

Network Rave Data Standards (NRDS) Policy and Governance WG

Judi Manola and Mike Montello

Agenda

- ALS Components Discussion
- NRDS Monitoring Review
- NRDS Policy and Governance Documentation
- Next Steps

NRDS Policy and Governance Suggestions and Responses

■ Which components of the ALS can be changed by the LPOs?

Regarding all CTSU Integrations:

- CANNOT BE CHANGED: Field & Form OIDs, Dictionaries & Dictionary LOVs
- 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.

NRDS Policy and Governance Suggestions and Responses

- **What happens when CTSU provides the final ALS to the groups and the LPOs want to use their own Short Name (OIDs), etc?**

Regarding all CTSU Integrations:

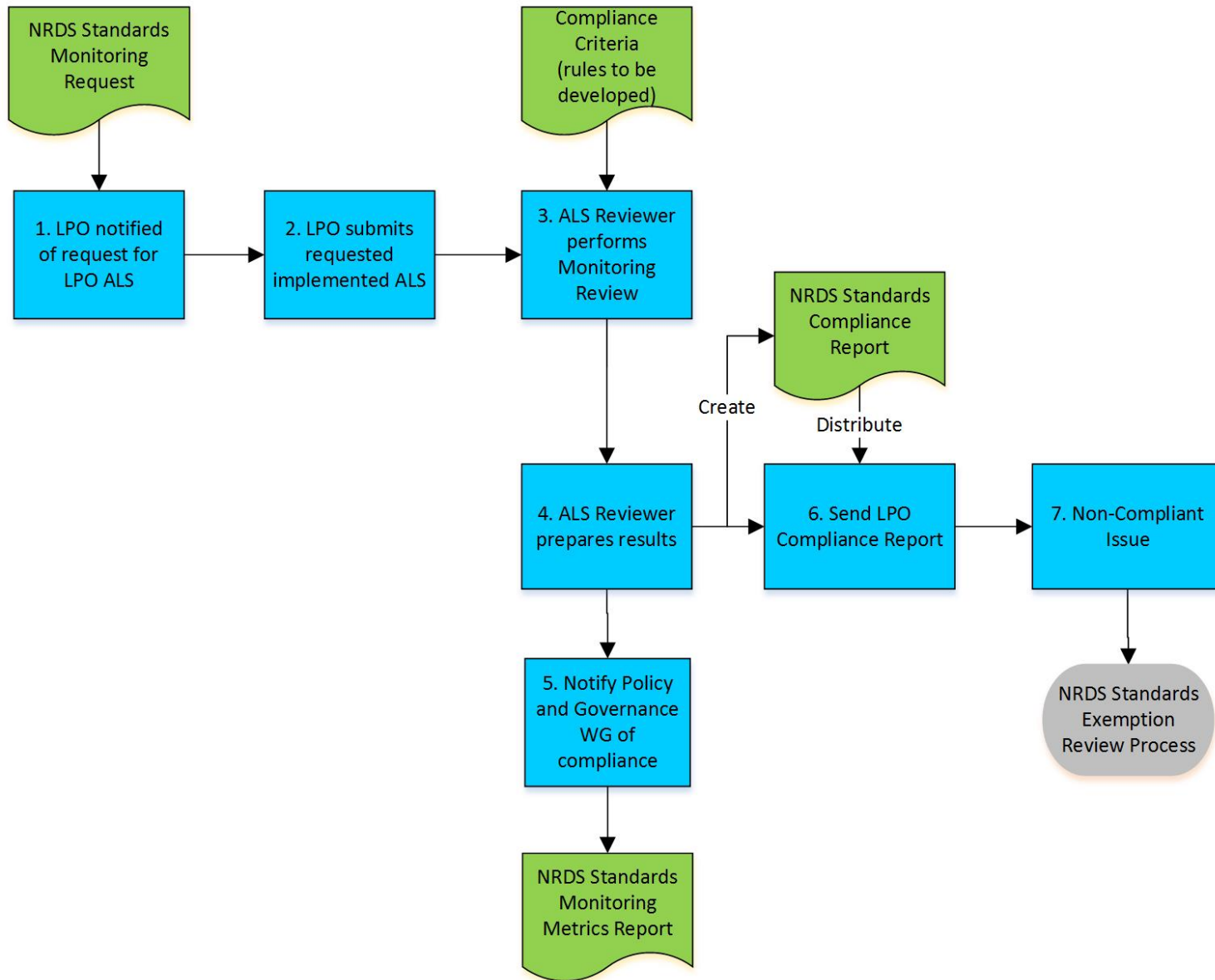
- If OIDs or dictionaries are changed, the integrations will break.

- **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.

NRDS Standards Monitoring Review



NRDS Policy and Governance Documentation

- **How do we want to formalize the policy documentation?**

Next Steps

- TBD

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