# DMU Complete Data Submission Requirements

26 July 2023

## Data Fields and Mappings Required for Web Reporting:

The following protocol - level information will be assigned by CTEP and made available to Theradex via CTEP systems:

**Protocol ID**: This is the number assigned to the study (protocol) by the NCI.

**Protocol Title:** Abstracted from the protocol document.

**Eligible Disease Names and Codes:** The names and codes for eligible diseases using the CTEP Simplified Disease Classification.

**CTCAE Adverse Event Codes & Descriptions:** Theradex will be able to convert from older versions of CTCAE to the current version (5) at the time the DMU submission is loaded for a study.

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| A. ENROLLMENT DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Patient ID (CDASH: SubjectID) | Yes | | The code that uniquely identifies the patient to this protocol. This unique code or ID was assigned when the patient was registered on the study. | No |
| Initial Treatment Assignment Code (CDASH: Planned Arm Code) | Only if study has more than one TAC | | The alphanumeric code associated with the treatment assigned at registration. | No |
| Registration Date (CDASH: Enrollment Date) | Yes | | Date patient was registered. Registration occurs when a patient has signed an informed consent AND required enrollment information has been collected with an assignment of an official study patient ID. | No |
| Birth Date | Yes | | The Month, Day, and Year of the patient's birth. | No |
| Gender (CDASH: Sex) | Yes | Yes | The gender of the patient, using values from your dictionary. In DMU, values will be mapped to one of the following: <ul><li>Female</li><li>Male</li><li>Unknown</li><li>Intersex</li></ul> | No |

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| A. ENROLLMENT DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Race | Yes | Yes | The race of the patient, using values from your dictionary. In DMU, values will be mapped to one of the following:<br><br>• American Indian or Alaska Native<br>• Asian<br>• Black or African American<br>• Native Hawaiian or Other Pacific Islander<br>• White<br>• Not Reported<br>• Unknown | No |
| Ethnicity | Yes | Yes | The ethnicity of the patient, using values from your dictionary. In DMU, values will be mapped to one of the following:<br><br>• Hispanic or Latino<br>• Not Hispanic or Latino<br>• Not Reported<br>• Unknown | No |
| Disease Code | Yes | | The patient's primary cancer diagnosis. Use CTEP Simplified Disease Classification (SDC) Codes as defined by CTEP. | No |

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| A. ENROLLMENT DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Registering Institution Code | Yes | | The unique CTEP Institution code where the patient was originally registered on study. | No |
| Treating Institution Code | Yes | | The unique CTEP Institution code where the patient is being treated. | No |
| Country Code | Yes, if patient participation from foreign countries is involved. | | For patients from outside the U.S., the foreign country code. CTEP is using the International Standards Organization country codes. | No |

# DMU Complete Data Submission Requirements

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| A. ENROLLMENT DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Prior Chemotherapy Regimens | Yes | | If a patient has previously received a chemotherapy regimen, provide the number of single or multi-agent chemotherapy regimens received. A regimen is described as a distinctive planned collection of agent(s) and/or modalities to be utilized together during a cycle or course of therapy. The total number should include a chemotherapy regimen that was discontinued for any reason (e.g., completion of therapy, Adverse Event, or disease progression). If a prior treatment was ABVD/CHOP, it should be coded as one chemotherapy regimen.<br><br>Note: The total number of other prior therapy types (e.g., surgery) is not required here and must not be included in this number. | No |
| Zip Code | Yes, if patient participation from the U.S. is involved. | | For U.S. residents, the patient's home (residence) five-digit Zip code, for example 12345. | No |

# DMU Complete Data Submission Requirements

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| A. ENROLLMENT DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Eligible Flag<br><br>(CDASH: Were all eligibility Criteria met?) | Yes | Yes | Yes/No flag indicating if the patient has been declared eligible. | No. If multiple eligibility reviews are used, map to the final reviewer's eligibility flag. |
| Subgroup Code | No | No | A subgroup (stratum) is a unique patient characteristic used to uniformly group patients for separate analysis or treatment. If study uses them, then they must be provided. Subgroup Descriptions will need to be provided once at the startup of the study. | No |

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| B. TREATMENT ASSIGNMENT DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Treatment Assignment Date | No | | If the Treatment assignment for a patient can change during time on study, the date for the assignment can be provided. | No |
| Treatment Assignment Code | No | | If the Treatment assignment for a patient can change during time on study, the current treatment assignment should be provided. | No |

