JMP Clinical® 4.0
adds Ways to Explore Clinical Trials Data Visually

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JMP Clinical is Parts of the JMP Family for Statistical Discovery

JMP
This is the JMP product you’ve known and loved for more than 20 years. It’s the standard for visual data analysis right on the desktop. JMP links statistics with graphics, making information accessible in ways a spreadsheet never could. JMP empowers you to enjoy one breakthrough after another.

JMP Pro
JMP Pro includes everything you’ll find in JMP, plus powerful new capabilities designed for advanced analytic users who need data mining techniques to create robust predictive models. If you have large data volumes, want to engage in data mining or build predictive models that generalize well, then JMP Pro is for you.

JMP Clinical
JMP Clinical software shortens the drug development process by streamlining safety reviews of clinical trials data. It helps clinicians and biostatisticians migrate into the modern review environment using CDISC data. Intuitive dashboards create a visual framework for rigorous statistical analysis.

JMP Genomics
The desktop solution for analysis and visualization of genomics data, JMP Genomics combines the power of the JMP statistical discovery platform with industry-leading SAS Analytics and customized applications tailored for vast genomic data sets.
What is JMP® Clinical?

- JMP Clinical software from SAS shortens the drug development process by streamlining both internal safety reviews during preclinical, clinical trials and final evaluation by the Food and Drug Administration (FDA).

- JMP Clinical creates reports from standard Clinical Data Interchange Standards Consortium (CDISC) and Standard for Exchange of Non-Clinical Data (SEND) data, facilitating communication between (pre-) clinicians and biostatisticians at the sponsor organization and, subsequently, between sponsors and FDA reviewers.

- It targets Pharmacovigilance sector by using the 4 industry standards algorithms for signal detection in the disproportionality analysis.

- It dynamically links advanced statistics and graphics, enabling sophisticated analysis in a user-friendly environment.

- Interactive graphs offer multiple views of patient profiles and reveal hidden patterns in drug-drug, drug-adverse events interactions.
JMP® Clinical is the *de facto* standard for clinical data analysis software.

- It uses standard data (CDISC: SDTM & ADaM; SEND)
- It follows standard reporting recommended by medical authorities reviewer guidance (ICH-E3)
- It is based on industry standard tools (JMP and SAS)
  - JMP is the most widely used review tool at the FDA (40% of medical reviewers at CDER/CBER)
  - JMP is used at the EMEA in Pharmacovigilance
  - JMP is widely used in clinical groups at sponsors
- SAS is the standard analysis and reporting tool of biostatistics groups at sponsors
Pourquoi intégrer SAS et JMP

JMP seul sur un ordinateur de bureau offre une plate-forme hautement productive pour visualiser, explorer et modéliser des données.

Par contre, SAS (SAS/Base, SAS/S/STAT) est utilisé comme un environnement de « haute production de données », et fourni des outils à l'accès aux données, la manipulation et l'analyse de données.

Les avantages de la combinaison de SAS JMP:

Les statistiques utiles à JMP sont exploitées, visualisées et à l'exécution, la modélisation de données. L'approche de l'analyse est alors déployé par SAS, celle-ci effectue la manipulation des données, la validation et à l'analyse statistique de haute qualité afin de visualiser dans JMP.
JMP® Clinical Platform

Consumers

Knowledge Deployment

Producers

Knowledge Generation

Data Layer

Data Gathering

Statistical Reporting Tools

Workflows

SDTM, ADAM, SEND

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SDTM data example

- **Interventions**
  - EX – Exposure
  - CM – Concomitant Medications
  - SU – Substance Use

- **Events**
  - AE – Adverse Events
  - DS – Disposition
  - MH – Medical History

- **Findings**
  - LB – Laboratory Tests
  - VS – Vital Signs
  - PE – Physical Examinations
  - EG – ECG Tests
  - IE - Inclusion/Exclusion Exceptions
  - SC - Subject Characteristics

- **Others – Special Purpose Domains**
  - DM – Demographics
JMP® Clinical Processes on the shelf

- JMP Clinical has all processes in place to go through a standard clinical review process.
- Based on the availability of the different data domains, you will be able to graphically review:
  - Interventions, Events, Findings, Special
  - All Graphics linked to the data, with drill-down options and patient profiles
Reports when a process is run
Reports when a process is run

Graphically display of the analysis results
Reports display when a process is run.
Reports when a process is run

Data directly linked to the graphics and can be visualised
Switch variables to be displayed in the graphics.
On selection, view patient profiles
Reports when a process is run

On selection, view related events and findings
Fast Getting Started: Basic Safety Workflow

You might be doing many similar experiments where the analytic methods used must be the same time after time. JMP Clinical has a remarkable flexibility how to proceed with your analysis. A very simple and not doubt an extremely fast way how to proceed, is the Basic Safety Workflow.

