NCI CDISC Harmonization Working Group Meeting

09 September 2020

NIH NATIONAL CANCER INSTITUTE

CTSU Standard Forms ALS- *Status*

- v2.3 Non-CDISC CTSU Standard Forms ALS
  - No new version needed at this time (no v2.4 scheduled)
  - Feedback/technical updates *– completed*
  - Central Study ALS v2.3 updates *– completed*
- v7.0 CDISC CTSU Standard Forms ALS *– no changes*
  - *LPOs will need to migrate from v7.0 to v7.1*
    - Only 1 version of CDISC Harmonized and 1 version of non CDISC ALS in production
- **v7.1 CDISC CTSU Standard Forms ALS** *– pending*
  - Completed NCI CDISC Focus Group Review
    - Getting formal confirmation on changes from NCI CDISC Focus Group
    - Posting preliminary changes to NCI CDISC Wiki
  - Corresponding new Central Study ALS v7.1 will be developed by CTSU
  - Timeframe TBD *– early 2021*

CDASH Off Treatment and Off Study Reasons - Integration Consistency

- Theradex is using CDE 6355981 for the reasons a patient goes off treatment and off study. Looks like it is one of the standard CDEs used by a number of organizations. It is a critical element of an SDTM submission.

	Long Name	Preferred Question Text	Owned By	Used By Context	Registration Status	Workflow Status	Public ID	Version
☐	Disposition Event Dictionary-Derived/Standardized Term	What was the subject's status?	NCI Standards	AMC, COG, NRDS, Theradex	Qualified	RELEASED	6355981	1.0

- CDEs that appear to be used across all our networks

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☐	Disposition Event Dictionary-Derived/Standardized Term	What was the subject's status?	NCI Standards	AMC, COG, NRDS, Theradex	Qualified	RELEASED	6355981	1.0
☐	Off Treatment Reason Category	Off Treatment Reason	NCIP	ABTC, AECC, Alliance, CITN, CTEP, LCC, NCIP, SWOG	Qualified	RELEASED	2956831	1.0

CDASH Off Treatment and Off Study Reasons - Integration Consistency

- Theradex Web Reporting system (WRS) is used by both the ETCTN and NCTN
- Did mapping into WRS via DMU
  - The previous simpler list of reasons has greatly expanded due to CDISC CT
  - The values highlighted in violet below are new, and we are mapping many of them to "Other".
  - May need to update our list of values in WRS
  - AMC, COG and Theradex are using this CDE, other members of the NCTN are missing.
  - Need confirmation from NCI to expand the list of reasons.

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Picklist Mappings for Off Treatment Reason

Your Value	Web Reporting Value
Complete	Treatment completed per protocol criteria
Adverse Event	Adverse Event/Side Effects/Complications
Death	Death on study during active treatment
Recurrent Disease	No mapped value
Failure To Meet Continuation Criteria	No mapped value
Failure to Meet Randomization Criteria	No mapped value
Lack of Efficacy	No mapped value
Non-Compliance With Non-Study Device	No mapped value
Non-Compliance With Study Device	No mapped value
Non-Compliance With Study Drug	No mapped value
Physician Decision	No mapped value
Pregnancy	No mapped value
Progressive Disease	Disease progression, relapse during active treatment
Protocol Deviation	No mapped value
Protocol Violation	No mapped value
Protocol-Specified Withdrawal Criterion Met	No treatment, per protocol criteria
Randomized By Mistake	No mapped value
Randomized By Mistake With Study Treatment	No mapped value
Recovery	No mapped value
Trial Site Terminated by Sponsor	No mapped value
Study Terminated By Sponsor	No mapped value
Technical Problem	No mapped value
Study Participant Withdrawal by Parent or Guardian	Patient withdrawal/refusal after beginning protocol therapy
Withdrawal by Participant	Patient withdrawal/refusal after beginning protocol therapy
Other	Other

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

DMU Complete Data Submission Requirements (Draft)

24 September 2019

IT DATA ITEMS	Field Required?	Dictionary Mapping Required?	Definition
			• 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 • Other
Off Treatment Other Reason	No		A Verbatim reason for off-treatment if "Other" selected.

CDASH Off Treatment and Off Study Reasons - Integration Consistency

Web Reporting Value
Adverse Event/Side Effect/Complications
Death on study during active treatment
Patient Withdrawal/Refusal after beginning protocol therapy
Patient Withdrawal/Refusal prior beginning protocol therapy
Alternative Therapy
Patient off treatment for other complicating disease
Lost to follow up
Cytogenic Resistance
Disease progression before active treatment begin
No treatment per protocol criteria
Other

CDASH Controlled Terminology
COMPLETED
PROGRESSIVE DISEASE
DISEASE RELAPSE
ADVERSE EVENT
DEATH
WITHDRAWAL BY SUBJECT
WITHDRAWAL BY SUBJECT
OTHER
OTHER
LOST TO FOLLOW-UP
OTHER

