

NCI CDISC Harmonization Working Group

Neesha Desai

Agenda

- NCI CDISC Harmonization WG Overview
- NCI CDISC Communication Plan
- CDISC Harmonization WG Roadmap
- LPO Discussion

NCI CDISC Harmonization WG

Purpose

- To harmonize non-standard CDISC content into draft CDISC standards across the NCTN/ETCTN and submit to CDISC for standardization.

Working Group Activities

- Review the proposed roadmap and prioritize the content for CDISC harmonization.
- Work collaboratively with WG members to harmonize the non-standard CDISC content across the NCTN/ETCTN.
- Vet the harmonized content for proposal to CDISC.
- Provide content for CDISC harmonization.

NCI CDISC Harmonization WG

Deliverables

- Prioritized list of content for CDISC Harmonization
- Spreadsheet of proposed CDISC content to use across the LPOs
- Best practices used during harmonization efforts

Working Group Expectations

- Each member represents an organization
- Meet goals and deliverables of the workgroup
- Value the input from each attendee
- Maintain an energetic and courteous environment
- Active participation
- Achieve consensus at each decision point
- Advance notification of meeting absence

NCI CDISC Communication Plan Overview

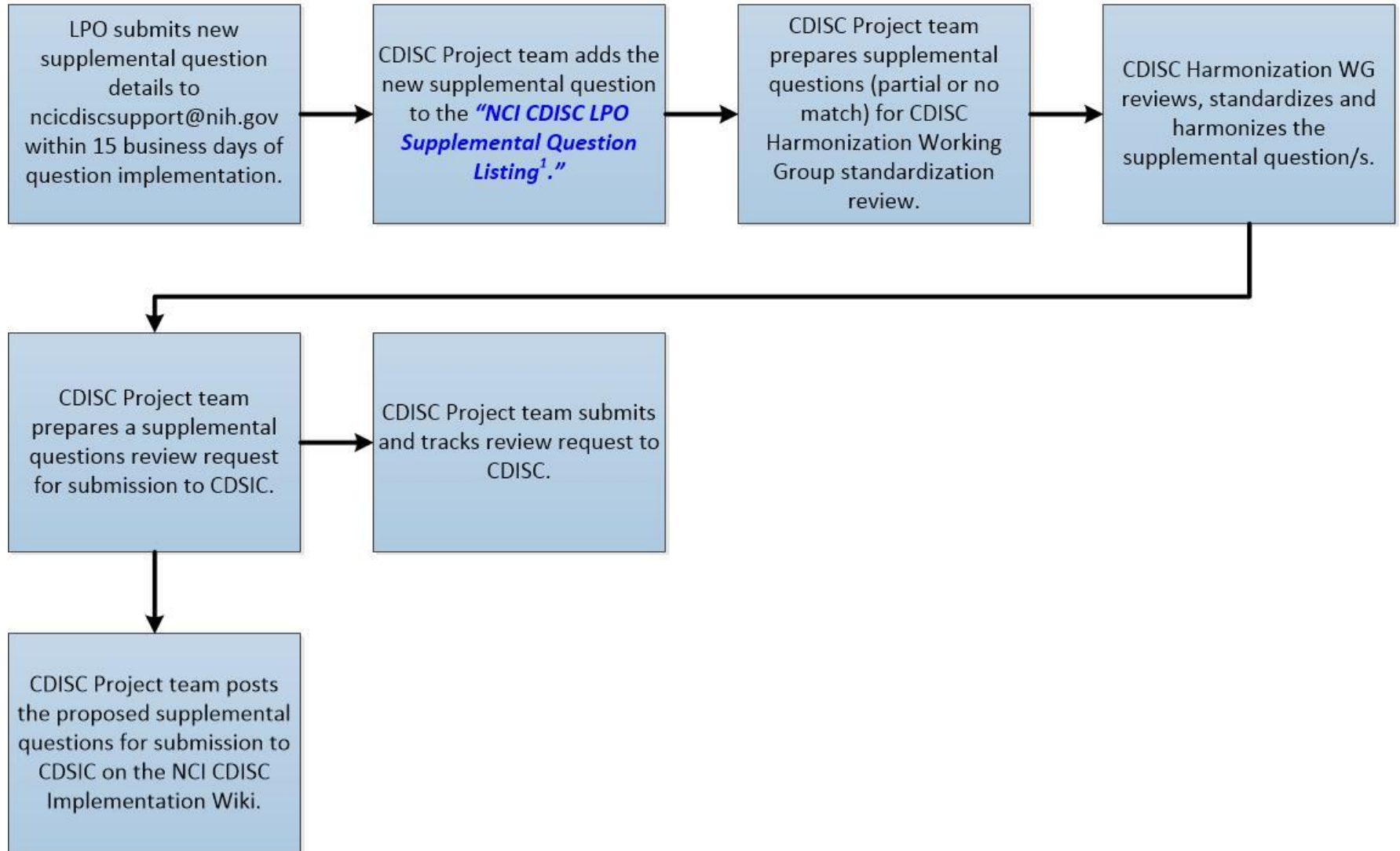
Purpose

- To provide appropriate, consistent, effective, and timely communications, applicable to all NCI CDISC Implementation Working Groups, Sub Groups and Stakeholders, for all CDISC project related activities.

