



# Revvity Clinical Data Review: Discovery solution



Revvity's Clinical Data Review (CDR) Discovery solution is geared towards use cases where clinical data or medical data reviewers are keen to drill down into their analysis in a self-service and exploratory manner.

Typically, this 'exploratory' way of drilling into data is ideal for more technical users who want greater flexibility and analysis options. Additionally, we also have a CDR workflow solution that is aimed at medical reviewers or less technical users that want to be guided through an entire process in a step-by-step manner (similar to a medical data review plan).

Powered by TIBCO Spotfire®, Revvity's CDR Discovery solution is designed to allow you to instantly drill down from population level (Figure 1) to subject level (Figure 2).

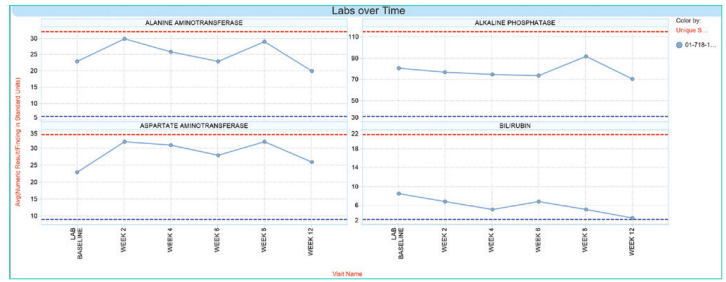


Figure 2: Subject level view.

Drill down further into your subject level data to gain a more comprehensive view using graphical representation of the data (Figure 3)

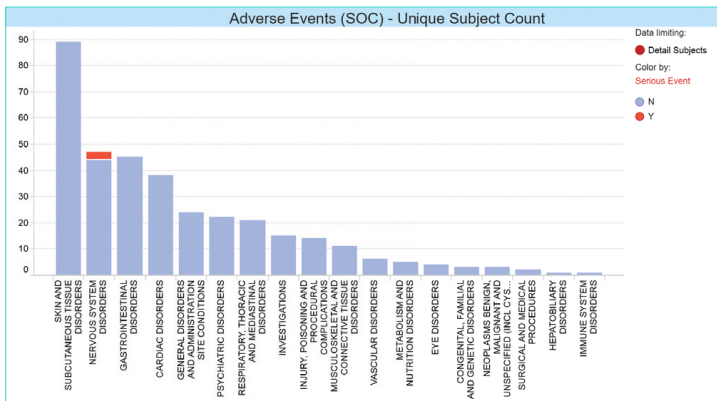


Figure 1: Population level view.

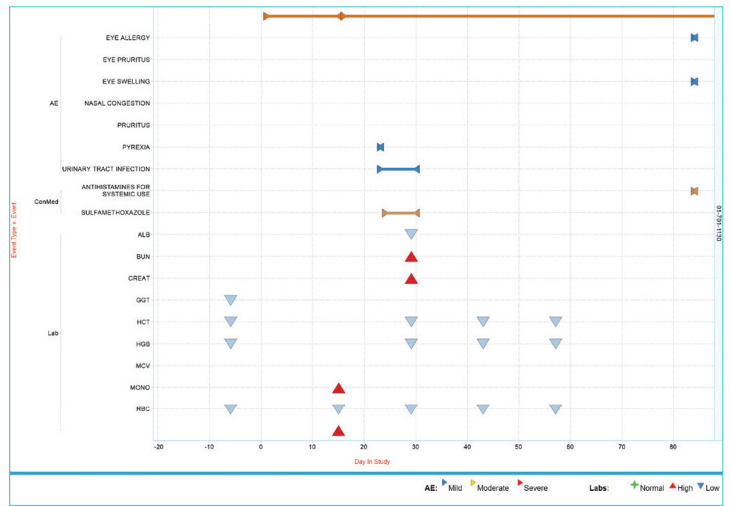


Figure 1: Graphical Patient Profile based on dynamically selected events and study subjects

Below are some examples of the visual analytics included in Revvity's CDR Discovery solution:



Demographic information (Distribution of gender, age and race by study arm).

