

The Right Tool for the Job

Enhancing Risk-Based Monitoring and Data Cleaning

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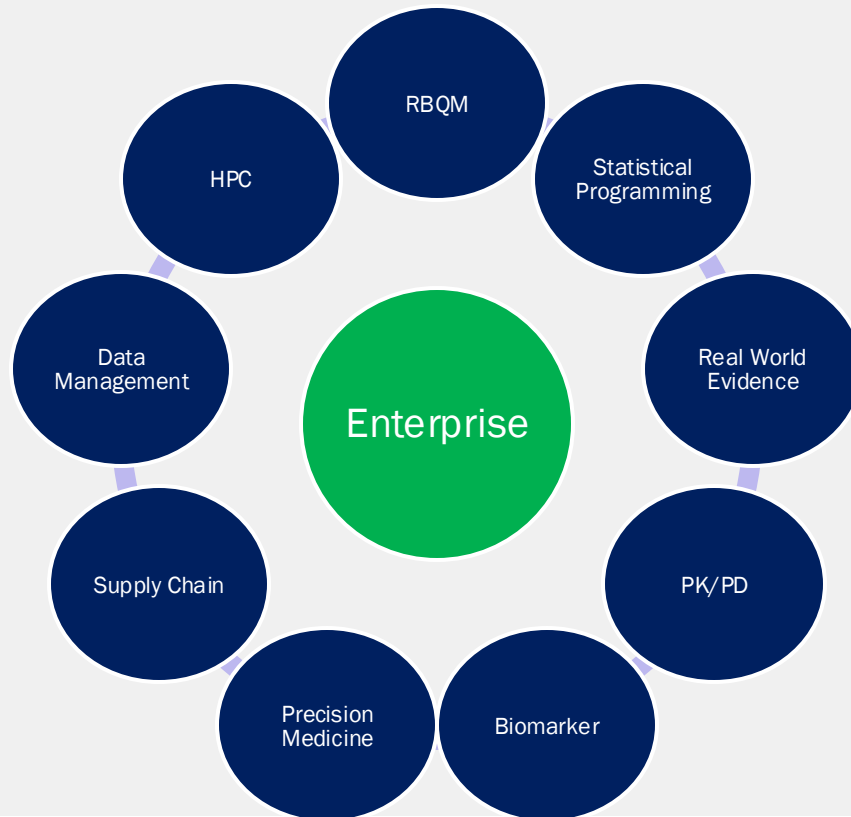
March 17, 2025



Agenda

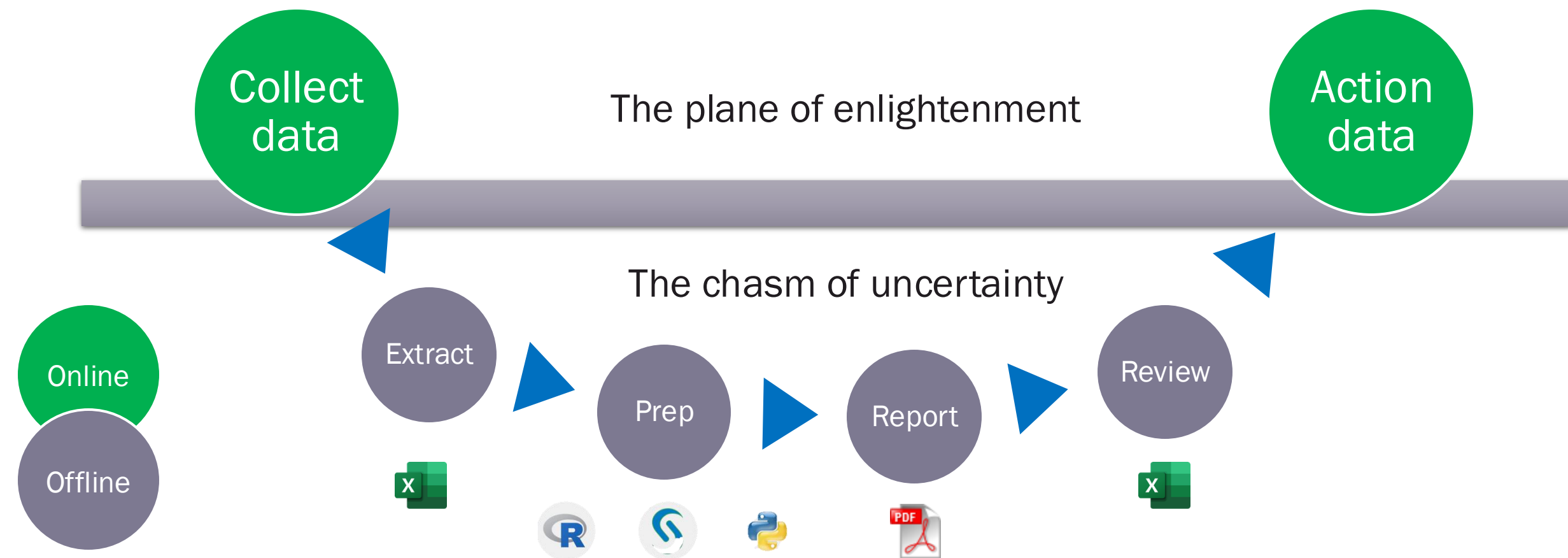
1. Perils of the Old Data Review Paradigm
2. Data Storage and Workbenches: Foundation of Data Quality
3. Analytics Tools: Connected Real-time Insights
4. Integrating the Systems into an Enterprise Solution

