CDISC Implementation Committee

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Agenda

- NCI Requirement

- Project Updates

- Project Timeline

- CTSU GLIB Demo

- CDISC LPO Support Plan

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**
  - In progress

- **CDISC Harmonization Working Group**
  - Email the name of 1 representative and 1 back up representative to be a party of this working group. Email to the CDISC Mailbox.

CDISC Implementation Timeline

Milestone	Completion Date
Create CDISC Rave GLIB ALS	Completed
Internal Compliance review on Beta CDISC Rave GLIB ALS	February 27, 2019
Release Beta CDISC Rave GLIB ALS to LPOs	March 5, 2019
Create CDISC-compliant OPEN Integration ALS v7.0	March 7, 2019
Compliance review on CDISC-compliant OPEN Integration ALS v7.0	March 20, 2019
Beta Release CDISC-compliant OPEN ALS v7.0	April 1, 2019
Create CDISC-compliant CTEP-AERS Integration ALS v4.0	March 7, 2019
Compliance review on CDISC-compliant CTEP-AERS Integration ALS v4.0	March 20, 2019
Beta Release CDISC-compliant Rave-CTEP-AERS Integration ALS v4.0.	April 1, 2019
Perform CDISC Rave GLIB Impact Analysis	May 3, 2019
Manage IA updates to CDISC Rave GLIB	May 17, 2019
Create Final CDISC Rave GLIB ALS	May 29, 2019
Compliance review on Final CDISC Rave GLIB ALS, CDISC-compliant Rave-CTEP-AERS Integration ALS v4.0	June 14, 2019
Release Final CDISC Rave GLIB ALS to LPOs	July 9, 2019
Build Seed Study in collaboration with CDISC SME	December 31, 2019
All Groups to use CDISC Standards on all studies. *All CTEP IND Trials	**January 1, 2020**

LPO Support Plan: SME Support Meetings

- **Time: 10:00am -12:00pm EST**

- **Pre-planned agendas based on requests**

- Tuesday March 5th
- Tuesday March 20th
- Wednesday April 10th
- Wednesday April 24th
- Wednesday May 1st
- Wednesday May 22nd
- Tuesday July 9th
- Tuesday July 23rd
- Tuesday August 6th
- Tuesday August 20th
- Tuesday September 3rd
- Tuesday September 17th
- Tuesday October 1st

- Tuesday October 15th
- Tuesday October 29th
- Tuesday November 5th
- Tuesday November 19th
- Tuesday December 3rd
- Tuesday December 17th

LPO Support Plan: 90 Minute CDISC Overview Webinar

- **March 7th, 2019**
  - **Webinar 1:** 10:00-11:30 EST
  - **Webinar 2:** 3:00pm-4:30 EST

- **Learning Outcomes:**
  - Describe the CDISC organization and purpose
  - Explain the high-level principles of CDASH, SDTM and Controlled Terminology (CT) standardization
  - Demonstrate finding and downloading the standards documentation, including how to create a CDISC online account and access SHARE documentation
  - Brief demos of ALS to show how CDISC standards are built in

LPO Support Plan: 90 Minute Webinar: Variable Naming, NSV

- **March 28th, 2019**
  - **Webinar 1:** 10:00-11:30 EST
  - **Webinar 2:** 3:00pm-4:30 EST

- **Learning Outcomes:**
  - Variable naming conventions
  - Non-standard variables

LPO Support Plan: 90 Minute Webinar: Controlled Terminology

- **April 2nd, 2019**
    - **Webinar 1:** 10:00-11:30 EST
    - **Webinar 2:** 3:00pm-4:30 EST

- **Learning Outcomes:**
    - Using Controlled Terminology
    - New Term Requests

LPO Support Plan: 90 Minute Webinar - Custom Domains

- **April 17th, 2019**
  - **Webinar 1:** 10:00-11:30 EST
  - **Webinar 2:** 3:00pm-4:30 EST

- **Learning Outcomes:**
  - Custom Domains

LPO Support Plan: 90 Minute Webinar - Using QRS Supplements

- **April 18th, 2019**
  - **Webinar 1:** 10:00-11:30 EST
  - **Webinar 2:** 3:00pm-4:30 EST

- **Learning Outcomes:**
  - Using QRS Supplements

LPO Support Plan: 90 Minute Webinar - Using TA User Guides

- **April 30th, 2019**
  - **Webinar 1:** 10:00-11:30 EST
  - **Webinar 2:** 3:00pm-4:30 EST

- **Learning Outcomes:**
  - Using TA User Guides

LPO Support Plan: 90 Minute Webinar - Overview of Supporting Tools

- **May 14th, 2019**
  - **Webinar 1:** 10:00-11:30 EST
  - **Webinar 2:** 3:00pm-4:30 EST

- **Learning Outcomes:**
  - Validation
  - Creation of Define-XML

LPO Support Plan: 90 Minute Webinar - Overview of FDA Submission Process

- **May 21st, 2019**
  - **Webinar 1:** 10:00-11:30 EST
  - **Webinar 2**: 3:30pm-5:00 EST

- **Learning Outcomes:**
  - FDA Submission Process

LPO Support Plan: 90 Minute Webinar – CDASH/SDTM/ADaM

- **May 28th, 2019**
  - **Webinar 1:** 10:00-11:30 EST
  - **Webinar 2:** 3:00pm-4:30 EST

