

Network Rave Data Standards (NRDS) Content WG

Tina Taylor and Dianne Reeves

Agenda

- caAERS/OPEN Discussion
- Ongoing check box
- Next Steps

OPEN Demography Recommended Changes

Integration	Type of Change	Number of CDEs Affected*	Number of Total Instances*
OPEN – Demography	Reformat of question text (Capitalization)	6	6
OPEN – Demography	Reformat of definition (Capitalization)	4	4
OPEN – Demography	New CDE due to incorrect use of existing CDE (retired and/or not standard)	2	2
OPEN – Demography	Reformat of PV (Capitalization)	2	2
OPEN – Demography	New CDE version due to version of value domain for an update	1	1
OPEN – Demography	Missing concept codes for PV	1	1

Assumptions

- Groups will be using this information from OPEN used in Rave without changes
 - Same questions
 - Same answer set
 - Same values

caAERS Integration Recommended Changes

Integration	Type of Change	Number of CDEs Affected*	Number of Total Instances*
caAERS – AE Forms	Reformat of question text	13	28
caAERS – AE Forms	Reformat of definition	8	17
caAERS – AE Forms	New CDE due to incorrect use of existing CDE	3	4
caAERS – AE Forms	New CDE due to change in value domain (Indicator VD)	1	1
caAERS – AE Forms	Remove CDE from form	1	2
caAERS – SAE Forms	Reformat of question text	52	68
caAERS – SAE Forms	Reformat of definition	33	47
caAERS – SAE Forms	New CDE due to incorrect use of existing CDE (Retired and/or Standard)	7	9
caAERS – SAE Forms	New CDE due to change in value domain (31 Indicator VD)	36	37
caAERS – SAE Forms	Remove CDE	1	2
Original Data Elements where “Derivations” Occurred in Forms Outside of caAERS CRFs	Reformat of question text	9	10

Assumptions

- Groups will be using these elements from caAERS used in Rave without changes
 - Same questions with approved exceptions
 - Same answer set
 - Same values

Next Steps

- Priority 1: CDUS Dataset
- Priority 2: 3 OPEN Forms
 - Step Information
 - Subject Enrollment
 - Treatment Assignment
- Next meeting will be on Tuesday December 1st at 4:00pm EST

Theradex Discussion

- Ongoing checkbox

Reference Information / Questions

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