**Drug Administration for Non-Investigational Agents is Optional as long as the study has a Course Initiation CRF that has been mapped. Otherwise Theradex derives Cycle from Start Dates of treatment. If course initiation is not provided then ALL drugs on the study must have Drug Administration CRF's mapped, including Non-Investigational Agents.  It is the study teams decision whether to provide the Course Initiation form or the Drug Administration form but one or the other is required.**

| C. DRUG ADMINISTRATION DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Drug Name (CDASH: Study Treatment Name) | Yes, if more than one agent for study | Yes, if more than one agent for study | The Agent name for CTEP-sponsored IND agent. For multi-investigational agent protocols (protocols that utilize more than one CTEP-sponsored IND agent), each agent should be provided as a separate entry. | No |
| Start Date | Yes | | The date the course (cycle) began. | No |

# DMU Complete Data Submission Requirements

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| C. DRUG ADMINISTRATION DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Course Number | No. Theradex can derive course numbers (cycles) from Start Dates. If there is a Course Initiation CRF, the optional Course Initiation mappings shown below can be provided. | | The course (cycle) of treatment that is being reported on (e.g., 1, 2, 3,), using the definition of treatment course given in the protocol. The field is optional because Course number can be derived by determining the earliest drug administration start date. <br><br> Use only sequential numeric values to define the course. For crossover studies, it is recommended that a second numbering convention be used to differentiate between the two regimens. For example: <br><br> Course ID sequence for initial courses: 1, 2, 3, etc. <br><br> Course ID sequence for crossover courses: 101, 102, 103, etc. | No |
| Dose | Yes | | The actual total dose (using numbers) the patient received during this course. For a multi- investigational agent protocol, there should be a separate entry for each agent. | No |

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| C. DRUG ADMINISTRATION DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Dose Change (CDASH: Was the dose adjusted?) | No | | Has this patient received either a dose escalation or a de-escalation of this investigational agent during this course of therapy? In DMU, values provided will be mapped to one of the following: <ul><li>Yes, planned (i.e., the dose was changed according to protocol guidelines)</li><li>Yes, unplanned (i.e., the dose change was not a part of protocol guidelines)</li><li>No</li><li>Unknown</li></ul> | No |

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**Course Initiation is Optional - Only applicable if Drug Administration CRF does not include Course # (Cycle) and the study has a Course Initiation CRF. Otherwise Theradex derives Cycle from Start Dates of treatment. However, if course initiation is not provided then ALL drugs on the study must have Drug Administration CRF's mapped, including Non-Investigational Agents.  It is the study teams decision whether to provide the Course Initiation form or the Drug Administration form but one or the other is required.**

| D. COURSE INITIATION | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Start Date | No | | The date the course (cycle) began. | No |
| Course Number | No | | The course (cycle) of treatment that is being reported on (e.g., 1, 2, 3,), using the definition of treatment course given in the protocol. | No |

| E. ADVERSE EVENTS DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Adverse Event Code (CDASH: Lowest Level Term Code) | Code or Term are sufficient | | Using the NCI Common Terminology Criteria for Adverse Events (CTCAE) select the appropriate code for each adverse event the patient experienced during treatment. | No |

# DMU Complete Data Submission Requirements

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| E. ADVERSE EVENTS DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Adverse Event Term (CDASH: Preferred Term from MedDRA Coding) | Code or Term are sufficient | | Using the NCI Common Terminology Criteria for Adverse Events (CTCAE) select the appropriate term for each adverse event the patient experienced during treatment. | No |
| Verbatim Term | No | | | No |
| AE Other Specify | Yes | | Verbatim term for an Adverse Event if a CTCAE term of "Other, Specify" is selected. | No |
| Adverse Event Grade (CDASH: Toxicity Grade) | Yes | | Grade represents the severity of the adverse event. General definitions of the grading scale include: 1 - Mild Adverse Event 2 - Moderate Adverse Event 3 - Severe Adverse Even 4 - Life-threatening or disabling Adverse Event 5 - Fatal Adverse Event | No |

