Janus Clinical Trials Repository—Modernizing the Review Process through Technology

Standard Safety Analysis Reports

Standard AE Analyses

Integration with JumpStart Service for Regulatory Review

Standard Reports using JReview

Ability to Select, Pool, Filter, or Subset Study Data, and/or Perform Complex Queries

Additional Views to Support Regulatory Review & Meta-Analysis

Enhanced SDTM Views

CTR

High-Level Process for Meta-Analysis of Study Data

Define the Problem

Identify Products & Studies

Determine Study Suitability

Perform Analysis

Produce Outputs

Top 5 Most Common Adverse Events

Multi-Study for Actos

Kaplan-Meier Curve for Bladder Cancer

Outputs in a Variety of Analytical Formats

Tools that Automate the Meta-Analysis Workflow

Study Browser (Select Studies)

Query Builder (Pool, Filter, Analysis Views)

CTR Reports (Analysis Panels, FIRRS, MAED)

Reviewer Analysis Tools (Reviewer, JMP, R, SAS)

Meta-Analysis (Template, Graphical Reports)

Enhanced SDTM Views (Templates, Graphical Reports)

Additional Views to Support Regulatory Review & Meta-Analysis (Study Browser, Query Builder, CTR Reports, Reviewer Analysis Tools, Meta-Analysis)