National Cancer Institute

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

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# Challenges



- Its NOT all about content

- Stay in your swim lane

  - Network Rave Data Standards: Policy and Governance

- Keeping big picture in mind

# NRDS Content Policy - Considerations

- Establish 'Balance of Powers' between WGs
- Policy WG to set general parameters on <u>scope</u> of Content WG
- Initially 'Guidance' and Broad
  - Will tighten as we learn

**Start the discussion on content scope today**

# NRDS content Policy - Macro

- ONLY standardize content that provides 'Value' to oncology community
- Value?
  - Integration; Science (primary; correlative; meta-analysis); Safety; Regulatory (CDISC); Efficiency (study build; site participants)
- Oncology Community
  - Patient; Site participants; data managers; study builders; statisticians; PIs; Group Leadership; NCI

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# NRDS Content  Policy – Micro: Components

- Modules of CRFs

- Case Report Form

- Question

- User Value

- Coded Value

– Strive for content that contains all 5 components (ex. standard set of CRFs)

– May have a sub-set of selected standard CDEs that do NOT contain all 5 components

  • Common response: Yes, No, Other, Unknown

  • Evolving Science: Genomics

# Next Steps

- Finalize NRDS Content 'Guidance'

- Identify Additional Policies/Procedures
  - Pick-list: additions, deletions, splits and mergers
  - Waivers: One time/temporary vs. Permanent
  - Where to store content (Rave)
  - Roles/responsibilities
  - Content review cycle

- Develop simple & effective governance process
  - Short vs. long term