Industry trends



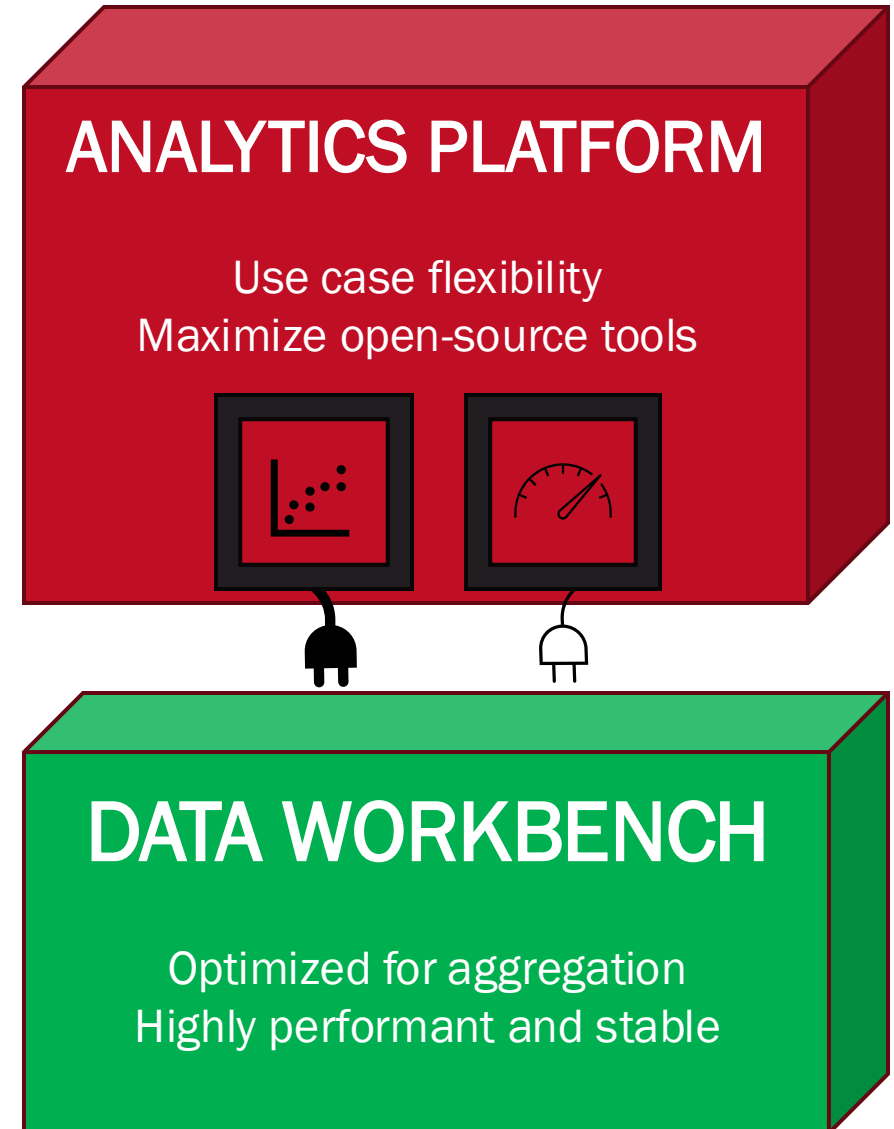
- Shift from function-specific to enterprise-wide data & tech adoption
- Embedded data science teams driving enterprise solutions
- Organizations choosing between internal development or customizing existing products

