Revvity Clinical Data Review: Workflow solution

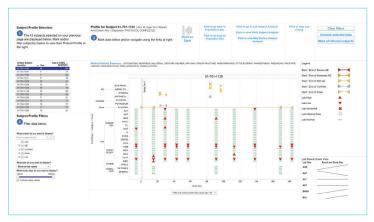




Powered by TIBCO Spotfire®, Revvity's Clinical Data Review (CDR) Workflow solution is a guided workflow aimed at medical reviewers or less technical users that want to be guided through an entire process in a step-bystep manner (similar to a medical data review plan).

The workflow is configurable to domains of interest to your use case and is designed to take you through a step-by-step guided workflow.

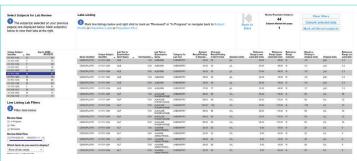
Below is an example of how a medical monitor may use the guided workflow to oversee their safety domains.



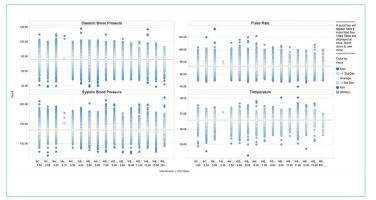
Step 3: Drill down into a specific subject's profile.



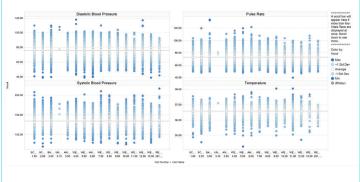
Step 1: Medical Monitors select a review workflow (E.g. Labs).



Step 4: Line listings for the selected subject.



Step 2: Explore data at the population level and identify outliers.



Step 5: Review and track the status of your line listings with our Revvity Signals Line Listing Review' – a Spotfire add-in.

Standard review workflows include:

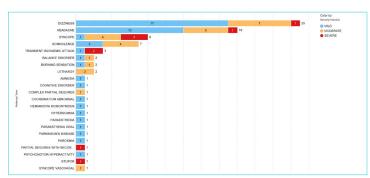
Adverse Events (AE), Labs, Medical History, Vital Signs, Concomitant Medications, Dosing, Disposition, AE Code Review, Concomitant Medications Code Review, and Medical History Code Review.

A comprehensive List of Analytics by workflow and review tier (Population, Subject, and Line Listing).

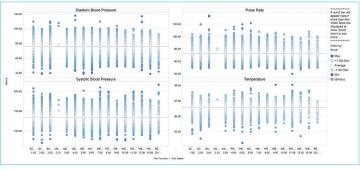
#	Domain	Population Page	Subject Page	Optional Subject Page	Listing
1	AE	Population Adverse Event	Subject Profile	Subject Lab / Vitals / Med History	AE Listing
2	AE Code Review	N/A	N/A	N/A	AE Code Review Listing
3	Con Med	Population Con Med	Subject Profile	Subject Lab / Vitals / Med History	Con Med Listing
4	CM Code Review	N/A	N/A	N/A	Con Med Code Review Listing
5	Medical History	Population Medical History	Subject Profile	Subject Lab / Vitals / Med History	Medical History Listing
6	MH Code Review	N/A	N/A	N/A	Medical History Code Review Listing
7	Labs	Population Lab / DILI	Subject Profile	Subject Lab / Vitals / Med History	Lab Listing
8	Vitals	Population Vitals	Subject Profile	Subject Lab / Vitals / Med History	Vitals Listing
9	Dosing	Population Dosing	Subject Profile	Subject Lab / Vitals / Med History	Dosing Listing Page
10	Disposition	Population Disposition	Subject Profile	Subject Lab / Vitals / Med History	Disposition Listing

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.

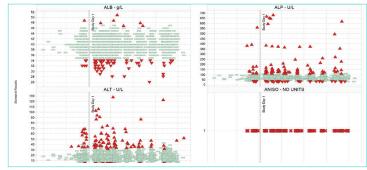
Below are some examples of Population view examples in Revvity's CDR Workflow solution:



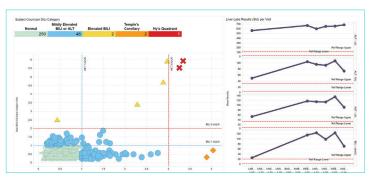
Population view of Adverse Events.



Population view of Vitals.



Population view of all lab results over time.



Population view of Drug Induced Liver Injury (DILI).

