



LUNDBECK'S APPROACH TO ENABLING DATA-DRIVEN INSIGHTS

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PhUSE Single Day Event – Copenhagen, June 2015



Agenda

- ★ Data Symphony Project
 - ★ Scope and Tracks
- ★ TIBCO Spotfire – Business Analytics Software
- ★ Clinical Data Layer
 - ★ Making full use of SDTM & components of ADAM
- ★ Development & Validation Approach
- ★ Overview of Apps in Production & Development
- ★ Examples
 - ★ MMSR
 - ★ Site Quality Monitoring
 - ★ Data Error Detection
 - ★ Biobank Catalog
 - ★ Omics data
- ★ Conclusion

Data Symphony Project

Scope

To establish:

- ★ A platform and governance structure
 - ★ To manage and aggregate Clinical Trial Data, Research Data, and Real World Data
- ★ An analytic environment
 - ★ Beyond programming skilled users to all scientists and business users to enable data-driven insights
- ★ New methods and tools
 - ★ To capture patients data - increase patient interaction, and the understanding of patient needs and their disease

Data Symphony Project

Four Tracks

Mobile health

Wearable devices for trials and observational studies

Real-world data

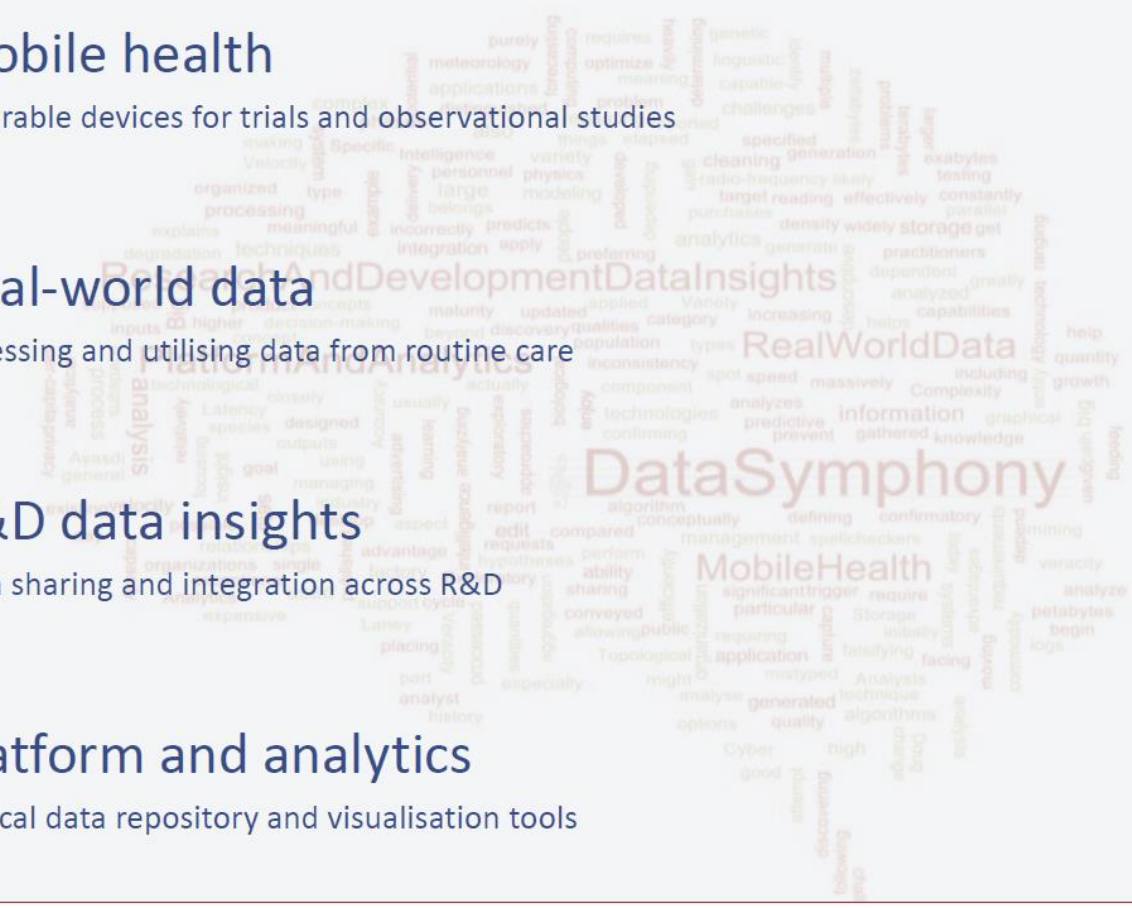
Accessing and utilising data from routine care

