Getting the JMP® on your Clinical Trial Analysis

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AGENDA

Part 1:

- Drug Discovery and Development Process
- CDISC Data Standards
- Clinical Trial Review Process
- JMP Clinical Overview and Architecture
- Live Demonstration

Part 2:

- Clinical Reports for Early Efficacy in Oncology
- JMP Virtual Joins and JSL Implementation
- Customizing JMP Clinical Reviews

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Part 1

Drug Discovery, JMP Clinical Overview and Introduction

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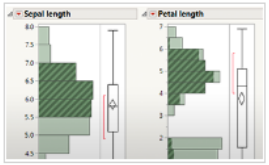
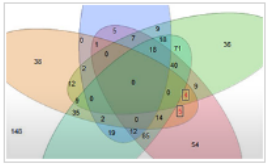
JMP Clinical is Part of the JMP Family for Statistical Discovery . . .



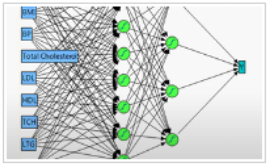
JMP

Statistical discovery software from SAS. Links dynamic data visualization with powerful statistics, in memory and on the desktop.



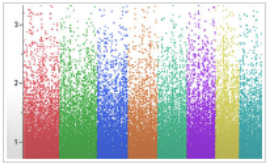
JMP Clinical

Shortens the drug development process by streamlining analysis of clinical trials data using JMP and SAS.



JMP Pro

Takes statistical discovery to the next level with all the tools in JMP plus advanced features for more sophisticated analyses.



JMP Genomics

Leverages JMP, SAS and customized applications for visualizing and analyzing vast genomics data sets.

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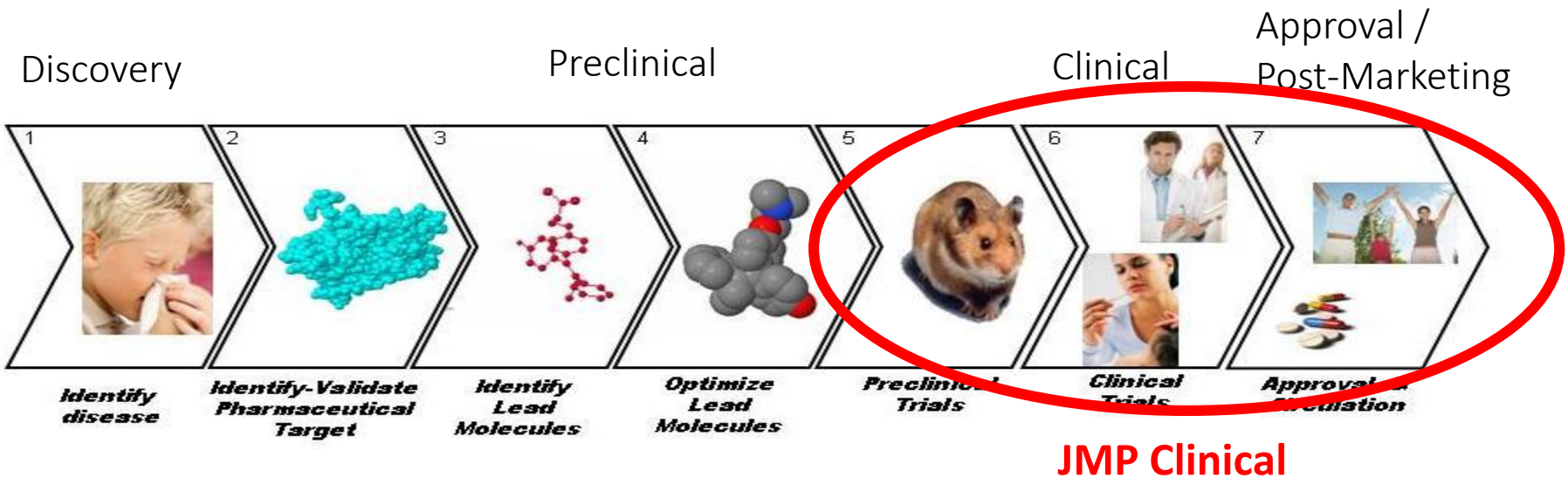
Drug discovery and development process



- A drug can be defined as any compound introduced into a living organism, animal or human, in order to prevent or to cure a disease, only to attenuate symptoms, or to establish a diagnosis.
- The process when a drug becomes a drug is extremely costly and long (10-15 years)

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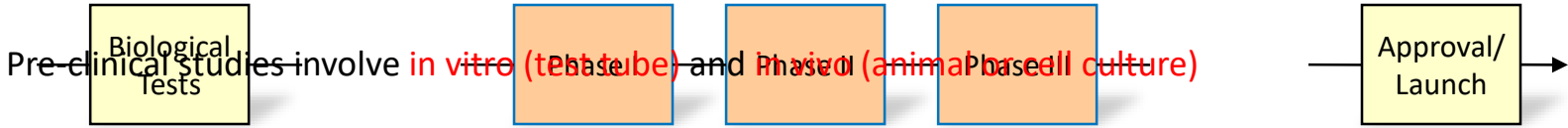
New Chemical Entity Timeline

From Discovery to Launch



Phase I trials are the first stage of testing in human subjects. Normally, a small (20-100) group of healthy volunteers will be selected. This phase includes trials designed to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics of a drug.

Phase II trials are performed on larger groups (20-300) and are designed to assess how well the drug works, as well as to continue Phase I safety assessments in a larger group of volunteers and patients.

Phase III studies are randomized controlled multicenter trials on large patient groups (300–3,000 or more depending upon the disease/medical condition studied) and are aimed at being the definitive assessment of how effective the drug is. Time consuming and expensive.

Approval and **Launch** is were clinical data needs to be submitted to medical authorities for approval before bringing the drug to market. After approval, post marketing surveillance is carried out.

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CDISC submission

FDA announcements since 2004

FDA Final Binding Guidance on Standards Now Available

17 December 2014

The FDA has just published the long-awaited binding guidance documents regarding submission of study data in standardized formats.

The **Guidance on Providing Regulatory Submissions in Electronic Format** requires submissions be submitted in an electronic format specified by the FDA beginning 24 months from the issuance of this document, and is **available here**.

The **Guidance on Standardized Study Data, available here**, states:
"After the publication of this guidance, all studies with a start date 24 months after the publication date must use the appropriate FDA-supported standards, formats, and terminologies specified in the Catalog (see section II.C) for NDA, ANDA, and certain BLA submissions."

The current **FDA Data Standards Catalog** specifies use of the CDISC SDTM, SEND, ADaM and Define-XML standards as well as CDISC Controlled Terminology. The catalog can be **accessed here**.

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CDISC submission standard

What is CDISC???

- **CDISC**: Clinical Data Interchange Standards Consortium (http://www.cdisc.org/)
- **SDTM**: Study Data Tabulation Model
  - standard for interchange of ***collected*** data
- **ADaM**: Analysis Data Model
  - standard for interchange of ***analysis*** data (derived data from SDTM)
- **Points about CDISC**
  - Mandatory! FDA only accept this form for submissions since 2016
  - System incredibly flexible and only requires a just a handful of variables
  - Conversion is NOT as difficult as it seems

Motivation: Convert your data so that your analyses are performed exactly how the FDA will review them!

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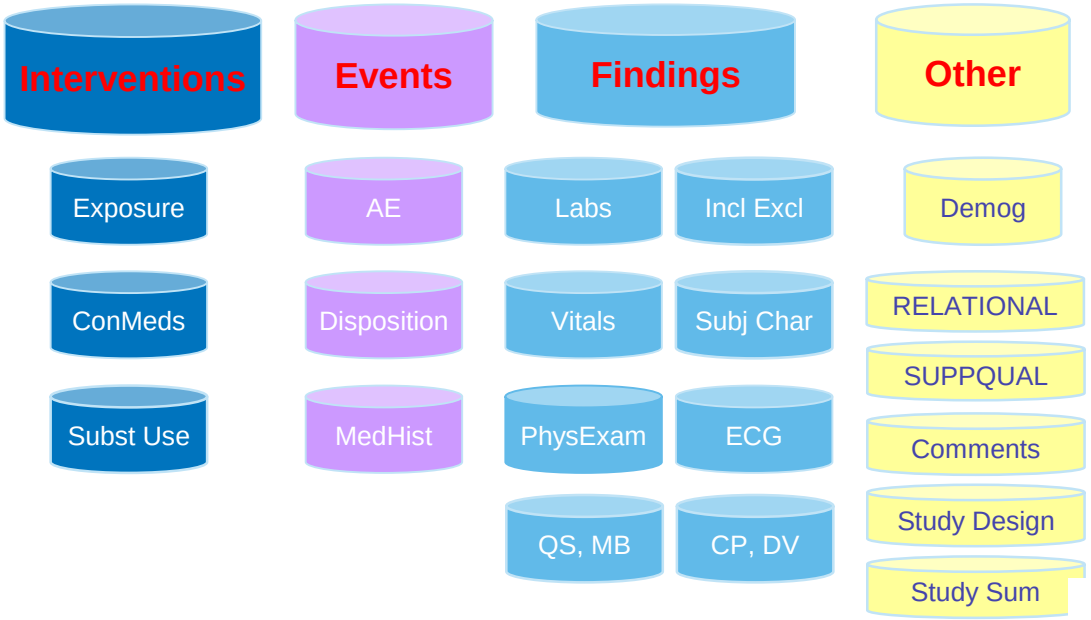
CDISC SUBMISSION STANDARD

CDISC SDTM Domains Example



Data are saved in separate domain tables, each with a two-letter name.

From CDISC SDTM Overview & Impact to AZ, 2004, by Dan Godoy, presented at the first CDISC/SDM meeting 20 October 2004

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Review Process

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User personas

Report Creators

Clinical or Statistical Programmers

Cleanse and prepare data for other groups

Statisticians
Biostatisticians
Biometrician

Reporting safety and efficacy (effectiveness)

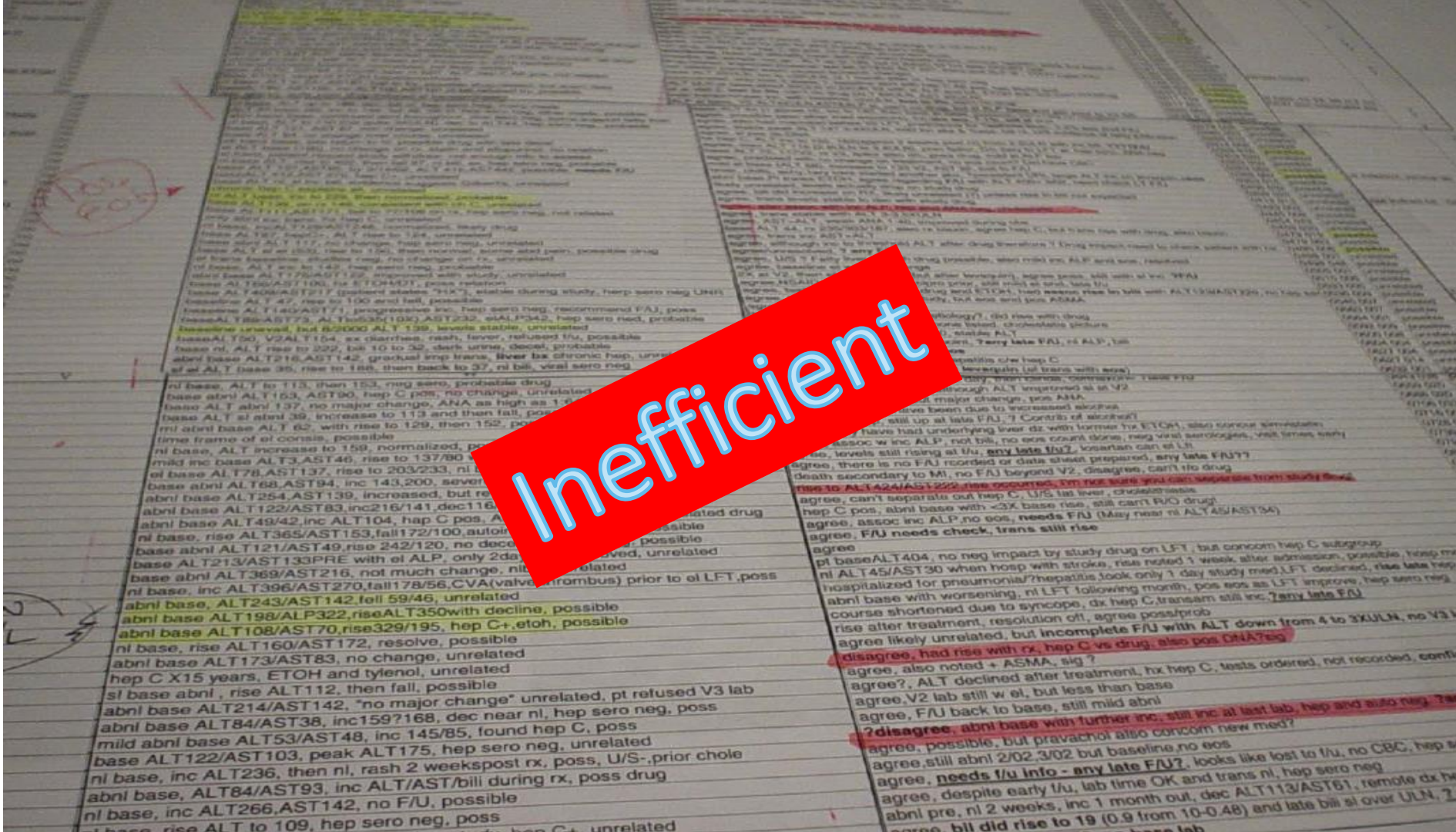
Report Consumers

Data Monitors/
Data Managers

(Clinical Operations Department):
Concerned with Data Quality and Fraud

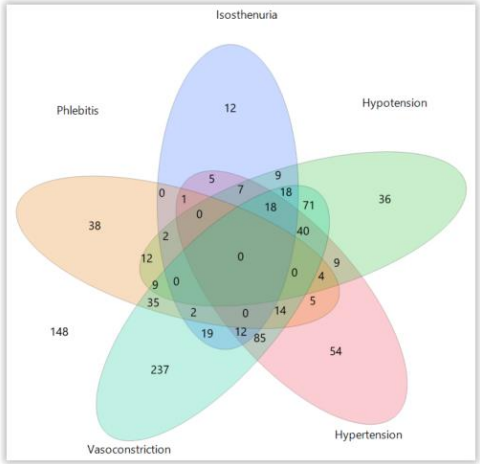
Medical Reviewers/ Medical Writers/
Medical Monitoring Clinicians

Concerned with bad side effects (adverse events)


Inefficient

Why JMP Clinical?

