

# Network Rave Data Standards (NRDS) Content WG Kick-Off Meeting

Tina Taylor and Dianne Reeves  
April 21<sup>st</sup>, 2015

# Agenda

- Introductions
- Goals
- Deliverables
- Standardization Methodology
- Proposed Set of Content
- Logistics
- NRDS Working Groups
- Next Steps

# Working Group Members

Organization	Representative
Alliance	Shauna Hillman
Alliance	Katie Allen Ziegler
ECOG-ACRIN	Mary Vienneau
ECOG-ACRIN	Tina Taylor*
NRG	Vanita Patel
NRG	Amy Krystkiewicz
NCIC	Chad Winch
Theradex	Peter Clark

Organization	Representative
COG	Smita Subramanian
COG	Thalia Beeles
SWOG	Cathy Rankin
SWOG	Angela Smith
NCI	Mike Montello
NCI	Dianne Reeves*
NCI	Gwen Deen
NCI	Neesha Desai

# Working Group Goals

- Define a process to identify and prioritize the content that will be reviewed in the NRDS Content WG.
  - Consensus building will be used to reach agreement on content areas.
- Identify the first set of CDEs for use in Rave by NCTN and ETCTN

# Working Group Deliverables

- Identification and prioritization strategy for first set of CDEs
  - Plan is to capture decisions and all input
- NCTN/ETCTN local dictionary content based on the identified first set of CDEs
- Set of recommendations for revisions and/or new CDEs based on the gap analysis exercise.
- Inventory of NCTN/ETCTN challenges to the implementation of NCI standards (group discussion)
- First set of CDEs for use in Rave by NCTN and ETCTN
  - Provide recommendations for testing/pilot

# How is this different from other CDE activities?

## caDSR/CRF Roadmap

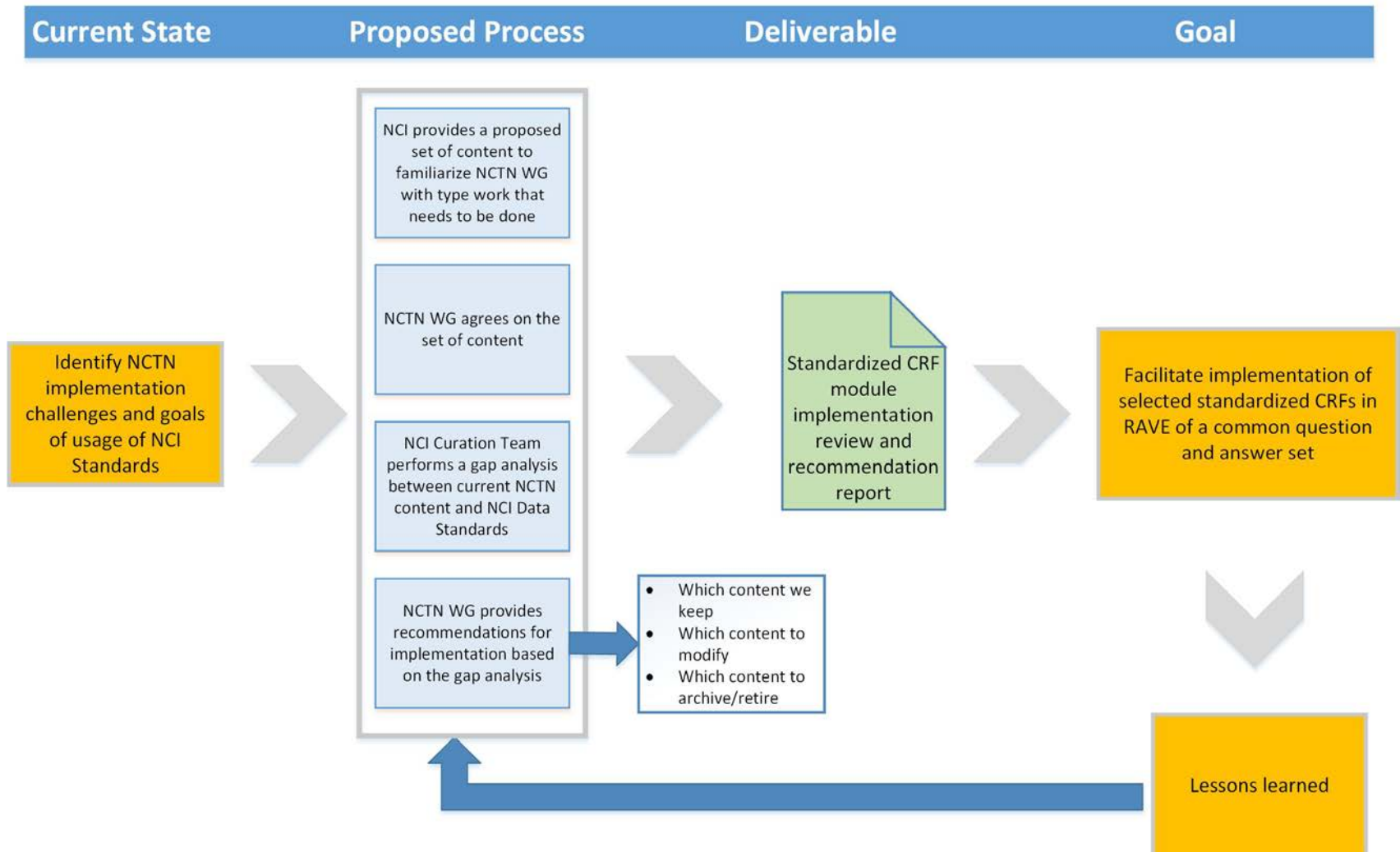
- Audience:
  - Entire NCI research community
- CDMS:
  - Agnostic
- Emphasis (caDSR):
  - Repository (vs. standards)
- Leadership:
  - NCI led
- Development:
  - 'Theoretical exercise'
- Implementation Plan
  - Loosely defined