1. dm													
Study Identifier	Unique Subj.	Domain Abbr.	Subject Ident.	Subject Refer.	Subject Refer.	Study Site M.	Age	Sex	Race	Planned Arm	Country	Count	USA
CDISCPL0101	01-701-1192	DM	1023	2014-01-02	2014-07-02	701	63	YEARS	F	HISPANIC (M)	Philo	1	USA
CDISCPL0101	01-701-1028	DM	1029	2014-01-19	2014-01-14	701	71	YEARS	M	CAUCASIAN	Xan_La	1	USA
CDISCPL0101	01-701-1033	DM	1033	2014-03-18	2014-04-14	701	74	YEARS	F	CAUCASIAN	Xan_La	1	USA
CDISCPL0101	01-701-1034	DM	1034	2014-07-01	2014-12-30	701	77	YEARS	F	CAUCASIAN	Xan_La	1	USA
CDISCPL0101	01-701-1047	DM	1047	2013-03-12	2014-03-29	701	85	YEARS	F	CAUCASIAN	Philo	1	USA
CDISCPL0101	01-701-1097	DM	1097	2014-01-01	2014-07-09	701	88	YEARS	M	CAUCASIAN	Xan_La	1	USA
CDISCPL0101	01-701-1111	DM	1111	2012-09-07	2013-09-17	701	81	YEARS	F	CAUCASIAN	Xan_La	1	USA
CDISCPL0101	01-701-1115	DM	1115	2014-01-01	2014-03-23	701	84	YEARS	M	CAUCASIAN	Xan_La	1	USA
CDISCPL0101	01-701-1118	DM	1118	2014-03-12	2014-06-09	701	52	YEARS	M	CAUCASIAN	Philo	1	USA
CDISCPL0101	01-701-1130	DM	1130	2014-01-03	2014-06-16	701	75	YEARS	M	CAUCASIAN	Philo	1	USA
CDISCPL0101	01-701-1133	DM	1133	2012-10-28	2013-04-29	701	81	YEARS	F	CAUCASIAN	Xan_La	1	USA
CDISCPL0101	01-701-1148	DM	1148	2013-05-20	2013-08-20	701	75	YEARS	F	CAUCASIAN	Xan_La	1	USA

2. SE													
Study Identifier	Unique Subj.	Reported Ter.	Start Date/Term	Sequence No.	Domain Abbr.	Sponsor-Def.	Standardized Med.	Body System	Severity/Inten.	Causality	Outcome of	Break	USA
CDISCPL0101	01-701-1023	VERBATUM...	2012-08-07	1.00	AE	E08	ERYTHEMA	SKIN AND SU...	MILD	N	POSSIBLE	NOT RESOLV...	N
CDISCPL0101	01-701-1023	VERBATUM...	2012-08-07	4.00	AE	E08	ERYTHEMA	SKIN AND SU...	MILD	N	POSSIBLE	NOT RESOLV...	N
CDISCPL0101	01-701-1023	VERBATUM...	2012-08-07	2.00	AE	E09	ERYTHEMA	SKIN AND SU...	MODERATE	N	POSSIBLE	NOT RESOLV...	N
CDISCPL0101	01-701-1023	VERBATUM...	2012-08-28	3.00	AE	E10	ERYTHEMA...	CARDIOVASC...	MILD	N	POSSIBLE	NOT RESOLV...	N

