

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 1: Population level view.



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: Graphical Patient Prole 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).

Study Identifier	Unique Subje	Domain Abbr	Subject ident	Subject Refer	Subject Refer	Study Site Id	Age	Age Units	Sex	Race	Planned Arm	Description o	Cour
CDISCPILOT01	01-701-1015	DM	1015	2014-01-02	2014-07-02	701	63	YEARS	F	HISPANIC (M	Pbo	Placebo	USA
CDISCPILOT01	01-701-1023	DM	1023	2012-08-05	2012-09-02	701	64	YEARS	м	HISPANIC (M	Pbo	Placebo	USA
CDISCPILOT01	01-701-1028	DM	1028	2013-07-19	2014-01-14	701	71	YEARS	M	CAUCASIAN	Xan_Hi	Xanomeline Hi	USA
CDISCPILOT01	01-701-1033	DM	1033	2014-03-18	2014-04-14	701	74	YEARS	M	CAUCASIAN	Xan_Lo	Xanomeline L	USA
CDISCPILOT01	01-701-1034	DM	1034	2014-07-01	2014-12-30	701	77	YEARS	F	CAUCASIAN	Xan_Hi	Xanomeline Hi	USA
CDISCPILOT01	01-701-1047	DM	1047	2013-02-12	2013-03-29	701	85	YEARS	F	CAUCASIAN	Pbo	Placebo	USA
CDISCPILOT01	01-701-1097	DM	1097	2014-01-01	2014-07-09	701	65	YEARS	M	CAUCASIAN	Xan_Lo	Xanomeline L	USA
CDISCPILOT01	01-701-1111	DM	1111	2012-09-07	2012-09-17	701	81	YEARS	F	CAUCASIAN	Xan_Lo	Xanomeline L	USA
CDISCPILOT01	01-701-1115	DM	1115	2012-11-30	2013-01-23	701	84	YEARS	M	CAUCASIAN	Xan_Lo	Xanomeline L	USA
CDISCPILOT01	01-701-1118	DM	1118	2014-03-12	2014-09-09	701	52	YEARS	M	CAUCASIAN	Pbo	Placebo	USA
CDISCPILOT01	01-701-1130	DM	1130	2014-02-15	2014-08-16	701	84	YEARS	M	CAUCASIAN	Pbo	Placebo	USA
CDISCPILOT01	01-701-1133	DM	1133	2012-10-28	2013-04-29	701	81	YEARS	F	CAUCASIAN	Xan_Hi	Xanomeline HL	USA
CDISCPILOT01	01-701-1146	DM	1146	2013-05-20	2013-06-30	701	75	YEARS	F	CAUCASIAN	Xan_Hi	Xanomeline Hi	USA
								2. ae					
Study Identifier	Unique Subje	Reported Ter	Start Date/Ti	Sequence Nu	Domain Abbr	Sponsor-Def	Dictionary.De	Body.System	Severitylinte	Serious Event	Causality	Outcome of	Invol
CDISCPILOT01	01-701-1023	VERBATIM_0	2012-08-07	1.00	AE	E08	ERYTHEMA	SKIN AND SU	MLD	N	POSSIBLE	NOT RESOLV	N
CDISCPILOT01	01-701-1023	VERBATIM 0	2012-08-07	4.00	AE	E08	ERYTHEMA	SKIN AND SU	MLD	N	POSSIBLE	RESOLVED	N
CDISCPILOT01	01-701-1023	VERBATIM 1	2012-08-07	2.00	AE	E09	ERYTHEMA	SION AND SU	MODERATE	N	PROBABLE	NOT RESOLV	N
CDISCPILOT01	01-701-1023	VERBATIM_1	2012-08-26	3.00	AE	E10	ATRIOVENTR	CARDIAC DIS	MLD	N	POSSIBLE	NOT RESOLV	N
													_
	Malaria Britala	Barrar d Ma		B	A			3. cm			B	Barrier Barrer	
Study Identifier	Unique Subje	Reported Na	Start Date/Ti	Domain Abbr	Sequence Nu	Sponsor-Defl	Standardized	Indication	Medication Cl	Dose per Ad	Dose Units	Dosing Frequ	Rou
CDISCPILOT01	01-701-1023	ASPIRIN	2006	CM	3.00	1	ACETYLSALI		NERVOUS SY	325.00	Miligram	AS NEEDED	ORA
