

JMP Clinical® 4.0

adds Ways to
Explore Clinical Trials Data Visually



Dr. Valerie Nedbal
JMP Pharmaceutical Technical Manager

SAS Institute



THE
POWER
TO KNOW®

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

JMP® Clinical

Highly Visual
Interactive Graphics
Intuitive



Scalable
Validated Powerful Analytics

JMP® Clinical Platform

Consumers

*Knowledge
Deployment*

Producers

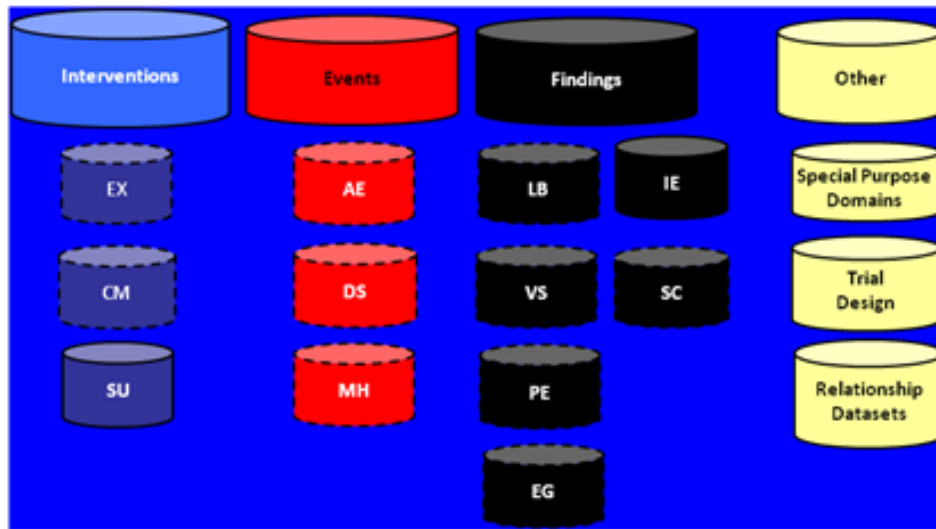
*Knowledge
Generation*

Data Layer

*Data
Gathering*

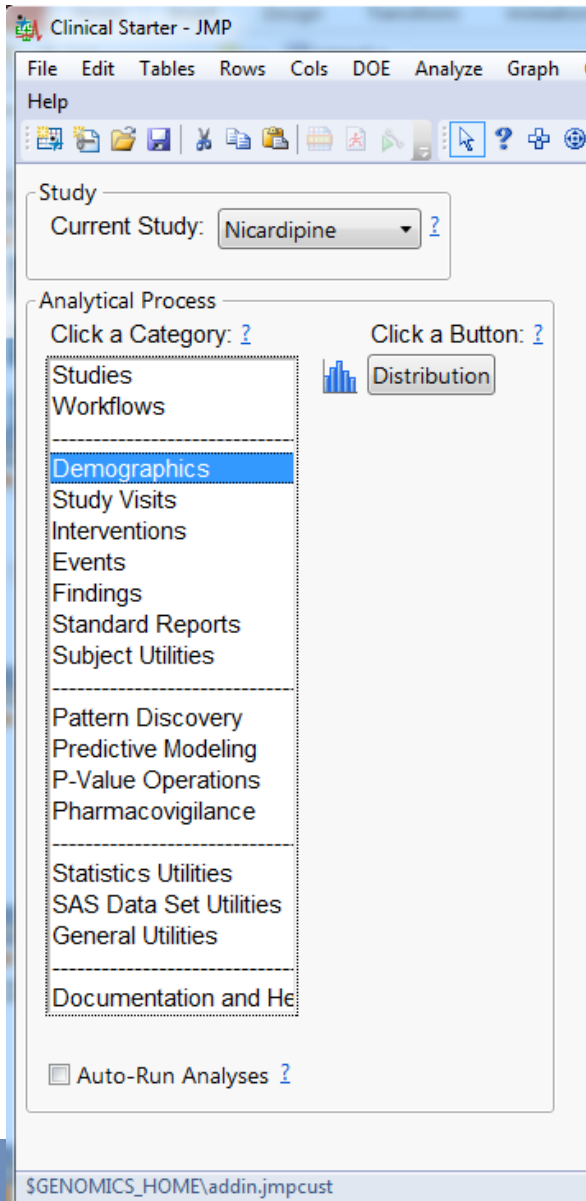


SDTM data example



- **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

File Edit Tables Rows Cols DOE Analyze Graph Genomics Clinical Tools Add-Ins View Window Help

Output Description

Tabs

Click Buttons for Tab Options

TreeMap Results

View Tab

Open in New Window

Remove Tab

View Data

Action Buttons

Column Switcher for TreeMap Tabs

Planned Treatment for Period 01

Serious Event

Causality

Outcome of Adverse Event

Sex

Race

Country

Study Site Identifier

Select Subjects then Click

Profile Subjects Show Subjects

Cluster Subjects Create Subject Filter

Click to View

Related CM Demographic Counts

Related Labs Related Vitals

Reopen Dialog

Create Report

Close All

TreeMap Results Body System or Organ Class TreeMap

Displayed counts indicate the number of subjects experiencing an event

Graph Builder

Dictionary-Derived Term

Planned Treatment for Period 01

NIC .15 Placebo

Vasoconstriction Hydrocephalus Hepatic function abnormal Vasoconstriction Intracranial pressure increased Hypertension

Anaemia Intracranial pressure increased Pyrexia Hypotension Anaemia Hydrocephalus Pyrexia Hepatic function abnormal

Hyperglycaemia Alveolitis Phlebitis Isosthenuria Ventricular Sepsis neonatal Pulmonary oedema Hypotension Hypokalaemia Heart rate increased Cerebral infarction

Oedema peripheral Heart rate increased Cerebral infarction Sepsis neonatal Pulmonary oedema Hypotension Hypokalaemia Heart rate increased Cerebral infarction

Brain oedema Atelectasis Hypernatraemia Respiratory disorder Gastric content Subarachnoid haemorrhage Enanthema Cerebral infarction

Urinary tract infection Hypokalaemia Vomiting Blood convulsions Urinary tract infection Atelectasis Hypokalaemia Vomiting Blood convulsions

Dictionary-Derived Term ordered by Total Count

Tabulate

Dictionary-Derived Term	NIC .15	Placebo
Vasoconstriction	246	314
Anaemia	145	167
Intracranial pressure increased	126	149
Hydrocephalus	130	129
Hypertension	91	163
Pyrexia	117	130
Hepatic function abnormal	126	111
Pulmonary oedema	132	104
Hypotension	155	80
Hyperglycaemia	114	96
Alveolitis	96	102
Oedema peripheral	94	91
Brain oedema	80	100
Atelectasis	94	72
Urinary tract infection	78	74
Hypokalaemia	73	73
Vomiting	63	64
Phlebitis	99	23
Heart rate increased	58	52
Isosthenuria	72	33
Cerebral infarction	45	49
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Sepsis neonatal	37	33
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Hypernatraemia	32	20
Supraventricular extrasystoles	25	22
Respiratory disorder	28	18
Cerebral haemorrhage	17	28

Data Filter

Select Show

Clear

1 ≤ Total Count

0,1 ≤ Percentage

Serious Event

Causality

NOT RELATED

UNLIKELY RELATED

POSSIBLY RELATED (12)

Severity/Intensity

MILD (3064)

MODERATE (64)

SEVERE (64)

Outcome of Event

RECOVERED

FATAL (785)

RECOVERING

NOT RECOVERED

RECOVERED

UNKNOWN (-)

??? (3)

Body System

BLOOD AND CARDIAC DIS

EAR AND LARYNGEAL

ENDOCRINE

Reports when a process is run

File Edit Tables Rows Cols DOE Analyze Graph Genomics Clinical Tools Add-Ins View Window Help

Output Description

Tabs

Click Buttons for Tab Options

TreeMap Results

View Tab
Open in New Window
Remove Tab
View Data

Action Buttons

Column Switcher for TreeMap Tabs

Planned Treatment for Period 01

Serious Event
Causality
Outcome of Adverse Event
Sex
Race
Country
Study Site Identifier

Select Subjects then Click

Profile Subjects Show Subjects
Cluster Subjects Create Subject Filter

Click to View

Related CM Demographic Counts
Related Labs Related Vitals

Reopen Dialog
Create Report
Close All

TreeMap Results Body System or Organ Class TreeMap

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Graph Builder

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Brain oedema Atelectasis Subarachnoid haemorrhage Hypertension Hypokalaemia Vomiting Phlebitis Heart rate increased Isosthenuria Cerebral infarction Ventricular extrasystoles Sepsis neonatal Sinus bradycardia Hyponatraemia Enanthema Subarachnoid haemorrhage Hypertension Supraventricular extrasystoles Respiratory disorder Cerebral haemorrhage

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Select Show

Clear

1 ≤ Total Count

0,1 ≤ Percentage

Serious Event

Causality

NOT RELATED
UNLIKELY RELATED
POSSIBLY RELATED (12)

Severity/Intensity

MILD (3064)
MODERATE (64)
SEVERE (64)

Outcome of Event

RECOVERED
FATAL (785)
RECOVERING
NOT RECOVERED
RECOVERED
UNKNOWN (4)
??? (3)

Body System

BLOOD AND CARDIAC DISORDERS
EAR AND EYE
ENDOCRINE

Graphically display of the analysis results

Reports display when a process is run

File Edit Tables Rows Cols DOE Analyze Graph Genomics Clinical Tools Add-Ins View Window Help

TreeMap Results Body System or Organ Class TreeMap

Options

Class TreeMap

for TreeMap Tabs

Event

ick

Subjects

ite Subject Filter

aphic Counts

Vitals

Displayed counts indicate the number of subjects experiencing an event

Graph Builder

Dictionary-Derived Term

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NIC .15 Placebo

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Enanthema	32	
Subarachnoid haemorrhage	26	
Hypernatremia	32	
Supraventricular extrasystoles	25	
Respiratory disorder	28	
Cerebral haemorrhage	17	
Platelet destruction increased	29	
Sinus headache	21	
Blood creatine phosphokinase increased	20	
Blood lactate dehydrogenase increased	22	
Cardiac failure congestive	24	
Convulsion	19	
Atrial fibrillation	18	
Coagulopathy	14	

Data Filter

☒ Select ☒ Show ☒ Include

Clear

☒ 1 ≤ Total Count ≤ 560

☒ 0,1 ≤ Percent Occurrence ≤ 62,1

Data Filters to automatically update your reports

Causality

NOT RELATED (4756)

UNLIKELY RELATED (747)

POSSIBLY RELATED (446)

Severity/Intensity

MILD (3064)

MODERATE (2364)

Body System or Organ Class

BLOOD AND LYMPHATIC SYSTEMS (4756)

ENDOCRINE DISORDERS (5)

EYE DISORDERS (22)

GASTROINTESTINAL DISORDERS (21)

GENERAL DISORDERS AND HEPATOBIILIARY DISORDER (21)

IMMUNE SYSTEM DISORDERS (17)

INFECTIONS AND INFESTATIONS (17)

INJURY, POISONING AND PROCEDURES (17)

INVESTIGATIONS (217)

Reports when a process is run

File Edit Tables Rows Cols DOE Analyze Graph Genomics Clinical Tools Add-Ins View Window Help

Output Description

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Click Buttons for Tab Options

TreeMap Results

View Tab

Open in New Window

Remove Tab

View Data

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Column Switcher for TreeMap Tabs

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Causality

Outcome of Adverse Event

Sex

Race

Country

Study Site Identifier

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Show Subjects

Cluster Subjects

Create Subject Filter

Click to View

Related CM

Demographic Counts

Related Labs

Related Vitals

Reopen Dialog

Create Report

Close All

TreeMap Results

Body System or Organ Class TreeMap

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Dictionary-Derived Term

Planned Treatment for Period 01

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Placebo

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Hydrocephalus

Hepatic function abnormal

Anaemia

Intracranial pressure increased

Pyrexia

Hypertension

Hypotension

Hyperglycaemia

Alveolitis

Phlebitis

Isosthenuria

Ventricular extrasystoles

Sepsis neonatal

Brain oedema

Atelectasis

Urinary tract infection

Subarachnoid haemorrhage

Hypernatraemia

Supraventricular extrasystoles

Respiratory disorder

Cerebral haemorrhage

Planned Treatment for Period 01

NIC .15

Placebo

Vasoconstriction

Intracranial pressure increased

Hypertension

Pyrexia

Hepatic function abnormal

Pulmonary oedema

Anaemia

Hydrocephalus

Hypotension

Hyperglycaemia

Alveolitis

Phlebitis

Isosthenuria

Ventricular extrasystoles

Sepsis neonatal

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Data Filter

Select

Show

Clear

1 ≤ Total Count

0,1 ≤ Percentage

Serious Event

Causality

NOT RELATED

UNLIKELY RELATED

POSSIBLY RELATED

RELATED (12)

Severity/Intensity

MILD (3064)

MODERATE (64)

SEVERE (64)

Outcome of Event

RECOVERED

FATAL (785)

RECOVERING

NOT RECOVERED

RECOVERED

UNKNOWN (-)

??? (3)

