

# Network Rave Data Standards (NRDS) Committee

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# Agenda

- Project Status
- Policy/Governance WG Update
- Training/Communication WG Update
- Content WG Update
- Discussion Questions

# PROJECT STATUS

# Project Status

- Kicked off the following working groups
  - Content WG
  - Policy and Governance WG
  - Training and Communication WG
- Agreed to combine the Policy and Governance WG
- Working on setting up recurring meetings for each WG
- Co-leads are meeting prior to each WG meeting to plan and strategies to stay within scope of the deliverables

# POLICY/GOVERNANCE WORKING GROUP UPDATE

# Policy and Governance Working Group

- Kick off meeting 4/20/2015
- Recurring meeting: 1<sup>st</sup> and 3<sup>rd</sup> Monday of each month at 2:00pm EST
- Representation from
  - Alliance, COG, ECOG-ACRIN, NRG, SWOG
- Co-leads
  - Judi Manola (ECOG-ACRIN)
  - Mike Montello

# 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

# Policy and Governance Working Group Deliverables

- Interim policy for the 1<sup>st</sup> phase of implementation
  - List of policy guidelines to support decisions on the adoption and usage of the standardized CDEs by NCTN and ETCTN
- Timeline for adoption (phased approach)
- Governance plan including the following:
  - Set of principles for the governance framework around data maintenance and storage
    - Organizational, Trust, Business and Technical
  - Roles and responsibilities for maintenance of standards within NCTN/ETCTN
  - Development of Standard Operations Procedures (SOPs) and Best Practices
  - Define a compliance methodology for the use of the identified CDEs in Rave
  - Development the process to handle exceptions to policies (rare)



# Policy and Governance Working Group Next Steps

- Identify a list of integrations and timelines and general philosophy
  - caAERS, CDUS, Quality Portal, CDISC, etc
- Develop use cases for harmonized data
- Define what level of standardization means
  - Case Report Forms, questions, user values, coded values
  - Develop a list of pros and cons on standardizing everything for a small set of standards or just part of the standards.
- Presentation from Alliance on their global library and the policies for usage of standards

# TRAINING WORKING GROUP UPDATE

# Training and Communication Working Group

- Kick off meeting 4/21/2015
- Recurring meeting: 2<sup>nd</sup> and 4<sup>th</sup> Tuesday at 11:00am EST
- Representation from
  - COG, ECOG-ACRIN, NRG, SWOG, Theradex, Westat
- Co-leads
  - Ginger Riley (Westat)
  - Holly Massett

# Training/Communication Working Group Goals

1. 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
2. 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

# Training/Communication Working Group

## Deliverables

- Develop a training plan for the 1<sup>st</sup> set of CDEs in Rave that includes
  - Goals of the training sessions
  - Training session structure/layout
  - Roles and responsibilities of who is providing the training
  - Roles and responsibilities of who is required to do the training
  - Timelines/coordination for each Network Group
- Develop a communication plan for the NRDS Project that defines the following
  - Roles and responsibilities of each project participant
  - Communication and outreach strategies during and after implementation
  - Develop a FAQ document for the implementation of the identified CDEs in Rave
  - Electronic implementation guide (IG)
  - Assumptions/critical considerations for integrations

# Training/Communication Working Group Next Steps

- Capturing documents, processes and roadmaps for training from each organization to understand what currently works.
- The group agreed to develop a FAQ document from both the user site perspective and the LPO perspective.
- Co-leads drafting an outline of components for the communication and policy plans to bring back to the group for feedback.
- The group emphasized the need to identify all the stakeholders and ensure the communication channels have been clearly defined.

# CONTENT WORKING GROUP UPDATE

# Content Working Group

- Kick off meeting 4/21/2015
- Recurring weekly meeting: Every Tuesday at 4:00pm EST
- Representation from
  - Alliance, COG, ECOG-ACRIN, NRG, NCIC, SWOG, Theradex
- Co-leads
  - Tina Taylor (ECOG-ACRIN)
  - Dianne Reeves



# Content 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

# Content 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

# Content Working Group Next Steps

- Each organization will submit standards to curation team for review from their global library
  - Adverse Events
  - End of Active Treatment
  - OPEN Demography
  - Progression Status
  - Vital status
- Group agreed the global library would be a very helpful tool to have everything in a central place
- Group agreed that evaluating external standards should be within the scope of this effort
  - DCP
  - CDISC (FDA requirements)

# Content Working Group Next Steps

- NCI is sending out the following sets of data to the organizations to review
  - Subset of Adverse Events
  - caAERS/Rave integration
  - Demography
  - OPEN Demography

# NRDS Committee Next Steps

- Provide an update on various integration activities
  - caAERS/Rave
  - CDUS
  - Quality Portal
  - SAE