R&D data insights

Data sharing and integration across R&D

Platform and analytics

Clinical data repository and visualisation tools



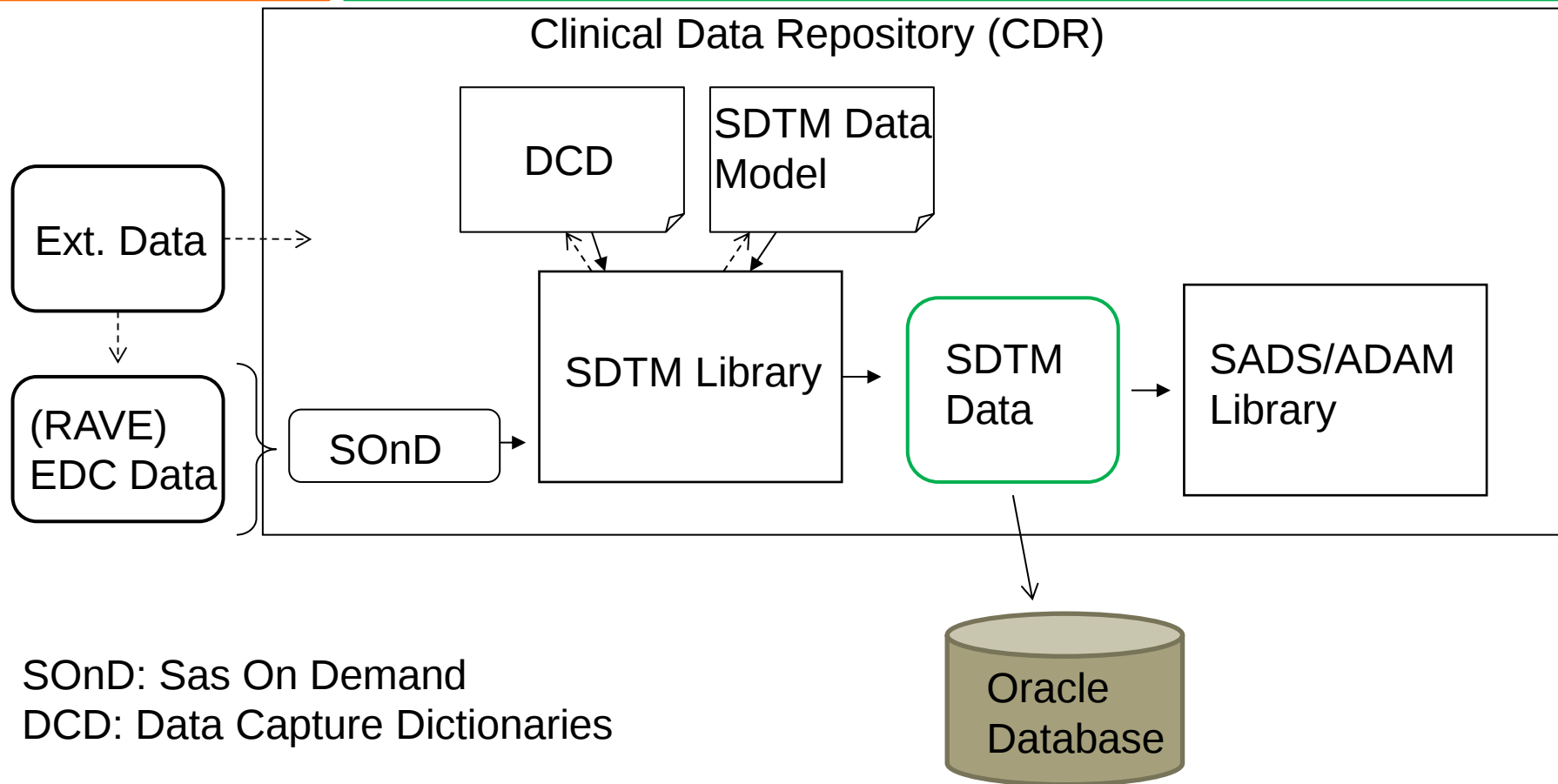
Spotfire

- ★ TIBCO Spotfire - Business Intelligence Analytics Software
- ★ In use in Lundbeck Research for 10+ years
- ★ Common Tool deployed in Pharma and CROs
- ★ Can handle multiple data sources
 - ★ e.g. SAS datasets, Excel, Oracle database