Body System

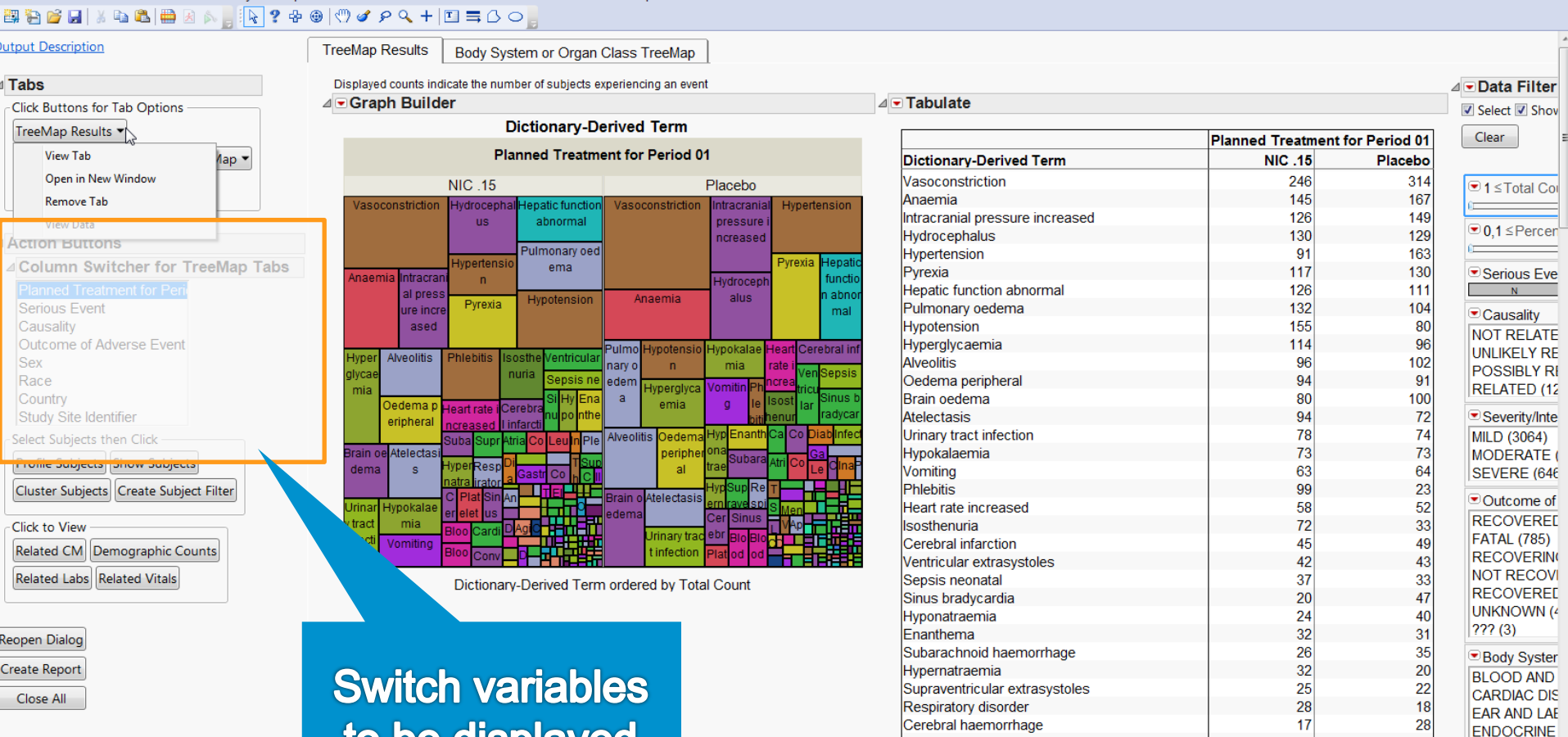
BLOOD AND CARDIAC DIS

EAR AND LARYNGEAL

ENDOCRINE

Data directly linked to the graphics and can be visualised

File Edit Tables Rows Cols DOE Analyze Graph Genomics Clinical Tools Add-Ins View Window Help



Reports when a process is run

File Edit Tables Rows Cols DOE Analyze Graph Genomics Clinical Tools Add-Ins View Window Help

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Hyperglycaemia	Alveolitis	Phlebitis	Hyperglycaemia	Vomiting	Phlebitis
Oedema peripheral	Heart rate increased	Cerebral infarction	Oedema peripheral	Subarachnoid haemorrhage	Cerebral infarction
Brain oedema	Atelectasis	Hypernatraemia	Brain oedema	Atelectasis	Hypernatraemia
Urinary tract infection	Hypokalaemia	Vomiting	Urinary tract infection	Hypokalaemia	Vomiting

Dictionary-Derived Term ordered by Total Count

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Serious Event

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POSSIBLY RELATED (12)

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RECOVERED

UNKNOWN (4)

Body System

BLOOD AND CARDIAC DIS

EAR AND LARYNGEAL

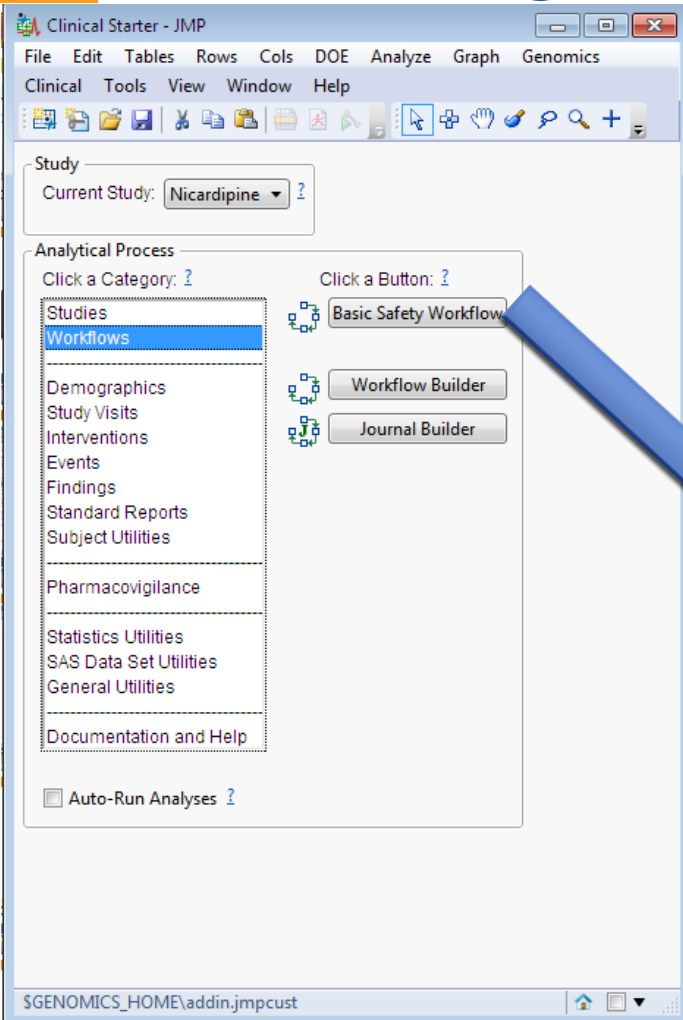
ENDOCRINE

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.

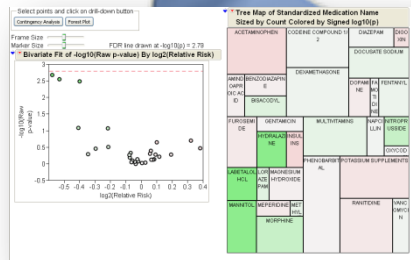
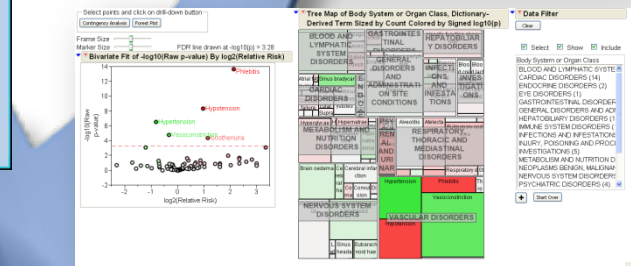
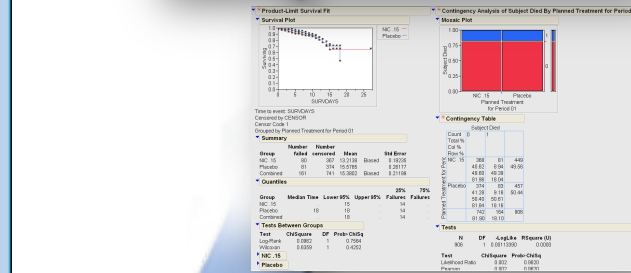
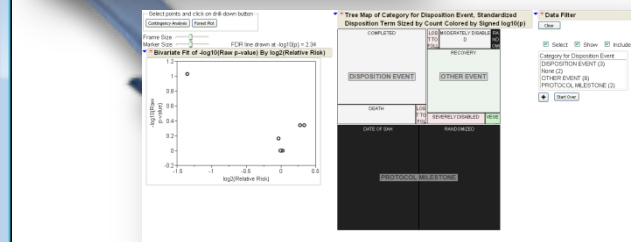
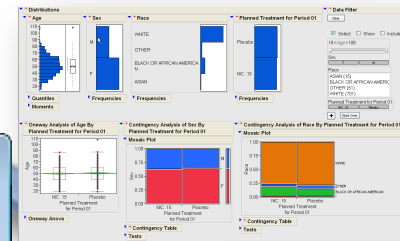
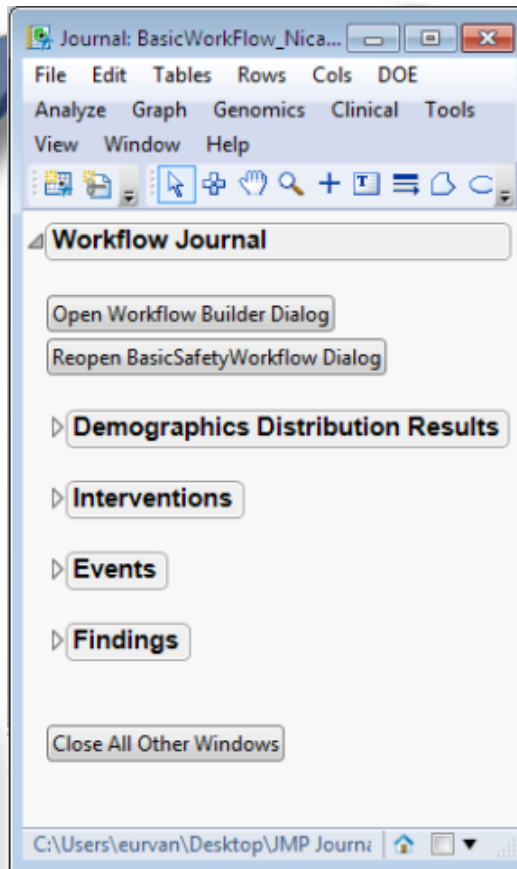
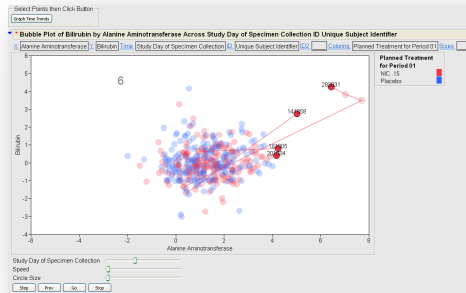


One Single Dialog to run a complete set of clinical safety reports

The screenshot shows the 'Basic Safety Workflow' configuration dialog. The 'General' tab is selected. The 'Interventions' section has 'Exposure', 'Concomitant Medications Distribution', and 'Concomitant Medications Incidence Screen' checked. The 'Events' section has 'Mortality', 'Adverse Events', and 'Disposition Distribution' checked. The 'Findings' section has 'Labs' checked. The 'Term Level(s) to Use for AE Incidence Screen' section has 'Preferred Term' and 'Body System' checked.

