

Network Rave Data Standards (NRDS) Content WG

Tina Taylor and Dianne Reeves

Agenda

- NRDS Project Update
- NRDS OPEN Demography Implementation
- Additional OPEN Forms Strategy
- Rave Integration Workflow
- Additional OPEN Forms Review

NRDS Project Update

- **Briefed 2 NCI Leadership teams on NRDS progress**
 - Positive response from both leadership teams on progress of work
- **Completed Deliverables**
 - Provided recommendations on content and sent to CTSU for review
 - (S)AE integration content with comparison to other integrations
 - OPEN Demography
 - Agreement to use the same question and answer set, formatted in the same way (i.e., text) for transmission to NCI.
 - Guiding principles for Content Working Group
 - Formal Voting Guidelines
 - Formal Voting Form
 - Communication workflows
 - News bulletins (ongoing)

NRDS Project Update

- **Next steps**

- Provide recommendations on remaining OPEN forms as another aspect of integrations
 - Step information
 - Subject Enrollment
 - Treatment Assignment
 - Patient information for NCI Reporting
- Present progress update at the Clinical Trials and Research Opportunities Committee (CTROC)
- Present progress update to the NCTN Group Chairs
- Review the remaining CDUS Content
- Additional area of interest is Biomarkers

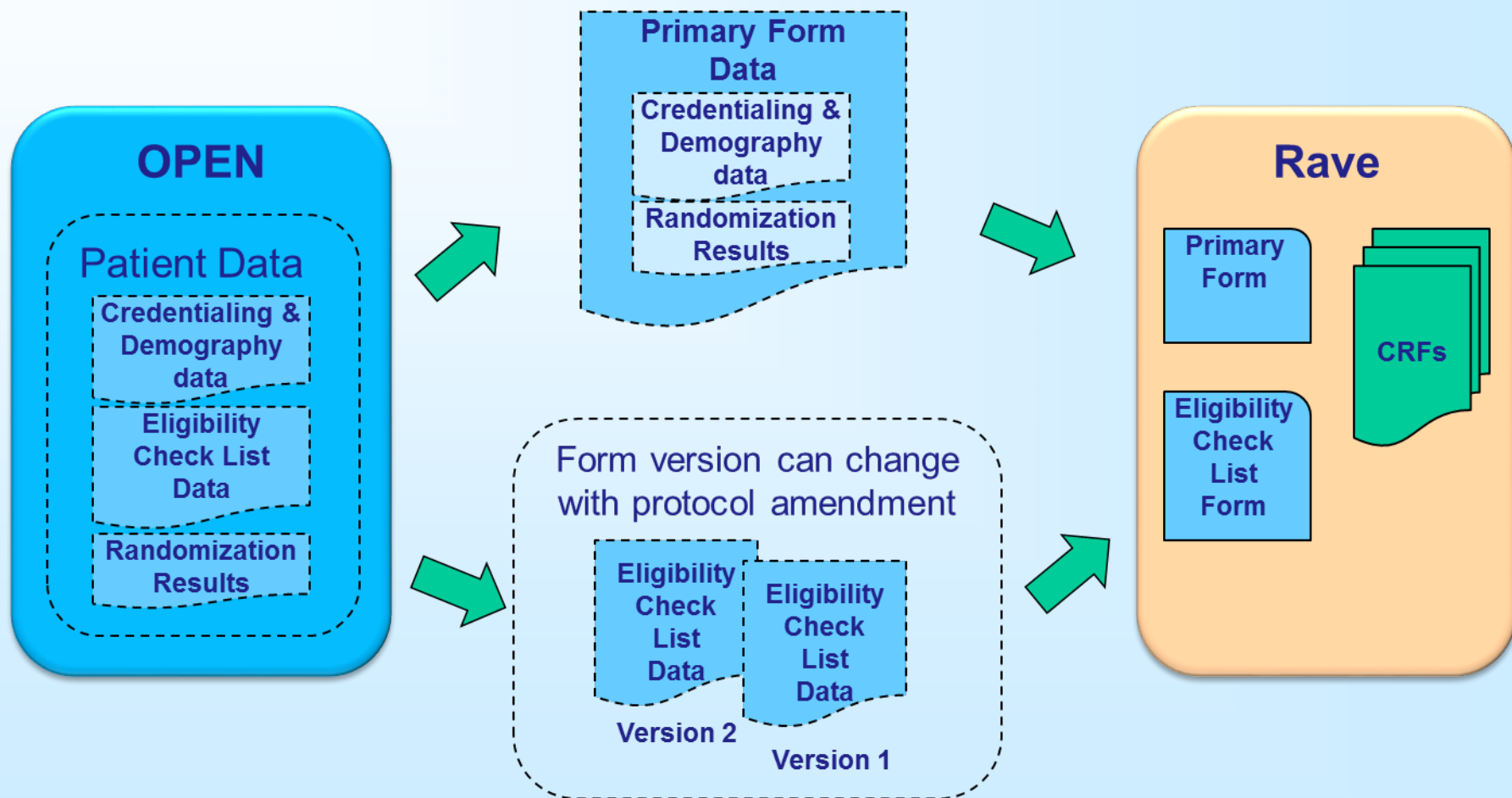
NRDS OPEN Demography Implementation Strategy

