

Network Rave Data Standards (NRDS) Committee Kick-Off Meeting

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V2.2

Agenda

- Introductions
- Background
- Deliverables and Activities
- Organization/Logistics
- Process before/after
- Discussion Questions

BACKGROUND

How is this different from other CDE activities?

caDSR/CRF Roadmap

- Audience:
 - Entire NCI research community
- CDMS:
 - Agnostic
- Emphasis (caDSR):
 - Repository (vs. standards)
- Leadership:
 - NCI led
- Development:
 - 'Theoretical exercise'
- Implementation Plan
 - Loosely defined

NRDS

- Audience:
 - NCTN, ETCTN & NCORP (step 2)
- CDMS:
 - Rave first
- Emphasis
 - Standardization
- Leadership:
 - NCI/Network co-led
- Development:
 - Practical use
- Implementation Plan
 - Comprehensive

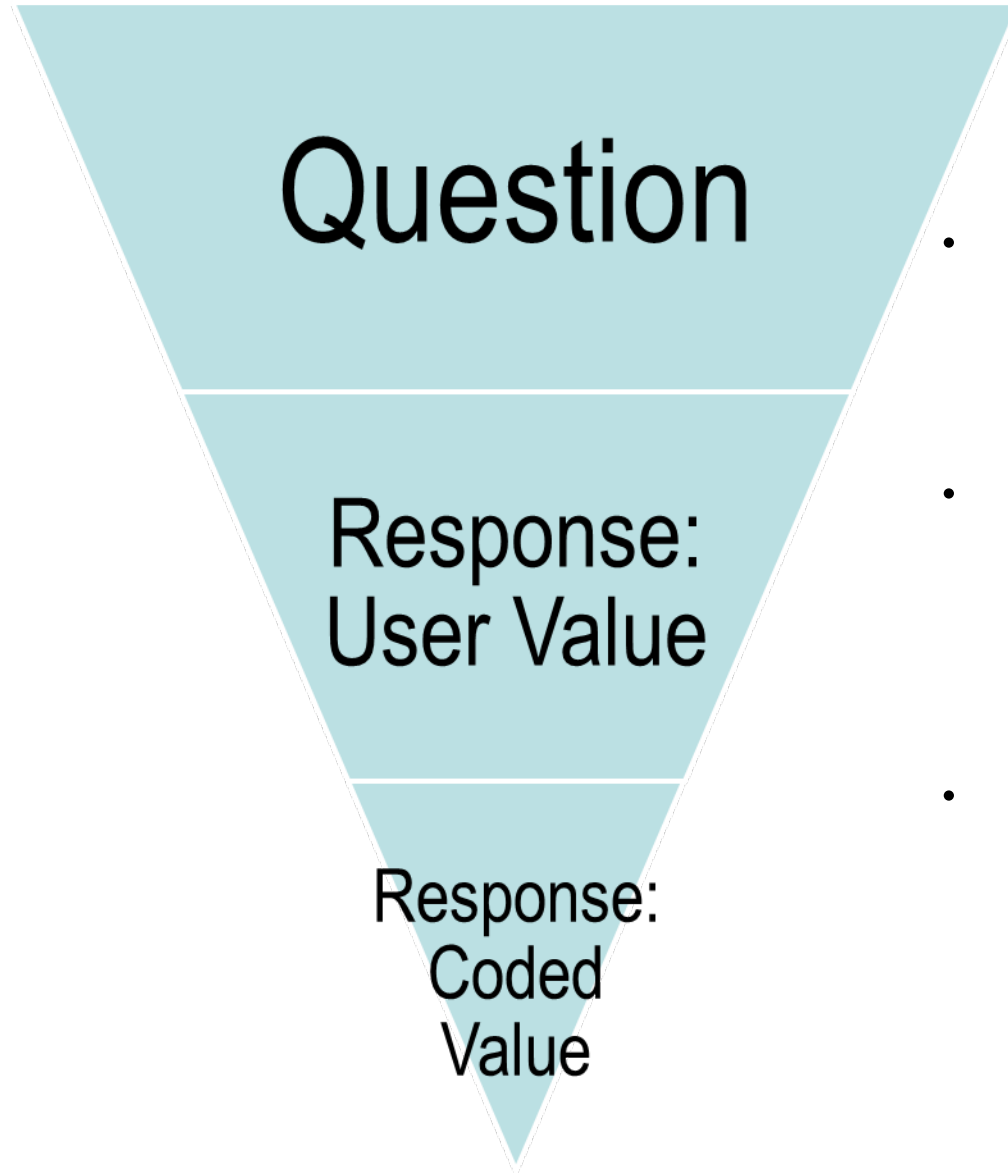
Goals and Objectives

- Goal
 - To facilitate the implementation of selected standardized Common Data Elements (CDEs) to be used in Rave to promote science, patient safety and efficiency across the NCI Networks (NCTN, ETCTN & NCORP).
- Objectives
 - Identify implementable CDE standards to be used in Rave.
 - To provide guidance on an implementation plan for the standardized CDEs.
 - Provide recommendation for long term CDE expansion, maintenance and compliance.

Benefits of Data Standards

- **Support Science**
 - Primary study
 - Re-use for Correlative studies
 - Re-use for Meta-Analysis
- **Promote patient safety**
 - Routine and serious AE reporting
- **Reduce research burden** on entire research community
 - Streamline Rave study build process
 - Simplify data entry/capture for local investigators and research staff
 - Maximize opportunity for system integration

Components of a Standardized CDEs



- If question asked:
 - Should ALWAYS be asked the same way*
- Response User Value
 - Pick list should be comprehensive BUT 'make sense' business rules allow exceptions
- Response Coded Value
 - Each User value shall be paired with a coded value (ex. No = 0).
 - Policy for utilization TBD.

Current Status of CRF Implementation

