Democratizing visual analytics in clinical development

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Safe Harbor

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- *Any unreleased products, services or features referenced herein are not currently available and may not be delivered on time or at all. Customers who purchase PerkinElmer informatics applications should make their purchase decisions based upon products, features, and services that are currently available.*

Goals and Approaches

Bring data analysis to the business functions

- Protecting safety of patients
- Reducing time to submission

- Streamlining data aggregation
- Simplifying analytics workflow

Democratizing visual analytics in clinical development

protecting the safety of patients and reducing time to submission

- Advent of self-service business analytics tools
- Democratizing data analytics amongst the business users
- Demand for user friendly interactive visual analytics tools

- Addressing specific needs of clinical development
- Analyst users outside of biostatistics or data management

Business needs

more than static listings and graphs

- Business needs go beyond
  - simplification of processes
  - streamlining of data management

- Instream review and safety analysis needs
  - analysis-ready
  - clean
  - reliable data
  - in real-time

Guided Interactive Data Analysis

Quickly assess trial safety - Limit trial duration

- Clinical physicians
- Medical reviewers
- Clinical pharmacologists

- Guided data assessment and analytics process
- Interactive persona-based workflows
- Freedom to ask and answer arising questions

Limited Efficiency in obtaining insights from clinical data

growing complexity / evolving regulatory landscape

- Study teams struggle to provision data
  - from multiple systems
  - in various formats

- Inability to leverage historical content for
  - safety signal detection
  - cross-trial analyses

What are You up Against?

New data sources, increasing complexity

- Persona-based workflows for specific use cases
- Rapid cloud and mobile adoption
- Increase in data sources/system & trial complexity

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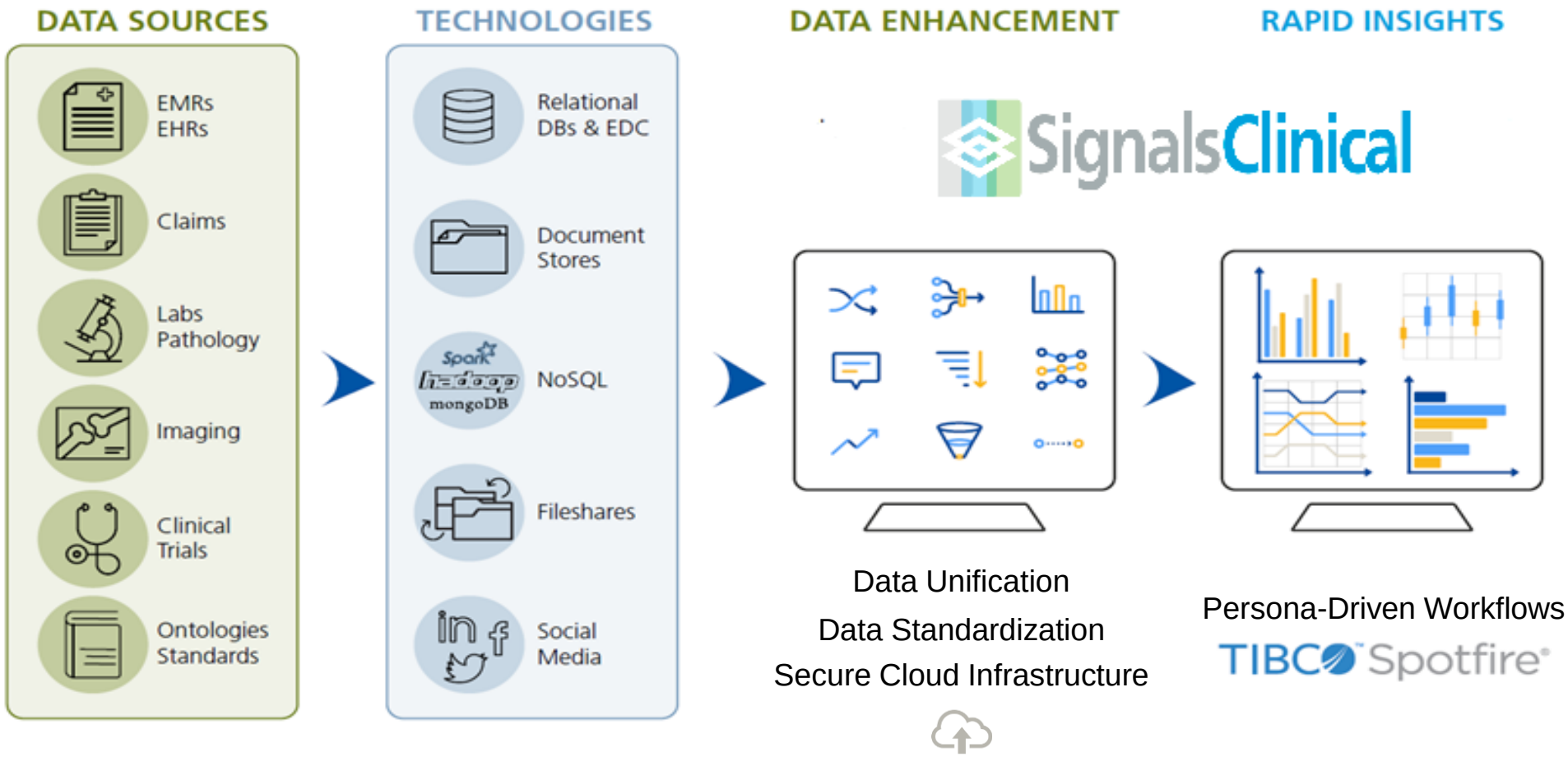
Getting clinical development teams to the right data insights, faster



