

Network Rave Data Standards (NRDS) Policy and Governance WG

Judi Manola and Mike Montello

Policy and Governance Plan Components

- Summary
- Purpose
- Scope
- Introduction
- Roles/Responsibilities
- Exemptions for Data Standards Usage
- NCTN and ETCTN Standard Usage Policies
- Validation Workflows
- Compliance Criteria
- Frequently Asked Questions
- Glossary

Summary and Purpose

■ Summary

- This NCTN and ETCTN Standards Policy and Governance document establishes framework, responsibilities and requirements for development, maintenance and implementation of standards within the NCTN and ETCTN.

■ Purpose

- A well implemented Standards Governance Policy supports management of data related financial resources and reduces risks associated with compliance, security, privacy, and data sharing. The audience for this document includes the NCTN and ETCTN as well as other stakeholders who create and use NCI data resources.

Scope

- **Scope**

- This Policy and Governance Plan applies to policies apply to the formulation and utilization of Network Rave Data Standards or NRDS-approved Standards in Rave for the NCTN and ETCTN. In particular NCI organizations, IT project managers, application developers, contracting officers and their technical representatives as well as grantees, contractors and others working on behalf of NCI who design, develops, compile, manipulate or maintain the NCTN and ETCTN standards.

Roles and Responsibilities

Role	Responsibility
NCI Leadership Committee	An oversight committee that provides strategic guidance and direction on the NRDS Project activities that align with NCI's vision and goals.
caDSR Registry Steward	NCI representative who reviews, analyzes and is responsible for maintenance of the NRDS Standards.
NRDS Content Working Group	<p>The committee established to identify and manage the NRDS approved Standards for use in Rave by NCTN and ETCTN.</p> <ul style="list-style-type: none"> a. Identify proposed NRDS Standards b. Review and approve updates to NRDS approved Standards c. Collaborate with the NRDS Policy and Governance WG to manage the NRDS approved Standards d. Collaborate with the caDSR Registry Steward when utilizing the NRDS Standards e. Verify the use of NRDS approved Standards in new or updated CTSU prepared ALS
NCTN and ETCTN	NRDS Project stakeholders that provide subject matter expertise for content standardization.
Lead Protocol Organization (LPO)	NCTN and ETCTN organizations that develop and conduct NCI Clinical Trials.

Roles and Responsibilities

Role	Responsibility
NRDS Policy and Governance WG	<p>A committee established to identify and govern the decisions on the adoption and usage of the NRDS Standards in Rave by the NCTN and ETCTN.</p> <ul style="list-style-type: none"> a. Review the recommended updates to existing NRDS Standards for compliance to the NCTN and ETCTN Governance Framework b. Enforce approved policies and governance c. Define an escalation strategy for the NRDS community
ALS Submitter	A person who distributes the ALS documentation and any changes to the ALS Reviewer.
ALS Reviewer	The caDSR curation team designee who reviews ALS documents to ensure they comply with the NRDS Standards.
caDSR Curator	The caDSR curator(s) who implements approved content as identified by the caDSR Data Registry Steward.

Exemptions for Data Standard Usage

■ **Types of Exemptions**

■ **Temporary Exemption**

- Exemption with a designated expiration date. A temporary exemption enables the system managers to wait until an appropriate time in the systems life cycle (e.g., modernization) or project to incorporate a new data standard.

■ **Permanent Exemption**

- Exemptions granted for the life of the system or project.

Exemptions for Data Standard Usage

■ **Determination of Need**

- The validation workflows will help determine whether the NCTN or ETCTN will have problems complying with a relevant data standard.
- Both NRDS Policy and Governance WG and the NRDS Content WG are consulted for compliance review and/or assistance. Every effort shall be made to achieve compliance.
- An exemption is required if an application or project that has reached its retirement date, but is not in compliance with the new version by the required implementation date.
- An exemption is data standard specific. A separate exemption must be issued for each data standard to which the application or project does not comply.

