JMP Clinical 18.0 - Release Notes

This document describes changes and enhancements from JMP Clinical, Version 17.2 to JMP Clinical, Version 18.0. Processes are described in the order in which they first appear in the JMP Clinical menu.

General Features

JMP Clinical 18.0 contains several new enhancements to the user interface, system configuration, and reports/reviews.

JMP Platform Updates

JMP Clinical 18.0 is built on the latest JMP release, JMP 18.0. For more information about the updates to JMP software that are included in this release, please see the <u>New in JMP</u> 18 web page.

JMP Clinical 18.0 now installs as a separate application on MacOS.

Software Documentation Updates

The *User Guide* has been updated to reflect all new and updated software features.

New Features in JMP Clinical 18.0

Drug Induced Liver Injury

This report assesses the results of multiple lab tests enabling you to determine whether trial subjects have sustained drug-induced liver damage. Analysis results are presented and summarized in multiple graphs and tables.

Risk Based Monitoring

Risk-based monitoring is a proactive method of clinical trial monitoring to detect patient safety risks and data quality issues at an early stage of a trial. Unlike traditional monitoring methods which often involve 100% Source Data Verification (SDV), which is costly and time consuming, this report uses a targeted approach to allocate monitoring resources based on specific risks identified at the study site, country, monitor, or vendor level.

Visit Order

This report determines whether visit dates are unusual for subjects when ordering dates according to visit number.

Patient Recruitment

This report estimates the likelihood that recruitment goals are met using enrollment data collected so far. The estimated parameters are then used to predict future enrollment patterns given the existing number of study centers. If the projected enrollment falls short, adaptive adjustment is launched to predict the number of new centers necessary for the target enrollment to be reached by the deadline with a prespecified parameter New Center Delay Days.

JMP Clinical Data Mapping Tool

This Add-In enables you to map column names in various file types, including .sas7bdat, .xls/.xlsx, .csv, .txt, or .jmp files, that may not be CDISC-compliant to variable names from SDTM and save them with proper file names and file extensions (.jmp) for the different data sets used by JMP Clinical.

JMP Clinical Recoder

This Add-In enables a user to select any of the domains for any of the studies registered to JMP Clinical and change how a value is encoded, map multiple values to a single value or split a single value into multiple values.

Subpopulation Builder

The tool enables users to narrow their analysis to a small subpopulation of interest. It limits the population or records of interest in the analyses to those meeting filtering criteria within and across the domains. Unlike the data filters or Where Clause Builder used in many reports, which are focused on a single domain, the Subpopulation Builder facilitates more advanced subpopulation specification across all available domains and guides the user as much as possible in creating a complex selection of subjects that can be saved and recalled in future analyses.

Improved Features in JMP Clinical 18.0

Algorithmic FDA Medical Query Risk Report

Sex-specific AFMQs are now shown in separate tables.

All Risk Reports

New widget enables users to specify alpha.

Ability to calculate and show FDR in volcano plots has been added.

All Reports with JMP Hotspots (Left-side Red Triangles)

Hotspots have been removed and the Control panels surfaced when clicking on the hotspots have been replaced with the ability to reopen the same analysis in a separate JMPwindow ant ability to save the analysis to a JMP script.

Explore in JMP

The **Show Tables** drill-down button surfaces a window containing Results tables, within the report where you can explore selected rows or all rows in JMP as well as convert character dates to numeric values.

Increased JMP Live Compatibility

The results of all JMP Clinical Reports can be posted as static images to our JMP Live product. With the release of JMP Clinical 18.0, an increased number of reports can be posted interactively to JMP Live.

Patient Profiles

New enhanced views have been added.

The speed of the generation of patient profilers has been improved. When selecting subjects in the report options window the patient profile now automatically updates.

Data Filters

Where Clause Builder

The Where Clause Builder is a specialized data filter that uses WHERE expressions to filter out and select observations meeting one or more specific defined criteria. A WHERE expression can be as simple as to use a single variable name. A WHERE expression can contain a function, or it can be a sequence of operands and operators that define one or more conditions for selecting observations. Currently, this tool is used in the Adverse Events Narrative and Risk Based Monitoring reports only.

Save Review Subject and Report Filters

Save review subject filter and report filter settings to Clinical Reviews

See New in JMP 18 and New Features in JMP Clinical 18 for more information.