## NRDS

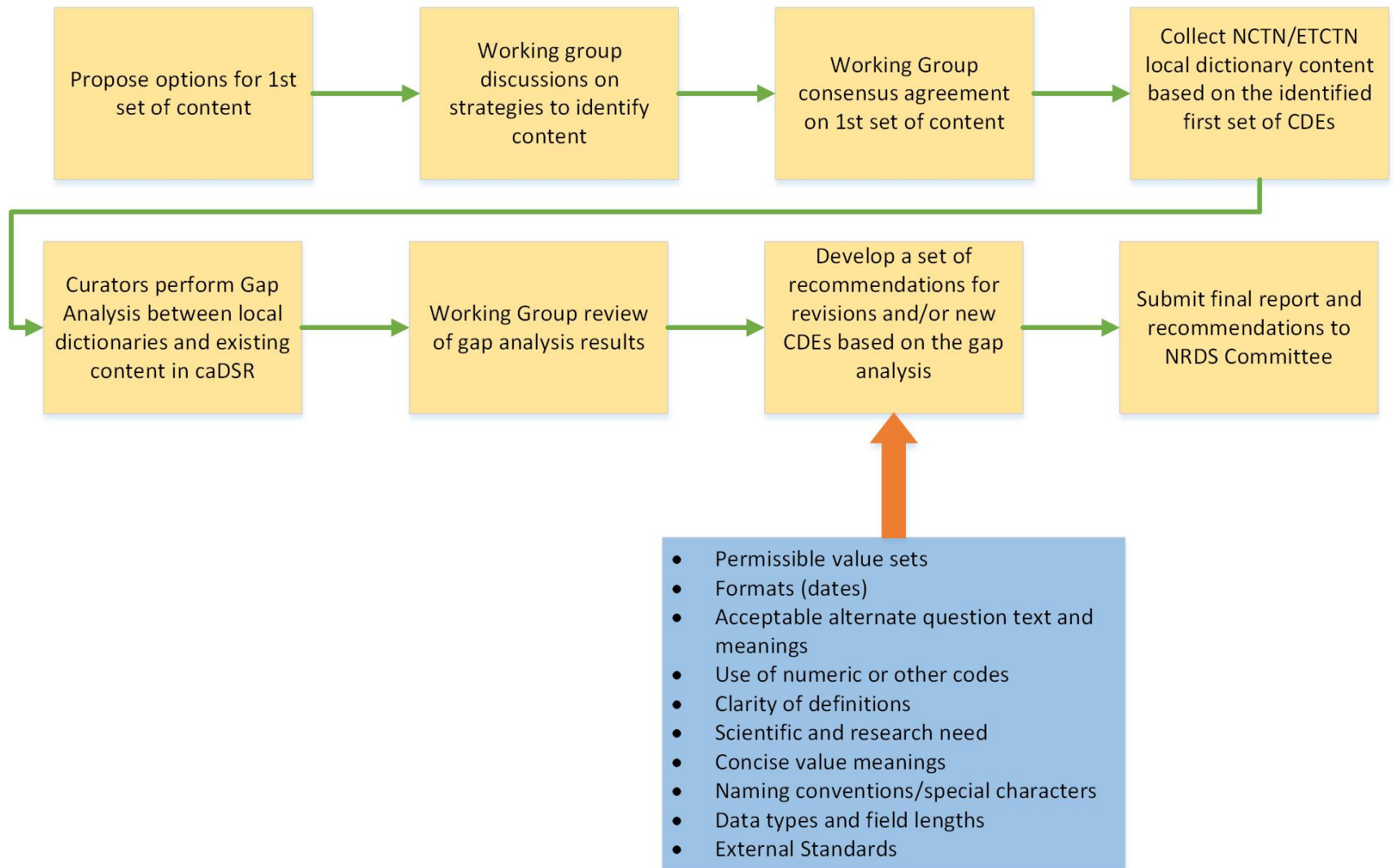
- Audience:
  - NCTN, ETCTN & NCORP (step 2)
- CDMS:
  - Rave first
- Emphasis
  - Standardization
- Leadership:
  - NCI/Network co-led
- Development:
  - Practical use
- Implementation Plan
  - Comprehensive

