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

- <u>QUESTION 1.</u> 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.
- <u>QUESTION 2</u>, 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

• <u>QUESTION 1, NCI Leadership (Mike M.)</u>: 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?

- RESPONSE, Alliance (Katie Z.): It is our study team collecting the information for any given trial; the best way to accomplish this is with paper CRFs. We do not have PIs going into Rave; the developer grabs a paper CRF, puts the packet together, and modifies elements required based on the trial. I go back and review to ensure they are not modifying certain fields, values or elements that are set as standardized, we have not yet found a way to accomplish this online. We do provide guidelines for the paper CRF to show which elements are standardized and why.
- <u>QUESTION 2</u>, NCI Leadership (Mike M.): Do you do mapping for the extra fields?
 - RESPONSE, Alliance (Katie Z.): We do not usually do extra mapping for these fields. An example, if the patient is to do off treatment therapy, we include a sub-question to add the off treatment location so we can still capture the information if it is needed.
 - *RESPONSE, Alliance (Shauna H.):* We would also like to eliminate the paper CRF but we are still looking at how to do so without losing the flexibility it provides.

Open Forum

- <u>QUESTION 1.</u> NCI CBIIT (Dianne R.): Do you change the codes you use from the NCI Reports (i.e. CDUS and Adverse Events)? Do you use your own codes or the ones the NCI Developer has designed for the reports?
 - RESPONSE, Alliance (Katie Z./Shauna H.): It depends on the trial, if we already had a standard prior to the NCI's standard we will usually use our own. If the standard from the NCI was already available when we created the system, we try to use the NCI standard.
- <u>QUESTION 2</u>, NCI Leadership (Mike M.): For the reports you spoke about in your presentation, is the export going to work in SAS instead of ensuring people are using the standard?
 - *RESPONSE, Alliance (Shauna H.):* Some reports are looking to how edit checks are written or outputs from the library. It is a mix of best practices, naming conventions, formatting, and things of that nature.
- <u>COMMENT 1,</u> NCI Leadership (Mike M.): There is nothing inherently within Rave to ensure they have not changed elements within that CRF.
 - *RESPONSE, Alliance (Katie Z.):* You might have a treatment form that requires the developer to add default values because the treatment is different from another.
 - *RESPONSE, Alliance (Shauna H.):* We do have naming conventions that are defined for editing if it is a Global Library edit, versus a field edit.
- <u>COMMENT 2</u>, WG Co-Lead (Judi M.): I see that you are running SAS codes to do the QA checks. For the process, you are starting with the standard and then have QA programs you run against the architecture sheet. I wonder if it would be better to use a Global Library in Rave instead of a local library to ensure the standard form was not modified.
 - *RESPONSE, Alliance (Katie Z.):* I think there is a tool out there where you can take the architectural loading file, upload it, and if it did not match on the required spots, it would kick it back as an error.
 - *RESPONSE, NCI CBIIT (Dianne R.)*: There is a tool out there that will do this but it is still in development but I can check on when it might be available.
- <u>QUESTION 3,</u> WG Co-Lead (Judi M.): What are other organizations doing?
 - RESPONSE, SWOG (Angela S.): We do the paper forms, the statisticians complete their forms, after the drafts are final, then we send the mock up to Rave for development. We have a Global Library, although I do not believe we have added anything to it within the last two years. We only have items in there that can be used

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.
- <u>COMMENT 3</u>, 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

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Attendance:

Name	Affiliation
Katie Allen Ziegler	Alliance
Shauna Hillman	Alliance
Thalia Beeles	Children's Oncology Group (COG)
Steven Jong	COG
Judy Manola	Eastern Cooperative Oncology Group-American College of Radiology's Imaging Network (ECOG- ACRIN)
Andrea Denicoff	NCI
Dianne Reeves	NCI
Janice Chilli	NCI
Mike Montello	NCI
Christina Warmington	NCI - Essex Management
Neesha Desai	NCI - Essex Management
Jennifer Thomas	NRG
Angela Smith	SWOG
Rodney Sutter	SWOG
Diana Vulih	Theradex
Pam Rapoport	Theradex