Announcements

April 6th, 2017: NRDS Update

CTSU deployed the final LPO Study ALS for the RE 2 Release of Rave-CTEP-AERS integration on the Collaboration Portal tab of the CTSU Members Website. Please note these standards are available for the entire NCI Community.

The ALS contains the approved NRDS Adverse Events CDEs. The NRDS Project Team has developed a list of FAQs to assist you in the process of implementing this content.

1. Which studies do these standards apply to?

a. The NRDS AE Standards in the ALS are for NEW STUDIES ONLY.

2. Can I use ALT OIDS?

a. You have the option to register and use your Context specific ALT OIDS in the caDSR for the SAE Integration AE forms ONLY. When registering your ALT OIDS in the Curation Tool, you must select "OID, NRDS Standard" as the "Alternate Name Type". Do not select your Context specific "Alternate Name Type" for registering this content.

3. How can I access the NRDS AE Standards in caDSR?

- All CDEs that are owned by NRDS or designated for reuse by NRDS are registered in the CDE Browser under the NRDS Context.
 - i. Click on the "NCTN/ETCTN" tab in the CDE Browser and then select the "NRDS (Network RAVE Data Standards)" file folder icon on the left hand side of the screen. Next, select the "Classifications" file folder icon, then the "Integrations" file folder icon, then the "Adopted Content" file folder icon and finally the caAERS file folder icon. The CDEs designated for use as the NRDSAE Standards appear in this folder.
 - ii. This content can also be accessed by using the "All Program Areas" tab and scrolling down to the NRDS (Network RAVE Data Standards).

4. How can I access the NRDS approved alternate question text?

a. Click on the Long Name of a single CDE in the CDE Browser. Alternate question text will appear on the "Data Element Details" page under "Reference Documents". NRDS approved "Alternate Question Text" are labeled "NRDS Question Text".

5. Who do I contact for questions?

a. If you have any additional questions regarding the NRDS AE Standards, please send an email to neesha.desai@nih.gov.

October 11th, 2016: NRDS Status Update

The NRDS Content WG completed their review and recommendations for a set of standardized content to be used for NCTN, ETCTN and Theradex. Below is a list of areas the Content WG provided recommendations for:

- OPEN Demography
- 3 additional OPEN forms
- Adverse Events (integration)
- Serious Adverse Event integration
- CDUS

The NRDS Policy and Governance WG developed a NRDS Policy and Governance plan around the usage of the recommended standards. The NRDS Policy and Governance Plan includes Principles for the NCTN/ETCTN/Theradex Standards, Roles and Responsibilities, Standards Usage Policies, and a set of Validation Workflows to monitor the use of NRDS Standards.

The NRDS Communication and Training WG developed a set of communication workflows to use throughout the phases of the NRDS Project. As implementation moves forward, they will be working on a training plans.

An impact analysis was done with CTSU, CTIS and Theradex to review the recommended standards and provide feedback on impacts, constraints and risks. This information was then collated and presented to CTEP. CTEP is currently reviewing the recommended standards and impacts and determining which standards provide the most benefit to implement.

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