National Cancer Institute

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Network Rave Data Standards (NRDS) Policy and Governance WG

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Agenda

- Logistics
- Recap
- Use Cases for Standardized Data
- CDISC Mapping Approach
- Interim Policy Subject Area Discussion
- Next Steps

Logistics

- Meeting changed to 2nd and 4th Monday of the month at 2:00pm EST
- Next Monday's meeting will be cancelled
- Next meeting will be Monday June 8th, 2015
  - The working group will work via email during those weeks we are not meeting

Recap

- Alliance provided an overview of their global library and the governance, curation and the QA Checklist Report of the standards.
- Group agreed to potentially move forward with the use of a Global Library.
  - Subset of the bigger library with a small scope/focus to ensure the standards are useful

Integrations Matrix

Level of standardization /Integrations	CRFs	Questions	Response User Value	Response Coded Value
OPEN	There are no CRFs For OPEN. The data from OPEN is pushed into Rave using 5 OPEN standard forms.	There are 27 questions that are part of the OPEN standard forms. These questions correspond to the CDEs. All of the Rave studies use these forms. Any changes in the questions will impact all of the studies. LPOs also use these data for derivations in many of the edit checks and custom functions. This amplifies the impact.	The data into the standard forms are from OPEN and not editable by the site users.	The valid values in these questions are from OPEN and correspond to CDEs
Data Quality Portal (DQP)	DQP Depends on the metadata and not the actual clinical data. DQP is impacted by all the Study CRFs indirectly. However, DQP needs uniform study calendar implementation for all the studies so that the form delinquency data can be pulled.	There is no direct impact of change of Questions on DQP	There is no direct impact	There is no direct impact
SAE Integration including caAERS	There are about 16 SAE specific unified CRFs. Some of these are based on the normal standard CDEs. Any change in the standard CDEs will impact this integration in ALL the studies where it is used.	Since the unified SAE forms are collections of CDEs, the change in any (CDE) question will impact the SAE integration. Rave sends the data to caAERS and CTEP AERS via safety gateway. caAERS is impacted if there is a change in CDEs used.	Rave sends the data to caAERS and CTEP AERS via safety gateway. caAERS is impacted if there is a change in CDEs used.	Rave sends the data to caAERS and CTEP AERS via safety gateway. caAERS is impacted if there is a change in CDEs used.

Integrations Matrix

Level of standardization /Integrations	CRFs	Questions	Response User Value	Response Coded Value
Central Data Repository (CDR) for Theradex Web reporting tool	There is a mapping form that will be used to map Rave questions to the fields needed by the web reporting portal. The mapping form minimizes impact of change eCRF or CDEs on CDR	The mapping form minimizes impact of change eCRF or CDEs on CDR	The mapping form minimizes impact of change eCRF or CDEs on CDR	The mapping form s handles the valid values also. The mapping form minimizes impact of change eCRF or CDEs on CDR
Site Audit Reporting	Site audit report needs uniform roles (for site and LPO auditors) to run the audit report for a specific patient or for any patient. Also the auditors need new uniform role in Rave to allow them to enter comments on the data and not able to changes the data itself.	There is no impact.	There is no direct impact. The reports will be based on the Configurable datasets or clinical views.	The reports will use the user data strings.
CDUS	There are no specific CRFs for CDUS. The data is extracted by the LPOs from the study CRFs (may be a standard CRF or may not be)	Any changes to CDEs will impact the LPOs indirectly because they may need to change their data extraction logic to build the Complete CDUS submission files.	The user response is normally mapped to the CDUS valid value by the LPO	There are few questions where the CDE valid values are not mapping exactly to the CDUS valid values. Dianne is in loop.

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

Interim Policy Subject Areas

- Discussion: What subject areas do we need policies around?
  - Where content should be stored?
  - Policies around a global library?

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.

Next Steps

- Continue to identify subject areas for policies
- Review draft policy components via email

Reference Information / Questions

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