please enter information in the free text field.
  If there is more than 1 sign and symptom that will be entered/selected, please add each additional sign and symptom using the add new logline option.

- **Was a specialist consulted?**
  Select the appropriate option *(No; Yes).*

  - **Services and result description**

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If Yes was selected, describe what type of consultation and/or additional procedures(s) were conducted.
For example: microbial cultures, 12-lead electrocardiograms, CT scans, echocardiography, magnetic resonance angiography, biopsies, etc.
If additional space is needed, enter the text on a new log line.
Additional information can also be added in the AESIA form.

- **Any additional laboratory investigations performed?**
  Select the appropriate option *(No; Yes).*

  If Yes was selected, complete the LabADD form and enter more complete information regarding the additional specialized lab tests such as serum troponin, creatine phosphokinase myocardial band, brain-type natriuretic peptide, erythrocyte sedimentation rate, etc and/or serum auto-antibody results (for those events that may have an autoimmune component).

  Laboratory results that are part of the regularly assessed laboratory panel (e.g., hemoglobin, amylase, leukocytes) should be entered in the LB page.

- **Any significant medical or surgical history relevant to this event?**
  Select thew appropriate option *(No; Yes).*

  - **If Yes was selected due to a relevant <u>Medical History</u>,**
    Enter a letter to trigger a drop-down menu and select appropriate medical history event.
    The data in the drop-down menu is based on the data entered in the MH Form.
    The medical history name and number will automatically be populated based on this selection.
    Multiple medical history events can be selected.
    Ensure all relevant medical history is entered into the MH form. Examples of relevant medical history include for example coronary artery disease, previous myocardial infarction, cardiomyopathy, previous myocarditis, pericarditis, heart failure, cardiac arrhythmias, previous thrombosis/pulmonary embolism, hypertension, hyperlipidemia, diabetes mellitus, smoking).
    If the appropriate medical history is not found in the drop-down menu, go back to the MH form and enter the appropriate information.

  - **If Yes was selected due to a relevant <u>Surgical History</u>,**
    Enter a letter to trigger a drop-down menu and select appropriate surgical history event.
    The data in the drop-down menu is based on the data entered in the HISS Form.
    The surgical history name and number will automatically be populated based on this selection.
    Multiple surgical history events can be selected.
    If the appropriate surgical history is not found in the drop-down menu, go back to the HISS form and enter the appropriate information.

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- **Any concomitant medication that triggered the event?**
  Select the appropriate option *(No; Yes).*
  . NOTE: Do not enter medications used for treatment/management of the event, only that which caused the event, if any

  - **If Yes, specify the medication number and name**
    Enter a letter to trigger a drop-down menu and select appropriate concomitant medication.
    The data in the drop-down menu is based on the data entered in the CM Form.
    The concomitant medication name and number will automatically be populated based on this selection.
    Multiple concomitant medications can be selected.
    If the appropriate concomitant medications is not found in the drop-down menu, go back to the CM form and enter the appropriate information.

- **Could disease progression have triggered the event?**
  Select the appropriate option *(No; Yes).*
  NOTE if the event is unequivocally due to disease progression, it should not be recorded as an AE (only PD) as per protocol section 8.4.7

  - **If Yes, specify below**

  - **Can the event be attributed to disease / metastasis?**
    Select the appropriate option *(No; Yes).*
  - **Anatomic location**
    Select an appropriate option *(Distant lymph nodes; Supraglottis; Hypopharynx; Subglottis; Cervix uteri; Colon; Small intestine; Esophagus; Rectum; Stomach; Liver; Pancreas; Thyroid Gland; Parathyroid; Pituitary; Fallopian tube; Ovary; Uterus; Prostate gland; Testis; Bladder; Kidney; Head and neck; Larynx; Oral cavity; Nasopharynx; Trachea; Spleen; Central nervous system; Brain; Lung; Pleura; Skin; Adrenal gland; Biliary tract; Glottis; Oropharynx; Peritoneum; Uvea; Breast; Muscle; Mucosa; Regional lymph node; Other).*

    If the anatomic location is the spinal cord, please select central nervous system.

- **Any potential alternate etiology excluding disease progression?**
  Select the appropriate option *(No; Yes).*

  - **If Yes, specify**
    Examples of alternative etiologies could include:
    - Bacterial, viral, parasitic or fungal infections
    - Concomitant or prior chemotherapy (such as anthracyclines or other drugs with cardio-toxic potential)
    - Prior or radiotherapy received towards the chest/mediastinum, which can potentially induce myocarditis
    - Autoimmune diseases such as lupus
    - Concomitant medications

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- **Additional comments**
  Provide any additional comments for this AESI (e.g., family history).
  Note: When responding to a query, directly enter appropriate data that is consistent with query response in the Additional comments field within the EDC database itself. Responses that are captured only in the query response are not sufficient to meet the query requirements for closure and query will remain open until appropriate data field is updated.

15.1.83.10 **POTENTIAL PNEUMONITIS**

NOTE: AESI form is required along all related forms in the CRS Signs and Symptoms folder for Potential pneumonitis AESI:

- Visit Dates (VISIT)
- Local Laboratory Test Results - ILDIS (LB9)
- Interstitial Lung Disease (ILDIS)
- Pulmonary Function Test (PULMOA)

- **Signs and symptoms**
  Select all appropriate options
  (Respiratory Insufficiency; Dyspnea; Cough; Other).
  If 'Other' is selected, please enter information in the free text field.
  If there is more than 1 sign and symptom that will be entered/selected, please add each additional sign and symptom using the add new logline option.
  NOTE: if Potential Pneumonitis is asymptomatic, please select Other as Signs and symptoms and specify NONE in the free text field.

- **Was a specialist consulted?**
  Select the appropriate option *(No; Yes).*

  - **Services and result description**

    If Yes was selected, describe what type of consultation and/or additional procedures(s) were conducted.
    For example: microbial cultures, 12-lead electrocardiograms, CT scans, echocardiography, magnetic resonance angiography, biopsies, etc.
    If additional space is needed, enter the text on a new log line.
    Additional information can also be added in the AESIA form.

  - **Any additional laboratory investigations performed?**
    Select the appropriate option *(No; Yes).*

    If Yes was selected, complete the LabADD form and enter more complete information regarding the additional specialized lab tests such as serum troponin, creatine phosphokinase myocardial band, brain-type natriuretic

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peptide, erythrocyte sedimentation rate, etc and/or serum auto-antibody results (for those events that may have an autoimmune component).

Laboratory results that are part of the regularly assessed laboratory panel (e.g., hemoglobin, amylase, leukocytes) should be entered in the LB page.

- **Any significant medical or surgical history relevant to this event?**
  Select thew appropriate option *(No; Yes).*

  - **If Yes was selected due to a relevant <u>Medical History</u>,**
    Enter a letter to trigger a drop-down menu and select appropriate medical history event.
    The data in the drop-down menu is based on the data entered in the MH Form.
    The medical history name and number will automatically be populated based on this selection.
    Multiple medical history events can be selected.
    Ensure all relevant medical history is entered into the MH form. Examples of relevant medical history include for example coronary artery disease, previous myocardial infarction, cardiomyopathy, previous myocarditis, pericarditis, heart failure, cardiac arrhythmias, previous thrombosis/pulmonary embolism, hypertension, hyperlipidemia, diabetes mellitus, smoking).
    If the appropriate medical history is not found in the drop-down menu, go back to the MH form and enter the appropriate information.

  - **If Yes was selected due to a relevant <u>Surgical History</u>,**
    Enter a letter to trigger a drop-down menu and select appropriate surgical history event.
    The data in the drop-down menu is based on the data entered in the HISS Form.
    The surgical history name and number will automatically be populated based on this selection.
    Multiple surgical history events can be selected.
    If the appropriate surgical history is not found in the drop-down menu, go back to the HISS form and enter the appropriate information.

- **Any concomitant medication that triggered the event?**
  Select the appropriate option *(No; Yes).*
  . NOTE: Do not enter medications used for treatment/management of the event, only that which caused the event, if any

  - **If Yes, specify the medication number and name**
    Enter a letter to trigger a drop-down menu and select appropriate concomitant medication.
    The data in the drop-down menu is based on the data entered in the CM Form.
    The concomitant medication name and number will automatically be populated based on this selection.
    Multiple concomitant medications can be selected.
    If the appropriate concomitant medications is not found in the drop-down menu, go back to the CM form and enter the appropriate information.

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- **Could disease progression have triggered the event?**
  Select the appropriate option *(No; Yes).*
  NOTE if the event is unequivocally due to disease progression, it should not be recorded as an AE (only PD) as per protocol section 8.4.7

  - **If Yes, specify below**

  - **Can the event be attributed to disease / metastasis?**
    Select the appropriate option *(No; Yes).*

  - **Anatomic location**
    Select an appropriate option *(Distant lymph nodes; Supraglottis; Hypopharynx; Subglottis; Cervix uteri; Colon; Small intestine; Esophagus; Rectum; Stomach; Liver; Pancreas; Thyroid Gland; Parathyroid; Pituitary; Fallopian tube; Ovary; Uterus; Prostate gland; Testis; Bladder; Kidney; Head and neck; Larynx; Oral cavity; Nasopharynx; Trachea; Spleen; Central nervous system; Brain; Lung; Pleura; Skin; Adrenal gland; Biliary tract; Glottis; Oropharynx; Peritoneum; Uvea; Breast; Muscle; Mucosa; Regional lymph node; Other).*

    If the anatomic location is the spinal cord, please select central nervous system.

- **Any potential alternate etiology excluding disease progression?**
  Select the appropriate option *(No; Yes).*

  - **If Yes, specify**
    Examples of alternative etiologies could include:
    - Bacterial, viral, parasitic or fungal infections
    - Concomitant or prior chemotherapy (such as anthracyclines or other drugs with cardio-toxic potential)
    - Prior or radiotherapy received towards the chest/mediastinum, which can potentially induce myocarditis
    - Autoimmune diseases such as lupus
    - Concomitant medications

- **Additional comments**
  Provide any additional comments for this AESI (e.g., family history).
  Note: When responding to a query, directly enter appropriate data that is consistent with query response in the Additional comments field within the EDC database itself. Responses that are captured only in the query response are not sufficient to meet the query requirements for closure and query will remain open until appropriate data field is updated.

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15.1.83.11 INFUSION RELATED REACTION INCLUDING ANAPHYLAXIS

NOTE: The IRRTQS form will appear in the AESI folder when this AESI category is selected as '*Infusion Related Reaction Including Anaphylaxis'*. Please ensure the **IRRTQS** form is completed as required.

- **Signs and symptoms**
  Start entering sign and symptom into field which will trigger any corresponding sign and symptom to appear as a selection from the drop-down menu.
  Alternatively, please select all appropriate signs and symptoms from the drop-down menu
  (Abdominal pain; Paresthesia; Loss of deep tendon reflexes; Rapid progressive weakness; Respiratory insufficiency; Autonomic instability; Appearance; Infection; Pruritis; Tenderness; Burning; Tightness; Pain; Fatigue; Vomiting; Pyrexia; Headache; Icteric sclera; Erythema; Oedema; Blistering; Ulceration; Striae; Superinfection – local; Superinfection – extensive; Hyperkeratosis; Hyperpigmentation; Telangiectasia; Fissures; Macules; Papules; Folliculitis; Cramping; Incontinence; Chills; Bloody stool; Rectal discomfort; Nausea; Ileus; Sepsis; Peritoneal signs; Malaise; Myalgia; Visual changes; Polyuria; Thirst; Behaviour changes; Changes to mental status; Vertigo; Unusual bowel habits; Hypotension; Weakness; Anorexia; Back pain; Chest pain; Dyspnea; Abnormal heart beat; Syncope; Skeletal muscular symptoms; Pulmonary edema; Pulmonary rales; Shock; Peripheral edema; Cardiac arrhythmias; Cardiac arrest; Sudden cardiac death; Changes in urine output; Rash; Proteinuria; Dehydration; Confusion; Seizure; Bullous eruptions; Vitiligo; Dysphagia; Articular pain; Gait disturbances; Arthralgia; Drowsiness; Symmetrical muscle fatigue; Cough; No symptoms; Other).
  Other is selected, enter information in the free text field.
  If there is more than 1 sign and symptom that will be entered/selected, add each additional sign and symptom using the add new logline option.

- **Was a specialist consulted?**
  Select the appropriate option *(No; Yes).*

  - **Services and result description**

    If Yes was selected, please describe what type of consultation and/or additional procedures(s) were conducted.
    If additional space is needed, enter the text on a new log line.
    Additional information can also be added in the AESIA form.

  - **Any additional laboratory investigations performed?**
    Select the appropriate option *(No; Yes).*

    If Yes was selected, please complete the LabADD form and enter more complete information regarding the additional specialized lab tests .

    Laboratory results that are part of the regularly assessed laboratory panel should be entered in the LB page.

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- **Any significant medical or surgical history relevant to this event?**
  Select the appropriate option *(No; Yes).*

  - **If Yes was selected due to a relevant <u>Medical History</u>,**
    Enter a letter to trigger a drop-down menu and select appropriate medical history event
    The data in the drop-down menu is based on the data entered in the MH Form.
    The medical history name and number will automatically be populated based on this selection.
    Multiple medical history events can be selected.
    If the appropriate medical history is not found in the drop-down menu, go back to the MH form and enter the appropriate information

  - **If Yes was selected due to a relevant <u>Surgical History</u>,**
    Enter a letter to trigger a drop-down menu and select appropriate surgical history event
    The data in the drop-down menu is based on the data entered in the HISS Form.
    The surgical history name and number will automatically be populated based on this selection.
    Multiple surgical history events can be selected
    If the appropriate surgical history is not found in the drop-down menu, go back to the HISS form and enter the appropriate information

- **Any concomitant medication that triggered the event?**
  Select the appropriate option *(No; Yes).*

  .

