DISCOVERY SOLUTION

Revvity Clinical Data Review: Discovery solution

revvity signals

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).

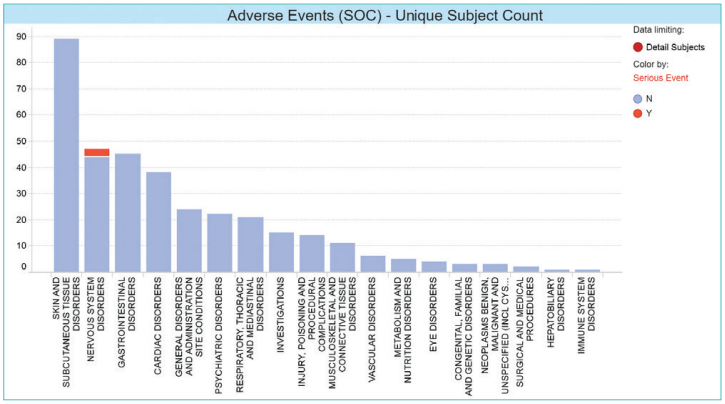


Figure 1: *Population level view.*

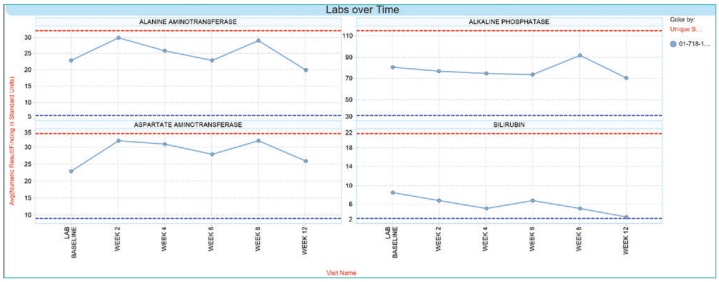


Figure 2: *Subject level view.*

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

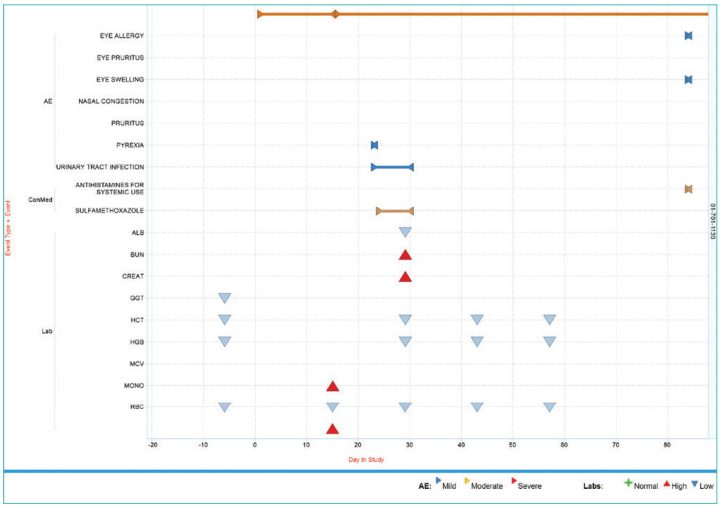
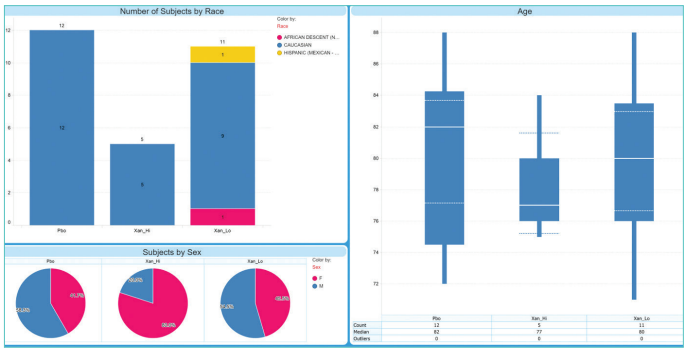
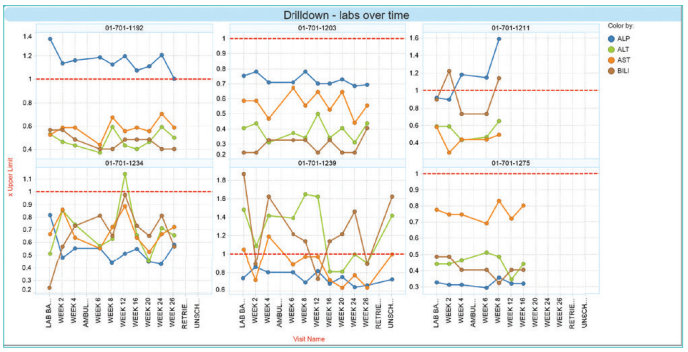


Figure 1: *Graphical Patient Prole based on dynamically selected events and study subjects*

