

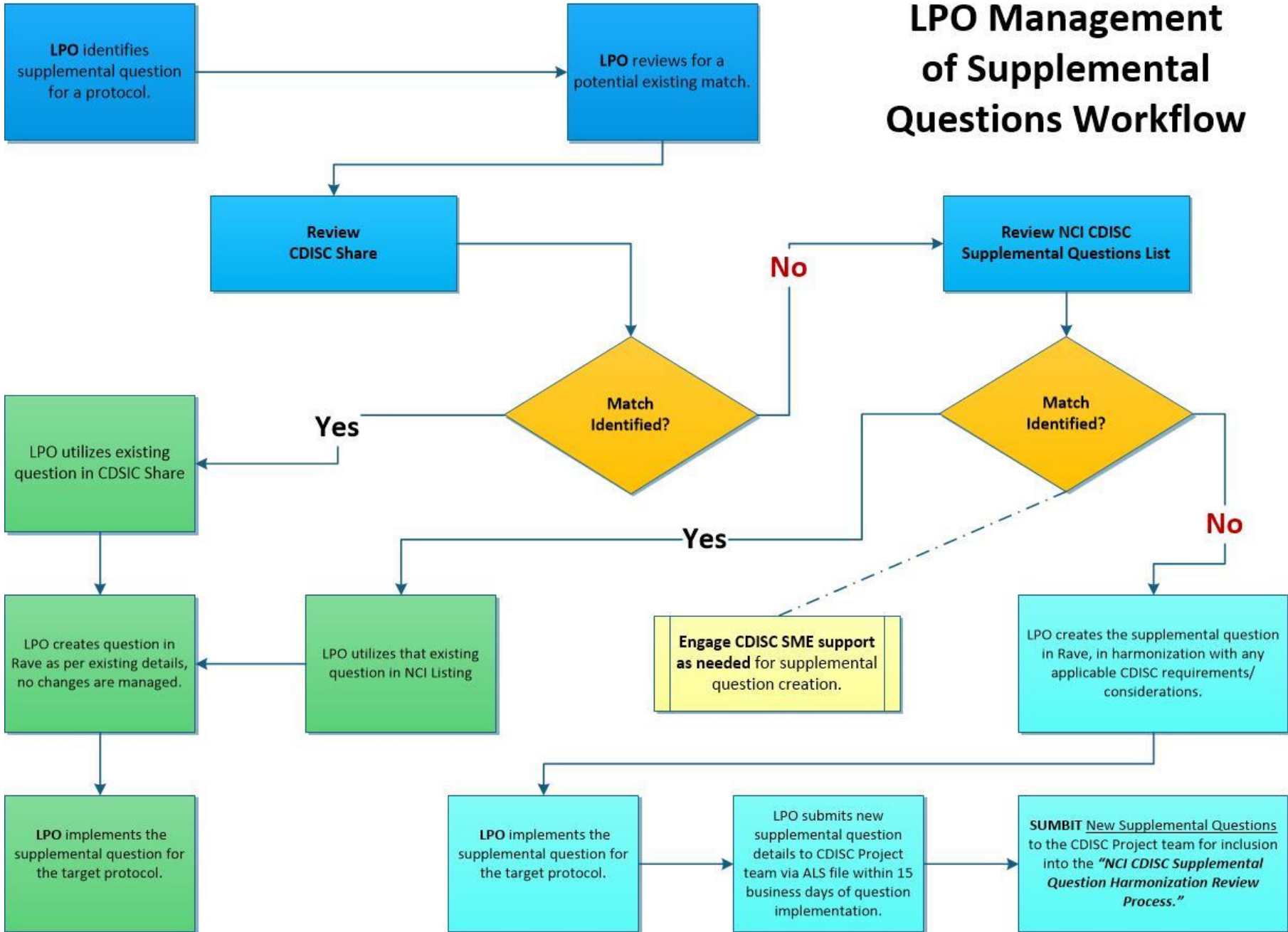
NCI CDISC Harmonization Working Group

Neesha Desai

Agenda

- Review Alternate Question Text Workflow
- LPO Discussion Items
- RECIST Discussion

LPO Management of Supplemental Questions Workflow



LPO Discussion Items

- **“PRO” Fragment**

- PRO is being used for PROTOCOL
 - Could be confused with Patient Reported Outcomes
 - **PROT**

- **How can we access the library of available CDASH compliant questions?**

- The Global Library includes all of the available CDASH-conformant questions from CDASHIG V2.0 and SDTMIG V3.3.
- Refer also to the GLIB ALS Release Notes at the top of page 10 in the Comments/Instructions for creating compliant questions for tests that have CDISC terminology published for Test Codes and Test Names.

- **Are we able to modify permissible values for existing CDASH compliant questions?**

- You can modify response values in three ways:
 - CDASH allows the use of synonyms to display questions on the EDC form. The value that is stored in the database should always conform to the published CDISC Submission Values.
 - If you only need a subset of the values from the data dictionary, you can subset the list to include only those values that you need for the study.
 - If the relevant CDISC codelist is Extensible, you can add values (provided the ones your add are not synonymous with already published values in that codelist)

Next Steps

- **Next Meeting**
 - October 7th, 2019
- Continue reviewing content

CDISC Harmonization WG Roadmap