  - **If Yes, please specify the medication number and name**
    Enter a letter to trigger a drop-down menu and select appropriate concomitant medication
    The data in the drop-down menu is based on the data entered in the CM Form.
    The concomitant medication name and number will automatically be populated based on this selection.
    Multiple concomitant medications can be selected
    If the appropriate concomitant medications is not found in the drop-down menu, please go back to the CM form and enter the appropriate information

- **Could disease progression have triggered the event?**
  Select the appropriate option *(No; Yes).*

  - **If Yes, specify below**

  - **Can the event be attributed to disease / metastasis?**
    Select the appropriate option *(No; Yes).*

  - **Anatomic location**
    Select the appropriate option *(Distant lymph nodes; Supraglottis; Hypopharynx; Subglottis; Cervix uteri; Colon; Small intestine; Esophagus; Rectum; Stomach;*

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Liver; Pancreas; Thyroid Gland; Parathyroid; Pituitary; Fallopian tube; Ovary; Uterus; Prostate gland; Testis; Bladder; Kidney; Head and neck; Larynx; Oral cavity; Nasopharynx; Trachea; Spleen; Central nervous system; Brain; Lung; Pleura; Skin; Adrenal gland; Biliary tract; Glottis; Oropharynx; Peritoneum; Uvea; Breast; Muscle; Mucosa; Regional lymph node; Other).

If the anatomic location is the spinal cord, select central nervous system

- **Any potential alternate etiology exclude.ng disease progression?**
  Select appropriate option *(No; Yes).*

  - **If YES, specify**

- **Additional comments**
  Provide any additional comments for this AESI (e.g., family history).
  Note: When responding to a query, directly enter appropriate data that is consistent with query response in the Additional comments field within the EDC database itself. Responses that are captured only in the query response are not sufficient to meet the query requirements for closure and query will remain open until appropriate data field is updated.

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15.1.83.12 **CYTOKINE RELEASE SYNDROME**

NOTE: When this AESI category is selected, CRS Signs and Symptoms folder (forms: CRSSS, CRASTCT) will be populated. Please ensure the CRSSS, CRASTCT forms are completed as required.

- **Signs and symptoms**
  Start entering sign and symptom into field which will trigger any corresponding sign and symptom to appear as a selection from the drop-down menu.
  Alternatively, please select all appropriate signs and symptoms from the drop-down menu
  (Abdominal pain; Paresthesia; Loss of deep tendon reflexes; Rapid progressive weakness; Respiratory insufficiency; Autonomic instability; Appearance; Infection; Pruritis; Tenderness; Burning; Tightness; Pain; Fatigue; Vomiting; Pyrexia; Headache; Icteric sclera; Erythema; Oedema; Blistering; Ulceration; Striae; Superinfection – local; Superinfection – extensive; Hyperkeratosis; Hyperpigmentation; Telangiectasia; Fissures; Macules; Papules; Folliculitis; Cramping; Incontinence; Chills; Bloody stool; Rectal discomfort; Nausea; Ileus; Sepsis; Peritoneal signs; Malaise; Myalgia; Visual changes; Polyuria; Thirst; Behaviour changes; Changes to mental status; Vertigo; Unusual bowel habits; Hypotension; Weakness; Anorexia; Back pain; Chest pain; Dyspnea; Abnormal heart beat; Syncope; Skeletal muscular symptoms; Pulmonary edema; Pulmonary rales; Shock; Peripheral edema; Cardiac arrhythmias; Cardiac arrest; Sudden cardiac death; Changes in urine output; Rash; Proteinuria; Dehydration; Confusion; Seizure; Bullous eruptions; Vitiligo; Dysphagia; Articular pain; Gait disturbances; Arthralgia; Drowsiness; Symmetrical muscle fatigue; Cough; No symptoms; Other).
  Other is selected, enter information in the free text field.
  If there is more than 1 sign and symptom that will be entered/selected, add each additional sign and symptom using the add new logline option.

- **Was a specialist consulted?**
  Select the appropriate option *(No; Yes).*

  - **Services and result description**

    If Yes was selected, please describe what type of consultation and/or additional procedures(s) were conducted.
    If additional space is needed, enter the text on a new log line.
    Additional information can also be added in the AESIA form.

  - **Any additional laboratory investigations performed?**
    Select the appropriate option *(No; Yes).*

    If Yes was selected, please complete the LabADD form and enter more complete information regarding the additional specialized lab tests .

    Laboratory results that are part of the regularly assessed laboratory panel should be entered in the LB page.

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- **Any significant medical or surgical history relevant to this event?**
  Select the appropriate option *(No; Yes).*

  - **If Yes was selected due to a relevant <u>Medical History</u>,**
    Enter a letter to trigger a drop-down menu and select appropriate medical history event
    The data in the drop-down menu is based on the data entered in the MH Form.
    The medical history name and number will automatically be populated based on this selection.
    Multiple medical history events can be selected
    If the appropriate medical history is not found in the drop-down menu, go back to the MH form and enter the appropriate information

  - **If Yes was selected due to a relevant <u>Surgical History</u>,**
    Enter a letter to trigger a drop-down menu and select appropriate surgical history event
    The data in the drop-down menu is based on the data entered in the HISS Form.
    The surgical history name and number will automatically be populated based on this selection.
    Multiple surgical history events can be selected
    If the appropriate surgical history is not found in the drop-down menu, go back to the HISS form and enter the appropriate information

- **Any concomitant medication that triggered the event?**
  Select the appropriate option *(No; Yes).*
  . NOTE: Do not enter medications used for treatment/management of the event, only that which caused the event, if any

  - **If Yes, please specify the medication number and name**
    Enter a letter to trigger a drop-down menu and select appropriate concomitant medication
    The data in the drop-down menu is based on the data entered in the CM Form.
    The concomitant medication name and number will automatically be populated based on this selection.
    Multiple concomitant medications can be selected
    If the appropriate concomitant medications is not found in the drop-down menu, please go back to the CM form and enter the appropriate information

- **Could disease progression have triggered the event?**
  Select the appropriate option *(No; Yes).*
  NOTE if the event is unequivocally due to disease progression, it should not be recorded as an AE (only PD) as per protocol section 8.4.7

  - **If Yes, specify below**

  - **Can the event be attributed to disease / metastasis?**
    Select the appropriate option *(No; Yes).*

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- **Anatomic location**
  Select the appropriate option *(Distant lymph nodes; Supraglottis; Hypopharynx; Subglottis; Cervix uteri; Colon; Small intestine; Esophagus; Rectum; Stomach; Liver; Pancreas; Thyroid Gland; Parathyroid; Pituitary; Fallopian tube; Ovary; Uterus; Prostate gland; Testis; Bladder; Kidney; Head and neck; Larynx; Oral cavity; Nasopharynx; Trachea; Spleen; Central nervous system; Brain; Lung; Pleura; Skin; Adrenal gland; Biliary tract; Glottis; Oropharynx; Peritoneum; Uvea; Breast; Muscle; Mucosa; Regional lymph node; Other).*

  If the anatomic location is the spinal cord, select central nervous system

- **Any potential alternate etiology exclude.ng disease progression?**
  Select appropriate option *(No; Yes).*

  - **If YES, specify**

- **Additional comments**
  Provide any additional comments for this AESI (e.g., family history).
  Note: When responding to a query, directly enter appropriate data that is consistent with query response in the Additional comments field within the EDC database itself. Responses that are captured only in the query response are not sufficient to meet the query requirements for closure and query will remain open until appropriate data field is updated.

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15.1.83.13 **OTHER POTENTIAL AESIs**

- **Signs and symptoms**
  Start entering sign and symptom into field which will trigger any corresponding sign and symptom to appear as a selection from the drop-down menu.
  Alternatively, please select all appropriate signs and symptoms from the drop-down menu
  (Abdominal pain; Paresthesia; Loss of deep tendon reflexes; Rapid progressive weakness; Respiratory insufficiency; Autonomic instability; Appearance; Infection; Pruritis; Tenderness; Burning; Tightness; Pain; Fatigue; Vomiting; Pyrexia; Headache; Icteric sclera; Erythema; Oedema; Blistering; Ulceration; Striae; Superinfection – local; Superinfection – extensive; Hyperkeratosis; Hyperpigmentation; Telangiectasia; Fissures; Macules; Papules; Folliculitis; Cramping; Incontinence; Chills; Bloody stool; Rectal discomfort; Nausea; Ileus; Sepsis; Peritoneal signs; Malaise; Myalgia; Visual changes; Polyuria; Thirst; Behaviour changes; Changes to mental status; Vertigo; Unusual bowel habits; Hypotension; Weakness; Anorexia; Back pain; Chest pain; Dyspnea; Abnormal heart beat; Syncope; Skeletal muscular symptoms; Pulmonary edema; Pulmonary rales; Shock; Peripheral edema; Cardiac arrhythmias; Cardiac arrest; Sudden cardiac death; Changes in urine output; Rash; Proteinuria; Dehydration; Confusion; Seizure; Bullous eruptions; Vitiligo; Dysphagia; Articular pain; Gait disturbances; Arthralgia; Drowsiness; Symmetrical muscle fatigue; Cough; No symptoms; Other).

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Other is selected, enter information in the free text field.
If there is more than 1 sign and symptom that will be entered/selected, add each additional sign and symptom using the add new logline option.

- **Was a specialist consulted?**
  Select the appropriate option *(No; Yes).*

  - **Services and result description**

    If Yes was selected, please describe what type of consultation and/or additional procedures(s) were conducted.
    If additional space is needed, enter the text on a new log line.
    Additional information can also be added in the AESIA form.

  - **Any additional laboratory investigations performed?**
    Select the appropriate option *(No; Yes).*

    If Yes was selected, please complete the LabADD form and enter more complete information regarding the additional specialized lab tests .

    Laboratory results that are part of the regularly assessed laboratory panel should be entered in the LB page.

- **Any significant medical or surgical history relevant to this event?**
  Select the appropriate option *(No; Yes).*

  - **If Yes was selected due to a relevant <u>Medical History</u>,**
    Enter a letter to trigger a drop-down menu and select appropriate medical history event
    The data in the drop-down menu is based on the data entered in the MH Form.
    The medical history name and number will automatically be populated based on this selection.
    Multiple medical history events can be selected
    If the appropriate medical history is not found in the drop-down menu, go back to the MH form and enter the appropriate information

  - **If Yes was selected due to a relevant <u>Surgical History</u>,**
    Enter a letter to trigger a drop-down menu and select appropriate surgical history event
    The data in the drop-down menu is based on the data entered in the HISS Form.
    The surgical history name and number will automatically be populated based on this selection.
    Multiple surgical history events can be selected
    If the appropriate surgical history is not found in the drop-down menu, go back to the HISS form and enter the appropriate information

- **Any concomitant medication that triggered the event?**
  Select the appropriate option *(No; Yes).*

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NOTE: Do not enter medications used for treatment/management of the event, only that which caused the event, if any

- **If Yes, please specify the medication number and name**
  Enter a letter to trigger a drop-down menu and select appropriate concomitant medication
  The data in the drop-down menu is based on the data entered in the CM Form.
  The concomitant medication name and number will automatically be populated based on this selection.
  Multiple concomitant medications can be selected
  If the appropriate concomitant medications is not found in the drop-down menu, please go back to the CM form and enter the appropriate information

- **Could disease progression have triggered the event?**
  Select the appropriate option *(No; Yes).*
  NOTE if the event is unequivocally due to disease progression, it should not be recorded as an AE (only PD) as per protocol section 8.4.7

  - **If Yes, specify below**

  - **Can the event be attributed to disease / metastasis?**
    Select the appropriate option *(No; Yes).*

  - **Anatomic location**
    Select the appropriate option *(Distant lymph nodes; Supraglottis; Hypopharynx; Subglottis; Cervix uteri; Colon; Small intestine; Esophagus; Rectum; Stomach; Liver; Pancreas; Thyroid Gland; Parathyroid; Pituitary; Fallopian tube; Ovary; Uterus; Prostate gland; Testis; Bladder; Kidney; Head and neck; Larynx; Oral cavity; Nasopharynx; Trachea; Spleen; Central nervous system; Brain; Lung; Pleura; Skin; Adrenal gland; Biliary tract; Glottis; Oropharynx; Peritoneum; Uvea; Breast; Muscle; Mucosa; Regional lymph node; Other).*

    If the anatomic location is the spinal cord, select central nervous system

- **Any potential alternate etiology excluding disease progression?**
  Select appropriate option *(No; Yes).*

  - **If YES, specify**

- **Additional comments**
  Provide any additional comments for this AESI (e.g., family history).
  Note: When responding to a query, directly enter appropriate data that is consistent with query response in the Additional comments field within the EDC database itself. Responses that are captured only in the query response are not sufficient to meet the query requirements for closure and query will remain open until appropriate data field is updated.

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15.1.84 AE OF SPECIAL INTEREST ADDENDUM (AESIA)

If the AESI form has been triggered, and additional laboratory investigations (i.e., consultation, additional procedure investigation) have been performed during treatment of the adverse event, the AESIA module can be completed to provide additional information of the additional investigations that was not added in the AESI form.

The following variables will be populated automatically based on the information entered in the Adverse Event Special Interest (AESI) form:

AE number, Adverse event, AE of special interest category and **If Other, specify.**

If the AE information that has been auto-populated is incorrect, please return to the AESI page and update the information there.

Investigation:
If an additional investigation has been performed during the treatment of the AESI, please select an appropriate option from the list below. If there are multiple additional investigations performed for this AESI, please enter each additional investigation and the results for each.

