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Actionable Insights: How to maximize value from data?

Presented by
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OmniComm Systems

Introduction

Nithiya Ananthakrishnan

SVP Data Sciences

FOCUS:

Clinical technology background that led to the big data analytics platform Acuity's growth in multiple areas like clinical data visualization, risk based monitoring, centralized monitoring and statistical monitoring.

PharmaVOICE 100

EXPERIENCE

Joined OmniComm with Acuity™ acquisition from Algorics.

Prior Leadership roles at ICON Clinical Research, Cognizant

- Statistical Programming & Interactive Technologies

MEMBERSHIP

Pharmaceutical Users Software Exchange (PhuSE)

Drug Information Association (DIA)

Clinical Development Innovation Crisis

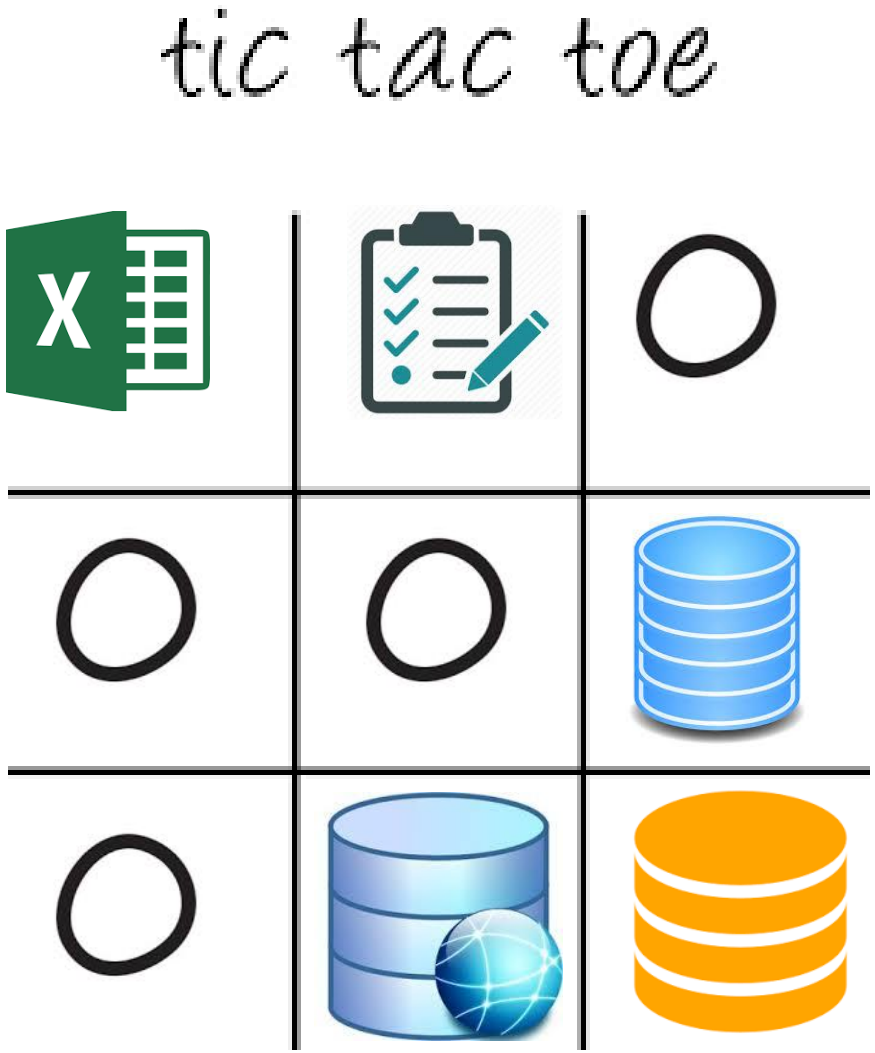
- Lower macro economic growth in developed economies
  - Lower GDP = Constrained Healthcare budgets
- Constant pressure to be first in market/ competitive advantage
  - Limited resources and higher need for patients
  - Multiple companies develop nearly identical therapies using small molecules targeted at the same narrowly defined patient subgroups
- Increasing complexity of Clinical trials
  - Payers are increasingly demanding demonstrable proof of value to support reimbursement for new treatments. These evidentiary demands add more complexity to trial process.

