

CDISC Implementation Committee

Neesha Desai

Agenda

- NCI Requirement
- Review Timeline
- CDISC Harmonization WG
- CDISC Mapping Support
- CDISC LPO Support

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.

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		

Milestone	Date	Responsibility
Identify and finalize the CDISC SHARE files for curation activities.	Completed	CBIIT
Curate CDASH Domain in caDSR.	Completed	CBIIT
Build CDASH Domain forms in the caDSR FormBuilder.	Completed	CTSU
Import caDSR CDASH Domain Forms into Rave via the OCI.	12/10/18	CTSU
Build Rave GLIB.	January 2019	CTSU
Update CTEP-AERS per CDISC requirements	*in parallel with CTSU activities	CTIS
Create CDISC Rave Global Library (GLIB) ALS.	February 15, 2019	CTSU
Perform compliance review on the CDISC Rave GLIB ALS.	Feb 22 nd , 2019	CDSIC PM
Beta Release CDISC-compliant OPEN ALS v7.0. *Timeline dependent on CDISC SME Support	March 31 st , 2019	CTSU CDSIC PM
Beta Release CDISC-compliant Rave-CTEP-AERS Integration ALS v4.0. *Timeline dependent on CDISC SME Support	March 31 st , 2019	CDSIC PM
Perform CDISC Rave GLIB Impact Analysis.	March/April 2019	LPO
Manage IA updates to CDISC Rave GLIB.	April/May 2019	CTSU
Release CDISC Rave GLIB ALS to LPOs. Build Seed Study in collaboration with CDISC SME	Jul 2019	CTSU, CTSU, CDISC PM
Per NCI: All Groups to use CDISC Standards on all studies. *All CTEP IND Trials	January 2020	LPOs

Project Updates

- **CDISC Harmonization Working Group**

- **Purpose:** To harmonize and get approval on supplemental questions requested by the LPOs with CDISC and package to send for CDISC standards.

- **Expectations:** Meet quarterly based on supplemental questions request

- **Members:**

- NCI Federal Lead: Barry Goldspiel

- NCI Project Manager: Neesha Desai

- CTSU: Ginger Riley

- CBIT: Brenda Duggan

- CDISC SME: Shannon Labout

- LPOs: 1 representative from each LPO

- **CDISC Mailbox**

- ncicdiscsupport@nih.gov – Pending

- **CDISC Wiki**

- In progress

Project Updates

- **CDISC LPO Support for data mapping**

- **Purpose:** To provide support to the LPOs for mapping their supplemental questions to CDISC
- **Expectations:** Meet as needed
- **Resources:**
 - NCI Federal Lead: Barry Goldspiel
 - NCI Project Manager: Neesha Desai
 - CTSU: Ginger Riley
 - CBIIT: Brenda Duggan
 - CDISC SME: Shannon Labout
 - LPOs

Project Updates

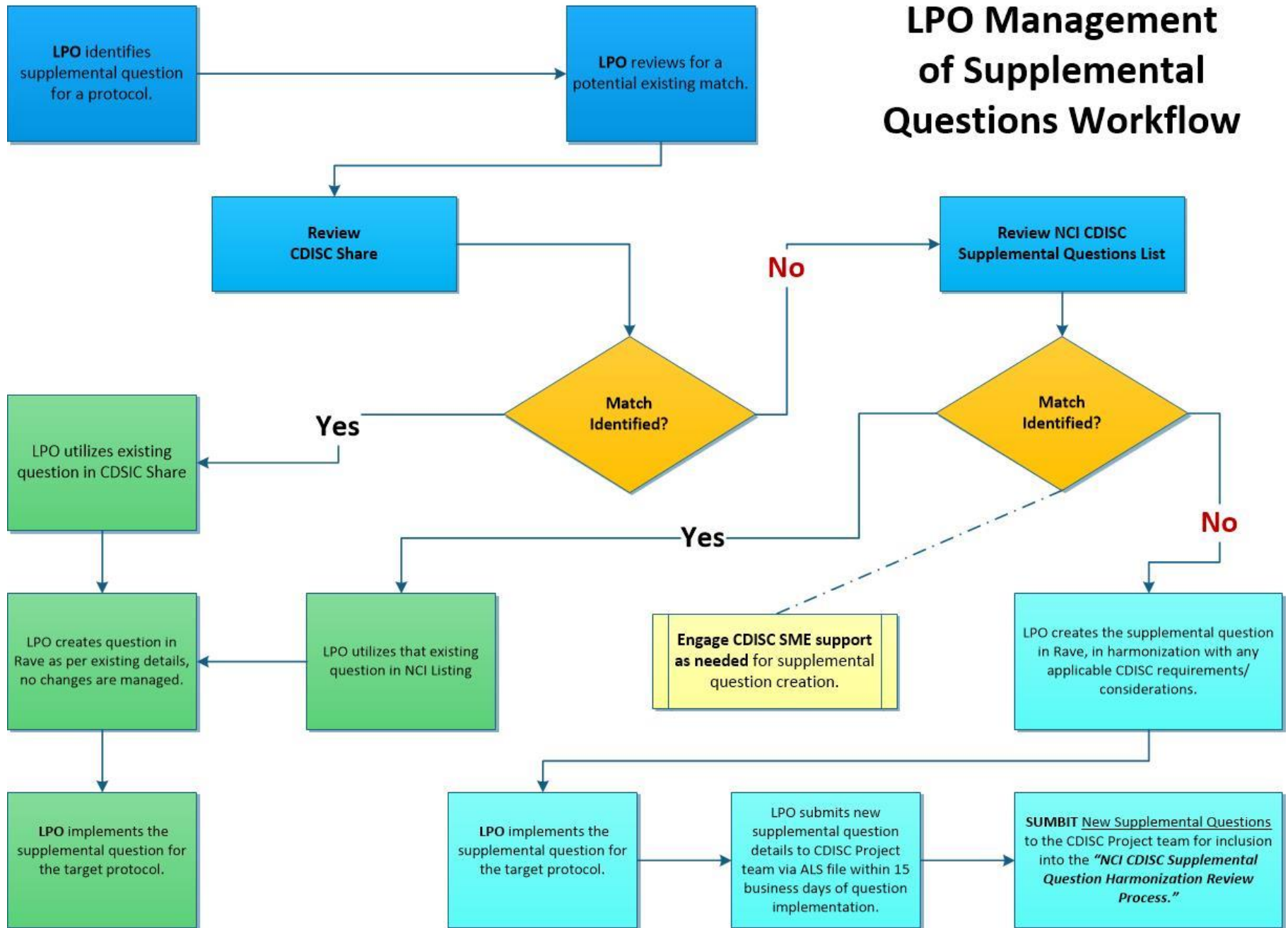
- **CDISC LPO Support for Implementation**

- **Purpose:** To provide support to the LPOs on the CDISC implementation.
- **Expectations:** Meet as needed
- Sent out an email requesting preliminary types of support and timeframes
 - Implementation
 - Training
 - Site Visit
- Goal is to schedule webinars with focused agendas to support the LPOs.

Next Steps

- Next Meeting is February 27th, 2019

LPO Management of Supplemental Questions Workflow





**NATIONAL
CANCER
INSTITUTE**

www.cancer.gov

www.cancer.gov/espanol