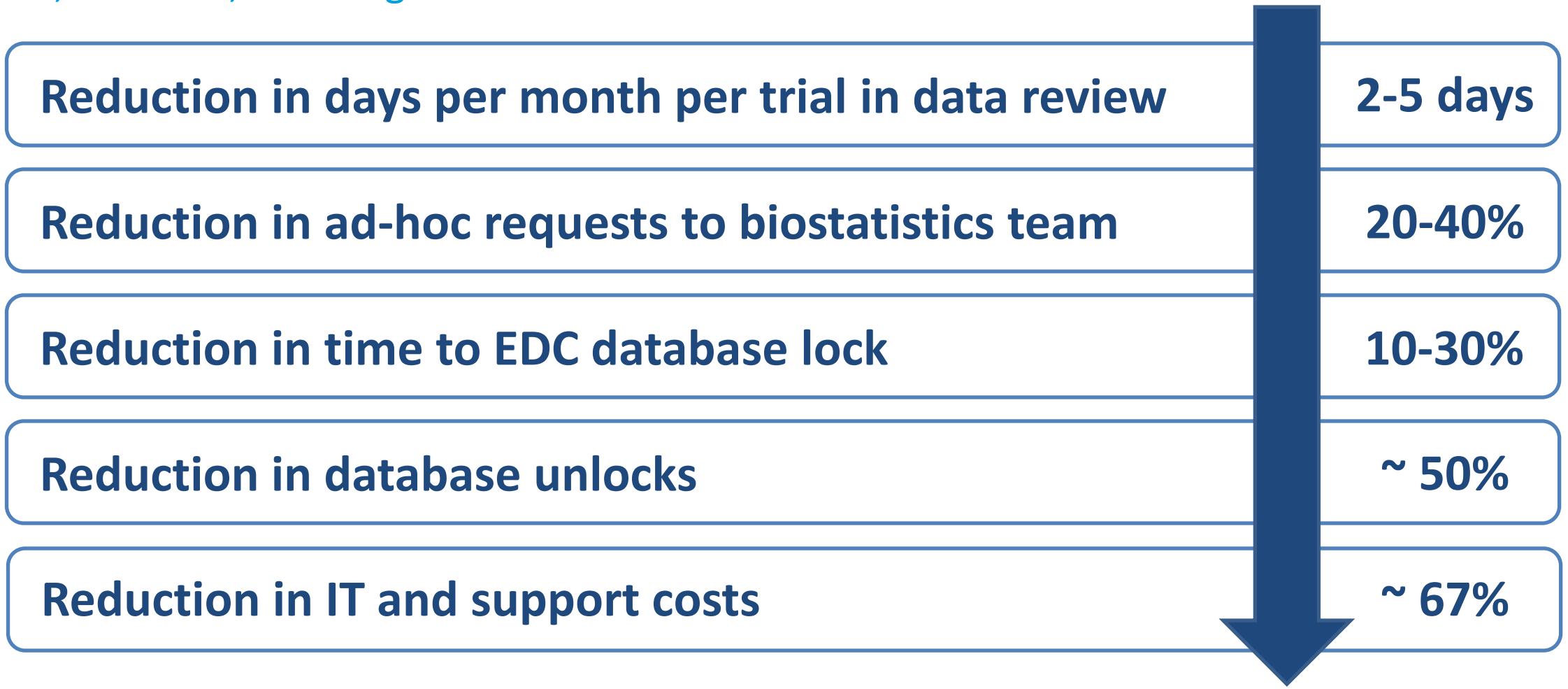
"What is the greatest challenge you face with Medical Review today?"*

