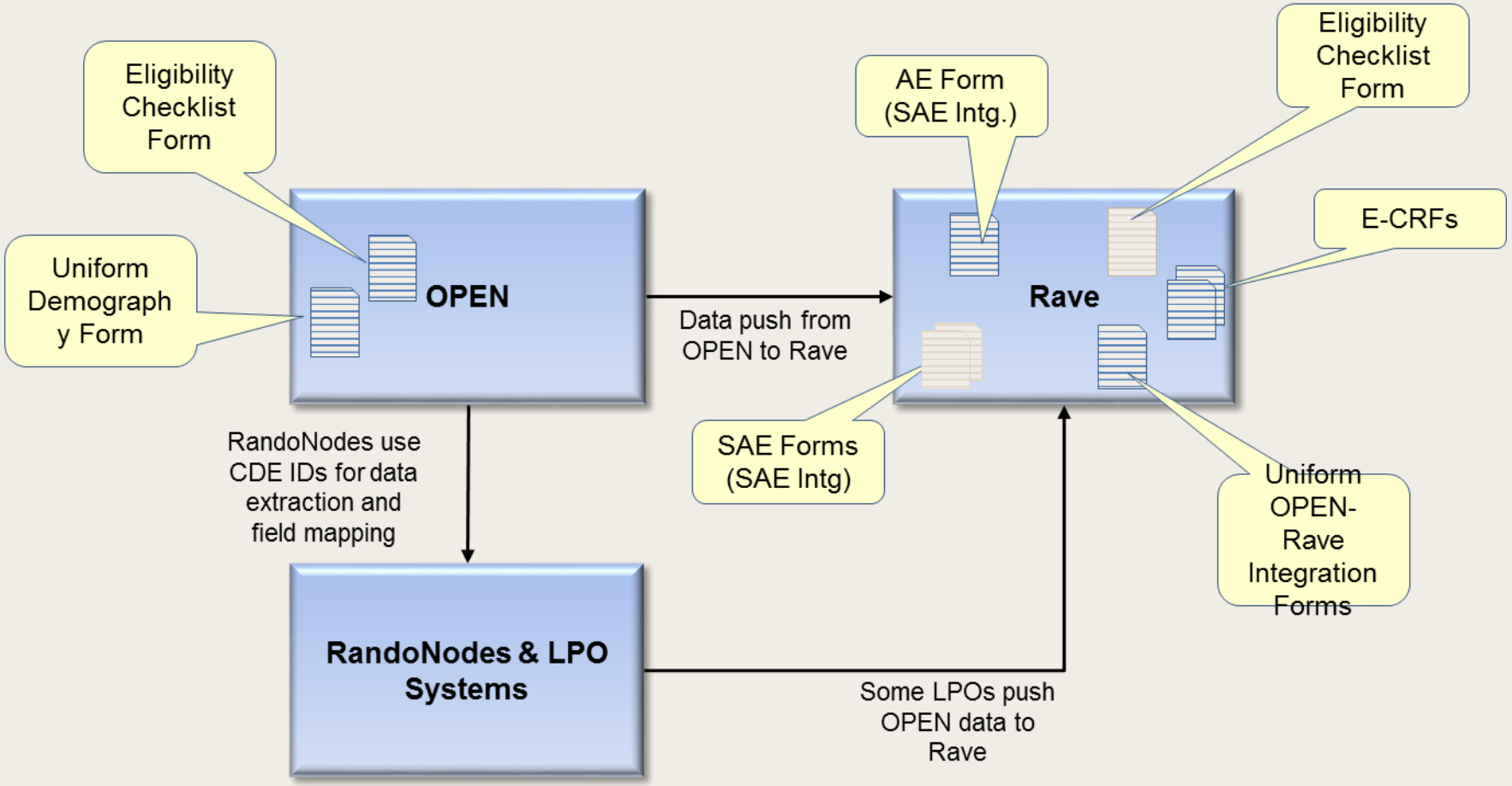
NRDS

Updating CDEs In Rave

05/27/2015

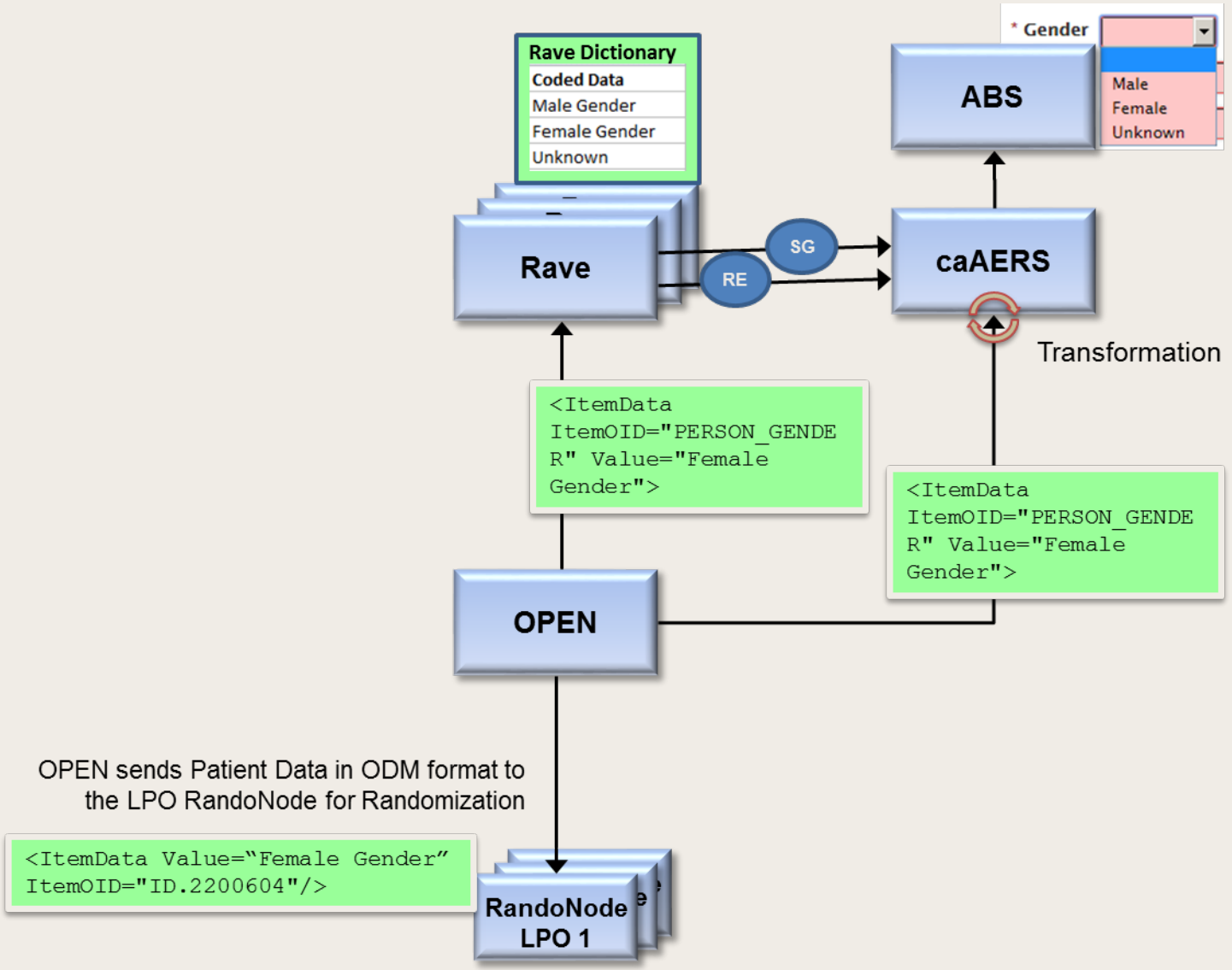
Background – Current CDE Usage



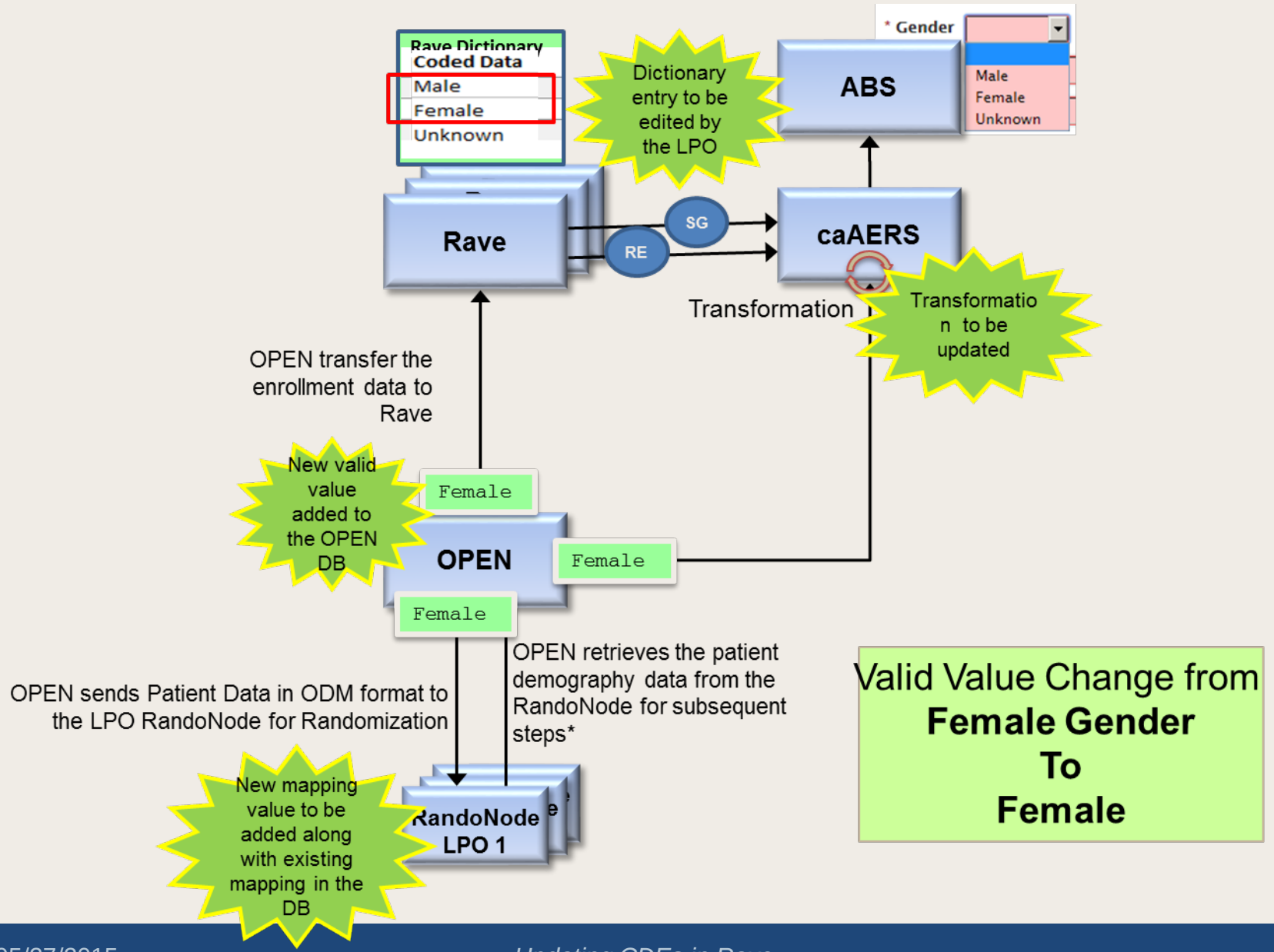
How CDE Fields are Used in OPEN, RandoNodes and Rave

OPEN		RandoNode (ODM)	Rave	
Field	Example	Example	Field	Example
Public ID	2200604	Used	Used	
Version	2.0	N/A	Used	
NA	NA	N/A	Field Name	Person Gender Text Type PID2200604_V2_0
Short Name	PRSN_GENDER_TXT_TP		FieldOID and VarOID	PRSN_GENDER_TXT_TP
Question Label	Gender of a Person	<ItemData Value="Female Gender" ItemOID="ID.2200604"/>	Field Label	Gender of a Person
Definition	Text designations that identify gender. Gender is described as the assemblage of properties….		Help Text	Text designations that identify gender. Gender is described as the assemblage of properties….

