NRDS Policy and Governance Working Group

Monday June 15, 2015

Meeting Minutes

Action Item	Who	By When
Send out meeting minutes	Neesha Desai	6/19/15
Send out the guiding principles to the working group	Neesha Desai	6/20/15

Agenda Topics

Introduction of members on the call – Neesha Desai welcomed the callers and reviewed the current agenda.

Guiding Principles – Judi Manola reviewed the list of guiding principles (and rational), focusing on content that the group came up with during the previous meeting. Judi and Mike Montello then opened the call up for additional suggestions and feedback. The principles below incorporate the comments and feedback provided by the working group.

1. Minimal Necessary
   - Rationale: There should be a core set of elements that we think are universally important, only standardize elements when the benefits outweigh the risks.
2. Keep it simple
   - Rationale: Makes sense
3. Start small
   - Rationale: We can test the impact of the most important changes before expanding.
4. Change codes for existing data elements ONLY when a need exists
5. Change codes for existing data elements ONLY when the benefits outweighs the risks
   - Rationale: Depending on the application, the codes can be mapped downstream. There will be no universally acceptable set of codes that will avoid the need for re-mapping, so harmonizing codes may not be the highest priority.
6. When creating new codes, keep it as short text strings with 10 characters or less
   - Rationale: There is a high chance of error with the use of numeric codes when it comes to mapping
7. When considering a new standard data element, try to use a short text string as the code where possible.
   - For example: instead of “1=CR” use “CR”
   - Rationale: Will prevent interference with groups’ existing coding systems
8. Change data elements ONLY when necessary
   - Rationale: Changes will have impact (and associated cost) on existing systems if there are changes that do not justify the associated cost

Open Forum

- The group agreed that as codes are created, short text string, instead of numeric code, should be used because it may cause fewer errors.
- The group also agreed that 10 characters or less is a good starting point for the short text limit. This is currently considered a guiding principle but it not a finalized standard.

Governance Discussion – Judi Manola opened the call up for discussion around how to handle audits. We want a low overhead, low maintenance way to ensure people are compliant. One way may be to use the "health inspector" approach, to just pop in with no notice.

- Angela: I like having a subset of protocols to do the work, instead of looking at every one. Is there a vision yet for who would do the checking and how often? I would want to know sooner, rather than later, if I am out of compliance so I can correct the error.
- Shauna: Migrations are costly; if we are required to go back and make many changes, it would not be good. It seems a better idea to catch the error/noncompliance/difference of interpretation up front; a congruency checker, although not easy to create, would be a good option. If we continue with a smaller subset, we should be able to create this congruency checker to ensure our data is correct when it is loaded.
    - Judi: What if we did not require a migration to a study to fix a compliancy issue, but instead required the change moving forward?
    - Shauna: If we do not require the change, it will never be standard.
    - Angela: If we do not require them to change the previous data, it defeats the purpose of standardizing. If the congruency checker is still an option, I would like to speak about it
- Mike: Each group has their own standard set of CRFs within their own group, how do you manage those to ensure they are done correctly?
    - Angela: It is not a policing effort, just a more efficient way to accomplish our tasks.
    - Mike: Part of what we are doing, in the long run, is for efficiency.
    - Shauna: Locally there is a large effort to police a large amount of standards without a lot of buy-in. It seems best to have a smaller set, with buy-in, to be successful.
    - Mike: We have agreed we will keep this small, and we have a standardize set of CRFs
- Judi: We have heard that the Content Working Group is starting with the CTEP AE Forms, what if we make a congruency checker, either a machine or person (caDSR possibly). When we have that standard form set up for the first study, we could then supply it to the congruency checker for those first trials. After this process, we can use that form and store it in the Global Library in confidence that it has been approved and is compliant. As each form is implemented, the first time, it will be reviewed.
- Shauna: What if one group built the form and sent it out to the group to use? Each group could use the form for the base elements and add their local questions as needed.
    - Mike: The NCI will support this, having one group build the form and the other groups add their own details, if the group agrees.
    - Shauna: Our Policy Working Group and curators, or any others selected (Dianne) could review the form to ensure it is compliant.
    - Angela: I like the idea because it forces everyone to use the same form but I want to make sure that whoever is responsible ensures it is done correctly.
    - Dianne: We will soon have the form loader capability, so we can talk about this as an option.
    - Judi: We can try it on the first form and see what we learn. If it works, we can continue with this method.
- Angela: Are we looking to have it as a centralized item or will the groups be responsible for it?
    - Mike: There would be curation for the standard set of CRFs and then curation for the study by study issues. For this small set of forms, we will have one way of doing things and there will be a different way of doing things for the others.
    - Shauna: We need to have a core of strongly policed set of elements that we can all agree on. There is so much we cannot use in the caDSR.

- Steven: When would that review happen?
  - Judi: Right after the content group finishes the form
- Jennifer: We have a process in place where we standardize forms in a community review, they are in caDSR. This is already happening isn't it?
  - Mike: Are these Rave ready? With standardized checks and all?
  - Jennifer: You make a good point, I am trusting that the Content WG will not ignore the work that has already been done.
  - Shauna: The Content WG is taking this information and adding it to a Rave form.
- Jennifer: There are modules in the caDSR they are not RAVE CRFs. How you put them together is LPO specific, so it is used very differently.
  - Dianne: Because each of them were created differently, when they are put together, they are not formatting the same.
- Jenn: Will we include edit checks?
  - Angela: This might need to be a different discussion because this may be different based on the location. We might start with a few that would make sense, but others would be a slippery slope. The benefit may not outweigh the risk
  - Shauna: Doing the caAERS forms may make sense.

Next Steps

- The group agreed to move this meeting to a monthly meeting until we get more content to work with.

Attendance:

Name	Affiliation
Katie Allen Ziegler	Alliance
Shauna Hillman	Alliance
Steven Jong	COG
Thalia Beeles	COG
Judi Manola	Eastern Cooperative Oncology Group-American College of Radiology's Imaging Network (ECOG-ACRIN)
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