DMU Light Data Submission Requirements (Final)

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
Sex (CDASH: Sex)	Yes	Yes	The sex sof the patient, using values from your dictionary. In DMU, values will be mapped to one of the following: • Female • Male • Unknown	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
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
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.

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A. ENROLLMENT DATA ITEMS	Field Required?	Dictionary Mapping Required?	Definition	Ok If Found on Multiple Forms?
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. Should this be required for DMU Light?	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. It is also derivable by Theradex.	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

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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

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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

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

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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

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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
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

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E. ADVERSE EVENTS DATA ITEMS	Field Required?	Dictionary Mapping Required?	Definition	Ok If Found on Multiple Forms?
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
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 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

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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
Cycle/Course Number	Yes, if Onset Date not provided	No	Cycle/Course of treatment during which the AE began.	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
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 • Pending • Yes • No	No

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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	No

F. OFF TREATMENT DATA ITEMS	Field Required?	Dictionary Mapping Required?	Definition	Ok If Found on Multiple Forms?
			• Adverse Event/Side Effects/Complications • Death on study during active treatment • 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 • Lack of Efficacy • Physician Decision • Pregnancy • Protocol Deviation • Protocol Violation	

F. OFF TREATMENT DATA ITEMS	Field Required?	Dictionary Mapping Required?	Definition	Ok If Found on Multiple Forms?
			• Protocol-Specified Withdrawal Criterion Met • Technical Problems • Approved Drug Available for Indication • Disease Recurrence • Failure to Meet Continuation Criteria • Failure to Meet Randomization Criteria • Never Dosed • Non-Compliance • Screen Failure • Screening Not Completed • Sponsor Request • Withdrawal of Consent • Other	
Off Treatment Other Reason	No		A Verbatim reason for off-treatment if “Other” selected.	No