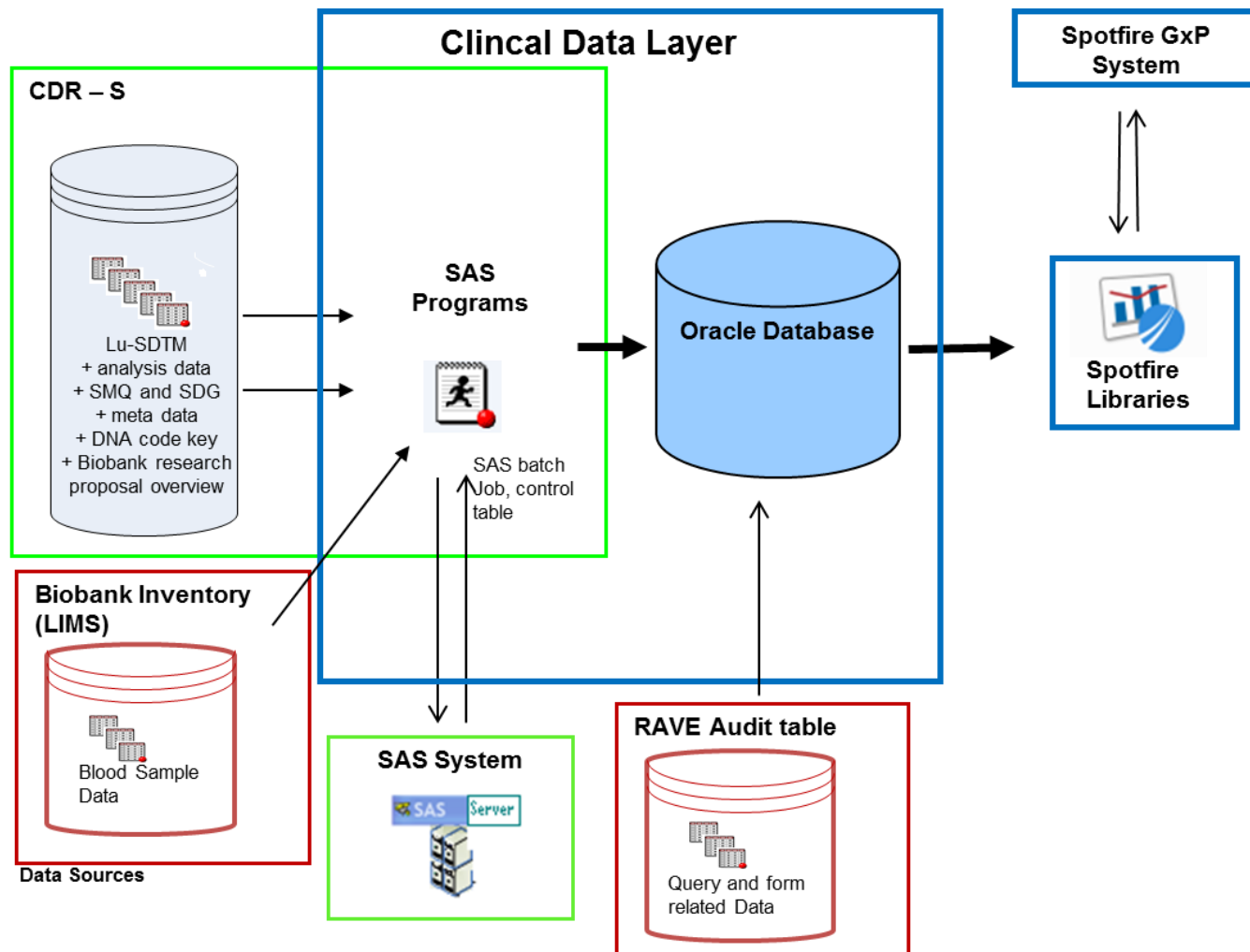
Data Flow – Lundbeck

CDM

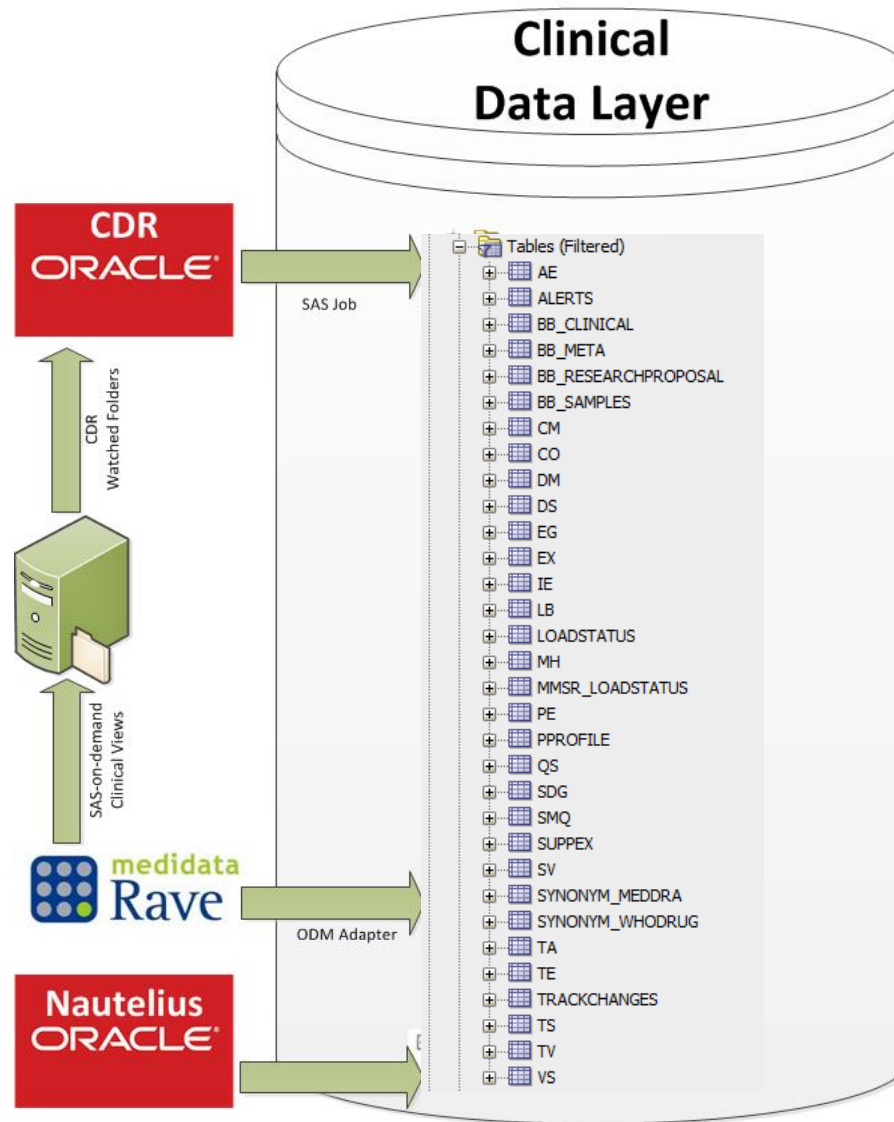
SP



Clinical Data Layer – 1 of 2



Clinical Data Layer – 2 of 2



Application Development & Validation Approach

- ★ Established a validated “Clinical Data Layer & Spotfire Platform”
 - ★ “traditional”, IQ, OQ and PQ
- ★ “Agile software development” like approach to Apps
 - ★ Develop “early” Prototypes
 - ★ End-User Workshop 1
 - ★ Rapid modifications
 - ★ End-User Workshop 2
 - ★ Requirements updated throughout the process
 - ★ Pilot on “real data”
 - ★ Flexible approach to changes
 - ★ Validation of the App