Flexibility of which applications to be run

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



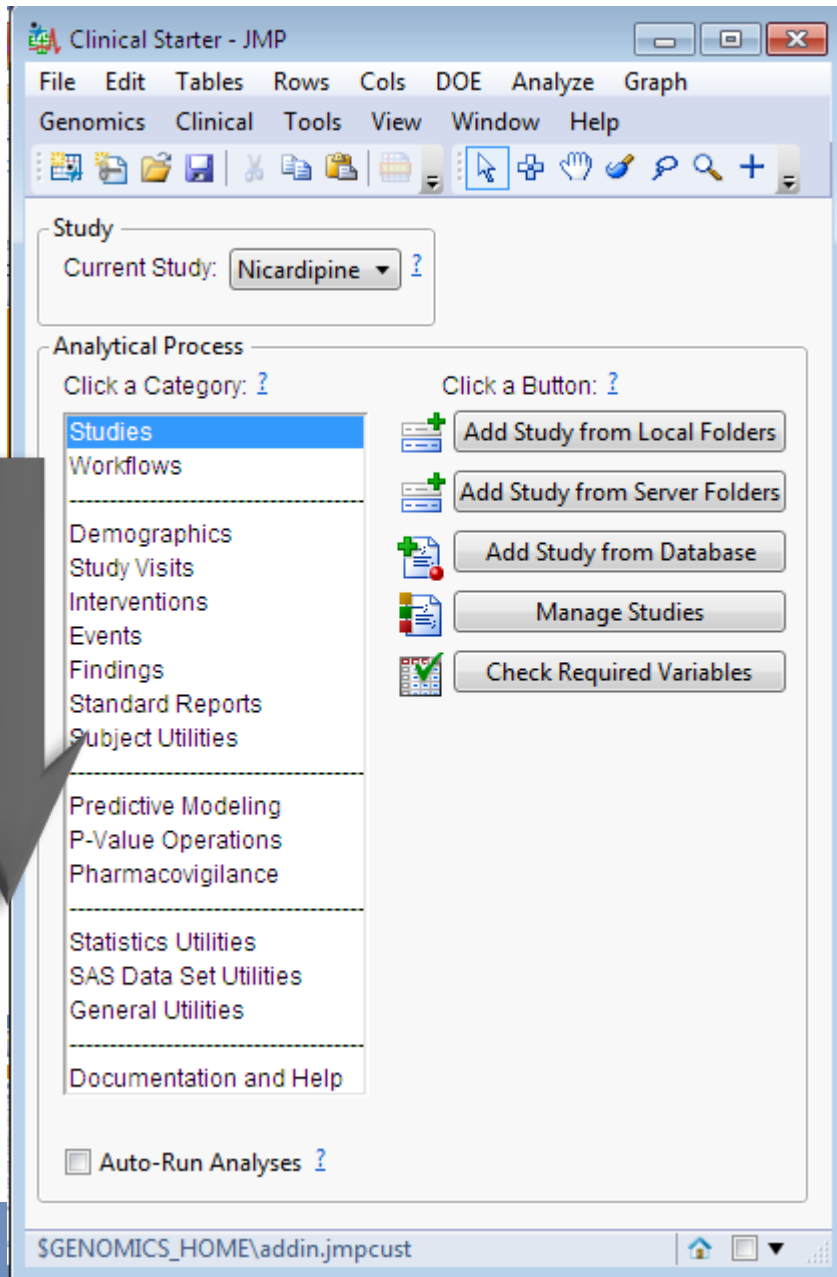
THE
POWER
TO KNOW®

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 Starter Menu

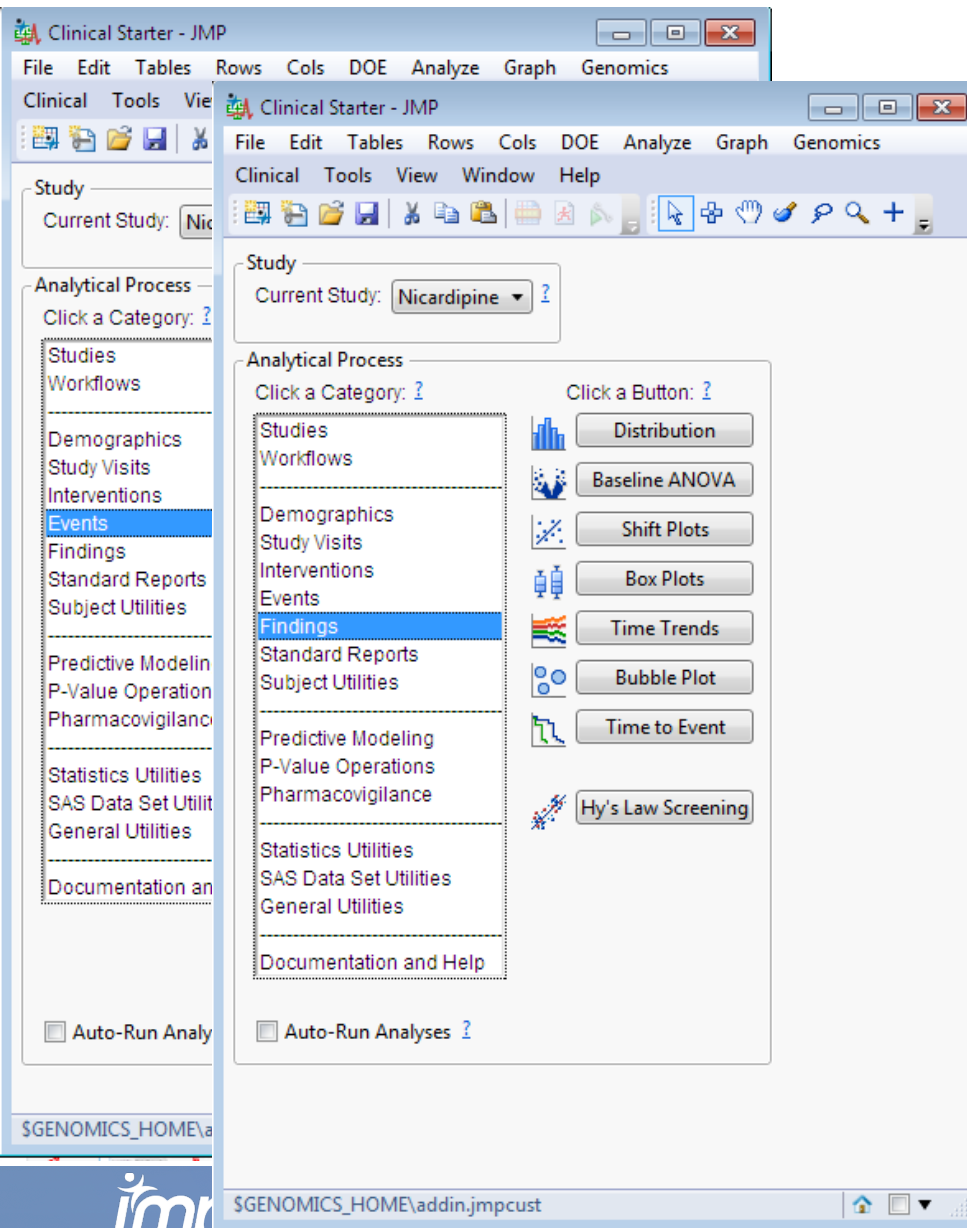


JMP Clinical comes with its JMP Clinical Starter.

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

The order of this menu is important. It follows roughly the order described in the ICH-E3 reviewer guidance

JMP® Clinical Starter Menu

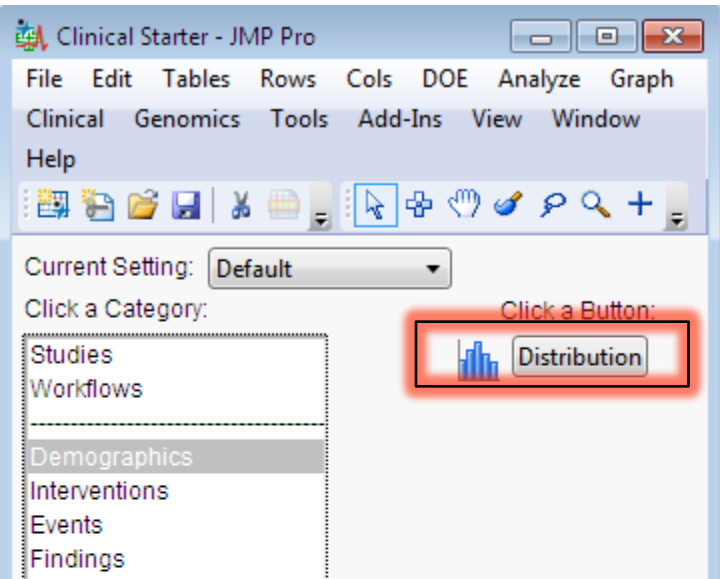


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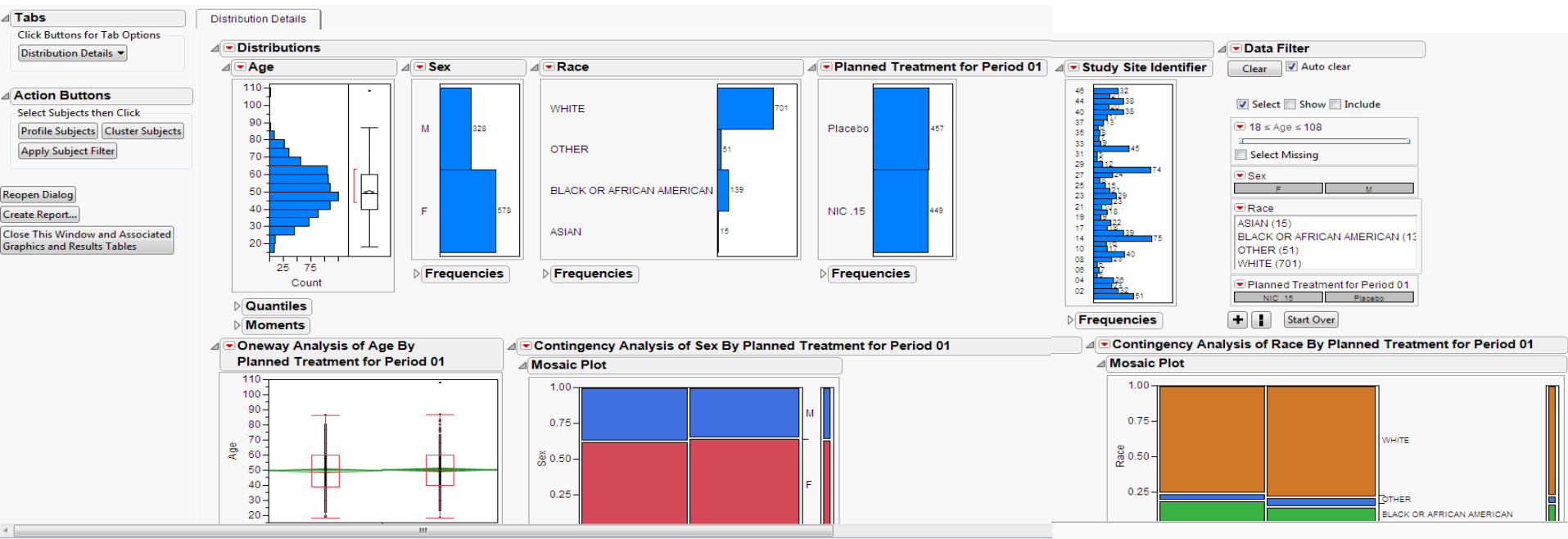
The Applications are ordered in categories and subcategories for the ease of use

JMP® Clinical Analysis Workflow

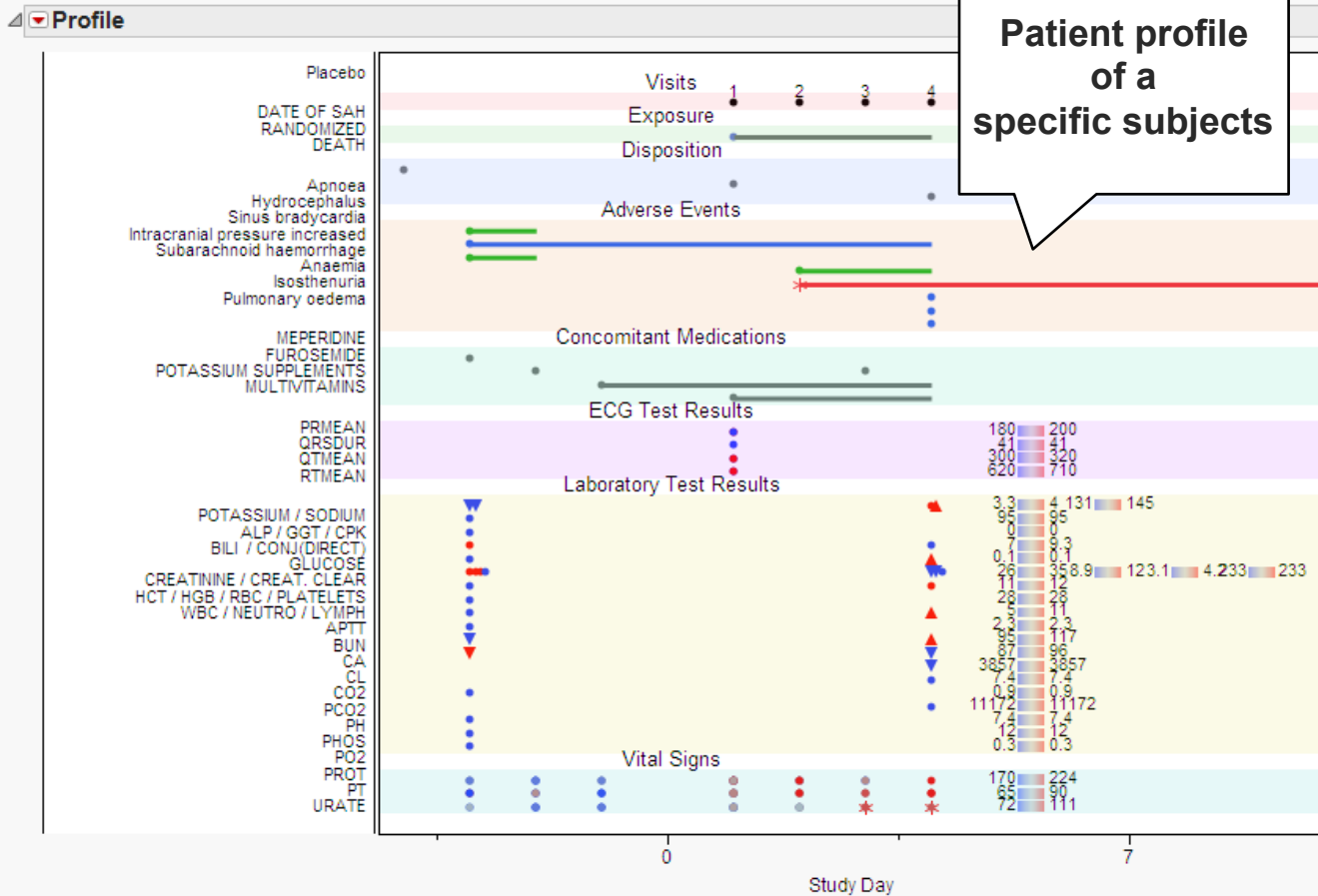


Visualize relationships between demographic characteristics and treatment groups

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



JMP® Clinical Analysis Workflow



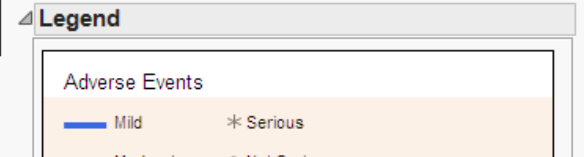
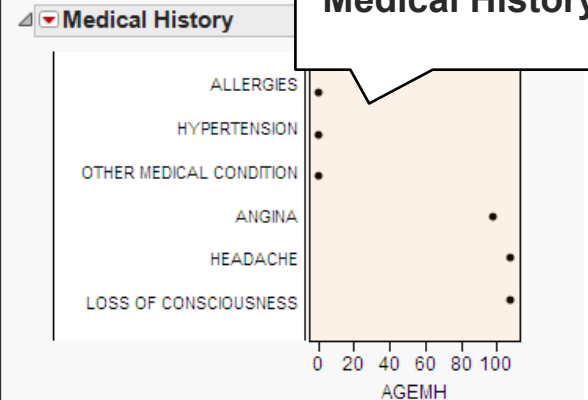
Patient profile
of a
specific subjects

Demographic
Attributes

Demographics	Subject	Age	Sex	Race
	21025	108	F	V

Review Status
21025 Status: Unreviewed

Review Status
Notification



JMP® Clinical Analysis Workflow

Patient Narratives

Subject: 101001
Randomized Arm: Placebo
Investigator: 101A

Subject 101001 was a 63-year-old white female. Her medical history included headache associated with sah (1988), hypertension with this sah (1988), vomiting associated with sah (1988) and hypertension prior to sah (1981). She began dosing with 40 mg/h of placebo on 21JAN1988 (Day 1). The subject discontinued the trial on 18FEB1988 (Day 29) due to death.