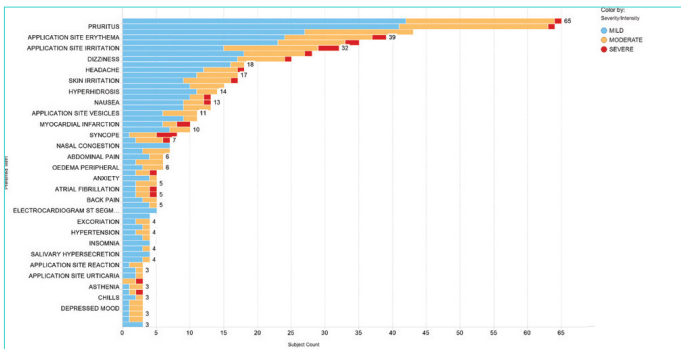
  

3. CM														
Study Identifier	Unique Subj.	Reported No.	Start Date/Term	Domain Abbr.	Sequence No.	Sponsor-Def.	Standardized Med.	Indication	Medication C.	Dose per Ad.	Dose Units	Dosing Presc.	Route	USA
CDISCPL0101	01-701-1023	ASPIRIN	2006	CM	3.00	1	ACETYSALU...	NEUROUS SY...	325.00	Miligram	AS NEEDED	ORAL	ORAL	
CDISCPL0101	01-701-1023	ASPIRIN	2006	CM	4.00	1	ACETYSALU...	NEUROUS SY...	325.00	Miligram	AS NEEDED	ORAL	ORAL	
CDISCPL0101	01-701-1023	ASPIRIN	2006	CM	9.00	1	ACETYSALU...	NEUROUS SY...	325.00	Miligram	AS NEEDED	ORAL	ORAL	
CDISCPL0101	01-701-1023	ASPIRIN	2006	CM	12.00	1	ACETYSALU...	NEUROUS SY...	325.00	Miligram	AS NEEDED	ORAL	ORAL	
CDISCPL0101	01-701-1023	ASPIRIN	2006	CM	15.00	1	ACETYSALU...	NEUROUS SY...	325.00	Miligram	AS NEEDED	ORAL	ORAL	
CDISCPL0101	01-701-1023	ASPIRIN	2006	CM	18.00	1	ACETYSALU...	NEUROUS SY...	325.00	Miligram	AS NEEDED	ORAL	ORAL	
CDISCPL0101	01-701-1023	ASPIRIN	2006	CM	21.00	1	ACETYSALU...	NEUROUS SY...	325.00	Miligram	AS NEEDED	ORAL	ORAL	
CDISCPL0101	01-701-1023	ASPIRIN	2006	CM	1.00	2	UNCODED	UNCODED	1.00	Telespoon	AS NEEDED	ORAL	ORAL	
CDISCPL0101	01-701-1023	MLFLATA	2002	CM	4.00	2	UNCODED	UNCODED	1.00	Telespoon	AS NEEDED	ORAL	ORAL	
CDISCPL0101	01-701-1023	MLFLATA	2002	CM	7.00	2	UNCODED	UNCODED	1.00	Telespoon	AS NEEDED	ORAL	ORAL	
CDISCPL0101	01-701-1023	MLFLATA	2002	CM	10.00	2	UNCODED	UNCODED	1.00	Telespoon	AS NEEDED	ORAL	ORAL	
CDISCPL0101	01-701-1023	MLFLATA	2002	CM	13.00	2	UNCODED	UNCODED	1.00	Telespoon	AS NEEDED	ORAL	ORAL	
CDISCPL0101	01-701-1023	MLFLATA	2002	CM	16.00	2	UNCODED	UNCODED	1.00	Telespoon	AS NEEDED	ORAL	ORAL	
CDISCPL0101	01-701-1023	MLFLATA	2002	CM	19.00	2	UNCODED	UNCODED	1.00	Telespoon	AS NEEDED	ORAL	ORAL	

