CDISC Implementation Committee

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April 24th, 2019

Agenda

- NCI Requirement
- Project Updates
- LPO Status Updates
- LPO Support Questions
- LPO Impact Analysis Review
- CBIIT Presentation
  - Curation support/ process for eligibility criteria
- Project Timeline

NCI Requirement

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

Project Updates *(1)*

- **CDISC Mailbox**
  - ncicdiscsupport@nih.gov

- **CDISC Wiki**
  - Ongoing NCI maintenance (project updates pending)
  - Project updates will be communicated via the NCI CDISC Support mailbox

Project Updates *(2)*

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

Project Updates *(3)*

- **LPO Support Webinars/Sessions**
  - May 3rd **"Using QRS Supplements"**
    - Session 1: 10- 11:30am ET
    - Session 2: 3- 4:30pm ET
  - May 10th CDISC SME Session
    - Confirmed agenda items
  - May 22nd **"Overview of FDA Submission Process"**
    - Session 1: 10- 11:30am ET
    - Session 2: 3- 4:30pm ET

Project Updates *(4)*

- **LPO Support Webinars/Sessions**
  - May 24th CDISC SME Session
    - Confirmed agenda items
  - May 28th **"CDASH/ SDTM/ ADaM"**
    - Session 1: 10- 11:30am ET
    - Session 2: 3- 4:30pm ET

Project Updates *(5)*

- **Rescheduled LPO Support Webinars**
  - July 9th* **"Validating Submission Data"**
    - Session 1: 10- 11:30am ET
    - Session 2: 3- 4:30pm ET
    - Learning Objectives:
      - Explain the use of validation tools to support FDA submissions
      - Review different sources for validation rules on which the validation tools are based
      - Good practices for reviewing and dispositioning validation report results
      - Prepare a Study/Analysis Data Reviewer's Guide
      - Understand what validation tools can and cannot do

    **Originally scheduled for May 14th 2019*

Project Updates *(6)*

- **Rescheduled LPO Support Webinars**
  - July 10th* **"Using Therapeutic Area User Guides"**
    - Session 1: 10- 11:30am ET
    - Session 2: 3- 4:30pm ET

    **Originally scheduled May 17th 2019*

LPO Status Updates

NCI/Group	Status	Beta Release IA: GLIB	Beta Release IA: CTSU Standard Forms
Alliance	Initial planning phase Discussing internally with IT staff, resourcing and prioritization, evaluating the next beta release	<Submitted>	
Theradex	Planning phase Waiting for tools; DMU is ready for CDISC implementation	<Submitted>	
NRG	Rolling out using CDISC from start to finish; Initial planning phase – Near completion of content for study build, next step to go to the global library and do a comparison on global library	May not be able to submit comments due to other activities	
SWOG	Initial planning phase Made change to standard forms to try CDASH		
ECOG-ACRIN	Started internal WG that includes study builders, programmers and stats, working on building simple forms, assessing and evaluating the standard forms ALS	Did not submit, not far enough along	
CCTG	Started an internal WG with stats, programmers. Going through GLIB, domain by domain. Started the CDISC CRFs, running into questions for custom data fields.	<Submitted>	
COG	Initial planning phase	Not far enough to go through the GLIB	

LPO Support Questions

LPO Question	LPO Feedback	NCI Answer
Can we be provided a copy of the CDISC SDTM Metadata?		NCI cannot provide the SDTM Metadata, it is a CDISC Member's only document.
I have a piece of general feedback that came out of the variables training session today. I like the pattern that Shannon described for variables and I think it would make a lot of sense to adopt that type of pattern in building our forms. The ALS that we were given does not follow this pattern, however, I think it would be easy enough for us to add the additional descriptors while creating our template study.	What do LPOs think about this? Would this be a benefit, if so what would they be? ECOG-ACRIN (Melinda) – 100% support this (all the forms) Alliance – Agrees that we use the pattern (all the forms) Theradex – Agrees – We should follow same pattern NRG - Agrees	
The concern I have is more about the AE forms, which I think are supposed to be provided to us next week. On those forms, we have to use them as they are provided and cannot change the variables. Would CTEP consider using this pattern on those forms? The AE domain is a critical piece of the SDTM and it would be a shame to have a pattern that works for everything else but have to do something completely different just for that form. Could be worth a discussion to see if all the groups agree on using that pattern for variables.		

