

Network Rave Data Standards (NRDS) Content WG

Tina Taylor and Dianne Reeves

Agenda

- CDUS Reporting Standardization Status
- CDUS Reporting Review
- Next Steps

NCI Recommendations for Standards	NRDS Recommendations for Standards	NRDS Pending Recommendations for Standards	NRDS Recommendations for NO standardization
Date of last treatment	Date of last treatment	Is the participant ineligible for inclusion on this study	Off treatment reason
Off treatment reason	Participant subgroup code	Prior Therapy Type	Off study reason
Off study date	Performance Status	Dose modification	Response evaluation status
Off study reason	Total number of prior chemotherapy regimens	Off study date	Baseline abnormality flag
Baseline abnormality (MEDRA AE code)	Height		Units of Measure
Baseline abnormality grade	Baseline abnormality (MEDRA AE code)		Response at this assessment
Response at this assessment	Weight		Observed date
Response observed date	Baseline abnormality grade		Assessment comments
DLT Type (CTCA v4)	Total dose of agent for this cycle		
DLT (AE), other, specify	Total dose of agent for this course		
	Total dose of agent for this visit		
	Verbatim term		
	Has an adverse event expedited report been submitted?		

Reasons for not standardizing

NRDS Recommendations for NO standardization	Reasons
Off treatment reason	Not a strong candidate for community reuse. Includes granular protocol specific items.
Off study reason	Not a strong candidate for community reuse. Includes granular protocol specific items.
Response evaluation status	Derived on the backend
Baseline abnormality flag	Not collected on the front end system
Units of Measure	Some groups hardcode this and some collect this information
Response at this assessment	CDUS is very tumor driven and not all studies are tumor driven.

Next Steps

- 2 week review of CDUS reporting
 - Purpose of review will be for this NRDS Content WG representatives to bring back the recommendation to their organization
- 5/17/2016 NRDS Content WG meeting will be cancelled to provide more review time

Reference Information / Questions

- NCTN Co-Lead
 - Tina Taylor, Health Metadata Analyst, SAIC
 - tina.taylor2@nih.gov
- NCI Co-Lead
 - Dianne Reeves, RN, MSN Associate Director, Biomedical Standards, NCI CBIIT
 - dianne.reeves@nih.gov
- Project Management Support
 - Neesha Desai, PMP, Project Manager, NCI CBIIT
 - neesha.desai@nih.gov



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