Best Practices

- Email communication should include all stakeholders of the NCI CDISC Harmonization WG. [CDISC Harmonization WG Members](#)
- Working Group decisions will be posted on the NCI CDISC Wiki.
- Stakeholders will be invited to all meetings related to CDISC Harmonization with the option to decline.
- Emails will be sent out using the distribution list.

NCI CDISC Supplemental Question Harmonization Review

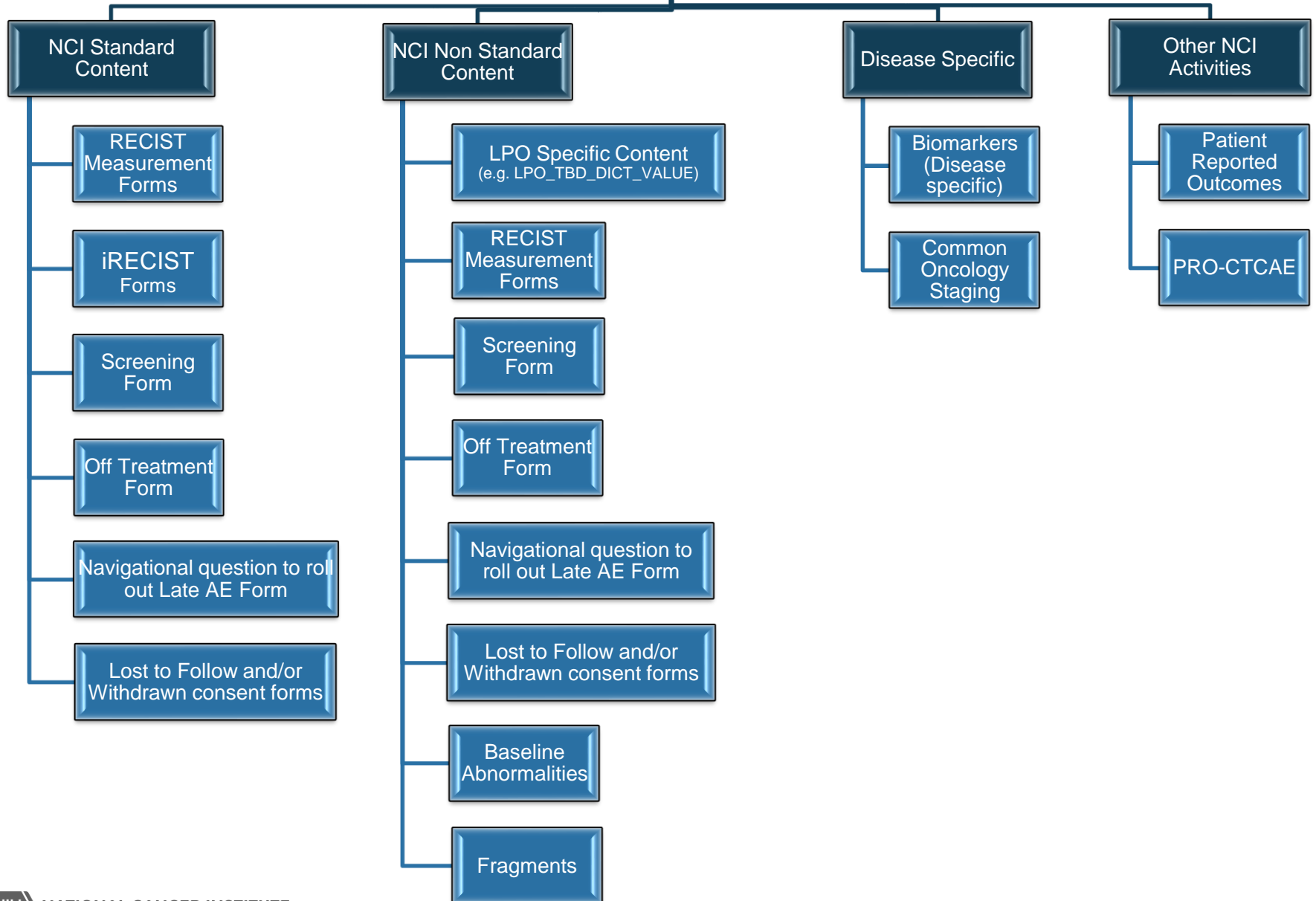


Prioritization Criteria

- **Criteria to prioritize proposed content with CDISC**
 - LPO Identified Content
 - NCI non standard content with no existing CDISC/SDTM variable
 - LPO protocol specific content
 - CBIIT Recommendations

- **Proposed Strategy**
 - Review Roadmap of proposed content to standardize
 - Prepare project plan to manage the harmonization of the content
 - Review and implement updated NRDS Voting Guidelines

CDISC Harmonization WG Roadmap



CDISC Harmonization WG Members

Group	Member	Contact Info
NRG	Deb Grant	GrantD@nrgoncology.org
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LPO Discussion

Next Steps

- **Next Meeting**

- August 26th 2019
- Review prioritization with your organizations and gap analysis
- Provide Neesha feedback by Monday August 19th
- Begin reviewing first set of content
- Verify you have access to the [NCI Implementation CDISC Wiki](#)