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Sept. 29 – Oct. 2, 2024 | Boston, MA

SCDM 2024 Annual Conference

Festival of Opportunity

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Information is the oil of the 21st century and analytics is the combustion engine

– Peter Sondergaard

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Efficiency ≠ Efficacy: How Does Technology Help Us to Identify When & What to Improve?

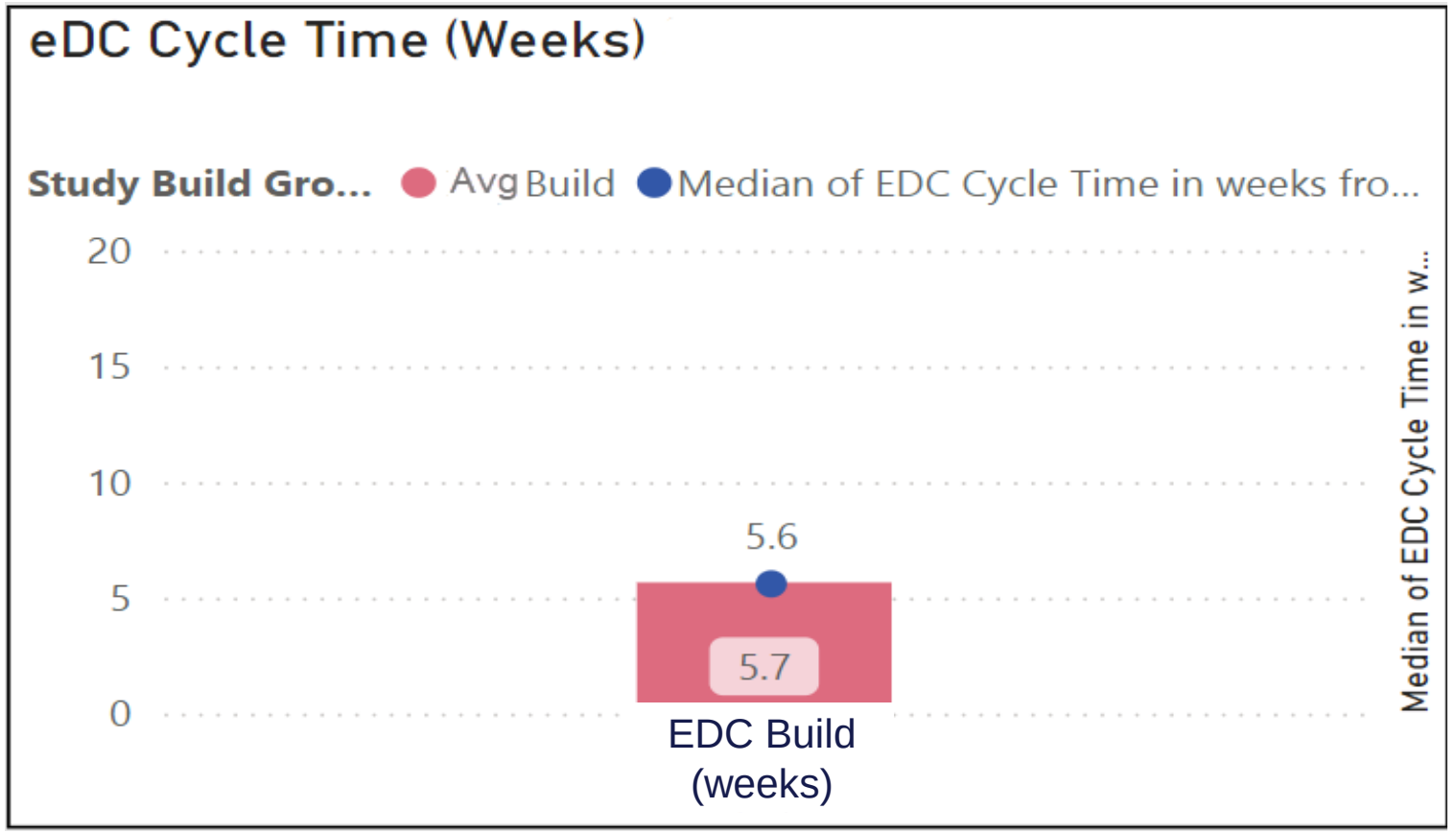
Jenn Showalter · Pavel Burmenko

Automation Enables Major Efficiencies in DM

50% shorter study build times

3-5 minutes saved per automated query

real-time purpose-built tools working together near real-time



Efficiency ≠ Efficacy

- Were EDC forms built well?
- Are sites getting important queries leading to better quality data?
- Are the right systems being used for the right task?