· MRCP
· Colonoscopy
· ERCP
· Electromyogram
· Nerve conduction investigations
· Repetitive stimulations
· Cultures
· ECG
· Eye exam
· ACTH (Cosyntropin) stimulation test
· Biopsy
· Endoscopy
· MRI
· CT scan
· Ultrasound
· X-ray
· Other
If OTHER, please update **If other, specify**

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Specialty labs that are not captured in the LB CRF should be entered under in the LabADD CRF and not here.

Please specify Procedure number and text

If a procedure has been checked, please link that procedure in the AESIA form to the data entered in the PR form

Please enter a letter to trigger a drop down menu and select appropriate concomitant procedure

The concomitant procedure name and number will automatically be populated based on this selection.

If the appropriate procedure is not found in the drop down menu, please go back to the PR form and enter the appropriate information

Results Description:

The free text field is available for the sites to enter the results from the additional investigations.

If a specialist was consulted for this AESI, please enter this in the results description field along with the outcome of the consultation

For lab related data that cannot be recorded on LABADD, please enter the reference ranges, in addition to the lab results.

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15.1.85 ADDITIONAL LABORATORY EVALUATIONS (LABADD)

AE number
AE number (derived, no entry required)

Adverse event
Derived, no entry required.

AE of special interest
Derived, no entry required.

If Other, specify
If 'Other' was selected, record the appropriate details.

Collection date
Record a complete date using YYYY-MON-DD format (for example 2000-JAN-01).

Test name
Study specific value list. Please select as appropriate (Hba1c (Blood) ;Thyrotropin Receptor Antibody (Serum) ;Thyroid Peroxidase Antibody (Serum);Thyroglobulin Antibody (Serum) ; Glutamic Acid Decarboxylase Antibody; Quant Islet Cell Autoantibodies, Qual Islet Cell Autoantibodies, Quant Other.)

If Other, specify
If 'Other' was selected, record the appropriate details.

Result
Record the appropriate data.

Laboratory value comment
Record the appropriate data.

Low normal
Record the appropriate data.

High normal
Record the appropriate data.

Units
Record the appropriate data.

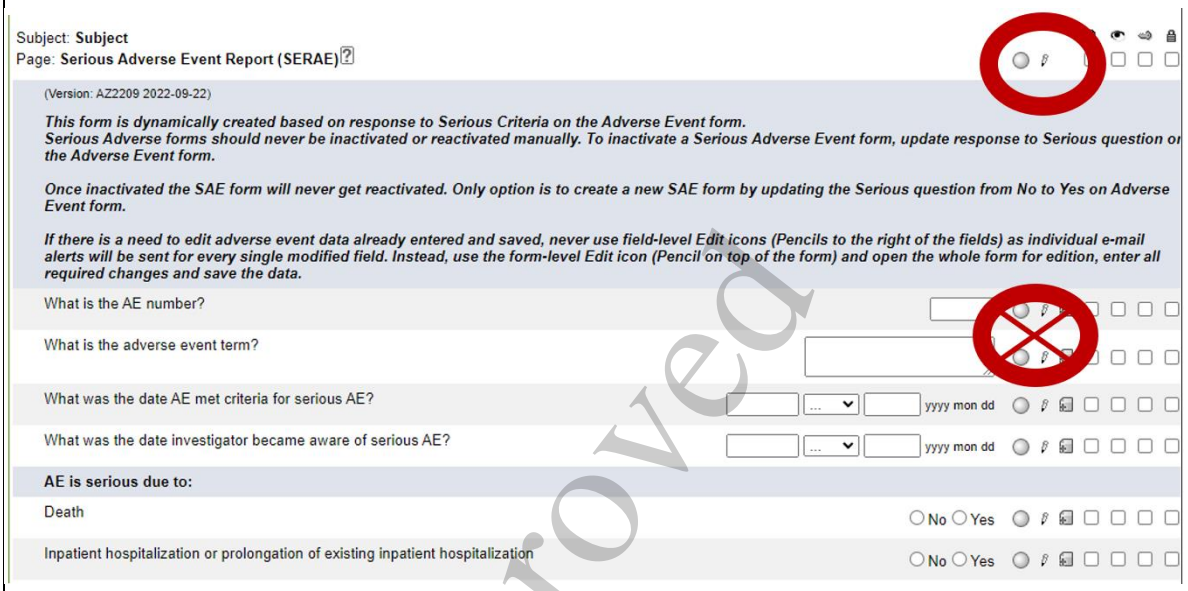
Clinically significant
Record the appropriate option (No; Yes).

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15.1.86 SERIOUS ADVERSE EVENT REPORT (SERAE)

IMPORTANT NOTE: *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.*



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.

Adverse event reporting

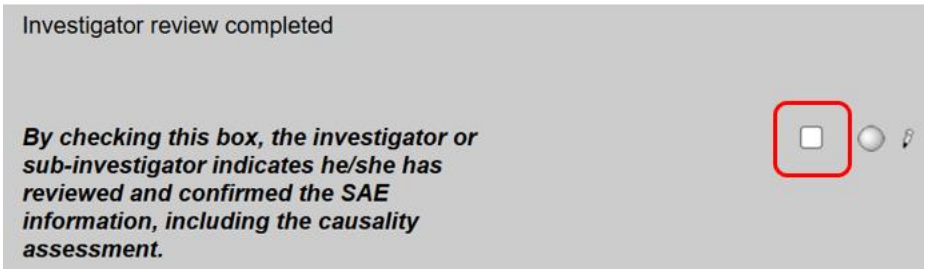
AE and SAE reporting are explained in CSP section 8.4

Rules of SAE reporting and SAE alert process can be found in General eCRF Completion Guideline Section 13

Investigator review completed

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IMPORTANT NOTE: By checking this box, the investigator or sub-investigator indicates he/she has reviewed and confirmed the SAE information, including the causality assessment. Please make sure the review is completed, and box is checked within 10 days from SAE reporting date and/or within 10 days of any change on causality assessment.

What is the AE number?
Field will be automatically populated from Adverse Event form.

What is the adverse event term?
Field will be automatically populated from Adverse Event form.

What was the date AE met criteria for serious AE?
Record a complete date in *YYYY-MON-DD* format (for example *2000-JAN-01*). The date when the adverse event was determined to be serious. Can be on or after the date the adverse event occurred.

What was the date Investigator became aware of serious AE?
Record a complete date in *YYYY-MON-DD* format (for example *2000-JAN-01*).

AE is serious due to:
Record '*Yes*' or '*No*' for each criteria, depending on applicability. At least one criterion should be selected as '*Yes*'. All questions have to be answered.

NOTE: Some criteria are specific to medicinal products or device event only. Where this is stated in the instructions, an answer of '*Yes*' should only be selected according to the established causal relationship to medicinal product, medical device, or both.

NOTE: Please refer to the CSP Appendix B for guidelines.

- **Death**
  Record the appropriate option *(No; Yes)*.
  NOTE: If Yes, update the Death Details (DD) form and Disposition (DS) form with all relevant details.

- **Inpatient hospitalization or prolongation of existing inpatient hospitalization**
  Record the appropriate option *(No; Yes)*.
  NOTE: Please make sure Hospital Admissions Details (HOSPAD) form is reported for each hospitalization.
  NOTE: When Subject is already hospitalized and experiences a new AE during hospitalization, it should be reported as a separate AE/SAE.

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- **Congenital anomaly or birth defect**
  Record the appropriate option *(No; Yes)*. Remember that this seriousness criterion applies to drug only.

- **Life threatening**
  Record the appropriate option *(No; Yes)*.

- **Persistent or significant disability/incapacity**
  Record the appropriate option *(No; Yes)*.

- **Important medical event**
  Record the appropriate option (No; Yes). Remember that this seriousness criterion applies to drug only.

- **Foetal distress, foetal death or congenital physical or mental or birth defect**
  Record the appropriate option (No; Yes).
  Note: this seriousness criterion applies to **Device Events** only.
  - If the AE/SAE is not associated with a Device Event, the expected response should be 'No';
  - If this AE/SAE is associated with Device Event, please make sure Device Event (DE) form is completed.

- **Permanent impairment/Chronic disease**
  Record the appropriate option (*No*; *Yes*).
  NOTE: this seriousness criterion applies to **Device Events** only.
  - If the AE/SAE is not associated with a Device Event, the expected response should be 'No';
  - If this AE/SAE is associated with Device Event, please make sure Device Event (DE) form is completed.

- **Medical or surgical intervention**
  Record the appropriate option (*No*; *Yes*). Medical or surgical intervention was required to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function.
  NOTE: this seriousness criterion applies to **Device Events** only.
  - If the AE/SAE is not associated with a Device Event, the expected response should be 'No';
  - If this AE/SAE is associated with Device Event, please make sure Device Event (DE) form is completed.

If Hospitalization is selected as Yes, complete below:

Date of hospitalization
Record a complete date *in YYYY-MON-DD* format (for example 2000-JAN-01).

NOTE: Enter the date when Subject was admitted to the hospital.
NOTE: Hospitalization date should not be earlier than Date AE met criteria for seriousness. When Subject is hospitalized and **new event** meets the seriousness

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criterium of ***Prolongation of existing hospitalization*****,** report the date when prolongation was decided as the Date of hospitalization for this new AE.

Date of discharge
Record a complete date in *YYYY-MON-DD* format (for example *2000-JAN-01*).

NOTE: Leave blank if the Subject died in the hospital or if the Subject was discharged after the study withdrawal/completion.

NOTE: If the Subject was hospitalized more than one time **for the same** (unresolved/ongoing) serious adverse event, report the first admission date as a Date of hospitalization and the last discharge date as the Date of discharge. The exact dates (admission and discharge) of each hospitalization should be included in SAE description (free text field on SERAE form).

Reasonable possibility SAE caused by other medication
Record the appropriate option *(No; Yes)*. If *Yes*, specify below.

If Yes, specify trade name(s)
Report the medication trade name(s) (or generic if the trade name is unknown) if there is a reasonable possibility that the event may have been caused by other medication. Ensure that the medication(s) is (are) entered on **Prior and** Concomitant Medication (CM) form.

Reasonable possibility SAE caused by study procedure(s)
Record the appropriate option *(No; Yes)*. If *Yes*, specify below.

If Yes, specify procedure(s)
Report the name of study procedure(s) if there is a reasonable possibility that the event may have been caused by study procedures. Ensure that the procedure is recorded on 1PR.

Description of AE
Please include only SAE 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 SAE text is consistent with data entered in fields. Do not provide personal information, e.g. e-code, country, any names, type of relationship and involvement of other people (family or other), addresses, official ID numbers, sexual orientation and lifestyle details, political opinions and religion, private circumstances related to events and patient words quotation, etc.

Note: Please avoid providing treatment revealing information or subject personal identifiers (ie, subject name, full date of birth, hospitalization number, etc.), the names of physicians or other healthcare professionals in the description of AE field.

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NOTE: Make sure SAE description doesn't exceed 1999 characters due to SAE reporting limitations and integration with Safety database. Do not copy paste any text to avoid disallowed characters.

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

NOTE: Please make sure to report all medical treatment in **Prior and Concomitant Medication** (CM) form. including new medications and any changes in treatment due to SAE.

NOTE: Please add any additional procedures to the **Procedure (1PR)** form.

Technical NOTE:

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

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15.1.87 INTERSTITIAL LUNG DISEASE (ILDIS)

This form is triggered in ILDIS folder if: In AE folder, 'If Adverse event of special interest category' is "Potential Pneumonitis" and "Is this an Adverse Event of Special Interest?" is "Yes"

What was the AE number?
Number will be populated from Adverse Event module.

What was the AE grade change number?

Symptoms associated with Interstitial Lung Disease:

Did the Subject have a fever?
Record the appropriate option *(No; Yes)*.

Did the Subject have dyspnea?
Record the appropriate option *(No; Yes)*.

Did the Subject have a cough?
Record the appropriate option *(No; Yes)*.

Was cough productive?
Record the appropriate option *(No; Yes)*.

Did the Subject have any other symptoms?
Record the appropriate option *(No; Yes)*.

If "Did the Subject have any other symptoms?" is '*Yes'*, specify all other signs and symptoms in "**If Other, specify"**.

What was the method used for the diagnosis?
Record all appropriate options used for diagnosis of pneumonitis/ILD *(Bronchoalveolar lavage; Lung biopsy; ILD markers; MRI; CT scan; High resolution CT; X-ray; Other*).

If the diagnosis was made through more than one radiographic method, record 'Other' and list each radiographic method in the "**If Other, specify**" free text field.

If Other, specify
If the diagnosis was made through a different method or through radiographic finding(s) and symptoms, record this information in the free text field here.

What was the axial distribution of lung findings?
Record the appropriate option *(Central lung predominant; Peripheral lung predominant; Both).*

What was the zonal distribution of lung findings?
Record the appropriate option *(Upper lung predominant; Middle lung predominant; Lower lung predominant; Not applicable).*

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What was distribution pattern of findings?
Record the appropriate option *(Focal pattern; Multifocal pattern; Diffuse pattern; Mixed pattern).*

Was there lobar involvement in the right upper lobe?
Record the appropriate option *(No; Yes)*.

Was there lobar involvement in the right middle lobe?
Record the appropriate option *(No; Yes)*.

Was there lobar involvement in the right lower lobe?
Record the appropriate option *(No; Yes)*.

Was there lobar involvement in the left upper lobe?
Record the appropriate option *(No; Yes)*.

Was there lobar involvement in the left lower lobe?
Record the appropriate option *(No; Yes)*.

Were ground glass opacities found in CT?
Record the appropriate option *(No; Yes)*.

Were reticular opacities found in CT?
Record the appropriate option *(No; Yes)*.

Was consolidation found in CT?
Record the appropriate option *(No; Yes)*.

Was traction bronchiectasis found in CT?
Record the appropriate option *(No; Yes)*.

