# Network Rave Data Standards (NRDS) Policy and Governance WG

Judi Manola and Mike Montello June 15<sup>th</sup>, 2015

## Agenda

- Review Guiding Principles
- **Governance Discussion**
- Next Steps

## Draft Policy Guiding Principles (from 6/1/2015)

- Minimal Necessary
  - Rationale: There should be a core set of elements that we think are universally important. We recognize the DCP approach - they identified a core set of elements that were important on all studies.
- Change codes ONLY when the benefits outweighs the risks
  - Rationale: Depending on the application, the codes can be mapped downstream. There will be no universally acceptable set of codes that will avoid the need for re-mapping, so harmonizing codes may not be the highest priority.
- Change data elements ONLY when necessary
  - Rationale: Changes will have impact (and associated cost) on existing systems if there are changes that do not justify the associated cost
- Keep it simple
  - Rationale: makes sense
- Start small
  - Rationale: We can test the impact of the most important changes before expanding.

#### **Governance Discussion**

- How do we want to handle audits?
  - "Health inspector" approach:
    - Random unannounced requests for a study's architect loader spreadsheet, and then examine the setup for that study.
    - Require the use of global libraries at each site and examine the library contents.
    - Other ideas for ongoing compliance?
    - Do we want to identify a set of metrics to report with the audit process to analyze success and failure rates?

## **Next Steps**

- Determine if we want to change our meeting to a monthly meeting
- Continue identifying Policy guidelines and Governance components as the Content WG moves forward

### Reference Information / Questions

- NCTN Co-Lead
  - Judith Manola, M.S., Biostatistician, Department of Biostatistics and Computational Biology, Dana-Farber Cancer Institute
  - jmanola@jimmy.harvard.edu
- NCI Co-Lead
  - Mike Montello, PharmD, MBA
     Associate Branch Chief for Clinical Trials Technology
  - montellom@mail.nih.gov
- Project Management Support
  - Neesha Desai, PMP, Project Manager, NCI CBIIT
  - Neesha.Desai@nih.gov