NCI CDISC Harmonization Working Group

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December 9th, 2019

Agenda

- Recap

NCI CDISC Harmonization Working Group Timeline

August 2019

- Kicked off NCI CDISC Harmonization WG
- Reviewed initial content roadmap
- Prioritized content on roadmap
- Reviewed 10 ECOG-ACRIN Use Cases for CDISC Harmonization

September 2019

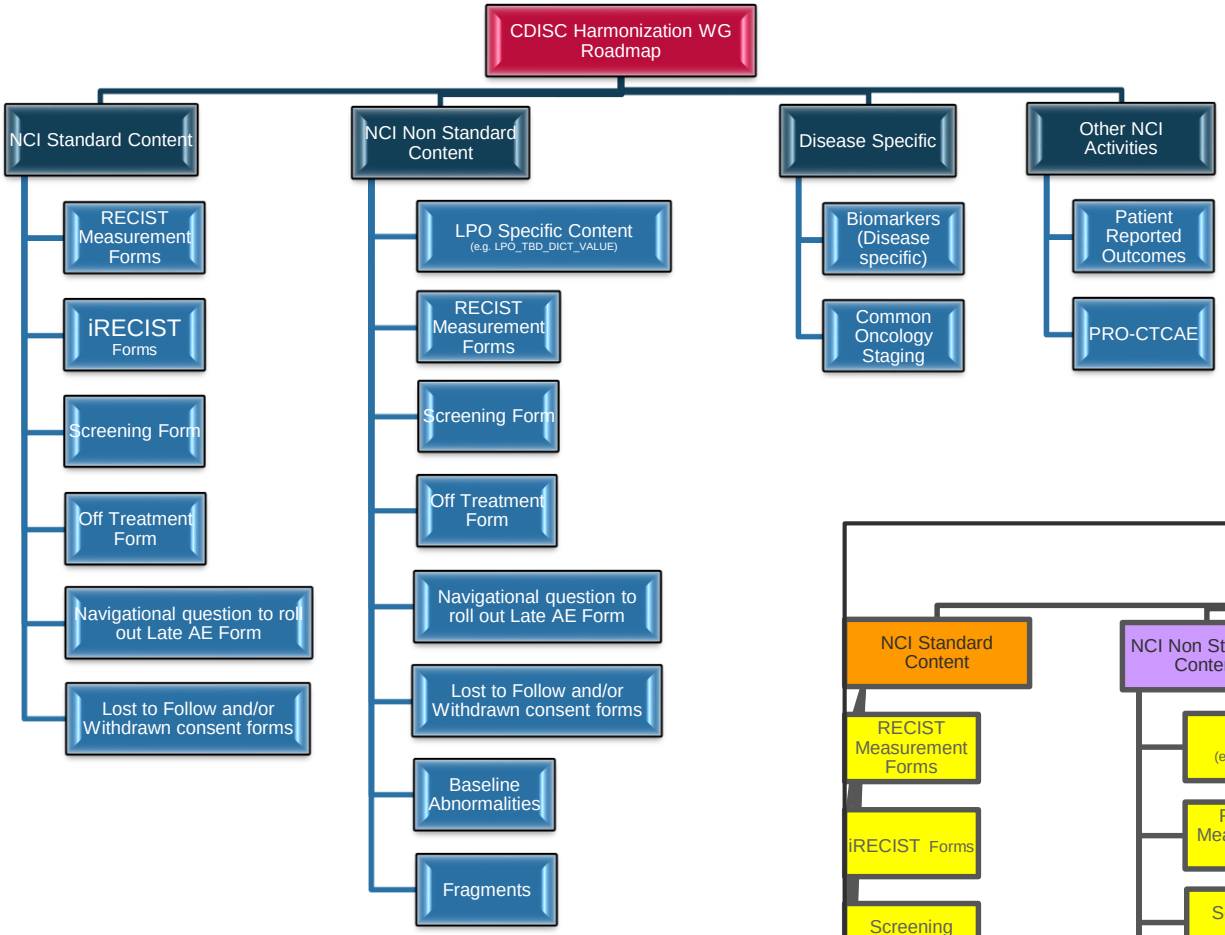
- Continued to review ECOG-ACRIN Use Cases and identify actions/next steps
- Addressed questions from NCI mailbox
- Began managing Fragments List
- CDISC SME presented on how to use the CDISC Oncology Domains