- Data Review Best Practices
  - Streamline the clinical trials data review process by having on the shelve all the analytical tools in place
  - Moving from obsolete medical review process (listings) to interactive statistically-driven dashboard coupled with effective data visualization key to efficient data review that medical reviewers, data managers and biostatisticians can employ
  - Based on industry standard tools (JMP and SAS)
  - Uses standard data (CDISC: SDTM & ADaM; SEND)
  - Open architecture, strategic adaptability to customer needs: medical monitoring, medical writing, data integrity and moves to a variety of therapeutic areas



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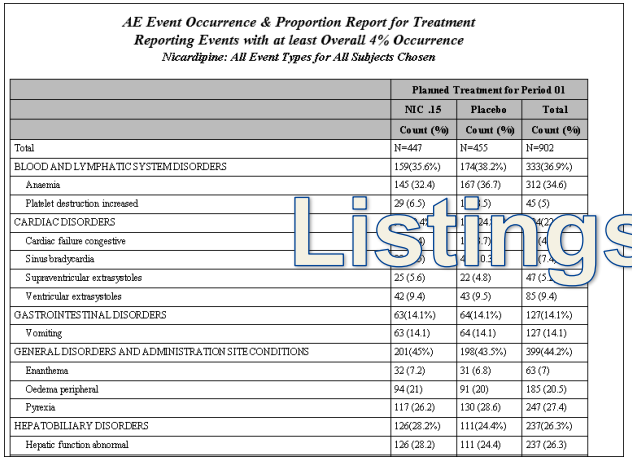
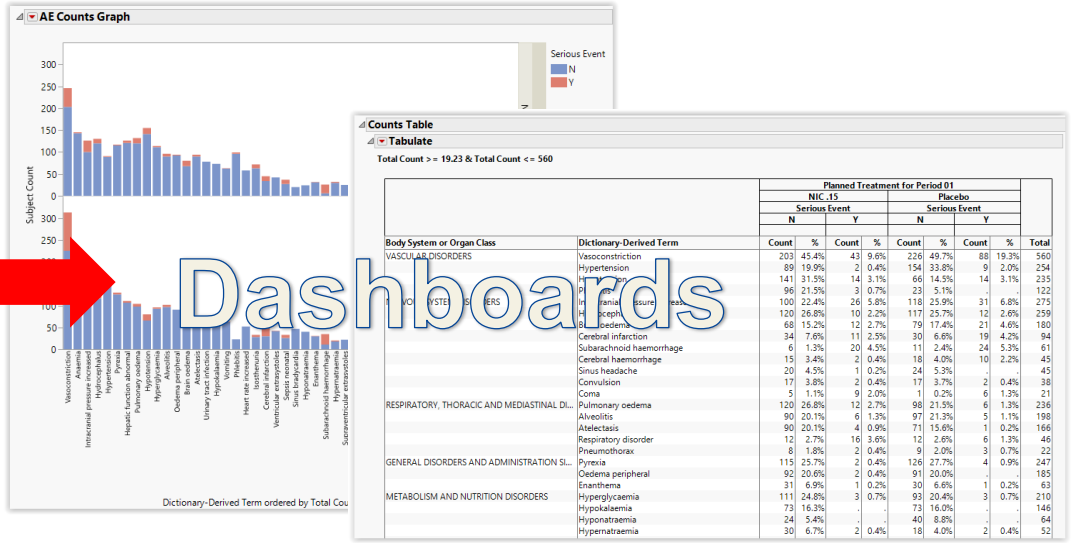
Moving from obsolete Medical review process



AE Event Occurrence & Proportion Report for Treatment
Reporting Events with at least Overall 4% Occurrence
Nicardipine: All Event Types for All Subjects Chosen

	Planned Treatment for Period 01		
	NIC .15	Placebo	Total
	Count (%)	Count (%)	Count (%)
Total	N=447	N=455	N=902
BLOOD AND LYMPHATIC SYSTEM DISORDERS	159(35.6%)	174(38.2%)	333(36.9%)
Anaemia	145 (32.4)	167 (36.7)	312 (34.6)
Platelet destruction increased	29 (6.5)	[illegible]	45 (5)
CARDIAC DISORDERS	[illegible]	[illegible]	[illegible]
Cardiac failure congestive	[illegible]	[illegible]	[illegible]
Sinus bradycardia	[illegible]	[illegible]	[illegible]
Supraventricular extrasystoles	25 (5.6)	22 (4.8)	47 (5.[illegible])
Ventricular extrasystoles	42 (9.4)	43 (9.5)	85 (9.4)
GASTROINTESTINAL DISORDERS	63(14.1%)	64(14.1%)	127(14.1%)
Vomiting	63 (14.1)	64 (14.1)	127 (14.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	201(45%)	198(43.5%)	399(44.2%)
Enanthema	32 (7.2)	31 (6.8)	63 (7)
Oedema peripheral	94 (21)	91 (20)	185 (20.5)
Pyrexia	117 (26.2)	130 (28.6)	247 (27.4)
HEPATOBILIARY DISORDERS	126(28.2%)	111(24.4%)	237(26.3%)
Hepatic function abnormal	126 (28.2)	111 (24.4)	237 (26.3)

Listings



		Planned Treatment for Period 01								
		NIC .15				Placebo				
		Serious Event				Serious Event				
		N		Y		N		Y		
Body System or Organ Class	Dictionary-Derived Term	Count	%	Count	%	Count	%	Count	%	Total
VASCULAR DISORDERS	Vasoconstriction	203	45.4%	43	9.6%	226	49.7%	88	19.3%	560
	Hypertension	89	19.9%	2	0.4%	154	33.8%	9	2.0%	254
	[illegible]	141	31.5%	14	3.1%	66	14.5%	14	3.1%	235
	[illegible]	96	21.5%	3	0.7%	23	5.1%	.	.	122
[illegible]	[illegible]	100	22.4%	26	5.8%	118	25.9%	31	6.8%	275
	[illegible]	120	26.8%	10	2.2%	117	25.7%	12	2.6%	259
	[illegible]	68	15.2%	12	2.7%	79	17.4%	21	4.6%	180
	Cerebral infarction	34	7.6%	11	2.5%	30	6.6%	19	4.2%	94
	Subarachnoid haemorrhage	6	1.3%	20	4.5%	11	2.4%	24	5.3%	61
	Cerebral haemorrhage	15	3.4%	2	0.4%	18	4.0%	10	2.2%	45
	Sinus headache	20	4.5%	1	0.2%	24	5.3%	.	.	45
	Convulsion	17	3.8%	2	0.4%	17	3.7%	2	0.4%	38
	Coma	5	1.1%	9	2.0%	1	0.2%	6	1.3%	21
RESPIRATORY, THORACIC AND MEDIASTINAL DI...	Pulmonary oedema	120	26.8%	12	2.7%	98	21.5%	6	1.3%	236
	Alveolitis	90	20.1%	6	1.3%	97	21.3%	5	1.1%	198
	Atelectasis	90	20.1%	4	0.9%	71	15.6%	1	0.2%	166
	Respiratory disorder	12	2.7%	16	3.6%	12	2.6%	6	1.3%	46
	Pneumothorax	8	1.8%	2	0.4%	9	2.0%	3	0.7%	22
GENERAL DISORDERS AND ADMINISTRATION SI...	Pyrexia	115	25.7%	2	0.4%	126	27.7%	4	0.9%	247
	Oedema peripheral	92	20.6%	2	0.4%	91	20.0%	.	.	185
	Enanthema	31	6.9%	1	0.2%	30	6.6%	1	0.2%	63
METABOLISM AND NUTRITION DISORDERS	Hyperglycaemia	111	24.8%	3	0.7%	93	20.4%	3	0.7%	210
	Hypokalaemia	73	16.3%	.	.	73	16.0%	.	.	146
	Hyponatraemia	24	5.4%	.	.	40	8.8%	.	.	64
	Hypernatraemia	30	6.7%	2	0.4%	18	4.0%	2	0.4%	52

Dashboards

- Static Tables give all the information
- Time-consuming to absorb information and easy to miss signals

- Efficient data review with highly visual and interactive graphics linked to data tables
- Streamline clinical data review process

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JMP Clinical Usage

Consumers (Reviewers)

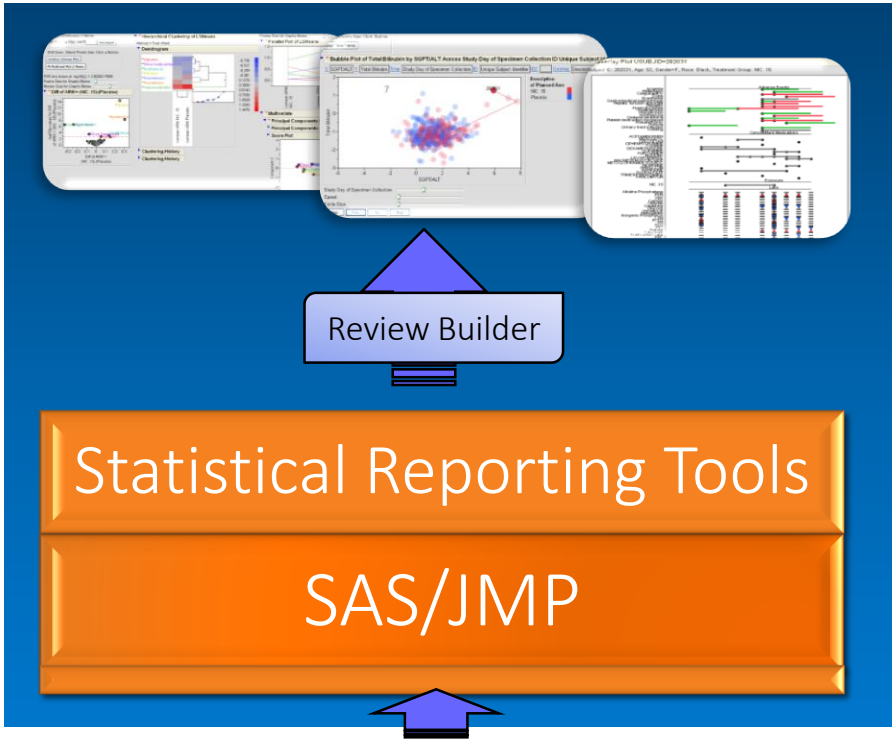
Knowledge Deployment

Creators (Statisticians)

Knowledge Generation

Data Layer

Data Gathering



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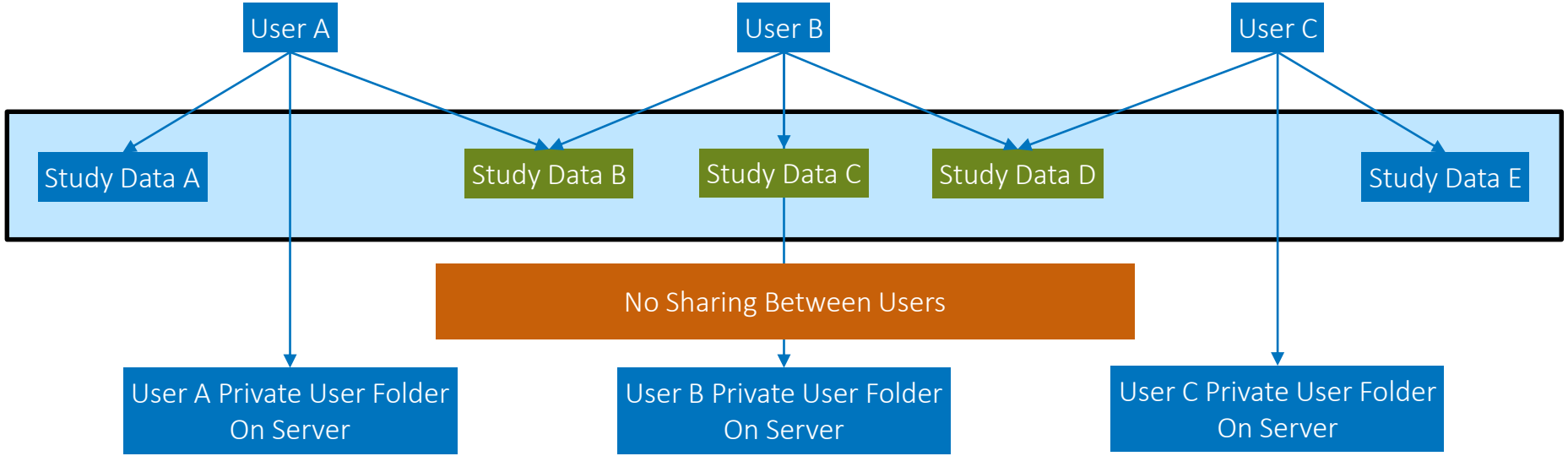
“Local” Configuration: Default Installation (Everyone is an ISLAND)



- All Access (Read/Write) Permissions Controlled By Active Directory (Study Data and User Folders)
- User B is allowed to see some Study Data (B, C, and D) that is also allowed to be seen by User A and C
  - User B cannot see Study Data A or E
- Any given user can only see the output they have generated within JMP Clinical
  - User B cannot see User A output generated within JMP Clinical automatically saved to a default location
- If users want to share output, there will have to be a folder setup so that the appropriate users have access
- Narrative Templates (Velocity and SAS Macro) are stored, by default, in Program Files (readable by all)

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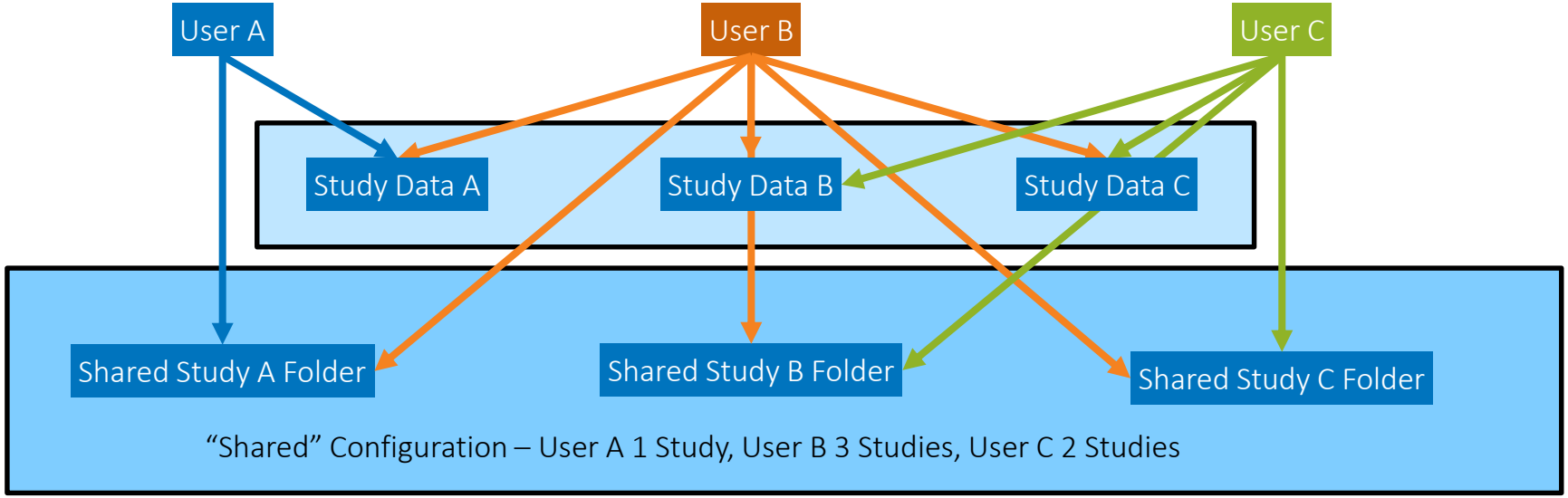
“Shared” Configuration: People have Shared JMP Clinical Folders



- In addition to the default “Local” configuration, one or more “Shared” configurations can be created
  - User can switch between configurations, but only one configuration can be active at any given time
- All Access (Read/Write) Permissions Controlled By Active Directory (Study Data and Shared Folders)
- When users save output, they are directed to save it to the default study specific shared folder
  - However, a user can optionally save the output wherever they have access
- Users can only see a study registered within JMP Clinical if they have access rights to the study data AND shared configuration folder
- When notes are created, they are automatically saved to the active study specific folder (no exceptions)

