

# US Department of Health and Human Services

## Privacy Impact Assessment

**Date Signed:**

09/24/2013

**OPDIV:**

FDA

**Name:**

Study Data Review Tools < Janus Clinical Trials Repository

**PIA Unique Identifier:**

P-1432914-729641

**The subject of this PIA is which of the following?**

Major Application

**Identify the Enterprise Performance Lifecycle Phase of the system.**

Test

**Is this a FISMA-Reportable system?**

No

**Does the system include a Website or online application available to and for the use of the general public?**

No

**Identify the operator.**

Agency

**Is this a new or existing system?**

Existing

**Does the system have Security Authorization (SA)?**

No

**Indicate the following reason(s) for updating this PIA.**

PIA Validation

**Describe in further detail any changes to the system that have occurred since the last PIA.**

None.

**Describe the purpose of the system.**

The CTR application encompasses a repository (e.g., warehouse) of clinical trials study data and the associated data extract, validation, transformation, and load functions required to populate the repository. The application also includes functionality to extract data from the CTR to populate a specialized database designed to provide enhanced views of the clinical trials study data in SDTM (Study Data Tabulation Model) format that can be accessed by FDA reviewers using a variety of tools (e.g., JReview, JMP, SAS, others). The CTR supports FDA's strategic goals to:

- Strengthen the science that supports product safety
- Improve the medical review process to increase the predictability & transparency of decisions using the best available science
- Increase the number of safe & effective new medical products available to patients
- Detect safety problems earlier & better target interventions to prevent harm to consumers.

**Describe the type of information the system will collect, maintain (store), or share.**

This system will collect, maintain and share (with FDA reviewers) clinical trials study data.

**Provide an overview of the system and describe the information it will collect, maintain (store), or share,**

The CTR manages, stores, and makes clinical trials study data available to FDA users for use in comparative effectiveness research and/or regulatory review of new product submissions. This data represents information collected as a result of clinical trial studies that are submitted with new product submissions. This system contains a copy of the clinical trials data--original study data is maintained/archived in the Center's Electronic Document Room. Contents of these datasets include de-identified subject information associated with a subject ID (randomly generated and assigned, and not specific to any personal information or linkable to any individual), general demographic information, information on what the subject was given during the trial and observations on results for the study duration, information on adverse events, concomitant medications, and study begin and end dates.

There is no privacy information about subjects themselves or any other individuals (e.g., no name, SSNs, no addresses or zip codes, or phone numbers, etc.). CTR does not collect, use or handle proprietary information about any drug product being reviewed.

**Does the system collect, maintain, use or share PII?**

No