

# JMP Clinical 8.0 - Release Notes

This document describes changes and enhancements from JMP Clinical, Version 7.1 to JMP Clinical, Version 8.0<sup>1</sup>.

## General Features

JMP Clinical 8.0 contains new reports along with several new enhancements to the user interface, system configuration, and existing reports/reviews.

## JMP and SAS Platform Updates

JMP Clinical 8.0 is built on the latest JMP release, JMP 15.2.1 For more information about the updates to JMP software that are included in this release, please see the [New in JMP 15](#) web page.

JMP Clinical 8.0 is built on the latest SAS release, SAS 9.4 M7. For more information about the enhancements to SAS analytical software that are included in this release, please see the [What's New in SAS 9.4](#) web page.

## Software Documentation Updates

Installation and Configuration documentation has been consolidated and placed at [jmp-clinical-software-updates.html](http://jmp-clinical-software-updates.html).

The **User Guide** has been restructured and updated to reflect all new and updated software features. You can opt to view the user guide either within the JMP Clinical UI or in a separate window with full browser controls.

## Study Management and Configurations

An option for automatically adding the Nicardipine sample study has been added to the welcome screen surfaced the first time you open JMP Clinical.

Improved support for ADaM data structures and Date/Time variables has been added to Study and Report management.

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<sup>1</sup>Note: If you have a suggestion, comment, or encounter a bug in JMP Clinical 8.0, please click Send a Comment or a Feature Request under Clinical > Documentation and Help , or email details to [Clinical@jmp.com](mailto:Clinical@jmp.com). For bugs, it is especially helpful if you can attach a settings file for the JMP Clinical process in which you encountered the problem, along with a subset of your data that can be used to reproduce the error. If you cannot share a subset of your own data, but can reproduce the problem with one of our sample data sets, please send us a settings file for this so that we can replicate the error. We make every effort to address the issue promptly. Thank you for taking the time to do this!

## Set Value Order and Color in Studies

This report now enables you to set and alter color themes, override colors, and swap colors between a pair of values, in one or more variables. In addition, you can set color themes and apply them specifically to any or all treatment variables.

## Manage Configurations

Backup copies of a configuration's *installation.paths.preferences* and *system.clinical.preferences* files are made when the user enters and selects a given configuration in the configuration manager.

## JMP Live Integration **New!**

JMP Live, a new collaborative analytics software system for sharing interactive reports, takes the robust statistics and visualizations in JMP and extends them to the web, privately and securely. The new **Create Live Report** process brings these capabilities to JMP Clinical 8.0. Users can now generate a publishable review of all open reports for uploading to the JMP Live portal or other website or file designated by your system administrator. Share graphics, data, and notes. Specify who may view and interact with your data or keep everything private. Reviews published on JMP Live can be viewed using JMP Clinical 8 or JMP 15.

## JMP Clinical Reports

### AE Narratives

An alert informing you to synchronize your current Adverse Event Narrative Templates for a given configuration is surfaced whenever you update JMP Clinical. Ability to add, delete, and edit templates as part of a user configuration is now available. Demographic variables AGE, SEX, RACE are no longer required to run a narrative. New option for using study days from the concomitant medications (CM) data set instead of derived JMP Clinical calculation of study days.

### Multiple Reports

For notes, with at least one subject selected, you can create a data filter for the selected subjects using the **View Notes** function. For each report that is run, JMP Clinical now captures the lines of the JMP log relevant to that report and saves them as a text file in the report run folder.

### Demographics and Visits

**Enrollment Patterns** and **Patient Recruitment** now allow TRTSDT to be used in place of RFSTDTC when using ADaM data.

## Distribution Reports

New sorting options allow users to sort the adverse events/events/interventions tables either by counts or by group or term levels.

Dynamic recalculation of subject percentages and incidence rates are now supported when By Variables are specified.

## Event Reports

JMP Clinical now preferentially uses AETOXGR over AESEV in all AE reports when assessing for severity.

The maximum value allowed for specifying an offset for the end of dosing has been increased from 30 to 60 days.

The **Adverse Event Distribution** report now supports ongoing studies for incidence rate calculations with an option to use AE table last modification date and offers new options for specifying an offset for Patient Duration calculation.

Numerically formatted Date/Time variables and duration variables are now included in the output of AE Distribution when calculating incidence rates.

## Mortality Time to Event

A new option to include deaths that occur before treatment has been added.

## Medical Query Risk Report *New!*

This new report screens Standardized Medical Query (SMQ) terms by performing Cochran-Mantel-Haenszel (CMH) tests on all 2 x 2 tables constructed from event incidence and treatment arm. Output is a two-sided plot with a dot plot showing percent occurrence and forest plot showing risk measurement. Additionally there are 4 tables for narrow queries with dictionary-derived terms, broad queries with dictionary-derived terms, broad and narrow queries, and queries by System Organ Class (SOC).

## Findings Reports

An option to plot time trend lines for each subject's findings measurement over the time of the study was added to **Findings Time Trends**.

An option for selecting and specifying the same *Findings Domain Tests for Analysis* across multiple Findings reports has been added.

Hy's Law Screening Shift Tables for Liver have updated the limit categories for elevations to reflect latest regulatory guidances.

## Reports

### Adverse Events Report

The report has been reformatted for consistency with CRO and Pharmaceutical industry standards. Options for specifying term and group levels have been added. An option for specifying a minimum percentage value for patients experiencing an event has been added. New option for sorting data in the Adverse Events table alphabetically or by counts.

### Standard Safety Report

An interactive table of contents has been added to the report and report tables have been reformatted for consistency with CRO and Pharmaceutical industry standards.

### DSUR/PSUR Report *New!*

This new report is used to generate a report for updating regulatory agencies regarding the safety of a clinical trial design and execution for the purpose of securing permission for the continuance of the trial..

## Patient Profiles

Patient Profiles have been re-architected to use JMP Graph Builder as the basis for the view, this allows publishing profiles to JMP Live or Interactive HTML formats.

The medical history end date now appears in tables.

An option for defining x-axis reference lines has been added.

New options in the **Manage Display Template** controls enable you to display the SUBJID instead of USUBJID, keep the subject identifier in the tables, and use the values in VISITNUM as the x-axis.

### JMP Clinical API

Continued enhancements have been added to use JMP Clinical APIs to support automation of study management actions and ability to create custom JMP Clinical reports.

A new API function has been added to support loading study data into JMP or JMP Clinical when creating custom analyses.