

NRDS Content Working Group Tuesday April 12, 2016 Meeting Minutes

Agenda Topics

CDUS OPEN Content Review – Gwen Deen

- Registration Step Request to change to numeric only
 - o Gwen: This is used by other groups for other reasons, so we cannot change to numeric only, but can change to alpha-numeric
 - Center Uses
 - Theradex starts with 1, we would never use 0. In some cases, 1 is the only step and some times there is a multi-step process
 - Alliance We start with 0 for Pre-registration, 1 for registration, and there could be more
 - ECOG-ACRING We use 0 and 1 but it is all generic
 - SWOG Numeric only
 - COG No Representation
 - NRG starts with 1 and can continue past 1
- Tracking Number Suggestion to remove system generated (Completed)
- Crediting Group This is not where CDUS collects the code for the group; this would be
 either the full name or abbreviation of the name of the group. This is used for funding, not
 to CDUS.
 - SWOG Vote for the shorter/abbreviated name
 - o Alliance Vote for the shorter/abbreviated name
 - o ECOG-ACRIN Vote for the shorter/abbreviated name
 - Theradex For us, it will list the lead org's CTEP code.
 - Gwen: There is one for the step information form and one from subject enrollment
 - Theradex For the step information, it is a code that represents the lead institution.
- Arm Shortened to Arm (instead of Arm Name)
- Event Date Changed description
 - o Dianne: Does the CDE reference only protocol activity? Our description is a little more specific, will that be an issue? The data element is broad.
 - Angela: The definition is pretty broad.
 - o Theradex I think it could be used in many places, in any research activity.
 - o **Change description to include: Protocol Activity, Research, or Registration.
- Treatment Assignment Code Request to share with other users
 - Gwen: We are working with CTRP and the integration with caAERS, so they will be aware of the new definition.
- Patient ID Suggest to make de-identification code
 - o Gwen: We can assign this as an identifier
- Current Site CTEP ID Angela: How is this definition different from the Enrolling Site CTEP ID?
 - Vanita: One must manually update this field in OPEN
 - o Angela: The current site is the one that will follow the site.

Field OIDs – We are working on the new approach for field OIDs (SAE integration activity and SWOG's local OIDs) and will provide information as it becomes available

Next Steps

• Next meeting is scheduled for April 19 @ 4:00 pm (ET)

Attendance:

Name	Affiliation
Shauna Hillman	Alliance
Kristina Laumann	Alliance
Wendy Wong	COG
Ginger Riley	CTSU
Melinda Flood	ECOG
Christina Warmington	Essex Management
Neesha Desai	Essex Management
Dianne Reeves	NCI
Vanita Patel	NRG
Gwen Deen	SAIC
Tina Taylor	SAIC
Angela Smith	SWOG
Cathy Rankin	SWOG
Peter Clark	Theradex