Was centrilobular nodularity found in CT?
Record the appropriate option *(No; Yes).*

Was honeycombing found in CT?
Record the appropriate option *(No; Yes)*.

Were there any further findings?
Update the findings as appropriate.

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

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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?
Record the appropriate option (No; Yes).

What was the description of cancer progression within the thorax?
Record the appropriate data.

At the time of diagnosis of the pulmonary event, was there any evidence of bacterial infection?
Record the appropriate option (No; Yes).

At the time of diagnosis of the pulmonary event, was there any evidence of viral infection?
Record the appropriate option *(No; Yes)*.

At the time of diagnosis of the pulmonary event, was there any evidence of fungal infection?
Record the appropriate option *(No; Yes)*.

At the time of diagnosis of the pulmonary event, was there any other type of evidence of infection?
Record the appropriate option *(No; Yes)*.

Analytes

Pre-printed value list on the eCRF

- *Common bacteria;*
- *Acid fast bacillus;*
- *Tubercle bacillus;*
- *Legionnaire;*
- *Pneumocystis;*
- *Cytomegalovirus;*
- *COVID-19;*
- *Influenza;*
- *Mycoplasma;*
- *Aspergillus;*
- *Cryptococcus;*
- *Candida;*

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- *Other*

Note: If *'Other'* for **"Analytes"** is selected, record the details in "**If Other, specify"**.

Test method
Record the appropriate option *(Sputum culture; Blood culture; Serum antibody titer; Broncho-alveolar lavage; Other fungal; Other).*

Note: If *'Other'* for **"Test method"** is selected, record the details in "**If Other, specify"**.

Date of examination
Record the date of examination in YYYY-MMM-DD format (*for example 2000-JAN-01*).

Result
Record the appropriate option *(Negative; Positive).*

Other, specify
Record the appropriate data. If *'Other'* for **"Analytes"** is selected, record the details in this field. If *'Other'* for "**Test Method"** is selected, record the details in this field.

Was the lung biopsy performed?
Record the appropriate option *(No; Yes).*

If *'Yes'* in **"Was the lung biopsy performed?"**, record **"What was the date the biopsy was performed?"; "Type of biopsy"; "If Other biopsy, specify"** and **"What were the biopsy findings, specify"** to provide details of the lung biopsy.

Type of biopsy
Record the appropriate option (*Transbronchial; Bronchial biopsy; Cryobiopsy; Other).*

If Other biopsy, specify
If '*Other'* for **Type of biopsy** is recorded, record the details in this field.

What was the date the biopsy was performed?
Record date using *YYYY-MMM-DD* format (for example *2000-JAN-01*).

What were the biopsy findings, specify
Record the details of findings in the lung biopsy.

Was bronchoalveolar lavage (BAL) performed?
Record the appropriate option. *(No; Yes)*

If *'Yes'* in **"Was bronchoalveolar lavage (BAL) performed?"**, record **"What was the date of examination of BAL?"** and **"Specify results of this examination"** section to provide details of the bronchoalveolar lavage (BAL).

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What was the date of examination of BAL?
Record date using *YYYY-MMM-DD* format (for example *2000-JAN-01*).

Specify results of this examination.

What was the total cells count?
Record the appropriate data.

What was the unit of the total cells count?
Record the appropriate unit (10/L)

What was the lymphocyte cell count?
Record the appropriate data.

What was the unit of the lymphocyte count?
Record the appropriate unit (%).

What was the neutrophil count?
Record the appropriate data.

What was the unit of the neutrophil count?
Record the appropriate unit (%).

What was the macrophage count?
Record the appropriate data.

What was the unit of the macrophage count?
Record the appropriate unit (%).

What was the eosinophil count?
Record the appropriate data.

What was the unit of the eosinophil count?
Record the appropriate unit (%).

What was the basophil count?
Record the appropriate data.

What was the unit of the basophil count?
Record the appropriate unit (%).

What was the CD4/CD8 count?
Record the appropriate data.

What was the unit of CD4/CD8 count?
Record the appropriate unit (ratio).

If there are any pathological findings in BAL, specify.
Record an appropriate data.

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Were there malignant cells in cytology?
Record the appropriate option *(No; Yes).*

If *'Yes'*, specify result of malignant cells on cytology in **"If there were malignant cells in cytology, specify results"**.

Did pleural effusion co-exist with the event?
Record the appropriate option *(No; Yes).*

Was cytology of pleural fluid done?
Record the appropriate option *(No; Yes).*

Was malignant cells present in cytology of pleural fluid?
Record the appropriate option *(No; Yes).*

If *'Yes'*, specify result of malignant cells on cytology in **"If malignant cells were present in cytology of pleural fluid, specify results"**.

Were blood gases performed at the time of the suspected pulmonary event?
Record the appropriate option *(No; Yes).*

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

Is there a history of radiotherapy to the thorax prior to entering the study?

Record the appropriate option *(No; Yes).*

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

Has the Subject ever had pleurodesis performed?
Record the appropriate option *(No; Yes).*

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

What was the type of pleurodesis?
Record the appropriate option *(Talc; Picibanil (OK-432); Tetracycline; Bleomycine; Other).*

If *'Other'* is selected, specify details in **"If Other, specify".**

At the time of the event, was there any evidence of an inflammatory reaction?

Record the appropriate option *(No; Yes).*

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If '*Yes'* is selected and there was evidence of an inflammatory reaction, that has not been captured on the AE or LB report forms, please record the appropriate data in **"If not captured on AE / LB, then add details here".**

Note: If there are relevant data recorded in AE or LB, record AE No. or AE term and Sampling date of the LB form here.

At the time of the event, was there any evidence of allergic reaction?

Record the appropriate option *(No; Yes).*

If '*Yes'* is selected and there was evidence of an allergic reaction, that has not been captured on the AE or LB report forms, please record the appropriate data in **"If not captured on AE / LB, then add details here".**

Note: If there are relevant data recorded in AE or LB, record AE No. or AE term and Sampling date of the LB form here.

Was prior radiation administered to the chest?
Record the appropriate option *(No; Yes).*

Clarification: Prior radiation could have been given before the study or during the study as palliative RT.

What were the radiological findings?
Record the appropriate option *(Confined to radiation field only; Outside of radiation field only; Both; No radiological findings).*

What was the pneumonitis type?
Record the appropriate option *(Radiation pneumonitis; Drug-induced pneumonitis/Interstitial Lung Disease; Other).*

If 'Other' is selected, specify details in **"If Other, specify"**

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15.1.88 PULMONARY FUNCTION TEST (PULMOA)

This form is triggered in ILDIS folder if: In AE folder, 'If Adverse event of special interest category' is "Potential Pneumonitis" and "Is this an Adverse Event of Special Interest?" is "Yes"

Was Pulmonary Function Test performed?
Record an appropriate option (No; Yes).

Date of collection
Record the complete date in *YYYY-MON-DD* format (for example *2000-JAN-01*).

Peripheral oxygen saturation
Record the appropriate value in %.

PaO2
Record the appropriate value.

PaO2 unit
This will be defaulted in RAVE as kPa.

FiO2 (Fraction of inspired oxygen)
Record the appropriate value.

Subject been prescribed oxygen therapy
Record the appropriate value (*No; Yes).*

Oxygen treatment start date
Record a complete date in *YYYY-MON-DD* format (for example *2000-JAN-01*).

Oxygen treatment stop date
Record a complete date in *YYYY-MON-DD* format (for example *2000-JAN-01*).

Oxygen treatment prior to study start
Record '*Yes'* if appropriate.

Oxygen treatment continues
Record '*Yes'* if appropriate.

Method oxygen provided
Record the appropriate value (*Nasal cannula; Mask; Other).*

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15.1.89 CRS SIGNS AND SYMPTOMS (CRSSS)

This form will be triggered when the AE category of AE of special interest is selected for Cytokine Release Syndrome

All information specific to the event of CRS is captured on this page. Complete this CRF to enter the individual signs and symptoms of CRS. CRS signs or symptoms entered on this CRF should not be entered on the AE CRF.

Record the severity using the CTCAE version 5.0 grading criteria. Enter grade changes (both increases and decreases) in separate loglines. If the event continues over several days, report all grade changes for CRS signs and symptoms and ensure the appropriate supporting assessment has been entered (i.e. lab assessments, vital signs, concomitant medications, etc.). If there is symptom that no longer meets the CRS criteria, please report it on the AE CRF if the symptom is reportable or report the new diagnosis as appropriate.

AE No.
This is auto populated from AE page.

Adverse Event
This is auto populated from the AE form.

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
Record each sign and symptom in a separate log line. Provide a clear, concise description of signs and symptoms of CRS. Include qualifying text to enhance the medical meaning (anatomic site; increased *vs*. decreased; etiology/cause of event). Do not use abbreviations or acronyms.

CTCAE grade
Record the severity according to NCI CTCAE grades *(Grade 1 Mild AE; Grade 2 Moderate AE; Grade 3 Severe AE; Grade 4 Life-threatening or disabling AE; Grade 5 Death related to AE).*

Sign/symptom start date
Record the start date of the sign or symptom. If a grade changes record a date of change in a new log-line. This is considered as an ‘on-study date’. Complete date is required in *YYYY-MON-DD* format *(for example 2001-JAN-01).*

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Sign/symptom end date
Record the date the signs and symptoms resolved. Complete date is required in *YYYY-MON-DD* format *(for example 2001-JAN-01).*

NOTE:
If the CRS AE resolves and a CRS symptom is ongoing but no longer determined to be a symptom of CRS following CRS resolution, the last date of when the event was a symptom of CRS should be recorded as the end date of the symptom. The ongoing symptom should then be recorded as a new separate event on the Adverse Events CRF, with the last date of when the event was a symptom of CRS recorded as the start date of the AE.

Sign/symptom ongoing
If a sign/symptom is ongoing at the time of end of study, record '*Yes*' and leave the **Sign/symptom end date** blank.

Description of Cytokine Release Syndrome
Record the appropriate details of what occurred during the event.
Description includes symptoms, course, results diagnostic investigations (ECG, Laboratory tests, X-ray etc.), treatment of ICANS (medication, surgical procedure etc.) and other comments – add any additional information related to the ICANS. Ensure the description doesn't exceed 1999 characters.

Were any medication given prior to study drug infusion for prophylaxis of CRS?
Record the appropriate option *(No; Yes).*

If Yes, enter the information on Prior and Concomitant Medication (CM) page.

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15.1.90 CRS ASTCT CRITERIA (CRASTCT)

This form will be triggered when the AE category of AESI is selected for Cytokine Release Syndrome

All information specific to the ASTCT criteria for CRS is captured on this page.
This page is Log form, please enter the grade changes as they occur in different log lines until event resolution. ASTCT criteria for CRS entered on this CRF should not be entered on the AE CRF but on the CRS signs and symptoms page

AE No.
This is pre-populated from the AE form.

Adverse Event
This is pre-populated from the AE form.

ASTCT CRS Criteria Version
This field is pre-defined in the CRF and is not editable.

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
Record the appropriate option *(<38.0C (100.4F); 38.0-39.0C (100.4-102.2F); >39.0-40.0C (102.3-104.0F); >40C (>104.0F) for =<24 hours; >40C (>104.0F) for >24 hours).*

Hypotension
Record the appropriate option *(None; Not requiring vasopressor; Requiring vasopressor with or without vasopressin; Requiring multiple vasopressors (excluding vasopressin)).*

Hypoxia
Record the appropriate option *(None; Requiring low flow nasal cannula or blow-by; Requiring high flow nasal cannula, facemask, non-rebreather mask or venturi mask; Requiring positive pressure (e.g. CPAP, BiPAP); Requiring intubation & mechanical ventilation).*

ASTCT CRS grade
Record the appropriate option *(Grade 1; Grade 2; Grade 3; Grade 4; Grade 5).*

Start date
Record the start date of the ASTCT CRS Grade. If a grade changes record a date of change in a new log-line. This is considered as an ‘on-study date’; provide complete date. Record the appropriate date in YYYY-MON-DD format (for example 2001-JAN-01).

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End date

Enter the date the ASTCT CRS Grade ended. Record the appropriate date in *YYYY-MON-DD* format *(for example 2001-JAN-01).*

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15.1.91 INFUSION RELATED REACTION TQS (IRRTQS)

AE No.
This is pre-populated from the AE form.

Adverse Event
This is pre-populated from the AE form.

AE of special interest
This is pre-populated from the AE form.

Provide formulation if applicable
Suspect drug name ± additives / excipients (trade name)
Record the appropriate details of data.

Timing between suspect drug administration and AE onset (hours/minutes)
Record the appropriate details of data.

