National Cancer Institute

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Network Rave Data Standards (NRDS) Policy and Governance WG

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Agenda

- Introductions
- Alliance Presentation
- Integration Matrix
- Use Cases for Standardized Data
- CDISC Mapping Approach
- Interim Policy Components
- Next Steps

Integrations Matrix

Level of standardization /Integrations	CRFs	Questions	Response User Value	Response Coded Value
caAERS				
CDUS				
Quality Portal				
SAE				
CDISC				
Site Audit Reporting				

Use Cases for Standardized Data, Other Initiatives

- Data Sharing Examples
  - RECIST
  - Alliance Lung Cancer
- Data Aggregation Example
  - Leukemia
- Cardiotoxicity example
- NCI Navigator
- Cancer Care Delivery Research

RECIST Data Share (should be easy)

- 1 record per patient per step
  - Prot, arm, eligibility, was patient treated
  - Measurable disease (y/n), response, progression
  - Months to progression, survival status and months
- 1 record per patient per timepoint
  - Months from registration
  - Response status at this timepoint
- 1 record per lesion per patient at baseline
  - Site, method of evaluation, days from reg to evaluation
  - Cytology, diameter, lesion type (target/nontarget)
- 1 record per lesion per patient per timepoint
  - Above plus response evaluation, status of new lesions

Alliance Lung Cancer Data Share

- Easy
  - Race
  - Ethnicity
  - Gender
  - Weight
  - Height
- Somewhat easy, but will be easier with standardization
  - Performance status
  - Smoking history
  - Symptoms (easy if baseline CTCAE)
  - Baseline comorbidities
  - Lab values

Alliance Lung Cancer Data Share

- Harder but potentially within scope
  - Histology
  - Stage
  - Clinical Outcome
  - How to summarize treatment, dose mods
- Beyond the scope of this project - example
  - “timing of start of radiotherapy (alone, prior to chemo, sequential to chemo, concurrent with chemo”

Data Sharing – Generic Issues

- Elements may be needed that aren't part of clinical database ("was patient included in the primary analysis?")
- We can have standard dates, but will probably convert dates to days from randomization/registration for data sharing
- There needs to be a way to mask small subsets to prevent inadvertent de-identification
- Blinded identifiers standardized across systems

Data Aggregation

- Example: extramedullary disease in leukemia
- A historical analysis (11 studies, 1980 – 2008)
  - Case report forms changed over time
  - Staging criteria changed over time (e.g., FAB)
  - Clinical databases changed over time
  - Technology for disease evaluation changed
  - This use wasn't anticipated
- We can standardize forms, but might want to think about how we manage other kinds of change

Other Initiatives: Example

- Cardiotoxicity – a priority of the Symptom Management Steering Committee
- EA Cardiotoxicity Working Group
- Building “Gold Standard” cardiac case report forms for future trials
- Should part of policy/governance be recommendations for how to do this consistently across the network?

NCI Navigator

- Standard front end for viewing tissue inventories for NCTN
- Requests sent to group concierges for evaluation, including accompanying clinical data
- If feasible, requests go through formal review through GBC
- GBC is looking at standardizing the outcome data to accompany the samples – should this governance/policy group interface with them?

Cancer Care Delivery Research

- Beyond the scope of this group, but…
- NCORP-wide Information Technology Working Group
- Gathering information about existing EMR resources in NCORP sites
- Virtual CCDR database: extract a common set of data elements from existing clinical and administrative systems, build standard SQL/SAS database locally, aggregate these standard local datasets

CDISC Mapping Approach

- This mapping will take place in the NRDS Content WG. This group will be working on polices around the content that they identify.

- NCI/CDASH Mapping
  - Review the bridging document that compares the NCI Content with the CDASH content
  - Develop a report that displays the similarities and differences between CDASH and NCI Content

- Exceptions to note
  - CDISC does not use OMB standards for demography because they are not Federal.
  - In Pharma, they collect AEs in a difference database
  - Major difference is they do not have any cancer-specific content. They have 16 safety domains; breast cancer under review now.

Interim Policy Plan Components

- Justification
  - The intent of this policy is to provide guidance, optimize utilization, and subsequently alleviate the excessive time and resources being invested by the NTCTN/ETCTN in their use of the NCI data standards.

- Benefits
  - Leveraging the previous investment the NCI Cooperative Groups have made in developing NCI standards
  - Streamlining overall clinical trial operations by linking Rave to existing systems (CDUS, SAE etc)
  - Increasing potential for investigators to share data for scientific collaborations and perform cross-study analyses
  - Reducing the time and effort needed to build studies in Rave
  - Reducing data management burden on participating sites and leading institutions
  - Promoting compliance with the Medidata Rave End User License Agreement and NCI CDMS Usage Guidelines
  - Facilitating the development of standardized reports to support study monitoring
  - Simplifying system-integration efforts

Interim Policy Plan Components

- Scope
  - This section will describe what is in scope and out of scope for the terms in the policy

- Divergence Process

Interim Policy Components

- Implementation (Phased Approach)
  - Standards finalized after X date must be utilized be the NCTN/ETCN within X months of approval date
  - Approved NCTN/ETCTN standards must be used when applicable to a trial to include policy guidelines around

Next Steps

- Continue to complete the integration matrix
- Draft a version of the interim policy components
- Identify additional scenarios

Reference Information / Questions

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