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

On 21JAN1988 (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/h 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 ± 3 -day window of the onset of the significant AE included vasoconstriction (moderate) 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 02FEB1988 (Day 13).

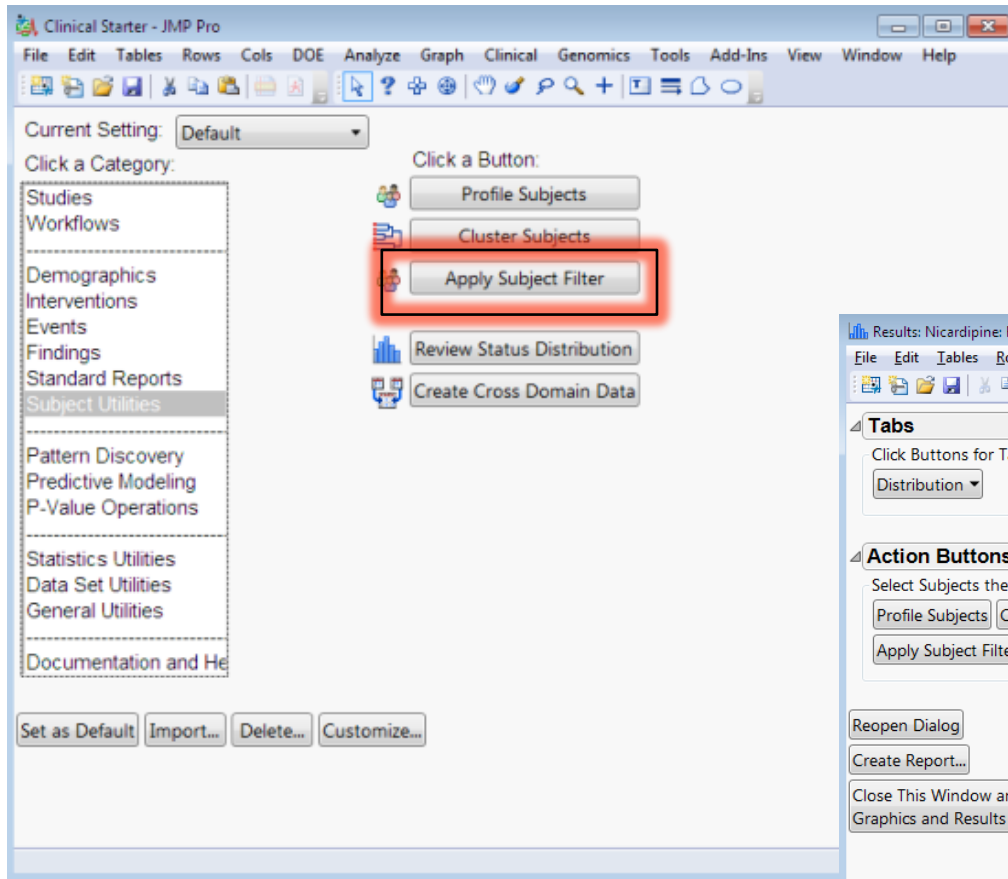
Other Significant Adverse Event (coded term [reported term]): PYREXIA [PYREXIA]

On 25JAN1988 (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/h of placebo and had been at this dose for 5 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.

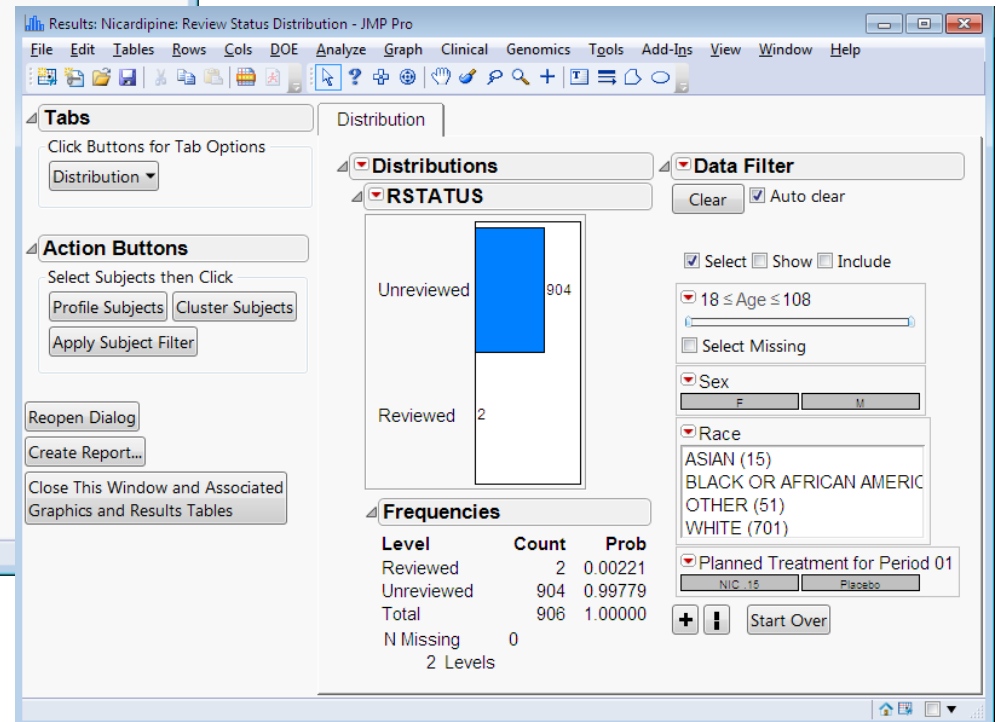
Adverse events that occurred within a ± 3 -day window of the onset of the significant AE included vomiting (mild). Concomitant medications taken at the onset of the significant AE included potassium supplements, docusate sodium, multivitamins and codeine compound 1/2.

The investigator considered the AE to be not related to study medication. The final outcome of the event was reported as recovered/resolved on 31JAN1988 (Day 11).

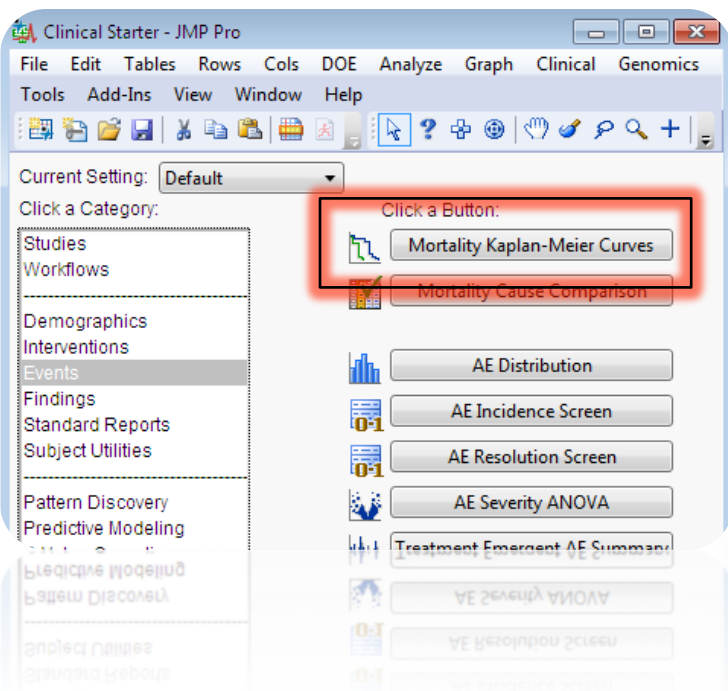
JMP® Clinical Analysis Workflow



The Process shows the distribution of the review status of subjects in a study.

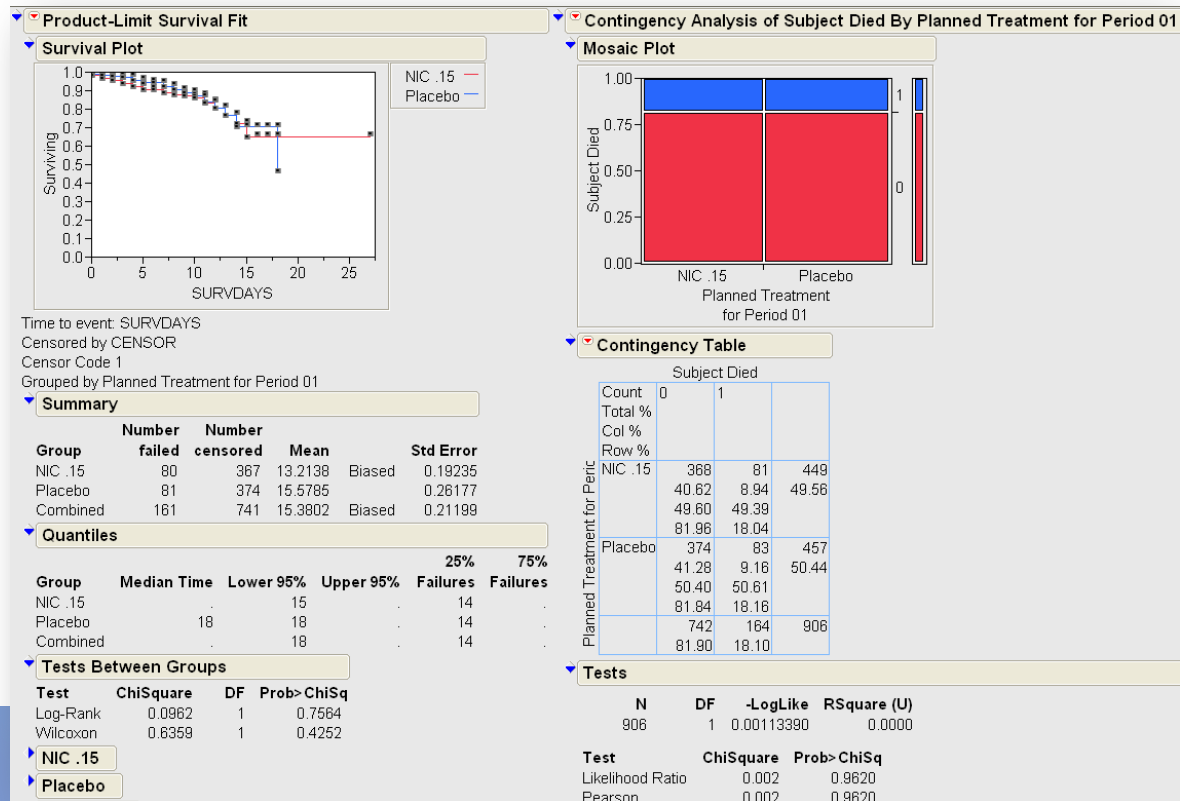


JMP® Clinical Analysis Workflow

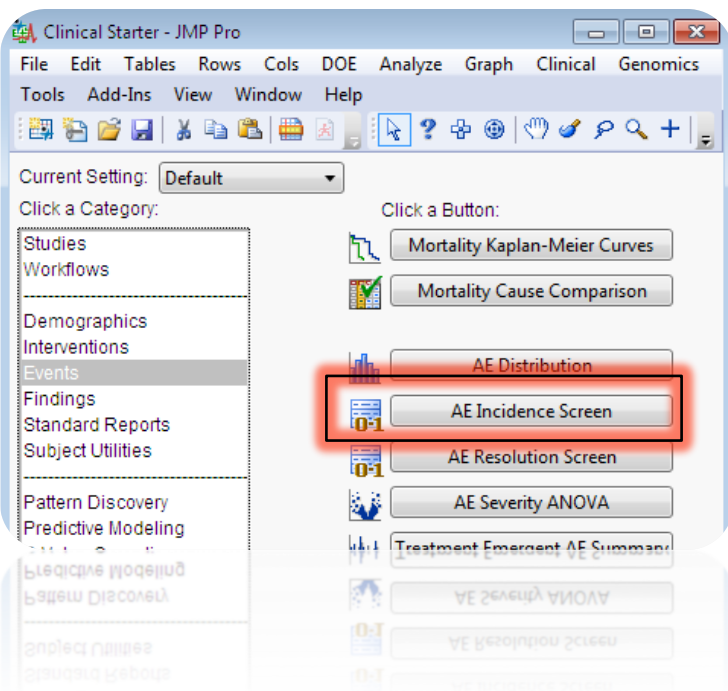


Visualize Relationships between Mortality Rate and treatment groups

It is Important to know if there are significant deviations in the mortality rate across treatment groups



