This document describes changes and enhancements from JMP Clinical, Version 5.0 to JMP Clinical, Version 5.1. Processes are described in the order in which they first appear in the JMP Clinical menu.

General Features

JMP and SAS Platform Updates

- JMP Clinical 5.1 is built on the latest JMP release, JMP 11.2. For more information about the updates to JMP software that are included in this release, please see the New in JMP 11 web page.
- JMP Clinical 5.1 is built on the latest SAS release, SAS 9.4 M2. 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.
- Full installation instructions are available on the JMP Clinical website. Please note the following when you install JMP Clinical 5.1:
  - You must uninstall JMP Clinical 5.0 first using either the Add or Remove Programs (Windows 7) or the Uninstall a program utility from the Control Panel.
  - If you have already installed SAS 9.4 on your computer before installing JMP Clinical, you might need to run the install twice. Initially, SAS is updated, and when that installation has completed, you can re-start the installer again to install JMP Clinical.
  - After installing, you will not see a desktop icon for JMP Clinical 5.1. If you want to create one, you can do so by navigating to the location of the JMP executable (typically C:\Program Files\SASHome\JMPClinical\11) and creating a new shortcut to this file on your desktop. To change the icon used for the shortcut on Windows 7, right-click on the shortcut and choose Properties. Click Change Icon and navigate to the JMP Clinical icon in C:\Program Files\SASHome\JMPClinical\11\LifeSciences\Documentation\Icons\JMPClinicalApp.ico.

1. **Note:** If you have a suggestion, comment, or encounter a bug in JMP Clinical 5.1, please click Send a Comment or a Feature Request under Clinical > Documentation and Help, or e-mail 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!
CDISC Variable Intelligence

- A new system for capturing and reporting all required and optional variables used by JMP Clinical reports has been added. You can view the results using the new Pre-Study Variable Report that is found under the Documentation and Help menu.
- System provides users with the ability to customize the JMP Clinical Starter to show only those reports for the specified study. Links are provided on Report dialogs showing variable requirements and usage.
- The Check Required Variables report has been redesigned to show process logic of variable requirements and usage by individual reports for a specified study.

System Performance

Overall system performance has been enhanced. Specifically:

- Domains are now filtered so that only that data needed to run a given report are loaded. Supplemental data are included in the filtering.
- Snapshot comparisons are optional and must be enabled using the Snapshot data are loaded only when snapshot comparisons have been enabled.

Software Documentation Updates

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

New Features

Support for ADaM Basic Data Structure (BDS) Variable Has Been Added.

- Data from the Basic Data Structure (BDS) ADaM data sets can be used for selected JMP Clinical Findings Reports.
- Data from the Basic Data Structure (BDS) ADaM data sets can also be used for Data Quality and Fraud Detection methods that use Findings data.

New Patient Profile Template Capabilities Have Been Added

- These enable users with complete control of domains/variables and values shown in patient profiles.
- Performance enhancements enable users to specify up the domains and variables for display in profile graphic and tables, respectively and thus avoid loading and manipulating unnecessary domain data.
- Display templates work interactively for customization of graphical views and specification of variables included in displays.
Supplemental Qualifier Data Sets

- Supplemental data are merged into an analysis only when the Merge Supplemental Domain option has been selected.

Japanese Language Support

A Japanese-version of JMP Clinical is now available and fully supported. Users can now view all dialogs and most reports in Japanese, and import and analyze Japanese-language data that has been formatted according to CDISC standards.

New Analyses and Reports

Studies

Add Study from SDD New!

This new process gives users the ability to connect to and navigate through a SAS Drug Development (SDD) server that contain CDISC-formatted data and select study data to transfer to JMP Clinical desktop system.

Migrate Studies (Experimental) New!

This experimental process enables you to migrate studies from previous versions of JMP Clinical to JMP Clinical 5.1. This process adds the enhanced study metadata needed for new features, such as snapshot comparisons, that have been added to JMP Clinical.

Snapshot History New!

This new process creates a summary report of the snapshot history for the currently selected study.

Notes Viewer New!

This process enables you to review the notes for a selected study.

Findings

Findings Waterfall Plots New!

This new analysis creates waterfall plots to show the distribution of changes in test measurements for a given Findings domain across subjects (ordered by their magnitude of change). The Findings measurements are summarized based on a specified summary statistic and a waterfall plot is created for each Findings test.
Subgroup Analysis

Optimal Treatment Regime *New!*

This new process follows the methodology of Zhang *et al.*, (2012), fitting both a response regression model and a propensity score logistic model to the input data set. It combines results from these model fits to compute a pseudo binary response and weight that are suitable for input to predictive modeling routines. A contrast response is also computed, and it can also be modeled or used directly to assign optimal treatment.

Documentation and Help

Pre-Study Variable Report *New!*

This new feature enables you to review all of the variables and domains, used by JMP Clinical reports.

Enhancements and Updates

Multiple Reports

Create Report

An option for generating customized titles has been added.

An option for changing the default size for PDF and RTF reports has been added.

Studies

Domain Viewer

An option for transposing the output data set so that results are divided into individual columns is available for the Findings domains.

Review Builder

A window indicating the path to the review package is now surfaced as part of the output of this report.
Interventions

Exposure Summary
The following new analyses have been added to the Exposure Summary report: Percent of Subjects Left on Study Medication by Day of Study, Distribution of Doses by Arm, Dose Descriptive Statistics by Arm and Box Plot of Doses, Planned Arm to Actual Treatment Comparison, Dose Changes During the Study.

Events

AE Time to Event
Options for Incidence Density Modeling have been added.

AE Narrative
A new templating functionality has been added; name and location for the templates is specified using the Configure Life Sciences Settings report.

Users can format decimal values of any numeric findings.

Narratives can now include:

- results from any three Findings domains,
- summaries of health-care encounters, such as hospitalizations, either in toto or within specified time periods.

Mortality Time to Event
Overall survival analysis now includes both number and proportion of subjects alive or censored on the specified end date. In addition, output has been updated to include Cox Hazard Ratios (with 95% confidence interval) for demographic subgroups (age groups, race, sex, ethnicity, country and site ID), abnormal high/low lab test subgroups at baseline, concomitant medication subgroups at baseline, and medical history event subgroups at baseline.

Standardized MedDRA Queries Distribution
Bar Charts summarize the frequency or percentage of major classes of SMQs by treatment have been added to output.
Findings

All Findings Analyses

The following enhancements have been made to multiple Findings reports:

- Values in xxSPEC are appended to both xxTESTCD and xxTEST to help determine unique findings test names when xxSPEC is found in the Findings domain. This feature is especially useful with the LB domain to fully identify unique lab tests according to SDTM IG.
- The performance and speed of algorithms used for loading findings data for analysis have been improved.

Findings Distribution

Report now supports test results of blinded studies and studies containing only one treatment arm.

Hy’s Law Screening

3-D scatterplot function has been restored.

Subject Utilities

Profile Subjects

An option to group y-axis values by category has been added.

This report now generates patient-specific comprehensive tables listing all of the data, results and other information available for each patient being profiled, and places them on a single tab. Tables can be customized and formatted according to user-defined templates.

The Create Reports feature can be used to generate a PDF- or RTF-formatted Report file containing the profile information.

Risk-Based Monitoring

Risk-Based Monitoring

Options for performing time trend analysis have been added.

Data Quality and Fraud

The Fraud Detection category has been renamed.

Digit Preference

An option for analyzing the observed frequency of either the first or last digit has been added.