October 2019

- CDISC SME reviewed proposed approach to address RECIST and iRECIST for CDASH compliance
- Addressed questions from NCI mailbox

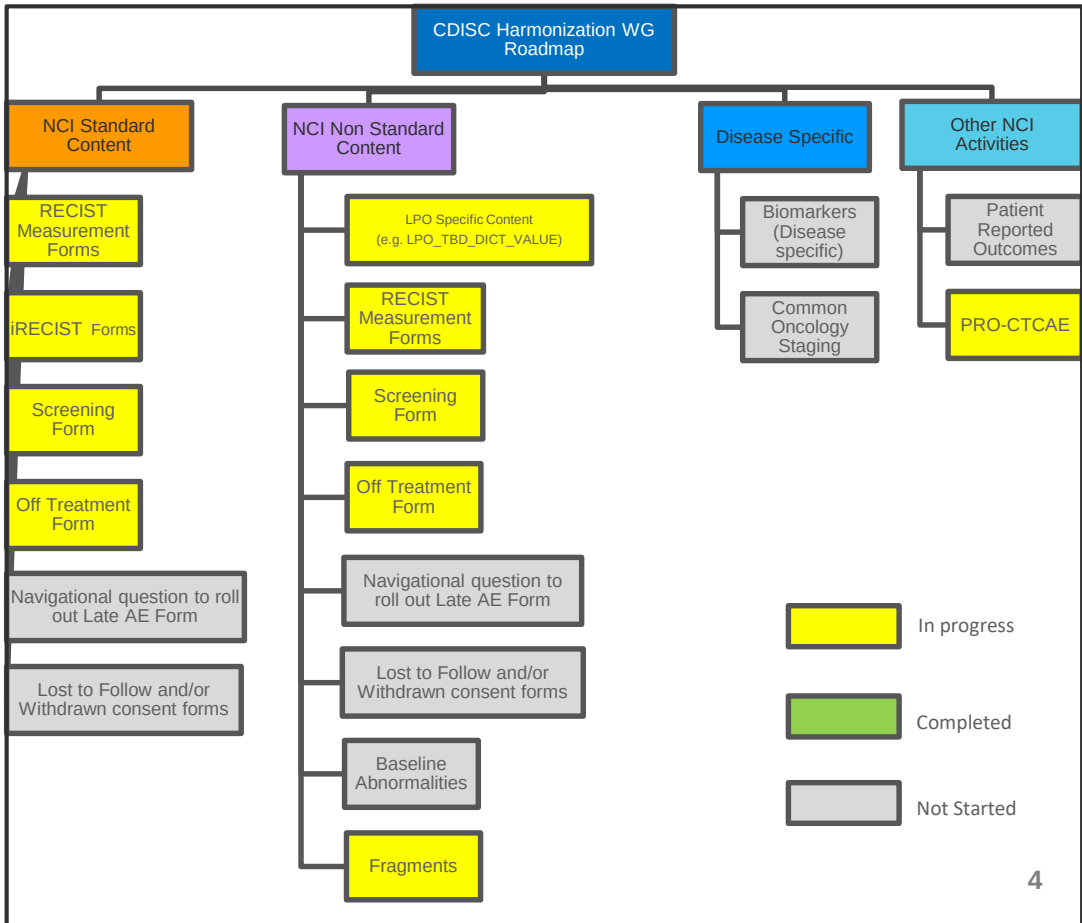
November 2019

- Reviewed 5 Alliance Use Cases
- Performed Gap Analysis on LPO Lost to Follow Up Standard Form, Consent Withdraw, Screening Form and Off Treatment
- Presented CDASH compliant Lost to Follow Up Standard Form, Consent Withdraw, Screening Form and Off Treatment content for review/use



August 2019

December 2019



LPO Use Cases

Source	Use Case	Status	Next Steps
ECOG-ACRIN	Propose different wording for MH_MHSTDAT	Active	CDISC PM: Propose to CDASH: What [is/was] the (intended/actual) [event/intervention] (start/admission) date ((of the observation)? CDISC PM: Update CDISC Wiki: GLIB CDISC Best Practices CBIIT: Add an alternate question text: "Initial Diagnosis Date."
ECOG-ACRIN	Proposed alternate text for LinkID (Lesion Number)	Active	CDISC PM: Proposed Lesion Number as alternate wording for LinkID CBIIT: Add an alternate question text: "Lesion Number." •Update CDISC Wiki: GLIB CDISC Best Practices
ECOG-ACRIN	Handling Clinical/Pathological AJCC v8 scoring: approach to define which was clinical and which was pathological	No Action	Proposed approach: Append the underscore and the test code value or use METHOD variable.