Operational Analytics as a DM Efficacy Tool

Defining Analytics:

The discovery, interpretation, and communication of meaningful patterns in data

Applying Analytics:

- What has been done and how?
- Should it be done the same way in the future?
- Choose metrics that drive change

Know When to Look

Decide on the cadence for review of each metric

Study startup, study conduct, study closeout

One-time, quarterly, monthly, weekly, daily?

One-time Analytics: Standards and Re-use

Study “grade”: Can build parameters communicate quality?

Build cycle time: What does speed tell us about performance?

Is unnecessary data being collected but not reported?

Queries per form: Was the design a problem?

Recurring Analytics: Driving Behaviors

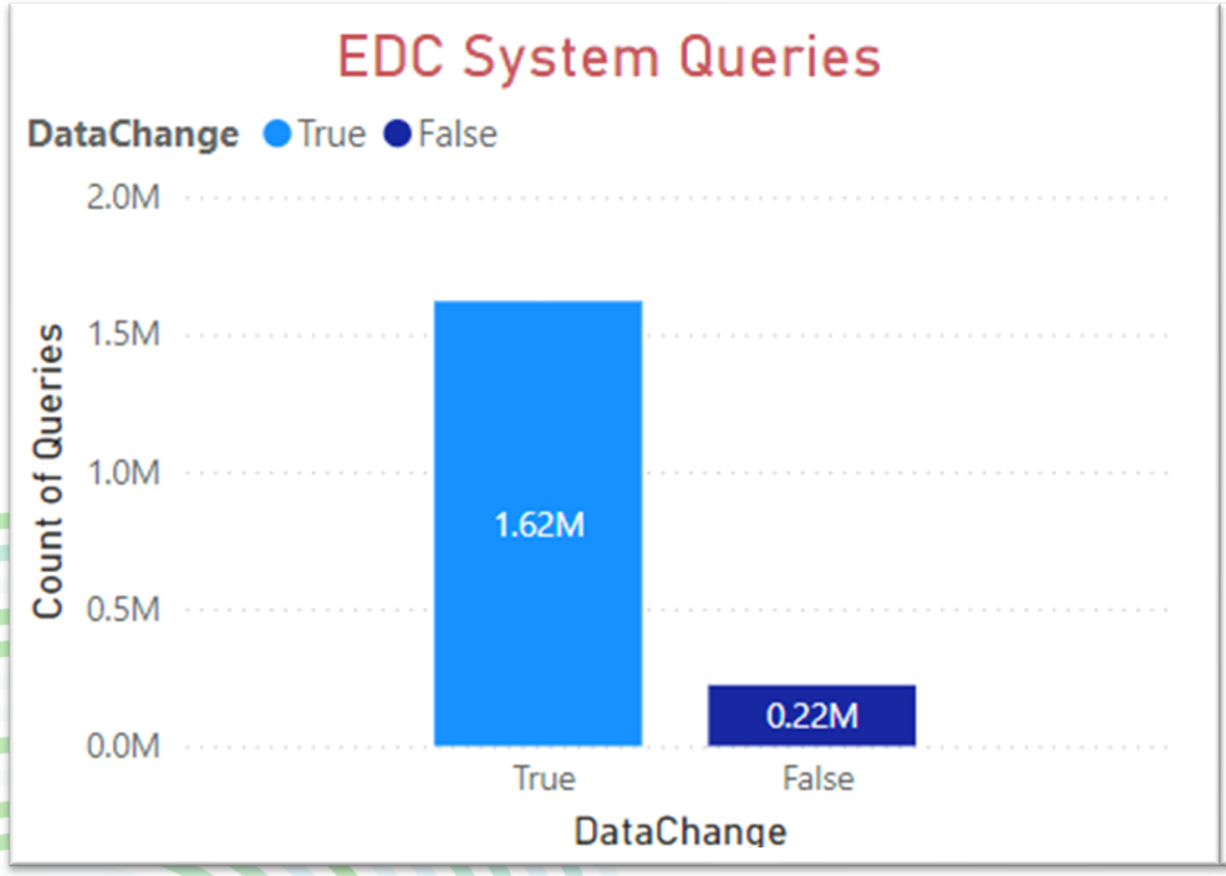
Query origination
Was the right tool used for the job?