- **37% risk of missing a safety signal**
- 31% slow and labor-intensive decision making
- 31% costly infrastructure support

**** Source: Informal poll question from Feb 7th 2017 webinar with 100 attendees: Propel Medical Review with Guided Analytics***

Average Metrics across Multiple Projects

Small, Medium, and Large Pharma



The PerkinElmer Clinical Data Review Solution

Driving value through key benefits, without compromising patient safety

Get submission-ready faster

Reduce the likelihood of a rejected submission or market withdrawal

Optimize data provisioning, aggregation, and review

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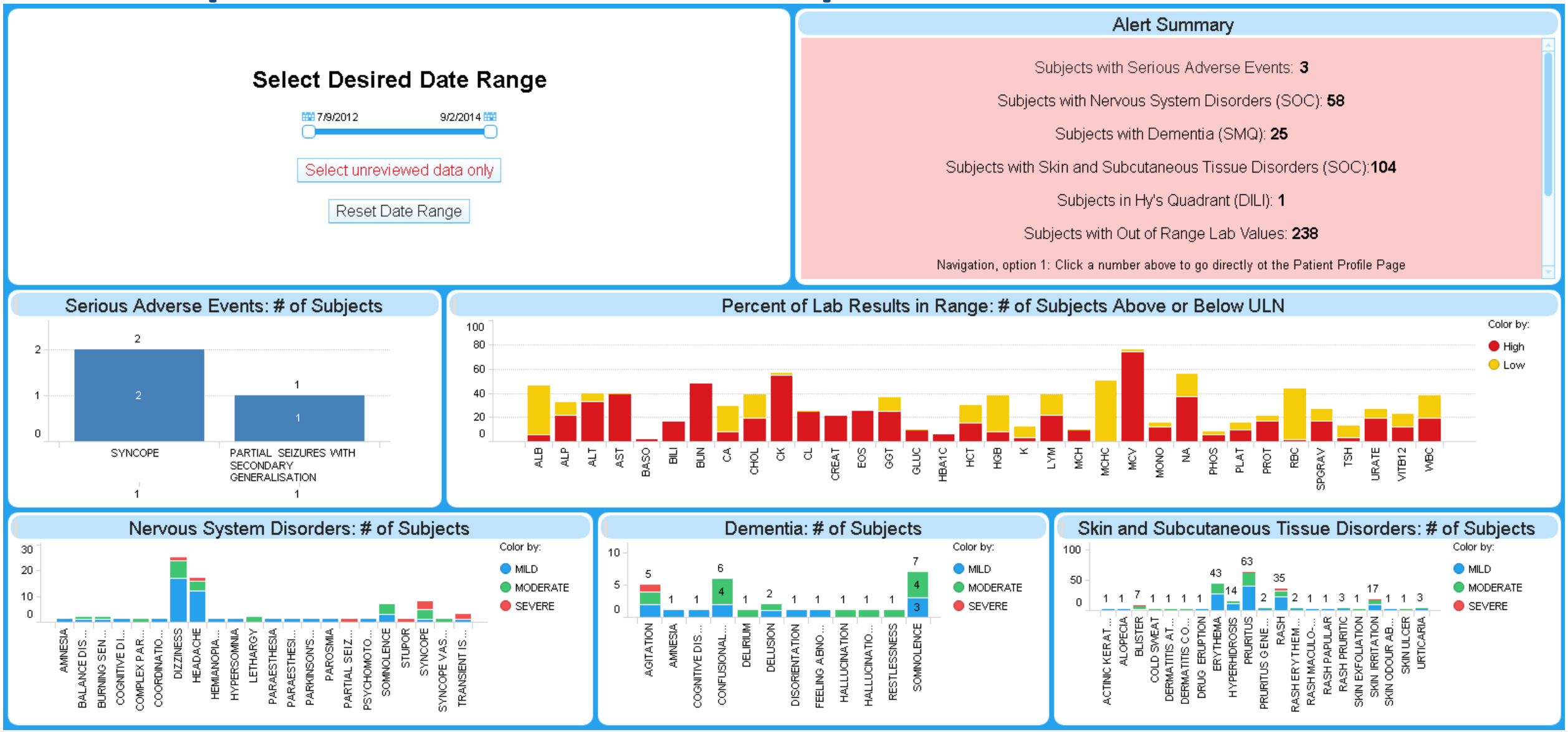
Get Submission Ready Faster