# DMU Complete Data Submission Requirements

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| E. ADVERSE EVENTS DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Related<br><br>(CDASH: Relationship to Study Treatment) | Yes | Yes | "Related" is a synonym for "Attribution". This field defines the relationship between the adverse event and the investigational agent(s)/intervention.<br><br>In DMU, values provided will be mapped to one of the following:<br><br>• Unrelated<br>• Unlikely<br>• Possible<br>• Probable<br>• Definite | No |
| Serious<br><br>(called "SAE Report Recommended" for CTEP-AERS integrated studies) | Yes | | A Yes/No flag entered by site indicating they view the event as serious. | No |
| Date of Onset<br><br>(CDASH: Start Date) | Yes, if study has registration intent or if Cycle/Course # is not provided | | Date that the event began for specified grade. | No |
| Date Resolved<br><br>(CDASH: End Date) | Yes, if study has registration intent | | Date that the event resolved. | No |

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| E. ADVERSE EVENTS DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Ongoing | Yes, if study has registration intent | Yes | Yes/No Flag indicating that AE continuing beyond current course. | No |
| Dose Limiting Toxicity | No | If field used | Yes/No flag indicating if AE was a dose limiting toxicity. | No |
| Action (CDASH: Action Taken with Study Treatment) | No | If field used | In DMU, values will be mapped to one of the following:<br>• Dose Reduction Only<br>• Treatment Delay<br>• Treatment Omission<br>• Permanent Discontinuation | No |
| Adverse Event ID | Yes, if use CTEP-AERS Integration. Else N/A | | | No |
| Report ID | Yes, if use CTEP-AERS Integration. Else N/A | | | No |
| Cycle/Course Number | Yes, if Onset Date is not provided | No | Indicates the cycle of treatment when the AE occurred | No |

# DMU Complete Data Submission Requirements

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| E. ADVERSE EVENTS DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Outcome | No | If field used | In DMU, values will be mapped to one of the following:<br>• Recovered/Resolved<br>• Recovering/Resolving<br>• Not recovered/Resolved<br>• Recovered/Resolved with sequalae<br>• Fatal<br>• Unknown | No |
| Therapy | No | If field used | In DMU, values will be mapped to one of the following:<br>• None<br>• Symptomatic<br>• Supportive<br>• Vigorous Supportive | No |
| Evaluated Question | Yes, if using solicited AE's | Yes | Indicates if the Solicited AE has been evaluated at this cycle. Values will be mapped to<br><br>• Pending<br>• Yes<br>No | No |

# DMU Complete Data Submission Requirements

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| F. OFF TREATMENT DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Treatment Status ( indicates if patient is off treatment vs waiting for next phase) | No | If field used | Some Case Report Forms have form with a field   indicating if the patient is off treatment versus waiting for next phase.  In DMU, values will be mapped to one of the following:<br><br>• On Treatment<br>• Off Treatment | No |
| Date of Last Treatment<br><br>(CDASH: Exposure End Date) | No | | The date that treatment was last administered to the patient.  The field is optional because Theradex can use the most recent date drug administration start date. | No |
| Off Treatment Reason | Yes | Yes | If the patient is off protocol treatment, the reason the patient has discontinued treatment is provided. In DMU, values will be mapped to one of the following: | No |

# DMU Complete Data Submission Requirements

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| F. OFF TREATMENT DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| | | | • Treatment completed per protocol criteria<br>• Disease progression, relapse during active treatment<br>• Adverse Event/Side Effects/Complications<br>• Death on study during active treatment<br>• Patient withdrawal/refusal after beginning protocol therapy<br>• Patient withdrawal/refusal prior to beginning a protocol therapy<br>• Alternative therapy<br>• Patient off-treatment for other complicating disease<br>• Lost to follow-up<br>• Cytogenetic resistance<br>• Disease progression before active treatment<br>• No treatment, per protocol criteria | |

# DMU Complete Data Submission Requirements

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| F. OFF TREATMENT DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| | | | <ul><li>Lack of Efficacy</li><li>Physician Decision</li><li>Pregnancy</li><li>Protocol Deviation</li><li>Protocol Violation</li><li>Protocol-Specified Withdrawal Criterion Met</li><li>Technical Problems</li><li>Approved Drug Available for Indication</li><li>Disease Recurrence</li><li>Failure to Meet Continuation Criteria</li><li>Failure to Meet Randomization Criteria</li><li>Never Dosed</li><li>Non-Compliance</li><li>Screen Failure</li><li>Screening Not Completed</li><li>Sponsor Request</li><li>Withdrawal of Consent</li><li>Other</li></ul> | |
| Off Treatment Other Reason | Yes | | A Verbatim reason for off-treatment | No |