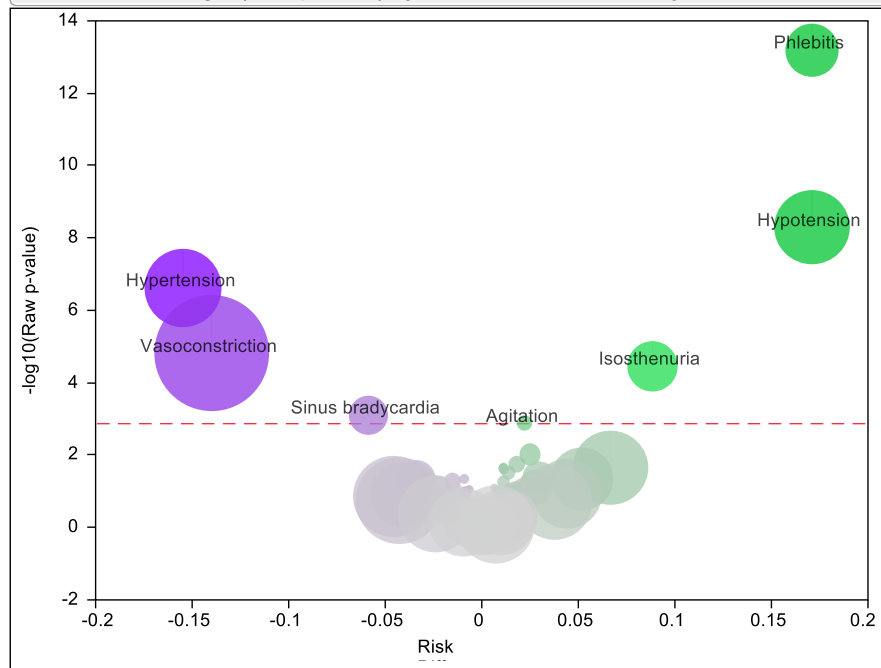
JMP® Clinical Analysis Workflow



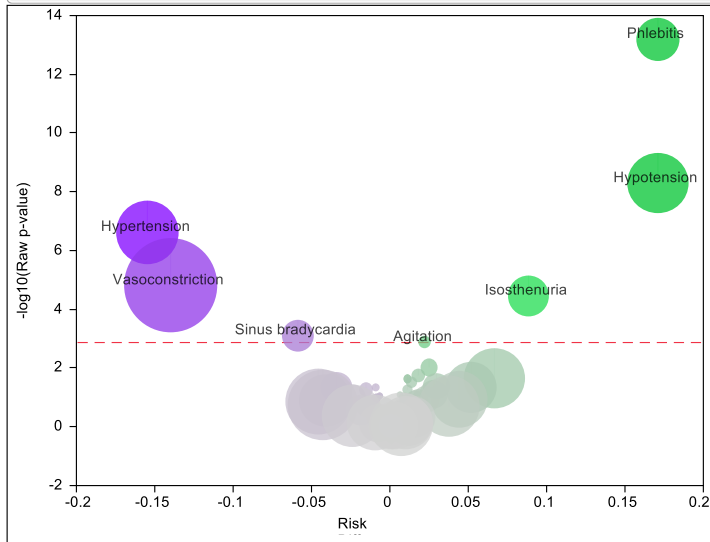
Visualise significance analysis tests reports of Adverse Events

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.

Bubble Plot of $-\log_{10}(\text{Raw p-value})$ by Risk Difference Sized by Count Ratio=NIC .15 over Placebo



Risk in Placebo Risk in NIC .15



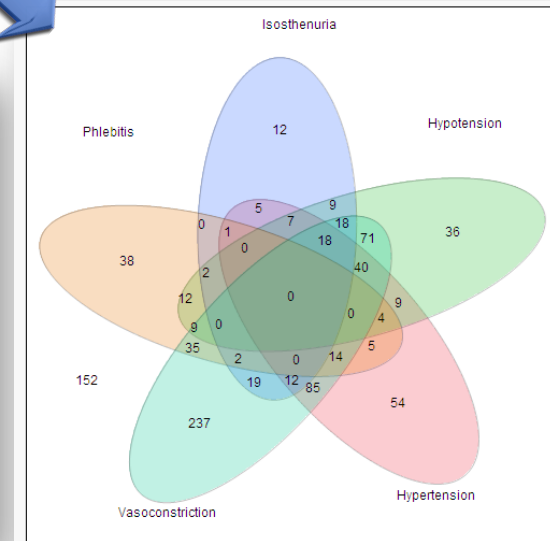
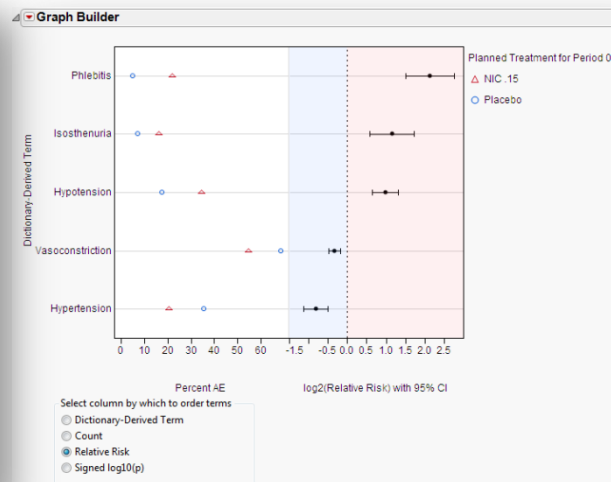
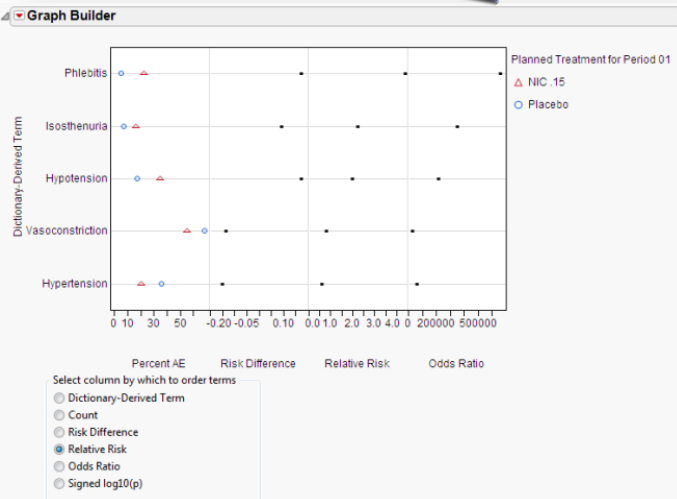
Circle
Size

Drill Down Options
From the incidence
Screen platform

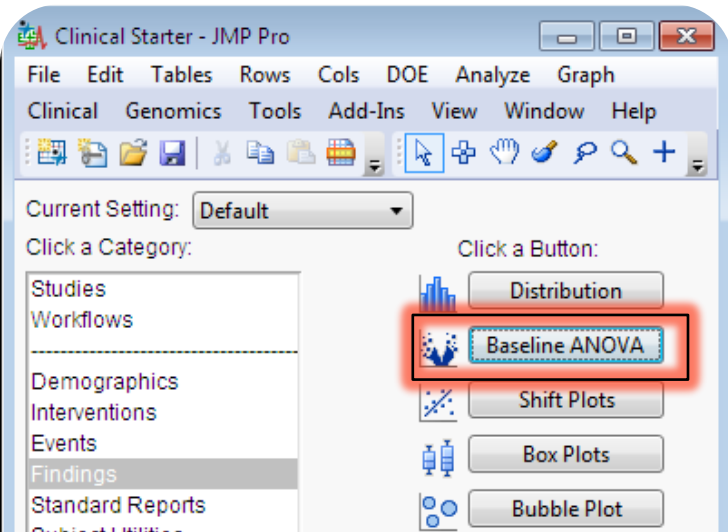
Drill down to
Dot Plot

Relative Risk
Plot

Venn Diagram

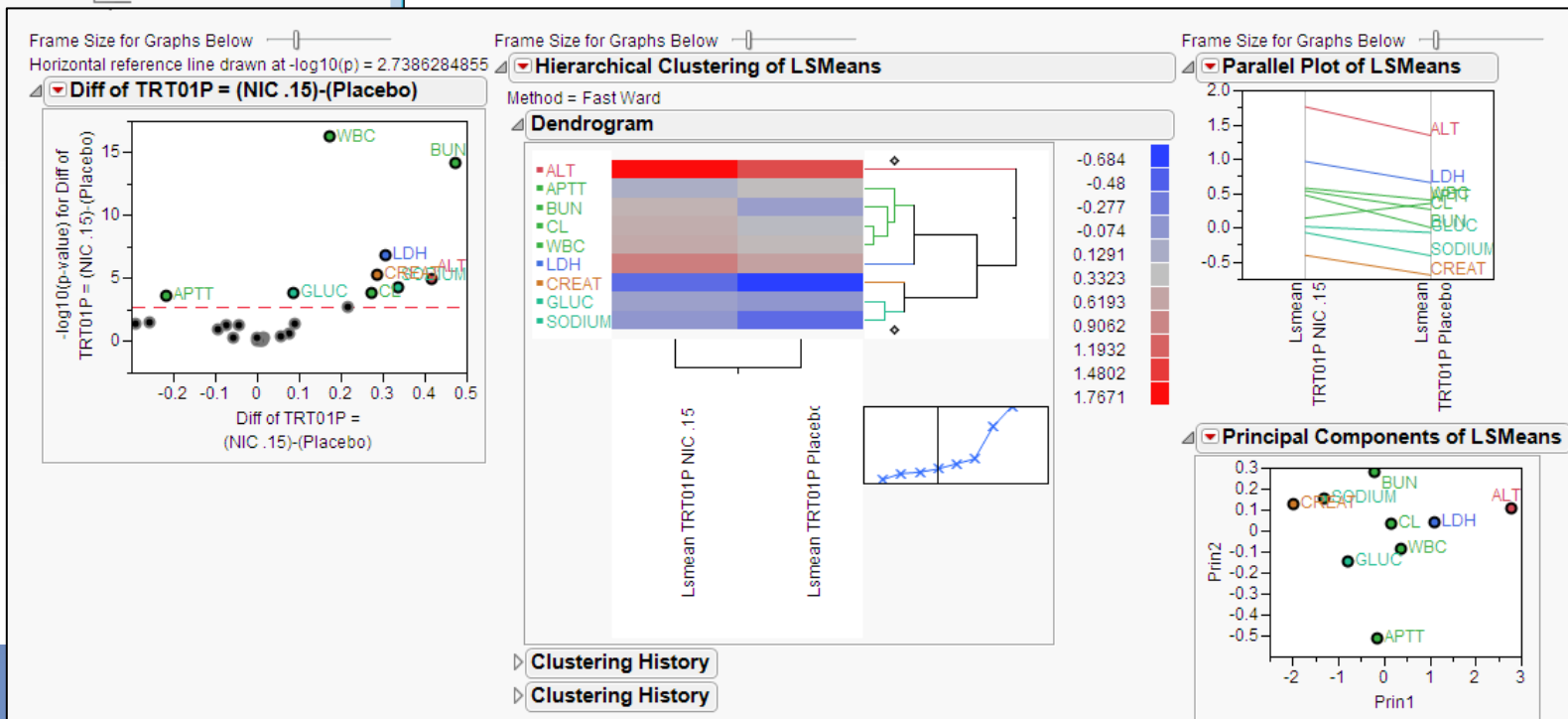


JMP® Clinical Analysis Workflow

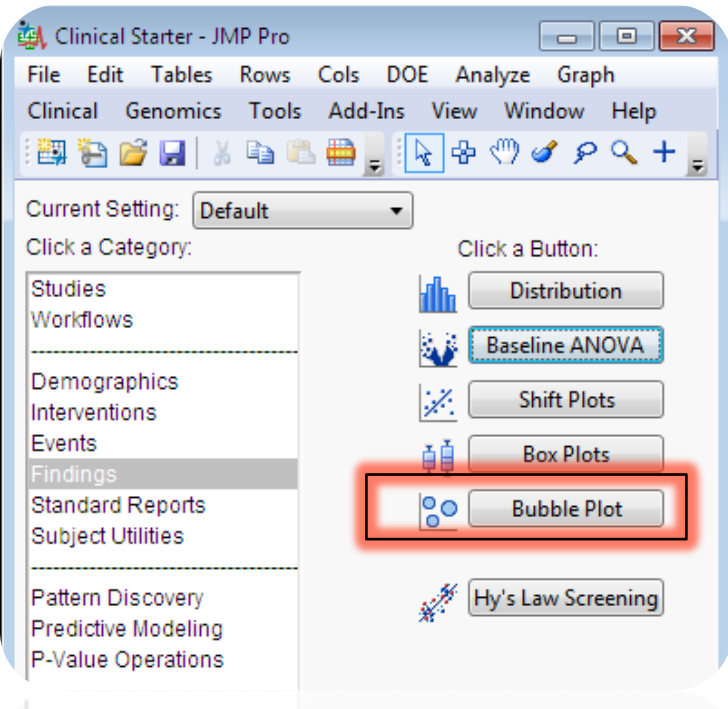


Visualise significant analysis test reports of lab measurements

Which Lab measurements are significantly different across treatment groups and have potentially higher risk to occur?