One Single Dialog to run a complete set of clinical safety reports
A complete set of reports that embrace the clinical safety review process
Benefits for producers and consumers

JMP Clinical streamlines the clinical reporting and reviewing process by:

- Faster and easier safety review process by delivering unparalleled flexibility, point and click and drill down functionalities for exploring prominent results in more detail.

- Lower cost-to-market via better decision making on safety outcomes: JMP Clinical reduces the false discovery rate, by mitigating the risk of over-reporting adverse events.

- Spending time more efficiently in the safety review process: more time spend by exploring patterns and predicting outcomes in clinical trials data – and less time programming or manipulating data tables.
JMP® Clinical
Data Analysis Workflow
Live Demonstration
The Study Design

The Clinical Study used is the following:

- Nicardipine treatment of 906 subjects that had Subarachnoid Hemorrhage.
- All the patients were included in a randomized double-blind placebo-controlled study; 449 patients received Nicardipine while 457 received the placebo.
- Patients in each group were balanced with regard to prognostic factors for overall outcome.
- Nicardipine and the placebo were delivered continuously at 0.15 mg for up to 14 days and patients were followed for up to 120 days following administration of the drugs.
- Results are formatted according to the CDISC Study Tabulation Model.
JMP Clinical comes with its JMP Clinical Starter.

This dialog enables you to quickly view and access all JMP Clinical, workflows, and applications.

The order of this menu is important. It follows roughly the order described in the ICH-E3 reviewer guidance.
JMP® Clinical Starter Menu

JMP Clinical comes with its JMP Clinical Starter.

This dialog enables you to quickly view and access all JMP Clinical, workflows, and applications.

The Applications are ordered in categories and subcategories for the ease of use.
**JMP® Clinical Analysis Workflow**

**Visualize relationships between demographic characteristics and treatment groups**

One would need to check for consistency in the demographics distributions to evaluate any significant deviation among age, sex, race groups and sites within the different treatment groups.
Subject: 101001
Randomized Arm: Placebo
Investigator: 101A

Subject 101001 was a 65-year-old white female. Her medical history included headache associated with subarachnoid hemorrhage (SAH) in 1983, hypertension with this event, vomiting associated with SAH (1983) and hypertension prior to SAH (1981). She began dosing with 40 mg/d of placebo on 21 JAN 1988 (Day 1). The subject discontinued the trial on 15 FEB 1988 (Day 29) due to death.

Other Significant Adverse Event (coded term [reported term]): HYDROCEPHALUS [HYDROCEPHALUS]

On 21 JAN 1988 (Day 1) the subject experienced a hydrocephalus (mild) which was considered a significant adverse event. At the time of the event, the subject was taking 40 mg/d of placebo and had been at this dose for 1 day. The significant AE occurred on the first day of dosing with any study medication. Trial medication had an action of drug withdrawn as a result of the event. It is not known from the case report form if therapeutic measures were administered to treat the event.

Adverse events that occurred within a 23-day window of the onset of the significant AE included vasoconstriction (mild) and vomiting (mild). Concomitant medications taken at the onset of the significant AE included potassium supplements, codeine compound 1/2, docusate sodium and multivitamins.

The investigator considered the AE to be not related to study medication. The final outcome of the event was reported as recovered/resolved on 02 FEB 1988 (Day 13).

Other Significant Adverse Event (coded term [reported term]): PYREXIA [PYREXIA]

On 25 JAN 1988 (Day 5) the subject experienced a pyrexia (mild) which was considered a significant adverse event. At the time of the event, the subject was taking 40 mg/d of placebo and had been at this dose for 4 days. The significant AE occurred 4 days after the first dose of any study medication. Trial medication had an action of dose not changed as a result of the event. It is not known from the case report form if therapeutic measures were administered to treat the event.

Adverse events that occurred within a 23-day window of the onset of the significant AE included vomiting (mild). Concomitant medications taken at the onset of the significant AE included potassium supplements, docusate sodium, multivitamins and codeine compound 1/2.