Increasing Complexity of Clinical Studies

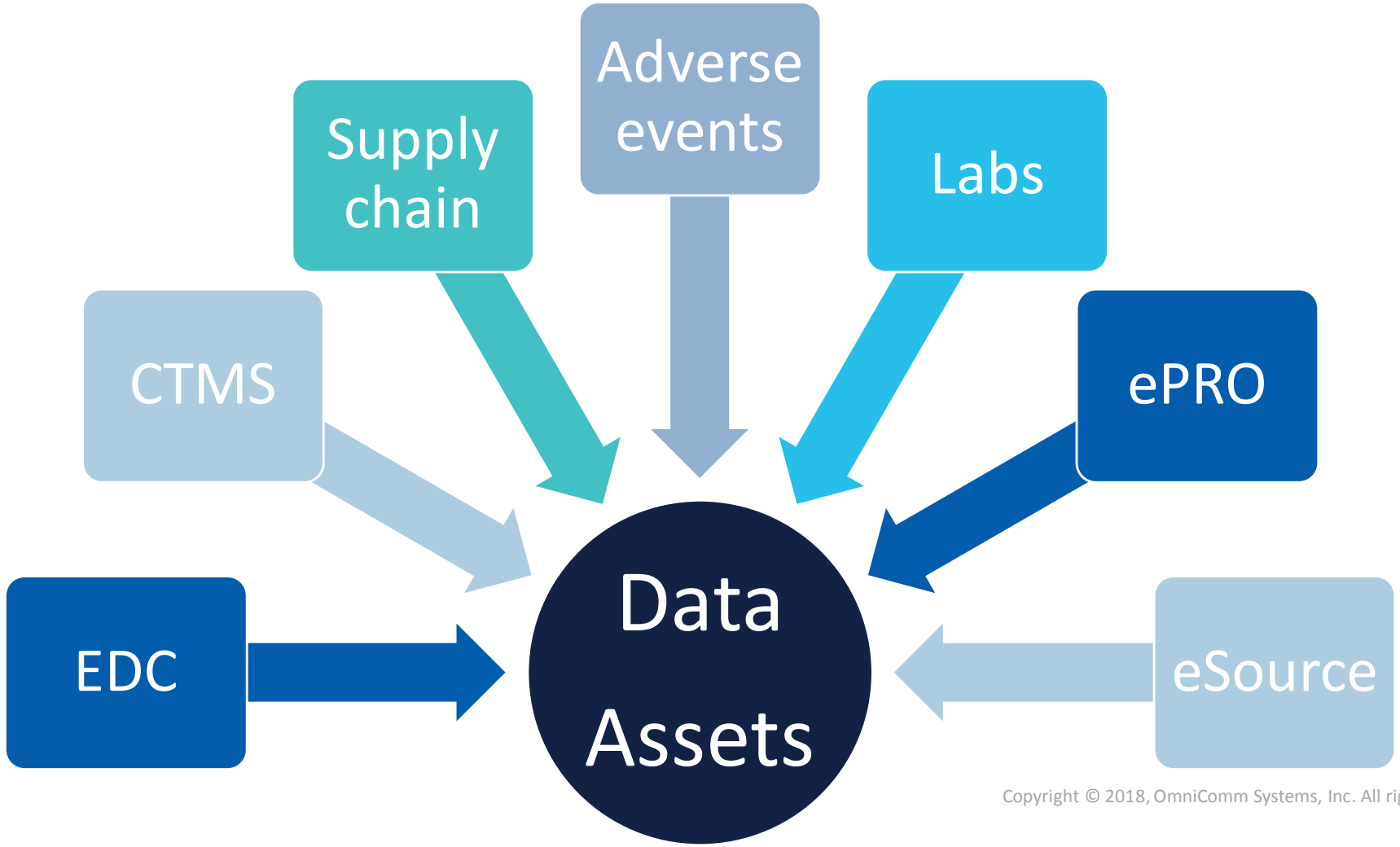
Design Characteristics	2002	2012	% Change
Total Number of Endpoints	7	13	86% ↑
Total Number of Procedures	106	167	58% ↑
Total Number of Eligibility Criteria	31	50	61% ↑
Total Number of Countries	11	34	209% ↑
Total Number of Investigative Sites	124	196	58% ↑
Total Number of Patients Randomized	729	597	18% ↓