Medical
Monitoring &
Safety Review



Ratings
Surveillance



Site Quality
Monitoring



Data Review &
Error Detection



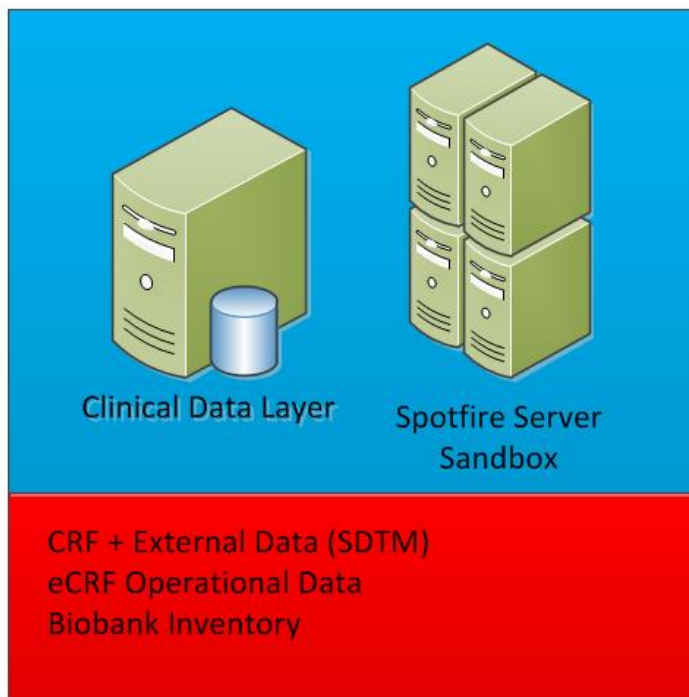
Project Specific
Apps



Biobank Catalog



Coding Reports



Benefit Risk
Assessment*



Data Cleaning &
Query
Management**

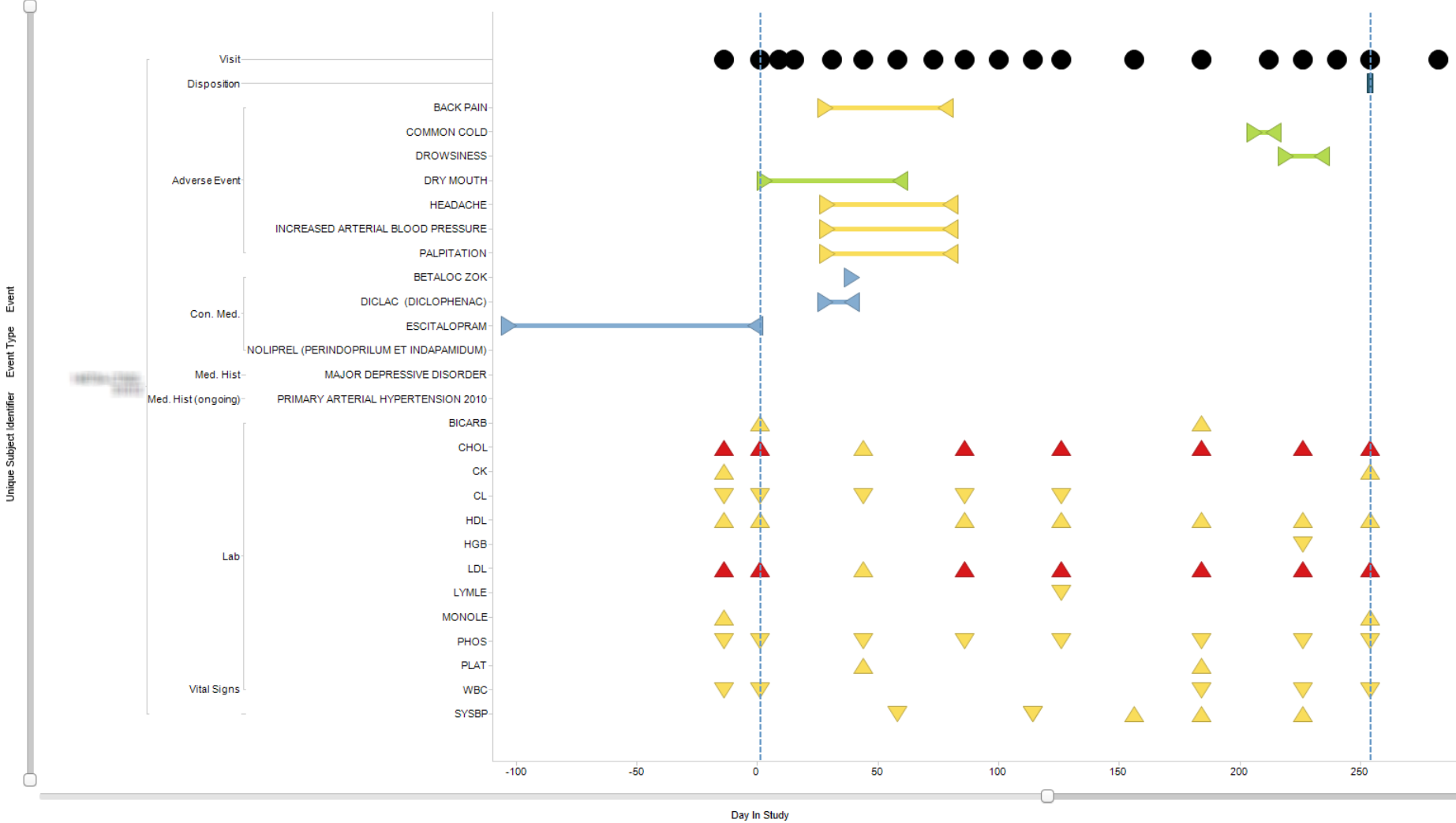
*Awaiting Regulatory Guidance

**Currently available in RAVE Reports

MMSR – Patient Profile Example

Patient Profile

Listing all events for a patient on the y-axis but only showing events with a date in the plot.



MMSR – Hy's Law Example



MMSR – MedDRA SMQ Example

Safety Overview AEs by SOC and PT AEs by Duration AE/SAE Heatmap AEs leading to Withdrawal **AEs of Special Interest** CM by Name or Class CM for Primary Indication Disallowed Medication Lab Edit

Patient Count by SMQ

Showing AEs falling into MedDRA's standardised MedDRA queries
Color is based on the number of subjects

