

Janus Nonclinical (JNC): A Unique Nonclinical Tool for FDA/CDER Reviewers

FDA/CDER/OTS/Office of Computational Science

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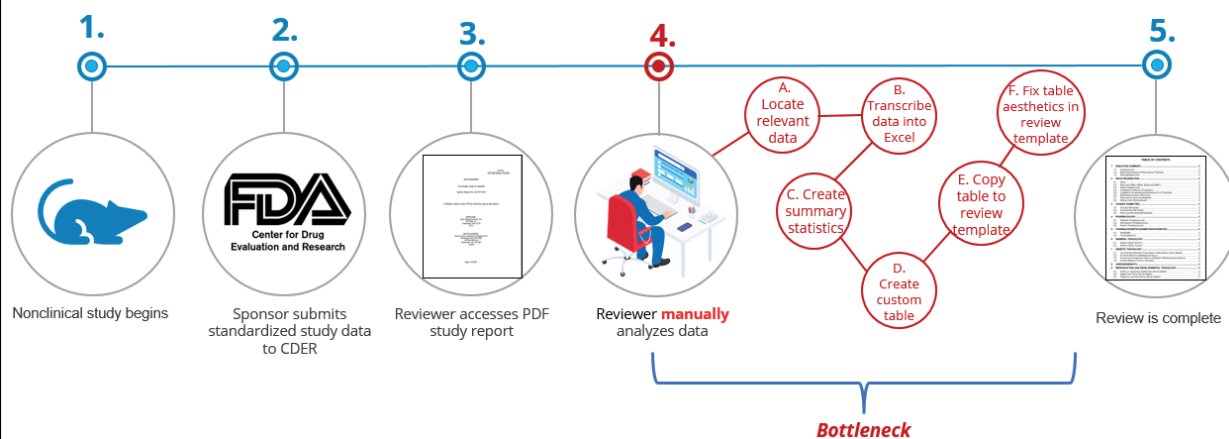
PP33

With Acknowledgement to Kevin Snyder and the OND Pharm/Tox Advisory Group

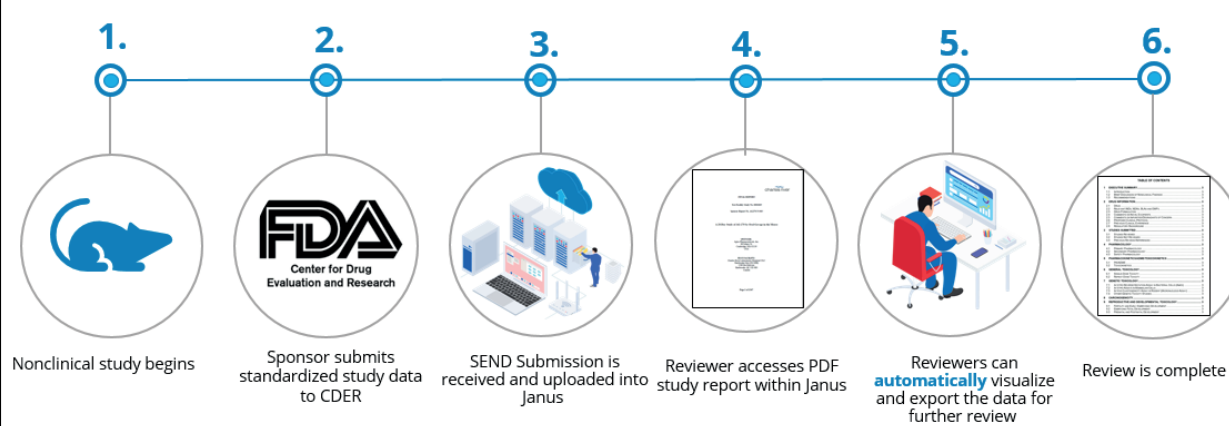
WHAT IS JANUS NONCLINICAL

- Janus Nonclinical is a web-based application that enables efficient review of validated Clinical Data Interchange Standards Consortium (CDISC) Standard for Exchange of Nonclinical Data (SEND) compliant study data submitted by sponsors in support of INDs, BLAs and NDAs.
- Designed by and for Pharm/Tox reviewers to interact directly with the study data and augment safety analyses by allowing interactive examination of the sponsor's data.
- Removes bottlenecks in the nonclinical review process through enabling reviewers to intuitively build review tables and charts to include in their review template.