Source – Int. J. Environ Res Public Health 2014; 11 5069-5080

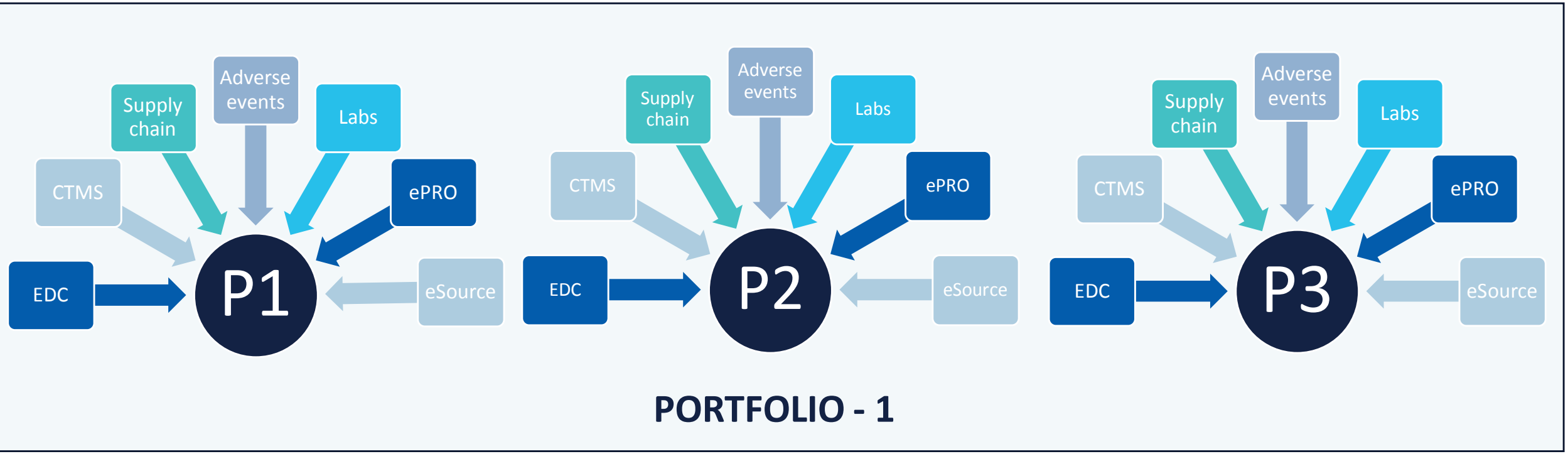
Where does all the data reside?



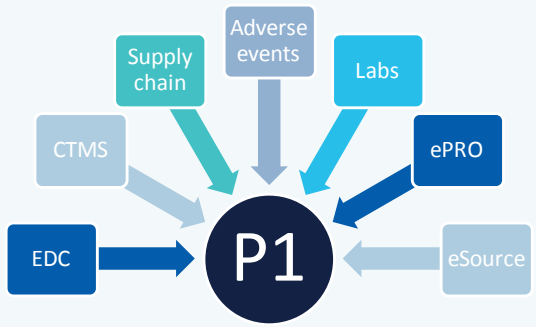
Disparate Data - Across source systems

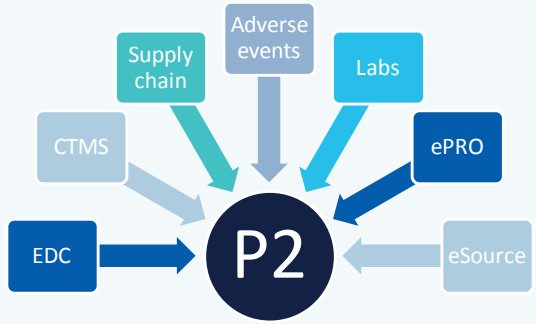


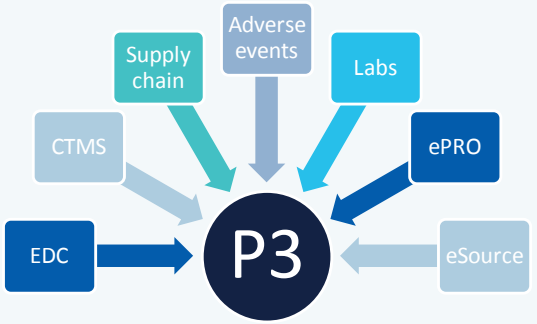
Disparate Data Sources – Across Protocols