- Build the forms with the new standards
 - 1 LPO will work in collaboration with CTSU to build the forms
 - Forms will be captured, shared and versioned
- Initiate a review process to ensure the standards meet the needs of the LPOs
- CTSU will update the Rave CRF Template and post it for reuse
- Act on quality assurance procedures to manage the use of the new standards.
- Develop governance procedures
- Put training procedures in place for use of the new standards.

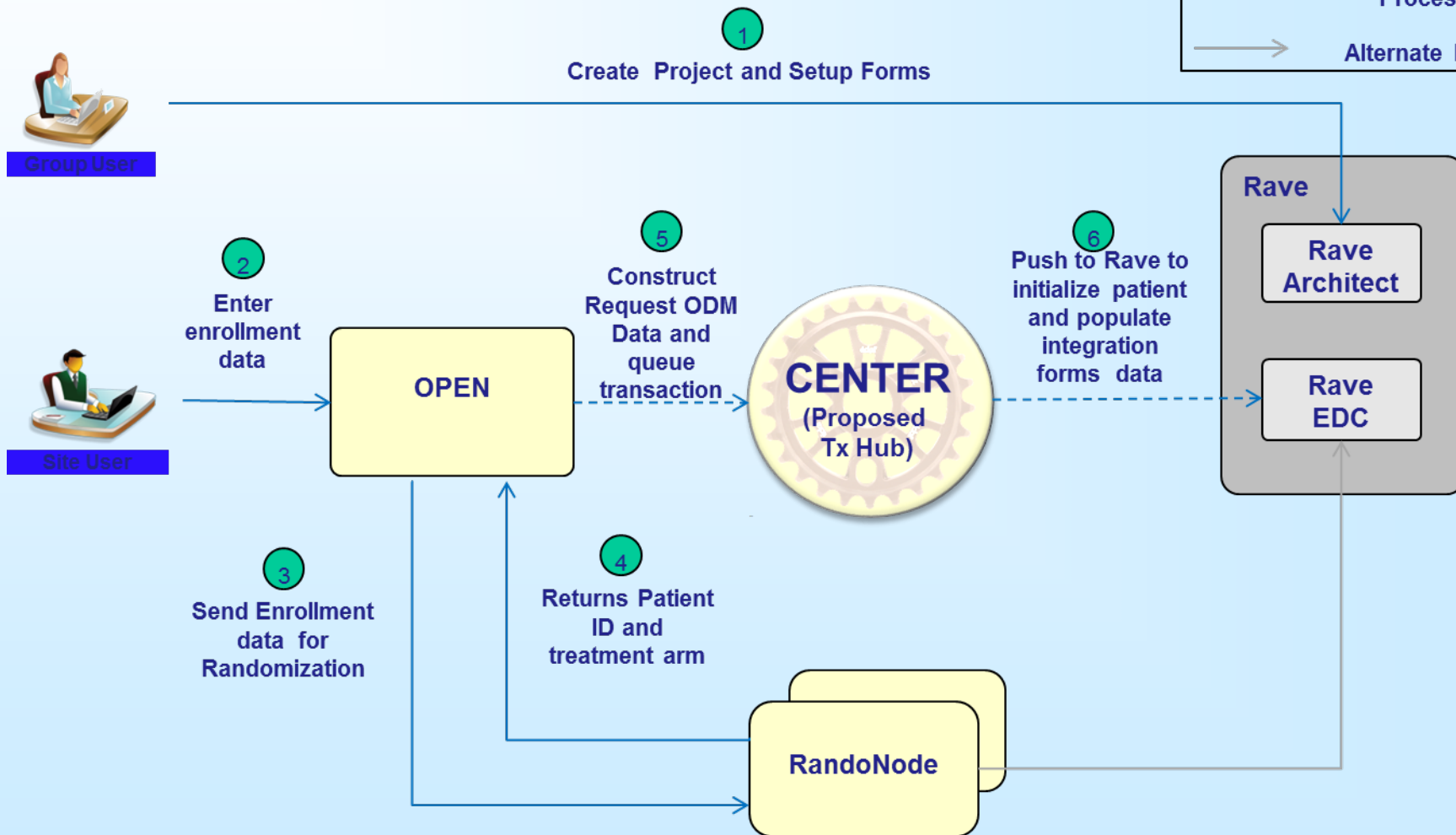
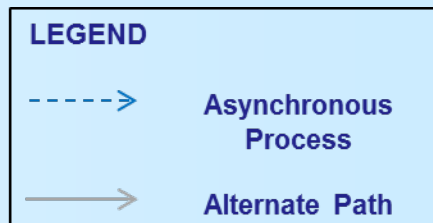
NRDS OPEN Review Strategy

