

Taking full advantage of the SEND data potential

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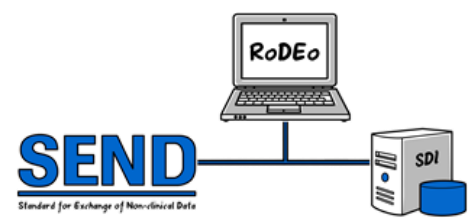
1 – Introduction

Establishing robust processes for SEND data package preparation for regulatory submissions to FDA present great challenges for the Industry, but created the opportunity of having digitized, machine readable, highly standardized study data for search, exploration, comparison across studies and analysis. In this poster, we present our current experiences in utilizing SEND data for three main business cases:

- 1) Improving efficiency of study monitoring with access to “real time” data for ongoing studies. For this purpose, we developed a fully automated workflow covering data acquisition, transfer and database upload.
- 2) Simultaneous review of [audited] draft reports with accompanying complete SEND data packages. Efficient report review and reconciliation while verifying the fitness, consistency, completeness and accuracy of the SEND data.
- 3) Cross-study analysis to facilitate data interpretation and gaining insights across individual studies or submission package(s).

The three use cases are supported by a single User Interface dubbed RoDEo.

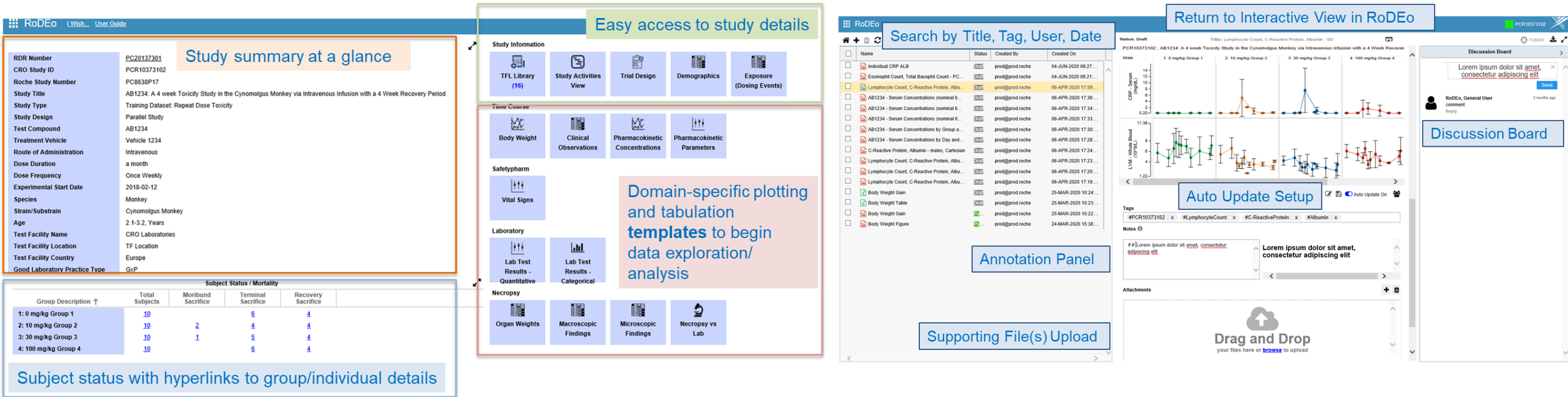
2 Safety Data Integration (SDI) Database & RoDEo Tool