Overview of Existing Data flow



What is Needed to Change a CDE



Number of CDEs in Use

System	Form	Number of CDEs
OPEN	Uniform Demography Form	11
OPEN	Study Specific Eligibility Checklist Form	Varies with studies
Rave	Uniform OPEN-Rave Forms	29 (v4.0) 37 (v5.0) (Additional CDEs are due to Admin data)
Rave	SAE Integration Forms	28 (v RE-1) 154 (full release) (In general impact is limited to the AE collection datapoints which is limited to 28 datapoints – RE-1)
Rave	Study CRFs	Varies with study

Recommendations and Best Practices for Changing CDEs Involved in OPEN-Rave-RandoNode and SAE Integration

General Recommendations

- CDE changes can impact multiple connected systems
- To maintain the data integrity of data already collected, it is appropriate to make changes only on new studies
- To reduce development and testing efforts
  - Limit the number of changes
  - Bundle all changes together so that efforts can be combined
  - Standardization of changes across LPOs are required when making changes on the forms which are used in any integration

Steps for making changes in Rave

- Recommend the use of a new ALS versions containing forms/data points updated
  - New studies will use the new version of the ALS while existing studies remain without any change
- Custom functions and edit checks that evaluate the valid values affected by the CDE change are to be (modified and) retested
- Data extraction and processing tools (E.g. Those that consume SAS on demand files) may need to be retested for the valid value change

Changes needed in OPEN

- Will add the new valid values to the OPEN database
- The new valid values will be hidden for the existing studies hence only the old values will be available for selection for the existing studies
- For new studies the new values will be made visible while the old values will be hidden
- Need to test the slot reservation and patient registry implementation

Changes needed on the RandoNodes

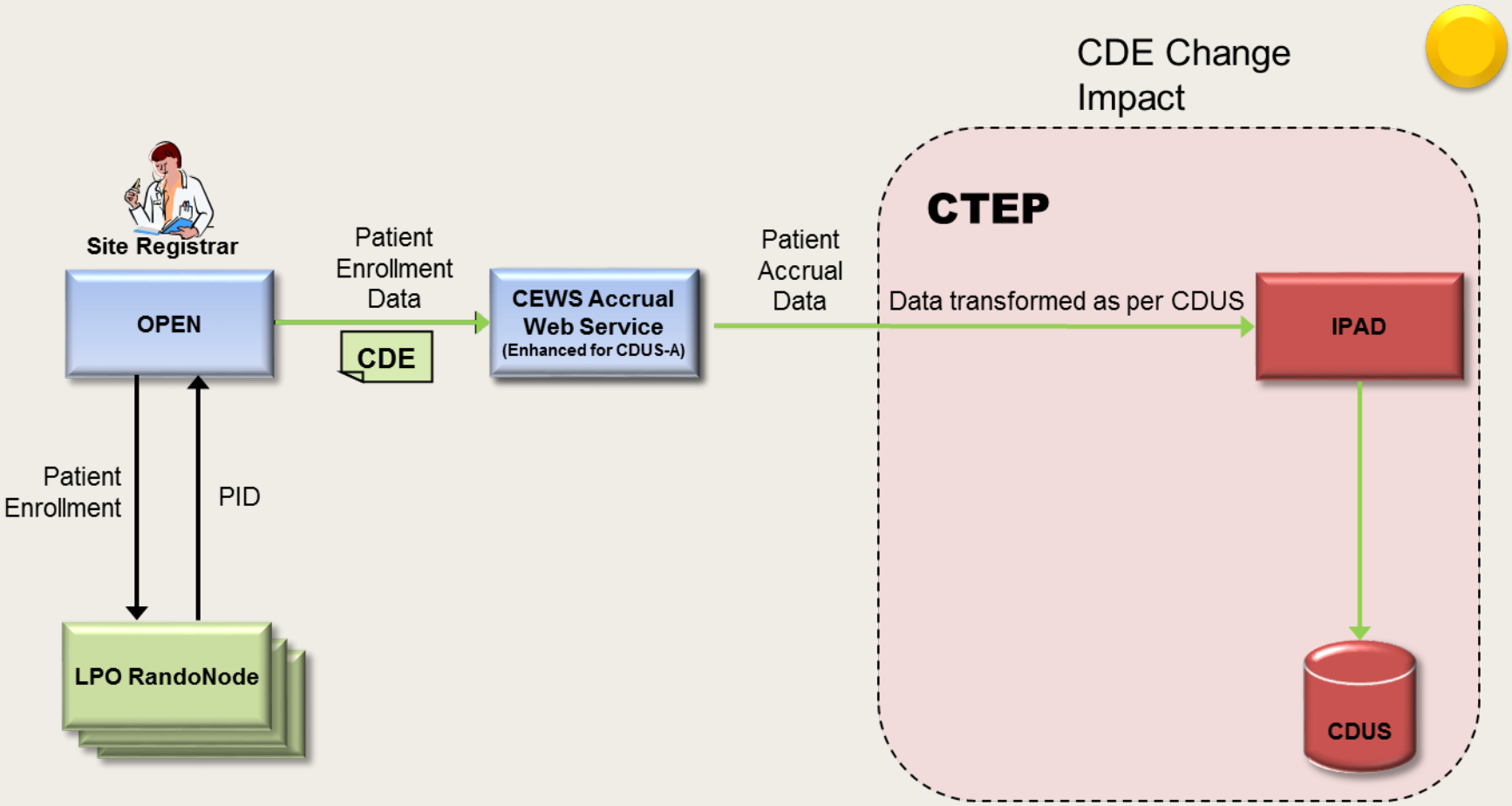
- Add new valid values to the RandoNode database
- Any connected LPO systems consuming the data must be retested to support both old and new valid values
- If the LPO is pushing data to Rave, the data push to Rave is to be rested to handle the new valid values