- Review the following forms in OPEN (approx. 37 CDEs)
 - Step information
 - Subject Enrollment
 - Treatment Assignment
 - Patient information for NCI Reporting
- In parallel, NCI co-leads and NCI curator will identify discrepancies in CDUS for those identified elements

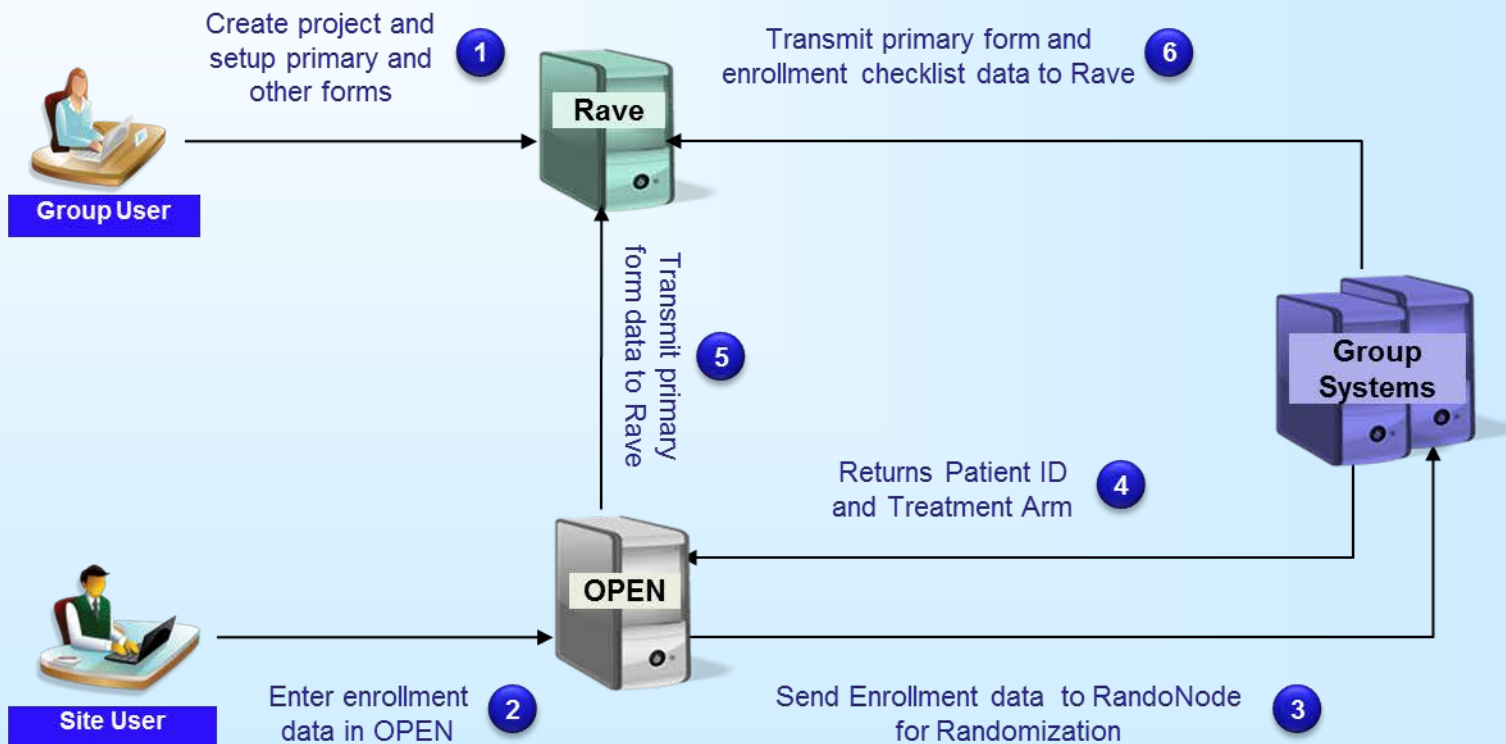