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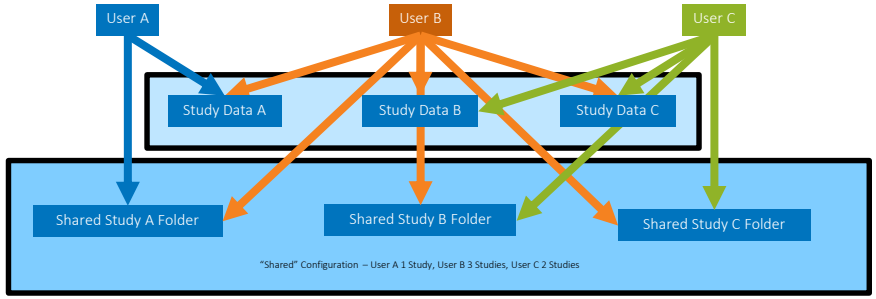
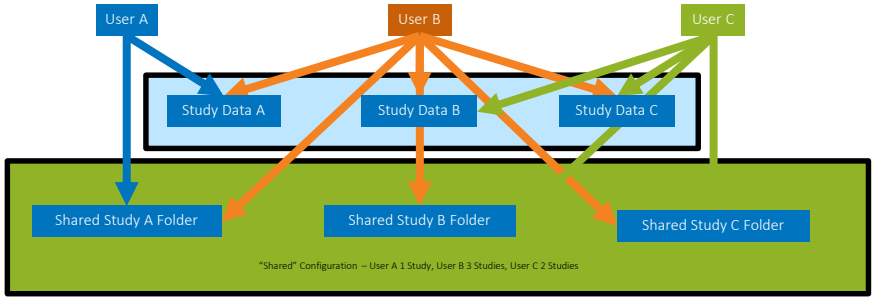
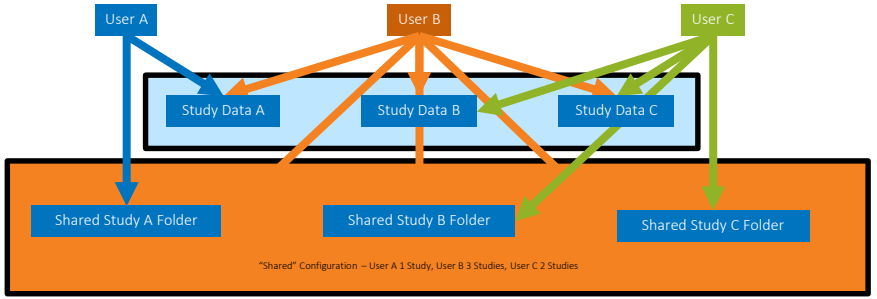
Multiple “Shared” Configurations: One for each Therapeutic Area







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JMP Clinical Usage Scenario

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User personas

Report Creators

Clinical or Statistical Programmers

Cleanse and prepare data for other groups

Statisticians
Biostatisticians
Biometrician

Reporting safety and efficacy (effectiveness)

Report Consumers

Data Monitors/
Data Managers

(Clinical Operations Department):
Concerned with Data Quality and Fraud

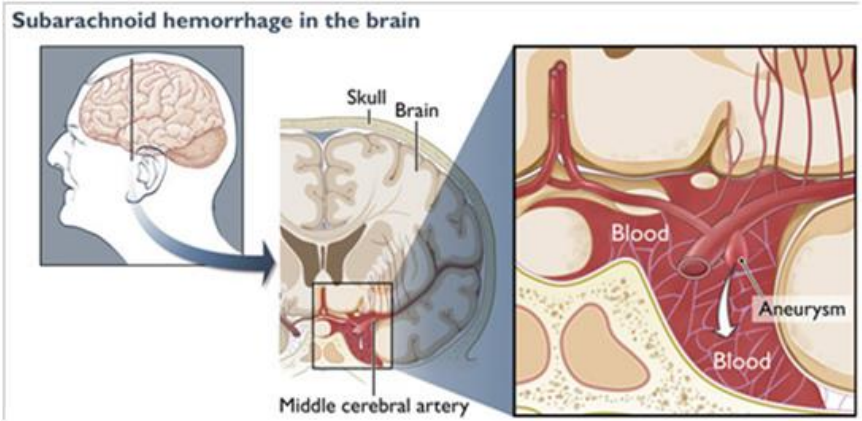
Medical Reviewers/ Medical Writers/
Medical Monitoring Clinicians

Concerned with bad side effects (adverse events)

Case Study

Nicardipine Study: Treatment of Subarachnoid Hemorrhage

- A subarachnoid hemorrhage (SAH) is bleeding into the subarachnoid space, the area between the arachnoid membrane and the pia mater surrounding the brain. This may occur spontaneously, usually from a ruptured cerebral aneurysm, or may result from head injury.



Nicardipine is a medication used to treat high blood pressure and angina. Therefore it reduces the risk for additional subarachnoid hemorrhage.

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Live Presentation

Next slides are screenshots from the live presentation

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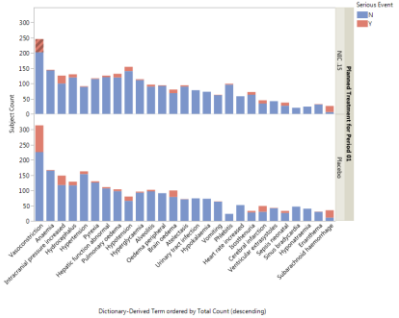
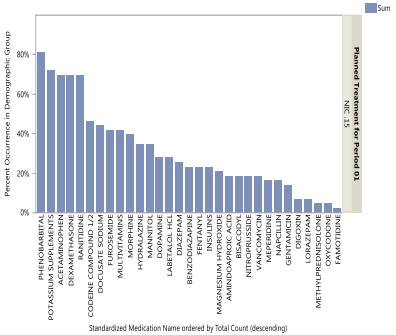
jmp®
Statistical Discovery.™ From SAS.

Medical Reviewers/ Medical Writers/ Medical Monitoring Clinicians

What count/percent of subjects on drug had a serious adverse event?

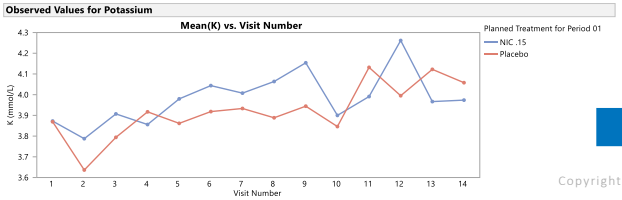


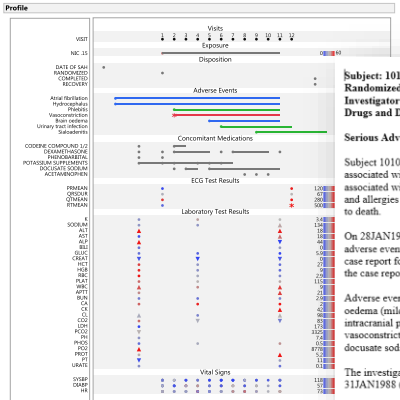
What medications were those subjects taking?



For selected subjects, what is the complete patient **profile** or **narrative**?

Did those subjects have abnormal lab results?





Subject: 101004
Randomized Arm: NIC .15
Investigator Name: 101A
Drugs and Doses on Day of Event: On Treatment

Serious Adverse Event (coded term [reported term]): COMA [COMA]

Subject 101004 was a 48-year-old white female. Her medical history included focal deficit associated with sah (1988), headache associated with sah (1988), loss of consciousness associated with sah (1988), vomiting associated with sah (1988), other medical condition (1977), and allergies (start date unknown). The subject discontinued the trial on 31JAN1988 (Day 4) due to death.

On 28JAN1988 (Day 1) the subject experienced a coma (severe) which was considered a serious adverse event (SAE). Though the event was considered serious, no reasons were provided on the case report form. The subject was on treatment when the event occurred. 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 SAE included brain oedema (mild), hydrocephalus (severe), hyperglycaemia (mild), hypotension (severe), intracranial pressure increased (severe), subarachnoid haemorrhage (severe), and vasoconstriction (severe). Concomitant medications taken at the onset of the SAE included: docusate sodium, phenobarbital, potassium supplements, and ranitidine.

The investigator considered the AE to be related to study medication. The event ended on 31JAN1988 (Day 4) with a final outcome of recovered/resolved.

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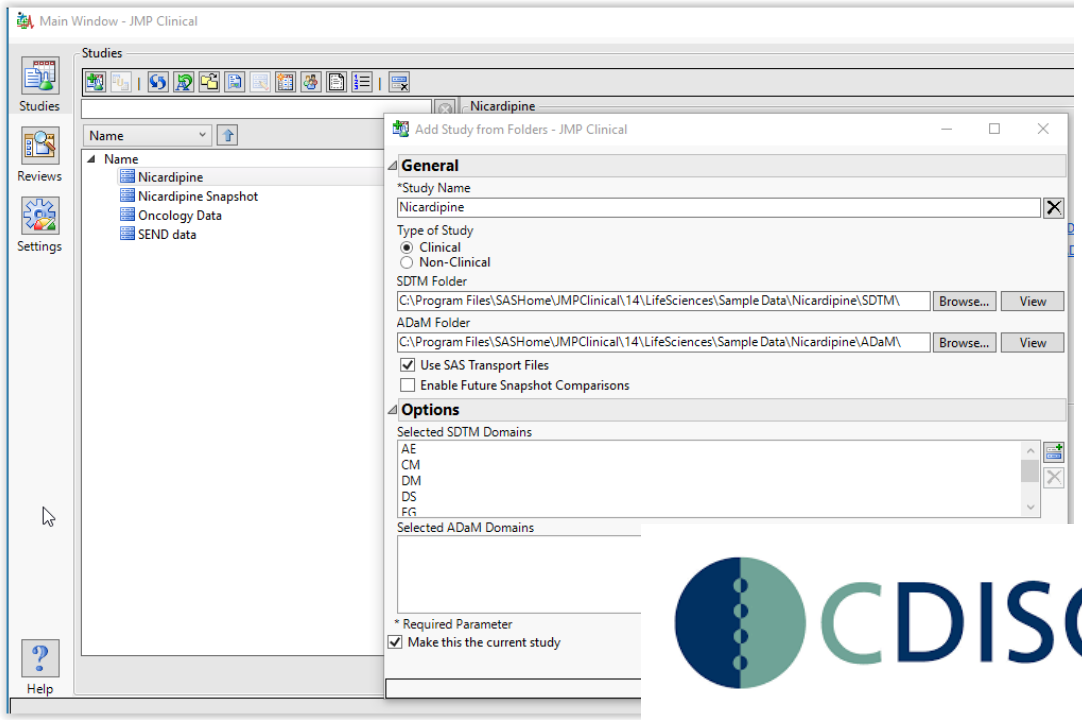
Adding a Study



A study is a collection of input data folders, settings, and an output folder.

JMP Clinical reads directly CDISC data, a combination of SDTM and ADaM. It reads also SEND.

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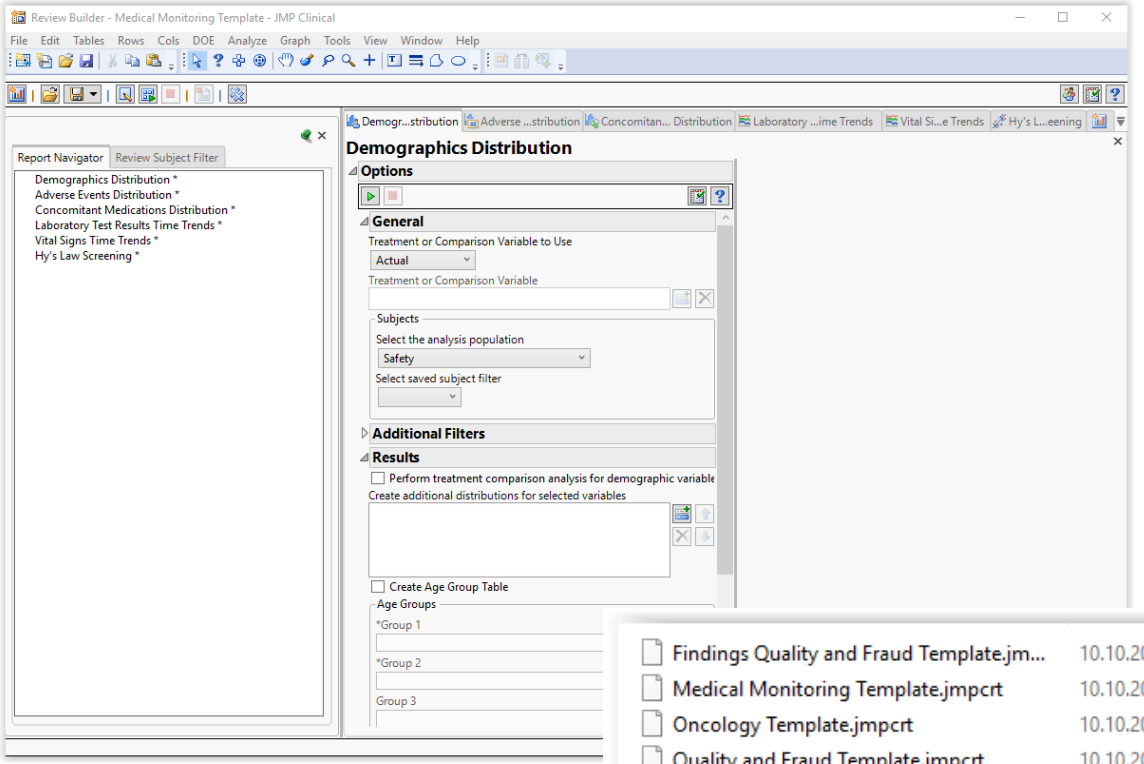
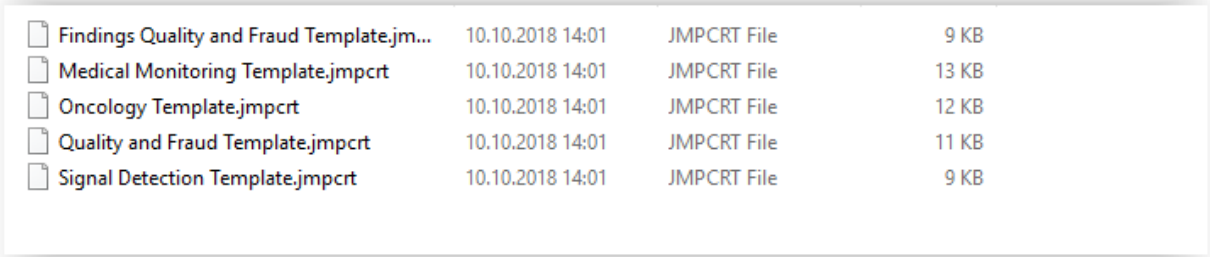
Building Review from Template

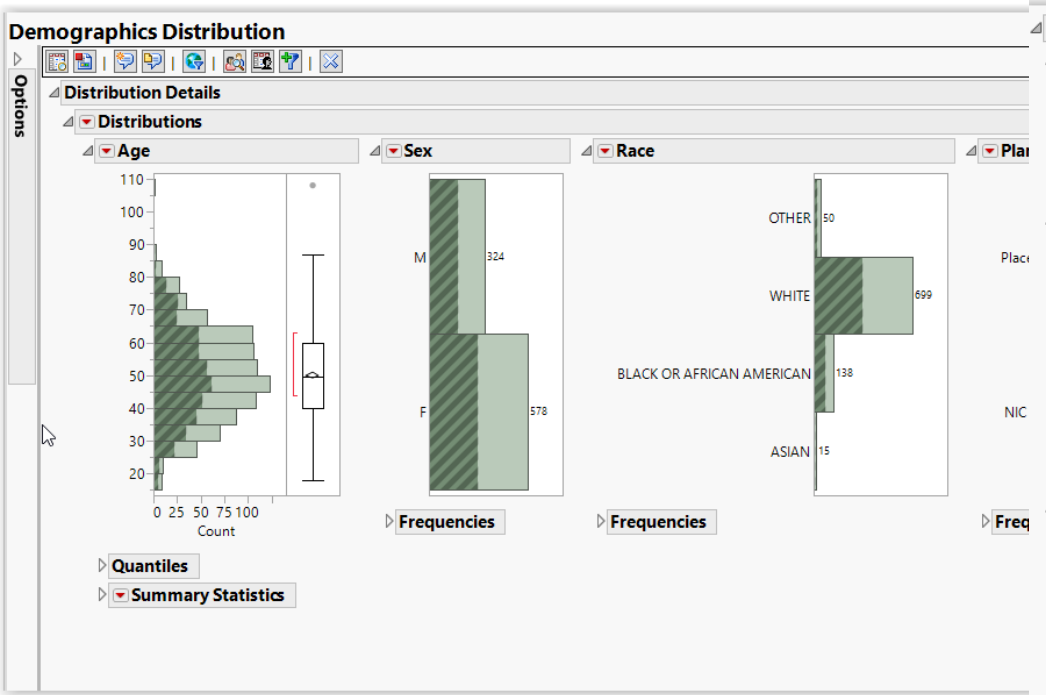


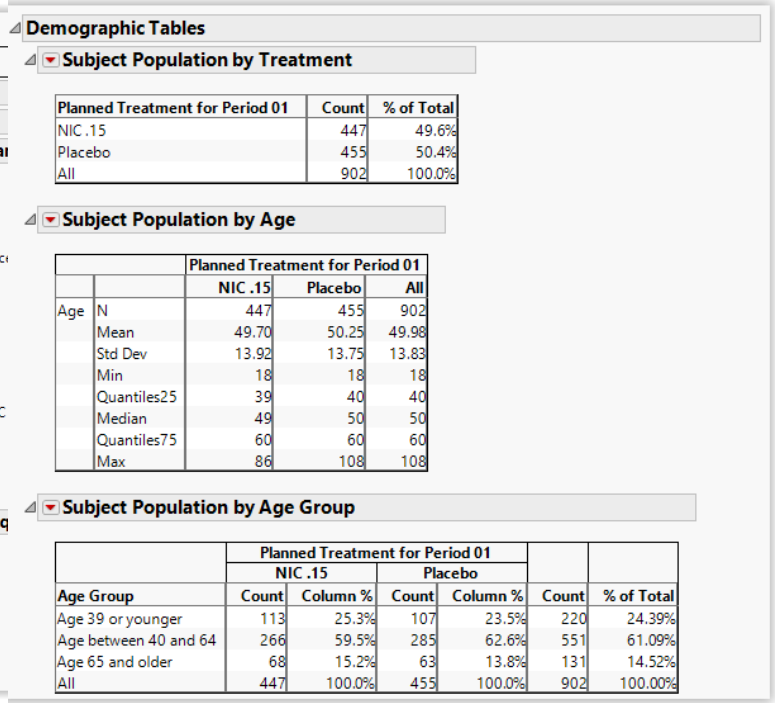
The Reviews tab enables to create a new review of the selected study, open an existing review, or use a template generated previously for another study to generate a review for the current study. Default templates for different user personas are in place.



