The Janus Clinical Trials Repository (CTR) is a data warehouse application that supports the automated extraction, transformation, loading, management, and integration of clinical trials data to support regulatory review and analysis needs. Developed in collaboration with the National Cancer Institute (NCI), the Janus CTR is a standards-based repository of subject-level clinical trial data that will facilitate the regulatory review of drug and biologic therapeutic products. The Janus CTR is designed to receive data in CDISC SDTM format and con support other study data exchange standards, such as CDISC SEND, HL7 v3, FHIR, and RDF. The Office of Computational Science (OCS) has been loading data to the Clinical Trials Repository since November 2014.

Future: Load all studies with SDTM datasets for all applications received at FDA

2016: Load all studies for applications that receive JumpStart Service in 2016. This includes the selected studies used during the JumpStart Service as well as any other studies within the application that contain SDTM datasets.

2015: Load selected studies for applications that receive JumpStart Service in 2014 or 2015. This includes only the selected studies used during the JumpStart Service.

Future: Load all studies with SDTM datasets for all applications received at FDA.

We tracked and inventoried all errors encountered in the loading of SDTM datasets for 180 clinical studies to date.

CTR First Load Failure Rate by Month

86 Studies (55%) had major blocking issues
28 Studies (18%) were missing TS domain files
17 Studies (11%) had misc. loading issues
8 Studies (4%) did not load to Janus CTR

- 65 studies (43%) had issues within the Define files
- 76 studies (49%) had issues within the TS domain data
- Had to create the TS domain file in order to load the studies
- Issues within other domain files that prevented the initial load or software problems that prevented the initial load
- 4 studies (2%) are missing define files
- 4 studies (2%) have significant data issues and we cannot fix them without more information from sponsor/sponsor resubmission