

## NRDS Content Working Group

Tuesday June 2, 2015

### Meeting Minutes

| Action Item   | Who          | By When |
|---|--------------|---------|
| Send out meeting minutes                              | Neesha Desai | 6/5/15  |
| Send the preliminary list of caAERS content to Neesha | Vanitha      | 6/5/15  |
| Develop an integrations matrix                        | Gwen Deen    | 6/5/15  |

### Agenda Topics

**Meeting Recap** – Neesha Desai welcomed the callers to the meeting and provided a brief meeting recap from the last meeting.

**Content Review Strategy** – Dianne Reeves discussed the content review strategy. At the last meeting, the group discussed the use of numeric or other codes for Permissible Values (PV) sets and agreed not to accept alternate question text and meanings for the items they want to standardize. Rave integrations was added to the list. Dianne also went over the guiding principles provided by the NRDS Policy Working Group (WG). These principles are a high level set of guidance to keep in mind when identifying the set of content and determining what changes need to be made.

- Katie: It would be helpful to see the values for all the integrations so we can look across all systems.
  - Gwen will develop an integrations matrix
  - Integrations, such as caAERS, OPEN, and CDUS reporting, will be inventoried. The last content will then be CDISC/CDASH elements for any of the first set of content.
- LPO RandoNodes - Dan: When a site registrar goes into OPEN and enrolls a patient, at one point in time, the OPEN system makes a RandoNode call to the LPO system. The demography form has a prepopulated form based on the patient registration ID from the LPO system. For COG, in OPEN, we have it so only the gender and birthday are editable by the users and all the other fields have to be populated by that system. So if any of these fields change, we need to make sure our system is updated to return the new values based on a metadata change. A lot of the public IDs are different from the xml files and the data in the OPEN system when comparing the CDEs referenced in the ODM.
  - Dan: We need to find out from Ravi's team which caDSR form they are using for the OPEN Demography form. OPEN is using the released CDEs, not the retired ones referenced in the Demography CRF.
  - Dan: The form discussed has patient initials in 1 field in Rave and OPEN has 3 separate fields. COG would like to stay with 3 fields because when there is 1 field and Last, First, Middle, a lot of site users can make mistakes and the data can get very confusing.
    - Shauna agreed that the 3 fields is the way to do it
  - Katie: Are we worried about which systems have the right information or the eCRF specification?
    - Dan: Having the data right is the goal
  - When we do the evaluation we need to look at the actual OPEN system and the Standard Exchange Format (SEF) version 5.2

**Integrations Matrix** - The group agreed to come back with the matrix of key integrations and then start targeting PVs

- Katie: Completing this matrix will help drive what the PVs are going to be
  - The group agreed everyone would benefit from creating this matrix.
  - The group agreed that they may decide to scope out a small section for the first set of content but seeing the whole matrix will help them determine what they want to start with.
- Shauna: We need to capture all the caAERS set of data, not just the core demography elements.
  - Vanitha: We have a complete list of the caAERS set of data. By August we will complete the release, so 16 SAE forms. We are doing more optimization and moving from CDEs to other forms so we are working on it right now. Vanitha to send Neesha the preliminary list of content.
- Site Audit Report: This report is used for programming purposes. We are using 2 fields to upload the data back into Rave. It is entered into the Excel sheet and uses custom functions, verifying if there are any flags. Those two fields need to be standardized.
- The group agreed on the following integrations/attributes to include in the matrix
  - caAERS
    - List of reference CDEs and how it is being collected in the application
    - 16 Forms (potentially 15)
  - OPEN (Ginger to provide 5.1)
    - 5 Forms
  - CDUS
    - Complete
  - CDISC
    - Include the elements that match the ones we have on the matrix and that are prioritized for our standardization effort.
  - Site Audit Report
    - 4 Fields (From Ravi)
  - Matrix layout
    - CDEs, Versions, PVS, Question Text, Public IDs, Format,
    - Purpose will be to show the difference in CDEs from the registry and the various applications.
    - Review how often a variable appears in the integrations.

## Next Steps

- Vanitha to provide Neesha with the complete list of caAERS data to include in the integrations matrix
- Gwen Deen to create the integration matrix which will be reviewed at the next meeting.
- Agenda for next week will center on the set of elements used in integrations in an effort to define the first set of content.

**Attendance:**

| <b>Name</b>         | <b>Affiliation</b> |
|---------------------|--------------------|
| Katie Allen Ziegler | Alliance           |
| Thalia Beeles       | COG                |
| Ginger Riley        | CTSU               |
| Mary Vienneau       | ECOG-ACRIN         |
| Neesha Desai        | Essex Management   |
| Dianne Reeves       | NCI                |
| Gwen Deen           | NCI                |
| Chad Winch          | NCIC               |
| Rebecca Paulas      | NRG                |
| Vanita Patel        | NRG                |
| Angela Smith        | SWOG               |
| Peter Clark         | Theradex           |