Report Screenshot

Demographic Distribution





Demographic Tables

Subject Population by Treatment

Planned Treatment for Period 01	Count	% of Total
NIC .15	447	49.6%
Placebo	455	50.4%
All	902	100.0%

Subject Population by Age

		Planned Treatment for Period 01		
		NIC .15	Placebo	All
Age	N	447	455	902
	Mean	49.70	50.25	49.98
	Std Dev	13.92	13.75	13.83
	Min	18	18	18
	Quantiles25	39	40	40
	Median	49	50	50
	Quantiles75	60	60	60
	Max	86	108	108

Subject Population by Age Group

	Planned Treatment for Period 01					
	NIC .15		Placebo			
Age Group	Count	Column %	Count	Column %	Count	% of Total
Age 39 or younger	113	25.3%	107	23.5%	220	24.39%
Age between 40 and 64	266	59.5%	285	62.6%	551	61.09%
Age 65 and older	68	15.2%	63	13.8%	131	14.52%
All	447	100.0%	455	100.0%	902	100.00%

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*

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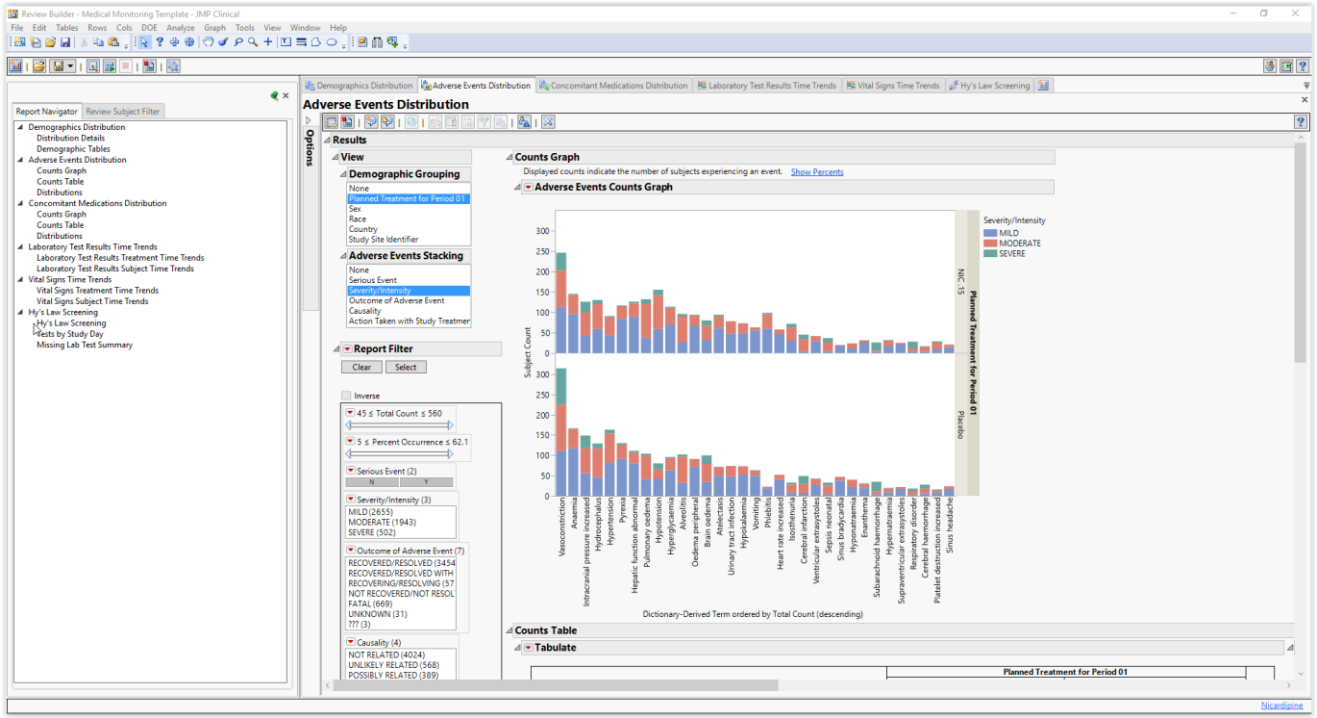
Report Screenshot

Adverse Event Distribution



Visualize relationships between adverse events frequencies and treatment groups:

One would to meed find particular adverse events more frequent in particular treatment groups than other.

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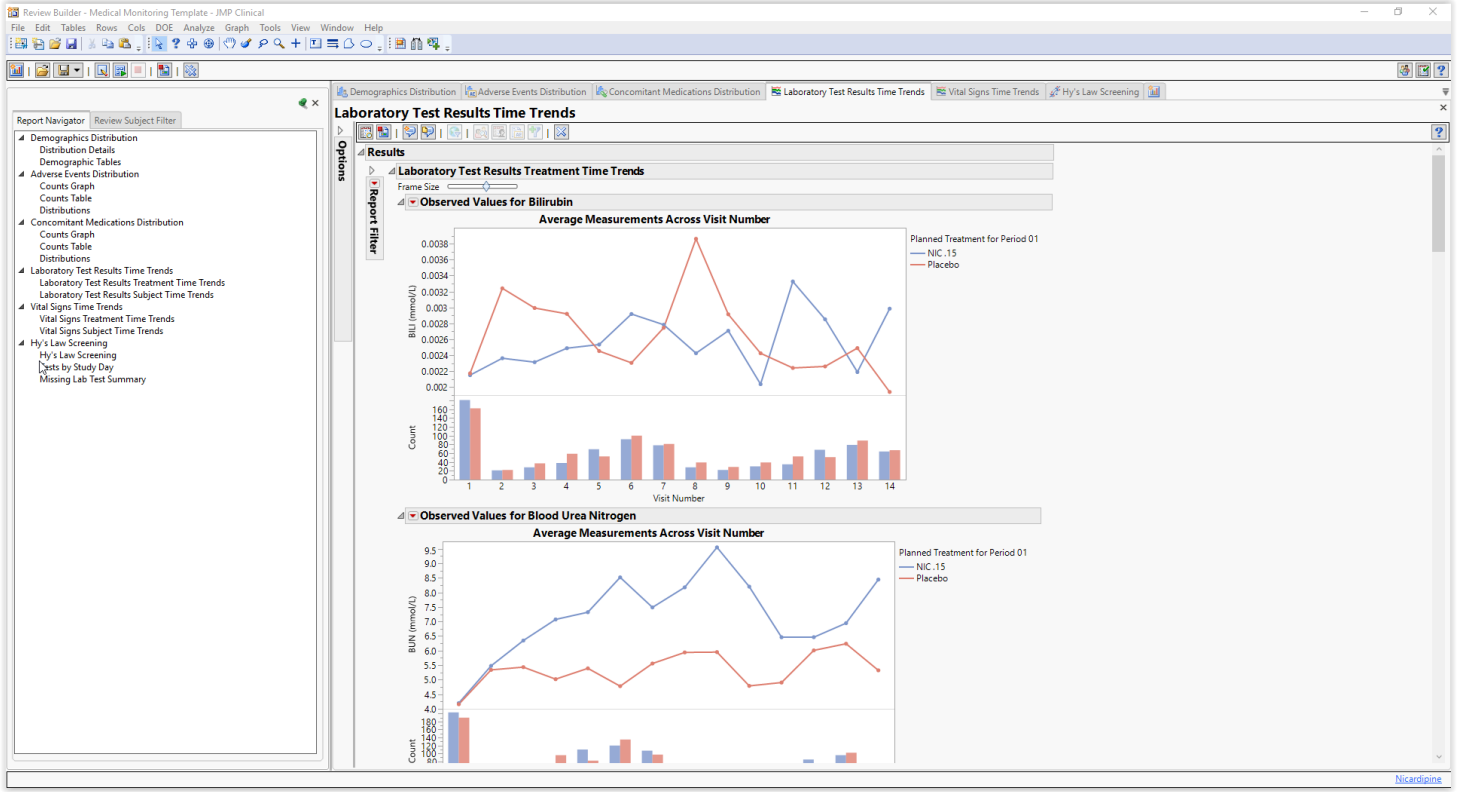
Report Screenshot

Laboratory Time Trends

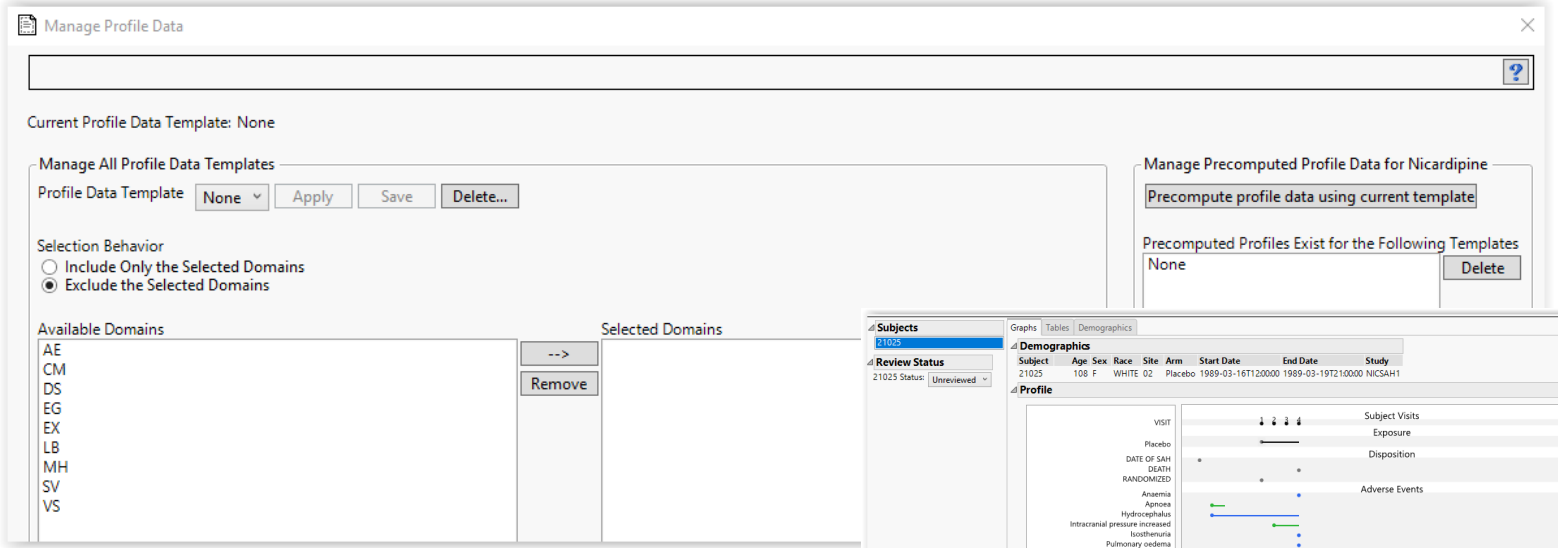


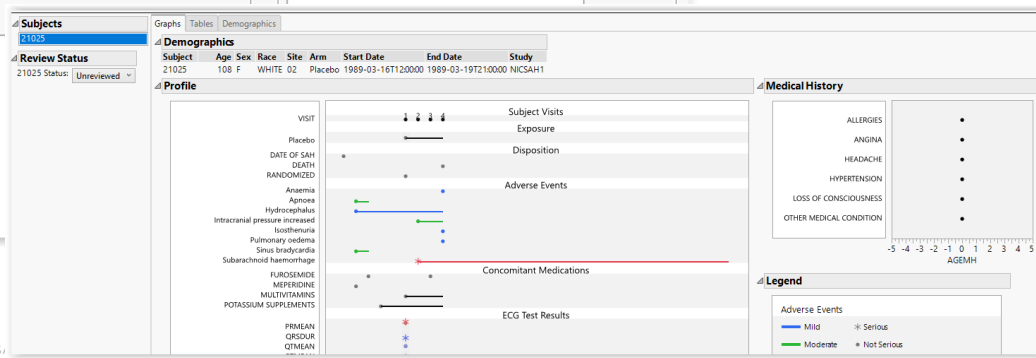
Visualize laboratory test results enables to visualize findings accross the time of the study.

Manage Profile Data

Patient Profile Precompute and Display Template

An action on the Studies window enables now to precompute profile data for faster processing and to create, save and apply multiple data templates per study.