Actionable insights, streamlined workflow

- ✓ Curated analysis visualizations
- ✓ Personalized landing page
- ✓ Configurable alerts on specific cohorts of subjects
- ✓ Configurable line listing review

Example: Alerts Workflow in Spotfire



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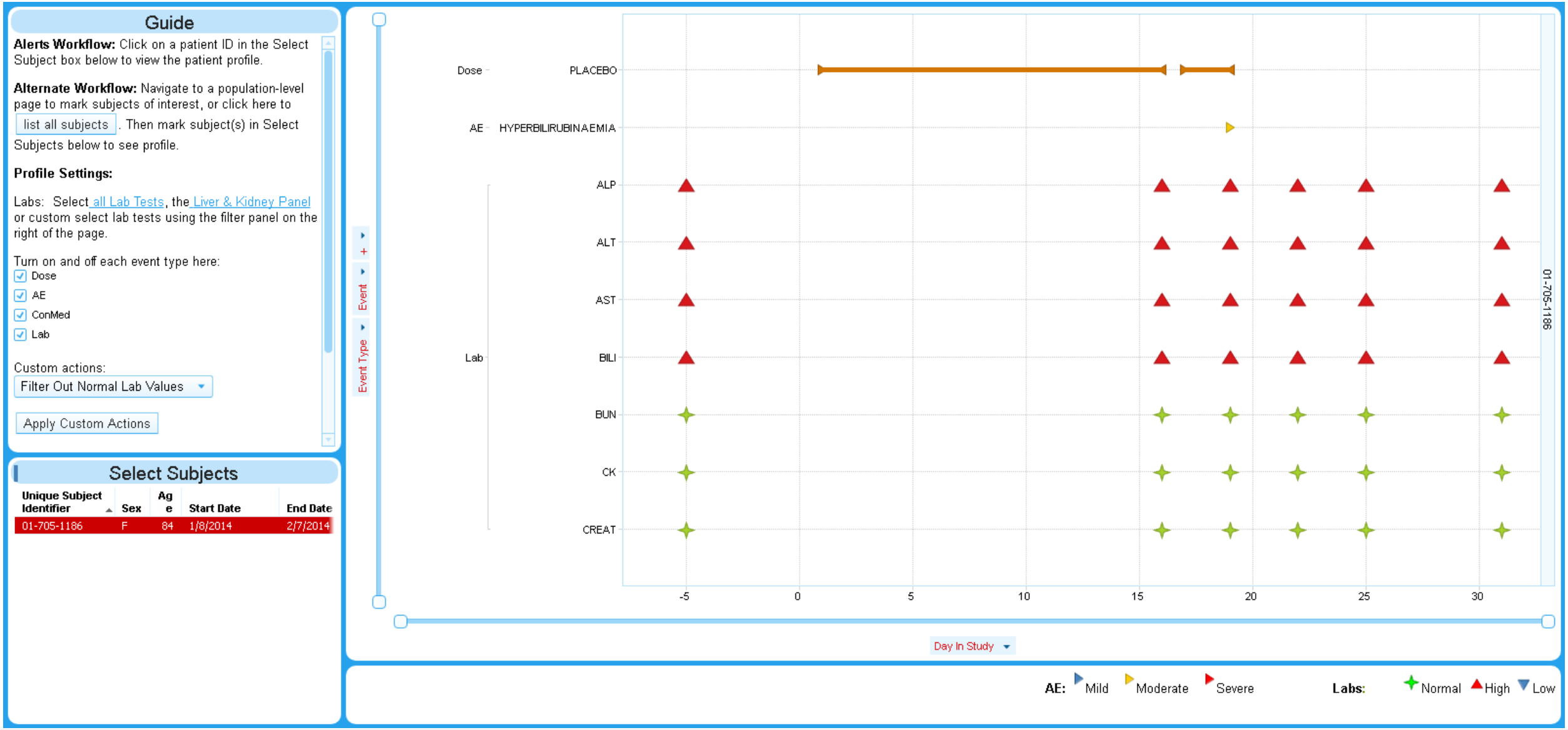
Example: Patient Profile