The investigator considered the AE to be not related to study medication. The final outcome of the event was reported as recovered/resolved on 31 JAN 1988 (Day 11).
The Process shows the distribution of the review status of subjects in a study.
JMP® Clinical Analysis Workflow

Visualize Relationships between Mortality Rate and treatment groups

It is Important to know if there are significant deviations in the mortality rate across treatment groups
Visualise significance analysis tests reports of Adverse Events

Once adverse events have been detected, it is important to find out if those are significant by means of Fisher’s exact test or for more complex models, by Mixed Model Analysis.
Drill Down Options
From the incidence
Screen platform

Drill down to
Dot Plot

Relative Risk
Plot

Venn Diagram
JMP® Clinical Analysis Workflow

Visualise significant analysis test reports of lab measurements

Which Lab measurements are significantly different across treatment groups and have potentially higher risk to occur?
JMP® Clinical Analysis Workflow

Monitor Animated Patients Laboratory Tests to detect Hy’s Law Profiles

Quickly identify subjects with high risk of liver toxicity, meeting the criteria of Hy’s Law.
JMP® Clinical Analysis Workflow

**Screen for Hy’s Law Profiles**

Quickly identify subjects with high risk of liver toxicity, meeting the criteria of Hy’s Law and drill down to patient profiles.
**JMP® Clinical Analysis Workflow**

**Screen for Hy’s Law Profiles**

Quickly identify subjects with high risk of liver toxicity, meeting the criteria of Hy’s Law and drill down to patient profiles.

Link those subjects to patient profile.
Find out relationships between different domains

JMP Clinical permits clustering of all adverse events, interventions and findings across safety domains. Reviewers can screen concomitant medications and medical history for drug-drug and drug-disease interactions, respectively, and find out relationships.
JMP® Clinical Analysis Workflow

The Process creates various standard safety tabular reports in rtf, pdf, html, or plain text format.
The Disproportionality analysis in JMP Clinical includes the 4 industry standard disproportionality analyses used for signal detection. PRR, ROR, MGPS and BCPNN.
Disproportionality analysis is associated to “Signal Detection” in Pharmacovigilance.

Pharmacovigilance, abbreviated PV, is the pharmacological science to detect signal or adverse events (ae) once the drug is on the market (post-submission), similar to drug-ae surveillance.

The Disproportionality analysis in JMP Clinical includes the 4 industry standard disproportionality analyses used for signal detection.
JMP Clinical Disproportionality Analysis for Signal Detection

### Signal Summary

<table>
<thead>
<tr>
<th>Drug</th>
<th>Adverse Event</th>
<th>BCPNN</th>
<th>MGPS</th>
<th>PRR</th>
<th>ROR</th>
<th>Number of Signals</th>
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</thead>
<tbody>
<tr>
<td>Drug A</td>
<td>Chest pain</td>
<td>1</td>
<td>0</td>
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<td>2</td>
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<td></td>
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<td>0</td>
<td>2</td>
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<td>0</td>
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<td></td>
<td>Dizziness emotional</td>
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<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
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<td></td>
<td>Extradural haematoma</td>
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<td>2</td>
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<td>0</td>
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<td></td>
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<td>1</td>
<td>0</td>
<td>1</td>
<td>3</td>
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<td></td>
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<td>Drug C</td>
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<td>0</td>
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<td>3</td>
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<td>Drug D</td>
<td>Convulsion</td>
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<td>1</td>
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<td>2</td>
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<tr>
<td></td>
<td>Intestinal perforation</td>
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<td>0</td>
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<td>1</td>
<td>2</td>
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<td>Drug E</td>
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<td>Haemolysis</td>
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<td>1</td>
<td>1</td>
<td>3</td>
</tr>
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<td>1</td>
<td>2</td>
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<td>1</td>
<td>3</td>
</tr>
<tr>
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<td>Cerebral infection</td>
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<td>0</td>
<td>1</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
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<td>0</td>
<td>1</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Pyrexia</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Drug J</td>
<td>Delirium</td>
<td>1</td>
<td>0</td>
<td>1</td>
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<td>Pyrexia</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>

### Data Filter

- Select
- Show
- Includes

### Number of Signals

- Drug
- Adverse Event

Overall Signal Detection Summary for the 4 algorithms
JMP Clinical Disproportionality Analysis for Signal Detection

Tree Map view of overall AE frequency and signal detection category (here an example of BCPNN)
JMP Clinical Disproportionality Analysis for Signal Detection

Hierarchical Clustering
Method = Fast Ward

Dendrogram

Views allowing to cluster either Drugs or AE with similar behavior
JMP Clinical Disproportionality Analysis for Signal Detection

Views allowing to compare AE frequency with Stratification variable
JMP Clinical Disproportionality Analysis for Signal Detection

Geographical distribution of AE frequency
Conclusion

**JMP® Clinical is**

- Intuitive, Interactive, Comprehensive, Highly Visual.
- Easy to use
- Platform embraced at all levels of safety review process
- Facilitates interpretation, communication and reporting
- Helps users to improve the safety review process better, faster, cheaper
For more information,

ask for a demo

or visit

http://www.jmp.com/software/clinical/