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| F. OFF TREATMENT DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| | | | if "Other" selected. | |

| G. OFF STUDY DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Date Off Study | No | | The date a patient went Off Study. | No |
| Date of Death | Yes | | The date a patient died. | Yes |

| Off Study Reason | No | If field used | The reason the patient went off-study. In DMU, values will be mapped to one of the following: <br><br>• Protocol-defined follow-up completed<br>• Patient lost to follow-up<br>• Patient refused follow-up<br>• Death<br>• Adverse Event/Side Effects/Complications<br>• Progressive Disease<br>• Protocol Deviation<br>• Protocol Violation<br>• Protocol-Specified Withdrawal Criterion Met<br>• Technical Problems<br>• Approved Drug Available for Indication<br>• Disease Recurrence<br>• Failure to Meet Continuation Criteria<br>• Failure to Meet Randomization Criteria<br>• Never Dosed<br>• Non Compliance<br>• Screen Failure<br>• Screening Not | No |
|---|---|---|---|---|
| (CDASH: Term associated with Disposition Decode) | | | | |

# DMU Complete Data Submission Requirements

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| G. OFF STUDY DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| | | | Completed<br>• Sponsor Request<br>• Withdrawal of Consent<br>• Disease Relapse<br>• Lack of Efficacy<br>• Physician Decision<br>• Pregnancy<br>• Other | |
| Off Study Other Reason<br><br>(CDASH: Disposition Term) | No | | Verbatim reason for off-study if "Other" is selected. | No |

# DMU Complete Data Submission Requirements

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**If you do not collect Efficacy data within Rave and your study is not randomized, you may provide a separate CSV file that will need to meet a specific Theradex-defined format.**

| H. EFFICACY DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Off Treatment Best Response | Off Treatment or Course Assessment is sufficient. N/A if Randomized | If field used | Off Treatment Best response is the Best Overall Response as indicated on an Off Treatment CRF.  In DMU, values will be mapped to one of the following:<br><br>• Complete Response<br>• Partial Response<br>• Less than Partial<br>• Stable Disease<br>• Disease Progression<br>• Not Assessed / Not Evaluable<br>• No Response Data<br>• Too Early | No |
| Off Treatment Best Response Date | Off Treatment or Course Assessment is sufficient. N/A if Randomized | | The Off Treatment Best Response Date is the initial date that the patient's disease was shown to have responded to therapy sufficient to meet the protocol-specified criteria for that level of response. | No |

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| H. EFFICACY DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Course Assessment Response | Off Treatment or Course Assessment is sufficient. N/A if Randomized | If field used | For each course assessment, the Course Assessment Response should be provided. Progression should be reported even if it is experienced after a response (e.g., Less than Partial Response, Partial Response, Complete Response). Can be collected on multiple forms and mapped to one field for reporting purposes. This will be available for the full studies but not yet available for pilots.<br><br>In DMU, values will be mapped to one of the following:<br><br>• Complete Response<br>• Partial Response<br>• Less than Partial<br>• Stable Disease<br>• Disease Progression<br>• Not Assessed / Not Evaluable<br>• No Response Data<br>• Too Early | Yes |

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| H. EFFICACY DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Course Assessment Date | Off Treatment or Course Assessment is sufficient. N/A if Randomized | | The date of the course assessment. Can be collected on multiple forms and mapped to one field for reporting purposes.  This will be available for the full studies but not yet available for pilots. | Yes |
| Date of Disease Progression. | Yes, but N/A if Randomized. | | The initial date that disease progression occurred. | Yes |

# DMU Complete Data Submission Requirements

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| I. BASELINE ABNORMALITIES DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Adverse Event Code<br><br>(CDASH: Lowest Level Term Code) | Code or Term are sufficient | If field used | Baseline Abnormality is defined by CTEP as any abnormal assessment (e.g., physical finding, subjective complaint, or diagnostic test abnormality) identified as part of the routine pre-study work-up for which a CTCAE term exists.<br><br>The Adverse Event Code is the appropriate CTCAE code for a baseline abnormality.<br><br>A patient's diagnosis and/or pre-existing condition are normally not CTCAE terms and should not be provided as baseline abnormalities. The Other, Specify option should only be used if there is not an appropriate adverse event term available. | No |
| Adverse Event Term<br><br>(CDASH: Preferred Term from MedDRA Coding) | Code or Term are sufficient | | The Adverse Event Term is the appropriate CTCAE term for a baseline abnormality. | No |