LPO Use Cases

Source	Use Case	Status	Next Steps
ECOG-ACRIN	Benefit of hiding unit fields vs displaying them on the form.	No Action	No next steps at this time. Suggestions were made by groups for methods of handling this scenario and are included in the 8_26_19 meeting minutes.
ECOG-ACRIN	DSCONT —"Will the subject continue" in IG model wording is not specific enough	No Action	As long as the wording includes "Will the subject continue" and the additional words do not change the meaning of the question, groups can add the specificity.
ECOG-ACRIN	Standardize Study Treatment Code List	Pending	CDISC PM: Performing a Gap Analysis on all LPO Treatment Code lists
ECOG-ACRIN	Using the FIELD_OID integer approach per release notes may not be the best approach in certain scenarios	No Action	No next steps at this time. Suggestions were made by groups for methods of handling this scenario and are included in the 8_26_19 meeting minutes.

LPO Use Cases

Source	Use Case	Status	Next Steps
ECOG-ACRIN Alliance	Data Dictionary with more meaningful names.	No Action	LPOs have the option to update the VD long name + PID to the VD short name + PID This update would need to be managed directly in Rave, the OCI does not import the VD short name
Alliance	CDISC Submission Values that differ by case	Pending	Workaround: Avoid using the same coded value only differing by case in the same dictionary.

Mixed case issues with the coded data in the Lab Unit dictionary (CDISC_SDTM_UNIT_PID6401717_V1_0F).

