

CDISC Implementation Committee

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Agenda

- NCI Requirement
- Project Updates
- CDISC LPO Support Questions
- Project Timeline

NCI Requirement

- January 2020 *Date will be assessed based on LPO Impact Analysis
 - All CTEP IND studies activated after 1/1/2020 shall be CDISC compliant.

Project Updates

- **CDISC Mailbox**

- ncicdiscsupport@nih.gov

- **CDISC Wiki**

- Updated with project documentation

- **LPO Support Webinars/Sessions**

Project Updates

- **CDISC Harmonization Working Group**
 - Alliance
 - ECOG-ACRIN
 - CCTG

Project Updates

LPO Question	NCI Answer
<p>We encountered a problem when uploading the CDISC Rave Glib Beta ALS. It seems there are multiple dictionaries that have commas or semicolons in the coded value, and Rave will not complete the ALS upload while this error stands.</p>	<p>NCI sent out an updated version without the commas.</p> <p>NCI is working with Medidata to coordinate the update to the LPO URLs before the release of the final ALS.</p>
<p>I know that there is a compliance checker for SDTM datasets. Is there anything available to validate our studies are following CDASH standards (using the Rave ALS)? If not, is there any plans for this in the future?</p>	<p>At this time there is nothing out there that will validate CDASH.</p> <p>We are internally reviewing tools to identify an SDTM validation option.</p>
<p>I can see that all of the CDASH fields have been curated. But, we will still have additional data collections items that we collect which are not part of CDASH for our trials– will we need to curate these as we do today?</p>	<p>CBIT can curate any additional data collection items needed. The Short Name/OID will need to be provided.</p> <p>For Inclusion/Exclusion Criteria it is the same curation process we have right now. If additional non-standard CDEs are needed for Eligibility then the CBIT team can curate those CDEs.</p>

Project Updates

LPO Question	NCI Answer
As none of the LPOs appear to be listed under research organizations to access the wiki, is there a plan to get them added or at least the NCTN?	The NCI is looking into the process of adding organizations.
Is there a plan to give the LPOs member access to the CDISC members site, as LPO users do not have nih email accounts?	No there is no plan, access is per organization.

Project Updates

LPO Question	NCI Answer
<p>Will the LPO's be provided with CDASH Implementation Guidance which outline what questions are required , versus optional? Or should we be using the SDTM IGs from the March 2018 training as our guide for required elements? Are there updated SDTM IGs available?</p>	<p>Guidance will be provided for how to determine which fields should be collected for each Form, and how to determine which fields should be set to Mandatory.</p> <p>The versions of the CDISC standards on which the implementation is based are publicly available from www.cdisc.org.</p>

Project Updates

LPO Question	NCI Answer
<p>What is the expectation from the CDISC working group of the format and extent of details from each LPO after their Impact Analysis? We want to be clear as to what feedback is expected , should the impact extend only to study build impact or beyond to report and table generation? Are there any examples of completed Impact analysis available?</p>	<p>A “LPO Reviewing Template” will be provided to LPOs to document feedback/ questions/ concerns.</p>

CDISC Implementation Timeline

Milestone	Completion Date
CDISC Rave GLIB ALS	
✓ 1) Created Beta ALS	February 15, 2019
✓ 2) Completed Internal Compliance review on Beta ALS	February 27, 2019
✓ 3) Released Beta ALS to LPOs	March 5, 2019
4) Complete Impact Analysis **LPOs**	April 2, 2019
5) Manage Impact Analysis updates	May 17, 2019
6) Complete Internal Compliance review on Final ALS	June 14, 2019
7) Release Final CDISC Rave GLIB ALS to LPOs	July 9, 2019
CDISC-compliant CTSU Standard Forms ALS v7.0	
✓ 1) Created Beta ALS	March 7, 2019
✓ 2) Completed Internal Compliance review on Beta ALS	March 20, 2019
3) Release Beta ALS to LPOs	April 1, 2019
4) Complete Impact Analysis **LPOs**	June 10, 2019
5) Manage Impact Analysis updates	June 13, 2019
6) Complete Internal Compliance review on Final ALS	June 28, 2019
7) Release Final CDISC-compliant CTSU Standard Forms ALS v7.0 to LPOs	July 9, 2019
Build Seed Study in collaboration with CDISC SME **LPOs**	December 31, 2019
All Groups to use CDISC Standards on all studies. *All CTEP IND Trials	January 1, 2020

Beta CDISC Rave Integration ALS to LPOs

- **Scope**

- Beta Release CDISC-compliant CTSU Standard forms ALS v7.0
 - Includes all Rave integration forms:
 - OPEN
 - Balance
 - Rave-CTEP-AERS integration
 - NCI reporting form
- Release Notes

Beta CDISC Rave GLIB ALS to LPOs

- **Members on the CDISC Implementation Committee will receive an email with the following items**
 - Beta Release CDISC-compliant CTSU Standard Forms ALS v7.0
 - Release Notes
 - Instructions on how to send question/feedback
 - “LPO Reviewing Template” will be provided to LPOs to document feedback/ questions/ concerns.
- **LPO Impact Analysis Phase**
 - Provide feedback from sample study build to ncicdiscsupport@nih.gov by **June 10th, 2019.**
 - CTSU will update ALS files based on feedback