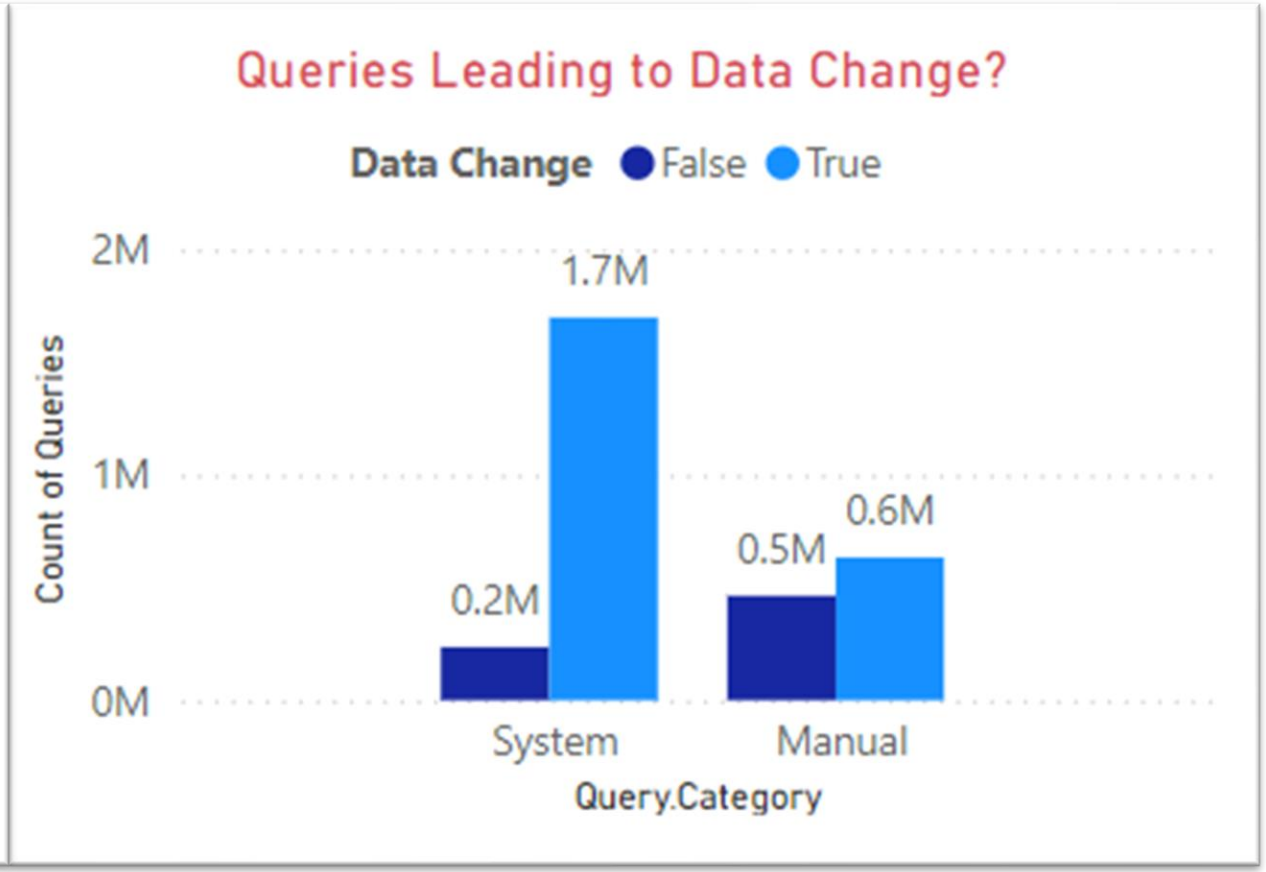
Data changes
Was the query wasteful*?

Checks with no queries
Was it ever needed*?

*Some data checks are necessary even if they never fire or cause data changes

Query Efficacy Metrics





Descriptive vs. Prescriptive Analytics

Descriptive: What happened?