Reduce the Likelihood of a Rejected Submission or Market Withdrawal

Reduce risk without introducing delays

- ✓ Visibility across CDISC domains
- ✓ Study setup console for study setup and administration
- ✓ Medical Review status reporting and tracking

Example: Interactive Hy's Law

Guide

Alerts Workflow: Click on a patient ID in the Select Subject box below to view the patient profile.

Alternate Workflow:

1. Show All Subjects

2. **Custom Subset Analysis:** Select a Subject Subsets by marking in visualizaition and graphs. This will populate the Select Subjects Below Window. You can then navigate to the Profile page or other pages

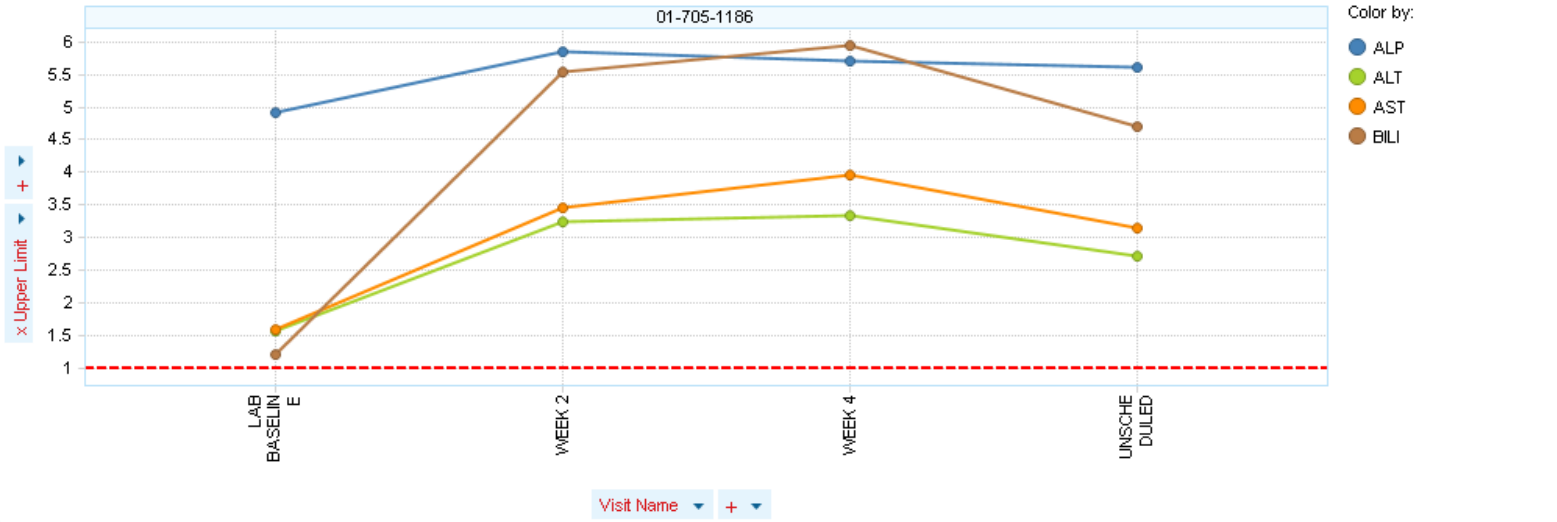
Go to Page:

Alerts | Profile | Vitals | Site Breakdown

DILI Category

DILI Category	No. of Subjects
Hy's Quadrant	1
Temple's Corollary	2
Elevated BILI	2
Mildly Elevated BILI or ALT	48
(Empty)	252