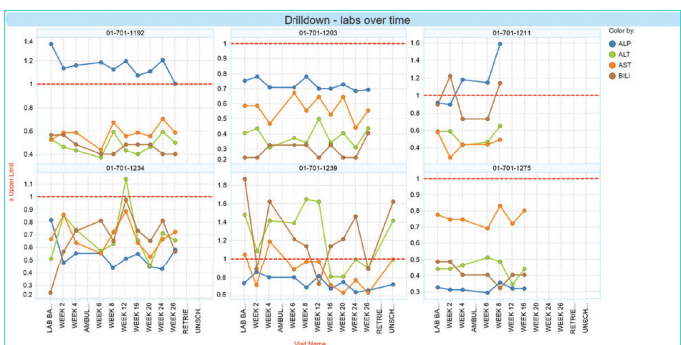
  

4. ECG														
Study Identifier	Unique Subj.	Visit Number	Domain Abbr.	Visit Name	Planned Start	Start Date/Term	End Date/Term	ECG	Baseline QTC	QTC Change L	Sex	Planned Arm	End C	USA
CDISCPL0101	01-701-1023	1.00	SV	SCREENING 1	-7.00	2012-07-22	2012-07-22	404.00	404.00	0.00	M	Philo	2207	
CDISCPL0101	01-701-1023	2.00	SV	SCREENING 2	-7.00	2012-08-03	2012-08-03	402.00	28.00	M	Philo	0508		
CDISCPL0101	01-701-1023	3.00	SV	BASLINE	1.00	2012-08-05	2012-08-05	406.00	52.00	M	Philo	0508		
CDISCPL0101	01-701-1023	4.00	SV	AMBILEDG	13.00	2012-08-06	2012-08-06	420.00	14.00	M	Philo	0508		
CDISCPL0101	01-701-1023	5.00	SV	WEEK 2	14.00	2012-08-27	2012-08-27	412.00	6.00	M	Philo	2708		
CDISCPL0101	01-701-1023	6.00	SV	WEEK 4	29.00	2012-09-02	2012-09-02	422.00	10.00	M	Philo	0309		
CDISCPL0101	01-701-1023	7.00	SV	UNCHEDULED	2013-01-18	2013-01-18	411.00	1.00	Telespoon	AS NEEDED	ORAL	1902		
CDISCPL0101	01-701-1023	10.00	SV	AE FOLLOWUP	2013-02-18	2013-02-18	419.00	15.00	M	Philo	1902			

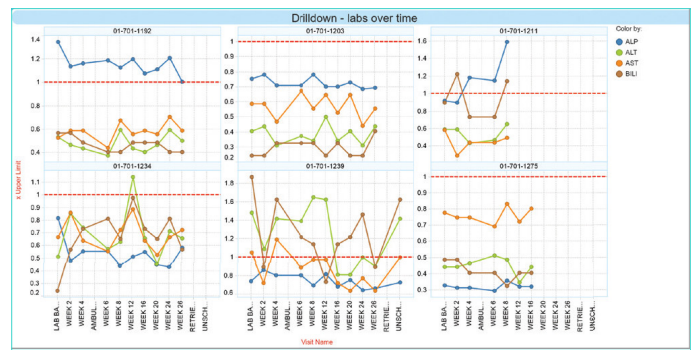
Tabular Patient Profile - A line listing view of user-specified set of data tables (Represent up to 4 domains).



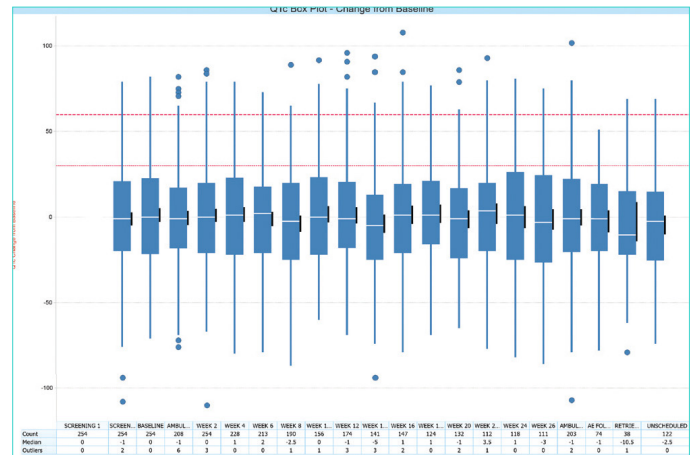
Adverse event attributes (Serious events, severity/intensity, causality, and body organ class by study arm).