CDISCPILOT01	01-701-1023		2006	CM		1	ACETYLSALJ		NERVOUS SY	325.00	Miligram	AS NEEDED	ORA
CDISCPILOT01	01-701-1023	ASPIRN	2006	CM	9.00	1	ACETYLSALI		NERVOUS SY	325.00		AS NEEDED	
CDISCPILOT01	01-701-1023			CM		1	ACETYLSALI		NERVOUS SY		Miligram	AS NEEDED	ORA
CDISCPILOT01	01-701-1023	ASPIRN	2006		15.00	1	ACETYLSALI		NERVOUS SY	325.00	Miligram	AS NEEDED	ORA
CDISCPILOT01	01-701-1023	ASPIRIN	2006	CM	18.00	1	ACETYLSALI		NERVOUS SY	325.00	Miligram	AS NEEDED	ORA
CDISCPILOT01	01-701-1023	ASPIRIN	2006	CM	21.00	1	ACETYLSALI		NERVOUS SY	325.00	Miligram	AS NEEDED	ORA
CDISCPILOT01	01-701-1023	MYLANTA.	2002	CM	1.00	2	UNCODED		UNCODED	1.00	Tablespoon	AS NEEDED	ORA
CDISCPILOT01	01-701-1023	MYLANTA	2002	CM	4.00	2	UNCODED		UNCODED	1.00	Tablespoon	AS NEEDED	ORA
CDISCPILOT01	01-701-1023	MYLANTA.	2002	CM	7.00	2	UNCODED		UNCODED	1.00	Tablespoon	AS NEEDED	ORA
CDISCPILOT01	01-701-1023	MYLANTA.	2002	CM	10.00	2	UNCODED		UNCODED	1.00	Tablespoon	AS NEEDED	ORA
CDISCPILOT01	01-701-1023	MYLANTA	2002	CM	13.00	2	UNCODED		UNCODED	1.00	Tablespoon	AS NEEDED	ORA
CDISCPILOT01	01-701-1023	MYLANTA	2002	CM	16.00	2	UNCODED		UNCODED	1.00	Tablespoon	AS NEEDED	ORA
CDISCPILOT01	01-701-1023	MPLANTA	2002	CM	19.00	2	UNCODED		UNCODED	1.00	Tablespoon	AS NEEDED	ORA
								. ecg					
Study Identifier CDISCPILOT01	Unique Subje 01-701-1023	Visit Number	Domain Abbr	Visit Name SCREENING 1	Planned Stud	Start Date/Ti 2012-07-22	End Date/Tim 2012-07-22	etc 404.00	Baseline QTc 404.00	QTc Change f 0.00	Sex	Planned Arm Pbo	End 22/01
CDISCPILOT01 CDISCPILOT01	01-701-1023	2.00	SV SV	SCREENING 2	-7.00	2012-07-22 2012-08-03	2012-07-22 2012-08-03	404.00	404.00	28.00	M	Pbo Pbo	03/08
CDISCPILOT01	01-701-1023	2.00	SV SV	BASELINE	-1.00		2012-08-03	432.00		28.00	M	Pbo	050
CDISCPILOT01	01-701-1023	3.50	SV	AMBUL ECG	13.00	2012-08-05 2012-08-26	2012-08-26	436.00		16.00	M	Pbo	260
											M	Pho	250
CDISCPILOT01	01-701-1023	4.00	SV SV	WEEK 2 WEEK 4	14.00	2012-08-27 2012-09-02	2012-08-27 2012-09-02	412.00		8.00	M	Pbo	
CDISCPILOT01		5.00			28.00			422.00					02/0
			SV	UNSCHEDULED		2013-02-18	2013-02-18			7.00	M	Poo	18/0
CDISCPILOT01 CDISCPILOT01	01-701-1023 01-701-1023	101.00		AE FOLLOW-UP		2013-02-18	2013-02-18	419.00		15.00	M	Pbo	18/02

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.

As an optional extra 'Review and track the status of your line listings with our Revvity Signals Line Listing Review '- a Spotfire® add-in

Revvity Signals Software, Inc 940 Winter Street | Waltham, MA 02451 USA P: (800) 762-4000 or (+1) 203-925-4602 revvitysignals.com/company/contact



Copyright ©, Revvity, Inc. All rights reserved. Revvity[™] is a registered trademark of Revvity, Inc. All other trademarks are the property of their respective owners.