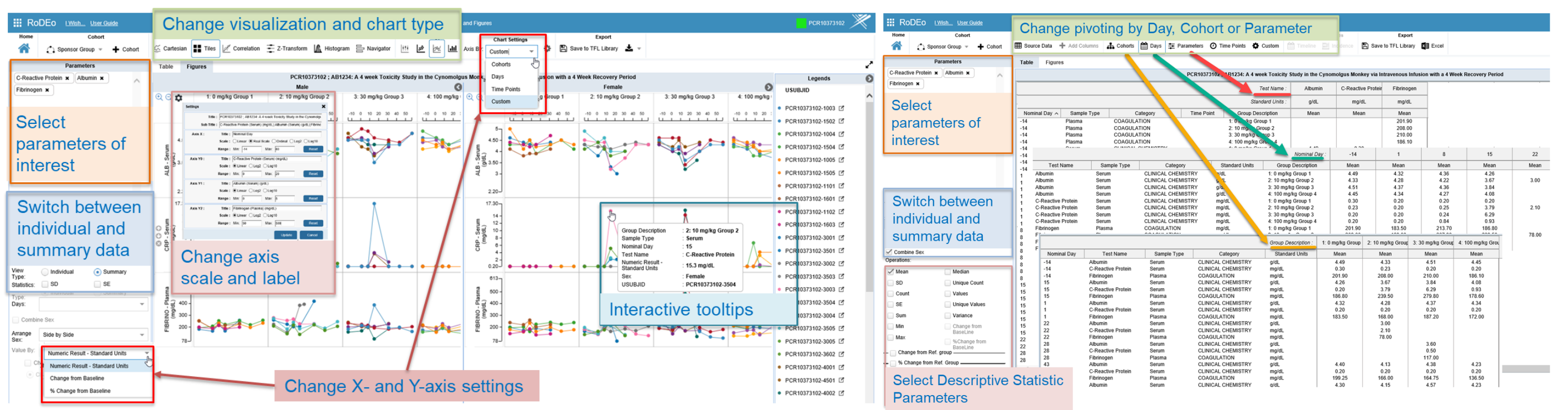
The Safety Data Integration (**SDI**) database holds data from a large number of non-clinical studies performed in-house or at CROs, including recent studies in SEND format and legacy studies not in SEND format. All data is mapped to Universal Data Model (**UDM**) containing harmonized, invariant terminology and units across studies. Data in SDI can be searched, accessed and extracted using different user interfaces (UIs). **RoDEo** (**R**oche **D**ata **E**xploration) is a new UI specifically developed for visualization of data in SEND format with user-friendly and intuitive graphical and tabulation capabilities as illustrated in the figures below.