Exemptions for Data Standard Usage

- **Disposition of Exemption Request.**
 - The NRDS Policy and Governance WG, NRDS Content WG, requesting party, CTSU and NCI Leadership (if it is appropriate or there is a dispute), evaluate applications and makes recommendations.
 - Exemption evaluation criteria include, but are not limited to, life cycle of the application or program, applicability of external data standards, burden on the community, and use of the data for secondary purposes.
 - NCI Leadership notifies the applicant in writing of the disposition of the request within 60 days of receipt.

Exemptions for Data Standard Usage

- Posting of Exemption Information
 - The appreciate party must record the exemption information in all relevant NRDS documentation.

NCTN and ETCTN Standards Usage Policies

- The standard question text can-NOT be changed unless pre-approved by NRDS WG (exception is NOT the rule)
- A response CAN be eliminated if it is not appropriate for a specific study.
- Additional responses can-NOT be added to a pick list.
- Responses can-NOT be merged.
- The question and answer sets MUST follow the style guide recommendations.
- Coded values specific to each group can be used in their own systems but NOT in Rave.
- An ALS **must** be submitted to document an **implemented** change.
- A CRF can be submitted with supporting evidence for a **proposed** change to a NRDS Standard CDE.

NCTN and ETCTN Standards Usage Policies

- The standard question text can-NOT be changed unless pre-approved by NRDS WG (exception is NOT the rule)
- A response CAN be eliminated if it is not appropriate for a specific study.
- Additional responses can-NOT be added to a pick list.
- Responses can-NOT be merged.
- The question and answer sets MUST follow the style guide recommendations.
- Coded values specific to each group can be used in their own systems but NOT in Rave.
- An ALS **must** be submitted to document an **implemented** change.
- A CRF can be submitted with supporting evidence for a **proposed** change to a NRDS Standard CDE.

Compliance Criteria

- **Purpose**

- A set of rules for the ALS reviewer to use as a validation checklist
- Check will be used to ensure that the forms built in the Global Library are compliant with the new ALS.

- **Criteria**

- All Permissible Values (User Data String) are included with the associated Common Data Elements
- The Permissible Values (User Data String) have not been altered unless a formal exemption has been approved
- All Designated Question Text/Alternates are included with the associated Common Data Elements
- All Common Data Elements included in the ALS are on the form
 - Only the CDEs that are required for the study need to be included for the CDUS Reporting Content
- It is recommended that the NRDS Style Guide be used when developing the forms in the Global Library

Frequently Asked Questions

- Which components of the ALS can be changed by the LPOs?
 - Regarding all CTSU Integrations:
 - CANNOT BE CHANGED: Field & Form OIDs, Dictionaries & Dictionary LOVs, unless an alternate compliant solution has been agreed upon.
 - CAN BE CHANGED: Field Label, Header text and Form Instructions
 - CAN BE ADDED: Edit checks/custom functions involving these forms, SAS labels, etc.
 - Regarding the CTSU OPEN-Rave Forms Integration:
 - The above items, *plus...*
 - CAN BE ADDED: LPOs can create/ add additional Edit Checks (ECs) and Custom Functions (CFs) for the OPEN-Rave Integration forms to verify or populate data in LPO-specific forms.

Frequently Asked Questions

- How does this (LPO customization) impact integrations?
 - Regarding all CTSU Integrations:
 - The allowable LPO customization should have no impact on the CTSU integration activities, provided the LPOs do not change the OIDs and dictionaries.

Next Steps

- Continue to review the NRDS Policy and Governance Plan components

Reference Information / Questions

- NCTN Co-Lead
 - Judith Manola, M.S., Biostatistician, Department of Biostatistics and Computational Biology, Dana-Farber Cancer Institute
 - jmanola@jimmy.harvard.edu
- NCI Co-Lead
 - Mike Montello, PharmD, MBA
Associate Branch Chief for Clinical Trials Technology
 - montellom@mail.nih.gov
- Project Management Support
 - Neesha Desai, PMP, Project Manager, NCI CBIIT
 - Neesha.Desai@nih.gov



**NATIONAL
CANCER
INSTITUTE**

www.cancer.gov

www.cancer.gov/espanol