- **Learning Outcomes:**
  - How to get from CDASH to SDTM to ADaM

Beta CDISC Rave GLIB ALS to LPOs

- **Members on the CDISC Implementation Committee will receive an email with the following items**

    - Beta CDISC Rave GLIB ALS

    - Implementation Notes

    - Draft Best Practices Document

    - Instructions on how to send question/feedback

- **LPO Impact Analysis Phase**

    - LPOs can build sample study with a few specific forms from CTSU global library

    - Provide feedback from sample study build to ncicdiscsupport@nih.gov
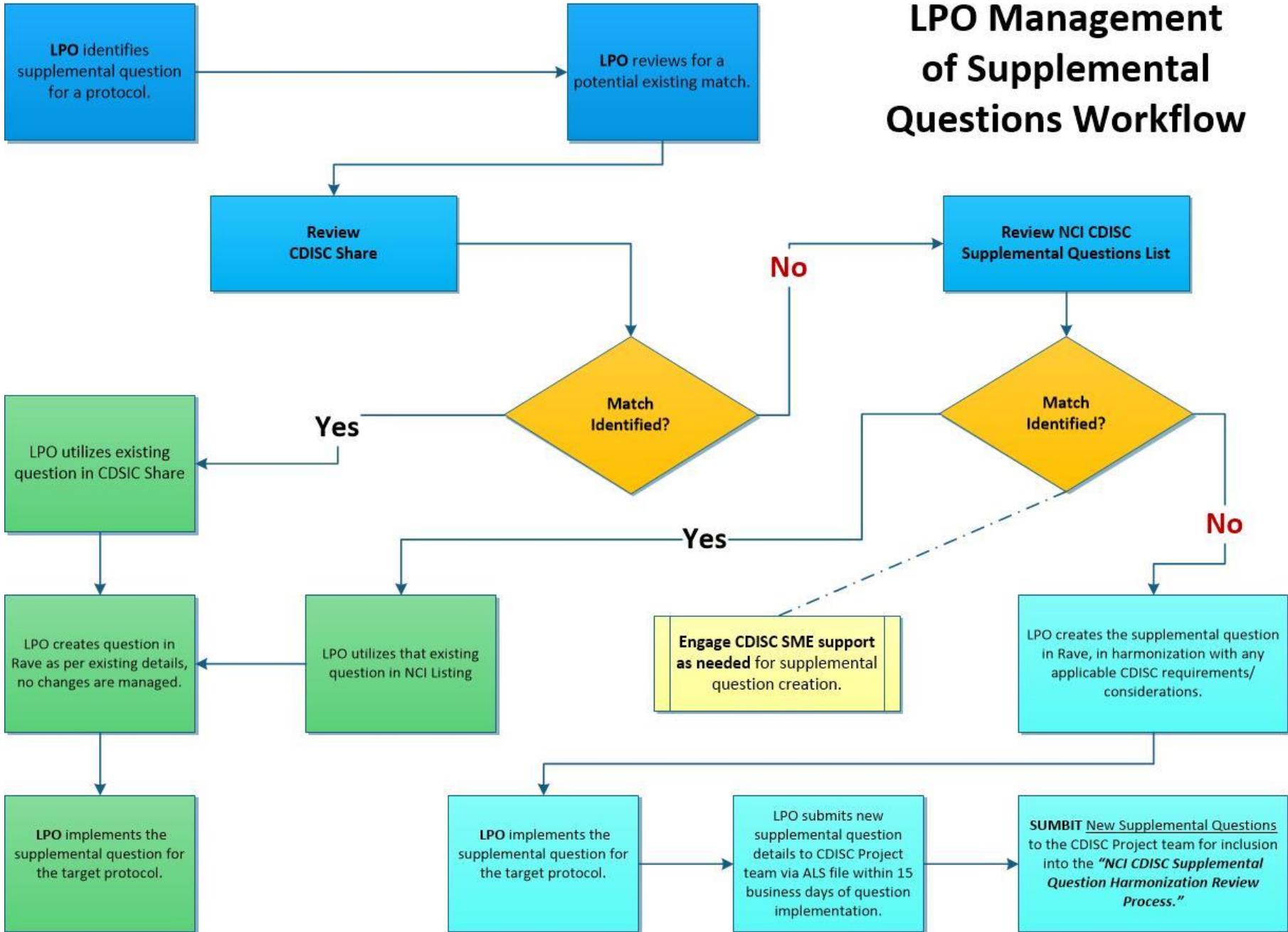
    - CTSU will update global library based on feedback

Next Steps

- Next Meeting is March 27th, 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

LPO identifies supplemental question for a protocol. → **LPO** reviews for a potential existing match.

Review CDISC Share

Match Identified?

No → Review NCI CDISC Supplemental Questions List

Yes → LPO utilizes existing question in CDSIC Share

LPO creates question in Rave as per existing details, no changes are managed.

LPO implements the supplemental question for the target protocol.

LPO utilizes that existing question in NCI Listing

Match Identified?

Yes

No

Engage CDISC SME support as needed for supplemental question creation.

LPO creates the supplemental question in Rave, in harmonization with any applicable CDISC requirements/ considerations.

LPO implements the supplemental question for the target protocol.

LPO submits new supplemental question details to CDISC Project team via ALS file within 15 business days of question implementation.

SUMBIT New Supplemental Questions to the CDISC Project team for inclusion into the *"NCI CDISC Supplemental Question Harmonization Review Process."*

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