Components of Patient Data



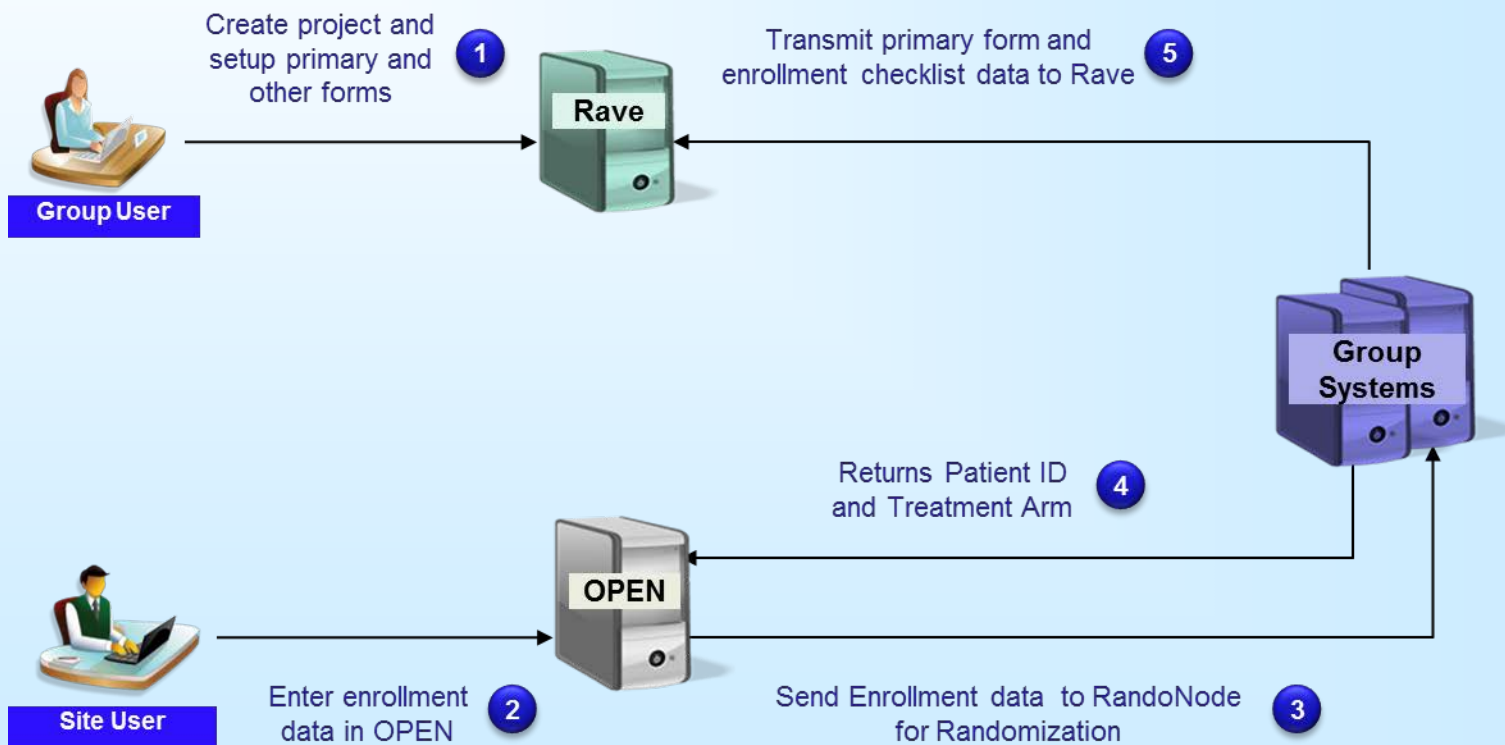
Workflow Diagram



OPEN initializes the patient



Group initializes the patient



Next Steps

- Continue reviewing OPEN Content

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



**NATIONAL
CANCER
INSTITUTE**

www.cancer.gov

www.cancer.gov/espanol