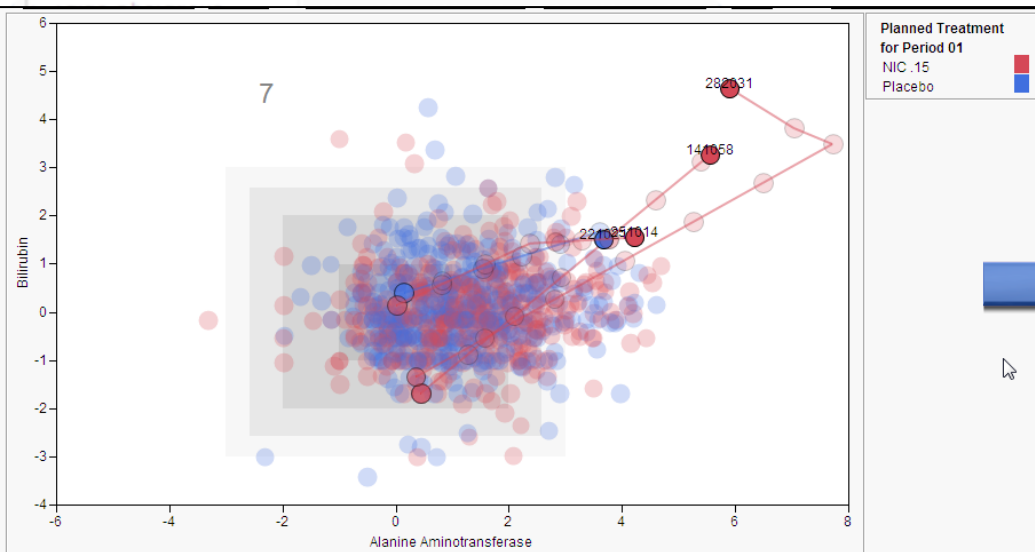


JMP® Clinical Analysis Workflow

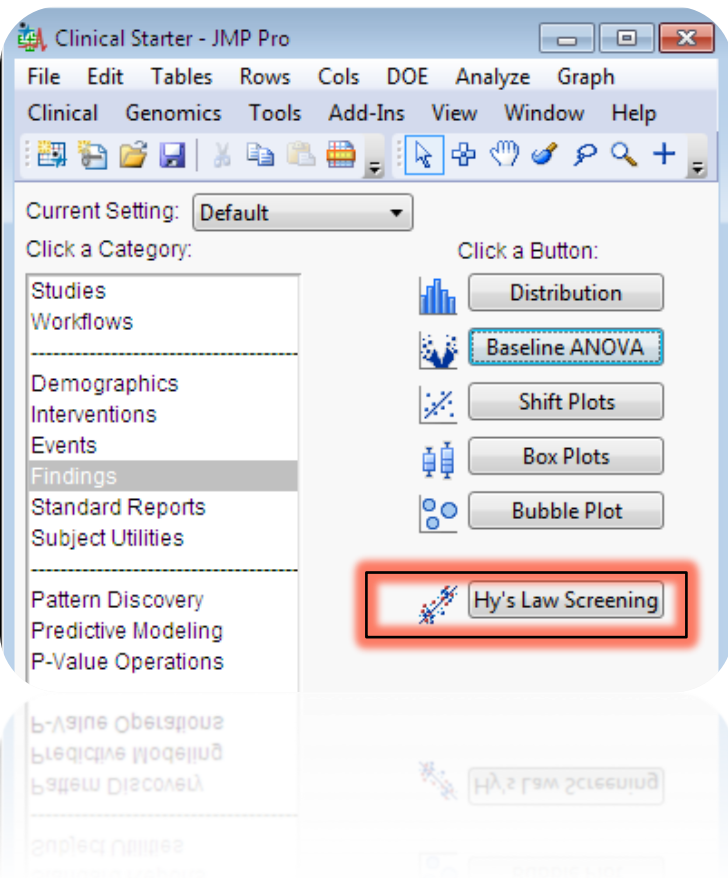


Monitor Animated Patients Laboratory Tests to detect Hy's Law Profiles

Quickly identify subjects with high risk of liver toxicity, meeting the criteria of Hy's Law.