Your Value
Complete
Adverse Event
Death
Recurrent Disease
Failure To Meet Continuation Criteria
Failure to Meet Randomization Criteria
Lack of Efficacy
Non-Compliance With Non-Study Device
Non-Compliance With Study Device
Non-Compliance With Study Drug
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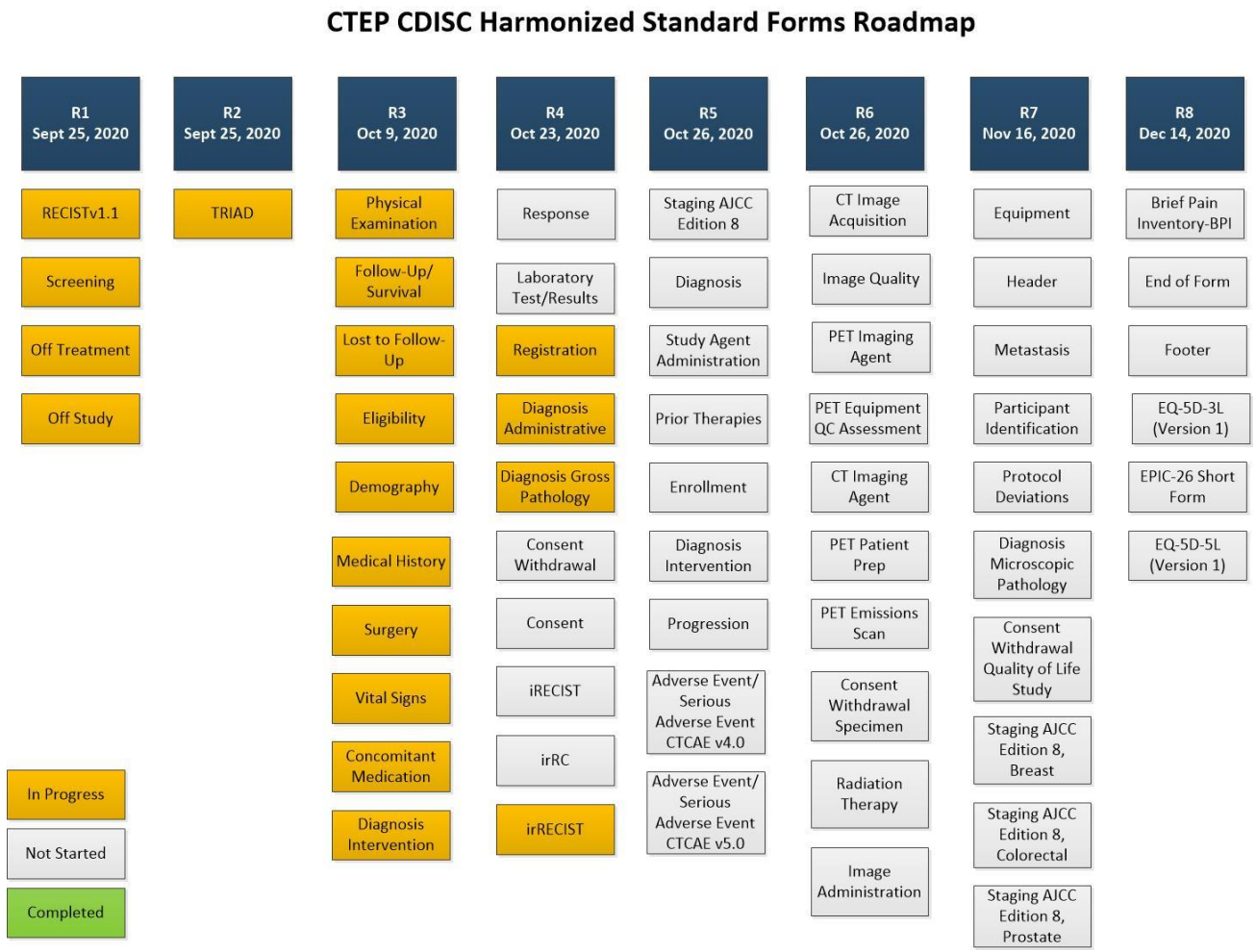
Study Terminated By Sponsor
Technical Problem
Study Participant Withdrawal by Parent or Guardian
Withdrawal by Participant
Other

CDASH Off Treatment and Off Study Reasons - Integration Consistency

- **Plan to handle Off Treatment Mappings**
  - **Standardize** the existing CTEP Off Treatment Controlled Terminology
    - Specificity is needed
    - Verify we are CDASH compliant
  - Review the content in the existing CDE (635598) in the NCI GLIB to verify consistency and add additional values as appropriate
  - Follow up with LPOs for potential additional values as appropriate

Progress on CDASH Mapping of NCI Standard Forms

- CDASH Mapping Completed (curation in caDSR in progress):
- Collaborating with CBIIT to make content available for CTEP CDISC Harmonized Forms



Send additional questions to the support email:

NCICDISCSupport.nih.gov