Changes needed on caAERS for the SAE Integration

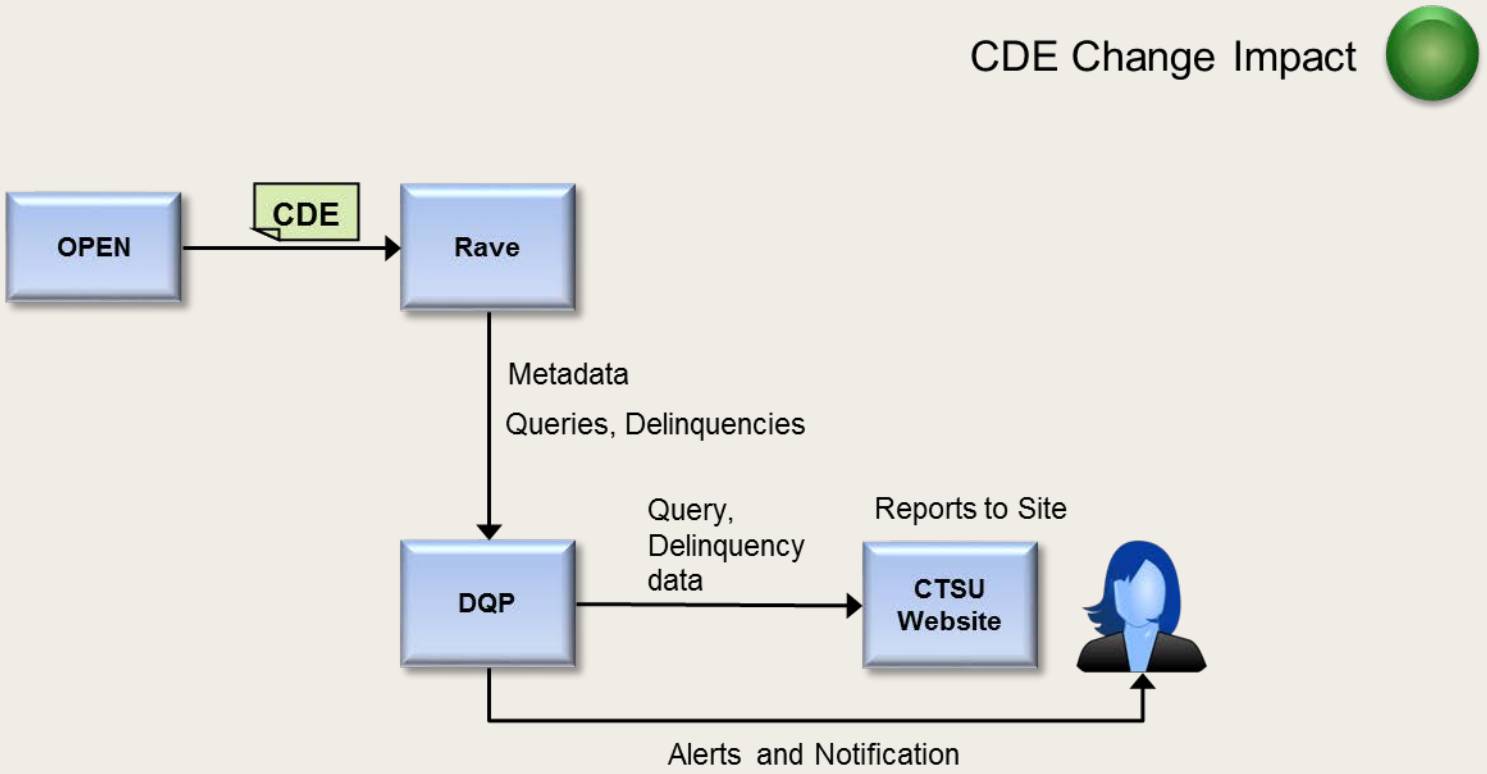
- The transformation logic used in caAERS for mapping the valid values sent by OPEN to match the values in ABS is to be modified and retested
- Any data validations on the changed valid values performed on the user interface layer must be evaluated and retested

