

NRDS Policy and Governance Working Group

Monday, May 4, 2015

Meeting Minutes

Action Item	Who	By When
Send the WG the completed integrations table for comments/feedback	Neesha Desai	5/12/15
Send out meeting minutes	Neesha Desai	5/7/15
Provide a status update on the tool that checks the standards across the architecture sheet and kick back as an error if there is not a match.	Dianne Reeves	5/15/15

Agenda Topics

Alliance Presentation – Shauna Hillman and Katie Allen Ziegler provided an overview of the Case Report Form (CRF) philosophy and the Global Library. The presentation focused on what currently exists in the MCCC/Alliance Global Library (types of forms and edit checks), the advantage of using a Global Library, and the governance, curation, and the QA Checklist Report of the standards.

MCCC/Alliance Global Library

- QUESTION 1, NCI Leadership (Mike M.): As we move forward with standardization and global standards, we need to keep in mind how these will affect internal standardization. How much of your process was driven by the local or internal systems/processes?
 - RESPONSE, Alliance (Shauna H.): The goal was to create standard data sets that come out of Rave. We have been working on standards for a long time and we were fortunate enough to be able to identify the standards prior to building our system, which is very important because the system is the policing mechanism for the standards. We wanted to ensure we had common forms, regardless of the funding sponsor(s). Overall, this takes a lot of work; this is one reason I believe we need to keep this relatively small to ensure we do not require more effort/resources than people are able to provide. It will be important to find the proper balance of standardization versus resources.
- QUESTION 2, WG Co-Lead (Judi M.): Are you using the Standard Lab Module or is the Lab Tests and Results CRF a stand alone?
 - RESPONSE, Alliance (Katie Z.): We pulled from the NCI Laboratory Test and Results module and just utilized the elements we needed. We are not using the Rave functionality.

Governance

- QUESTION 1, NCI Leadership (Mike M.): Why is the paper step necessary? I hear it is a complicated process, why can't we start as a Global Library and use some of the Rave features to ensure people cannot change the forms?

- across all diseases. In our Global Library, we have standard forms (no real changes expected) and template forms (more changes are possible and expected).
- *RESPONSE, COG (Steven J.):* We have a similar approach; the study teams go over the forms on paper and then send to the CRF review team for QA. The studies are then built into Rave and tested. Our studies are very disease based and differ quite a bit; we do get some things from the Global Library (like CDMS) but not many.
 - *RESPONSE, Theradex (Diana V.):* We have a master set of forms we require and if there is a request to create something new, we do so and keep it just in case it is needed again. We keep our changes to a minimum.
 - *RESPONSE, WG Co-Lead (Judi M.):* ECOG-ACRIN has not been using a Global Library but we have a study template that we use to start building CRFs. Our process is very quick but have gotten in trouble with variable changes, so maybe it may be best to not build so early. We have a standard ID treatment form to start the basis of the CRF but there are different numbers of agents and requirements.
- *COMMENT 3, Alliance (Shauna H.):* We do have some trials where we have achieved our goal of 80% of the data collected was from the Global Library but some of the trials were only 50%.
 - The group agreed to move ahead with the recommendation to use a Global Library; this Global Library should be a subset of the bigger library with a smaller scope/focus to ensure the standards are useful
 - *RESPONSE, NCI Leadership (Mike M.):* The Content Working Group would define the content around the actual Global Library and part of this group's scope will be to govern the standards.

Integration Matrix – Neesha Desai presented the integration matrix and explained the goal of this activity will be to understand what level of standardization we want to accomplish for the various integrations. The approach for this integration matrix will be

- Judi Manola add any additional fields to the matrix
- Send the integrations matrix to CTSU to complete
- Send the completed integration matrix to the NRDS Policy and Governance WG for comments/feedback

Next Steps

- Send the completed integration to the NRDS Policy and Governance WG for comments/feedback
- Send completed meeting minutes to NRDS Policy and Governance WG for comments/feedback