Broad										Narrow																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																						
Anticholinergic syndrome (SMQ)	Noninfectious encephalopathy/delirium (SMQ)	Hyperglycaemia/new onset diabetes mellitus (SMQ)	Dementia (SMQ)	Extrapyramidal syndrome (SMQ)	Retroperitoneal fibrosis (SMQ)	Guillain-Barre syndrome (SMQ)	Arthritis (SMQ)	Depression (excl. suicide and self injury) (SMQ)	Depression and suicide/self injury (SMQ)	Gastrointestinal nonspecific inflammation and dysfunctional conditions (SMQ)	Oropharyngeal disorders (SMQ)	Accidents and injuries (SMQ)	Extrapyloric syndrome (SMQ)	Hypertension (SMQ)	Haemorrhage terms (excl. laboratory)																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																	
		Hearing and vestibular disorders (SMQ)	Noninfectious encephalitis (SMQ)		Pseudomembranous colitis (SMQ)	Rhabdomyolysis/myopathy (SMQ)	Hypersensitivity (SMQ)	Dystonia (SMQ)	Lipodystrophy (SMQ)			Haemorrhages (SMQ)	Drug related hepatic disorders (SMQ)	Hepatic disorders (SMQ)	Oral self-injury (SMQ)	Suicide/self-injury (SMQ)																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																
				Cardiomyopathy (SMQ)		Peripheral neuropathy (SMQ)	Eosinophilic pneumonia (SMQ)	Ischaemic heart disease (SMQ)																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																								
	Acute pancreatitis (SMQ)	Neuroleptic malignant syndrome (SMQ)	Vestibular disorders (SMQ)	Noninfectious meningitis (SMQ)	Drug abuse, dependence and withdrawal (SMQ)	Parkinson-like events (SMQ)	Cardiac arrhythmias (SMQ)	Akathisia (SMQ)	Noninfectious dermatitis (SMQ)			Myocardial infarction (SMQ)	Aggravated ulcer (SMQ)	Oropharyngeal conditions (excl. neoplasms, infections and allergies) (SMQ)	Depression and suicide/self-injury (SMQ)	Hearing and vestibular disorders (SMQ)	Cardiac arrhythmias (SMQ)	Cardiac arrest (SMQ)																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																														
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Arrhythmic disorders (SMQ)								Lens disorders (SMQ)	Glaucoma (SMQ)	Gas troi	Gas troi	Gas troi	Gas troi						Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi	Gas troi

Patient Count by PT

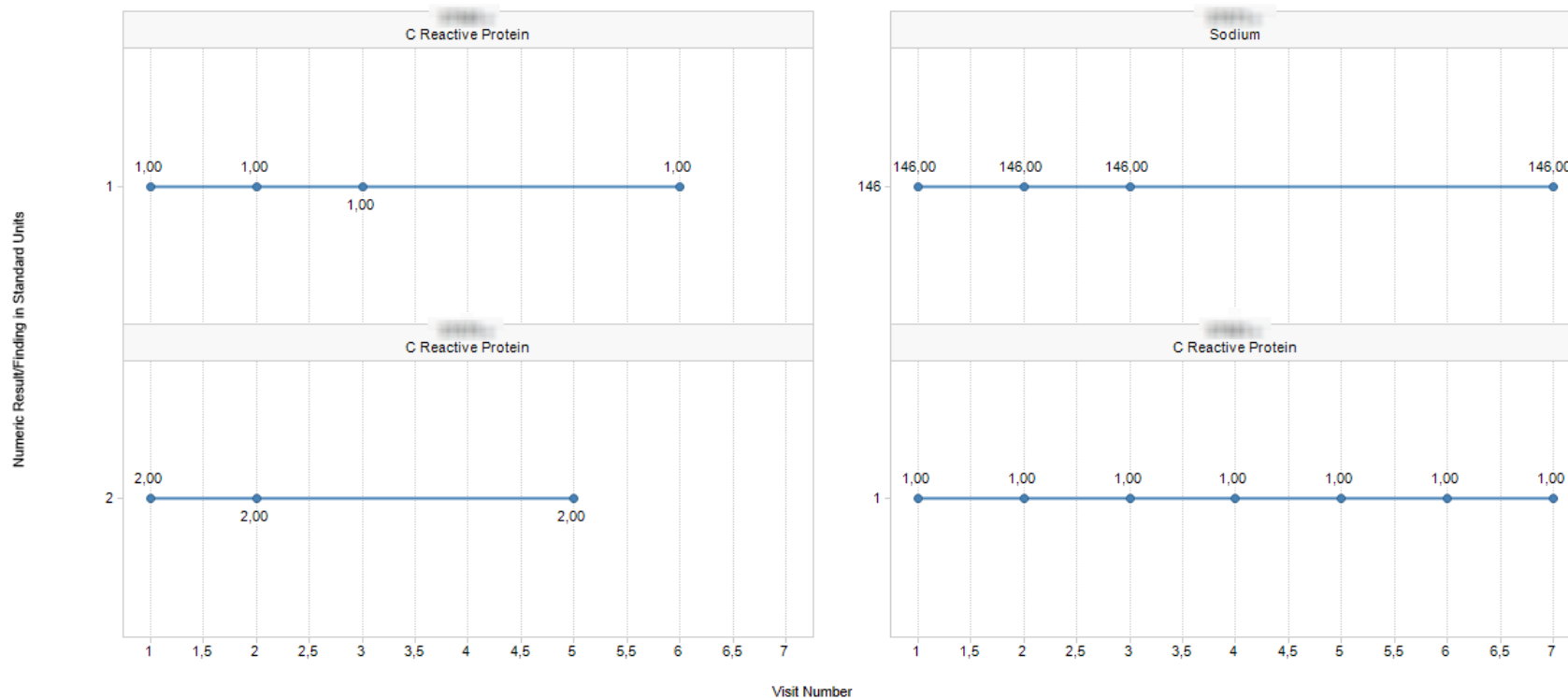
Color is based on the number of subjects