Impact on other Integrations

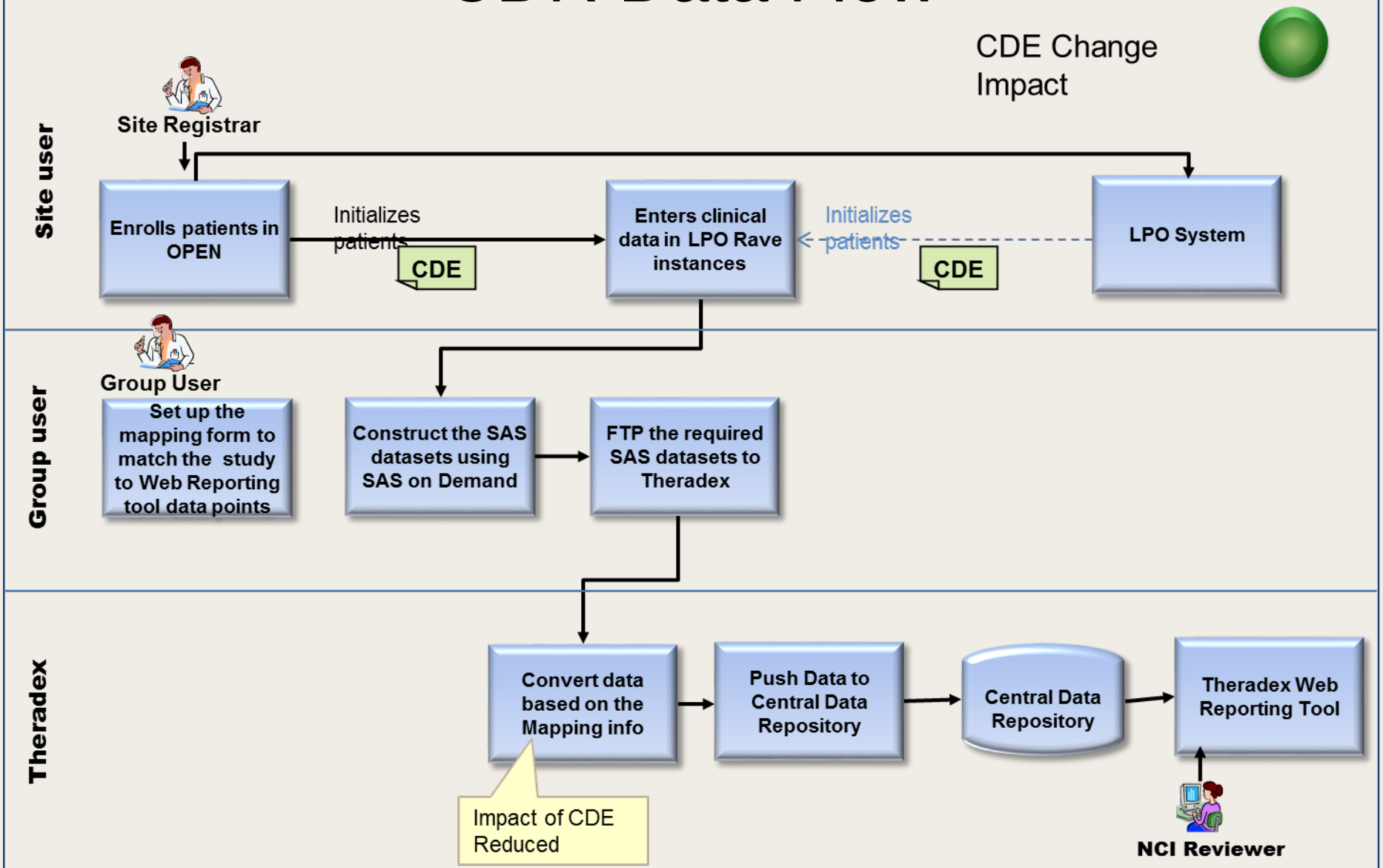
CDUS-A: Workflow Diagram