- EDC build cycle time
- Design re-use
- Post-production change
- Query cycle time
- Queries per item

Prescriptive: What to do next?

- Cycle time above threshold
- Re-use % below threshold
- Post-production change reason
- Study grade below threshold
- Data change rate below threshold

Prescriptive Analytics Review

Empower teams to:

- Act
- Be accountable
- Be less dependent on management

Cycle time above threshold	Training required?
Re-use % below threshold	Review standards?
Study grade below threshold	Add SME to next cycle?
Data change rate below threshold	Retire check?

“Whole is larger than the sum of its parts”

- Aristotle

Over-emphasizing one metric leads to gaming of the system

Implementing Analytics

- Emphasize simplicity
- Generate prioritized list of desired metrics
- Decide on format and target audience
- Start with existing reports/dashboards
  - Don’t overburden teams
- Add metrics over time
  - Collaborate with partners before collecting your own

Implementation Approach

Types of actions	Example actions
• System enhancement requests • Form updates • Completion guideline updates • Training	• Instructional text added to form for clarity on type of medications to enter • Updated data review check to standardize for all studies • Updated form design to make it easier for data entry • Developed dashboard to monitor if changes are having desired impact

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Key Takeaways

- Your efficiency may come at someone's expense. Measure efficacy instead.
- Implement prescriptive analytics to drive change and empower teams.
- Start with basics and evolve. Don't overburden teams.

Analytics fueled Clinical Data Science

An anthology of case studies

Presented by:

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Sr. Principal Clinical Data Analyst
Data and Analytics - Strategic Capabilities
Eli Lilly and Company

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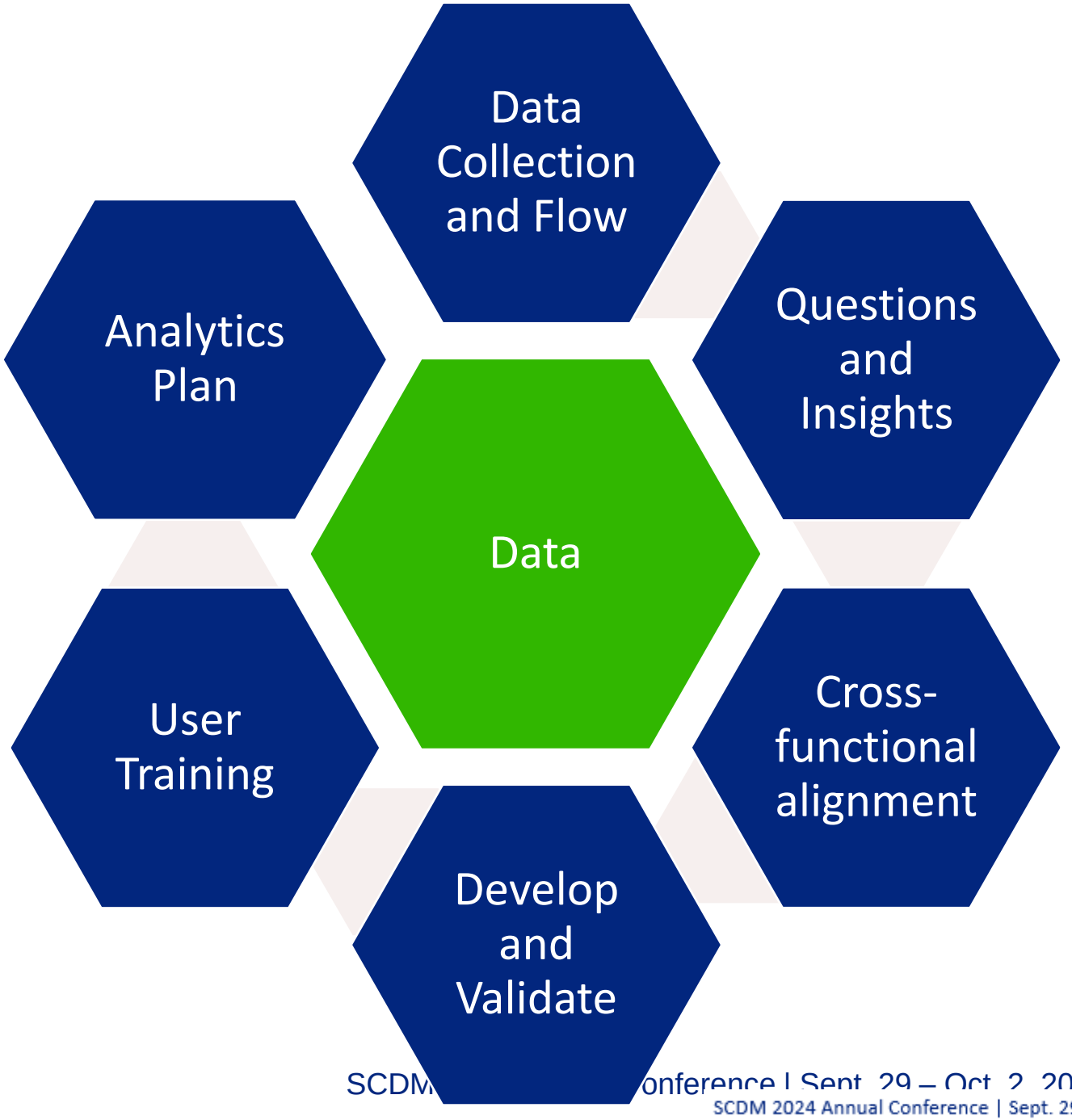
Analytics in Clinical Data ~~Management~~ Sciences