Disparate Data Sources – Across Portfolio

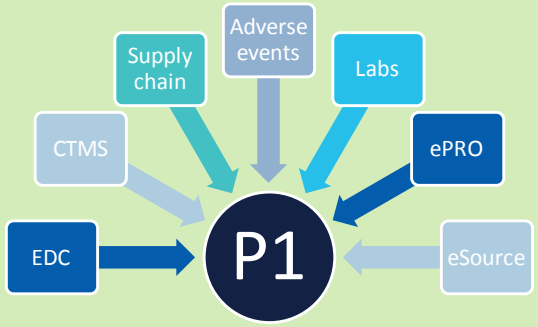


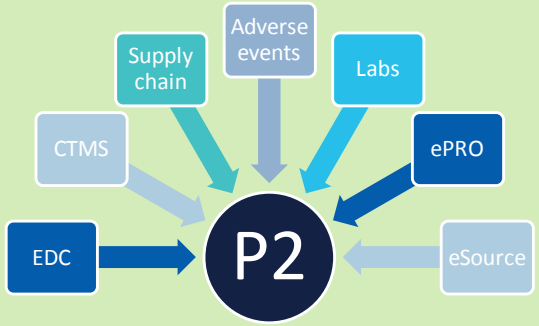


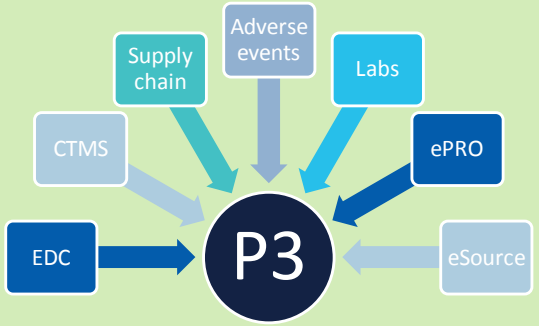


PORTFOLIO - 1

Portfolio – Added after Merger/ Acquisitions



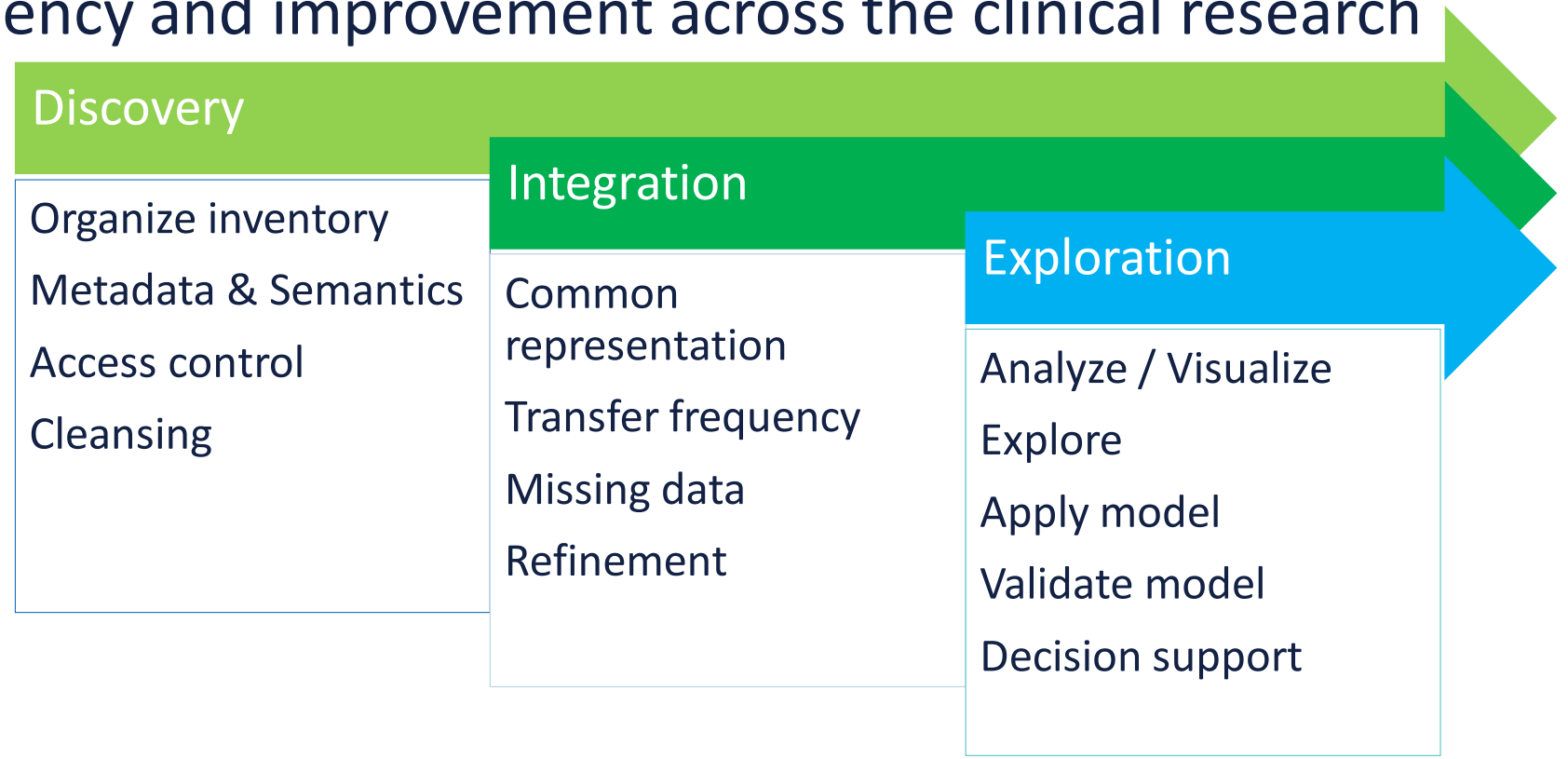




PORTFOLIO - 2

Make data work for you

- The pooling of data sets and capabilities brings new opportunities to produce efficiency and improvement across the clinical research continuum



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Actionable Insights

How Can Actionable Insights Enable Your Organization?

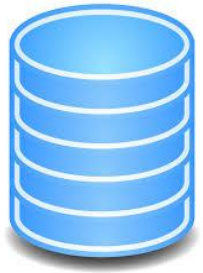
acuity

- Real time data aggregation of trial data across systems and across protocol
- Transparent reporting of portfolio trial progress without vendor/ CRO dependency
- In depth view of patient trial progress with focus on safety signals and protocol compliance
- End to end solution for risk based monitoring aligned with ICH E6 (R2)

Clinical Analytics Platform

How Acuity Works?

Subject data



Operational data

System agnostic integration

Real time insights

Informed decisions

Optimized SDV

Adaptive monitoring