- Groups strived to implement standard CRF modules but encountered challenges.
- Agreed upon questions, but with differing answer sets, stored in different formats.
- 2013 draft policy circulated
- Sept 2014
 - NCTN Group Statisticians Response to NCI Standardization and Harmonization CRF initiative
 - *“The NCTNs agree in principle that harmonization of selected human readable content (PVMs) and coded values (PVs) is important to improve efficiency and effectiveness of clinical trial data management in order to streamline the CDMS study build process and to ensure that data can be shared across the NCTNs and with the NCI.”*
 - Taken from Dan Sargent’s presentation on caDSR Policy Proposal NCTN’s Group Statisticians’ Response)

Background

Rave

- Implementation
 - First Group Rave trials ~4/2012
 - ~160+ Rave trials
- Standardized:
 - Core Configuration
 - Business rules: ex. Data delinquency
 - Integration (ex. IAM, OPEN)
 - *CDEs/CRFs – Limited standardization*
 - *Network wide – Demography via OPEN*
 - *Group centric – Reusable CRFs with local standard CDEs, custom functions and edit checks*

DELIVERABLES AND ACTIVITIES

Deliverable and Activities

- Deliverables
 - Network Rave Data Standard Project Charter
 - Network Rave Data Standard Implementation Plan
 - Data standards
- Implementation plan will include
 - Policy
 - Roles and responsibilities
 - Define scope
 - Timelines
 - Communication plan
 - Training activities
 - Governance/Maintenance plan
 - Compliance process

Criteria to Prioritize CDEs for Standardization

- CDEs that achieve multiple benefits of data standardization (see slide #7)
- Starting with treatment trials first
 - Once process established expand to other areas (Prevention, PRO, cancer control....)
- High Use CDEs:
 - Content that applies to >80% of trials
- Responses that are applicable for large volume of questions:
 - Yes, no, unknown (Indicators)
- Common disease/therapy vs. specific disease/therapy CDEs:
 - Breast Carcinoma or NCI Breast Oncology Local Disease (BOLD)