Was premedication given?
Record the appropriate option *(No; Yes).*

Acetaminophen
Record the appropriate option *(No; Yes).*

Antihistamines
Record the appropriate option *(No; Yes).*

Glucocorticoids
Record the appropriate option *(No; Yes).*

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

Skin signs / symptoms:

Maculopapular rash
Record the appropriate option *(No; Yes).*

Hives/urticaria
Record the appropriate option *(No; Yes).*

Macular rash

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Record the appropriate option *(No; Yes).*

Papular rash
Record the appropriate option *(No; Yes).*

Vesicular rash
Record the appropriate option *(No; Yes).*

Skin exfoliation
Record the appropriate option *(No; Yes).*

Vasculitic rash
Record the appropriate option *(No; Yes).*

Eczematoid rash
Record the appropriate option *(No; Yes).*

Bullous lesions
Record the appropriate option *(No; Yes).*

Acute generalized exanthemous pustulosis (AGEP)
Record the appropriate option *(No; Yes).*

Only pruritus
Record the appropriate option *(No; Yes).*

Angioedema
Record the appropriate option *(No; Yes).*

Respiratory symptoms:

Cough
Record the appropriate option *(No; Yes).*

Dyspnea
Record the appropriate option *(No; Yes).*

Bronchospasm/wheezing
Record the appropriate option *(No; Yes).*

Sensation of throat tightening or closing/dysphonia/change in voice quality
Record the appropriate option *(No; Yes).*

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Hyperventilation
Record the appropriate option *(No; Yes).*

Cardiovascular signs/symptoms:

Palpitations/tachycardia
Record the appropriate option *(No; Yes).*

Hypotension
Record the appropriate option *(No; Yes).*

Chest discomfort/tightness/pain
Record the appropriate option *(No; Yes).*

Arrythmia
Record the appropriate option *(No; Yes).*

Gastrointestinal symptoms:

Nausea
Record the appropriate option *(No; Yes).*

Vomiting
Record the appropriate option *(No; Yes).*

Diarrhea
Record the appropriate option *(No; Yes).*

Abdominal pain/GI cramps
Record the appropriate option *(No; Yes).*

Dysphagia (difficulty of swallowing)
Record the appropriate option *(No; Yes).*

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

Fear / panic reaction
Record the appropriate option *(No; Yes).*

Other associated signs/symptoms :

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Fever
Record the appropriate option *(No; Yes).*

Flushing
Record the appropriate option *(No; Yes).*

Erythema
Record the appropriate option *(No; Yes).*

Headache
Record the appropriate option *(No; Yes).*

Chills / rigors (shivering)
Record the appropriate option *(No; Yes).*

Cold, clammy sensation/extremities
Record the appropriate option *(No; Yes).*

Injection site pain, burn, extravasation
Record the appropriate option *(No; Yes).*

Paresthesia (abnormal sensation)
Record the appropriate option *(No; Yes).*

Lightheadedness
Record the appropriate option *(No; Yes).*

Edema
Record the appropriate option *(No; Yes).*

Back pain
Record the appropriate option *(No; Yes).*

Arthralgia/myalgia (joint/muscle pain)
Record the appropriate option *(No; Yes).*

Pre-syncope/dizziness
Record the appropriate option *(No; Yes).*

Syncope
Record the appropriate option *(No; Yes).*

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Blurred vision
Record the appropriate option *(No; Yes).*

Seizure / convulsions
Record the appropriate option *(No; Yes).*

Cardiac arrest
Record the appropriate option *(No; Yes).*

Other
Record the appropriate option *(No; Yes).*

Other, specify
Record the appropriate details of data.

Was non-drug treatment given for management of the adverse event?
Record the appropriate option *(No; Yes).*

Infusion speed reduction
Record the appropriate option *(No; Yes).*

Supine positioning
Record the appropriate option *(No; Yes).*

Cardiopulmonary resuscitation (CPR)
Record the appropriate option *(No; Yes).*

Oxygen therapy
Record the appropriate option *(No; Yes).*

Airway management (bag-mask ventilation, etc.)
Record the appropriate option *(No; Yes).*

Was treatment given in consultation with a specialist?
Record the appropriate option *(No; Yes).*

Specialist consulted for treatment, specify
Record the appropriate details of data.

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

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Specialist concluding interpretation

Record the appropriate option *(Type 1 reaction (ige mediated; anaphylactic response); Type II reaction (cytotoxic-mediated); Type III reaction (immune complex-mediated); Type IV reaction (cell-mediated, late- or delayed-type reaction); Pseudoallergic reaction; Pharmacological reaction; Psychophysiological reaction; Other).*

Specialist concluding interpretation, specify

Record the appropriate details of data.

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15.1.92 HOSPITAL ADMISSIONS DETAILS (HOSPAD)

This module should be completed whenever the Subject has attended or been admitted into the hospital. The form should be filled in for each hospital admission, outpatient or emergency room attendance encountered.

To include this form when required, select it from the **ADD EVENT** menu.

Do not include routine follow up clinic visits.

Any hospital/ inpatient/ emergency room visit
Record 'Yes' or 'No' from the available option.

If 'Yes' is recorded, record the below details.

If 'No', leave rest of the fields blank.

Type of attendance
Record the appropriate option:

- Outpatient/physician office attendance;
- Planned hospital admission with no emergency room visit;
- Unplanned hospital admission with no emergency room visit;
- Emergency room attendance only (Patient was discharged direct from the emergency room);
- Emergency room attendance resulting in a hospital admission at the same time (Further hospital care outside the emergency room).

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NOTE: If 'Unplanned hospital admission with no emergency room visit' or 'Emergency room attendance resulting in a hospital admission at the same time (Further hospital care outside the emergency room)' are recorded, then ensure SAE module has been completed to capture the relevant and corresponding hospital information.

Start date of admission or attendance
Record the complete date of hospital admission. This should be in YYYY-MON-DD format (*for example 2000-JAN-01*).

Stop date of admission or attendance
Record the complete date of hospital discharge. This should be in YYYY-MON-DD format (*for example 2000-JAN-01*).

NOTE:

1. "Stop date of admission or attendance" needs to be recorded as soon as the Subject is discharged from hospital.

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2. If the Subject dies whilst in hospital, record the date of death.

3. If the Subject attends an outpatient/physician office or Emergency room only (without a hospitalization) or is hospitalized only during the day (i.e. a day case), record the same date as day of admission or attendance.

Admission or attendance continues
If Subject is still hospitalized, then record 'Yes' for this data point.

If this has been answered as 'Yes', then do not record the "Stop date of admission or attendance".

ICU/HDU stay during hospital admission
Record 'Yes' or 'No' from the available option.

If 'Yes' is recorded, record the "Start date of ICU/HDU stay", "End date of ICU/HDU stay" or "ICU/HDU stay continues".

If 'No', leave these fields blank.

Start date of ICU/HDU stay
Record the complete date of admission. This should be in YYYY-MON-DD format (*for example 2000-JAN-01*).

End date of ICU/HDU stay
Record the complete date of discharge. This should be in YYYY-MON-DD format (*for example 2000-JAN-01*).

ICU/HDU stay continues
If Subject is still in ICU or HDU then record 'Yes' for data point.

If this has been answered as 'Yes', then do not record the "Stop date of admission or attendance".

Primary symptom for hospital /inpatient/ emergency room visit
Record one option as the main sign or symptom *(Pain; Fatigue; Difficulties breathing/short of breath; Vomiting (with or without nausea); Nausea; Diarrhea; Constipation; Weight loss; Swelling; Fever; Headache/migraines; Numbness/tingling; Depression/mood change; Dehydration; Bone fracture; Coughing (no blood); Coughing up blood; Difficulties swallowing; Rectal discomfort; Poor bladder control; Hot flushes; Breast swollen; Breast area skin issues; Stomach or abdominal cramps/pain; Stomach or abdominal bloating/swelling; Difficulty in eating/feeling full quickly; Increased urinary frequency or*

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urgency; Jaundice; Eye pain/irritation; Loss of light perception; Rash; Hair loss; Other (disease related); Other (non disease related)).

If the sign or symptom is not on the list provided, use values 'Other (Disease related)' or 'Other (Non disease related)'.

If Other, specify
If 'Other (Disease related)' or 'Other (Non disease related)' is recorded, then specify the sign or symptom as free text in the specification field provided.

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15.1.93 DEVICE EVENTS LOG (DELOG)

Were any Device Events reported during Mandatory screening tumor sample (SPCBEDT1) collection?

Indicate if the Subject experienced any device events. Record the appropriate option *(No; Yes).*

If '*Yes*', the DE (Device Events) eCRF for recording appropriate event details is triggered.

Note: Complete this form only for events observed during Mandatory Tumor Sample collection at Screening visit (SPCBEDT1).

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15.1.94 DEVICE EVENTS (DE)

Important note: *The Device Events Module should be completed first to access drop down fields that will be present in the Adverse Events Module. The linking of the two modules is done through the Adverse Events Module. Please complete SERAE form if SAE is observed with association of the Device Event.*

Note: Report this form if any related events (AE related to biopsy, False positive PD-L1 results, False negative PD-L1 results, or Other events) observed during mandatory tumor sample collection process (sample collection is reported on Mandatory screening tumor sample (SPCBEDT1) form).

Relationship to Subject
Defaulted to Study participant

Associated Person's Identifier
Update as appropriate

Category of Device Event
Record the appropriate option *(Procedure; In-vitro device deficiency; Device deficiency).*

It is acceptable to choose '*Procedure'* and either '*In-vitro device deficiency'* or '*Device deficiency*' at the same time if the event is applicable to both.

*'**Procedure'*** - any activity relating to the use of an *in-vitro* diagnostic device procedure (the mandatory tumor sample collection at Screening Visit).

*'**In-vitro device deficiency'*** – a deficiency associated with an *in-vitro* diagnostic device.

'Device deficiency' – a deficiency associated with a medical device or a device constituent part of a combination product.

Device Event number
This will be generated automatically. Each Device Event number is patient specific and will be generated per event in sequential fashion, i.e. Event 1, Event 2.

Standardized Device Event
Record the appropriate anticipated Event term from the dropdown (AE related to biopsy; False positive (PD-L1); False negative (PD-L1) ; '*Other*' if none applies.)

If other, specify Device Event

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Device Event (Reported Term for Device Event)
This is the reported term for the device event if the **Standardized Device Event selected was '***Other*'. Record the verbatim name of the observed event. Examples may include: "*Screw Breakage*", "*Fissure Formation*", "*Battery Issue*".

Description of Device Event (DE Description)
Include only device event related information and remember to keep chronological order. Avoid duplicating non-relevant details recorded in eCRF fields (e.g., Serious adverse event, 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, if applicable
- How the product was used, if applicable
- 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 **Prior and Concomitant Medication** (CM) form.; including new medications and any changes in treatment due to the event.

Technical NOTE:

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;

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- do not use bullet points, hyphens etc.;
- do not use abbreviations/acronyms difficult to define;

Device Event expected/unexpected
Record the appropriate option *(Expected; Unexpected (unanticipated)).*
'*Expected*' - event specified in the Dx IB provided for the product (Product label, instructions for use, etc.).

Device Event start date
Record the start date of the device event in *YYYY-MON-DD* format *(for example 2001-JAN-01).*

Device Event end date
Record the end date of the device event in *YYYY-MON-DD* format *(for example 2001-JAN-01).*

Any Adverse Event caused by this Device Event?
Indicate if the Subject experienced any Adverse Event related to this device event. Record the appropriate option (*No*; *Yes*).

If '*Yes*', the AE eCRF should be completed to record appropriate event details and ensure linkage to the Device Events module.

Serious Device Event
Assess if the device event should be classified as "serious" as defined in the study protocol. Record the appropriate option *(No; Yes).*

If 'No', could the event have led to an SAE? (Potential Seriousness)
Where no SAE has occurred, could an SAE have occurred if suitable action had not been taken, if intervention had not been made, or if the circumstances had been less fortunate? Record the appropriate option *(No; Yes).*

Outcome of Device Event
Record the appropriate outcome of the device event in relation to the Subject's status *(Recovered/resolved; Recovered/resolved with sequelae; Not recovered/not resolved; Fatal).*

Relationship to Device
Record the appropriate relationship to device *(Not related; Possible; Probable; Causal).*

Relationship to procedure associated with the Use of the Device
Record the appropriate relationship to procedure associated with the use of the device *(Not related; Possible; Probable; Causal).*

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Procedure name
Record the procedure name if **Category of Device Event** is '*Procedure*'.

Device trade/brand name
Record the device trade/brand name.

Device Identifier
Record the device's serial number. Include the device information even if the event was "Related to Procedure", if available

Current device location (Reported Term for the Tracking Event)
Record what is the current location of the device *(Implanted; Explanted; Returned; Installed; Retained; Discarded; Unknown; Other).*

If Other, specify
Record the appropriate details if **Current device location** is recorded as *'Other'.*

Action taken date
Record the date the action was taken in *YYYY-MON-DD* format *(for example 2001-JAN-01)* related to **Current device location** (applicable for *'Implanted' and 'Explanted' options*).

Party responsible for the Device
Defaulted as *Manufacturer*.

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15.1.95 LIVER DIAGNOSTIC INVESTIGATIONS (LIVERDI)

What is the category of the liver event?
Prespecified as **POTENTIAL HY'S LAW.**

What is the subcategory of the liver event?
Prespecified as **DIAGNOSTIC INVESTIGATION.**

What is the potential Hy's law case number?
Record potential Hy's Law case number.

The first potential Hy's law case for this patient should be numbered '1'. Any recurrent potential Hy's law case for this patient should be numbered in consecutive order.

Please note that each distinct Potential Hy's Law episode per Subject is to be tracked by the Potential Hy's Law case number. Enter the same case number for that Potential Hy's Law case on all 3 of the liver forms (LIVERDI, LIVERSS and LIVERRF).

AE number
Select appropriate AE number from the search list populated from the AE form.

If the potential Hy's Law criteria are met, Serious AE must be reported using AE verbatim "Potential Hy's Law case", related to IMP (causality assessment: Yes) and seriousness criteria 'Important medical event' selected on SERAE page, according to the protocol process for SAE reporting.

If there is alternative explanation for the ALT or AST and TBL elevations which is an AE/SAE: update the previously submitted Potential Hy's Law SAE and AE eCRFs accordingly with the new information (reassessing event term, causality and seriousness criteria) following the AstraZeneca standard processes.

If the alternative explanation is not an AE, record the alternative explanation on the **Liver diagnostic investigation specification** and **Liver diagnostic investigation results** data fields for the *Specialist (e.g. hepatologist) consulted logline* (Please refer to the screenshot as below). Please refer to Study Protocol Appendix E for Actions Required in cases of Increases in liver Biochemistry and Evaluation of Hy's Law.