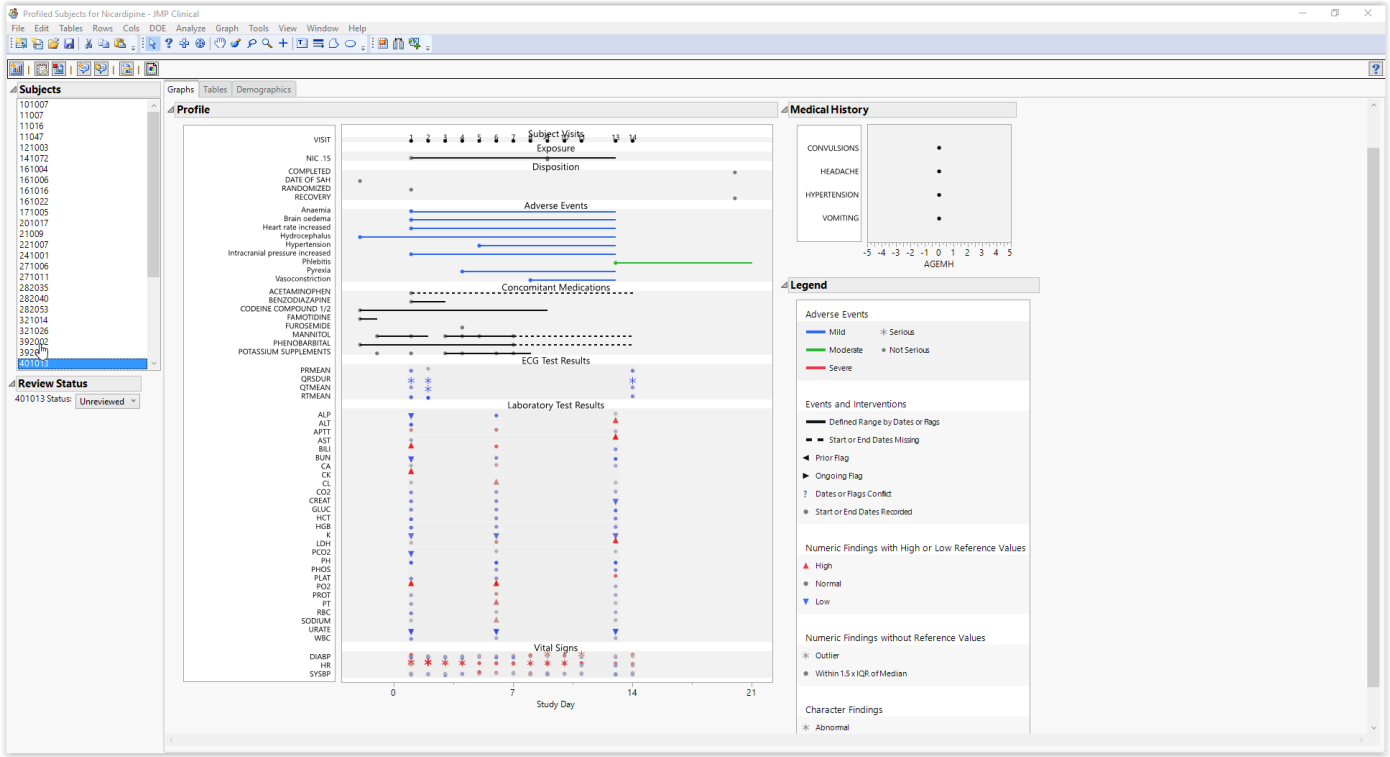




Copyright © S

Report Screenshot

Patient Profiles



- Individual Patient profiles summarized each event happening accross study days

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Report Screenshot

Adverse Event Narratives with Tables

Subject: 101004
Randomized Arm: NIC .15
Investigator Name: 101A

Subject 101004 was a 48-year-old white female. Medical history is included in Table 1.

The subject had the following vital signs at baseline: DIABP (89, 86, 90, 93, 72, 94, 88, 89, 85 and 81 mmHg at 16:00, 16:15, 16:30, 16:45, 17:00, 18:00, 19:00, 20:00, 21:00 and 22:00, respectively), HR (66, 84, 118, 119, 145, 96, 99, 95, 94 and 91 BEATS/MIN at 16:00, 16:15, 16:30, 16:45, 17:00, 18:00, 19:00, 20:00, 21:00 and 22:00, respectively), and SYSBP (172, 168, 166, 168, 149, 177, 169, 183, 166 and 148 mmHg at 16:00, 16:15, 16:30, 16:45, 17:00, 18:00, 19:00, 20:00, 21:00 and 22:00, respectively).

Table 1: Medical History

Term	Year
focal deficit associated with sah	*1988*
headache associated with sah	*1988*
loss of consciousness associated with sah	*1988*
vomiting associated with sah	*1988*
other medical condition	*1977*
allergies	*start date unknown*

The subject's concomitant medications are listed in Table 2.

Table 2: Concomitant Meds

Reported Name	Standardized Name	Indication	Dose per Administration	Start Date	End Date	Start Study Day	End Study Day
DOCUSATE SODIUM	*DOCUSATE SODIUM*	*STOOL SOFTNER*	*200*	*1988-01-27T 14:35:00*	*1988-01-31T 12:30:00*	*-1*	*4*
PHENOBARBITAL	*PHENOBARBITAL*	*SEDATIVE*	*120*	*1988-01-27T 14:35:00*	*1988-01-31T 12:30:00*	*-1*	*4*
POTASSIUM SUPPLEMENTS	*POTASSIUM SUPPLEMENTS*	*FLUIDS*	*50*	*1988-01-27T 14:35:00*	*1988-01-31T 12:30:00*	*-1*	*4*
RANITIDINE	*RANITIDINE*	*DECREASE ACIDITY*	*150*	*1988-01-27T 14:35:00*	*1988-01-31T 12:30:00*	*-1*	*4*
DOPAMINE	*DOPAMINE*	*ELEVATED BP*	*381*	*1988-01-30T 01:30:00*	*1988-01-31T 00:00:00*	*3*	*4*
DOPAMINE	*DOPAMINE*	*ELEVATED BP*	*250*	*1988-01-31T 01:00:00*	*1988-01-31T 12:30:00*	*4*	*4*

CONFIDENTIAL

Patient narrative is a brief summary of specific events experienced by patients, during the course of a clinical trial.

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User personas

Report Creators

Clinical or Statistical Programmers

Cleanse and prepare data for other groups

Statisticians
Biostatisticians
Biometrician

Reporting safety and efficacy (effectiveness)

Data Monitors/ Data Managers

(Clinical Operations Department): Concerned with Data Quality and Fraud

Medical Reviewers/ Medical Writers/ Medical Monitoring Clinicians

Concerned with bad side effects (adverse events)

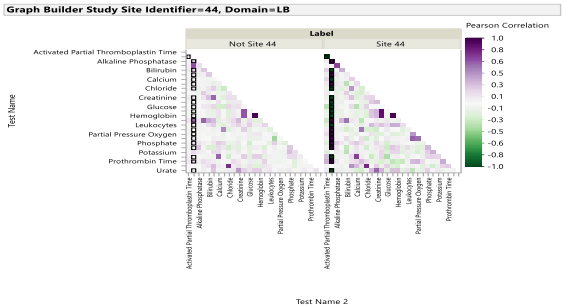
Report Consumers

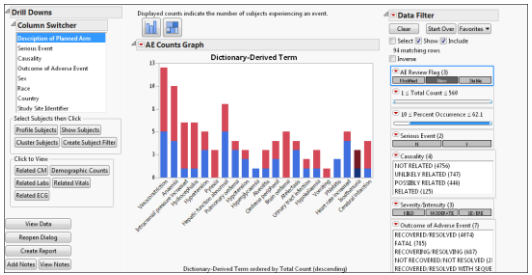
Data Monitors/ Data Managers

Regular review of study data is important to identify issues relating to **data quality and fraud,** unusual data patterns. It can be at the patient or at the data collection level.

- Patient re-enrolling several times
- Preferred scheduled attendance
- Constant or Correlated findings
- Find outliers and inliers
- Digit Preferences
- Risk Based Monitoring

…





Risk Based Monitoring: analyse site performance, evaluate risks and visualize sites based on metrics
Snapshot comparison: Comparisons between current and previous data snapshot accelerate clinical review to avoid redundant work effort

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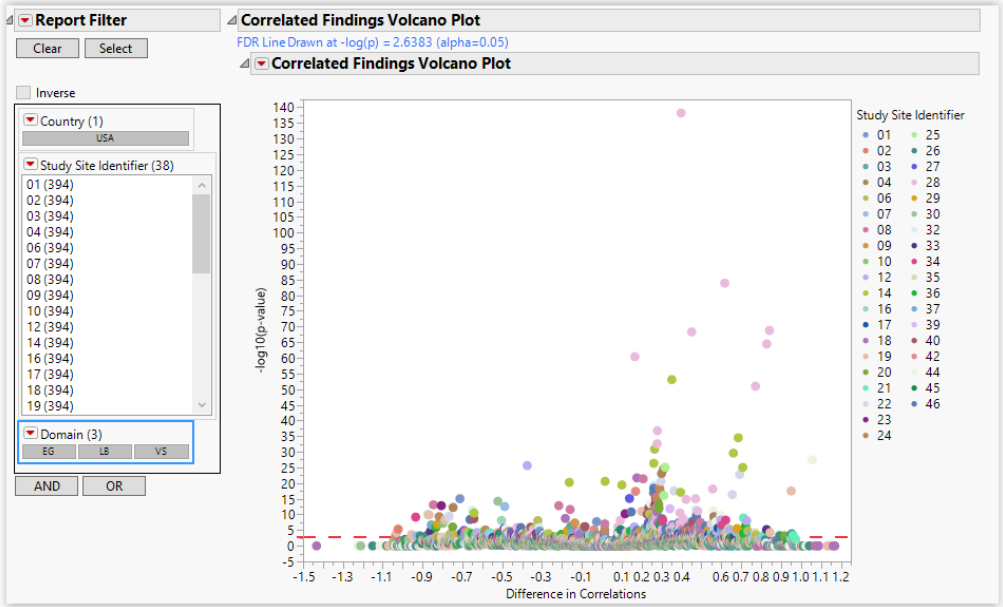
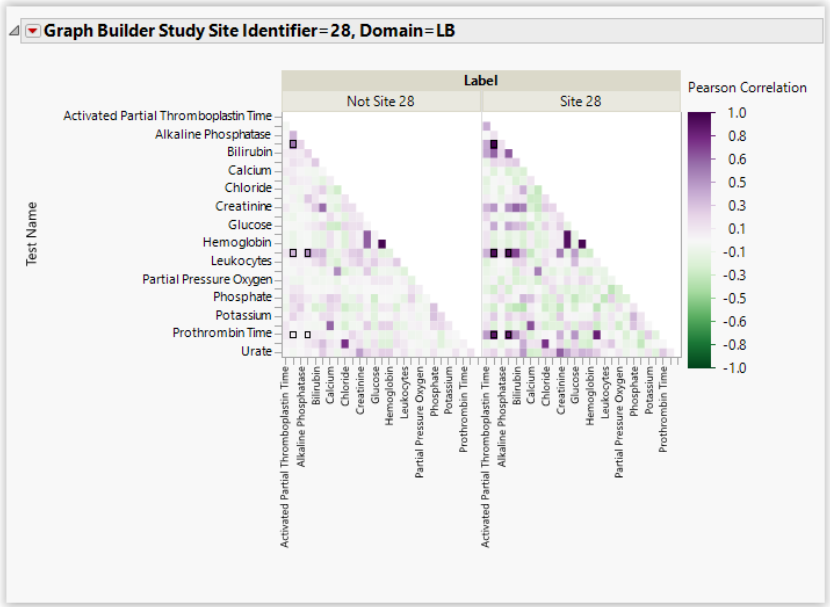
Report Screenshot

Correlated Findings





This report calculates pairwise correlations between tests within each findings domain and identifies unusual results at specific study sites

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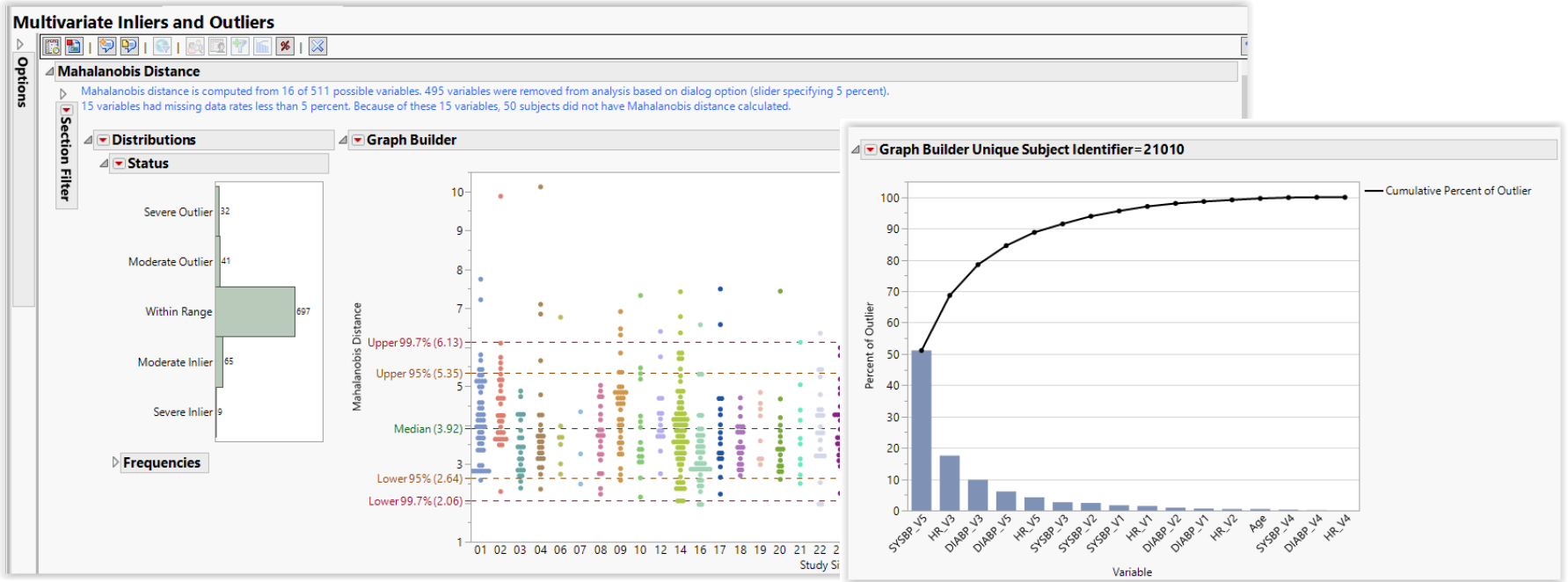
Report Screenshot
Multivariate Inliers and Outliers



This report calculates Mahalanobis distance based on available data to identify subject inliers and outliers in multivariate space from the multivariate mean. It generates results by site to see which sites are extreme in this multivariate space.

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Review Subject Filter

- System-wide **Review Subject Filter** can be used to filter all subject-level reports comprehensively by using row state synchronization across virtually joined tables.
- The review subject filter is based on demographic characteristics.
- One can filter on a particular report and the filter gets propagated to each reports

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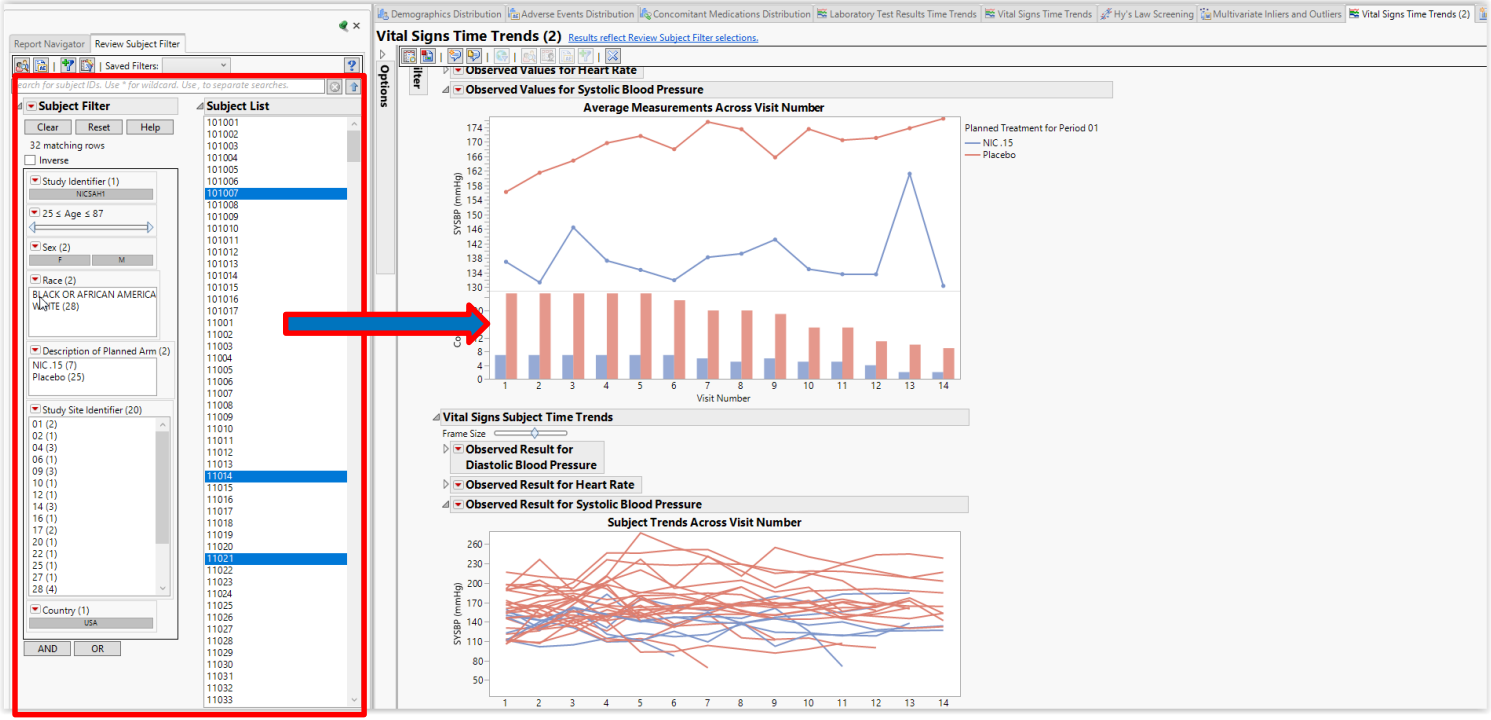
Review Subject Filter