Nonclinical Review Process *without* JNC



Nonclinical Review Process *with* JNC

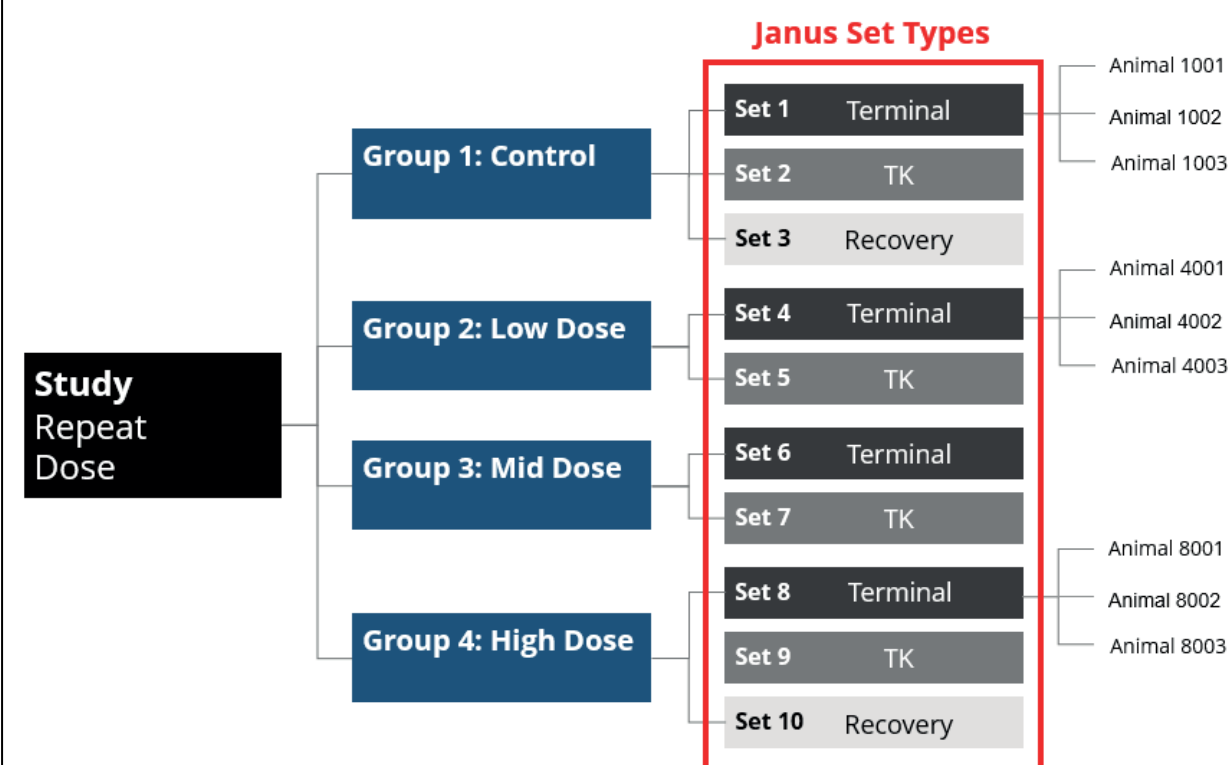


BUILT ON STUDY DATA PLATFORM (SDP)

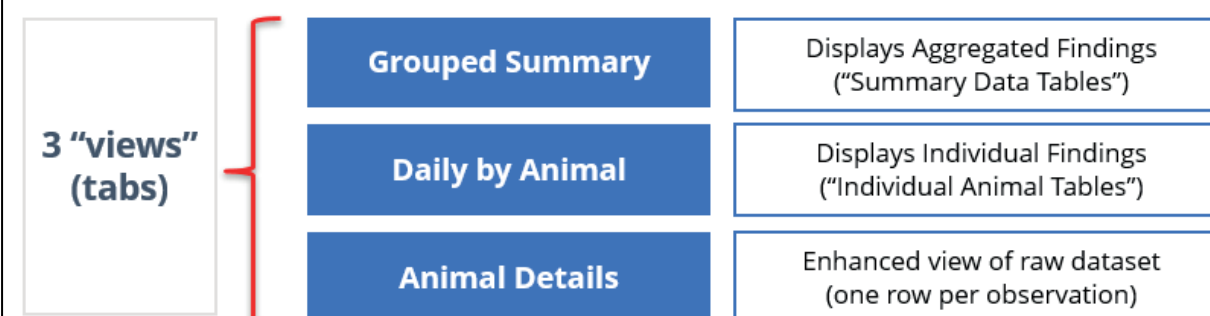
- Janus Nonclinical queries nonclinical study data from the OCS SDP in a structured relational database format.
- SDP is a clinical and nonclinical trials data warehouse application that facilitates automated processing, management, and reviewer access to standard subject-level clinical and nonclinical trials data to meet a variety of regulatory review and analysis needs.
- SDP is designed especially to support analytical and reporting functions involved in the regulatory review of drug applications.