Potential methodologies to identify NRD CDEs

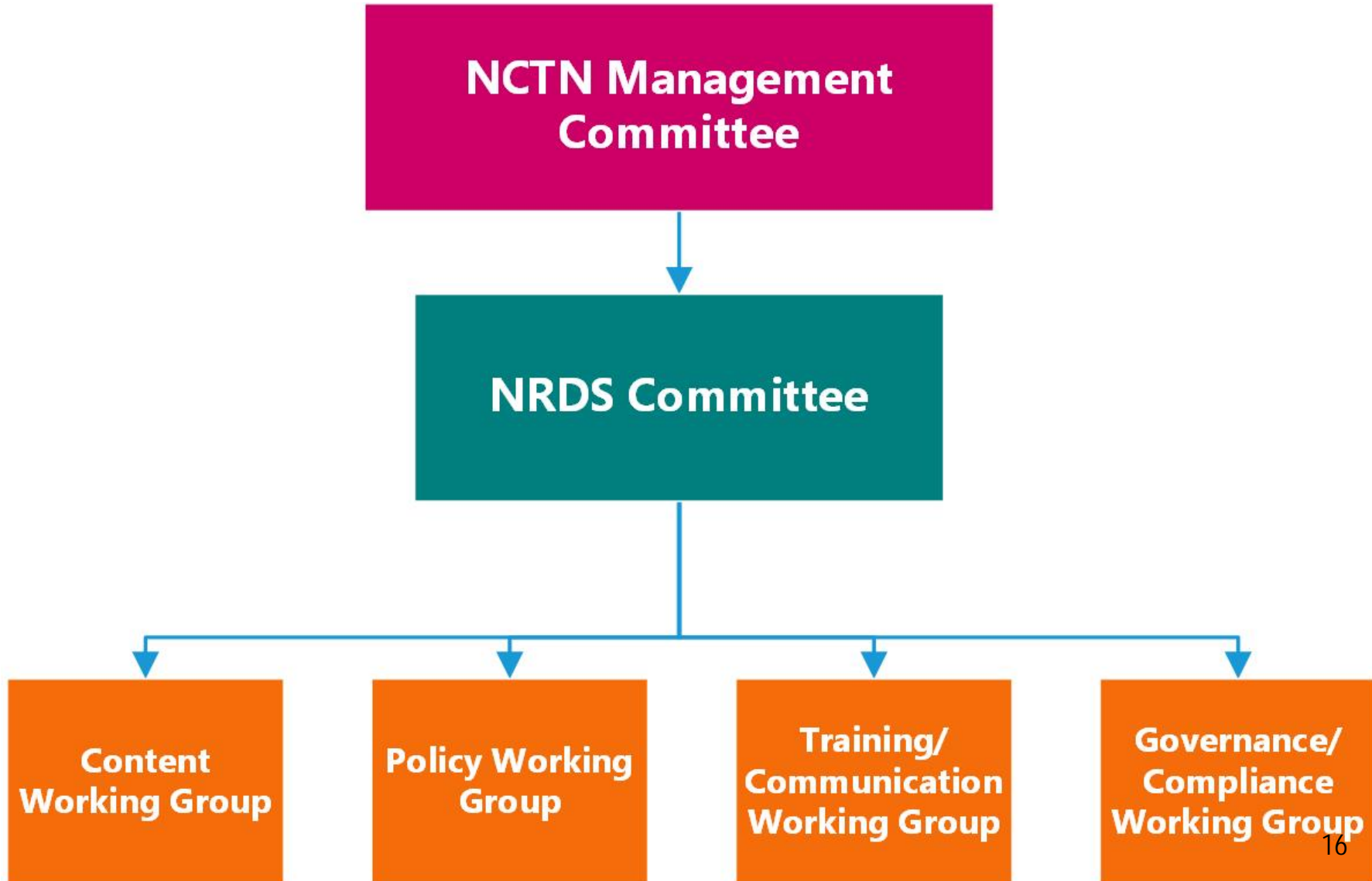
- Leverage Prior Experience
 - Rave – Previously developed reusable Rave eCRFs developed by the Network Groups and Theradex
 - CRF Roadmap
 - caDSR
 - Data Elements Working Group (DEWG)
 - Pre-Rave Phase 3 CDE Validation by EMMES
 - Disease/therapy
 - BOLD
- Data driven identification of potential CDEs – ID highest frequency:
 - Publication
 - Meta-analysis
 - Use in Rave

Misc. CDE Considerations

- Start date TBD
- Implementation will only apply to new studies
- Develop processes for new/emerging CDEs:
 - New genetic targets
 - Biomarkers
 - Precision Medicine

ORGANIZATION/LOGISTICS

Suggested Organization



NCTN Management Committee

- Standing NCTN Management Committee, comprised of NCTN and NCI leadership.
- Purpose
 - Serve as an oversight committee for the NRDS Project.
 - The NCTN Management Committee will receive periodic updates from NRDS Committee.