- With the subject filter all reports gets updated on subject level.
- Powerful way to directly find relationships

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Part 2

Oncology, JMP Infrastructure and Clinical Review Customization

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Oncology Clinical Trials

Analysis Challenges

- Creating deterministic/consistent endpoints for tumor response
- Data capture and evaluation of solid tumor lesions
- **Appropriate Analysis and Visualization of early efficacy**
  - Complex trial designs and small sample sizes

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Response Evaluation Criteria in Solid Tumors (RECIST)

International guidelines originally developed by World Health Organization (WHO)

- RECIST Overview
  - Identify Target Lesion Response
    - Max 5 lesions (generally >10mm in size), Max 2 lesions per organ
    - Sum of the longest diameters (uni-dimensional)
      - short axis consideration for nodal tumors.
  - Disease Response Identification
    - Complete Response (CR): All target lesions disappear/shrink.
    - Partial Response (PR): At least 30% decrease in the sum of target lesions WRT baseline.
    - Progressive Disease (PD): At least 20% increase in tumor burden response WRT minimum lesion sum on study (nadir).
    - Stable Disease (SD): Change in tumor burden response fails to qualify for either PR or PD.
- RECIST Endpoints common for regulatory approval by both FDA and EMA
  - Objective Response Rate (CR + PR) for early efficacy

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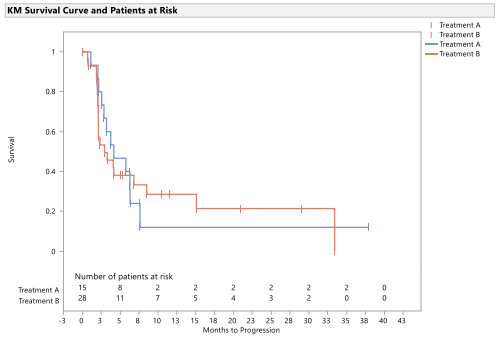
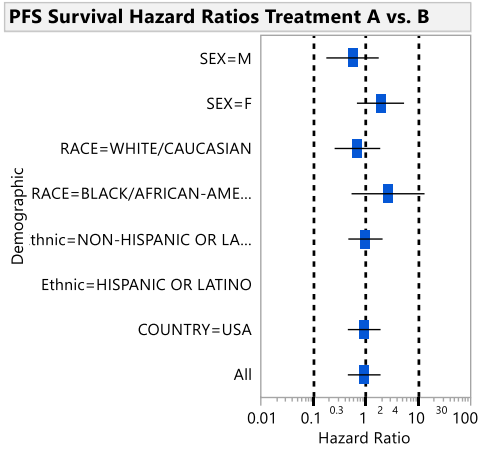
Efficacy Signals

FDA Industry Guidance for Clinical Trial Endpoints

- Survival Analysis (OS)
  - Time to Death



- Progression Free Survival Curves (PFS)
  - Time to “disease progression” OR Death



- Objective Response Rate (ORR)
  - Trend and summaries in “Best” Response

Best Response Summary: Overall Response Test Results

	Description of Planned Arm					
	Treatment A (N = 17)		Treatment B (N = 33)		Total Subjects (N = 50)	
Objective Response Rate (ORR)	**Count**	**%**	**Count**	**%**	**Total Count**	**Total %**
CR + PR	4	23.5%	6	18.2%	10	20.0%
Best Response						
CR	.	.	3	9.1%	3	6.0%
PR	4	23.5%	3	9.1%	7	14.0%
SD	6	35.3%	8	24.2%	14	28.0%
PD	5	29.4%	14	42.4%	19	38.0%

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Detecting Early Efficacy Signals

Waterfall Plots

- Ordered Quantitative Best Response

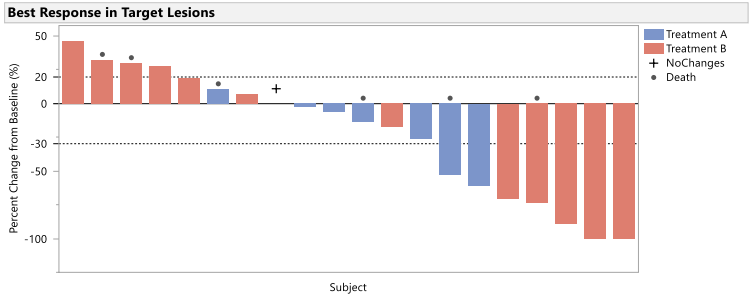
Time Trend Plots

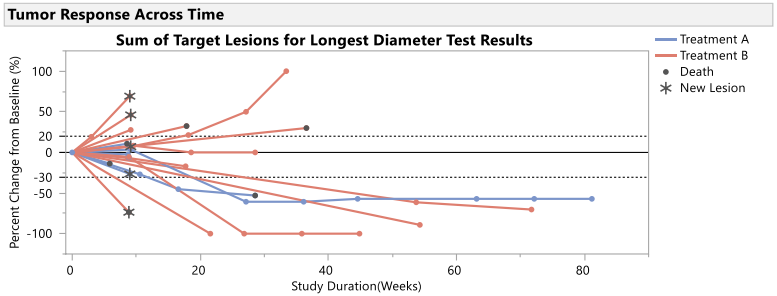
- Tumor Burden response across time
- Nicknames: Line, Spider, Spaghetti Plots

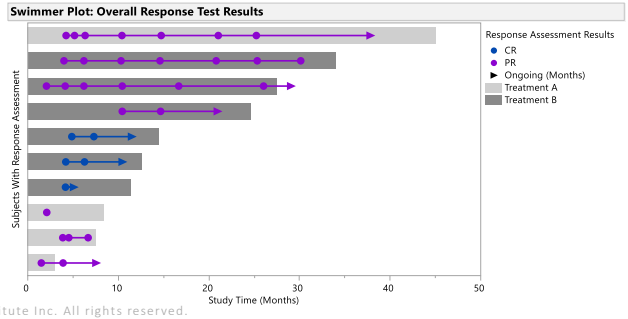
Swimmer Plots

- Qualitative response and duration

Effective Tumor Response Visualization







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Oncology Visualization in JMP/JMP Clinical

Demo

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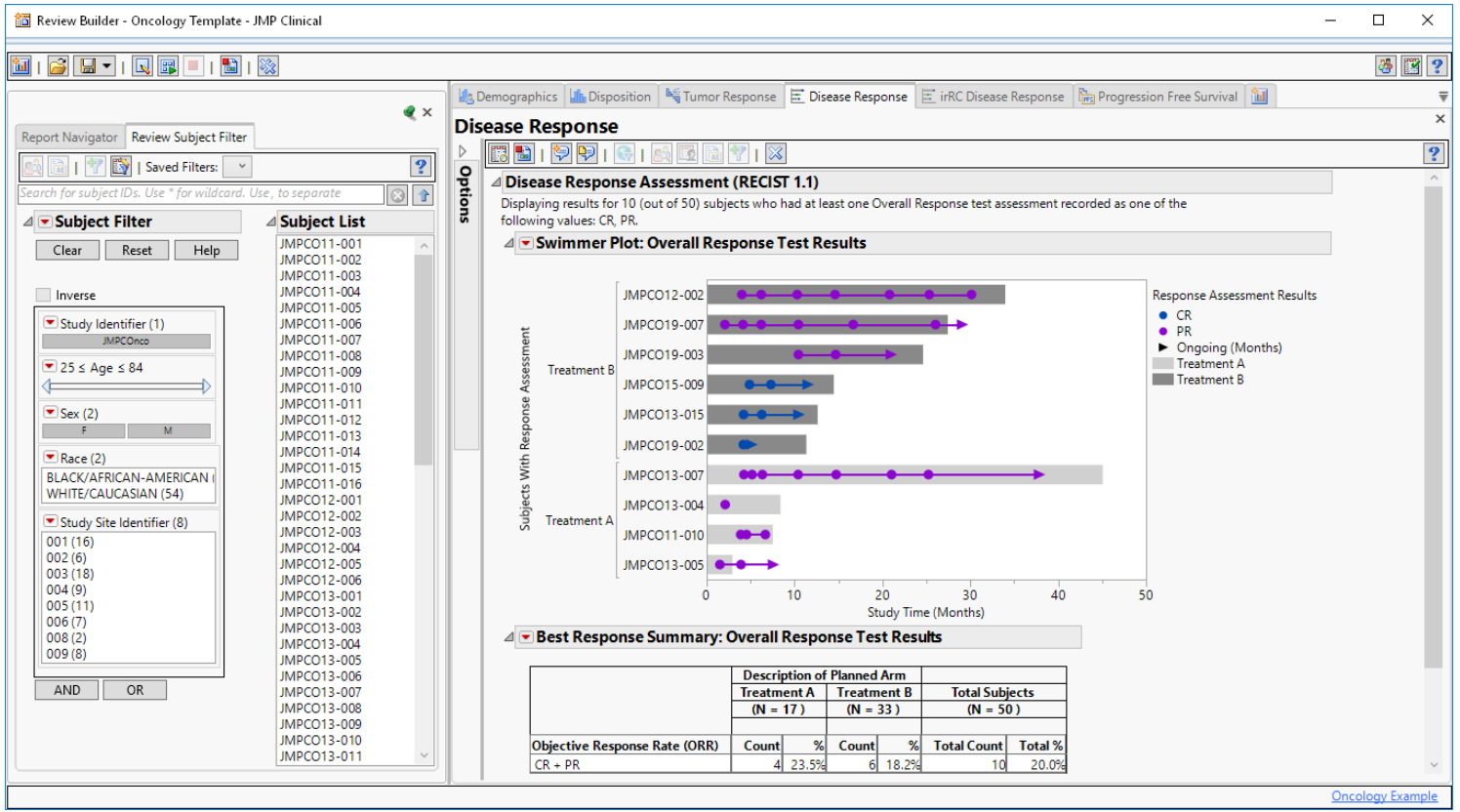
JMP Clinical Solution Screenshot

Solid tumor oncology clinical review



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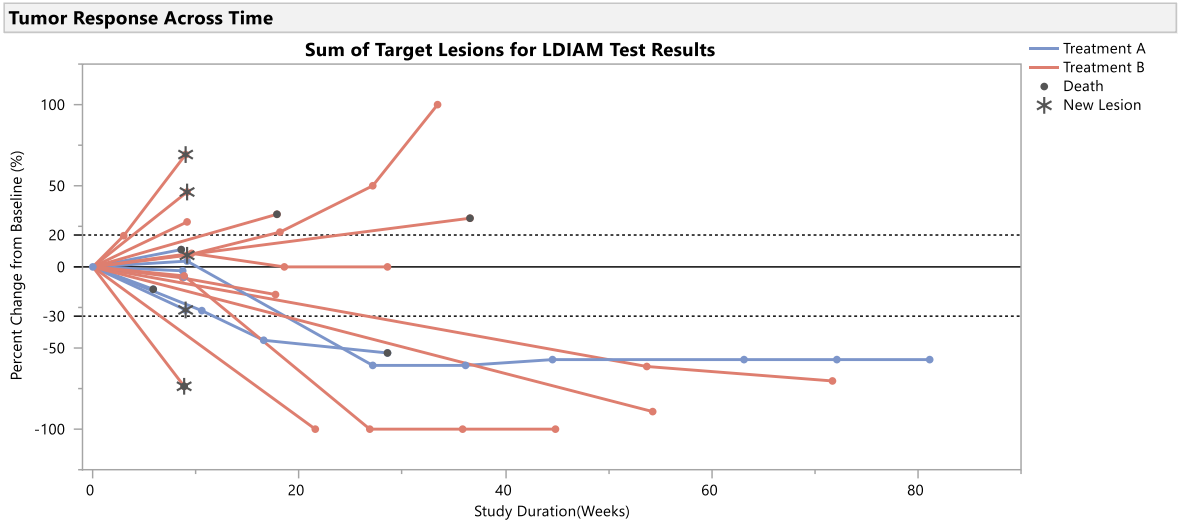
Tumor Burden Spider Plot




```
Variables(
        X( :Name( "Study Duration(Weeks)" ) ),
        X( :Death, Position( 1 ) ),
        X( :New Lesion, Position( 1 ) ),
        Y( :Name( "Percent Change from Baseline (%)" ) ),
        Overlay( :Unique Subject Identifier ),
        Color( "Description of Planned Arm" )
),
Elements(
        Line( X( 1 ), Y, Legend( 1 ), Summary Statistic( "Min" ) ),
        Points( X( 1 ), Y, Overlay( 0 ), Legend( 2 ) ),
        Points( X( 2 ), X( 3 ), Y, Overlay( 0 ), Color( 0 ), Legend( 3 ) )
),
```

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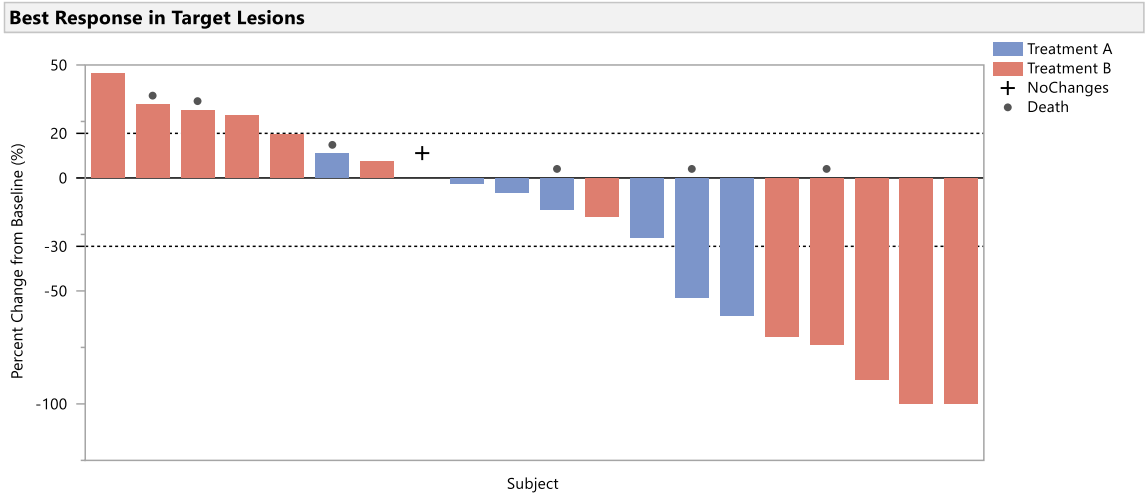
JMP Implementation

- 3 Elements
  - Line, Points, Points
- 6 Variables
  - 3 in X Role (point annotation)
  - 1 Y Role for all elements
  - Overlay
  - Color
- Element/Variable Control
  - Overlay for Subject Lines (new in 14)
  - Color
  - X Variables
- Legend Control
  - Item ID() to control Legend Items
  - Set Marker Size and Marker
  - Legend Index to Hide Elements

Best Response Waterfall Plot




```
Variables(
        X( :Unique Subject Identifier, Order By( :Name( "Percent Change from Baseline (%)" ), Descending, Order Statistic( "Min" ) ) ),
        Y( :Name( "Percent Change from Baseline (%)" ) ),
        Y( :NoChanges, Position( 1 ) ),
        Y( :_DSDECOD_, Position( 1 ) ),
        Color( :Description of Planned Arm )
),
Elements(
        Bar( X, Y( 1 ), Legend( 7 ), Bar Style( "Stacked" ), Summary Statistic( "Min" ) ),
        Points( X, Y( 2 ), Y( 3 ), Color( 0 ), Legend( 6 ) )
),
Where( :Best == 1 ),
```