TABULAR VIEWS

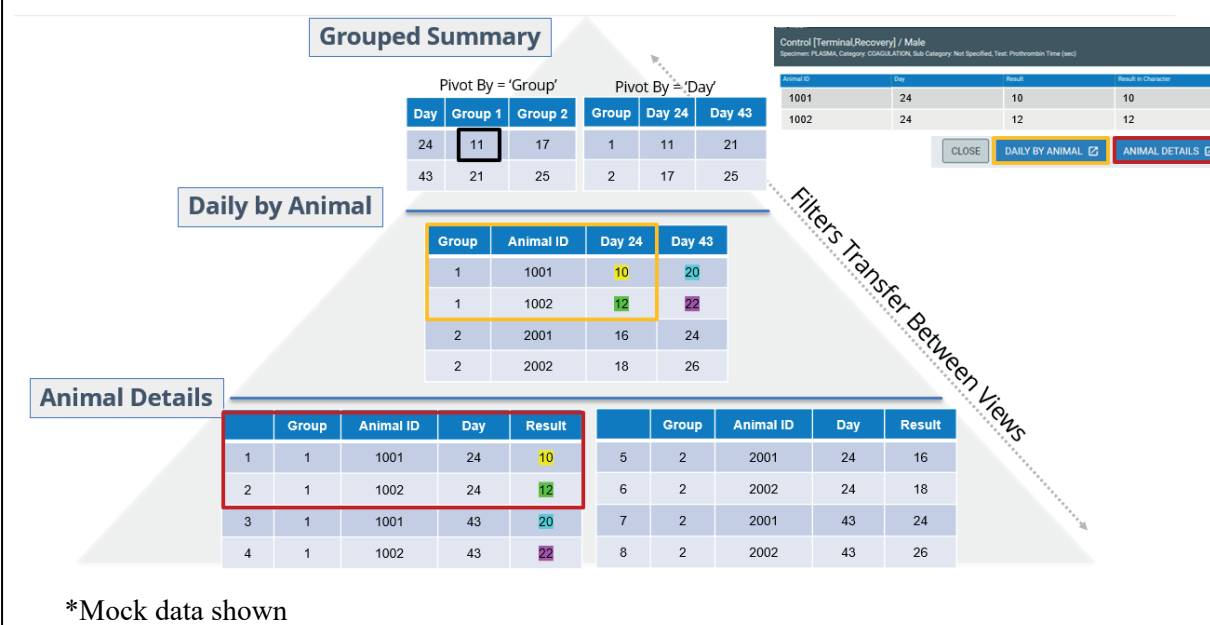
- Set Types in Janus Nonclinical enable reviewers to view data at the dose-group level.
- Set Types are a classification of the purpose of a Set of animals and are combined for summary statistic calculations in the Grouped Summary tables.



- Janus Nonclinical contains 3 tabular views to view the data at different levels.



- Data filters are retained across all 3 tabular views.
- Easily drill-down from Grouped Summary to Animal Details or Daily by Animal by clicking a datapoint or header.



*Mock data shown

CHARTS

- Reviewers can build and export highly customizable, dose-group level charts with settings that utilize Pharm/Tox-specific business rules.
- Reviewers can customize numerous aspects of the visualization, from baseline normalization down to the location of the legend, and export for their reviews.



*Public Dataset Shown

- Click on a datapoint to examine aggregated group data and drill-down to the Daily by Animal or Animal Details view.

Animal ID	Study Day	Result
PDS2017-1	8	8
PDS2017-11	8	7
PDS2017-12	8	6.4
PDS2017-13	8	5.9
PDS2017-14	8	5.7
PDS2017-15	8	5.9
PDS2017-2	8	6.5
PDS2017-3	8	9.3

*Public Dataset Shown

- Integration with the CDER IND Smart Template for the auto-population of Pharm/Tox reviewer specified, default, Body Weight charts.

KEY BENEFITS

- Tremendous time saver that enables reviewers to meet strict review timelines (over 4,000 unique studies reviewed since July 2019).
- Personalized reviewer views provide expedited access to reviewer-specific assignments and shortcuts to key features for streamlined reviews.
- Improves review quality by removing potential errors associated with manually creating tables/charts from the PDF study report.
- For more information about JNC, please contact: catherine.li@fda.hhs.gov.