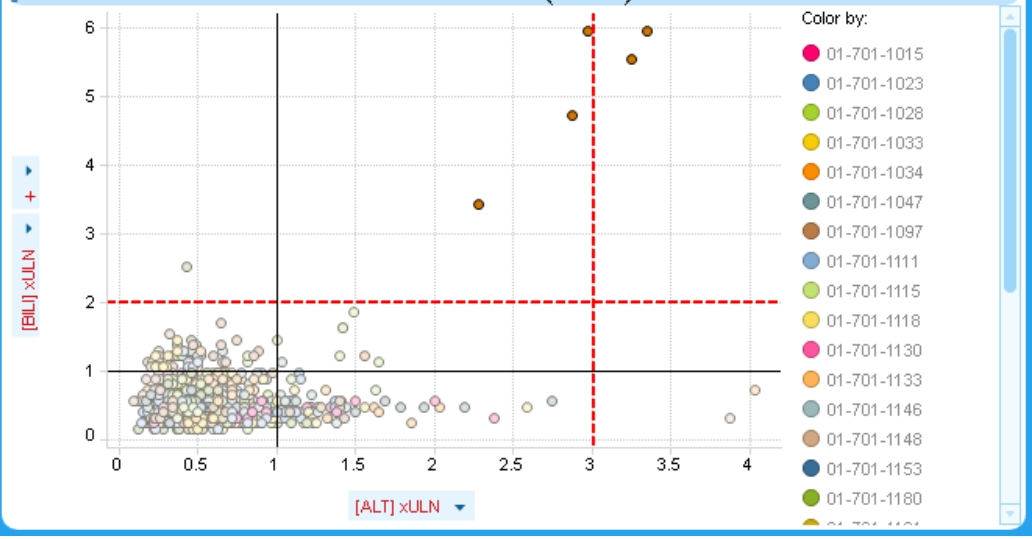
Drilldown - labs over time



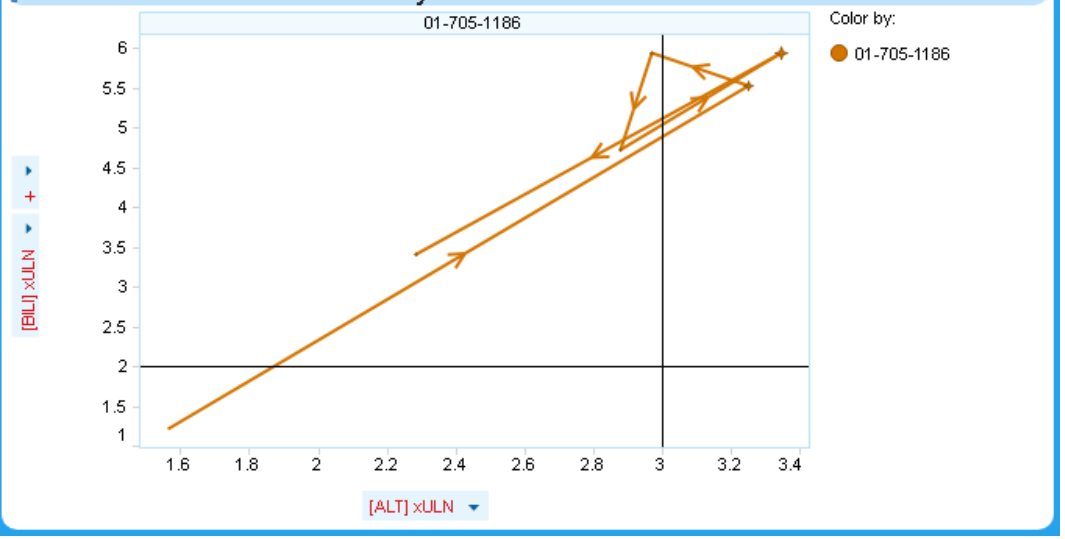
Select Subjects Below

Unique Subject Identifier	S...	Age
01-705-1186	F	84

Lab vs Lab (xULN)



Hy's Law Over Time



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Optimize Data Provisioning, Aggregation, and Review

