# JMP Clinical 7.0 - Release Notes

This document describes changes and enhancements from JMP Clinical, Version 6.1 to JMP Clinical, Version 7.0[1].

## General Features

JMP Clinical 7.0 contains several new enhancements to the user interface, system configuration, and reports/reviews.

### JMP and SAS Platform Updates

JMP Clinical 7.0 is built on the latest JMP release, JMP14.1. 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 7.0 is built on the latest SAS release, SAS 9.4 M5/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.

### System Configuration

Any changes made to the JMP Clinical 6.x system.clinical.preferences and installation.path.preferences files can be migrated to and merged into the JMP Clinical 7 system.clinical.preferences and installation.path.preferences files[2]. Additional modifications to these files are made using the new **Manage Configurations** user interface. This interface provides a centralized mechanism for users to specify system preferences, configuration paths for system files, role assignments, and the sequential order of reports within the user interface. This option is available to those users with ConfigurationManager role assignment and is accessed from the **Settings** tab.

1. **Note**: If you have a suggestion, comment, or encounter a bug in JMP Clinical 7.0, 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!
2. Changes are migrated provided you have not deleted either JMP Clinical 6.x or its file locations.

### System Preferences

New preferences include an option for compressing SAS data sets, options for specifying use of Domain Labels, an option for Review Authors to manage Report Defaults, and whether or not the review subject filter is used.

### User Roles

Two new User Roles can be specified.

- **Study List Manager**: A user with this role can manage and delete studies from shared folders. By default, this role is not assigned.
- **Configuration Manager**: A user with this role can add and define JMP Clinical configurations.

### Software Documentation Updates

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

## Study Management

You must update studies from JMP Clinical 6 to JMP Clinical 7 using the **Refresh Study Metadata** option.
**Caution**: Once updated your studies cannot be opened in prior versions of JMP Clinical

Available study domains are now grouped by CDISC category on the **Studies** window.

Users with new **Study List Manager** user role can view unlisted studies and resolve deletion of studies that failed to add or whose data has been deleted or moved and is no longer available in the Study List.

### Set Value Ordering *New!*

A new study management level tool that enables you to globally specify the CDISC variable value order within results. This includes most plot legends, distributions, and tables, as well as some outlined sections.

### Manage Profile Data *New!*

A new action on the **Studies** window that enables users to precompute profile data for faster processing and to create, save, and apply multiple data templates per study.

### Add Study

- Extensive metadata for both study variables and all available values of key variables used in report analysis are now captured and used for more intelligent, study-specific dialog options.
- Study processing and data loading has been restructured for more efficiency
- New options enable you to specify whether the study that you are adding is a clinical or nonclinical (SEND) study. The SEND flag is derived based on this selection.
- Studies using XPT files are now read directly to write SAS data sets, instead of first being saved to the directory.
- The requirement that study names must begin with a letter (A-Z, a-z) have been relaxed. Study names can now begin with any acceptable study name character.
- Both POOLDEF and RELREC domains are included in the study and their presence/absence is flagged in the study metadata.
- Import of V8-formatted SAS Transport files is now supported.

### Update Study with New Snapshot

- A new option to include variables from supplemental domains in snapshot comparisons is available when you update a study.
- New options enable you to select certain variables to exclude from comparisons
- User-defined keys for detecting unique records can now be specified using text files or the Define.xml file.

## User Interface

Significant enhancements have been made to the JMP Clinical **Review Builder** and **Review Viewer**.

### Review Subject Filter *New!*

- A new system-wide **Review Subject Filter** can be used to filter all subject-level reports comprehensively by using row state synchronization across virtually joined tables. Making selections in the Review Subject Filter broadcasts subject selections to all reports in a review that are at the subject-level. New reports run are automatically filtered.
- A new action button on all subject-level report output enables users to make domain selections in a report and then, broadcast that selection to the Review Subject Filter.
- A system preference to disable or enable the Review Subject Filter has been added. This preference is enabled by default.