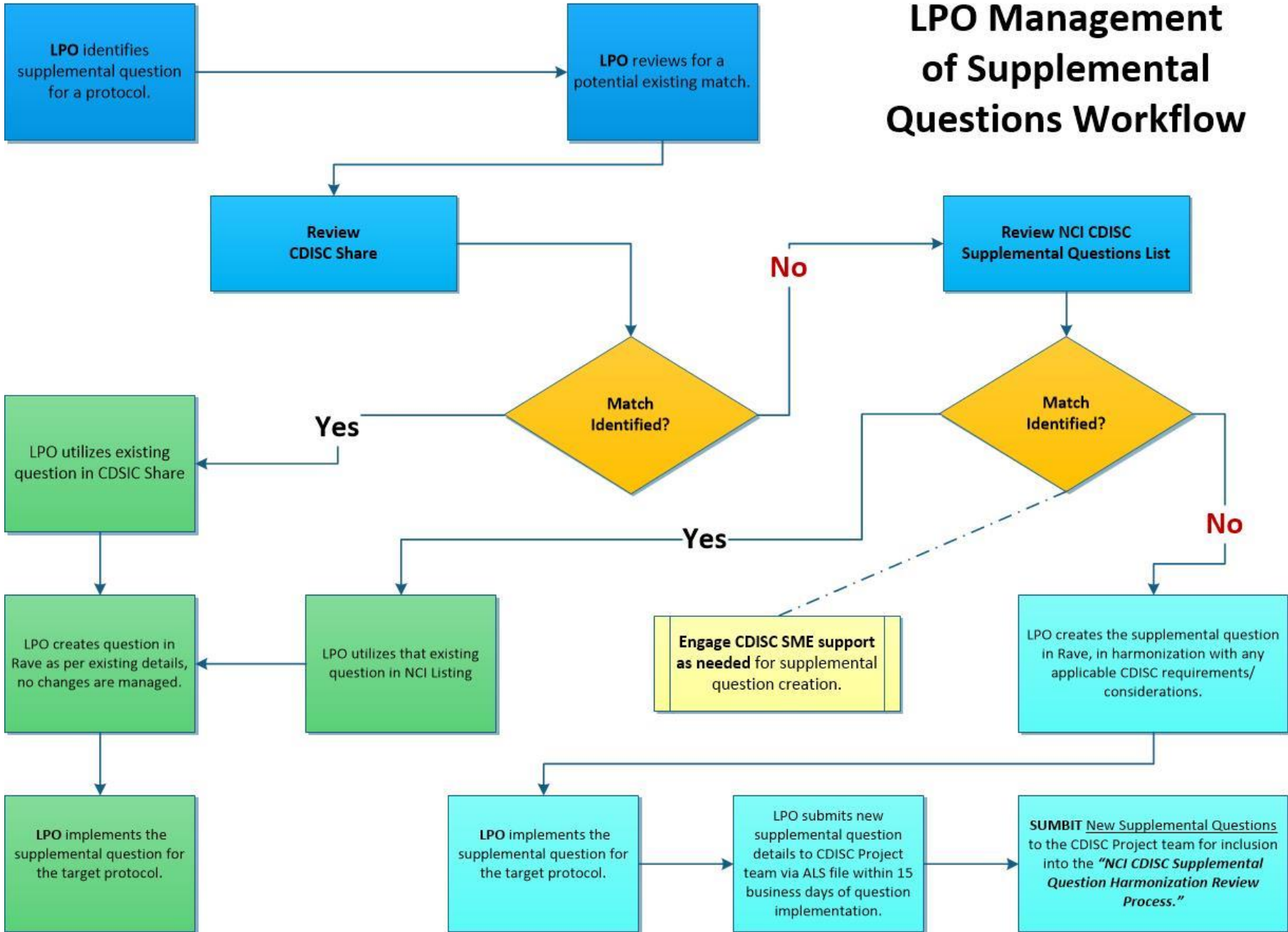
Next Steps

- Next Meeting is April 24th, 2019
- Send email to ncicdiscsupport@nih.gov for 1 representative and 1 back up representative for CDISC Harmonization WG

Status Updates

NCI/Group	Status	Supplemental Questions	Version Management
Alliance	Initial planning phase		Roll it into the global library process, quarterly updates for form changes
Theradex	Initial planning phase Waiting for tools; working on DMU updates	Continue to do curation through caDSR that are not part of standard CDASH	Changes to standard forms, keep track of which studies need changes, custom forms – update based on need, have an SOP to maintain versions
NRG	Rolling out using CDISC from start to finish; Initial planning phase – Beginning of study build		Have a standard global library, make updates as needed
SWOG	Initial planning phase Made change to standard forms to try CDASH	EC Questions discussions internally	Each form as a form #, date and those are updated based on updates for standard forms
ECOG-ACRIN	Initial planning phase Tools	Utilize caDSR	Global library – replace forms with new ones in library based on CDISC updates
CCTG	Initial planning phase		Global Library, changes made based on need for existing studies
COG	Initial planning phase		

LPO Management of Supplemental Questions Workflow





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