JMP Clinical 7.1 - Release Notes

This document describes changes and enhancements from JMP Clinical, Version 7.0 to JMP Clinical, Version 7.1[1].

General Features

JMP Clinical 7.1 contains several new enhancements to the user interface, system configuration, and reports/reviews.

JMP and SAS Platform Updates

JMP Clinical 7.1 is built on the latest JMP release, JMP 14.3. For more information about the updates to JMP software that are included in this release, please see the New in JMP 14 web page.

JMP Clinical 7.1 is built on the latest SAS release, SAS 9.4 M6. 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.

Localization

JMP Clinical now supports analysis of data recorded in either Japanese or Chinese, in addition to English.

JMP Clinical is now fully localized for Chinese users.

Software Documentation Updates

Installation and Configuration documentation has been consolidated and placed at 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.

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[1]Note: If you have a suggestion, comment, or encounter a bug in JMP Clinical 7.1, please click Send a Comment or a Feature Request under Clinical > Documentation and Help , or email details to 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!

Study Management and Configurations

JMP Clinical Studies will now detect and register split Findings About (FA) domain data if present in the study data directory folders.

Enhanced metadata collection on domains and variable names and labels is performed when adding a JMP Clinical Study. Note this may increase the processing time needed to add a new study or to refresh the metadata of a JMP Clinical Study.

A mechanism enabling users to add new and edit or delete Adverse Events Narrative templates has been added to the **Manage Configurations...** window.

The default configuration is now created at installation and placed in the User Configurations list. The *installation.path.preferences* and *system.clinical.preferences* files for this configuration are also now placed in the configuration folder.

A new JMP Clinical Study Management API enables users to programmatically get information, add, update, and remove studies in the their JMP Clinical configurations; potentially allowing for automation of repetitive tasks on a schedule or in response to some external trigger.

An option for converting data sets to U8 format has been added to the **Settings** window.

ADaM Data Support

JMP Clinical reports support enhanced use of ADaM variables, including ADaM occurance data (ADAE, ADCM, and ADMH) and date/time variables without the presence of SDTM DM domains for study date calculations.

Crossover Analysis

Improved detection and display of multiple period or crossover trial data, have been added to all **distribution** reports, **Adverse Events Narratives**, **Adverse Events Resolution Screen**, all of the **Incidence Screen** reports, **Findings ANOVA**, and **Findings Time Trends**.

Updates to period calculations to support existing domain period variables and to assign pre-treatment records have been made to all reports supporting multiple period studies. Notes regarding detection of multiple periods are now written to report output.

Support for period-matched baseline calculations has been added to **Adverse Events Narratives** and select **Findings** reports.

Automatic detection of multiple periods can now be disabled by manually setting the Treatment Variable in report options to a variable specified from DM or ADSL.

JMP Clinical Reports

All Reports

The new **Derived Population Flag** feature enables Review Authors to create indicator variables for subjects that meet criteria based on selections in any of the subject-level reports. The variables will have values of Y or N based on whether the subjects meet the criteria. These variables can be used for comparison, grouping, or filtering in subsequent JMP Clinical Reports so that Reviewers to easily compare subject populations based on ad-hoc criteria. Derived Population Flags can be viewed and managed from the Review Subject Filter.

A new option (located on the Settings window) enables you to include report descriptions on the report output dashboards.

JMP Clinical now collects metadata on both the SAS names and SAS labels of all domain variables and these are surfaced in the clinical report options panel.

AE Narratives

Ability to add, delete, and edit templates as part of a user configuration.

Two new oncology template have been added. The **ByNarrativeCategoryDetails** and **ByNarrativeCategorySummary** templates group adverse events into four categories: TEAE with a fatal outcome, Serious TEAE, TEAE leading to study drug discontinuation, or TEAE of special interest.

Documentation has been added describing the variables, that are used by the template to create the narrative and are contained in the output *narrtext* dataset, and how these variables are derived.

Adverse Event Narratives now support multiple treatment periods or crossover studies, including calculation of period-matched baselines in Findings domains.

Distribution Reports

Intervention/Events/AE Distribution

Percents are now fully calculated dynamically based on selections made in the Report Subject Filter to update both numerator and denominator subject counts. In previous versions, the denominator for percents was calculated in advance and did not reflect ad-hoc subject filtering.

Count (and percent) summary tables for events and interventions have been restructured to include the dynamic demographic group totals into the single table view.

Demographics Distribution

Improved detection and display of multiple period or crossover trial data.

Adverse Events Distribution

New options to compute rates of event occurrence (either based on Patient Years of Exposure or Patient Years on Study) have been added. When enabled, new output includes dynamic adverse event incidence rates as a view in the Counts Graph and in the Counts Table.

A new option to specify a percent threshold to include events that exceed that threshold in any of the treatment groups in terms of the percent occurrence within that group.

Findings Distribution

Improved support for using the **FA** domain by including FAOBJ (Object of Observation) in the analysis.

Oncology Reports

Disease Response Swimmer Plot

New options to specifically control the start date and end date for defining subject bars on the swimmer plot.

New options support showing all subjects on swimmer plots, regardless of disease response.

Progression Free Survival

An option for selecting whether to measure Progression Free Survival (Consider Death and/or Disease Progression as events for analysis) or Time to Progression (only consider Disease Progression events for analysis) has been added.

An option for specifying the marker used to indicate censoring has been added.

Other Reports

Findings Time Trends

New properties in the JMP output table organize tests by their category and create column properties about their category and subcategory membership.

Option to calculate Geometric Means in summary statistics is now supported.

New option enables you to select whether to use full or short test names as column names in the results tables and plots.

New option enables you to specify a subset of visits to include in the analysis

Adverse Events Time to Events

Users can now specify inclusion of events based on either treatment duration or time on study. Time to event study calculations have been updated to capture time to event only for events occurring in the specified time period for analysis.

Domain Viewer

Supports split Findings About (FA) domains.

Static Reports

New option on the Create Static Reports window enables you to specify the inclusion of all notes for the selected subjects in the report.

Patient Profiles

Option to display Subject Identifiers (SUBJID) instead of Unique Subject Identifiers (USBJID) has been added

A progress bar for monitoring generation of the profile has been added to the UI.

Ability to revert template changes has been added.

Study Day calculation will now use Treatment Start Date from ADSL if present when Reference Start Date (RFSTDTC) is missing.