### Report Section Filters

- **Section Data Filters** in reports are now local JMP Data Filters and no longer contain demography variables for filtering unless the preference to use the **Review Subject Filter** is disabled. Their states are retained in saved reviews.

### Saving Customizations *New!*

- JMP Clinical Reviews now retains any customizations to the JMP table in a report. User-created columns, row states, and review and report filter states are retained in a saved review.
- If a user creates a new analysis using JMP platforms on a report output table and saves the JMP script to the data table, the analysis is kept and re-run when a review is opened.

## Patient Profiles

### Manage Profile Data *New!*

A new Manage Profile Data user interface that enables you to specify and merge the study and supplemental domains used to build and/or reuse multiple custom patient profiles, has been added to Study Management. This interface enables you to precompute profiles in the background, thus facilitating more rapid analysis.

### Manage Display Templates

In Manage Data Templates, you can now specify which variables are in each domain table as well as the order in which they are presented in the profiles. In addition, up to three sort variables and the order in which they are used can be specified.

You can also choose to display either the reported terms for events, interventions and test codes for findings on the *y*-axis.

# JMP Clinical Reports

## All Reports

- Report option selections can now be saved as default selections. Check the ReviewAuthorCanManageDefaults option on the **Manage Configurations** window to add an option to Save current options as defaults to the report-specific  drop-downs.
- Result dashboards now list full domain labels instead of abbreviations ("Adverse Events" instead of "AE" for example) by default. An option on the **Manage Configurations** window enables continues to use of abbreviations.
- All review and report data filter selections are now captured and included in the static reports. Additionally report options that apply a filter on the domain or subject population are also printed in the static report.
- Default color selections can be set using the Set Value Ordering in Studies option. Colors are then consistent within and across reports anywhere treatment levels are shown with a color legend.
- Report option names and organization have been revised to improve consistency across reports.
- The default order of the reports and report categories in the Review Builder has been revised to match CDISC classification and intuitive report usage.
- The Cluster Subjects Action action button has been removed from all Results dashboards and replaced by improved usability of the Review Subject Filter.

## Templates

A new report template for the oncology reports is available.

## Oncology Reports *New!*

Three new reports (**Tumor Response**, **Disease Response Swimmer Plot**, and **Progression Free Survival**) enable a comprehensive analysis of oncological progression and response to therapeutics.

**Tumor Response**

- This process uses the TR, TU, and RS oncology domains to create spider plots showing quantitative tumor response and waterfall plots showing Best or Last recorded responses. Summary text states the time scale and test used for summarizing tumor burden.
- Measurements plotted on the spider plot and summarized in the waterfall plot represent change or percent change of tumor burden from baseline in target or measurable lesions. Measurements can be summed by visit or study day. Subjects who show no change in tumor size are represented by a + symbol on the plots instead of a bar. Plots are annotated to show the occurrence of new lesions as well as selected disposition events.
- For direct lesion measurement tests such as LDIAM or DIAMETER, lesions are summed and compared to the baseline lesion summation by study visit or study day. If a derived summary test such as the sum of diameters or percent change from baseline is run, then the report plots the recorded values across time for subjects with recorded measurements. Unless specified, this report preferentially uses measurements from the following tests in the following order: LDIAM, LONGDIA, DIAME-

TER or DIAM, SUMLDIAM, and SUMDIAM. Default value for tumors too small to measure can be set.

- When the study includes multiple evaluators, the report generates a separate waterfall plot and spider plot for each evaluator.