What's Possible?

- Holistic clinical data review
- Risk identification
- Near real-time monitoring
- Insights-driven decision making
- Data-driven cross-functional collaboration
- Integration with study design
- Automation

Analytics in Clinical Data Sciences

What's needed?




Analytics in Action

Screening Analytics Tool

- **Integration with study design**
- **Holistic Review**
- **Data-driven Cross-functional collaboration**

Case Study

- Large outcomes trial
- Data collection spread across multiple systems
- Fast enrollment
- Complex inclusion/exclusion criteria

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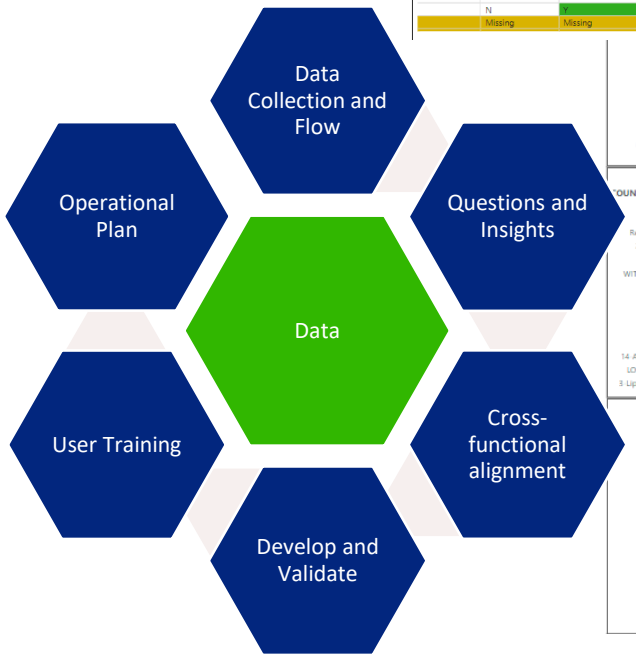
Screening Analytics Tool

- Prespecified medical history CRF design
- Near real-time eligibility data review at participant level
- Pinpoint missing and exclusionary data
- Screening trends at Study, Country, Site level
- Reduce chance of inadvertent enrollment
- Cross-functional users
  - Site Engagement
  - Project Management
  - Data Management
  - Medical
  - Monitoring
  - Statistics



eCOA Data Surveillance

- **Near real-time monitoring**
- **Automation**

Case Study

- Primary/Secondary protocol objectives based on eCOA data
- Missing eCOA data
- Short recall periods
- Site level compliance