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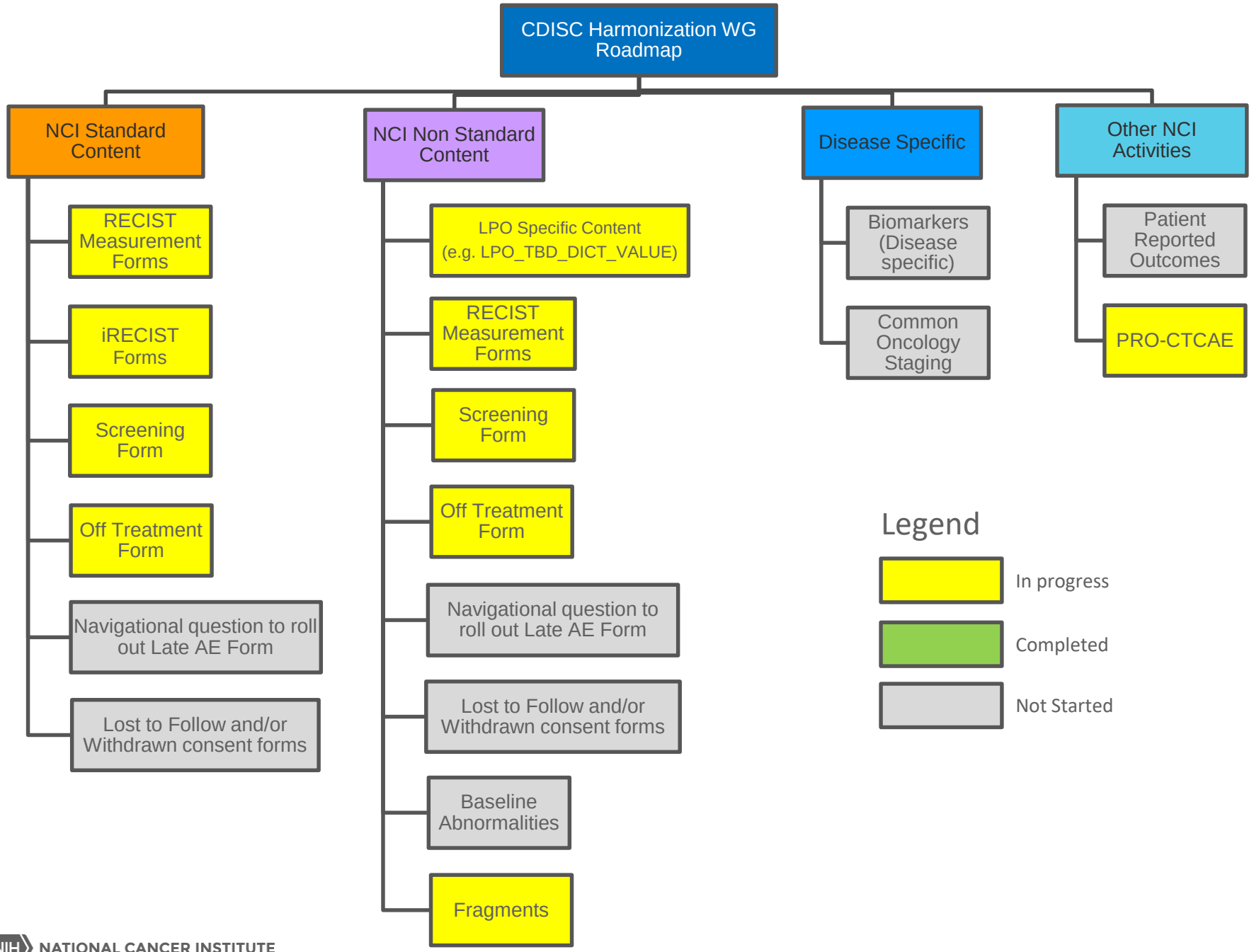
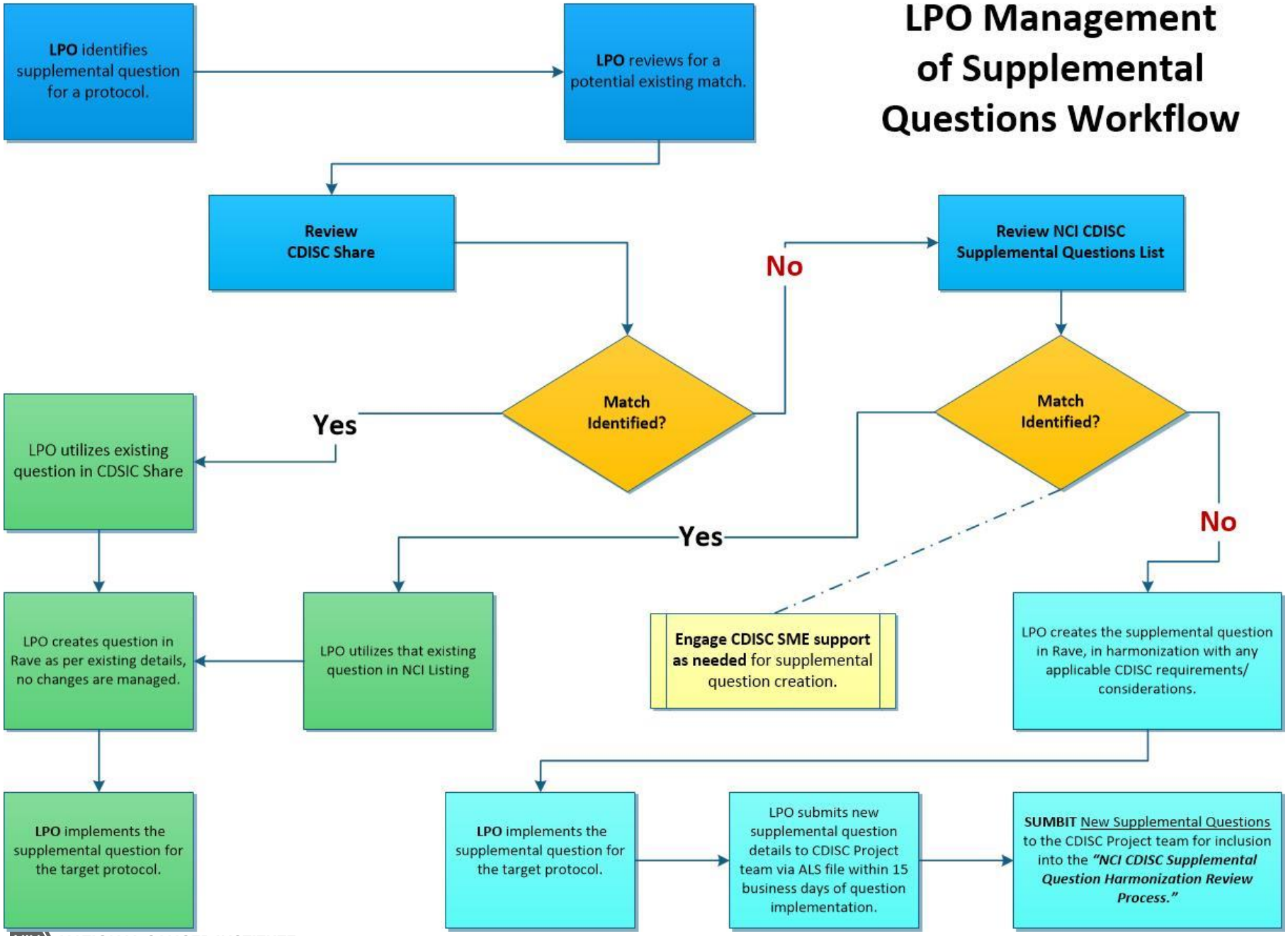
LPO Use Cases