Offline data review is fraught with delays and quality issues



A data and analytics platform keeps teams online and “in line”

- Data scientists deliver data products, not just reports
- Open source tools allow plug and play use of the right approach for each use case, e.g.
 - novel statistical techniques
 - data mining and sentiment analysis
 - machine learning
- A data workbench serves as a stable foundation on which these tools are built
 - Avoid duplicative data aggregation, reconciliation, and mapping at the analytics layer



Data workbench provides data foundation

Data source
validation against
specification

Cross-source
reconciliation

Automated value-
level data checks

Review tracking

Provide clean,
aggregated data
downstream

Operational
reporting

Analytics platform provides insights and automation

Study Overview

Showing **Red** Sites

16 of 176 sites with at least one red KRI (9.1% of total).
60 of 176 sites with at least one red or amber KRI (34.1% of total).

Site	Red KRIs	Amber KRIs	AE	SAE	PD	IPD	LB	SDSC	TDSC	QRY	OQRY	ODAT	CDAT	SF
28	4	0	✓	✗	✓	✗	✗	✗	✗	✓	✓	✓	✓	✓
173	2	1	✓	✓	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓
43	2	1	✗	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓
75	2	1	✗	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓
83	2	1	✗	✓	✓	✗	✗	✓	✓	✓	✓	✓	✓	✓
161	2	0	✓	✓	✓	✓	✗	✗	✗	✓	✓	✓	✓	✓
114	1	1	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓
186	1	1	✓	✓	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓
20	1	1	✓	✓	✓	✗	---	---	---	✓	---	✓	✓	✗
60	1	1	✓	✓	✓	✓	✗	✗	✓	✓	✓	✓	✓	✓
68	1	1	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✗
78	1	1	✓	✓	✓	✓	---	---	---	✓	✗	✓	✓	✗
145	1	0	✓	✓	✓	✗	---	---	---	---	---	---	✓	✓
171	1	0	✓	✗	✓	✓	✓	---	---	✓	✓	✓	✓	---
32	1	0	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓
62	1	0	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗

Summary by SOC/PT

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS - vial_Playboi

Value 12 (24.4%)
n = 14

Unique Subject Identifier	Actual Treatment	Dictionary Defined Term	Body System or Organ Class
01700-000	Placebo	APPLICATION SITE PRURITUS	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS
01700-000	Placebo	APPLICATION SITE PRURITUS	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS
01700-000	Placebo	APPLICATION SITE PRURITUS	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS
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01700-000	Placebo	APPLICATION SITE PRURITUS	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS

Site- or Country-level Quality Tracking

- Identify quality trends
- Workflow based on KRI threshold

Patient-level Trending and Interactive TLFs

- Data review (con meds, AEs, dosing labs)
- Safety signals (Hy's Law, toxicity criteria)