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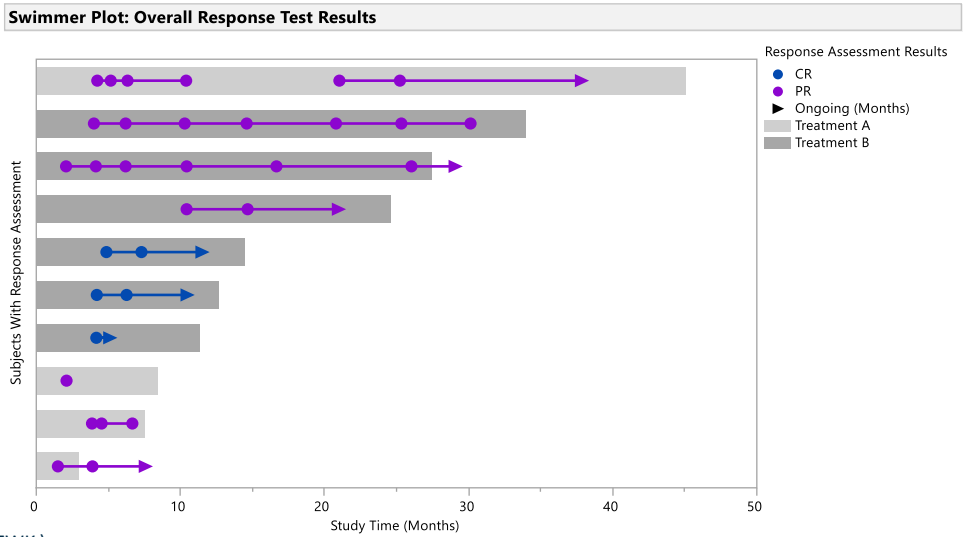
JMP Implementation

- 2 Elements
  - Bar, Points
- 5 Variables
  - 3 Y Roles (Bar Height & Point annotation)
  - 1 X ordered by Y
  - Color (Bar)
- Element/Variable Control
  - Color
  - Y Variables (Bar vs. Point)
- Legend Control
  - Item ID() for Marker Control
- Where Statement
  - JSL to LINK Spider Plot to Waterfall Plot
  - BEST column value in data

Swimmer Plot: Duration of Positive Tumor Response




```
Variables(
        X( :RFWK ),
        X( :RSWK, Position( 1 ) ),
        X( :Response Assessment, Position( 1 ) ),
        X( :Name( "Ongoing (Months)" ), Position( 1 ) ),
        Y( :Unique Subject Identifier, Order By( :RFWK, Ascending, Order Statistic( "Mean" ) ) ),
        Overlay( :Unique Subject Identifier ),
        Color( :Name( "Character Result/Finding in Std Format" ) ),
        Color( :Description of Planned Arm )
),
Elements(
        Bar( X( 1 ), Y, Overlay( 0 ), Color( 2 ), Legend( 2 ), Summary Statistic( "Max" ) ),
        Line( X( 2 ), Y, Color( 1 ), Legend( 5 ), Row order( 1 ), Missing Values( "No Connection" ) ),
        Points( X( 3 ), X( 4 ), Y, Overlay( 0 ), Color( 1 ), Legend( 4 ), Jitter( "None" ) )
),
```

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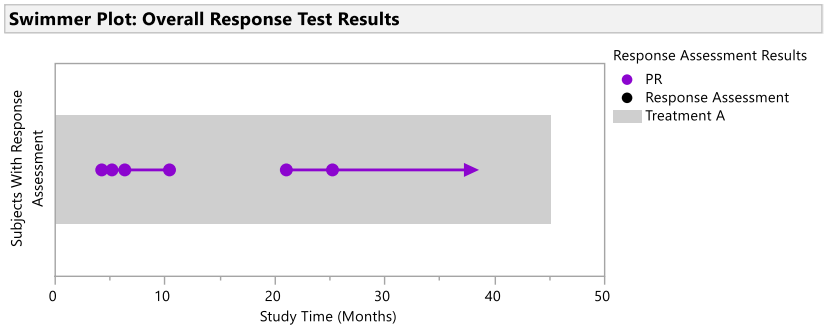
JMP Implementation

- 3 Elements
  - Bar, Line, Points
- 8 Variables
  - 4 X Roles
  - 2 Color Roles
- Element/Variable Control
  - Overlay for Lines on Subject Lanes*
- Legend Control
  - Item ID() for Color/Marker Control
  - Legend ID to Hide Elements
- Data Formatting
  - Record duplication
  - Support Line/Point Response Color Changes
  - Support “Breaks” in Response

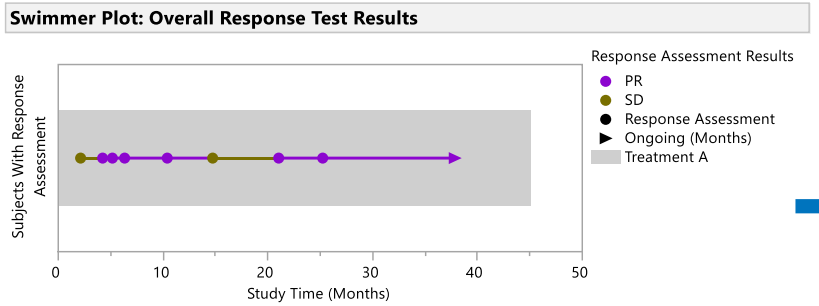
Swimmer Plot Data Formatting

- Supporting Line Breaks



	Unique Subject Identifier	Character Result/...	Visit Number	Visit Name	RSWK
1	JMPCO13-007	PR	7	CYCLE 7	4.2333333333
2	JMPCO13-007	PR	•		5.1666666667
3	JMPCO13-007	PR	7.1	UNSCHEDULED	5.1666666667
4	JMPCO13-007	PR	•		6.3333333333
5	JMPCO13-007	PR	10	CYCLE 10	6.3333333333
6	JMPCO13-007	PR	•		10.4
7	JMPCO13-007	PR	16	CYCLE 16	•
8	JMPCO13-007	PR	•		•
9	JMPCO13-007	PR	31	CYCLE 31	21.033333333
10	JMPCO13-007	PR	•		25.233333333
11	JMPCO13-007	PR	37	CYCLE 37	25.233333333
12	JMPCO13-007	PR	•		37.833333333
13	JMPCO13-007	PR	55	CYCLE 55	•

- Supporting Color Changes



	Unique Subject Identifier	Character Result/...	Visit Number	Visit Name	RSWK
1	JMPCO13-007	SD	4	CYCLE 4	2.1333333333
2	JMPCO13-007	SD	•		4.2333333333
3	JMPCO13-007	PR	7	CYCLE 7	4.2333333333
4	JMPCO13-007	PR	•		5.1666666667
5	JMPCO13-007	PR	7.1	UNSCHEDULED	5.1666666667
6	JMPCO13-007	PR	•		6.3333333333
7	JMPCO13-007	PR	10	CYCLE 10	6.3333333333
8	JMPCO13-007	PR	•		10.4
9	JMPCO13-007	PR	16	CYCLE 16	10.4
10	JMPCO13-007	PR	•		14.733333333
11	JMPCO13-007	SD	22	CYCLE 22	14.733333333
12	JMPCO13-007	SD	•		21.033333333
13	JMPCO13-007	PR	31	CYCLE 31	21.033333333
14	JMPCO13-007	PR	•		25.233333333
15	JMPCO13-007	PR	37	CYCLE 37	25.233333333
16	JMPCO13-007	PR	•		37.833333333
17	JMPCO13-007	PR	55	CYCLE 55	•

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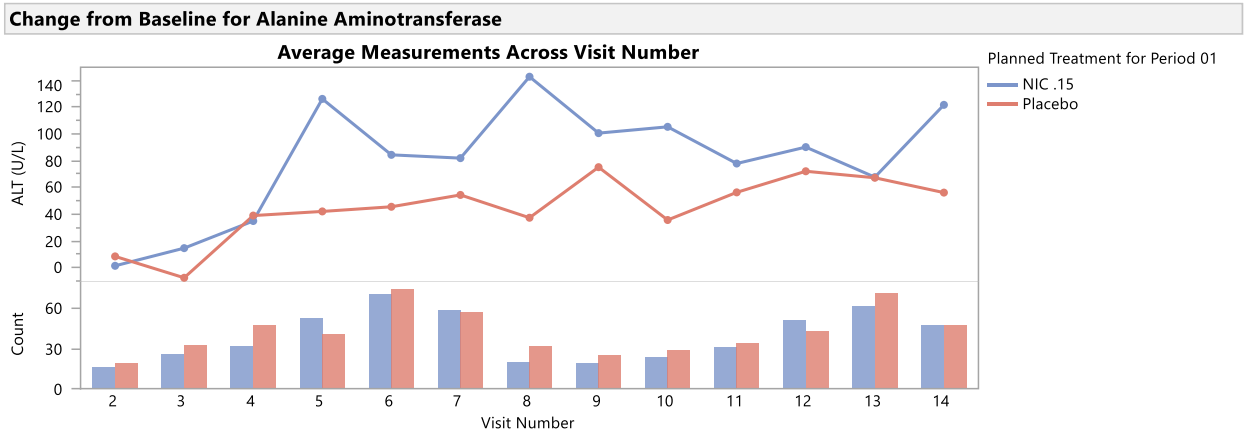
Summary Time Trends With Count Plots



- Incorporate subject counts into visualization of treatment summaries

```
Variables(
        X( :Visit Number ), Y( :ALT ), Y( :ALT ), Overlay( :Planned Treatment for Period 01 )
),
Relative Sizes( "Y", [2 1] ),
Elements( Position( 1, 1 ),
        Line( X, Y, Legend( 1 ) ),
        Points( X, Y, Legend( 2 ), Summary Statistic( "Mean" ) )
),
Elements( Position( 1, 2 ),
        Bar( X, Y, Legend( 19 ), Summary Statistic( "N" ) )
),
Where( !Is Missing( :ALT ) )
```

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JMP Implementation

- Multiple Frames Elements
  - Use of Relative Sizes Option
- Elements for Each Frame
  - Line & Points
  - Bar
- Summary Statistic Control
  - Y Value
    - Show average in line trend
    - Count of records for bar chart

JMP Clinical with JMP 14 Features

Leveraging JMP and JSL to Create our Vertical Solution

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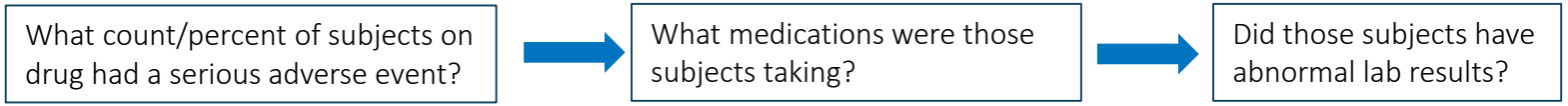
JMP Clinical Review Subject Filter

Linking Domains to Demography with Virtual Joins

- Clinical Review “Line of Question” Analysis



- Virtual Joins within JMP Clinical architecture enable this analysis to be
  - Immediate
  - Interactive
  - **Accomplished with Row States only and NO DATA STRUCTURE MANIPULATION**

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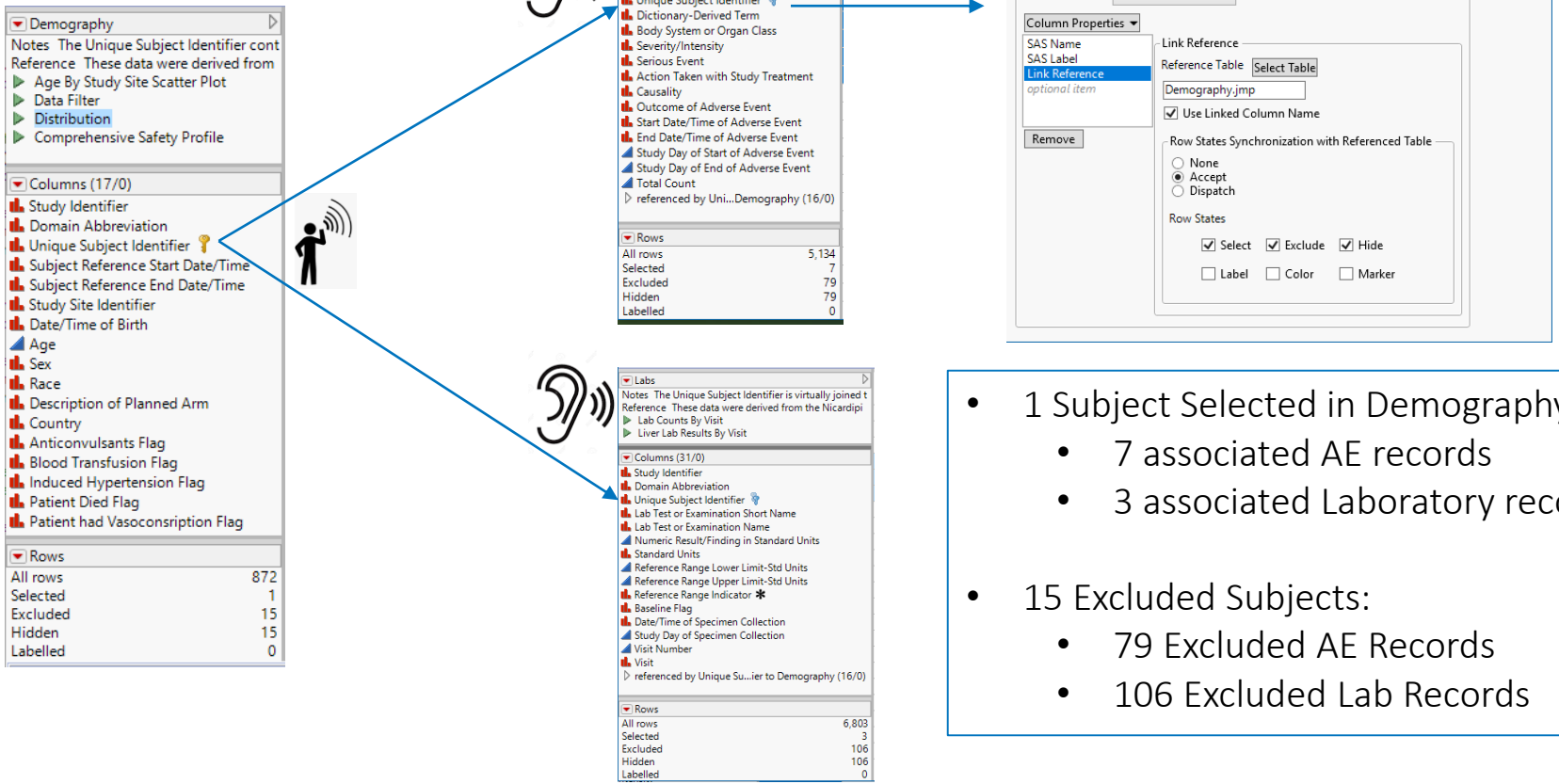
JMP Virtual Joins & Row State Synchronization

- See JMP Discovery US Tutorial “Talking Tables”
  - https://community.jmp.com/t5/Discovery-Summit-2018/Let-s-Talk-Tables-US-2018-412/ta-p/80248

Excluding 15 Asian Patients

Single Selected Subject



- 1 Subject Selected in Demography:
  - 7 associated AE records
  - 3 associated Laboratory records
- 15 Excluded Subjects:
  - 79 Excluded AE Records
  - 106 Excluded Lab Records

