NRDS Content Working Group
Tuesday September 29, 2015
Meeting Minutes

Agenda Topics - DRAFT

OPEN Demography Review – Gwen Dean reviewed the OPEN Demography items that were open from the last meeting.

- Method of Payment
  - Cathy: We have spoken to Scot Ramsey and Joe Unger, they suggested not making any chances.
  - Judi: I think your answer makes sense
  - ****Decision:** Add the one that is still active and use it as the standard.

- Country Codes
  - Gwen did some research with the current list we have; she highlighted the countries that currently have no current concept associated with them (including the ones that have ampersands). She also reviewed the current ISO Code list for countries. I have emailed Dianne to see if we should just update the current countries with the new concept associations or just update the whole list.
  - Judi: I would have no problem just updating our whole list
  - Gwen: I would also like to get rid of the current "other"; ISO list does not have an "other" option.
  - ****Action Item:** Ginger: I will follow-up with the OPEN team to see if they have had an instance where they needed to use "other"

- Patient SSN (not mandatory), Hospital Number (not mandatory), Disease Code (mandatory)
  - Dan: Our site users do not provide the disease code; I don't know exactly how that field is dealt with.
  - Alliance: We derive it, we don't ask the center to provide it
  - Judi: Same here, we derive it
  - Shauna: Maybe we should remove all elements that are not mandatory
  - Judi: This is data that will be in Medidata Rave, so we cannot say what is required in OPEN is the same thing that is required in Rave. We capture SSN in OPEN and store it in a confidential database at our center but not send it to Rave.
  - Tina: There was a study we had to collect the full patient name, which we don't usually collect, but it had to be pushed to Rave. We had to de-restrict the fields to ensure it got through; I was uncomfortable with this way but there was no way to configure fields to not be pushed to Rave. SSN is not currently a field that is pushed to Rave.

Open Forum

- Shauna: When we are ready to send stuff to our group for input, can we get a paper CRF (curator format) instead of spreadsheet.
  - Tina: We can provide you with that or something that is easier for others to review.
  - Gwen: Each center has access to OPEN but I do not have access to OPEN. We can create a Word document to add this information.

Next Steps

- Shauna: CDUS (Abbreviated and then Complete) makes sense

- o Neesha: Is there a lot of overlap between the two?
- o Peter: I do not know, we work on CDUS Complete
- o There are some who still use CDUS Abbreviated but much of the data is not CDUS Complete.
- o Judi: A dosing change would require CDUS Abbreviated
- o Peter: Since the TAC is on the AE form, I think it is relevant
  - ▪ Judi: It is in AdEERS, so it will be in the fully integrated version.
- o **Decision** - Next week we can bring forward the spreadsheet for Abbreviated and Complete and we can decide on which fields we want to standardize.

- Judi: The Policy working group (WG) has been on hold until the Content WG got some stuff done. It might be a good idea for the Content WG to go on hold until the Policy WG digests what the Content WG has done.
  - o Shauna: I would rather get it all at once if I could
  - o Pete: I support that, let's keep going

Attendance:

Name	Affiliation
Shauna Hillman	Alliance
Dan Jameson	COG
Wendy Wong	COG
Ginger Riley	CTSU
Judi Manola	ECOG-ACRIN
Christina Warmington	Essex Management
Neesha Desai	Essex Management
Gwen Dean	NCI
Rebecca Paulus	NRG
Vanita Patel	NRG
Tina Taylor	SAIC
Angela Smith	SWOG
Cathy Rankin	SWOG
Peter Clark	Theradex