JMP Clinical 6.0 - Release Notes

This document describes changes and enhancements from JMP Clinical, Version 5.1 to JMP Clinical, Version 6.0. Processes are described in the order in which they first appear in the JMP Clinical menu[1].

General Features

JMP Clinical has been redesigned to support its use as an enterprise solution as well as for the following areas:

Redesigned User Interface

- The new **JMP Clinical Main Window** is organized with tabs for **Study** management, **Reviews** operations, and **Settings** configuration.

- Creation and use of review templates simplifies data analysis and sharing of generated clinical reviews. All analysis reports now contained in a single tabbed pane window for easy navigation of results. Review Template management options enable you to duplicate analysis reports in a review, rename/move/delete reports, and apply subject filters across selected reports.

- *Patient Profile Reviews* allow patient profiles to be shared and dynamically reviewed without study data access. Enhanced options for creating static reports of an entire review - including PowerPoint support - have been added.

- The extensive JMP Clinical documentation has been more closely tied into the user interface and is surfaced in the **UI**.

- Better error trapping and study compliance in both templates and while running reports in a review.

- The new **Subject Explorer** widget allows for direct creation of patient profiles or creation/management of subject filters from a list of subjects in a study.

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1. **Note**: If you have a suggestion, comment, or encounter a bug in JMP Clinical 6.0, 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 will make every effort to address the issue promptly.   Thank you for taking the time to do this!

JMP Clinical Now Supports Configurable USER Roles

System preferences allows specification of certain users of the software to have any combination of the following roles:

- **Study Manager**
  - Can perform study operations such as adding, updating, combining, and deleting studies in the JMP Clinical system.
- **Review Author**
  - Can run analysis reports by creating review templates and/or running custom review templates and generate finished reviews for Reviewer consumption.
- **Reviewer**
  - Can access, view, and make notes on finished reviews.
  - Note: Reviewer-Only mode surfaces a custom interface that defaults to a view to show the set of completed reviews to which the particular reviewer has access.

JMP and SAS Platform Updates

JMP Clinical 6.0 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 6.0 is built on the latest SAS release, SAS 9.4 M3. For more information about the enhancements to SAS analytical software that are included in this release, please seethe What's New in SAS 9.4 web page.

Software Documentation Updates

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

Study Management

The creation/manipulation of JMP Clinical studies has been greatly simplified. In conjunction with new UI changes, study management operations have been grouped on the new **Studies** tab, which displays and organizes all the clinical studies and displays relevant information about each study when selected. Operations have been re-organized into more intuitive utility actions enabling you to:

- add a new study (from local data sets or SDD),
- combine multiple studies into a single study via a *union* of the studies' domains instead of the *intersection*. (Note: This can often lead to unexpected results and is very dependent on merging appro-

priate data if the studies do not match well! A new report on study creation summarizes the study combination and possible issues.),

- refresh the metadata for multiple studies at once,
- rename or change the data locations of a study,
- update a study with a new *snapshot*, and
- delete a study

Further updates to study management include:

- new options to select specific domains from the SDTM/ADaM folders,
- improved detection of ADaM BDS Findings domains,
- support for up to 8 character ADaM data sets for domain detection, and
- support for SDTM V3.2 new variables and domains (including the use of DD Death Data for RBM).
- The Updating Study Risk Data for RBM function has been moved onto the **Studies** tab.

Note: When working in a new shared/centralized study configuration, user permissions are assessed automatically to display studies to a particular user based on their study access.

Centralized Study Configurations

New configuration options allow sharing of studies, analysis review templates, finalized study reviews, and user notes. These options can also be used to customize alternate "local" individual machine implementations and complete control over locations where JMP Clinical will access/save any data. JMP Clinical can support a user having access to multiple system configurations.

Enhancements to notes architecture to allow for multiple users to create and automatically access all notes at study/report/country/site/subject/record level.

JMP Clinical Reports

General Updates

The redesigned JMP Clinical UI has improved how you interact with the clinical reports. A new report selector window appears when you start a new review template. Available reports (filtered by assigned user roles and available domains and variables) are selected from this window and added to a single contained "review" that can be built from the report selector window or from saved/shared review templates.

The updated User Interface changes has led to the following design changes:

- All reports are now laid out in browser-like vertical outline components.
- All action buttons/drill downs have been added as icons to the report toolbar. These actions buttons are automatically enabled/disabled in response to the specific component of the report and selection of subjects necessary to run the action without error. **Note**: Given the new ease to share finalized reviews, actions/drill-downs in a review that require access to the JMP Clinical Study are automati-

cally removed when access to the study data is disabled (to support a reviewer-only mode user, for example).

- Docker windows are available for underlying data tables and report-specific help. **Note**: Help can also be popped out into a separate window or browser as specified in user settings.

An option to generate AE Narrative reports has been added as an action button to all relevant subject-level reports.