Automatically unify and standardize clinical data

- ✓ Single unified data analytics solution from source to visualization to action
- ✓ Secure, regulatory compliant cloud solution
- ✓ Data factory with SDTM data standardization and data persistence

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Example: End User driven Relative Risk calculation

Please make the following selections:

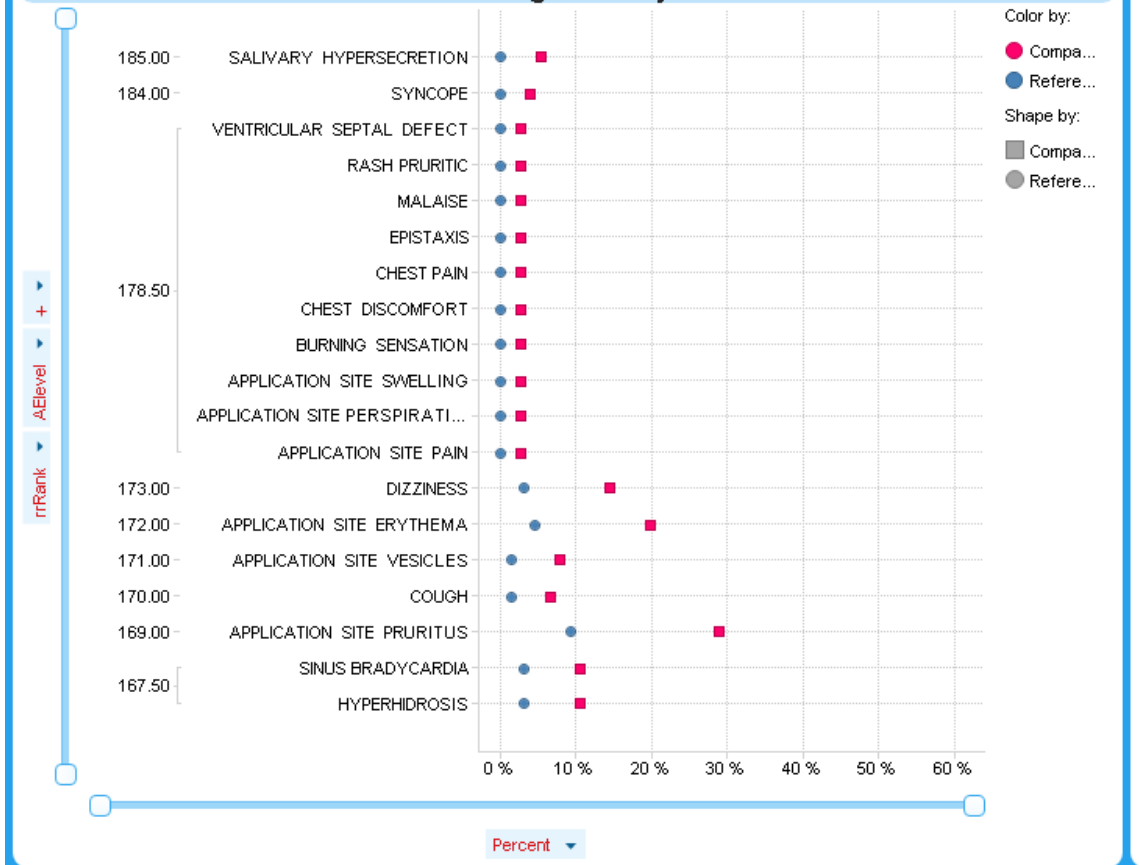
Reference treatment: Pbo Test treatment: Xan_Hi MedDRA Term: Dictionary.Derived.Term