RoDEo Navigation Panel

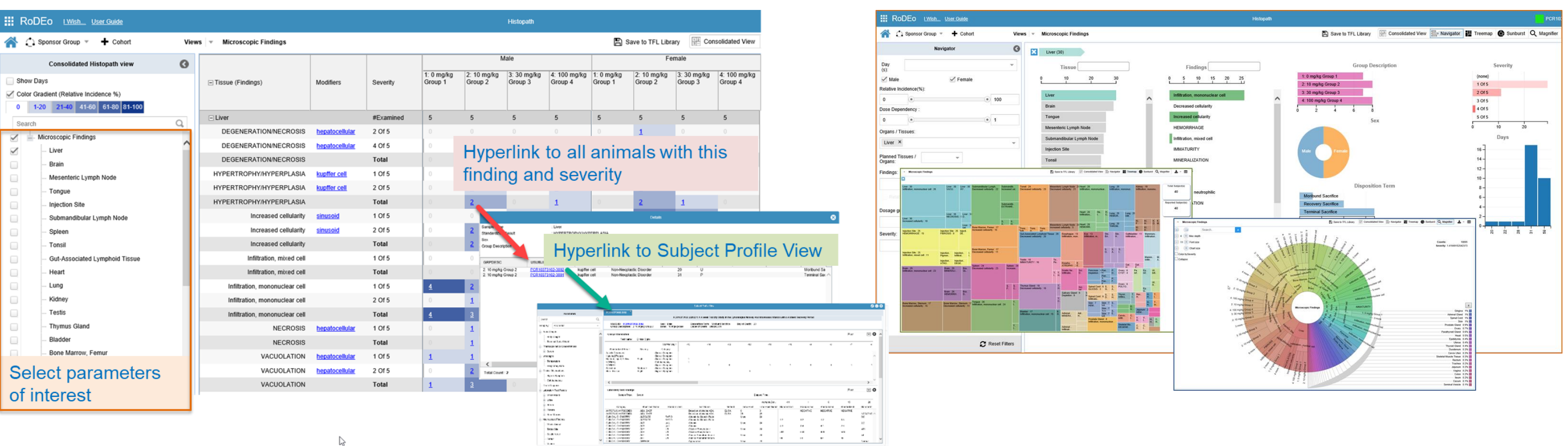
Team Space Features



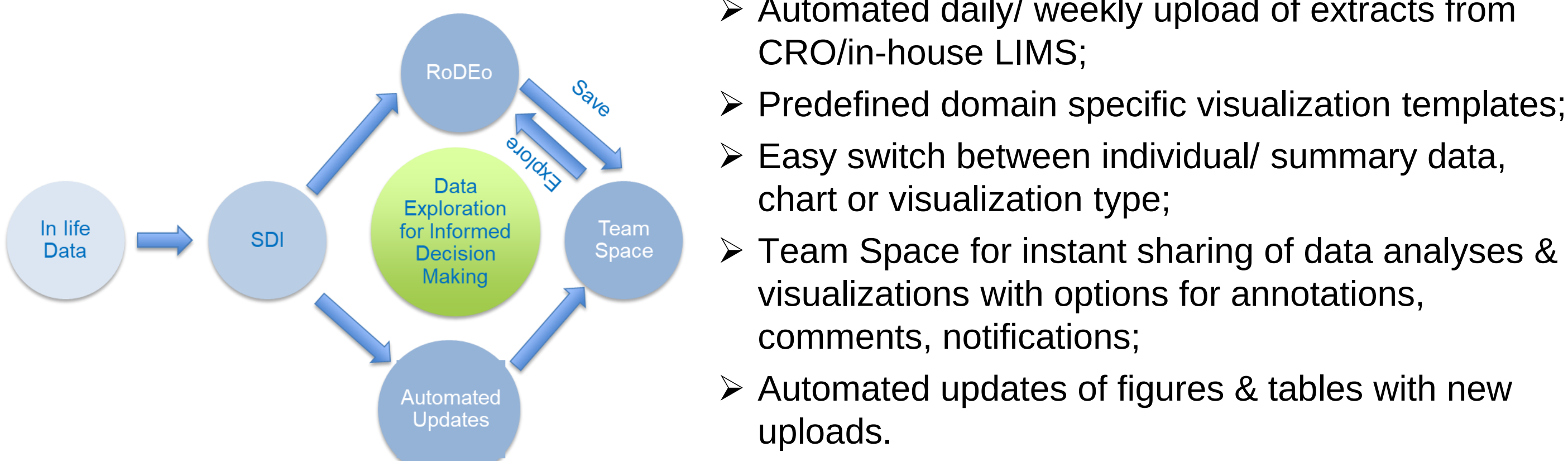
Highlights of Numeric Data Visualizations



Highlights of Categorical Data Visualizations

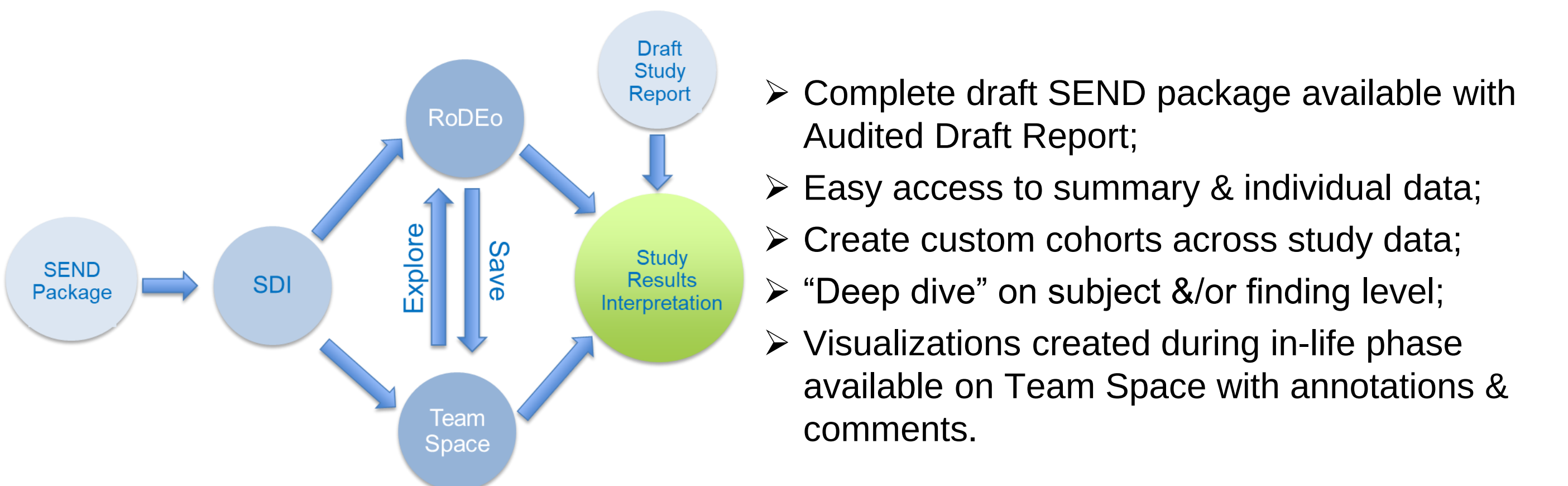


3 – “Real time” data for efficient study monitoring and informed decision making



? Clinical signs of toxicity; Dose-dependency of onset &/or severity of findings; Decisions on changes in study design (dose adjustment or holiday); Dose selection for fixed-dose phase based on MTD.

