NRDS Policy and Governance Working Group
Monday March 14, 2016
Meeting Minutes

Action Item	Who	By When
Review the definition for NRDS Content and Policy WGs (add examples)	Tina Taylor	2/29/16
Update the compliance review process to accommodate a paper document for changes	Tina Taylor	2/29/16

Agenda Topics

Action Items
- **Discuss ALS Components** (Ginger Riley) reviewed which of the ALS components can be changed by the LPO and the reasons for the components that cannot be changed.
  - Angela: We are in the habit of changing the field OIDs and form names, this will have great impact on us. Is there any flexibility for this?
    - Ginger: There is little flexibility for this
    - Mike: We are talking about a limited number of fields, not all of them.
    - Angela: I understand this, but it would still have a great impact on us.
    - Mike: We are coming up with a new standard, taking caDSR out of the equation currently, then populate the caDSR once we can find a common ground.
  - Ginger: Are you part of the SAE integration discussions? We can discuss this more offline but it is my understanding that all of the groups were aware of this.
  - Judi: Is there a naming convention for OIDs that you are using?
    - Angela: Technically, they have to be fewer than 30 characters, it is more based on our database and our meanings. I am hesitant to agree with anything prior to seeing the details.
    - Judi: If you can share a few of the foreign field orgs you are using, that would be helpful.
  - Ginger: Are you referring to the OIDs that have been vetted? We found some considerations and flexibility for some field OIDs
    - Angela: We use SWOG conventions for the naming OIDs, nothing that is vetted. My concerns may be unfounded because it may not be an issue, but until I better understand the scope, I cannot agree.
  - Shauna: It is challenging to implement something that is a little grey (i.e. custom functions and edit checks).
    - Mike: If we provide some examples, would that help?
    - Shauna: Yes but it is likely it will not fully define the scope. We may need to be more specific about the verbiage.
    - Ginger: We can do a query and ask for feedback about this issue and to capture more use cases.

Discuss Monitoring Report/Trigger/Frequency – Should there be a report or frequency to trigger the monitoring review. There is currently a trigger available but no defined trigger.
- o Shauna: It would be good to have a general sense of the frequency of the monitoring. If you do one or two early, after that, it should monitor itself. The integration will not work if you do not have the proper standards.
- o Mike: I agree to do monitoring at the beginning but we may need a periodic monitoring (maybe annually or bi-annually) to ensure things are still correct.
- o Shauna: I agree, but then we would have to test every single one. I envisioned us created one in the global library and others just copying that one.
- o Mike: That makes sense, maybe we just review at the beginning a few times and then again if there are modifications.
- Neesha: Are there any metrics validations we need to add?
  - o Mike: If we are doing this correctly, the metrics should only be tested/validated once.
- Gwen: There will be AE forms that are not on a standard form that will need to be reviewed.
  - o Shauna: I thought that once we agree on the standard, we would just use that as a basis; if a center wanted to add additional items they can.
  - o Gwen: Yes, but there are accidents when working with custom checks and such.
  - o Shauna: Once I have a trial built, can I test this in a test environment (a fake one to ensure the operation works before I go live)
  - o Vanitha: We do always have a UAT environment prior to production of the form. If it looks good in UAT, then we will push it to production.
- Ginger: Are we expecting the Alliance to do the same level of testing?
  - o Vanitha: Yes, for each trial.
  - o Jayan: There is an important distinction between the first study and additional studies. The first one will need to be completed tested, subsequent ones will only require a few tests.
- The group agreed that we may need to do a review prior to putting it into Production (UAT) but after that, this monitoring review should not be required.

Formalizing Policy Documentation
- The group agreed that a combined document with the comments would be helpful for formalizing the policy documentation
- Judi: We should define our scope and provide examples when possible. We may need to have commitment from CTSU about their change process, so we can better understand their changes and the timeline required with changes.

Next Steps
- Review collated document.

Attendance:

Name	Affiliation
Shauna Hillman	Alliance
Mike Montello	CTEP
Ginger Riley	CTSU
Jayan Nair	CTSU
Vanitha Chockalignam	CTSU
Judi Manola	ECOG-ACRIN
Gwen Dean	NCI
Janice Knable	NCI
Tina Taylor	NCI
Christina Warmington	NCI - Essex Management
Neesha Desai	NCI - Essex Management
Jennifer Thomas	NRG
Angela Smith	SWOG
Diana Vulih	Theradex