5X faster time to implementation

Standards-based approach | TransCelerate-based RACT | Prebuilt EDC connectors | SDTM data models | 50+ Standard dashboards | Setup in weeks and not months

Clinical Operations-centric

- Acuity is more than just a reporting platform. It was designed with the challenges of clinical operations in mind, and to avoid regulatory findings and the associated cost to quality.
- Specific views of interest are
  - Recruitment
  - Subject Safety
  - Supply Chain
  - Protocol Deviation
  - Subject Compliance
  - Data Quality
  - Monitoring trends

Use Cases – Pain Points

Clinical Insights

Operational transparency | Aggregating data from multiple sources | Dependency on silos of information for real-time progress

Cross-Study Reporting

Lack of program level insights | Better protocol design and benchmarking

Patient Insights

Visual narrative of data domains | Safety analysis | Correlation analysis | Change from baseline

Risk-Based Monitoring

Traceability | Reusability | Compliance with new ICH E6 (R2)

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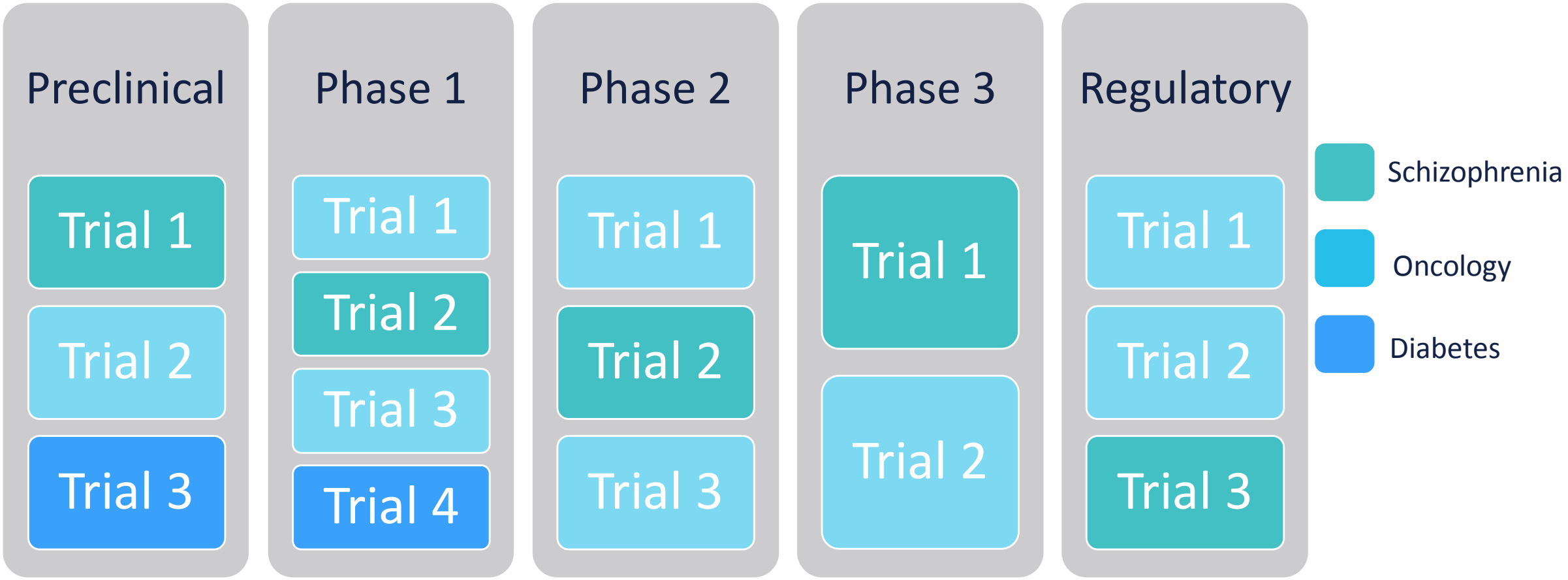
Cross Study Reporting – R&D Pipeline