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What is the category of the liver event?	POTENTIAL HY'S LAW
What is the subcategory of the liver event?	DIAGNOSTIC INVESTIGATION
What is the potential Hy's law case number?	1
AE number ? Data is required. Please complete. Opened To Site from System (2026 Jul 05) Not due to AE	

#	Liver diagnostic investigation	Examination(s) performed	Liver diagnostic investigation specification	Liver diagnostic investigation date	Liver diagnostic investigation results
1	Ultrasound	No		yyyy mon dd	
2	CT scan	No		yyyy mon dd	
3	MRI	No		yyyy mon dd	
4	Magnetic resonance cholangiopancreatography	Yes		2026 Jan 20 yyyy mon dd	Cholestasis
5	Endoscopic retrograde cholangiopancreatography	No		yyyy mon dd	
6	Biopsy	No		yyyy mon dd	
7	X-ray	No		yyyy mon dd	
8	Tox screening for acetaminophen/paracetamol	No		yyyy mon dd	
9	Tox screening for ethanol	No		yyyy mon dd	
10	Tox screening, other	No		yyyy mon dd	
11	Specialist (e.g. hepatologist) consulted	No	The events are related to disease progression	yyyy mon dd	
12	Serology for hepatitis A	No		yyyy mon dd	
13	Serology for hepatitis B	No		yyyy mon dd	
14	Serology for hepatitis C	No		yyyy mon dd	
15	Serology for hepatitis D	No		yyyy mon dd	

Liver diagnostic investigation
Indicate if Examination(s) has been performed By checking 'Yes' or 'No' *(Ultrasound; CT scan; MRI (Magnetic Resonance Imaging); Magnetic resonance cholangiopancreatography (MRCP); Endoscopic retrograde cholangiopancreatography (ERCP); 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
Record the appropriate option (*No; Yes*).

Liver diagnostic investigation specification
If serology for hepatitis A, B, C, D & E has been performed, specific test performed should be clarified in detail e.g. for Hepatitis A was it IgM antibodies or total or IgG, for Hepatitis B was it surface antigen, core antibodies or surface antibodies. If Autoimmune serology has been performed, specific test performed should be clarified in details e.g. Anti-mitochondrial antibodies (AMA), Anti-smooth muscle antibodies (SMA), Anti-nuclear antibodies (ANA).
Other: e.g. results from GGT, PT, INR, Immunoglobulins (electrophoresis), Ferritin and iron binding capacity (TIBC) Creatinine kinase, Alfa-1-antitrypsin, Ceruloplasmin, Carbonhydrate deficient transferrin (CDT) and Herpes simplex virus tests (any test included in standard lab panel should be deleted).

Specification should be entered if value for Liver Diagnostic Investigation is any of the below values:

- Tox Screening, Other
- Serology for hepatitis A
- Serology for hepatitis B
- Serology for hepatitis C

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- Serology for hepatitis D
- Serology for hepatitis E
- Serology for cytomegalovirus (CMV)
- Serology for Epstein Barr Virus (EBV)
- Autoimmune serology
- Other 1
- Other 2
- Other 3
- Other 4
- Other 5
- Other 6

Liver diagnostic investigation date
Record the date of Liver Diagnostic Investigation using *YYYY-MON-DD* format *(for example 2000-JAN-01)*. Every effort should be made to obtain the complete date.

Liver diagnostic investigation results
If assessment was performed, then Liver Diagnostic Investigation results should be entered.

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15.1.96 LIVER RISK FACTORS/LIFE STYLE EVENTS (LIVERRF)

What is the assessment date?
Record the date in *YYYY-MON-DD* format *(for example 01-JAN-2000)*.

What is the Potential Hy's Law case number?
Record the Potential Hy's Law case number.

The first Potential Hy's Law case for this patient should be numbered '1'. Any recurrent Potential Hy's Law case for this patient should be numbered in consecutive order.

Please note that each distinct Potential Hy's Law episode per Subject is to be tracked by the Potential Hy's Law case number. Enter the same case number for that Potential Hy's Law case on all 3 of the liver forms (LIVERRF, LIVERDI and LIVERSS).

AE number
Select appropriate AE number from populated search list.

If the potential Hy's Law criteria are met, Serious AE must be reported using AE verbatim "Potential Hy's Law case", related to IMP (causality assessment: Yes) and seriousness criteria 'Important medical event' selected on SERAE page, according to the protocol process for SAE reporting. If there is alternative explanation for the ALT or AST and TBL elevations which is an AE/SAE: update the previously submitted Potential Hy's Law SAE and AE eCRFs accordingly with the new information (reassessing event term, causality and seriousness criteria) following the AstraZeneca standard processes. If the alternative explanation is not an AE, record the alternative explanation on the Liver diagnostic investigation specification and Liver diagnostic investigation results data field for the Specialist (e.g. hepatologist) consulted logline.
Please refer to Study Protocol Appendix E for Actions Required in cases of Increases in liver Biochemistry and Evaluation of Hy's Law.

Liver risk factor
Record '*No'* or '*Yes'* to "**Liver risk factor occurrence***"* for each of the items in the list *(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 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).*

Investigator instructions:

Alcohol abuse - If 'Yes' the details giving an indication of the degree of abuse and whether the patient is/was an alcoholic should be provided.

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Increased alcohol consumption in the 4 weeks prior to reported event - If 'Yes' the details such as the amount of alcohol consumed and was it on a single occasion or persistent over several days should be provided. This is particularly relevant in the week before the event.

IV drug abuse - If 'Yes', frequency, duration, quantity and type should be provided.

Tattoo - If 'Yes', information on the location and if the Subject had jaundice or was sick after the procedure should be provided.

Acupuncture - If 'Yes', information on the location and if the Subject had jaundice or was sick after the procedure should be provided.

Sexually transmitted diseases - If 'Yes', diagnosis should be provided.

Toxic/Chemical agent exposure - If 'Yes', the toxic agent should be provided.

Travel (areas at risk in the last year) - If 'Yes', details of where and when should be provided.

Pregnancy - If 'Yes' and more than one pregnancy, number of pregnancies should be stated in 'Liver risk factor details' and start and stop dates of most recent pregnancy should be entered.

Parenteral nutrition - If 'Yes', details should be provided.

Excessive physical exercise - If 'Yes', details such as dates and whether the patient was accustomed to such levels of physical exercise should be provided.

Changes diet/fasting episodes/weight loss diet - If 'Yes', details including if the patient has eaten anything unusual should be provided.

Previous drug reaction (associated with an elevation of liver tests) - If 'Yes', details of drug should be provided.

Blood transfusion - All blood transfusions are relevant regardless of when they occurred, if the patient has received more than one transfusion use the ‘Other’ field to document additional transfusions’.

Patient exposed to anyone with jaundice in the 4 weeks - If 'Yes', indicate if there was a diagnosis associated with the jaundice and the dates when the patient was exposed.

History of hypotension - If 'Yes', relevant details such as a possible reason for the hypotension should be provided.

Low blood pressure at time of event of liver injury and/or abnormal liver laboratory value - If yes, the lowest BP reading should be recorded

History of liver disease - If yes, details should be provided).

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Details of any other possible predisposing factor to liver injury e.g. heat stroke, hypoxic injury or sepsis should be provided for the following: *Other 1, Other 2, Other 3, Other 4, Other 5, Other 6*.

Liver risk factor occurrence
Record the appropriate option (*No; Yes*).

Liver risk factor reference period (in reference to assessment date)
Record the appropriate option *(Before; Ongoing).*

If '*Ongoing'*, a start date but no stop date should be recorded. If '*Before'*, start and stop date should be recorded.

Liver risk factor details
Details of liver risk factor should be recorded.

Liver risk factor start date
Record the start date of the liver risk factor using *YYYY-MON-DD* format *(for example 01-JAN-2000)*. If exact start date is not known, record the year. Every effort should be made to obtain the complete date.

Liver risk factor stop date
Record the end date of the liver risk factor using *YYYY-MON-DD* format *(for example 01-JAN-2000)*. If exact stop date is not known, record the year. Every effort should be made to obtain the complete date.

Liver risk factor comment
Record any additional risk factor information.

If there is insufficient space in the "*Liver risk factor details*" field in the table, record additional information here.
Make sure all medication, including over the counter medication (especially flu/cold or pain relief) or herbal remedies, is recorded on CM.
Make sure all relevant medical history such as diabetes, obesity, hypertriglyceridemia and congestive heart failure is recorded on MH.

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15.1.97 LIVER SIGNS AND SYMPTOMS (LIVERSS)

What is the category of the clinical event?
Pre-specified as POTENTIAL HY'S LAW

AE number
Select appropriate AE number from populated search list.

If the potential Hy's Law criteria are met, Serious AE must be reported using AE verbatim "Potential Hy's Law case", related to IMP (causality assessment: Yes) and seriousness criteria 'Important medical event' selected on SERAE page, according to the protocol process for SAE reporting. If there is alternative explanation for the ALT or AST and TBL elevations which is an AE/SAE: update the previously submitted Potential Hy's Law SAE and AE eCRFs accordingly with the new information (reassessing event term, causality and seriousness criteria) following the AstraZeneca standard processes.If the alternative explanation is not an AE, record the alternative explanation on the Liver diagnostic investigation specification and Liver diagnostic investigation results
data field for the Specialist (e.g. hepatologist) consulted logline.
Please refer to Study Protocol Appendix E for Actions Required in cases of Increases in liver Biochemistry and Evaluation of Hy's Law.

What is the Potential Hy's Law case number?
Record the Potential Hy's Law case number.

The first Potential Hy's Law case for this patient should be numbered '1'. Any recurrent Potential Hy's Law case for this patient should be numbered in consecutive order.

If Subject has one of the symptoms listed but you do not believe it is related to liver injury it should still be captured as '*Yes*'.

Please note that each distinct Potential Hy's Law episode per Subject is to be tracked by the Potential Hy's Law case number. Enter the same case number for that Potential Hy's Law case on all 3 of the liver forms (LIVERSS, LIVERRF and LIVERDI).

Sign or symptom
Indicate if sign/symptom has occurred/is occurring by checking 'Yes' or 'No' in **Sign or symptom occurrence** *(Anorexia; Asthenia; Pyrexia; Pruritus; Jaundice; Arthralgia; Abdominal pain; Abdominal tenderness; Nausea; Vomiting; Rash; Mucosal inflammation; Purpura; Hepatomegaly; Splenomegal; Lymphadenopathy; Ascites; Confusional state; Coma; Upper Quadrant tenderness; Biliary obstruction; Eosinophilia; Dark urine; Other 1; Other 2)*.

Sign or symptom occurrence
Indicate if sign/symptom has occurred/is occurring by checking '*Yes*' or '*No*'.
Signs/symptoms should only be recorded as '*Yes*' if they are present and have not been reported as an AE e.g. the sign/symptom is present but not considered an AE or the

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sign/symptom is part of a wider diagnosis and only the diagnosis has been reported as an AE (Subject has an AE of hepatitis with symptoms of jaundice and nausea, jaundice and nausea should be captured on this form as signs and symptoms and hepatitis should be reported as an AE).
A sign/symptom should not be selected as '*Yes*' on this form and reported as an AE.
If eosinophilia is captured as '*Yes*', provide laboratory data with reference ranges.

Start date
Record the start date of the liver sign/symptom using *YYYY-MON-DD* format (for example *2000-JAN-01*). Every effort should be made to obtain complete date.

Ongoing
Indicate if the **Sign or Symptom** has not resolved at the time of data collection. If ongoing leave the **Stop date** blank.

Stop date
Record the end date of the liver sign/symptom using *YYYY-MON-DD* format (for example *2000-JAN-01*). Every effort should be made to obtain complete date. If the liver sign/symptom is ongoing, leave the field blank.

Intermittent
Record if the Subject has repeated episodes of the symptom or sign or it can be described as 'intermittent' (*No; Yes*).

Liver sign/symptom specification
Record the appropriate data.

Liver sign/symptom test
Record the appropriate data.

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15.1.98 MEDICATION ERROR REPORT (MER)

To include this form when required, select it from the ADD EVENT menu.

Medication Error is an unintended failure or mistake in the treatment process for an AZ study drug that either causes harm to the patient or has the potential to cause harm to the patient. A medication error is not lack of efficacy of the drug, but rather a human or process related failure while the drug is in control of the study site staff or subject. Medication error includes situations where an error:

- occurred
- was identified and intercepted before the subject received the drug
- did not, but circumstances were recognized that could have led to an error

Examples of events **to be** reported in clinical studies as medication errors:

- Drug name confusion
- Dispensing error e.g., medication prepared incorrectly, even if it was not actually, given to the subject
- Drug not administered as indicated, for example, wrong route or wrong site of administration
- Drug not taken as indicated e.g., tablet dissolved in water when it should be taken as a solid tablet
- Drug not stored as instructed e.g., kept in the fridge when it should be at room temperature
- Wrong subject received the medication (excluding IVRS/IWRS errors)
- Wrong drug administered to subject (excluding IVRS/IWRS errors)

Examples of events that **do not** require reporting as medication errors in clinical studies:

- Errors related to or resulting from IVRS/IWRS - including those which lead to one of the above listed events that would otherwise have been a medication error
- Subject accidentally missed drug dose(s) e.g., forgot to take medication
- Accidental overdose (will be captured as an overdose)
- Subject failed to return unused medication or empty packaging
- Errors related to background and rescue medication, or standard of care medication in open label studies, even if an AZ product
- Temperature excursions - should only be considered as a ME if it was a result from a misunderstanding from the site regarding study drug storage conditions

Medication errors are not regarded as AEs, but AEs may occur as a consequence of the medication error. All medication errors from clinical studies on AZ IMPs must be reported from phase II (inclusive), that is those associated with no AEs, non-serious AEs or SAEs.

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Medication Error need to be reported within 24 hours from awareness date.

IMP and/or suspect device associated with Medication Error

Enter only for AZ IMP that was associated with occurrence of Medication error *(IMP)*

For studies that use several IMP, capture of IMP which was associated with ME should be done in Description of error occurrence without disclosing the real treatment if study is DB study.