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| I. BASELINE ABNORMALITIES DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Adverse Event Grade<br><br>(CDASH: Toxicity Grade) | Yes | | Grade represents the severity of the adverse event. General definitions of the grading scale include:<br><br>1 - Mild Adverse Event<br><br>2 - Moderate Adverse Event<br><br>3 - Severe Adverse Even<br><br>4 - Life-threatening or disabling Adverse Event<br><br>5 - Fatal Adverse Event | No |
| AE Other Specify<br><br>(CDASH: Adverse Event Verbatim Term) | Yes | | Verbatim term for an Adverse Event if a CTCAE term of "Other, Specify" is selected. | No |

| J. PRIOR THERAPIES DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Prior Therapies Question<br><br>(CDASH: Did the subject take the treatment?) | No | If field used | Since some Case Report Forms provide checkboxes to indicate which prior therapies were given to the patient, this field is a Yes/No indicator for each therapy. | No |

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| J. PRIOR THERAPIES DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Prior Therapy Type | Yes | | All prior cancer treatment the patient has received is specified by providing MedDRA terms for prior therapy. More than one therapy may be included. Multi-modality treatments should be listed separately (e.g., mastectomy followed by tamoxifen – code as surgery and hormonal therapy). Acceptable values are:<br><br>• Anti-retroviral Therapy<br>• Antisense<br>• Bone Marrow Transplant<br>• Chemotherapy (NOS)<br>• Chemotherapy multiple agents systemic<br>• Chemotherapy non-cytotoxic<br>• Chemotherapy single agent systemic<br>• Drug and/or Immunotherapy<br>• Gene Transfer<br>• Hematopoietic Stem Cell Transplantation<br>• Hormonal Therapy<br>• Image Directed Local Therapy<br>• No prior therapy<br>• Oncolytic Virotherapy | No |

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| J. PRIOR THERAPIES DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| | | | • Prior Therapy NOS<br>• Radiation Therapy<br>• Surgery<br>• Therapy (NOS)<br>• Vaccine | |

| K. LATE ADVERSE EVENTS DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Adverse Event Code<br>(CDASH: Lowest Level Term Code) | Code or Term are sufficient | | A "Late Adverse Event" is an adverse event observed after a patient has completed treatment, regardless of whether the event has been identified as part of a scheduled or an unscheduled follow-up.<br><br>Using the NCI Common Terminology Criteria for Adverse Events (CTCAE) the appropriate code is provided for each late adverse event. | No |
| Adverse Event Term<br>(CDASH: Preferred Term from MedDRA Coding) | Code or Term are sufficient | | Using the NCI Common Terminology Criteria for Adverse Events (CTCAE) select the appropriate term for each late adverse event. | No |

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| K. LATE ADVERSE EVENTS DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Verbatim Term<br>(CDASH: Adverse Event Verbatim Term) | No | | | No |
| AE Other Specify | Yes | | Verbatim term for an Adverse Event if a CTCAE term of "Other, Specify" is selected. | No |
| Adverse Event Grade<br>(CDASH: Toxicity Grade) | Yes | | Grade represents the severity of the late adverse event. General definitions of the grading scale include:<br><br>1 - Mild Adverse Event<br><br>2 - Moderate Adverse Event<br><br>3 - Severe Adverse Even<br><br>4 - Life-threatening or disabling Adverse Event<br><br>5 - Fatal Adverse Event | No |

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| K. LATE ADVERSE EVENTS DATA ITEMS | Field Required? | Dictionary Mapping Required? | Definition | Ok If Found on Multiple Forms? |
|---|---|---|---|---|
| Related<br>(CDASH: Relationship to Study Treatment) | Yes | Yes | "Related" is a synonym for "Attribution". This field defines the relationship between the late adverse event and the investigational agent(s)/intervention.<br><br>In DMU, values provided will be mapped to one of the following:<br><br>• Unrelated<br>• Unlikely<br>• Possible<br>• Probable<br>• Definite | No |
| Date of Onset<br>(CDASH: Start Date) | Yes, if trial has registration intent | | Date that the late adverse event began for specified grade. | No |