DMU Complete Data Submission Requirements

01 May 2020

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.

Investigational Agent Names and NSC Codes: The names and NSC codes for CTEP-sponsored IND agents.

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

Treatment Assignment Codes and Descriptions: A treatment assignment is a unique treatment characteristic that will be used to uniformly group patients for separate analysis or treatment (e.g., Phase 2 or 3 treatment arm and Phase 1 dose levels). Each arm or dose level should be considered a distinct treatment assignment. A Treatment Assignment Code (TAC) is the alphanumeric code associated with a treatment description.

Registering Group Code: The unique CTEP group code where the patient was originally registered on study.

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: • Female • Male • Unknown • Intersex	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: • American Indian or Alaska Native • Asian • Black or African American • Native Hawaiian or Other Pacific Islander • White • Not Reported • 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: • Hispanic or Latino • Not Hispanic or Latino • Not Reported • 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

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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. 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

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A. ENROLLMENT DATA ITEMS	Field Required?	Dictionary Mapping Required?	Definition	Ok If Found on Multiple Forms?
Eligible Flag (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

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

DMU Complete Data Submission Requirements

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B. TREATMENT ASSIGNMENT DATA ITEMS	Field Required?	Dictionary Mapping Required?	Definition	Ok If Found on Multiple Forms?
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

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

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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. 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: Course ID sequence for initial courses: 1, 2, 3, etc. 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: • Yes, planned (i.e., the dose was changed according to protocol guidelines) • Yes, unplanned (i.e., the dose change was not a part of protocol guidelines) • No • Unknown	No

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.

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

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D. COURSE INITIATION	Field Required?	Dictionary Mapping Required?	Definition	Ok If Found on Multiple Forms?
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
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

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E. ADVERSE EVENTS DATA ITEMS	Field Required?	Dictionary Mapping Required?	Definition	Ok If Found on Multiple Forms?
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 Event 4 - Life-threatening or disabling Adverse Event 5 - Fatal Adverse Event	No
Related (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. In DMU, values provided will be mapped to one of the following: • Unrelated • Unlikely • Possible • Probable • Definite	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?
Serious (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 (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 (CDASH: End Date)	Yes, if study has registration intent		Date that the event resolved.	No
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

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E. ADVERSE EVENTS DATA ITEMS	Field Required?	Dictionary Mapping Required?	Definition	Ok If Found on Multiple Forms?
Action (CDASH: Action Taken with Study Treatment)	No	If field used	In DMU, values will be mapped to one of the following: • Dose Reduction Only • Treatment Delay • Treatment Omission • 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

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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: • Recovered/Resolved • Recovering/Resolving • Not recovered/Resolved • Recovered/Resolved with sequalae • Fatal • Unknown	No
Therapy	No	If field used	In DMU, values will be mapped to one of the following: • None • Symptomatic • Supportive • Vigorous Supportive	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: • On Treatment • Off Treatment	No
Date of Last Treatment (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: • Treatment completed per protocol criteria • Disease progression, relapse during active treatment • Adverse Event/Side Effects/Complications • Death on study during active treatment	No

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F. OFF TREATMENT DATA ITEMS	Field Required?	Dictionary Mapping Required?	Definition	Ok If Found on Multiple Forms?
			• Patient withdrawal/refusal after beginning protocol therapy • Patient withdrawal/refusal prior to beginning a protocol therapy • Alternative therapy • Patient off-treatment for other complicating disease • Lost to follow-up • Cytogenetic resistance • Disease progression before active treatment • No treatment, per protocol criteria • Other	
Off Treatment Other Reason	Yes		A Verbatim reason for off-treatment if "Other" selected.	No

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

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G. OFF STUDY DATA ITEMS	Field Required?	Dictionary Mapping Required?	Definition	Ok If Found on Multiple Forms?
Off Study Reason (CDASH: Term associated with Disposition Decode)	No	If field used	The reason the patient went off-study. In DMU, values will be mapped to one of the following: • Protocol-defined follow-up completed • Patient lost to follow-up • Patient refused follow-up • Death • Adverse Event/Side Effects/Complications • Other	No
Off Study Other Reason (CDASH: Disposition Term)	No		Verbatim reason for off-study if “Other” is selected.	No

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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: • Complete Response • Partial Response • Less than Partial • Stable Disease • Disease Progression • Not Assessed / Not Evaluable • No Response Data • 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. In DMU, values will be mapped to one of the following: • Complete Response • Partial Response • Less than Partial • Stable Disease • Disease Progression • Not Assessed / Not Evaluable • No Response Data • 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 (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. The Adverse Event Code is the appropriate CTCAE code for a baseline abnormality. 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 (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 (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 Event 4 - Life-threatening or disabling Adverse Event 5 - Fatal Adverse Event	No
AE Other Specify (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 (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: • Anti-retroviral Therapy • Antisense • Bone Marrow Transplant • Chemotherapy (NOS) • Chemotherapy multiple agents systemic • Chemotherapy non-cytotoxic • Chemotherapy single agent systemic • Drug and/or Immunotherapy • Gene Transfer • Hematopoietic Stem Cell Transplantation • Hormonal Therapy • Image Directed Local Therapy • No prior therapy • Oncolytic Virotherapy • Prior Therapy NOS • Radiation Therapy • Surgery	No

J. PRIOR THERAPIES DATA ITEMS	Field Required?	Dictionary Mapping Required?	Definition	Ok If Found on Multiple Forms?
			• Therapy (NOS) • Vaccine	

K. LATE 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		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. Using the NCI Common Terminology Criteria for Adverse Events (CTCAE) the appropriate code is provided for each late adverse event.	No
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 late adverse event.	No
Verbatim Term (CDASH: Adverse Event Verbatim Term)	No			No

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K. LATE ADVERSE EVENTS DATA ITEMS	Field Required?	Dictionary Mapping Required?	Definition	Ok If Found on Multiple Forms?
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 late adverse event. General definitions of the grading scale include: 1 - Mild Adverse Event 2 - Moderate Adverse Event 3 - Severe Adverse Event 4 - Life-threatening or disabling Adverse Event 5 - Fatal Adverse Event	No
Related (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. In DMU, values provided will be mapped to one of the following: • Unrelated • Unlikely • Possible • Probable • Definite	No

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K. LATE ADVERSE EVENTS DATA ITEMS	Field Required?	Dictionary Mapping Required?	Definition	Ok If Found on Multiple Forms?
Date of Onset (CDASH: Start Date)	Yes if trial has registration intent		Date that the late adverse event began for specified grade.	No