Headache	Nasopharyngitis	Weight increased	Somnolence	Accidental overdose	Insomnia	Constipation	Anxiety	Upper respiratory tract infection	Vomiting	Restless legs syndrome	Suicidal ideation	Oropharyngeal pain	Increased appetite	Decreased appetite	Gastric pain	Migraine	Abdominal pain	Hypertension	Balloon	Muscle pain	Healed	Hydroxy	Irritation	Joint pain	Ligament	Loose	Measles	Pyrexia	Reflux	Seizure
				Fatigue	Tremor	Influenza	Akathisia	Toothache	Waist circumference increased	Vision blurred	Tachycardia	Pain in extremity	Night sweats	Myalgia	Muscle tightness	Salivary gland	Hot flashes	Tinnitus	Musculoskeletal pain	Chills	Healed	Hydroxy	Irritation	Joint pain	Ligament	Loose	Measles	Pyrexia	Reflux	Seizure
								Weight decreased	Cough	Blood creatine phosphokinase	Viral upper respiratory	Palpitations	Rash	Rhinitis	Oral herpes	Cystitis	Muscle pain	Poor appetite	Gastric pain	Healed	Hydroxy	Irritation	Joint pain	Ligament	Loose	Measles	Pyrexia	Reflux	Seizure	
								Hypertension	Abdominal pain upper	Contusion	Dyspepsia	Bronchitis	Sinusitis	Tension	Disturbance	Parasitosis	Respiratory distress	Pharyngitis	Dysuria	Sexual dysfunction	Defecation	Healed	Hydroxy	Irritation	Joint pain	Ligament	Loose	Measles	Pyrexia	Reflux
Nausea	Dizziness	Hyperhidrosis	Dry mouth	Diarrhoea	Back pain	Restlessness	Arthralgia	Asthenia	False positive investigation	Pruritus	Muscle spasms	Fall	Abnormal dream	Gammaglobulin	Vertigo	Urinary tract	Agitation	Healed	Hydroxy	Irritation	Joint pain	Ligament	Loose	Measles	Pyrexia	Reflux	Seizure			

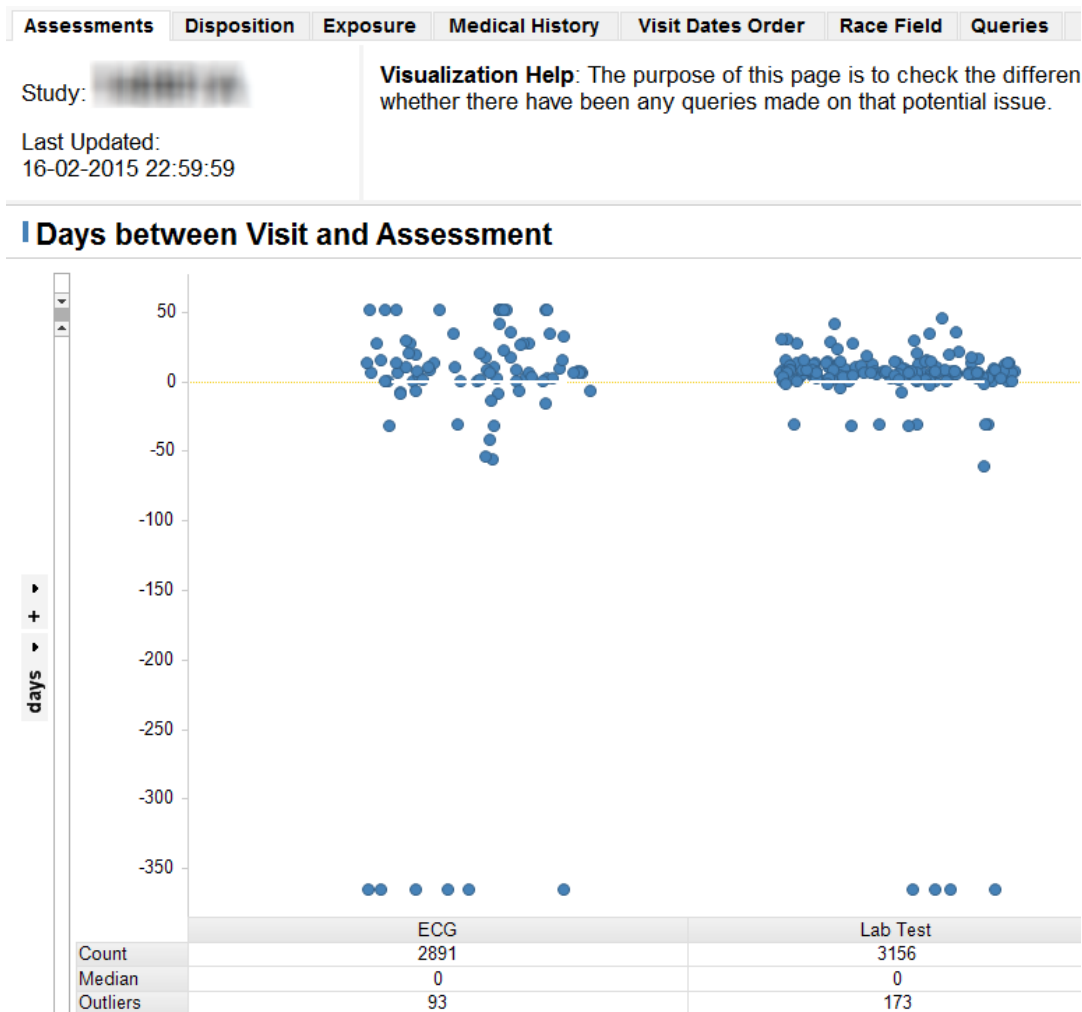
Site Quality – AE Reporting Rate Example