All reports contain an enhanced CDISC clinical variable intelligence system that documents the explicit use of all CDISC (SDTM/ADaM) variables that might be required or used for each report. This information is used to filter the reports available to run for a given Study and inform the user if a report/review is runnable based on report option selection. **Note**: A simplified list of all variables that are required/preferred for the use of a given review template is also available.

New Analyses and Reports

Several new data integrity reports have been added

- **Correlated Findings** - Calculates pairwise correlations between tests within each findings domain and identifies unusual results at specific study sites.
- **Enrollment Patterns** - Determine whether enrollment patterns within each site appear unusual.
- **Frequencies** - Identifies unusual frequencies across the entire study or by study visit.
- **Missing Findings** - Determines whether individuals are missing data for all test codes across all Findings domains.
- **Outliers** - Identifies outliers and sites with excessive (or too few) outliers.
- **Screening Bias** - Identifies regression to the mean in assessing study entry criteria.
- **Summary Statistics** - Identifies unusual summary statistics across the entire study or by study visit.
- **Patient Recruitment** - Examines current enrollment patterns to determine whether patient recruitment will be met by a specified deadline. If not, simulations are performed to identify the number of additional centers to recruit to meet the deadline.

New support for SEND Animal studies

- **Animal Profile** - Generates a static report (PDF or RTF) summarizing the general information and pathological observations for each animal in a study.
- **Findings Incidence Report** - Compares distributions of demographic variables across treatment arms.
- **Trial Design** - Visualizes findings measurements for each subject across the time-line of the study.

Enhancements/Updates to Existing Reports

Medical Monitoring Reports

- **AE Distribution** now contains a new action button that creates a dashboard of Unique Occurrence Subject Counts based on user selection and data filter use as well as a new option to calculate relative risks to compare incidence in treatment and control groups.

- **Demographics Distribution** now contains By Variable Support for all Demography Tables and an option to specify custom age groups. All tables now include columns indicating missing values.

- New summary statistic tables has added to display user-selected summary statistics in addition to the visit has been added to **Box Plots**. In addition, plots now contain Hi/Low reference ranges, when appropriate variables are available.

- A new option for displaying symmetrical axes has been added to **Shift Plots**.

- A new option for displaying subject identifiers along the x-axis has been added to **Waterfall Plots**.

- Support for xxDOSE has been added to **Interventions Distribution**.

- **TEAE Summary** now includes an option for specifying the number of decimals to show in percentages on static reports.

Assessing Data Integrity

- The following options have been added to **Risk Based Monitoring**:
  - Users can now specify an externally created supplemental SAS data set. This enables you to more easily capture non-database data into the RBM analysis using a data sets that follows the CDISC-Like data standard.
  - Users can perform monitor-level and/or vendor-level analyses, creating additional summaries by monitor/vendor. A new action button is available to the report enabling you to select sites based on monitor/vendor selection
  - Users can now analyze selected sites and/or selected site categories.
  - Monitoring Comments (CO), Death Data (DD), and Hospitalizations (HO) is now supported.

AE Narratives

- Template selections are now made using a drop-down menu. Patient-level narratives are now available.(need to request template)

- A CM window has been added, enabling you to identify medications that were taken within *x* days of the event's occurrence.

- Both STUDYID and SUBJID are added to the narrative data set.

- Options that enable you to use SUBJID within narrative, to set missing dosing end date to the start date (**Note**: EXENDTC is required and this option assumes dosing ends same day the last dose was given), and to summarize all abnormal labs regardless of baseline value have been added.

- An option for subject-level table of contents has been added.

Patient Profiles

- Profiles can now be added into a clinical analysis review and saved or regenerated by reviewers regardless of their access to the original study data.

- Profile displays and data templates can be shared among users and also saved and honored in profile reviews.

- Enhanced logic for handling missing start/stop dates in conjunction with existing Prior and Ongoing Flags has been added for Events/Interventions domains. A new legend describes how lines/markers might change based on these conditions has been added to the profile.

- Review status can now be shared and accessed by multiple users (including when the profiles were saved into a finalized clinical review).

JMP Clinical Settings

Use the new settings tab in the JMP Clinical main window to switch their active configuration (if multiple configurations have been set up), manage Holiday and Event Data Sets for Studies for use in relevant data integrity reports, manage Risk Thresholds for Risked Based Monitoring, and configure how documentation and help is accessed and displayed.

JMP Clinical documentation is available online. You can also download the most current version for use when an Internet connection is not available. You can also choose whether to display the Help pages within the current working JMP window (through use of docker panels), in a separate JMP window, or outside the JMP system in a Browser window.

Deprecated Components and Reports

Support for **SAS Metadata Server** and **CDI Integration** has not been included in this release of JMP Clinical. Our new enterprise architecture and user interface provide supersedes the functionalities offered by these integrations in a more user-friendly environment.

Non-CDISC-specific reports used in predictive modeling, pattern discovery, and pharmacovigilance, as well as many SAS data set utilities have not been reformatted for the new user interface and have been dropped from this release. Some of these reports can be reformatted and included in future releases depending on customer requests.