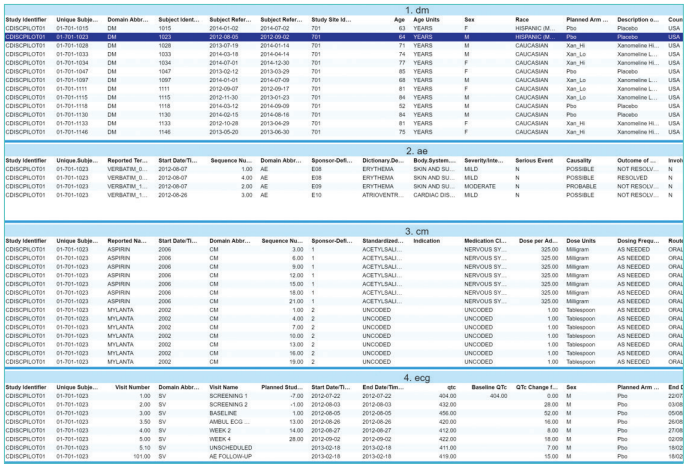
Below are some examples of the visual analytics included in Revvity's CDR Discovery solution:



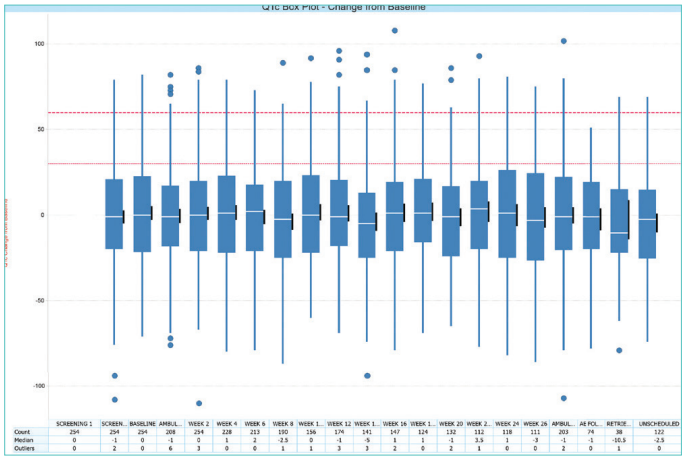
Demographic information (Distribution of gender, age and race by study arm).



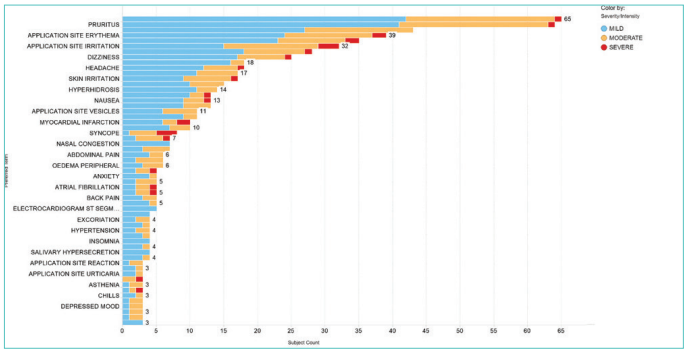
Subject attrition trends by time and reported term by study arm.



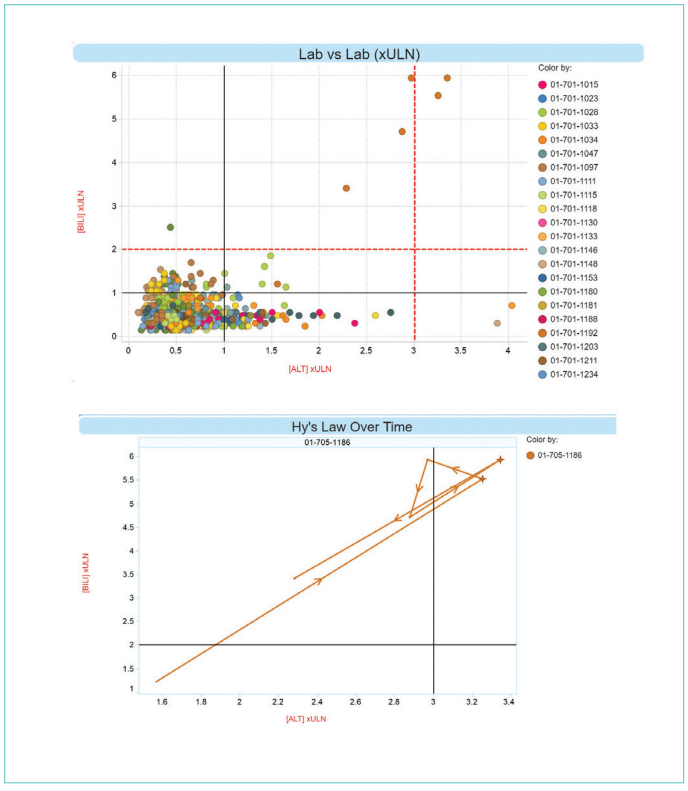
Tabular Patient Profile - A line listing view of user-specified set of data tables (Represent up to 4 domains).

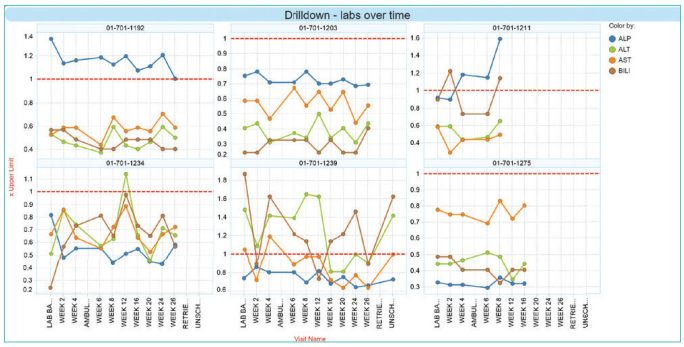


Review changes in the baseline measurement of QTc - Identify outlier subjects.



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.

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

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revvity signals