

NCI CDISC Harmonization Working Group

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Agenda

- Review Use Cases
- LPO Questions
- Review Roadmap
- Review Lost to Follow Up Standard Form
- Review Consent Withdraw Standard Form

LPO Discussion Use Cases

- **CDISC Submission Values that differ by case**

- Had mU and MU in a GL for a while and this actually popped up in a study where Rave removed one during a publish & place
- Workaround: Avoid using the same coded value only differing by case in the same dictionary.
- NCI to look into this to see if there are implications with this scenario

Issue ID	Module	Severity	Description	Workaround	Found In	Resolution	Submitted
MCC-145445	Rave - Architect	3 - Standard Impact	Publish in place assigns wrong coded value to coding entry when data dictionary contains two coded values that differ only in case	Do not enter Dictionary values with the same coded data value that differs only by case for the studies.	Rave 2013.2.0.1	Unresolved	Jan 25, 2015

LPO Discussion Use Cases

- **Death Date is in DM domain in the NCI GLIB**
 - In SDTM this maps to the Demographics Domain
 - This is more of a Disposition Domain
 - Recommendation to move it to the DS Domains (DSSTDAT)
- **Primary Cause of Death Response**
 - No data dictionary in CDISC for now
 - Create a standardized list across the LPOs to use
 - Examples: Tumor, new primary, drug related, unknown, other

LPO Discussion Use Cases

- **Off Treatment Intervention Reasons Code list**
 - The NCI required list is not inclusive of what the groups need. Our groups interested in performing a gap analysis and identify the missing values that can be used across groups?
 - Alliance to advise to see if they are mapping the collected terms to the required CDUS values for reporting.

LPO Discussion Use Cases

- **Discuss OPEN Enrollment System**

- The OPEN system does not provide information on failed criteria. It does provide information on criteria that passed for eligible patients.
- Per our CDISC SME, it is important to have that data if Sponsors or FDA Reviewers ask for it. This information is also universally useful. It's important to have that data and report it in SDTM format or have it available if organizations are asked for that information.
- CTSU will review this item.

LPO Questions

■ Group Discussion (Alliance Question)

- Concerned about the question text for the Off Treatment Reason/Off Study Reason being recommended as “Subject Status.”
- I understand where this comes from in the disposition domain. Concerned about whether or not our sites will really get what this means. That is a very generic term – and we’re asking a much more specific thing. Maybe it’s just that it’s so different from our existing terminology.
- Alliance: 1) Verify this question is CDUS related, and 2) to confirm if the concern is that the proposed CDISC text does not match the required CDUS text?

Question	CDASH Question / Prompt	CDASH Variable Name	CDASH Controlled Terminology	SDTM Mapping
Off Treatment Reason	Subject Status (when they came off treatment)	DS_DSDECOD_DISPOSITION_TREATMENT		DS_DSTERM = collected value, DS_DSDECOD = SDTM Controlled Terminology (NCOMPLT)

LPO Questions

- Group Discussion (Alliance Question)
 - On the screening form, the CDASH Prompt is:
 - “Were all eligibility criteria met?” being the replacement for our current screening form.
 - Screening and eligibility as separate processes and don’t think these are synonymous.
 - At Alliance we’re likely not using the “Does the participant meet all screening criteria?” is the way the question reads.
 - Our actual purpose of this question is to track if the patient will continue onto the next step – a data cleaning/reconciliation exercise.
 - How have other groups implemented the screening questions

Question	CDASH Question / Prompt	CDASH Variable Name	CDASH Controlled Terminology	SDTM Mapping	CDE	CDE Public ID	CDE Version	Question Definition
Does the participant meet all screening criteria?	Were all eligibility criteria met? / Met Criteria	IE_IEYN	NY	Does not map to SDTM - used for form navigation	Clinical Trial Screening Indicator	2960675	1.0	Text response that indicates whether the participant satisfies all of the screening criteria.