LPO Impact Analysis: Beta Release GLIB *(1)*

#	Document	LPO Findings/ Recommendations/ Questions	Decision
1	GLIB ALS	04/18/2019: I'm assuming a new release of the Controlled Terminology (CT) will be released prior to July. I wanted to confirm the final ALS release will contain the most up-to-date information. KL With the final release in July, will the GLIB and other ALS files be updated using the newest CDASH and SDTM controlled terminology packages?	CTSU will do an impact analysis (for CT Packages released by CDISC before July 2019) to understand the potential impact to our timeline. The intent it to provide documents as current as possible to CDISC releases/ updates; this must be done in consideration of the implementation timelines.
2	GLIB Release Notes: Section 3.2 Standard Conventions – Table 6	This table states that we cannot modify the Field OID. However, on the Variable Naming NVS webinar (3/28), Shannon presented several instances where it is expected and best practice to rename field OIDs in Rave for data collection purposes. In addition, the guide provides examples in 6.3 where it is OK/expected to change the field OIDs thus conflicting with the table. Please confirm Table 6 will be updated to reflect this.	Pending discussion with LPOs during the Committee call. • Domain names are already part of OIDS, recommend using it as is but need to understand why the groups want to do this. We need to know the rationale from the Alliance on their request and need to check with other LPOs on their thoughts for this request. • Alliance – If we want to capture height, Shannon gave how to name it with domains, OIDS, but does not provide how we would collect that in Rave in a meaningful way for our sites • Theradex - Vital signs forms, need to differentiate your results in Rave. • Follow up with Shannon to get additional details, offline discussion
3	GLIB Release Notes: Section 3.2 Standard Conventions – Table 7	Given the needed updates to the Field OID to be specific (see situations/comment from 2), the SAS label should be modified for Rave data collection to ensure our programmers using CDASH Rave outputs can correctly identify the fields using the OIDs and Labels. Therefore, the SAS Label should be allowed to be modified when the Form OID is changed. (When data is transformed into SDTM format, the SAS Label can also be updated)	Maintain the same SAS label as in the CDISC GLIB for consistency across LPOs. Include this on the offline discussion
4	GLIB ALS	In the ALS, the Field name is the Variable Label + PID. Why the Variable Label? At the Alliance, we find having the Field Name match the Field OID + PID is much easier for specification writing, debugging and general viewing. (Medidata help guides state that in most cases, the Field name is the same as the Field OID.) As far as we understand, the Field Name isn't used for anything site facing or outputs. If the global ALS will not be changed, can the Alliance modify this?	Pending further discussion with NCI/ CBIIT. Alliance: When you are writing edit checks in Rave, the drop down displays the field name and if it's generic, it's hard to understand what it actually means to grab the correct field. ECOG-ACRIN - Agree