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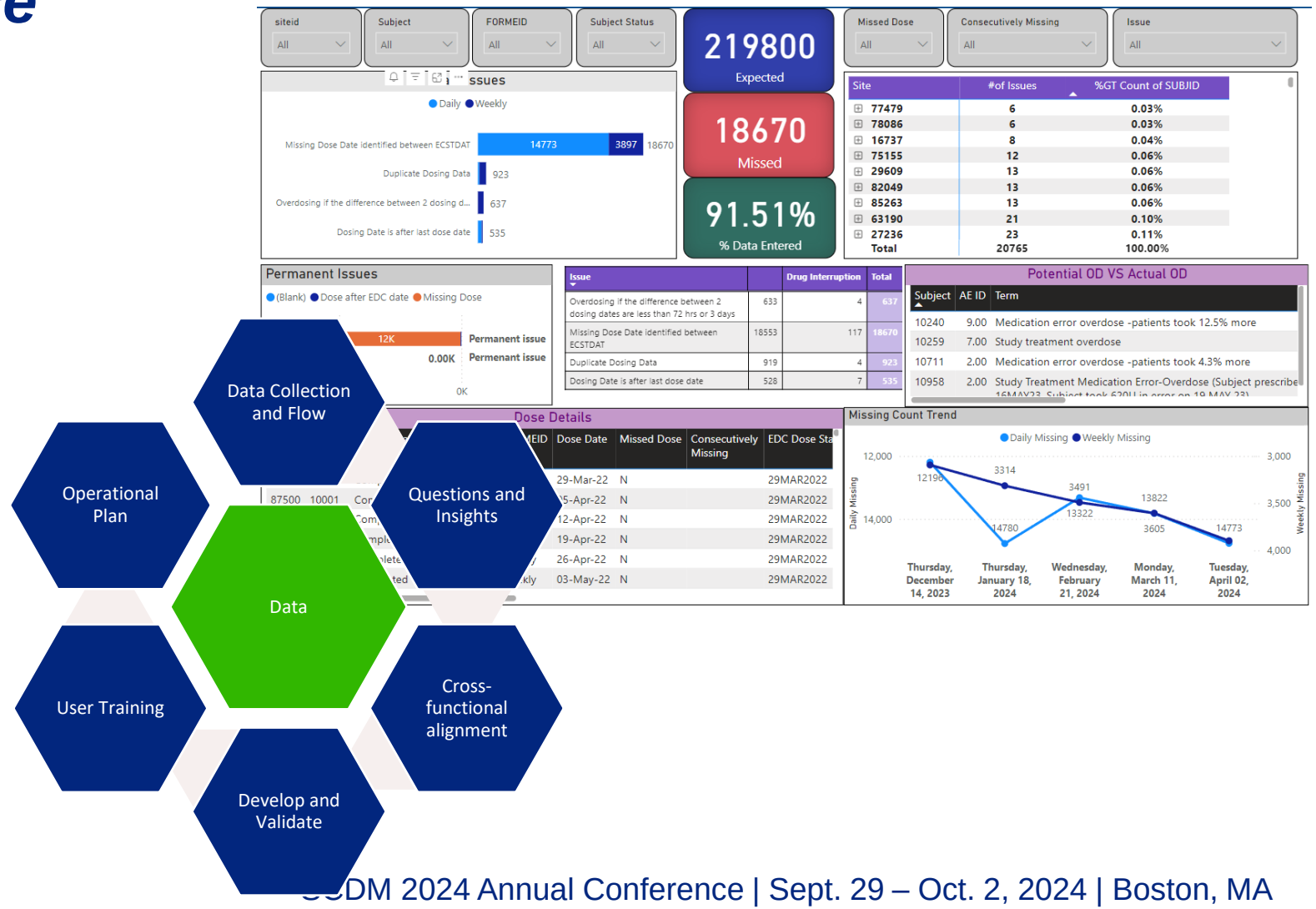
eCOA Data Surveillance

- Plug and Play setup
- Customizable per protocol SoA and PROs being collected
- Near real-time data flow
- Identify issues and trends early on
- Root cause analysis and address systematically
- Major improvement in compliance
- Automated communication with Sites



Patient Retention Dashboard

- **Risk Identification**
- **Data-driven Cross-functional collaboration**

Case Study

- Large event-drive outcomes trial
- Patient retention drives statistical power
- High-risk population
- Manual tracking
- IP compliance