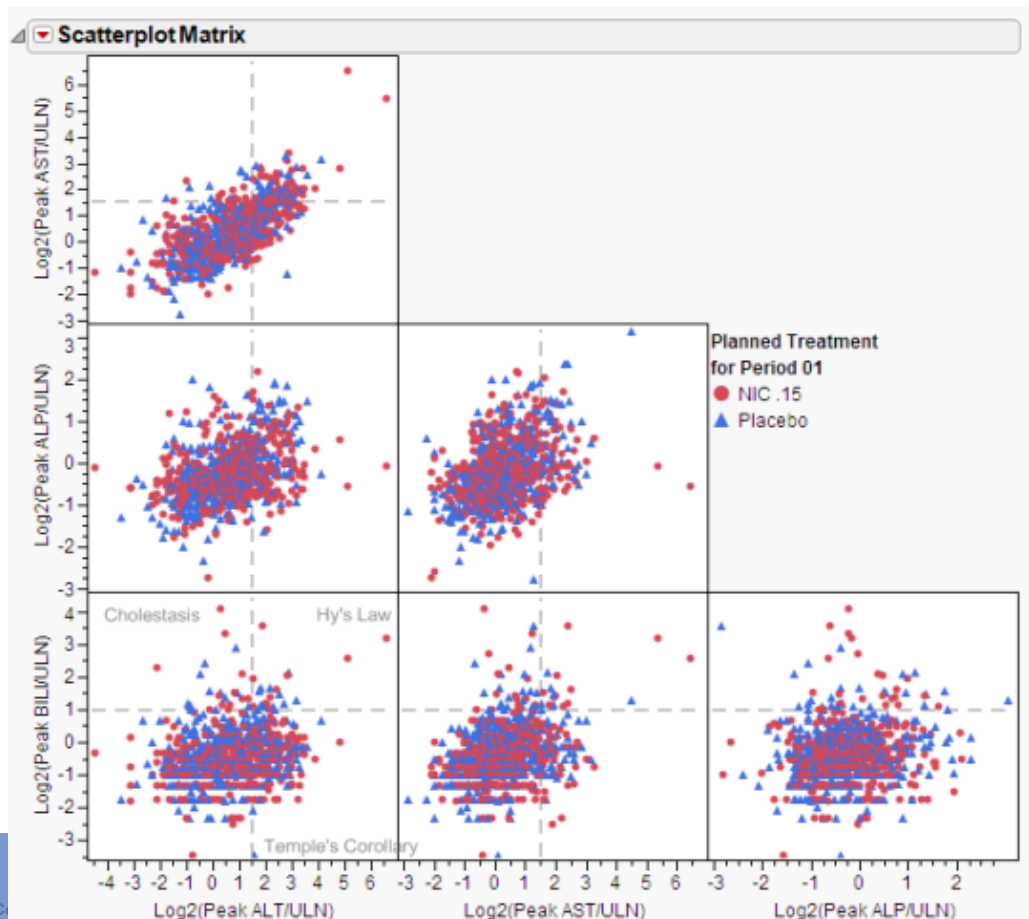


JMP® Clinical Analysis Workflow

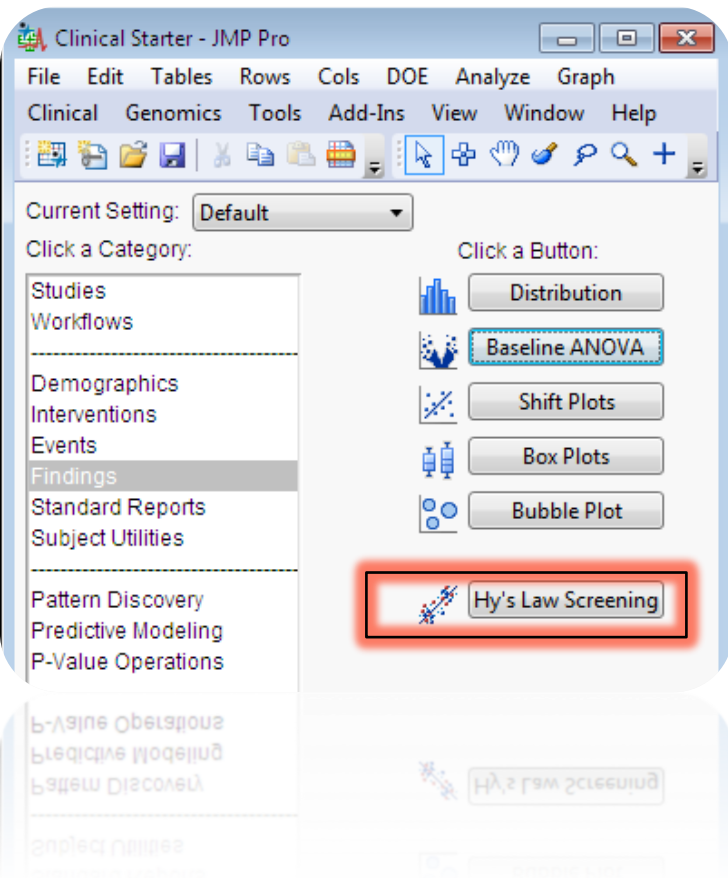


Screen for Hy's Law Profiles

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

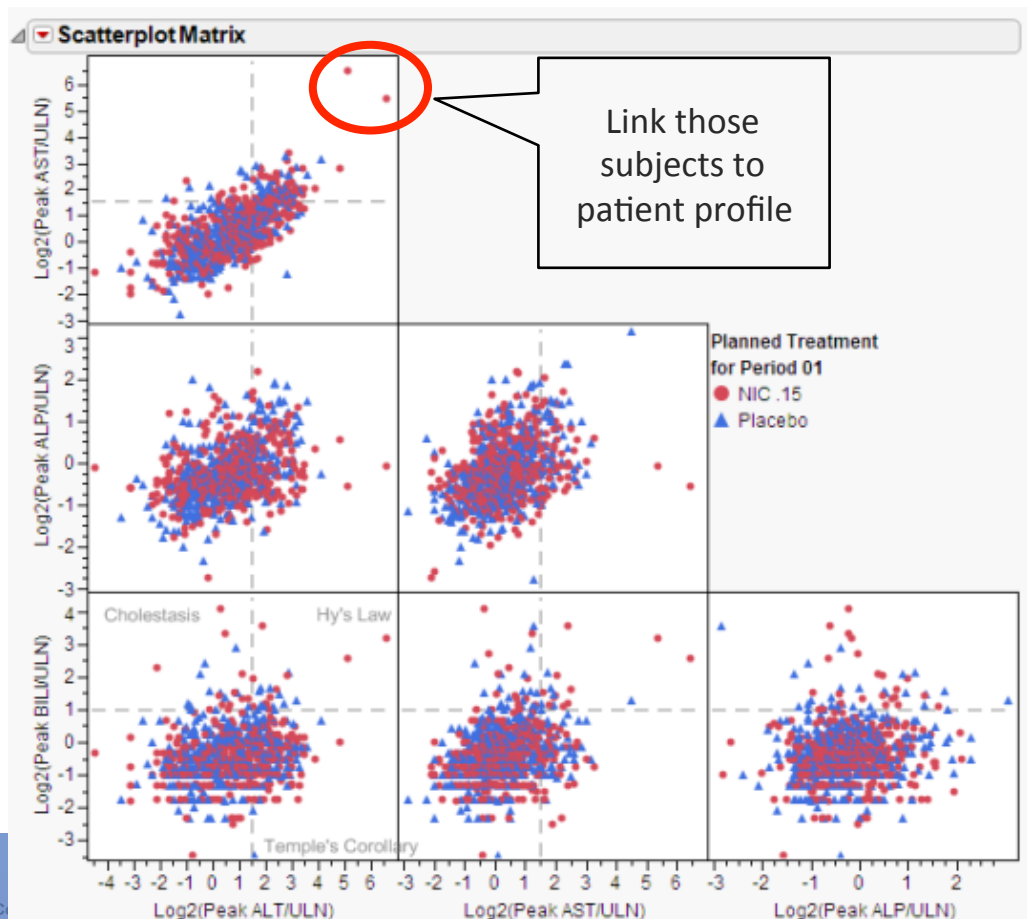


JMP® Clinical Analysis Workflow

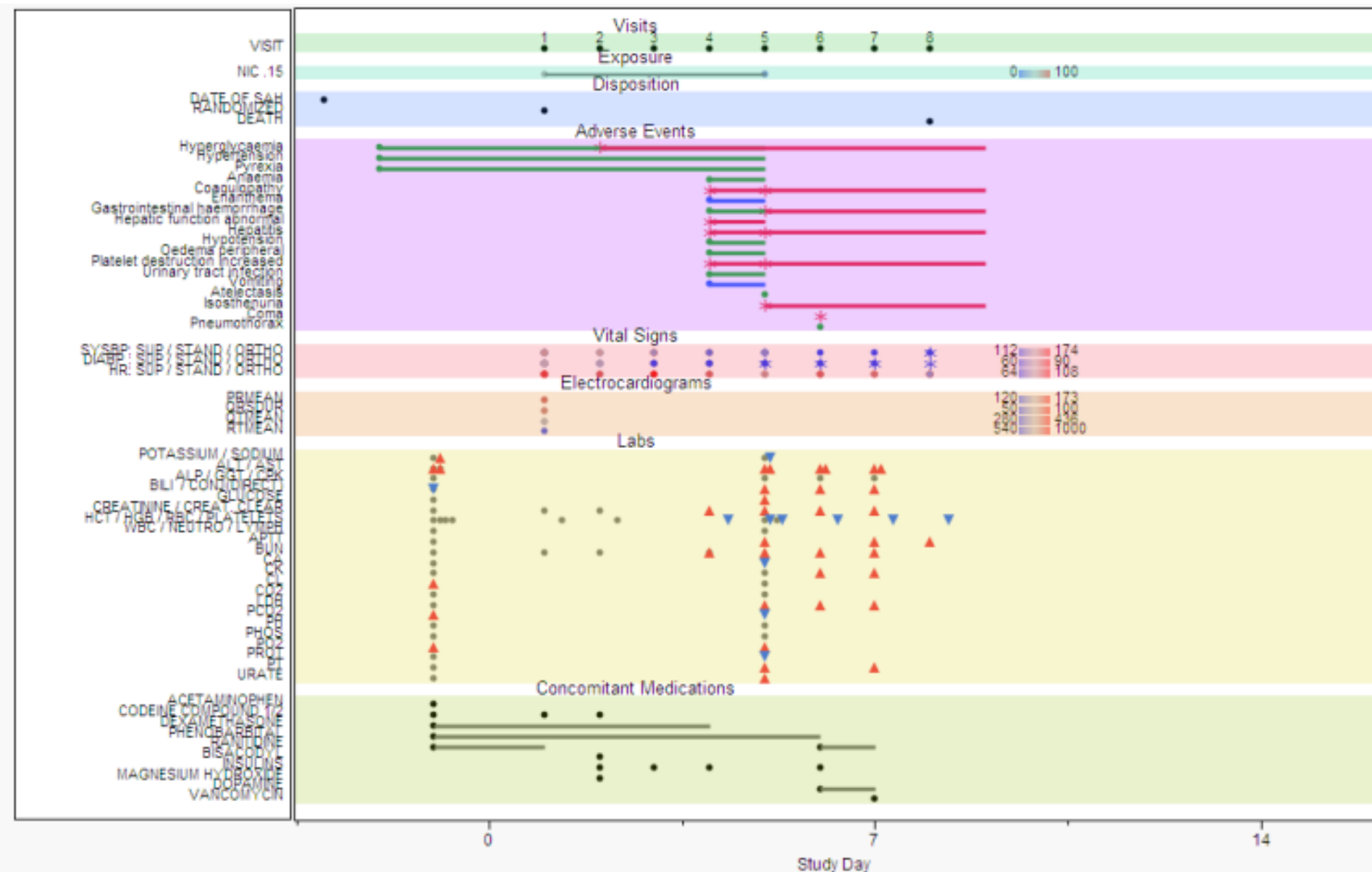


Screen for Hy's Law Profiles

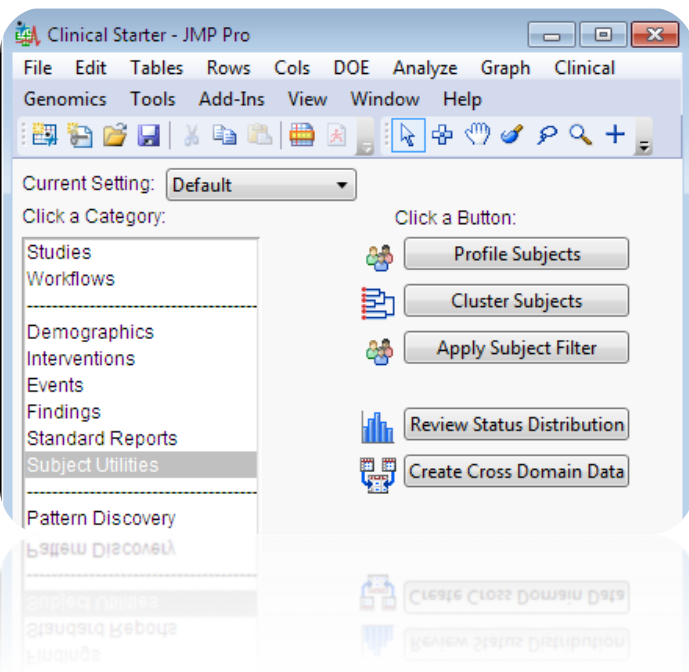
Quickly identify subjects with high risk of liver toxicity, meeting the criteria of Hy's Law and drill down to patient profiles



100%

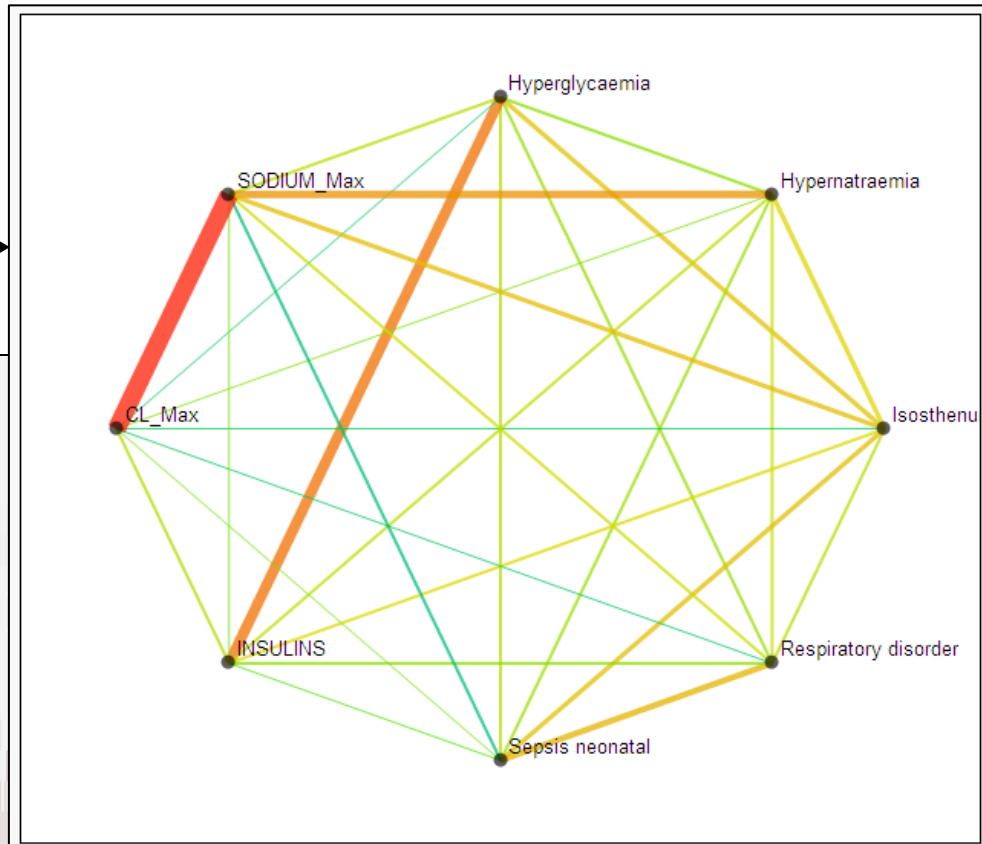
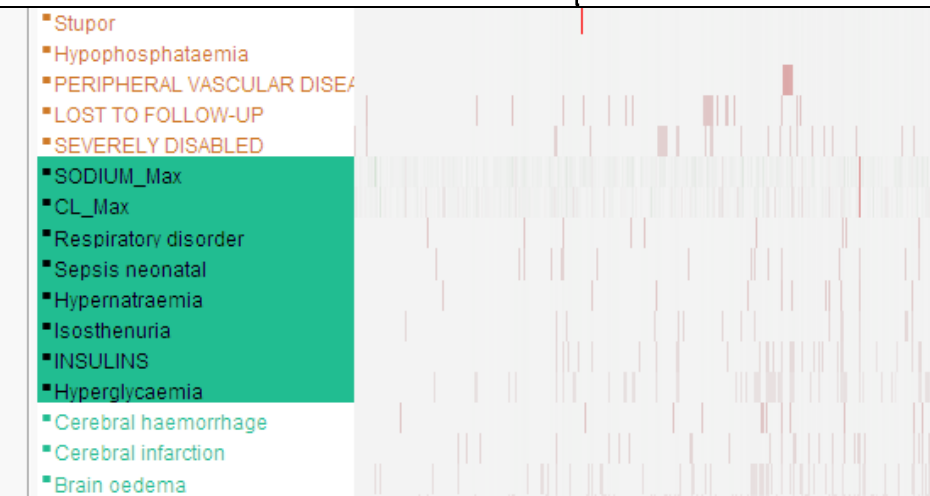


JMP® Clinical Analysis Workflow



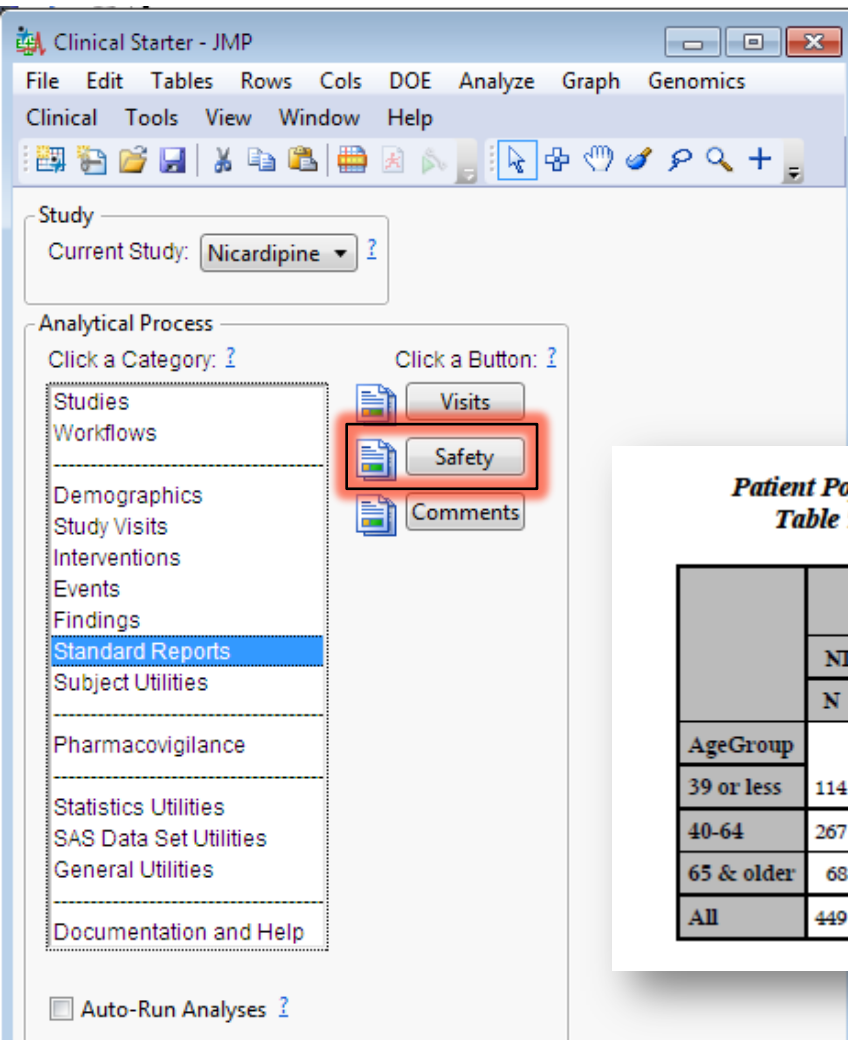
Find out relationships between different domain

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



Patient Population By Age Group
Table 7.2.1.2.1 of the GRP

10:47 Friday, March 11, 2011

	Description of Planned Arm				All	
	NIC .15		Placebo			
	N	%	N	%	N	%
AgeGroup						
39 or less	114	12.58	108	11.92	222	24.50
40-64	267	29.47	286	31.57	553	61.04
65 & older	68	7.51	63	6.95	131	14.46
All	449	49.56	457	50.44	906	100.00

10:47 Friday, March 11, 2011

System Organ Class and Preferred Term,

Description of Planned ARM				
C .15	Placebo			
(%)	N	(%)	Fishers Exact P-value	
(22)	23	(5)	.0000	
(15)	143	(31)	.0000	
50 (33)	79	(17)	.0000	
70 (15)	30	(6)	.0000	
39 (53)	307	(67)	.0000	
25 (5)	4	(0)	.0000	
73 (16)	37	(8)	.0002	
15 (3)	41	(8)	.0005	
10 (2)	0	(0)	.0008	
85 (30)	498	(8)	.0011	
6 (1)	0	(0)	.0146	

JMP Clinical Disproportionality Analysis for Signal Detection

Disproportionality Analysis - JMP

File Edit Tables Rows Cols DOE Analyze Graph Genomics Clinical Tools Help

[Process Description](#)

General Statistical Measures Options

Calculate the Following Statistics

- ☒ Reporting Odds Ratio (ROR) ?
- ☒ Proportional Reporting Ratio (PRR) ?
- ☒ Multi-Item Gamma Poisson Shrinker (MGPS) ?
- ☒ Bayesian Confidence Propagation Neural Network (BCPNN) ?

Minimum AE Frequency for Interval Signals [1,50]

1 ?

Proportional Reporting Ratio (PRR) Criteria for Signal Generation

Signal Type ?

- ☒ Confidence Interval
- ☐ Triple

PRR Lower CI [0,10000]

1 ?

PRR [1,10000]

2 ?

Chi-square [0,10000]

4 ?

AE Frequency [1,10000]

3 ?

Other Criteria for Signal Generation

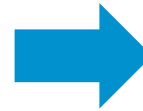
ROR Lower CI [0,10000]

1 ?

MGPS Lower PI [0,10000]

* Required Parameter

Run Settings Cancel



The Disproportionality analysis in JMP Clinical includes the 4 industry standard disproportionality analyses used for signal detection. PRR, ROR, MGPS and BCPNN

JMP Clinical Disproportionality Analysis for Signal Detection

- 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 Tree Map for BCPNN Tree Map for MGPS Tree Map for PRR Tree Map for ROR Adverse Event Distribution Record Distribution

A value of 1 for any of the selected measures is indication that the signal criteria was met for a particular statistic.