LPO Impact Analysis: Beta Release GLIB *(2)*

#	Document	LPO Findings/ Recommendations/ Questions	Decision
5	GLIB Release Notes: Table 6	For the User Data String, Table 6 states we must use the NCI Preferred term. However, CDISC training has stated we can use the NCI Preferred Term or CDISC Synonym. Please clarify which is correct.	LPOs can decide to use the NCI Preferred Term or the CDISC Synonym for the User Data String in Rave. If LPOs decide to use the CDISC Synonym instead of the NCI Preferred Term, they will be responsible for related study build activities and mapping activities for SDTM submission. The 'CDISC GLIB Release Notes' document will be updated to provide details for use of the CDSIC Synonym versus the NCI Preferred Term. The CDISC GLIB ALS will remain as is, no changes will be made to the User Data String and NCI Preferred Terms.
6	GLIB ALS	Why is the Data Dictionary Name not modifiable? Some dictionaries will be used across several fields; however, different sub-sets of responses will be needed for the questions. i. Rave does not allow us to subset the dictionary choices at the field level – a separate dictionary must be created ii. Example: NY. Sometimes Unknown or Not Applicable are not valid responses for a question iii. The Alliance would be open to a standard naming convention in this situation.	LPOs should use a standard naming convention of an appended integer (e.g., NY1, NY2, NY3) when subsetting. No changes will be made to the CDISC GLIB ALS. The CDISC GLIB Release Notes will be updated to include this naming convention for subsetted dictionary names. Ensure format does not begin or end with a number Alliance doesn't use OCI – so will not append automatically, add this information into the release notes
7	GLIB ALS	When the GLIB is updated/versioned, can we get a detailed change log with the future releases?	A change log will be provided in the release notes for each updated GLIB release.

LPO Impact Analysis: Beta Release GLIB *(3)*

#	Document	LPO Findings/ Recommendations/ Questions	Decision
8	NCI/CDISC Best Practices Document	04/18/2019: In this section, it talked about all of these documents needed to be provided. I'm curious if there is any guidance to expected/required format and/or the level that we have to have prepared for CTEP-IND trials. We do not submit data directly to the FDA; I'm curious if we have to have annotated CRFs, and all these other documents that are listed for all trials. And if the trial has intent to submit to FDA, can we negotiate with our pharma partner on these. KL Section 4.3: What does this mean for us as LPO's? We are not translating all of these statements into what actions need to be done on Alliance trials. (Maybe the training is still coming?)	All CTEP IND studies activated on/after 1/1/2020 must be CDISC compliant. CDISC Compliance is highly recommended for studies that activate prior to the 2020 date. The CDISC SME will provide additional feedback at the "Overview of FDA Submission Process" Webinar on May 22nd, 2019. *Flagged as an agenda item
9	NCI/CDISC Best Practices Document	Could a real life example/demo of the described best practices for the Eligibility Checklist Forms be provided? We're not following the workflows, when to curate/not curate, etc.	The CBIIT caDSR team is presenting an overview of the curation support/ process for eligibility criteria at the April Committee Meeting. NOTE: It may be that some LPOs are not familiar with the established process due to curating their own content versus the CBIIT caDSR curating it for them.
10	NCI/CDISC Best Practices Document	Does NCI/CTEP submit data to FDA on NCTN trials? If so, study by study or aggregated across studies?	No decision required, NCI does not submit to the FDA.
11	NCI/CDISC Best Practices Document	Throughout the entire document, please be specific what CDISC compliant means. CDASH, SDTM, ADaM, etc. a. Additionally, our understanding from previous meetings is that the requirement is to be CDASH compliant only. We understood that it is up to the LPOs discretion and negotiations with the Pharma partner on SDTM programming. Please be specific in the document about whether we are referring to CDISC-CDASH or CDISC-SDTM.	The FDA requirement is SDTM. the NCI requirement is CDASH. CDASH compliance makes SDTM compliance easier to achieve. CDISC PM to review and update the NCI CDISC Best Practices document as needed to ensure clear communication of the NCI requirement for CDASH compliance.