**Disease Response Swimmer Plot**

- This process creates a disease response swimmer plot and tables for either the Best or Last recorded responses and calculated objective response rate for solid tumor oncology clinical trials. Response rates represent values from the RS domain using RECIST criteria or for some options, iRECIST. Custom color options for treatments and associated responses are available.
- The output includes a swimmer plot for subjects who have responded favorably to treatment for solid lesion trials per RECIST criteria using evaluation responses of Complete Response (CR), and Partial Response (PR) from RSSTRESC. Options enable use of values from either RSCAT. or RSTEST. Subjects can also be annotated with responses of Stable Disease (SD) and/or Progressive Disease (PD). The results of these assessments are summarized based on selecting either the Best response per subject, based on preferred order: CR, PR, SD, PD for controlled terms, respectively, or Last recorded response.
- Subject counts and percentages of responses are displayed in a summary table split by Treatment Variable based on report selection. The objective response rate (ORR, the sum, and percentage of subjects who had CR + PR assessment result) is also calculated and listed in the summary table.
- Time is reported in days, weeks, or months. Date information is typically taken from RS. However, if there is no date information in RS, it is taken from SV.

**Progression Free Survival**

- This process uses a modified survival plot and hazard ratio plot to compare the number and percentage of patients who have tumor progression or death, with patients who show no tumor progression or death at the cut-off date. Survival plot displays number of patients at risk and can be viewed with/without confidence interval shading.
- Time is reported in days, weeks, or months. Date information is typically taken from RS. However, if there is no date information in RS, it is taken from SV.

## Distribution Reports

All distribution reports have been updated.

The following enhancements to specific reports have been made:

- **Events Distribution**, and **Interventions Distribution** now have consistent options to Calculate Relative Risks and set a percent overall occurrence threshold for including events/interventions. In addition, these reports, now support a more generalized detection of variables for inclusion in stacking and data filters. These options were previously available only for **Adverse Events Distribution**.

Finally, their abilities to support multiple grouping and term levels and noting missing values have been improved and made consistent across the different distribution reports.

- **Adverse Events and Events Distribution** now scans both AEACN and AEREL for value of Multiple, which indicates multiple drugs are being dosed per ARM. In this case the report merges in multiple variables pertaining to the individual study drugs in each ARM from SUPPAE or SUPPXX.
- An option to select additional variables for which to show distribution details and enable generation and display customized distributions has been added to **Demographics Distribution**.
- New report options enable the user to customize the variable available in report filters.

### Findings Reports

The following enhancements have been made:

- The option to remove unscheduled visits has been added to selected reports for enhanced behavioral consistency.
- The ability to input findings test codes (xxTESTCD) and convert spaces to underscores(_).
- The option to include BY variables, only if they are domain keys, to subset the available variables has been added to multiple Findings reports. All data integrity Findings reports now contain this option.

In addition, the following enhancements to specific reports have been made:

- **Findings Distribution** now includes an option to specify a subset of visits to analyze. Additional code modifications enable more rapid data input. A new option enables you to perform one-way ANOVA or contingency analysis only when desired, instead of by default. A new option to accept *None* as a treatment variable; if chosen, ANOVAs/contingencies are not performed and count plots are not split out by treatment.
- **Findings Shift Plots** now uses JMP's Graph Builder tool to generate plots. Shift plots for each findings test now include overlaid treatment-specific histograms. Users can now opt to display: 1) shift tables of subject counts and percentages (per treatment group) of laboratory elevations in reference to the upper limit of normal for measurements taken at baseline versus trial summary measurements, 2) separate lab elevations crosstabulation tables by Treatment groups, and 3) the aggregated sum of subjects that falls in each of the crosstabulation categories based on laboratory elevations from baseline versus trial in the shift tables.
- **Findings Time Trends** now includes an option to display subject count bar charts on average time trend plots. This option aids in visually understanding the trends in findings test measurements. The bar chart of the count of subjects that contribute to the mean line trends the option generates helps understand fluctuations or anomalies in the trend pattern.
- **Hy's Law Screening** now includes a default option to filter out any screening/baseline measurements so that only on-trial measurements are considered for the Hy's law calculation. A new table listing the number of subjects missing all 4 of the liver tests (ALP, ALT, AST, and BILI) is displayed only when there is at least 1 subject missing all four tests.