☒ Drug-Event Combinations with at Least One Signal

Drug	Adverse Event	BCPNN	MGPS	PRR	ROR	Number of Signals
Drug A	Chest pain	1	0	0	0	1
	Palpitations	1	0	1	0	2
	Urinary retention	1	0	1	1	3
Drug B	Arrhythmia	1	0	0	0	1
	Dizziness exertional	1	0	0	0	1
	Extradural haematoma	0	0	1	1	2
	Hypoglycaemia	1	0	0	0	1
	Injection site abscess	1	0	1	1	3
	Palpitations	1	0	1	1	3
	Dyspnoea	1	0	1	1	3
Drug C	Hypophosphataemia	1	0	1	1	3
	Convulsion	0	0	1	1	2
Drug D	Intestinal perforation	1	0	0	0	1
	Epistaxis	0	0	1	1	2
Drug E	Haemolysis	0	0	1	1	2
	Pneumothorax	1	0	1	1	3
	Asthenia	0	0	1	1	2
Drug F	Delirium	1	0	1	1	3
	Cellulitis	0	0	1	1	2
	Pneumocephalus	1	0	1	1	3
Drug G	Subdural haematoma	1	0	1	1	3
	Inappropriate antidiuretic hormone secretion	0	0	1	1	2
	Urinary tract infection	1	0	1	1	3
Drug H	Vascular occlusion	1	0	1	1	3
	Cerebral infarction	1	0	1	1	3
	Hypocalcaemia	1	0	1	1	3
Drug I	Pyrexia	1	0	1	1	3
	Disorientation	1	0	1	1	3
	Pneumocephalus	1	0	1	1	3
Drug J	Pyrexia	1	0	0	0	1
	Tracheobronchitis	0	0	1	1	2

☒ Data Filter

☒ Select ☒ Show ☒ Include

Clear

☒ Number of Signals

1

2

3

☒ Drug

Drug A (3)

Drug B (6)

Drug C (2)

Drug D (2)

Drug E (3)

Drug F (2)

Drug G (3)

Drug H (3)

Drug I (3)

Drug J (4)

Drug K (1)

Drug L (3)

Drug M (5)

Drug N (7)

Drug O (7)

☒ Adverse Event

Arrhythmia (1)

Asthenia (2)

Atrioventricular block first degree (1)

Atrioventricular block second degree

Bladder pain (2)

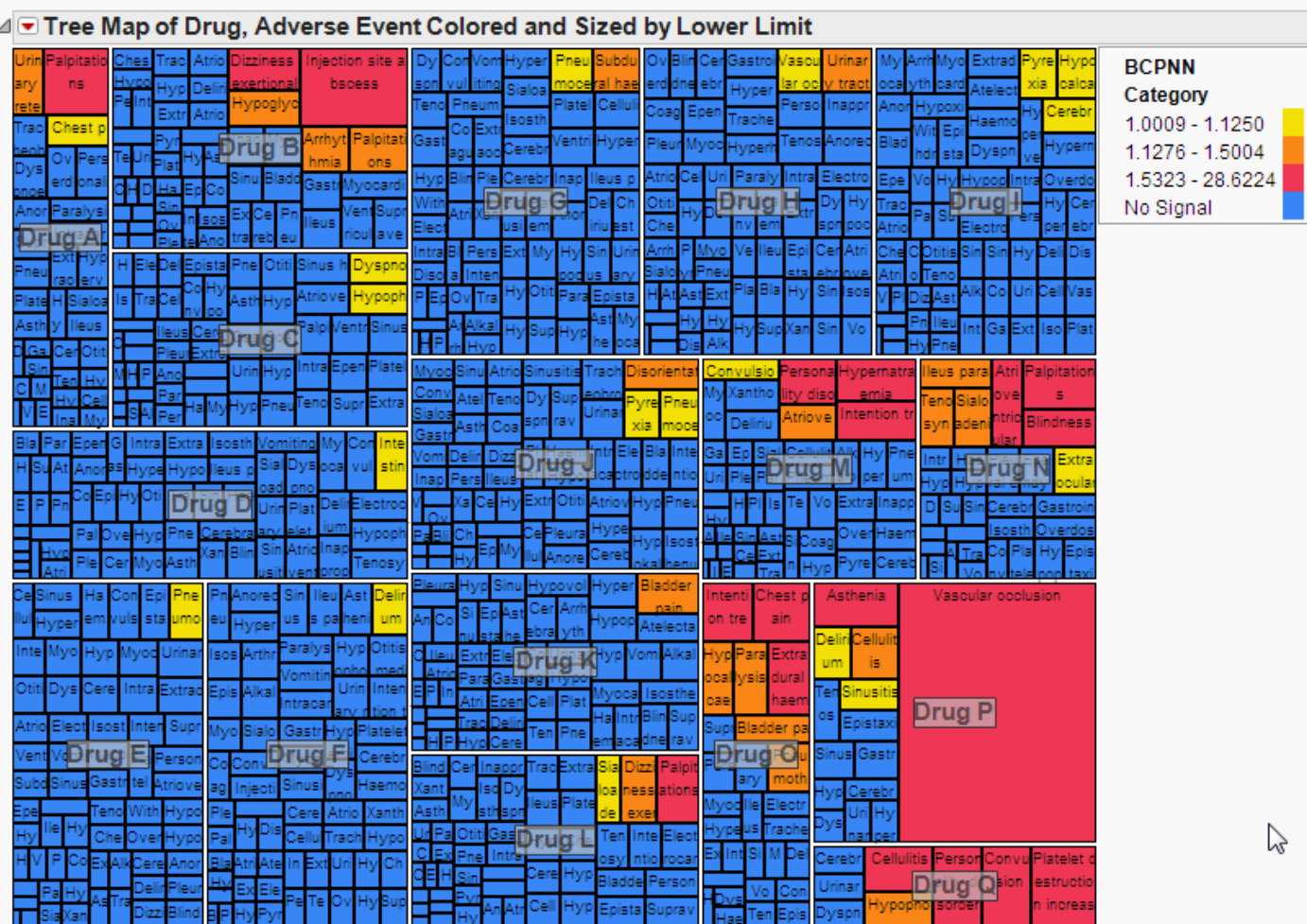
Blindness (1)

Cellulitis (3)

Cerebral infarction (1)

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

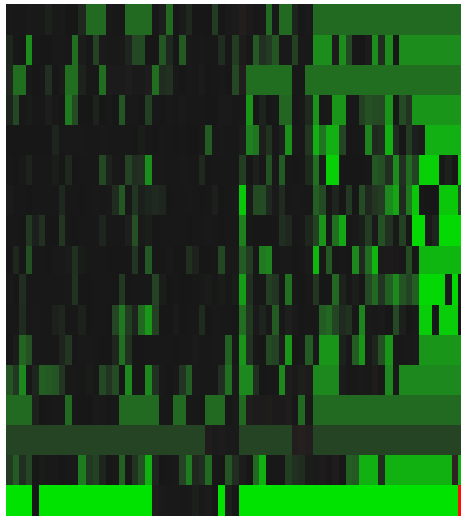
Views allowing to cluster either Drugs or AE with similar behavior

Hierarchical Clustering

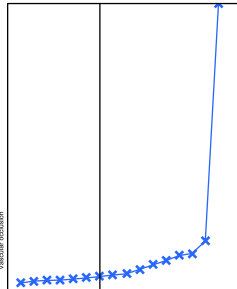
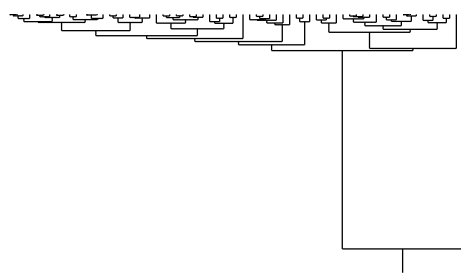
Method = Fast Ward

Dendrogram

- Drug A
- Drug L
- Drug N
- Drug C
- Drug D
- Drug F
- Drug E
- Drug G
- Drug J
- Drug H
- Drug I
- Drug K
- Drug M
- Drug O
- Drug Q
- Drug B
- Drug P

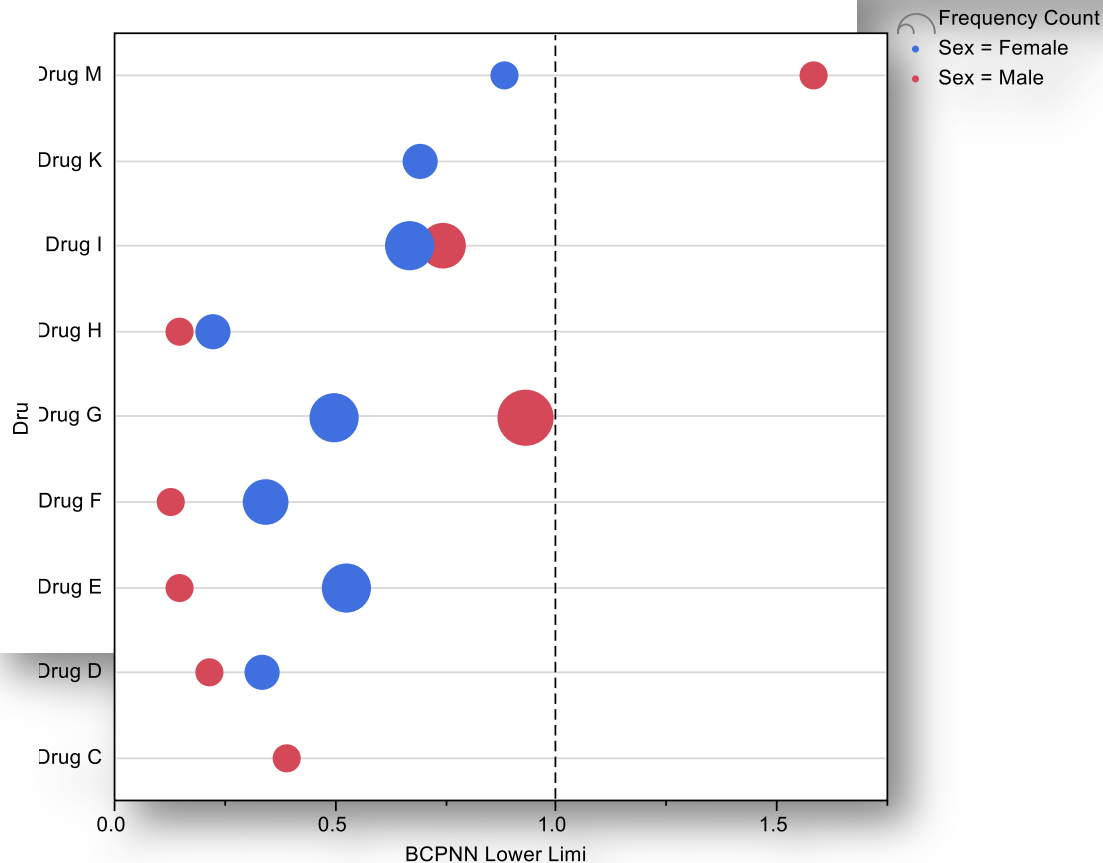


-0.595
-0.476
-0.357
-0.238
-0.119
0
5.6054
11.211
16.816
22.422
28.027



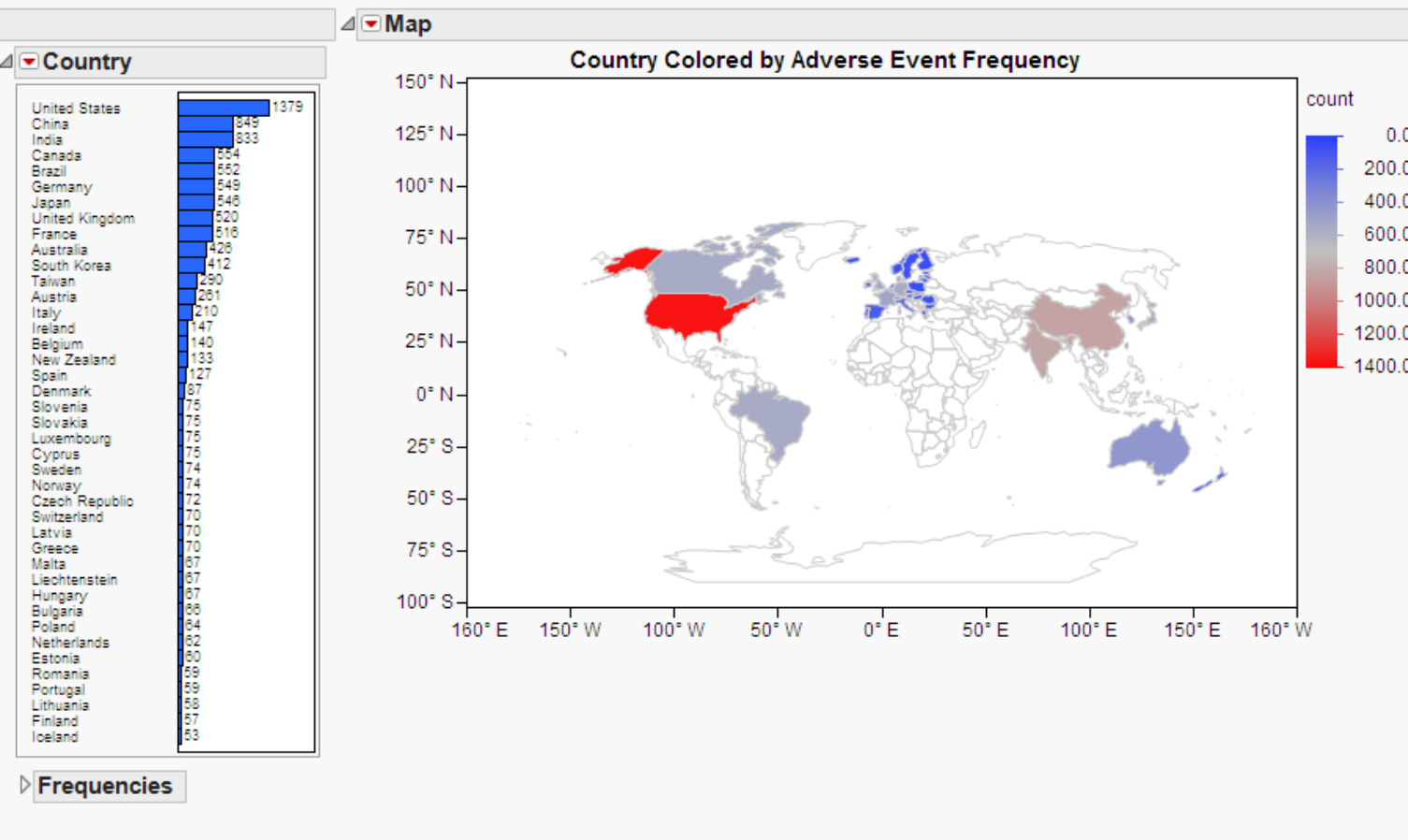
JMP Clinical Disproportionality Analysis for Signal Detection

BCPNN Lower Limit by Strata for Hypernatraemia



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/>