NRDS Committee

- Purpose
 - Participate and provide oversight to the working groups
 - Periodically report out to the NCTN Management Committee
 - Facilitate the implementation of selected CDEs in Rave
- Leadership
 - Co-Led by NCI and Network Group
 - Proposed: NCI – Montello; NCTN/ETCTN – TBD
- Representation:
 - NCTN - One representative per Network Group with alternate
 - ETCTN – Theradex plus Mayo
- Coordination/Facilitation:
 - Neesha Desai, Essex Management
- Frequency
 - Monthly
- Communication:
 - Meetings will be set up via Webex.
 - Agendas, minutes and presentations will be posted on the [NRDS Committee Standards Wiki](#)

Content Working Group

- Purpose
 - Identify a set of CDEs for use in Rave by NCTN and ETCTN.
- Leadership
 - Co-Led by NCI and Network Group
 - Proposed: NCI – Dianne Reeves; NCTN/ETCTN – TBD
- Representation:
 - NCTN - One representative per Network Group
 - ETCTN – Theradex plus Mayo
 - Additional nominated representatives; send nominations to Neesha.Desai@nih.gov
- Coordination/Facilitation:
 - Neesha Desai, Essex Management
- Frequency
 - Weekly
- Communication:
 - Meetings will be set up via Webex.
 - Agendas, minutes and presentations will be posted on the [National Cancer Institute NRDS Content Wiki](#)

Policy Working Group

- Purpose
 - Identify requirements to guide decisions on the adoption and usage of the standardized CDEs by NCTN and ETCTN
- Leadership
 - Co-Led by NCI and Network Group
 - Proposed: NCI – Mike Montello; NCTN/ETCTN – TBD
- Representation:
 - NCTN - One representative per Network Group
 - ETCTN – Theradex plus Mayo
 - Additional nominated representatives; send nominations to Neesha.Desai@nih.gov
- Coordination/Facilitation:
 - Neesha Desai, Essex Management
- Frequency
 - Every 2 weeks
- Communication:
 - Meetings will be set up via Webex.
 - Agendas, minutes and presentations will be posted on the [NRDS Policy Wiki](#)

Governance/Compliance Working Group

- Purpose
 - Establish principles, responsibilities and requirements for development, maintenance and implementation of standards governance policies within NTCTN and ETCTN
- Leadership
 - Co-Led by NCI and Network Group
 - Proposed: NCI – Dianne Reeves; NCTN/ETCTN – TBD
- Representation:
 - NCTN - One representative per Network Group
 - ETCTN – Theradex plus Mayo
 - Additional nominated representatives; send nominations to Neesha.Desai@nih.gov
- Coordination/Facilitation:
 - Neesha Desai, Essex Management
- Frequency
 - Every 2 weeks
- Communication:
 - Meetings will be set up via Webex.
 - Agendas, minutes and presentations will be posted on the [NRDS Governance and Compliance Wiki](#)

Training and Communication Working Group

- Purpose
 - Outline components of a training plan
 - Define the roles and responsibilities of NRDS Committee project participants in the review, approval and dissemination of information about key project processes, events, documents and milestones
- Leadership
 - Co-Led by NCI and Network Group
 - Proposed: NCI – TBD; NCTN/ETCTN – TBD
- Representation:
 - NCTN - One representative per Network Group
 - ETCTN – Theradex plus Mayo
 - Additional nominated representatives. Send nominations to Neesha.Desai@nih.gov
- Coordination/Facilitation:
 - Neesha Desai, Essex Management
- Frequency
 - Every 2 weeks
- Communication:
 - Meetings will be set up via Webex.
 - Agendas, minutes and presentations will be posted on the [NRDS Training and Communication Wiki](#)