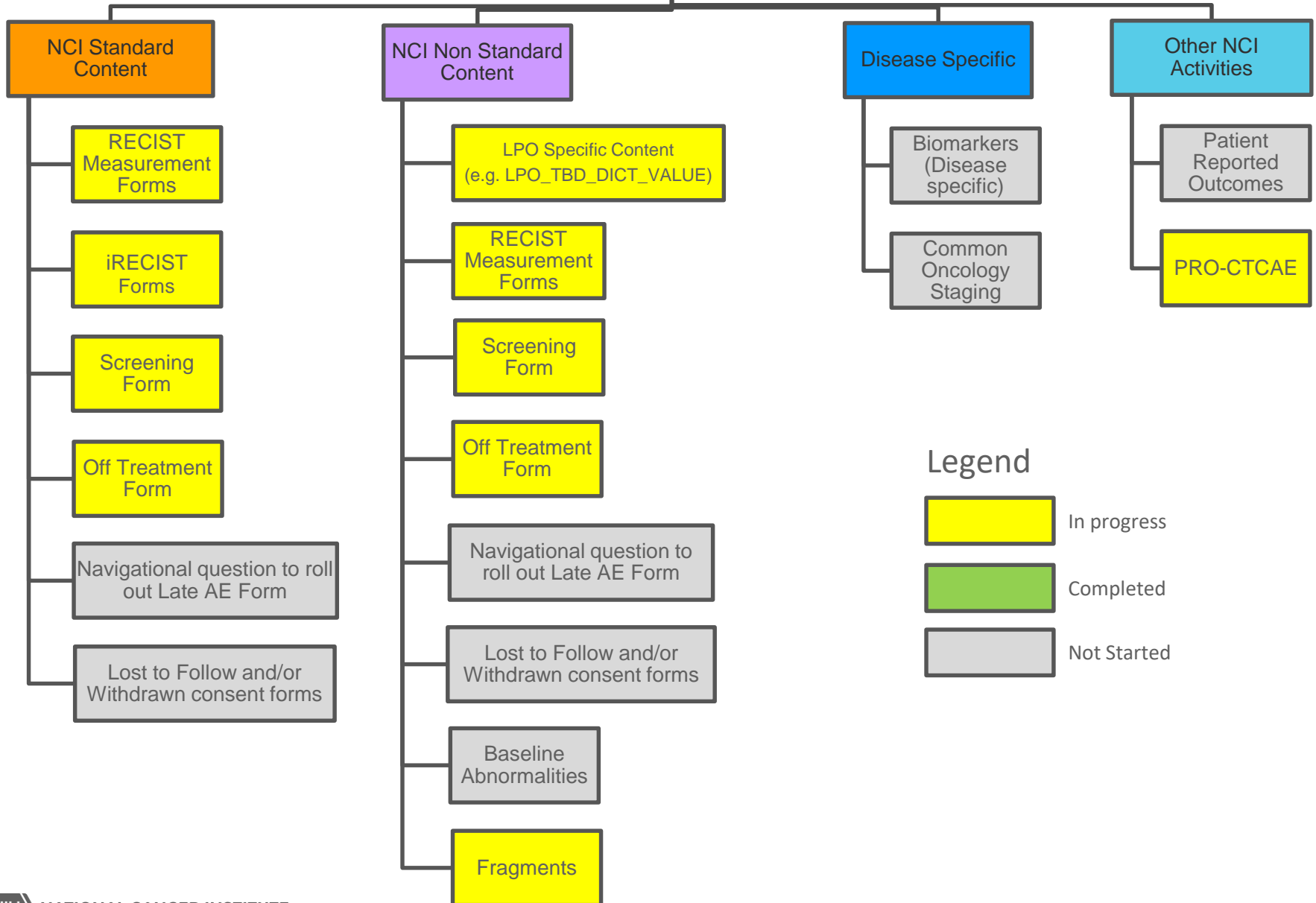
LPO Questions

- Group Discussion (Alliance Question)
 - Struggled with the off treatment reasons in the NCI standard forms for years.
 - In particular for our non-treatment or early stage trial.
 - Are there any efforts are being done at the NCI level to update these with fresher languages and maybe some new options?
 - Or are they planning to make the existing standard CDASH compliant, as Shannon started to outline in the documents provided.