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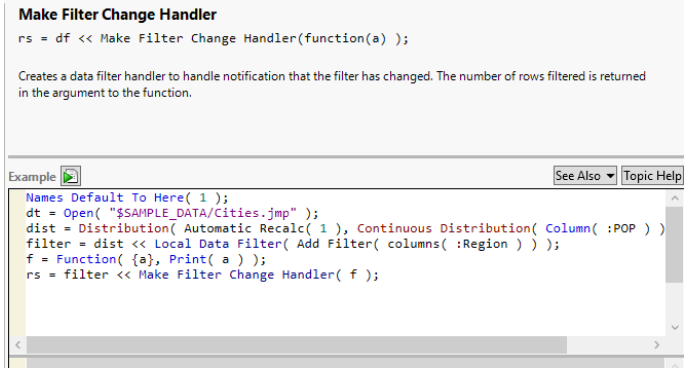
JMP Virtual Joins

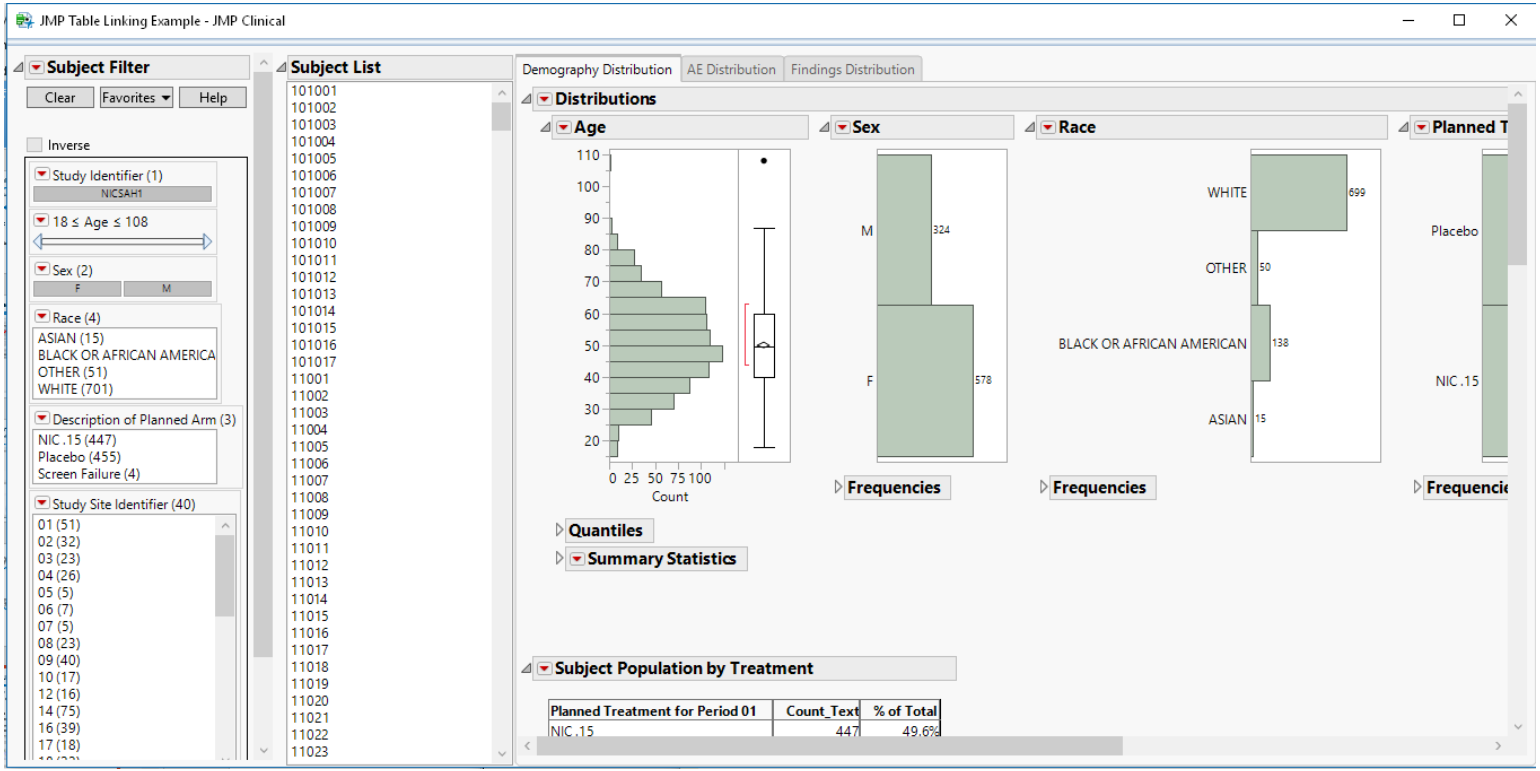
You can't go both ways….

- A Referencing Table may only dispatch or accept row states from source.
  - Loops, inconsistent rows states may easily ensue
- JMP Clinical Application
  - Domain Tables are all "listening" to demography updates
  - We can drive all clinical report domain analyses from demography data filter
  - Globally filter from any domain signals enabled with action buttons that rely on JSL scripted data table and local data filter Listeners



Demo

JMP implementation of table and filter listeners Screenshot



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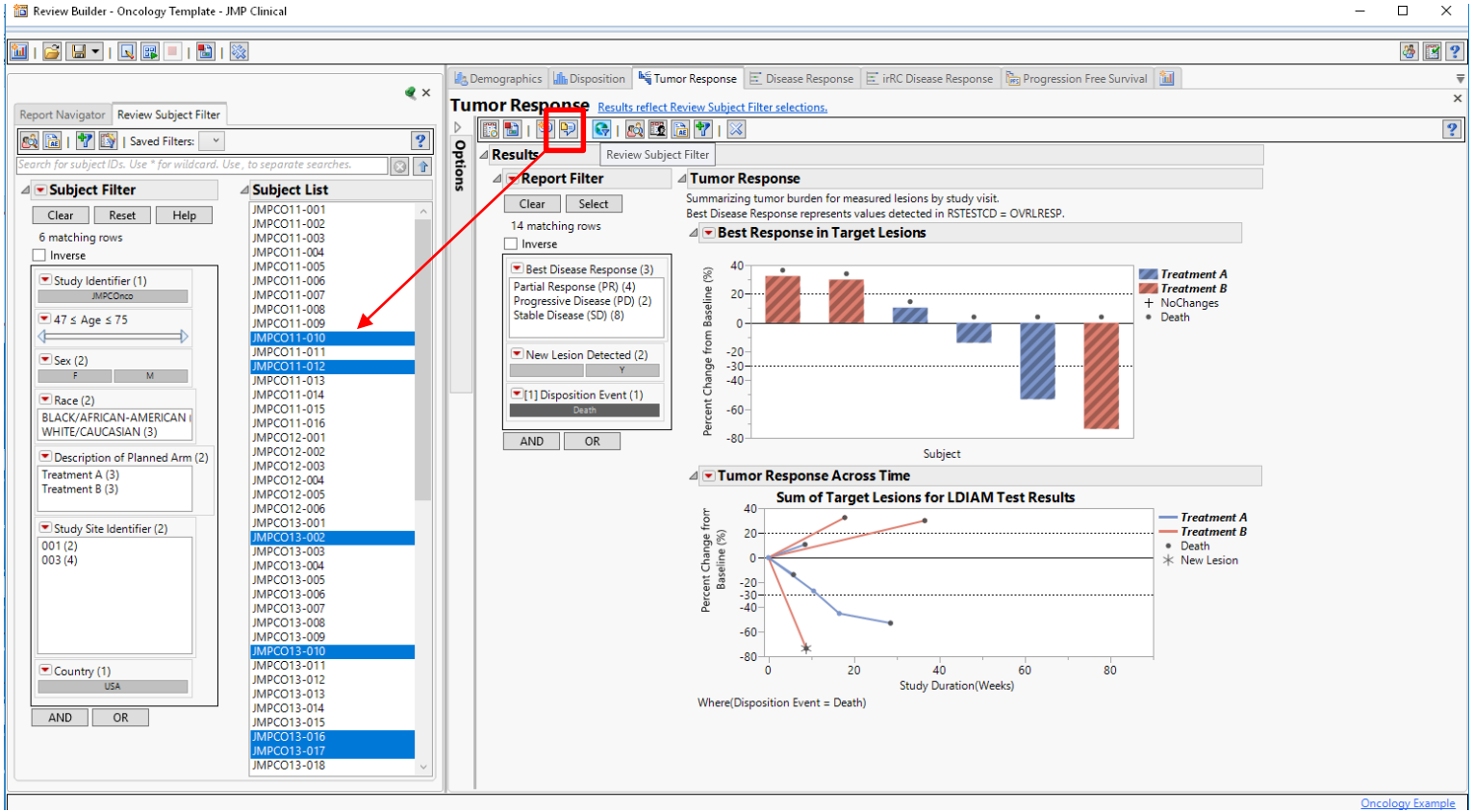
JMP Clinical Review Subject Filter Screenshot

Enable efficient “global” filtering of subjects in a Review



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Customizing a Clinical Review

Including JMP exploration in standard review process

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The Trouble with Vertical Applications

"I Like it! BUT….."

- Even with a rich set of report options, no "out-of-the-box" report will do 100% of everything everyone wants.

- ***JMP Clinical comes with JMP***

- JMP Clinical 7 enables saving Filter Settings, Data Table changes, and JMP custom scripts into a JMP Clinical Review Package

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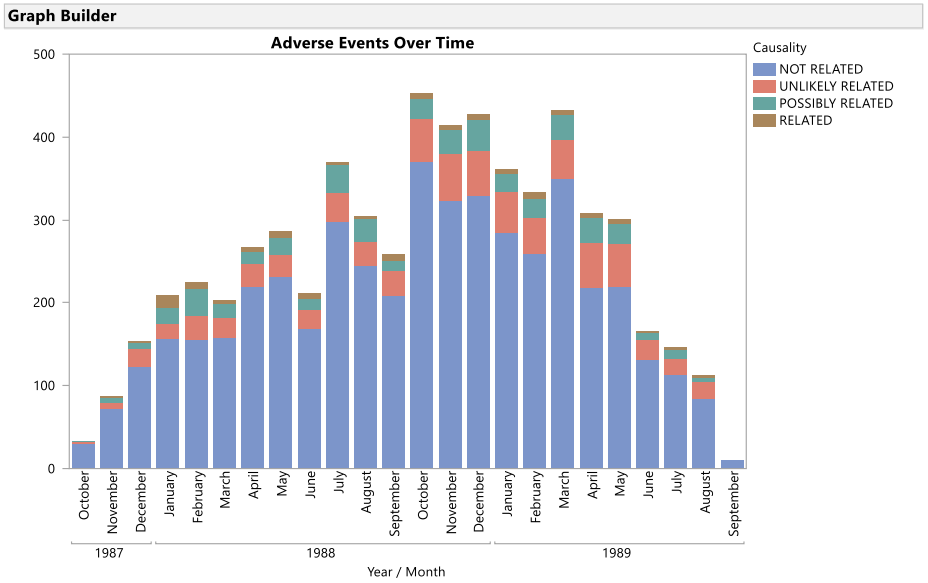
JMP Clinical Customization

JMP Exploration on Report Output

- JMP Clinical Reviews
  - Retain Data Table updates (e.g. creation of a new column)
  - Includes any data table scripts and automatically runs them on review open.

Live Example:
Create an include a custom adverse events graph in a JMP Clinical AE Distribution Review



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JMP Clinical API

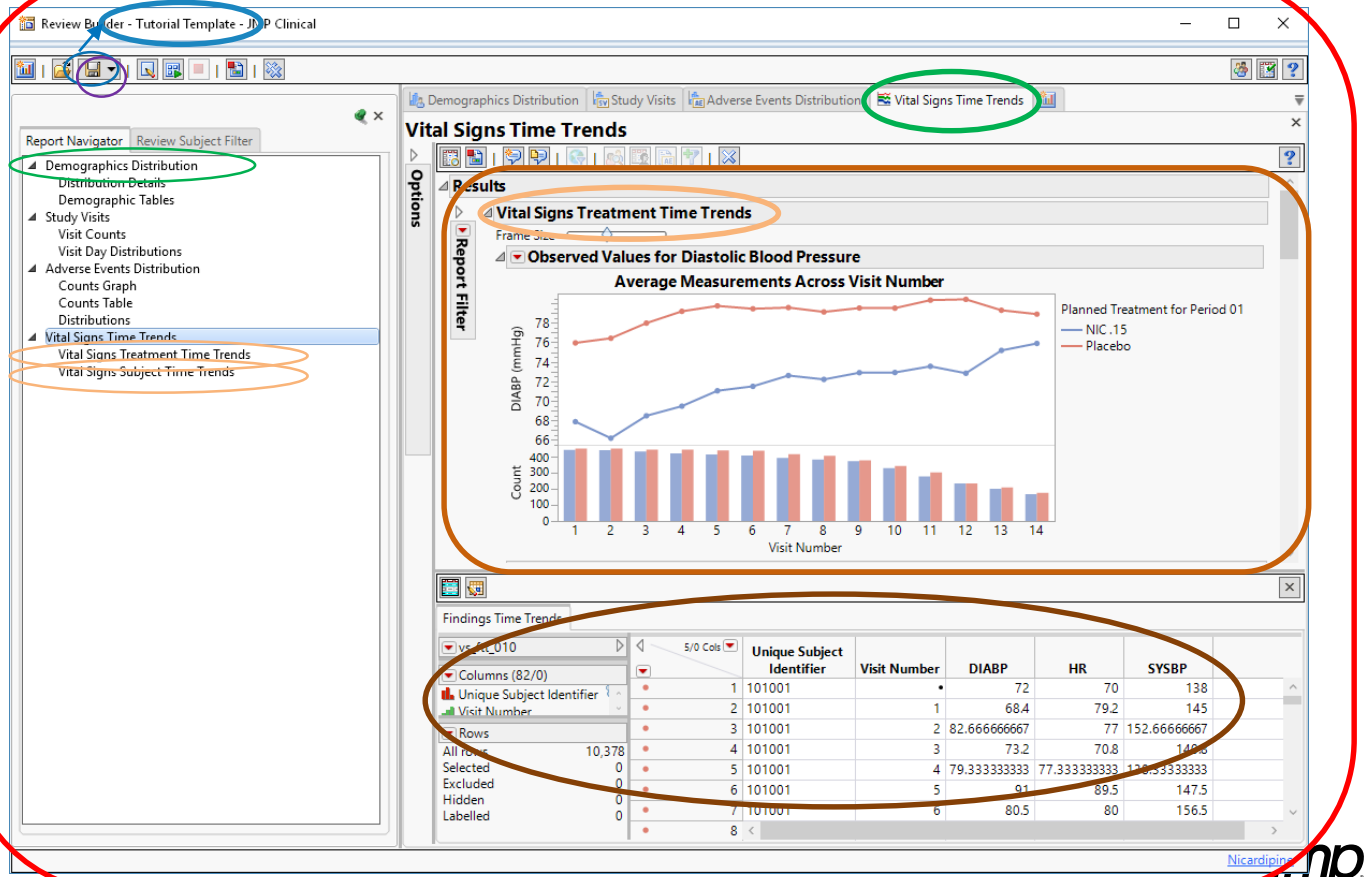
Control Execution and Content of JMP Clinical Reviews

Standard Terminology

- Review Builder
- Review Template
- Report (Title)
- Report Results
  - Section(s)
  - Data Table
- Review
  - Saved Review Builder

Save -> Review Template
Open -> Review Template*
*Opens in Review Builder

Save -> Review
Open ->Review**
**Opens in Review Viewer



JMP Clinical API

Examples

- Insert a new section into a Review

```
If( Is Empty( JMPClinicalReviewID ),
    JMPClinicalReviewID = (JMPClinicalReviewAPI:getReviewBuilder()) << getName
);
Show( JMPClinicalReviewID );
reportTitle = "Vital Signs Time Trends";

JMPClinicalReviewAPI:insertSectionIntoReportByTitleAndSectionName(
    JMPClinicalReviewID,
    reportTitle,
    "Blood Pressure Plot",
    V List Box(
        /* Put Display Object Code here */
    ),
    1
);
```

- Automate opening and running Review Templates to Create Reviews

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Thank you!
Q/A

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