## Events/Intervention Reports

In all reports, for both On treatment events and Off treatment follow up events, the date of last dosing is normally taken from EXENDTC. However, in cases where you have single-day dosing, EXENDTC will not exist. In this event, a new option enables you to take the date from EXSTDTC instead.

**Mortality Time to Event** now offers a subgrouping option for the hazard ratio plots. An additional option enables you specify an end date variable and an offset for censoring. The last disposition event (DSDECOD) is reported for censored individuals. A new text summary has been added; notes include the variable used for censoring and factors that might preclude computing hazard ratios. Option to include shaded confidence intervals on survival plots. Analyses can now be run using BY variables.

## AE Narratives

Extensive updates and enhancements have been made to the narratives. These include the following:

- Total dose of all treatments up to and including the day of the event is computed and summarized with the narratives. Total dose will be printed unless the patient was on PLACEBO or VEHICLE for the entire treatment. However, if a patient has a mix of placebo-vehicle and non-placebo-vehicle treatments, placebo is included in the list, but no dose amount is provided.
- An option has been added to include summaries of medical history terms
- You can opt to generate a table of concomitant medications. The report uses either CMDOSE (Dose per administration) or CMDOSTXT (Dose description) to generate this table.
- When merging with supplemental data, events are now merged using USUBJID and AESEQ. If AESEQ is not available in the original SDTM/ADaM data, AESEQ is defined after sorting events by USUBJID, AESTDTC, and AETERM for events where AETERM is nonmissing. This feature allows the user to merge on any data for each AE.
- An option for specifying the starting number for tables has been added.
- The default template has been changed to DefaultBySubject. Note: This template was named DefaultByName in previous versions.
- The final narrative data set is now sorted by USUBJID, AESTDTC, and AETERM. AESEQ is no longer used. However, AESEQ is still used for adding data from supplemental data sets. If AESEQ does not exist, it is generated from USUBJID, AESTDTC, and AETERM.
- The narrative now shows all abnormal baseline results for tests determined to be unique by other variables.
- An option to use the Related Records (RELREC) data set in the SDTM folder to identify concomitant medications that were given to a patient due to an event.
- By default, reporting other adverse events that occur close in time to each summarized event includes all adverse events experienced by the patient. An option has been added limiting these other events to serious adverse events only.

### Assessing Data Integrity

- Users can subset which visits to use for the analyses for several data integrity reports. Note: This option is not available for Risk-Based Monitoring, Birthdays and Initials, Perfect Scheduled Attendance, Screening Bias, Weekdays and Holidays, and Enrollment Patterns.
- Users can select which events/interventions domains to analyze.
- Option to exclude unscheduled visits has been added to relevant reports.

In addition, the following enhancements to specific reports have been made:

- **Frequencies** has a new option to specify the maximum number of distinct levels (determined based on the selected variable of analysis) or values a findings test can have to be included in the analysis.
- **Constant Findings** and **Duplicate Records** now include an option for restricting the analyses to study sites that exceed a specified minimum subject count.

### Cross Domain Reports

- **Multivariate Inliers and Outliers** has been enhanced to enable a better exploration of outliers. You can now select a percentage of patients based on exceeding a threshold and create a Pareto plot for each selected patient that explains how much each variable contributes to a patient being an outlier.
- **Cluster Subjects Across Study Sites** and **Cluster Subjects Within Study Sites** now include a filtering option to specify the number of overlapping variables to make it easier to subset to pairs that have a high-number of nonmissing overlapping pairs of variables.
- **Risk Based Monitoring** now locks all variables for all tables to prevent inadvertent changing or deleting data. Rows cannot be added or deleted. Columns cannot be deleted. However, columns can be added if users want to explore additional variables.

## View Notes

The interface has been redesigned and enhanced. Users can view all notes or filter and subset notes that meet specified criteria. Notes can be grouped and sorted by the columns you specify. Static reports can be generated in varied formats.