LPO Feedback

- Are each of the groups using the Global Library ALS, is it useful and how, what can be improved.
 - Alliance
 - COG
 - ECOG-ACRIN
 - Theradex
 - SWOG
 - NRG
 - CCTG
 - ABTC
 - PBTC
 - AMC

CDISC Harmonization WG Roadmap

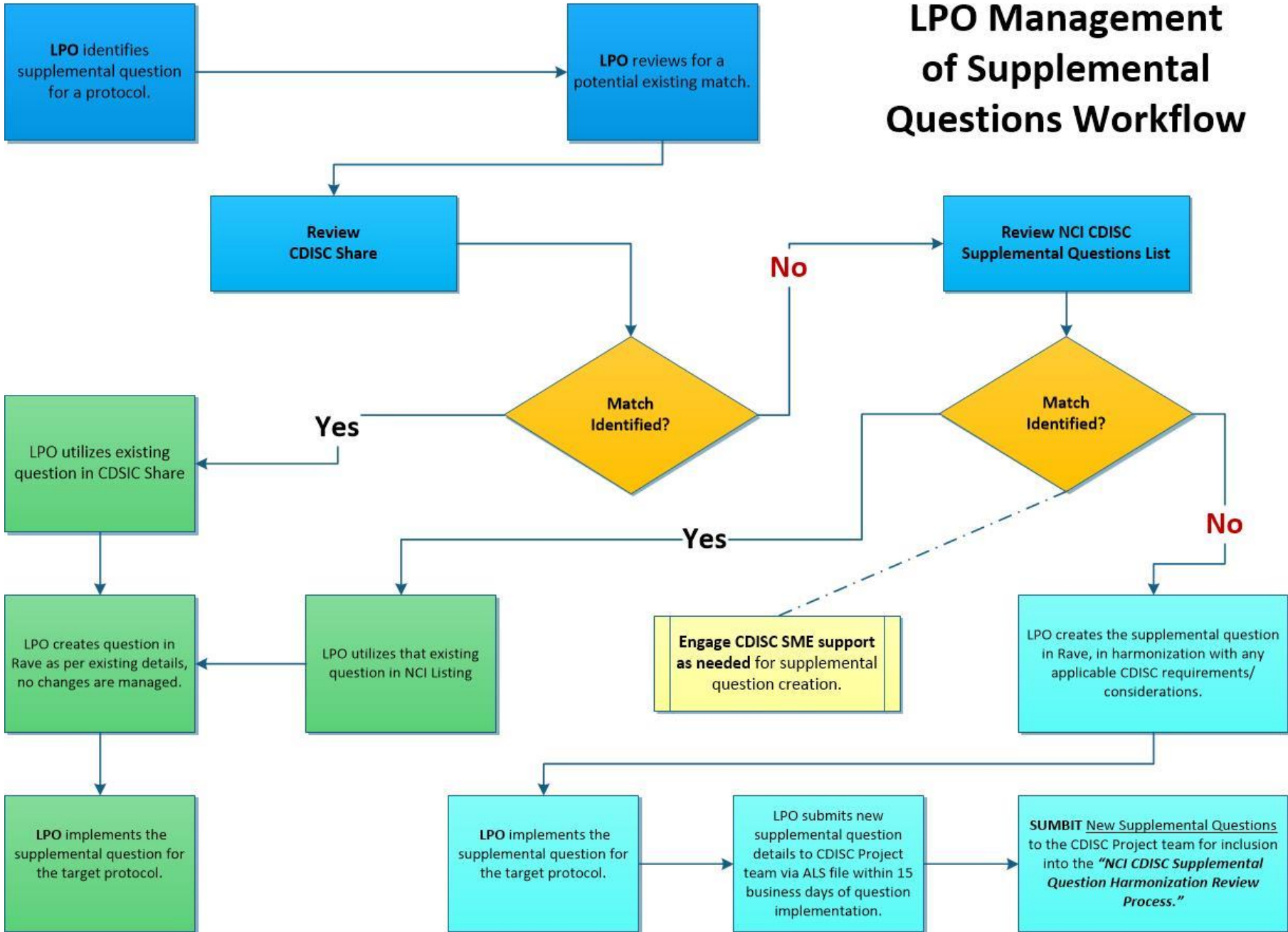


Next Steps

- **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



CDISC Harmonization WG Roadmap