Site Quality – Value propagation Example

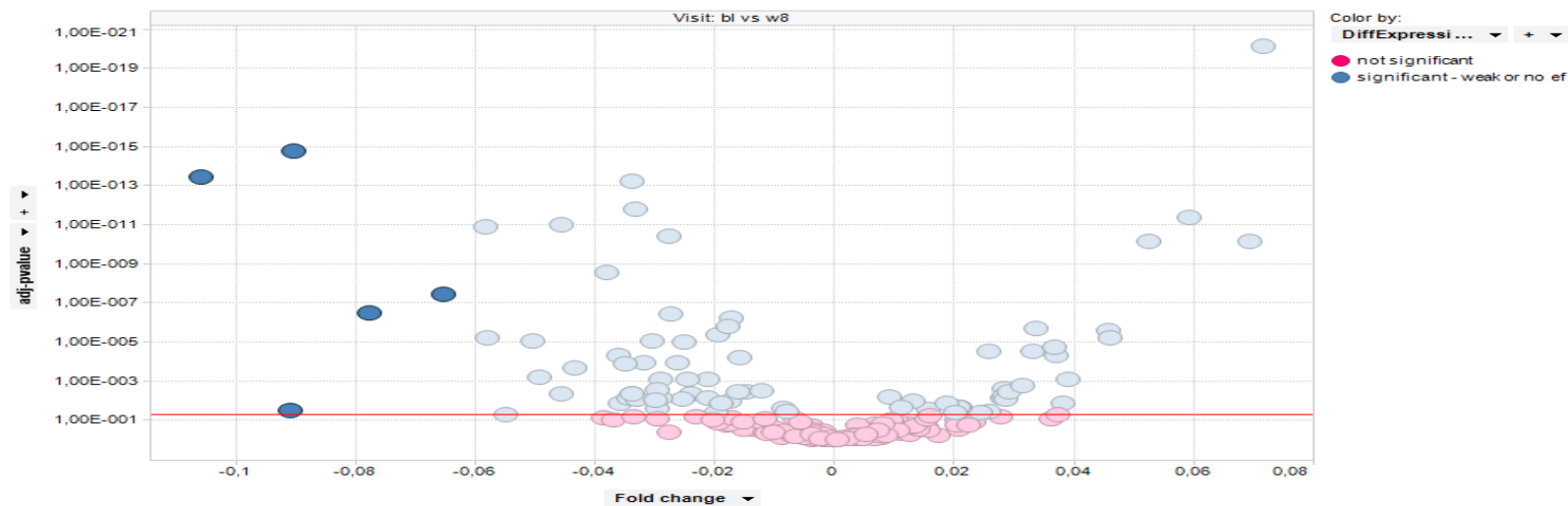


Data Cleaning – Days between Visit and Assessment Example



Omics Office – Gene Expression

Volcano plot of differential expression



Differential Expression Details for selected targets

Comparison	Diff. Expression Group	Fold change (Log2)	p-value	adj_pvalue
nos3				
Visit: bl vs w8		-0,08	2,14E-008	3,12E-007
pten				
Visit: bl vs w8		-0,07	2,45E-009	3,85E-008
rap1gap				
Visit: bl vs w8		-0,09	1,21E-002	3,34E-002
smox				
Visit: bl vs w8		-0,11	5,45E-016	3,71E-014
sod1				
Visit: bl vs w8		-0,09	1,69E-017	1,73E-015

Conclusion

- ★ Starting to meet expectations
 - ★ broaden access to data to users without programming skills
 - ★ allowing them to focus their energies on analyzing the data, instead of struggling to get to data.
- ★ Agile Development approach
 - ★ To develop apps that meet user expectations
 - ★ In a timely manner
 - ★ Not an approach that all are comfortable with
 - ★ Expect to improve the acceptability of the approach if we can consistently release valuable applications
- ★ We believe exposure to a wider audience of what Programming can enable, is benefiting the organization