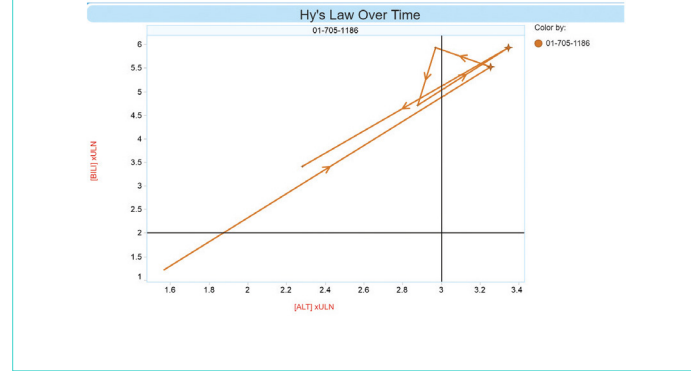
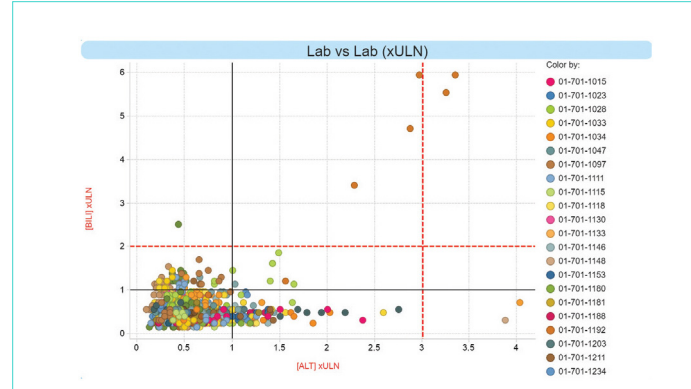
Lab test trends for all subjects or specific cohort(s) and changes from baseline over Time.



Subject attrition trends by time and reported term by study arm.



Review changes in the baseline measurement of QTc - Identify outlier subjects.



Overview of drug-induced liver toxicity (Evaluation based on Hy's Law).

## Appendix:

A comprehensive list of the visual analytics included in Revvity's CDR Discovery solution.

These visual analytics are fully customizable and can be extended to include additional use cases such as PK/PD, safety, therapeutic and study specific plots (E.g. Swimmer, Waterfall, and spider plots for Oncology) and biomarkers.

### Visualizations Available

#### Overview

Navigation and Homepage.

An overview of the distribution of gender, age, and race by study arm.

Visualizations of subject attrition trends by time and reported term by study arm.

Graphical Patient Profile table based on dynamically selected events and study subjects.

A tabular Patient Profile – a line listing view of user-specified set of data tables that can represent up to 4 domains.

#### Adverse Event

An overview of adverse events and adverse event attributes (e.g. type of adverse event, serious events, severity/intensity, causality, and body or organ class by study arm).

Patient-level data and adverse event attributes in a line listing view.

AE incidence trends over time and identification of abnormal trends and/or outliers.

Compare different study arms to establish relative risk of Adverse Events by body system/organ class or dictionary derived term.

\*\* Most useful for Phase 3 trials, Requires statistics server\*\*

#### Labs

Representation of lab results by category (high, low, normal abnormal) for lab test/examination.

Visual distribution for all labs and range category color.

#### Labs continued

Representation of lab test values change from baseline over time showing the magnitude of the change for each test outliers to be identified and the distribution of results.

Visualizations for easy lab outlier identification.

Reading trends by lab test/examination name and their evaluation of dynamic query of a specific group of interest.

Lab trends to identify subjects with abnormal values for selected lab tests.

Trends of selected lab tests with reference lines for the normal ranges and the display of their related adverse events and concomitant medication.

Overview of subjects with drug-induced liver toxicity (evaluation based on Hy's Law) and their progress over time.

Lab test/examination test trends of the total or specific subgroups of patients during the study.

#### Vitals and QTc

Vital Sign distributions.

A comprehensive view of trends of selected vital signs in relative terms and the QTc changes.

Review of changes in the baseline measurement of QTc and easily identify outlier subjects.

#### Site specific

Site-based count-check on overall analysis – A distribution of subjects of interest across sites in relative terms.

Overview of data entry issues specific to a certain site or vital sign.