Automation

- API (Reporting, Audit Trail)
- User Provisioning

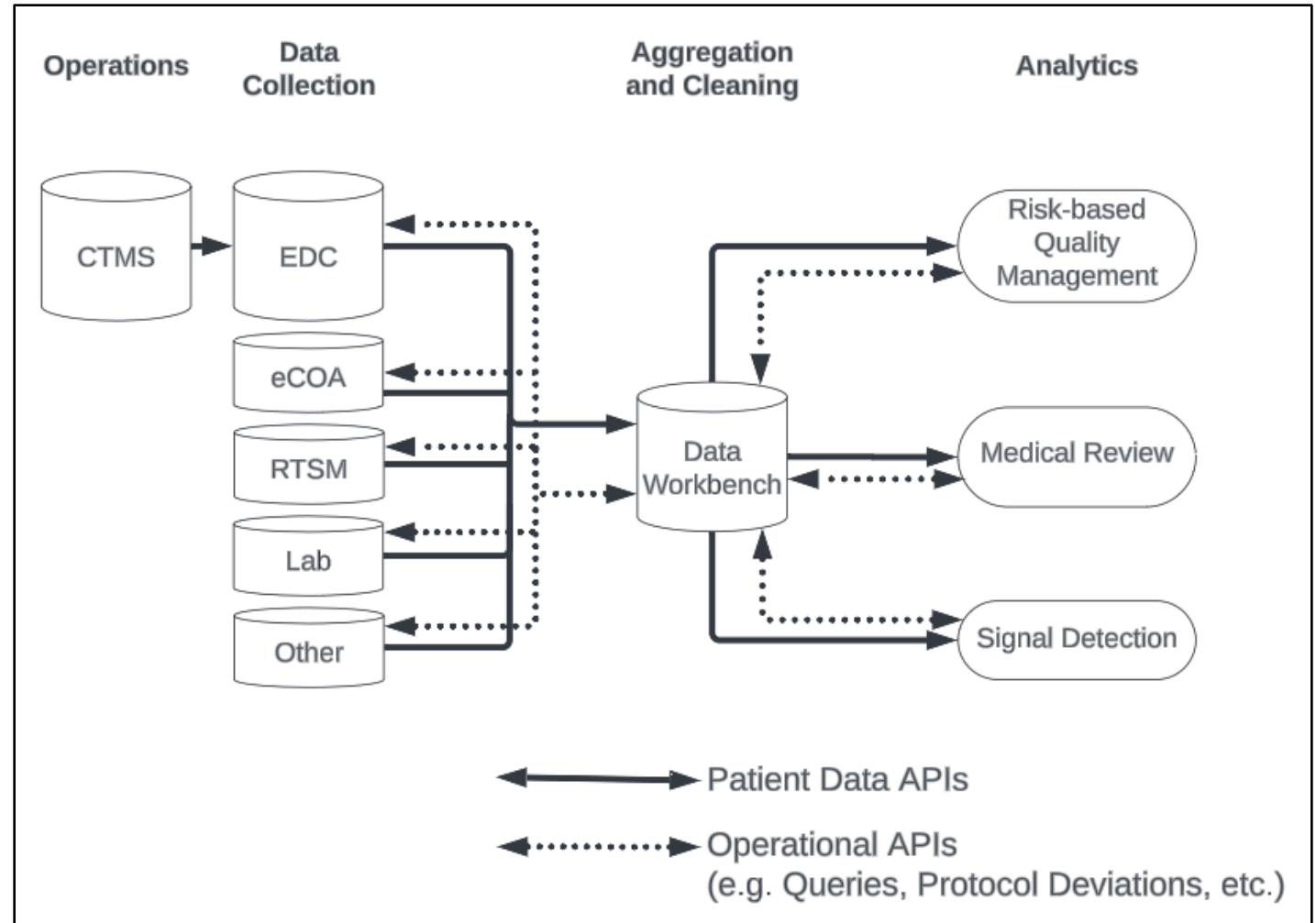
APIs enable GxP compliant workflows and documentation

Avoid middleware

- Data workbench APIs publish data for analytics platform to consume directly
- Intermediary data models slow teams down and reduce system interoperability

Automation-first philosophy

- If action (e.g. query) can be automated, do not produce a report for expert review
- Use APIs to trigger actions or surface action status to reviewers



Change Management Model

Aspect	Commercial Product	Internally Developed Product
Stakeholder Buy-In	Requires justification of cost and fit. Users may resist due to lack of customization.	Stakeholders are involved early, but concerns may arise about technical maturity.
Training and Documentation	Relies on vendor-provided materials, adapted to organizational workflows.	Internal team must create all training and documentation, tailored to specific workflows.
Customization and Flexibility	Limited customization; processes must adapt to product limitations.	Highly flexible; feedback loops may require handling during implementation.
Vendor Dependency	Relies on vendor for updates, support, and troubleshooting.	Depends on internal team, requiring strong collaboration and expertise.
Risk Management	Integration challenges, unforeseen costs, or functionality limitations are key risks.	Delays, development hurdles, or scalability issues are the primary concerns.
Cultural and Behavioral Shift	Adapting to external processes may require significant user mindset changes.	Users may feel ownership, but disputes over design decisions may occur.

Conclusions

1. Enterprise data solutions will require a balance of commercial product and internal development
2. Leveraging product best practices and intended data cleaning usage while augmenting with workbenches for Shiny apps, APIs, and automation
3. Utilize the automation and reporting to empower the functions to be independent of centralized system admin



Questions

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