Date of medication error

Enter a complete date in *YYYY-MON-DD (for example 2000-Jan-01)* format.

Medication error occurrence

Select the appropriate option:

- **Actual error** - if yes, please complete *"Description of error occurrence, action taken"*
- **Intercepted error** – select, if the error was identified and caught before the patient received the drug and please complete *"Description of error occurrence, action taken"*
- **Potential error** – select, if an error was not made but you recognize circumstances that could lead to a medication error and please complete *"Description of potential error and possible harm"*

At what stage in the patients' drug treatment did/may the actual/intercepted/potential error occur?

Stage of error occur (storage)

Select the appropriate option (*No; Yes*).

Stage of error occur (dispensing)

Select the appropriate option (*No; Yes*).

Stage of error occur (preparation for administration)

Select the appropriate option (*No; Yes*).

Stage of error occur (administration)

Select the appropriate option (*No; Yes*).

Please select one of the below options

AE on medication error

Select the appropriate option (*Medication error without any associated AE; Medication error with non-serious AE; Medication error with SAE*).

Please fill in the AE description in the table below (and fill in the SAE module or SAE form as applicable)

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AE number
Select from populated list.

Adverse Event
Select from populated list.

Error associated to product defect
Select the appropriate option (*No; Yes*).

NOTE: Example: Defect – IP affected by temperature excursions at site. Temperature excursions at the site should only be considered as a Medication Error if it was a result from a misunderstanding from the site regarding study drug storage conditions. Ex: the medication should be kept at room temperature and the site kept the medication in a refrigerator. Other common temperature excursion should not be reported as medication error.

Error associated to product defect, specify
Enter the description of product defect if yes

Description of error occurrence, action taken
Capture of IMP associated with ME is expected to be updated in this field.
Please describe how the actual/intercepted error occurred, actions taken and any contributing factors that lead to the error.

Description of potential error and possible harm
Please provide description of the circumstances around any potential error and possible harm to the patient if they had received the IMP

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15.1.99 OVERDOSE REPORT (OVERDOSE)

All pertinent information must be obtained, and OVERDOSE must be completed with all available information. Inform the AstraZeneca representative immediately, no later than 24 hours.
For overdoses associated with an SAE the standard reporting timelines for SAEs apply, for overdoses with no associated SAEs reporting should be within 30 days.

To include this form when required, select it from the **ADD EVENT** menu.

Study drug
Select the name of study drug *(Rilvegostomig; Durvalumab; Gemcitabine ;Cisplatin).*

Route
Pre-specified as *Intravenous.*

Total dose
Record the total dose or amount of study treatment that was administered to the Subject in the period recorded; from the start date to the end date inclusive. If exact information is not known, record the estimated dose.

Unit
Select the unit of overdose taken per period recorded (*mg; mg/m2*).

Date overdose started
Record the date of first overdose in *YYYY-MON-DD* format (*for example 2000-JAN-01*). If exact information is not known, record the estimated date.

Date overdose stopped
Record the date of last overdose in *YYYY-MON-DD* format (*for example 2000-JAN-01*). If exact information is not known, record the estimated date.

Intentional overdose
Indicate whether the overdose was a result of an intentional or un-intentional intake.
Must be answered No or Yes.

Overdose associated with AE
Indicate whether the overdose was associated with any Adverse event.
Must be answered *No* or *Yes*.
NB: If '*Yes*' (the overdose was associated with Adverse event) fill in Adverse Event form and Serious Adverse Event form, if applicable.

AE number associated with overdose
Record Adverse Event number from AE.

AE number associated with overdose
Record Adverse Event number from AE.

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CRF text for AE associated with overdose
This field to be auto populated from ODAENO1 (on OVERDOSE) which is derived from corresponding AENO and AETERM (on AE)

Further Information (for non SAE)

Add any additional medically relevant information regarding the overdose event (cause/reason, any treatment received and action taken).

If the overdose of a medication was an intake during consecutive days, the daily dose should be specified if known.

If other medication(s) than the randomized treatment also has been taken as overdose include as much information as possible about the other medication(s) e.g. drug name/dose taken.

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15.1.100 CONTACT (CONTACT)

This form collects Information about contacts with subjects *outside* the clinical site.

To include this form when required, select it from the **ADD EVENT** menu.

Was any contact made?
Record the appropriate option (No; Yes).

If 'No', specify reason
If 'No' has been recorded for "Was any contact made?" then specify the reason.

If 'Yes', specify below
This will be present as default in RAVE. If "Was any contact made?" is 'Yes' then record the appropriate details below.

What was the contact date?
Record the date when Subject was contacted in YYYY-MON-DD format (for example 2000-JAN-01).

Who was the contact respondent?
Record the appropriate option (Study subject; Caregiver).

What was the type of contact?
Record the appropriate option (Telephone; Home visit; Letter; e-mail; Other).

If 'Other', specify
If "What was the type of contact?" was 'Other' then specify.

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15.1.101 SECOND TIME OF PROGRESSION (PFS2)

This form is located in *Survival follow-up* folder and available to be added through *ADD EVENT.*

- The PFS2 form is expected to be completed until progression event has occurred after start of subsequent therapy that is started not earlier than after first progression.
- In case of there is no first-time progression observed by RECIST 1.1 tumor assessments, please *inactivate* the form in *Survival follow-up* folder.
- If the event occurs outside of a Survival Follow-up visit, use the *ADD EVENT* menu to add this form and report data.

Assessment performed
Record the appropriate option (No; Yes).
Please note if the reason assessment is not performed is due to the Subject's death, then record the Date of death on the DEATH form.

Date of scan/assessment for second progression
Record the date of last CT/MRI scan or other assessment to diagnose the progression in YYYY-MON-DD format (for example 2000-JAN-01).

Investigator assessment of Subject's response
Record the appropriate option (Progressive disease; Non progressive disease; Not evaluable).

Note: Not evaluable is applicable if patient status was not assessed or not evaluable in the follow-up assessments.

If progression, specify the type of progression
Record the primary type or method used to assess progression (Symptomatic progression; Objective radiological progression; Other).

If Other, specify
If 'Other' is recorded for If progression, specify the type of progression, specify the progression type details.

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15.1.102 PARTICIPANT FOLLOW UP CHECKLIST (PFU)

This form is used to capture data recorded on the site Participant Follow Up checklist.

Checklist to be used if a participant who has discontinued all study treatment/s decides to either:

- modify the follow-up visit schedule specified in the clinical study protocol (CSP);

or

- change the previously agreed method of follow-up.

This checklist is only be added into EDC when a participant has decided to modify visit schedule.

To include this form when required, select it from the **ADD EVENT** menu.

PFU module can be added at any time when the subject changes the level of follow-up options during the study. To add more than one record, please select 'Add a new Log line':



Has the drug been permanently discontinued?
Record the appropriate option (No; Yes).

Patient follow up options
Select the appropriate option:

- Agrees to continue according to the current CSP visit plan/schedule;
- Agrees to continue in the study with a modified visit plan;
- Agrees to continue in the study but will not come to the site for visits but can be contacted by phone according to CSP visit plan;
- Agrees to come to the site at the end of the study (or at time of data analysis) but does not want to be contacted or come to the site until then;
- Agrees to be contacted by phone at the end of the study (or at time of data analysis) but does not want to be contacted or come to the site until then;
- Does not want to be contacted but agrees that personal and medical information about him or her can be collected from medical records;
- Agrees to be contacted by phone when needed but will not come to the site for visits;

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- Agrees for contact to be made with a treating physician or relative but will not come to the site for visits

NOTE: Please make sure that only one option is selected as a preliminary choice. In case of any change e.g. Subject changes his/her decision on Patient follow up options, new option to be added through add logline option along with new Decision date and Decision time (if applicable). Previous Patient follow up options records will remain as were originally collected.

Patient follow up option selection
Record 'Yes' for the follow up option selected by the subject.

Decision date
Record a complete date in *YYYY-MON-DD* format (for example 2000-JAN-01) for the selected Patient follow up options recorded is yes.

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15.1.103 SURVIVAL STATUS (SURVIVE)

Every effort should be made to establish the survival status of the Subject by contacting the Subject directly, contacting the Subject's family, contacting the Subject's current physician/ general practitioner or checking publicly available death registries.
At least one date (Date Subject confirmed to be alive, or Date of the latest unsuccessful contact attempt) must be entered in the eCRF for every logline.
If at the time of survival follow-up, the Subject has died, please only complete the death details on the death module, we do not expect a Date Subject confirmed to be alive, nor a Date of latest unsuccessful contact attempt.

SURVIVE module is available in below folders:

- **End of Treatment**
- **Post-treatment 90 Days Safety follow-up**
- **Survival Status:** This folder can be added as an ADD EVENT at any time during the study to document the subject's status when a change occurs or when reporting is required by the sponsor. This folder can be added multiple times via the ADD EVENT menu.

Date Subject confirmed to be alive
Record a complete date in YYYY-MMM-DD format (for example 2000-JAN-01).
Provide the most recent date when the Subject was known to be alive.

Date of the latest unsuccessful contact attempt
Record a complete date in YYYY-MMM-DD format (for example 2000-JAN-01).
Please enter the date when the Investigator tried to contact Subject unsuccessfully.

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15.1.104 REVIEW OF PRO/QUESTIONNAIRE/DIARY (REVPRDI)

This form is required to be completed in the event that any protocol required questionnaires is missed during a visit, including instances where only a single questionnaire is not completed.

To include this form when required, select it from the **ADD EVENT** menu.

Questionnaire name
Automatically defaulted as REVIEW OF PRO/QUESTIONNAIRE/DIARY.

Reason Subject did *not* complete questionnaire
If Subject did *not* respond to their questionnaire(s) at a scheduled time point, the "Reason Subject did not complete questionnaire" must be completed and the reason also documented in the source.

Record an appropriate option:

- **Unwilling** (used only after training the patient and explaining the importance of completing PROs)
- **Cannot understand instructions** (if Subject cannot understand the instructions, it is important to retrain the patient)
- **Technical problems with device** (it is important to immediately contact the vendor to remedy any technical problems)
- **Too sick, other than disease under investigation**
- **Cannot use device due to physical limitations** (including forgot glasses at home when questionnaire(s) are administered at site or if the Subject is blind)
- **Too affected by symptoms of disease under investigation** (including comorbidities)
- **Relevant language version not available**
- **Administrative failure distribute questionnaire to Subject** (Forgot to administer to patient)
- **Illiterate**
- **Patient forgot**
- **Unsolvable patient device training issues** (used only if the patient was thoroughly trained on how to use the device, but the Subject still expresses they can't complete the PROs due to not being able to use electronic devices)
- **Other**

If 'Other' recorded, specify in the text box labelled "**If Other, specify".**

Note: It is required that the site review compliance with the Subject at each visit and if there is no response to the questionnaire(s) at any scheduled time point, the reason Subject did not complete questionnaire is to be completed.

Questionnaire Expected Completion Date
A complete date when the questionnaire(s) was scheduled to be completed by the Subject (respondent) must be recorded using *YYYY-MON-DD* format (for example 2000-JAN-01).

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15.1.105 WITHDRAWAL OF INFORMED CONSENT (CONSWD)

This page is used to record data related to the withdrawal of **Informed Consent.**

To include this form when required, select it from the **ADD EVENT** menu.

Consent withdrawal category
This field will be pre-specified in eCRF

NB:
For consent withdrawal categories:

1. *Optional Blood Tests*
2. *Participation to Optional Biopsy at first day of Cycle 3 of study treatment*
3. *Participation to Optional Biopsy at Cancer Progression*
4. *Use of Optional Services and Transfer of Contact Details to Service Providers*
5. *Use of Coded Data (Including Images), Biosamples and Analysis of Genetic Information for Future Research*
6. *Optional Multi-omics Research and Analysis of Their Multi-omics Information, including Their Genetic Information*
7. *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.*
8. *Withdrawal from the Study and any Use of Already Collected Biosamples (Including Data and Biosamples for Future Research and Multi-omics if Applicable)*
9. *Patient Withdrew Informed Consent without Providing any Detailed Information*

Consent withdrawn
Record '*No*', '*Yes*' or '*Not applicable*' to indicate whether each category of consent was withdrawn:
'Yes' – if patient withdraws consent for this option,
'*No*' – if patient does not withdraw consent for this option,
'*Not applicable'* - if patient has not consented for this option on the main ICF.

Informed consent withdrawal date
Record the date of Consent Withdrawal as defined in the protocol using this format *YYYY-MON-DD* (*for example 2000-JAN-01*).

NB: If the withdrawal of consent includes a category related to the collection/use of a biological sample(s) covered in either the main or optional study consent, contact your AstraZeneca monitor to discuss. Depending on the scope of the Consent Withdrawal, there may be study samples at the site or at the central laboratories that will need to be destroyed.

Note: "Patient withdrew informed consent without providing any detailed information." This option means that in cases where a patient has withdrawn consent and where there is no documentation/documented evidence detailing whether or not consent has been withdrawn related to use of samples/data, the business decision is that samples will be used according to most recent signed

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consent form, unless there is a specific information in the Informed Consent or country legislation that would prevent this.

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15.1.106 DEATH DETAILS (DD)

If the cause of death is due to an adverse event, the details must also be reported on the Adverse Event Module and the SERAE module.
If cause of death is due to disease progression, this should **not** be reported as an AE/SAE.

What was the Subject's date of death?
Record the date in *YYYY-MON-DD* format (for example *2000-JAN-01*). All efforts should be made to obtain full date of death. The date of death must be obtained from a hospital record, death certificate or other acceptable death documentation.

If any part of the date is truly unknown, record UN/UNK for the unknown part of the date. Any additional clarification should then be provided in 'what was the cause of death narrative" for deaths other than due to AE.