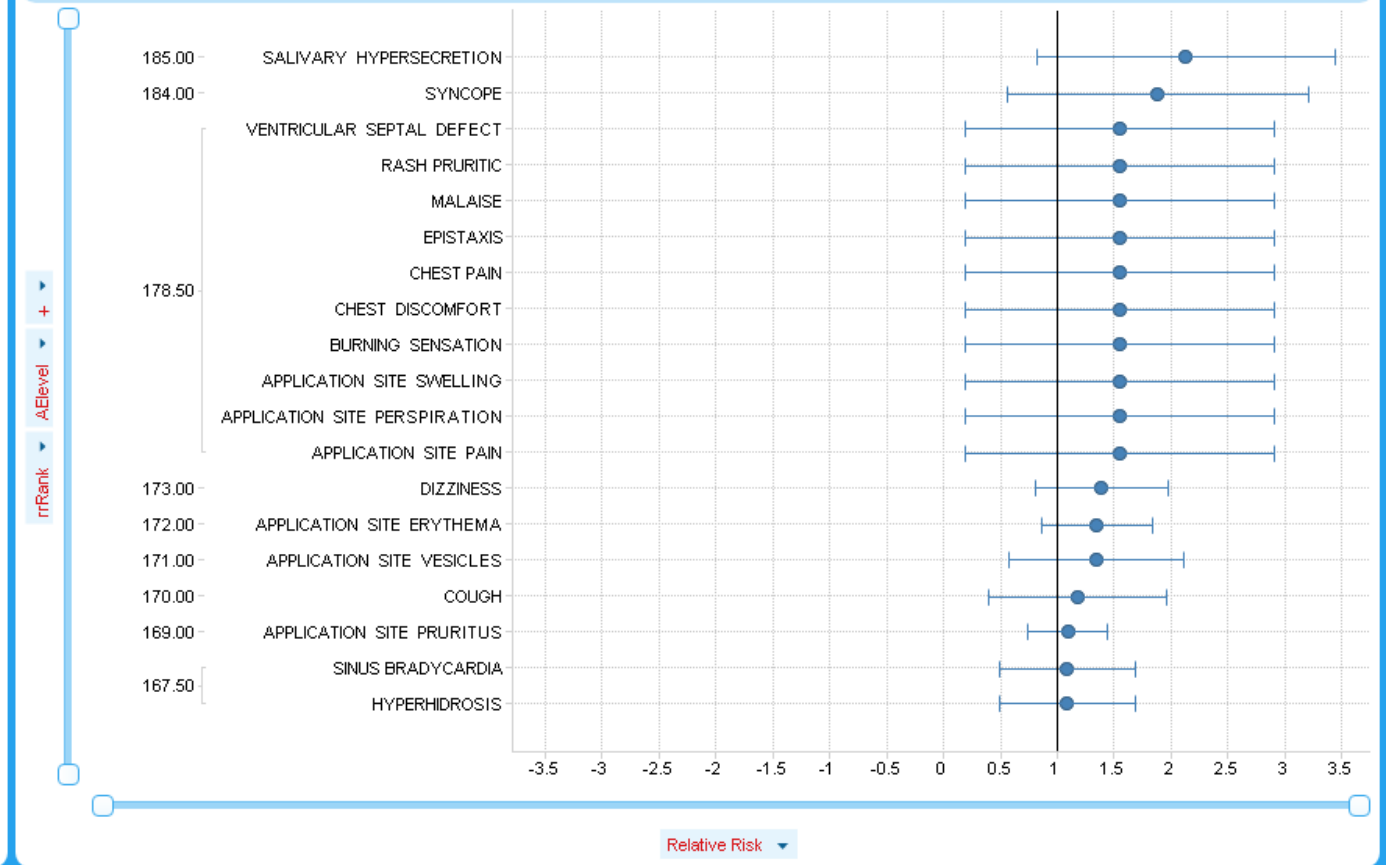
Please adjust Y zoom to line up the same adverse events in both plots by adjusting the RR rank:

148.02 185.00

Relative risk (RR) is the risk of an event relative to exposure. Relative risk is a ratio of the probability of the event occurring in the exposed group versus a non-exposed group (here: between test treatment and reference treatment). Here RR is presented along with the frequency (percentage) of adverse event occurrence using a double dot plot (Amit et al., 2006). In this graph the relative risk is shown in an additional panel to the original dot plot. Adverse events are sorted by the relative risk.

The **Double Dot Plot** displays relative risk (RR) along with the frequency of adverse event occurrence:





How can you remove your greatest obstacles?

Get submission-ready faster by

- making it easier for medical reviewers to spot trends and detect safety signals
- streamlining the decision making process

Reduce the likelihood of a rejected submission or market withdrawal by

- reducing the risk of a missed safety signal
- Maintaining vendor oversight and regulatory compliance

Optimize data provisioning, aggregation, and review by

- **Using a single end-to-end analytics solution**
- **Viewing data unified from multiple sources**

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