# Proposed Process

## Proposed NCTN Data Standards Review and Implementation Process



# NRDS Content WG CDE Identification Process





# Proposed Set of Content

- Demography Module
- Demography subset from OPEN
- Subset of Adverse Events

# Content Working Group Logistics

- Teleconference will be held weekly
- Next meeting is TBD
- Tina Taylor and Dianne Reeves will co-lead the working group activities
- Neesha Desai, CRF Project Manager, will provide project management support to complete the project
- Gwen Deen, WG Curator, will provide support in curation activities
- All documentation will be posted on the [NRDS Content WG Wiki](#)

# Content Working Group Wiki

- Access to wiki
  - <https://wiki.nci.nih.gov/display/NNRDSC/Content+Working+Group>
- Purpose
  - Provide a centralized place to manage and document Content WG activity
  - Working group lead contact and meeting information
  - Calendar of meetings
  - Working group project documentation
  - Working group rosters
- Neesha Desai will manage and maintain the wiki site

# Membership / Expectations

- 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

# Next Steps

- Review the proposed set of content
  - Identify source of changes
  - Identify types of changes needed
- Begin the discussion of NCTN/ETCTN challenges to the implementation of NCI standards
- Identify a NCTN/ETCTN co-lead for the NRDS Committee
- Identify a recurring meeting time

# Other NRDS Working Groups

- Policy and Governance Working Group Goals
  - Identify requirements to guide decisions on the adoption and usage of the standardized CDEs by NCTN and ETCTN.
  - Define an interim policy on the usage of the set of standardized CDEs
    - This policy will be completed in an iterative approach
  - Establish principles, responsibilities and requirements for development, maintenance and implementation of standards governance policies within NTCTN and ETCTN
  - Identify a process for divergence (the exception not the rule)
  - Establish compliance methodology for the use of the CDEs in Rave within NTCTN and ETCTN

# Other NRDS Working Groups

- Training and Communication Goals
  - Define the requirements and key components of a training plan for NCTN/ETCTN
    - Training for implementation of the 1<sup>st</sup> set of identified CDEs in Rave
  - 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

# Reference Information / Questions

- NCTN Co-Lead
  - Tina Taylor, Project Specialist II, American College of Radiology Imaging Network
  - [ttaylor@acr.org](mailto:ttaylor@acr.org)
- NCI Co-Lead
  - Dianne Reeves, RN, MSN Associate Director, Biomedical Standards, NCIP
  - [dianne.reeves@nih.gov](mailto:dianne.reeves@nih.gov)
- Project Management Support
  - Neesha Desai, PMP, Project Manager, NCI CBIIT
  - [Neesha.Desai@nih.gov](mailto:Neesha.Desai@nih.gov)



# 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

# 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)

# Misc. CDE Considerations

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