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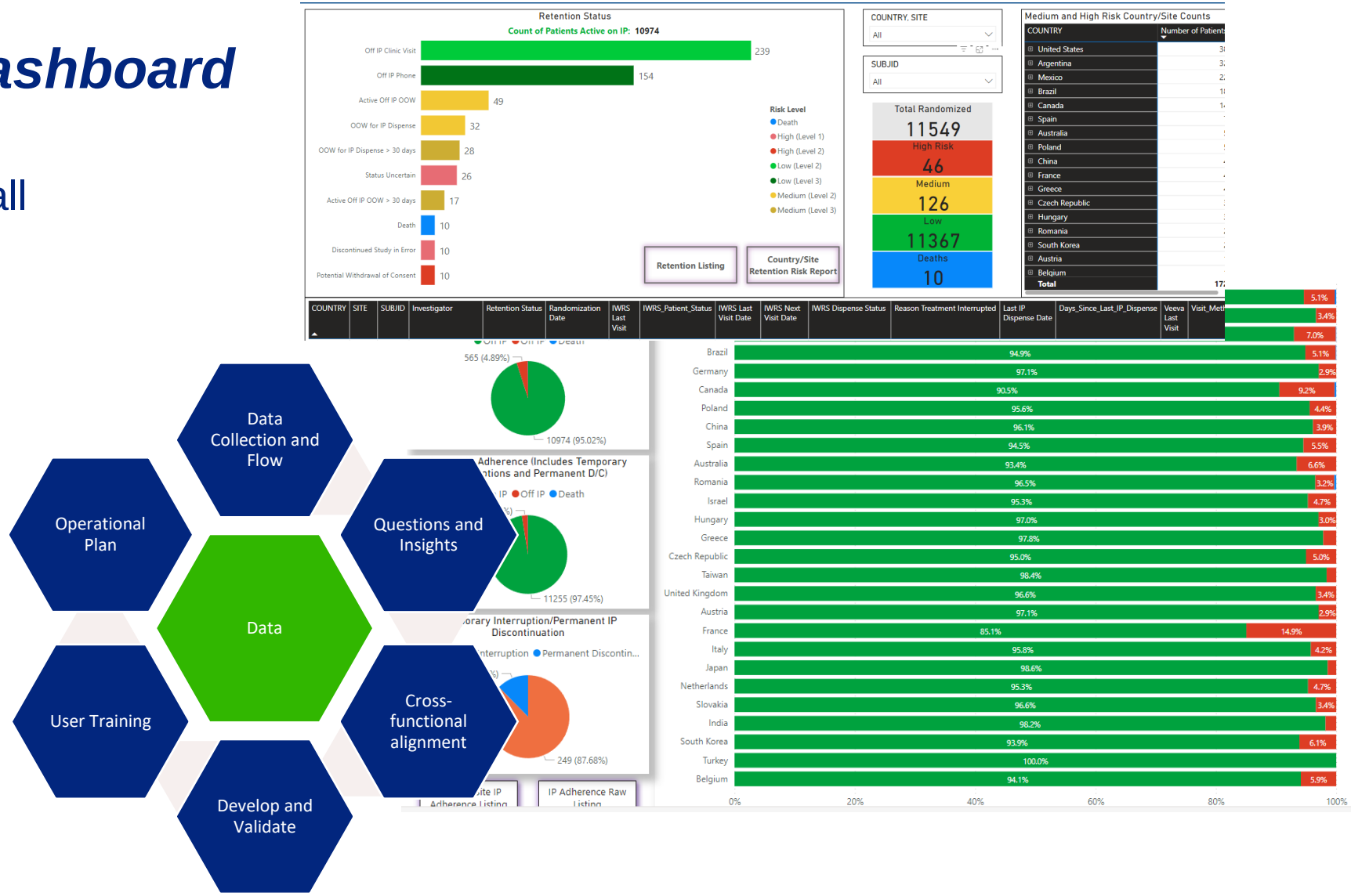
Patient Retention Dashboard

- Participant status based on all available data sources
- Customized retention status
- Associated risk level
- Country and Site level risks
- IP Adherence
- Operational planning
- Cross-functional users
  - Site Engagement
  - Project Management
  - Data Management
  - Medical
  - Monitoring



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Analytics in Clinical Data Sciences

Impact

- Enhanced data quality
- Risk-based approach
- Improved Decision Making
- Operational Efficiency
- Patient-centric approaches
- Regulatory Compliance