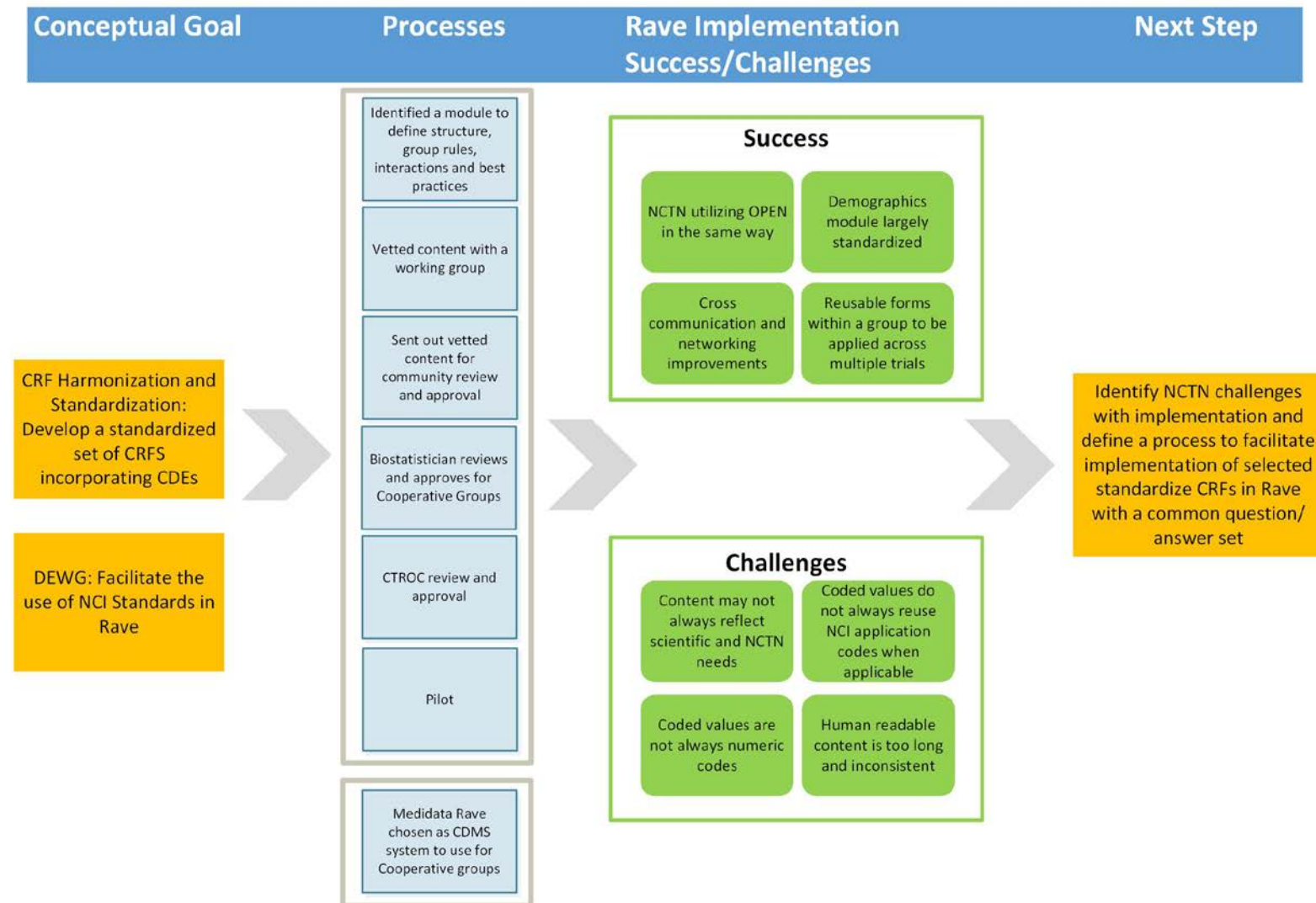
Target Timelines

- Project Charter
 - Approval: ~4/25
- Implementation Plan (timelines, policy, maintenance, compliance...)
 - Approval: ~6/15
- Content Working Group
 - Quarterly releases starting ~7/15
 - Initially proactively ID appropriate treatment CDEs to standardize
 - Modular approach similar to CRF-Roadmap
 - Once reach diminishing returns switch to other focus areas (prevention)
 - Approved CDEs will be stored on Wiki and/or Rave for access by each LPO