CDISC Implementation Timeline

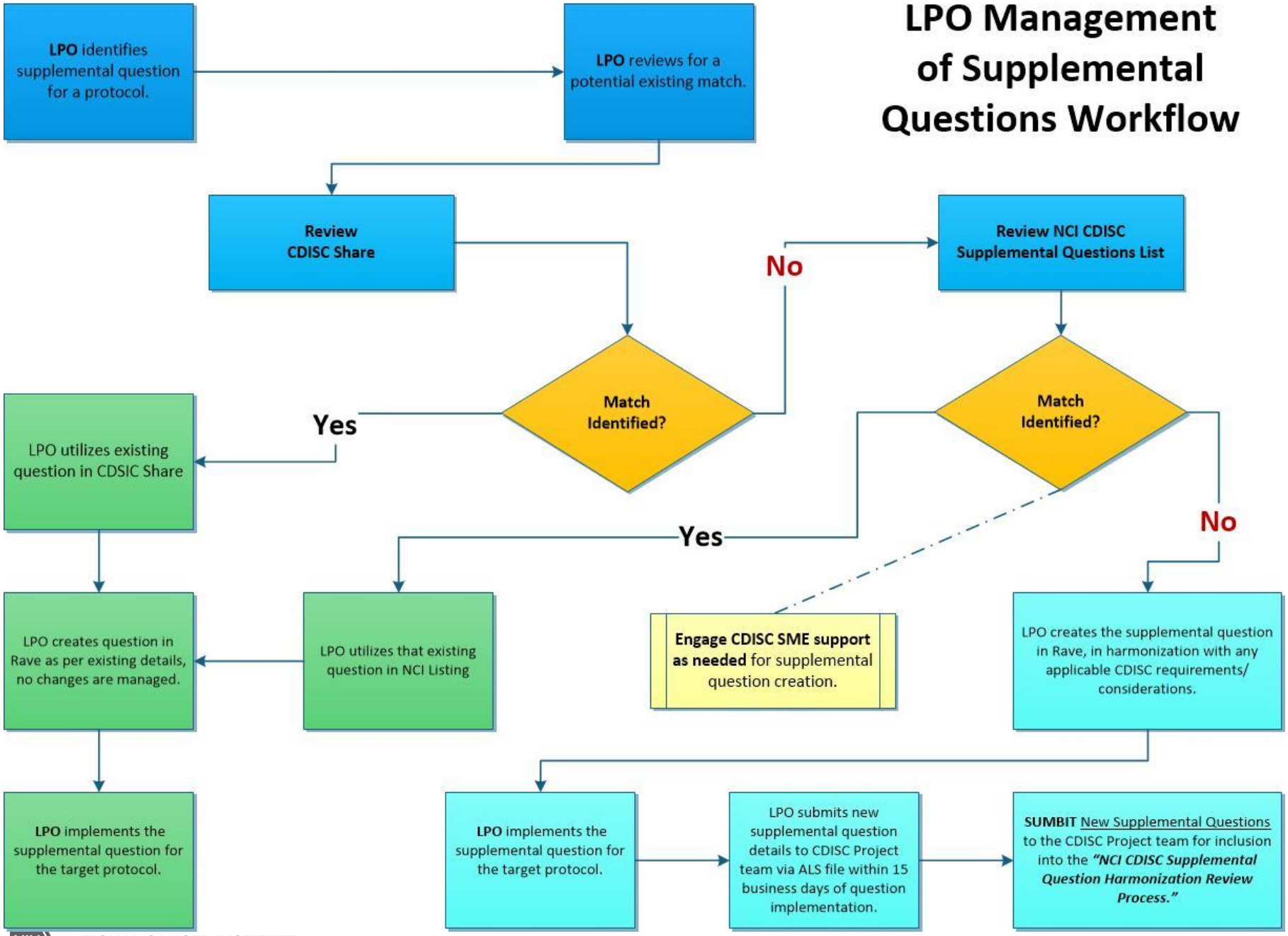
Milestone	Completion Date
CDISC Rave GLIB ALS	
✓ 1) Created Beta ALS	February 15, 2019
✓ 2) Completed Internal Compliance review on Beta ALS	February 27, 2019
✓ 3) Released Beta ALS to LPOs	March 5, 2019
4) Complete Impact Analysis **LPOs**	**April 2, 2019**
5) Manage Impact Analysis updates	May 17, 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**	May 13, 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 CTEP IND Trials*	**January 1, 2020**

Next Steps

- Next Meeting is May 22nd, 2019
- Send email to ncicdiscsupport@nih.gov for 1 representative and 1 back up representative for CDISC Harmonization WG

CBIIT Presentation

LPO Management of Supplemental Questions Workflow



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