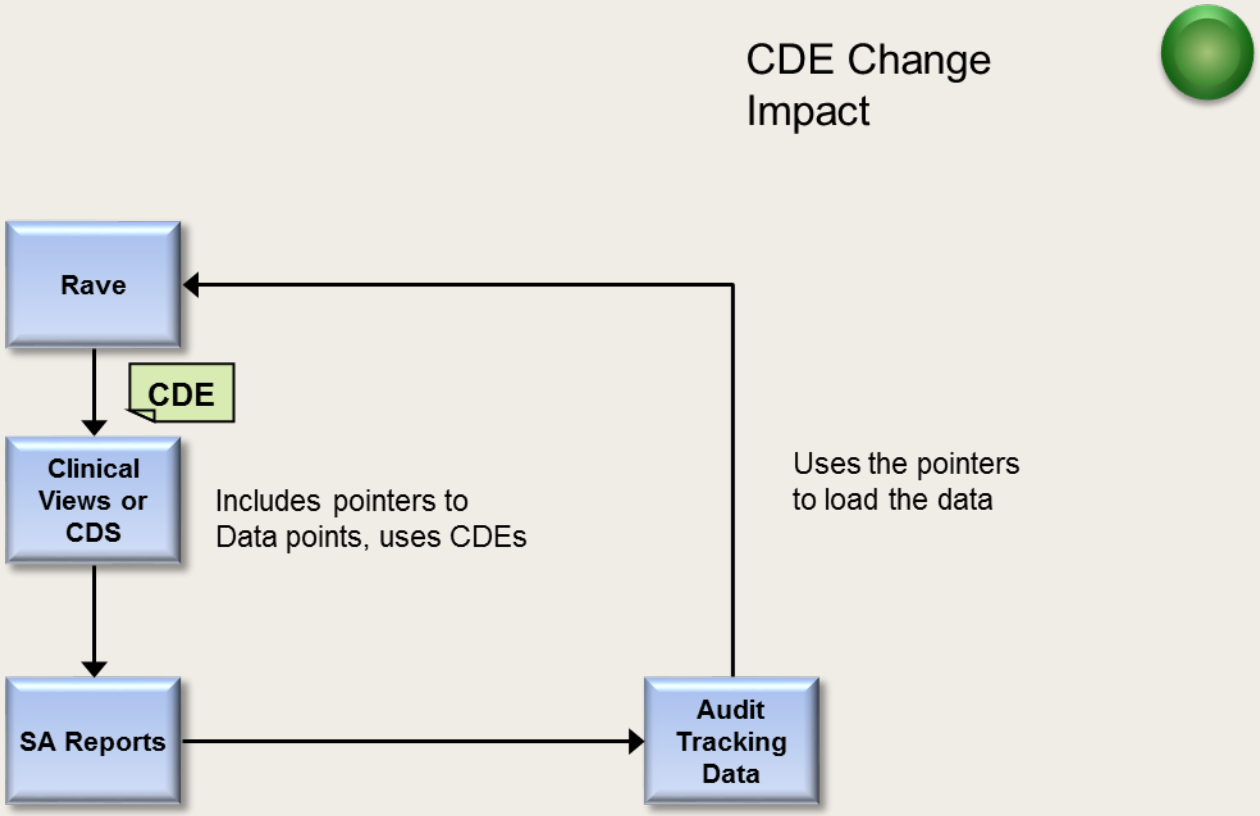
Data Quality Portal



CDR Data Flow



Site Audit Reporting



Questions