Is death related to disease under investigation?
Record the appropriate option *(No, Yes)*.

Is death related to adverse event?
Record the appropriate option *(No, Yes)*.

If Yes, provide **What is the AE number?** corresponding to the Fatal AE

NOTE - Death due to AE: It is expected that only one Adverse Event has an outcome of 'Fatal' reflecting the primary cause of death. For any other events that are occurring, or ongoing, at the time of the fatality, AE Outcome field should reflect the outcome at the time of death.

Was the autopsy performed?
Record the appropriate option *(No, Yes, Unknown)*.

If an autopsy was performed, please supply a copy of the report to the Monitor and for deaths other than due to AE – provide any relevant additional information into '**What was the cause of death narrative?'.** Every effort should be done to retrieve information if an autopsy was performed or not. Unknown should only be used if this is truly not known.

Field to be completed only when death was NOT related to Fatal Adverse Event.

What was the cause of death narrative?
Provide the description of cause of death and any relevant supporting death-related details further clarifying the information reported in the fields above.
Note: Please avoid providing treatment revealing information in the narrative field. Thanks.

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Technical NOTE:

Make sure the description doesn't exceed 1999 characters due to technical reporting limitations and integration with Safety database. Do not copy paste any text to avoid disallowed characters.

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

Death detail assessment name Primary cause of death.

Primary cause of death *is the disease or injury that initiated the train of morbid events leading directly to death or the circumstances of the accident or violence that produced the injury.*
Record one primary cause of death. The text must be consistent with the death documentation (certificate) and with:

- AE term and information in AE description (free text field on SERAE form) - for fatal Adverse Events
- Information provided in the below 'What was the cause of death narrative' field- for deaths other than due to fatal AE

Death detail assessment name *Secondary cause of death*

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Secondary *cause of death* *is a contributory cause of death, a significant condition that unfavourably influences the course of the morbid process and thus contributes to the fatal outcome, but which is not related to the disease or condition directly causing death*.

Record one secondary cause of death. The text must be consistent with the death documentation (certificate) and with:

- information in AE description (free text field on SERAE form) - for fatal Adverse Events
- below 'What was the cause of death narrative' - for deaths other than due to fatal AE

NOTE: If there are cases of multiple secondary causes of death, enter the most probable. Provide all secondary causes into:

- AE description (free text field on SERAE form) - for fatal Adverse Events
- below 'What was the cause of death narrative" - for deaths other than due to AE

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15.1.107 DISPOSITION (DS)

Complete the study Disposition (DS) form for all enrolled Subjects.

This form **should NOT** be entered for Subjects who permanently discontinued the drug but will participate in follow-up assessments.

NOTE: this is the last form of the subject. If subject discontinued from study drug but still participating the follow up period, please do *NOT* complete this form.

What was the completion or discontinuation date?
Record the date of disposition event as defined in the protocol and/or CRF completion instructions using *YYYY-MON-DD* format (for example *2000-JAN-01*).
The date of study completion or premature withdrawal from study is the last day on which data, required according to the Clinical Study Protocol, was collected for this Subject.

In case of death, completion or discontinuation, the date of obtaining the information should be recorded on the relevant form, for example Contact (CONTACT) or Survival Status (SURVIVE)).

If the reason is Death or Completion, the date should be the reported as:

- **Death**: Record the date of death.
- **Completed**: Only when the patient is still on study at the time of the final analysis (end of study). The date should be recorded as the date of Survival Status (SURVIVE) during last survival sweep.

NB: This does not include follow-up visits for unresolved adverse events.
The date when the Subject completed/prematurely withdrew is not necessarily the same date as the date of last dose of investigational product as documented on the Exposure as Collected (EC) form.

What was the Subject's status?
Document the Subject's status. Subject’s status describes whether a Subject completed the study or the reason they did not complete. If the Subject discontinued prematurely, record the primary reason for discontinuation.
Record the appropriate option *(Site terminated by sponsor; Completed; Death; Lost to follow-up; Physician decision; Screen failure; Study terminated by sponsor; Withdrawal by Subject; Other*).

Important information regarding options Screen failure, Completed, Other, Lost to follow-up or Withdrawal by subject:

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- "**Screen failure"** should be used for Subjects who fail to meet one or more criteria before randomization.
- **"Screen failure**" is the potential Subject who does not meet one or more criteria required for participation in a trial.
- "**Completed"** is not to be used until end of the study (final analysis). Please use this option for patients who are still on study at the time of the final analysis (end of study).
- "**Lost to follow-up":** A participant will be considered lost to follow-up if the participant repeatedly fails to return for scheduled visits and no contact has been established by the time the **study is completed**, such that there is insufficient information to determine the participant's status at that time.
    - Participants who have been contacted, including telephone contact, and decline to continue participation in the study, should be documented as "withdrawal of consent" rather than "lost to follow-up.
    - For more definitions, please see CSP section 7.
- If the Subject's status is 'Other', provide the verbatim reason within the "**Status, specify"** text field.

Ensure that the appropriate corresponding forms have been completed as indicated according to CSP.

NB: If the Subject's status is "Death"
please make sure that appropriate corresponding forms have been completed.

Subject's status was related to a global/country situation
If the Subject's status was related to a global/country situation (i.e. epidemic/pandemic, healthcare crisis, natural disaster etc.) record 'Yes'. Otherwise leave the field blank.

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15.1.108 SUBJECT CONTINUATION (CONT)

Subject Continues to the Next Visit?
Select *Yes* or *No* as appropriate.

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15.1.109 INVESTIGATOR REVIEW (INVRE)

This form is used to document that investigator reviews study data on an ongoing basis.

Date(s) of ongoing eCRF review by investigator
Record the date in *YYYY-MON-DD* format (for example *2000-JAN-01*).

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.

NOTE: This form should be completed by the investigator/sub-investigator on a calendar **quarterly basis**, for enrolled/randomized study participants until study completion (not required for screen failures).

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15.1.110 UNSCHEDULED VISIT (UNS_VIS)

Refer to section 12.

Unscheduled data can only be added if specified in the Clinical Study Protocol (CSP).

Please choose the form(s) required for this unscheduled visit:

- Physical Examination (PE)
- Vital Signs (VS4)
- ECOG Performance Status (ECOG)
- ECG Test Results (EG)
- Additional ECG (EG1)
- Additional ECG (EG2)
- Echocardiography (ECHOC)
- Pregnancy Test (PREG1)
- Non-central Laboratory Test Results - Chemistry (LB)
- Non-central Laboratory Test Results - Hematology (LB1)
- Non-central Laboratory Test Results - Coagulation (LB2)
- Non-central Laboratory Test Results - Thyroid function test (LB3)
- Non-central Laboratory Test Results - Troponin and Creatine phosphokinase (LB4)
- Non-central Laboratory Test Results - CA-19-9 and CEA (serum)(LB5)
- Non-central Laboratory Test Results - Urinalysis (LB6)
- Non-central Laboratory Test Results - Hepatitis B and C testing (LB7)
- Non-central Laboratory Test Results - Hy's Law (LB8)

  NOTE: Please do not record duplicated results that already been reported in LB8 of Hy’s Law folder.

- Non-central Laboratory Test Results - Interstitial Lung Disease (LB9)
- Non-central Laboratory Test Results - Tuberculosis testing (LB10)

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- Non-central Laboratory Test Results - HIV testing (LB11)
- Non-central Laboratory Test Results - Additional Chemistry (LB12)
- Sample Collection, Predose_ADA Sample (SPCBEDB)*
- Blood sample for plasma Pre-Dose ctDNA (SPCBEDB1) **
- PBMC for immune profiling_Pre dose (SPCBEDB2) **
- Whole blood for RNA analysis_Pre-dose (SPCBEDB3) **
- Blood samples for Serum biomarker analysis Pre-Dose (SPCBEDB4) **
- Sample Collection, ADA Sample (SPCBEDB5)*
- Blood sample for plasma ctDNA (SPCBEDB6)
- Genomics Initiative (optional), exploratory genetic sample (SPCGB) ***
- Optional on study tumor sample (SPCBEDT) **
- Biological Sample Collection, PK (SPCPKB2)*

NOTE:

* PK/ ADA sample collection forms are available for Rilvegostomig arm ONLY;

** These sample collection forms are not available for sites in China or Brazil;

*** SPCGB form is not available for sites in China, Brazil, Taiwan, Denmark, Turkey, Belgium, Norway, Chile, The Netherlands.

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16 REVISION HISTORY

Version	Description of Change	Section
V1.0	Initial version	ALL
V2.0	GROUP: Updated label as "What was the group allocation?".	15.1.2
	EG/EG1/EG2: Added code No/Yes in the instruction.	15.1.26
	PREG/PREG1: Notes are added to be consistent with CRF labels.	15.1.28/29
	LB: Added HbA1c to clarify	15.1.31
	LB4: Corrected spelling for 'Sensitivity' in analyte names	15.1.35
	SPCBEDB2: updated default value of "Biofluid processed" as 'PBMC'.	15.1.47
	SPCBEDB1/SPCBEDB2/SPCBEDB3/SPCBEDB4/SPCBEDB5/SPCBEDB6/SPCBEDT/SPCBEDT1: Removed the incorrect note under "Sample collected".	15.1.46/47/48/49/50/51/52/53
	Note updated.	15.1.60
	4RECIST1: Added variable "Tumor laterality".	15.1.61
	RECIST2: Added label "New lesions', and variable "Criteria type". Removed duplicated text.	15.1.62
	EC3, EC1, EC2: Removed 'Home' from "Study drug administration/location impacted by global/country situation"; Corrected options for "Administration performed by - global/country situation".	15.1.65/66/67
	ETRT, ETRT3 :Corrected the label "What was the study treatment discontinuation date?"	15.1.68/69
	ETRT, ETRT3, ETRT1, ETRT2 Updated the notes to be consistent with CRF labels	15.1.68/69/70/71
	ETRT1/ETRT2: Corrected the label "Completion or reason for study treatment discontinuation".	15.1.70/71
	CAPRX/CAPRXR/CAPRX1: Updated label "Has cancer therapy been previous/current/post withdrawn of IP?"	15.1.72/73/74
	CAPRXR: NB note is updated.	15.1.73
	CM: Corrected label "Were any concomitant medications taken?"	15.1.77
	AESI: Added 'Eye' in the list for "Anatomical site (up to 5)"; Added additional instruction to "If Yes, specify the Medical/Surgical History number and text"	15.1.83

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Version	Description of Change	Section
	ILDIS: Added the first 3 variables to be consistent with CRF; Updated label "Other, specify" when Analytes/Test Method is selected as 'Other'.	15.1.87
	PFU: Updated label "Has the drug been permanently discontinued?".	15.1.102
	REVPRDI: Corrected label "Questionnaire Expected Completion Date"	15.1.104
	DD: Label "Is death related to adverse event?" is corrected to be consistent with CRF.	15.1.106
	UNS_VIS: Added EG1, EG2 in the list.	15.1.110
V3.0	Table 4: Additional Forms Required if Subject Has Experienced an SAE: Note 1 and 2 added for Concomitant Medication	6
	SAE reporting: Flow chart is modified to exclude CRA manual triggers.	13
	Field “Visit not done” re-ordered as per the CRF design.	15.01.03
	(CONSENT) and (CONSENT1) guidelines updated on format of Protocol number.	15.1.4 and 15.1.5
	(IE): Scenario 1 to 5 updated along with guidelines updated on format of Protocol number.	15.01.08
	(IE1)- Scenario 1 to 4 updated	15.01.09
	(DISEXT): “Metastatic/locally advanced” was reordered and notes added. “Was there recurrence after curative intent resection of BTC?” updated	15.01.10
	1MH): Start date guidelines updated	15.01.11
	LB07 and LB13 : For site local lab report shows a result of “Not Detected	15.1.38 and 15.1.44
	SPCGB: “What was the sample category?” guidelines modified.	15.01.54
	SPCPKB, SPCPKB1, SPCPKB2: ‘Last investigational product date’ and Last investigational product time’ deleted	15.1.55 , 15.1.56, 15.1.57
	2RECIST1, 4RECIST1: Specify location updated	15.1.59, 15.1.61
	EC1, EC2, EC3 and EC4: Note on Rounding Rules for Numeric Values updated. Example 1 and 2 added.	15.1.64, 15.1.65, 15.1.66 and 15.1.67
	CM: Table 15 Reason for medication/treatment taken: Protocol specified Pre-medication updated	15.1.78

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Version	Description of Change	Section
	1PR: Notes for SAE related PR and Adverse event number added.	15.1.79
	AE: Note on Events which are unequivocally due to disease under study	15.1.81
	Table 17: Description for corresponding Action Taken for Not Applicable.	
	Note updated for: Cases where no medication was administered for the adverse event (AE)	
	Derived Maximum CTCAE Grade	
	Field updated.	
	AESI: Note updated under Anatomical site	15.1.83
	SERAE: Note for Description of AE	15.1.86
	ILDIS:' What was the unit of the total cells count?' unit updated.	15.1.87
	LIVERDI", LIVERRF and LIVERSS update made under the AE number guidelines. Screenshot added for LIVERDI	15.1.95, 15.1.96 and 15.1.97
	REVPRDI: instructions on when to complete the form is updated	15.1.104
	DD: note added for What was the cause of death narrative?	15.1.106
	DS: note added	15.1.106
	What was the Subject's status? Instructions updated.	

17 TEMPLATE REVISION HISTORY

Version	Description of Change	Section
1	Initial Version	NA
2	Periodic review updates	All
3	Periodic review updates	3.2, 8
4	Periodic review updates	3.12

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Reason for signing: Document Reviewed and Approved	Name: Shu Zhang Date of signature: 08-Jul-2026 04:15:42 GMT+0000

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