JMP Clinical 6.1 - Release Notes

This document describes changes and enhancements from JMP Clinical, Version 6.0 to JMP Clinical, Version 6.1. Processes are described in the order in which they first appear in the JMP Clinical menu.

General Features

JMP Clinical 6.1 contains several new enhancements to the user interface, system configuration, and reports/reviews.

JMP and SAS Platform Updates

JMP Clinical 6.1 is built on the latest JMP release, JMP12.2. For more information about the updates to JMP software that are included in this release, please see the New in JMP 12 web page.

JMP Clinical 6.1 is built on the latest SAS release, SAS 9.4 M4. 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

The Settings tab on the JMP Clinical Main Window now contains an About JMP Clinical section listing the current version numbers of JMP Clinical, JMP, and SAS along with options to renew the software licenses.

New system options are available through the system.clinical.preferences file. These include:

- the ability to restrict users with reviewer-only roles from viewing underlying data tables.
- an option to display the JMP Home Window icon on the JMP Clinical UI.
- an option to display either icons, labels, or both on the JMP Clinical UI. While displaying both icons and labels can crowd the interface, it can be useful for new users learning the actions/options available of the reviews and reports.

1. Note: If you have a suggestion, comment, or encounter a bug in JMP Clinical 6.1, 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 will make every effort to address the issue promptly. Thank you for taking the time to do this!
User Interface

- A Report Navigator is available for use while building and viewing clinical reviews. **New!**
  - When building a review, click the dark gray border to dock the review to the navigator.
  - Report contents in the navigator are dynamically updated as reports are added and run. Reports that have been added to the navigator but not run are marked with an asterisk (*).
  - Selection of major sections of report output content in the navigator automatically displays that content while simultaneously closing the outlines of other content components.

- Tab Management **Updated!**
  - Reports that have not been run are tagged with an asterisk (*).
  - Users can now run selected reports from within the tab manager.

- The search capabilities of the Subject Explorer have been expanded
  - A wildcard (*) can be used with non-exact subject ID matches.
  - The wildcard is inferred at the beginning and end of text entered in the subject search box.
  - Commas and tabs are recognized as delimiters between subject IDs. This feature is especially useful when copying and pasting lists of subjects from other sources.

Software Documentation Updates

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

Study Management

- The Import SAS Transport Files option is now checked by default.
- The Enable Future Snapshot Comparisons option is now unchecked by default.
- Both Add Study and Manage Study operations now generate a document enabling you to view included and excluded domains.
- Combine Studies... now includes options enabling you to specify the SDTM/ADaM domains to be combined.

JMP Clinical Reports

Medical Monitoring Reports

- A new dynamic table lists the denominator(s) used for percent calculations in Adverse Event Distribution, Event Distribution, Intervention Distribution, Demographic Counts action drill down now filters down to subject level counts across demography groups.
• General Subject Drill Down Actions (Profile Subjects, AE Narrative, Show Subjects, Create Subject Filter) are now available as Distribution drill-downs.
• Findings reports options panels include a new Select Findings widget to filter available tests for use in an analysis.
• STUDYID is now available as an option in report output data filters when multiple study IDs are detected.
• Adverse Events reports now support an option to ignore any TEAE flag variables and use date imputation to determine Treatment Emergent Adverse Events. A statement indicating how TEAEs were determined is now displayed in the report output.
• Mortality Time To Event now offers an option to determine the End Date Variable for censored records.

Assessing Data Integrity
• Several new options have been added to multiple reports to help with controlling and filtering data signals in data integrity reports. These include:
  • An option to specify the alpha level used for site-level anomaly testing.
  • An option to limit the events/interventions used in subject outlier and clustering analyses based on a percent threshold occurrence.
  • An option to filter/exclude sites with low subject or subgroup counts from subject outlier and clustering analyses.
  • An option to choose whether by variables (xxPOS, xxLOC, for example) are considered in site-level anomaly testing to identify units of measurement for findings test comparison
• Demographic data is now integrated into output tables in the Duplicate Records report.
• An option to select Findings tests has been added to the Missing Findings report.

AE Narratives
• An option to include only new adverse events since last snapshot has been added.
• An option to select Findings tests for each Findings domain included in the narrative has been added.
• Variables from AE, ADSL, and DM are no longer subsetted. This was done to make more variables available for the narrative template.
• New logic to order by event dates has been added. Events are organized by USUBJID and AESEQ, if available. If AESEQ is not available, terms are organized by USUBJID, AESTDTC, and AETERM
• Narratives that are run using a drill-down action from any report can now be embedded into the review and saved.
• Additional Narrative templates displaying narratives in English and Chinese have been added.

Risk Based Monitoring
• This report now supports entering site-level metric variables via a supplemental data set using SITEID as the row identifier.
• “Manually Entered” variables are now referred to as “Supplemental Variables”
• The mechanism to add variables, import/export tables via the Update Study Risk Data operation in Study Management have been deprecated in preference of new supplemental data format.
Patient Profiles

- Numeric legends for Findings data are now off by default.
- When legends are shown, reference ranges for laboratories are now determined by LBSTRNLO and LBSTRNHI instead of by outlier detection ranges.