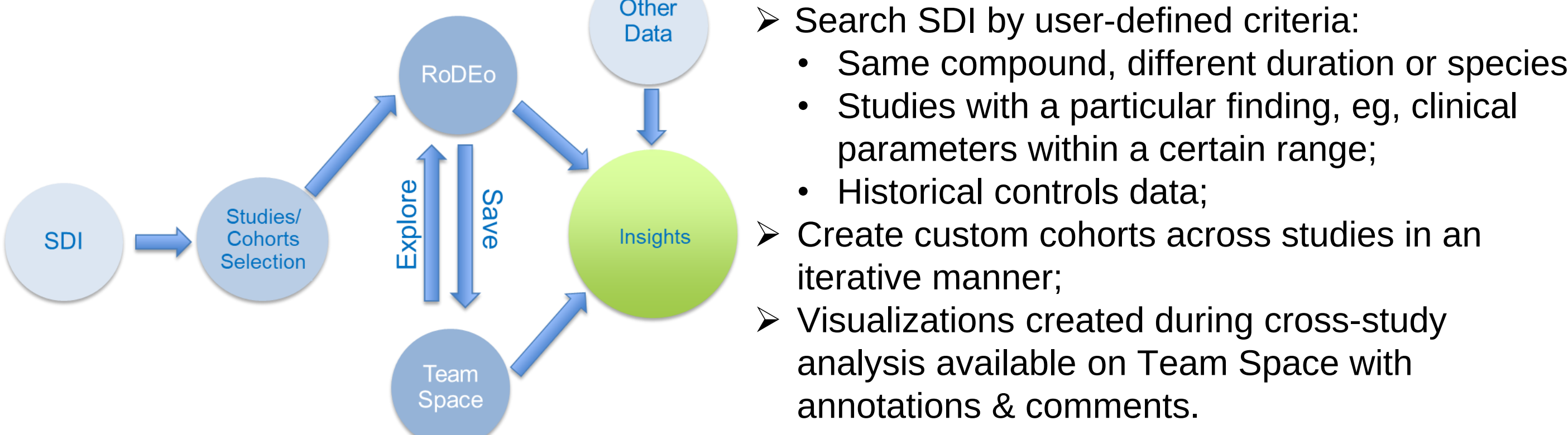
4 – Facilitation of draft report review



? Are the findings, interpretations, conclusions in draft report supported by the raw data? Are there new observations, interpretation, conclusions from SEND data analysis not reflected in the draft report? Exploration of findings-driven cohorts including quantitative or qualitative findings.

? Is the SEND dataset fit for purpose – can the data be plotted & tabulated as expected? Are there any discrepancies between the SEND data & results presented in the draft report? If yes, **reconciliation** process is initiated.

5 – Cross study analysis



? **Data exploration:** Are specific findings related to a compound consistent across studies? Is their appearance dose & time related? Do they correlated with other findings? Are there species &/or gender differences?
Hypothesis testing: Do data from the cross-study analysis support or reject given hypothesis for compound/ dose-related findings; causality?

6 – Conclusions

In the examples provided in this poster, a custom UI developed specifically for SEND data exploration and analysis was successfully employed to explore and analyze SEND-like or non-SEND data sets (extracts from LIMS and legacy studies, respectively) by mapping to an UDM and applying harmonized terminology. This allows efficient data utilization from ongoing studies, along with cross study analysis for ongoing and completed studies, regardless of their SEND status.

Acknowledgments

SDI is supported by Xbion 3.1 software developed by PointCross Life Sciences Inc. RoDEo is an enhanced and customized UI developed in close collaboration between Roche and PointCross based on the Immersive Graphic Object (IGO) application. This collaboration was sponsored by internal Roche pREDi grants: SDI Enhancements (2019) and Non Clinical Study Data FAIRification (2020). The authors would like to acknowledge the ideas, feedback and contribution of many colleagues at both companies during the development, testing and employment of RoDEo and SDI enhancements.