PROCESS

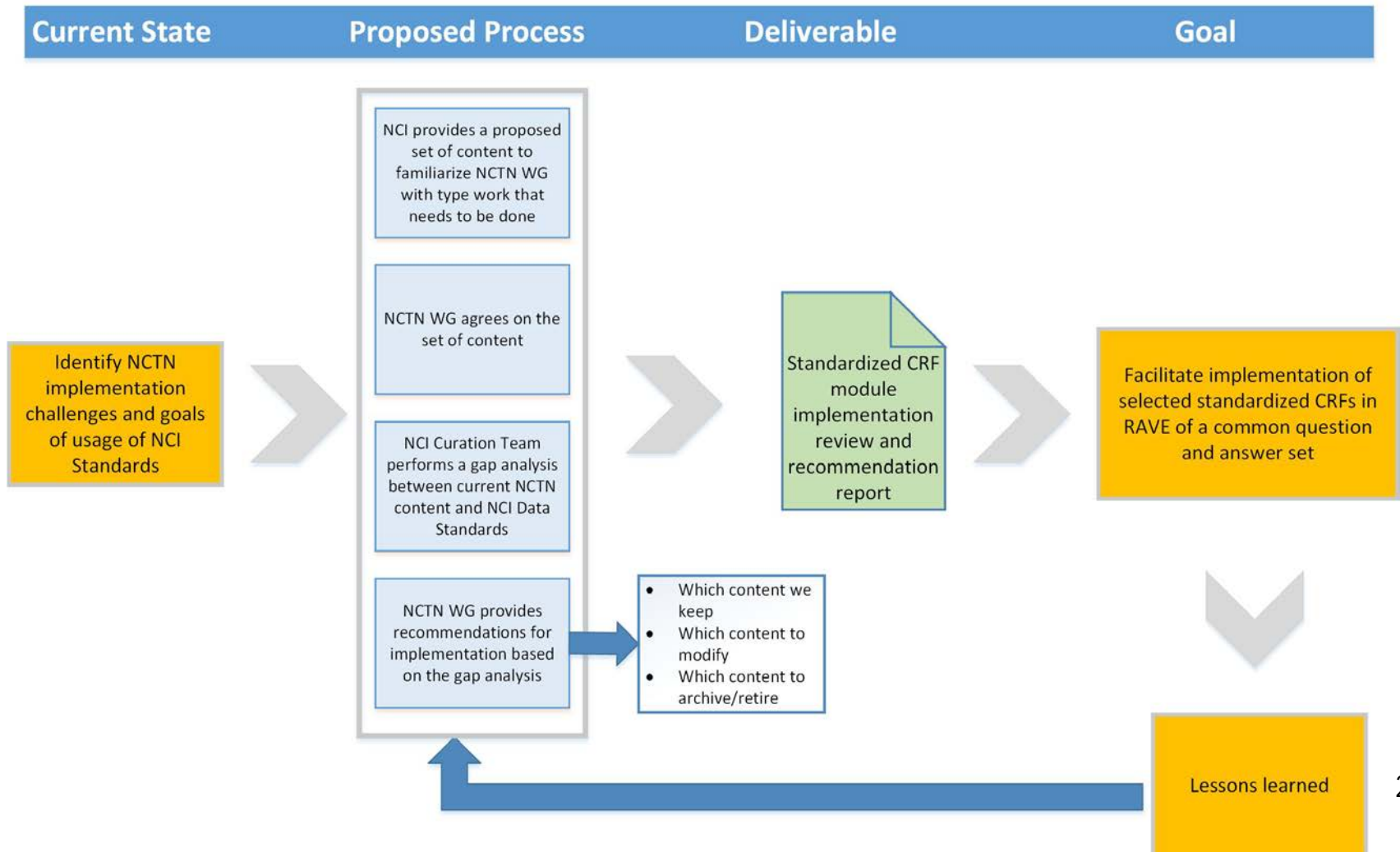
Current Methodology

Current NCI Data Standards Process



Proposed Process

Proposed NCTN Data Standards Review and Implementation Process



DISCUSSION QUESTIONS

Discussion Questions

- Proposed process
 - Collaborative effort with input from all committee members
- NRDS committee co-chair
- Working groups
 - Send nominations to Neesha Desai at neesha.Desai@nih.gov
 - Content
 - Policy
 - Training/Communication
 - Governance/Compliance