Source	Use Case	Status	Next Steps
Alliance	Death Date should be in DS Domain	No Action	CDISC PM: A recommendation will be sent to NCI to update the Global Library to move the Death Date to the Disposition Domain. This will be taking back to the NCI Integration Focus Group.
Alliance	No Primary Cause of Death Response list in the CDISC Data Dictionary.	Pending	CDISC PM: Gather Primary Cause of Death response from LPOs and perform a gap analysis with the NCI Standard Form.
Alliance	OPEN Enrollment System and Screen Failures	Pending	CTSU will provide an update
Alliance	Concerned about the question text for the Off-Treatment Reason/Off Study Reason being recommended as “Subject Status.”	No Action	CDISC SME Recommendation: Question Text for Off Treatment Reason/Off Study Reason recommended as “Subject Status.: Add a placeholder for some context (i.e., "Subject Status (when [context])", as in: "Subject Status when they came off treatment", "Subject Status when they came off study", as that is the intent of these standard CDASH questions.

LPO	Using GLIB as a tool	Enhancement Recommendations	SME Meeting Topics
Alliance	Use it as a reference tool (PID, caDSR Link) Not using for building because our data is captured in a denormalized way	Include Oncology Response Dictionary	
COG	Helpful, will be using it	No recommendations at this time	
ECOG-ACRIN	Using the GLIB, cannot use it directly to copy all domains but do review fields to enter into Rave	No recommendations at this time Include Oncology Response Dictionary	
Theradex	Used the GLIB as a reference, building the forms in form builder and have denormalized structure	No recommendations at this time	
NRG	Had to have our seed study for initial study, but for newer study teams are starting to use	No recommendations at this time	
SWOG	Imported for reference, not using it to build forms, easier to use the model itself		
CCTG	Using as a reference tool for PID, not using it for build at this time	Core Designations and references to dictionaries	
ABTC			
PBTC	Use the GLIB as a reference		How to use the CDISC GLIB – Potential one off call to address this
AMC			


CDISC Harmonization WG Roadmap
NCI Standard Content
RECIST Measurement Forms
iRECIST Forms
Screening Form
Off Treatment Form
Navigational question to roll out Late AE Form
Lost to Follow and/or Withdrawn consent forms
NCI Non Standard Content
LPO Specific Content (e.g. LPO_TBD_DICT_VALUE)
RECIST Measurement Forms
Screening Form
Off Treatment Form
Navigational question to roll out Late AE Form
Lost to Follow and/or Withdrawn consent forms
Baseline Abnormalities
Fragments
Disease Specific
Biomarkers (Disease specific)
Common Oncology Staging
Other NCI Activities
Patient Reported Outcomes
PRO-CTCAE
Legend
In progress
Completed
Not Started

Next Steps

- **CDISC Project Team Activities**
  - Package up completed content to send to CDISC for proposed standards
  - Begin tracking active studies that are harmonized with CDISC
  - Update roadmap as needed
  - Continue to track LPO Use Cases

LPO Management of Supplemental Questions Workflow