Cross Study Reporting – Step #1

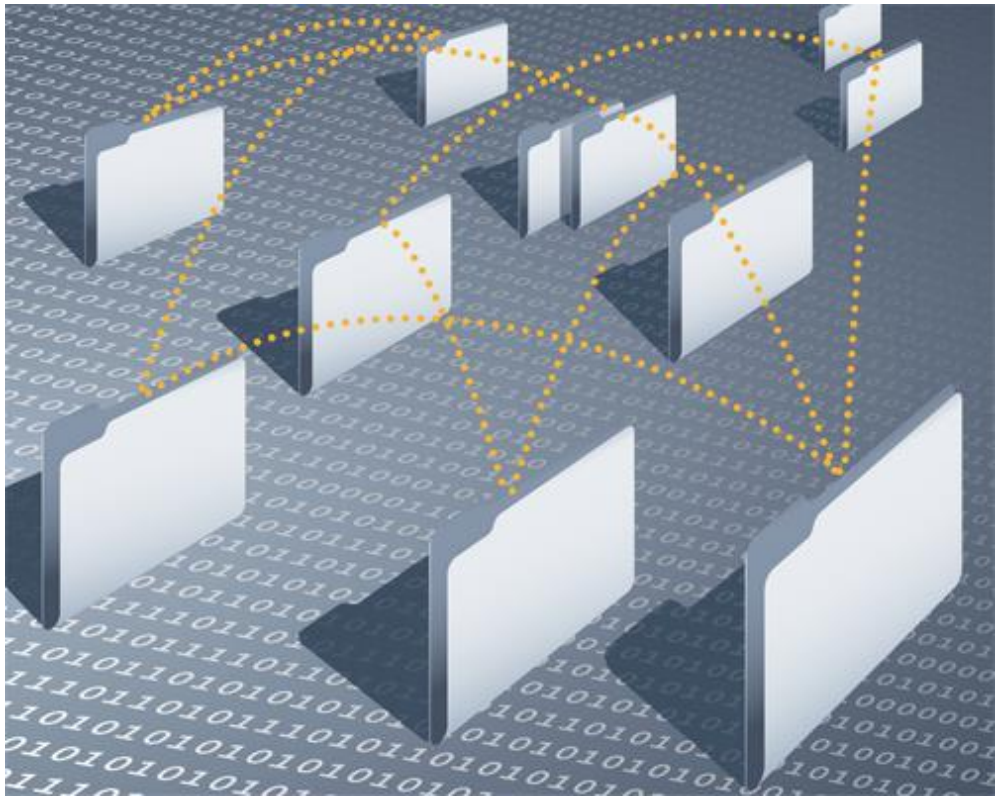
Identifying the right potential candidates for cross study reporting

- Portfolio strategy
- Portfolio performance risk
- M&A integration possibilities
- New product development strategy
- Financial budget forecast

Cross Study Reporting – Step #2

Standardization – Challenges

- Multi vendor solutions can impose significant challenges as there is lack of standardization.
- Prioritizing the key performance areas to monitor could breakdown the integration into measurable smaller components
- Four biggest hurdles or concerns faced in integration
  - Data security and information breach
  - Lack of standardization (Standards have evolved)
  - Missing data
  - Paper records



Tangible benefits

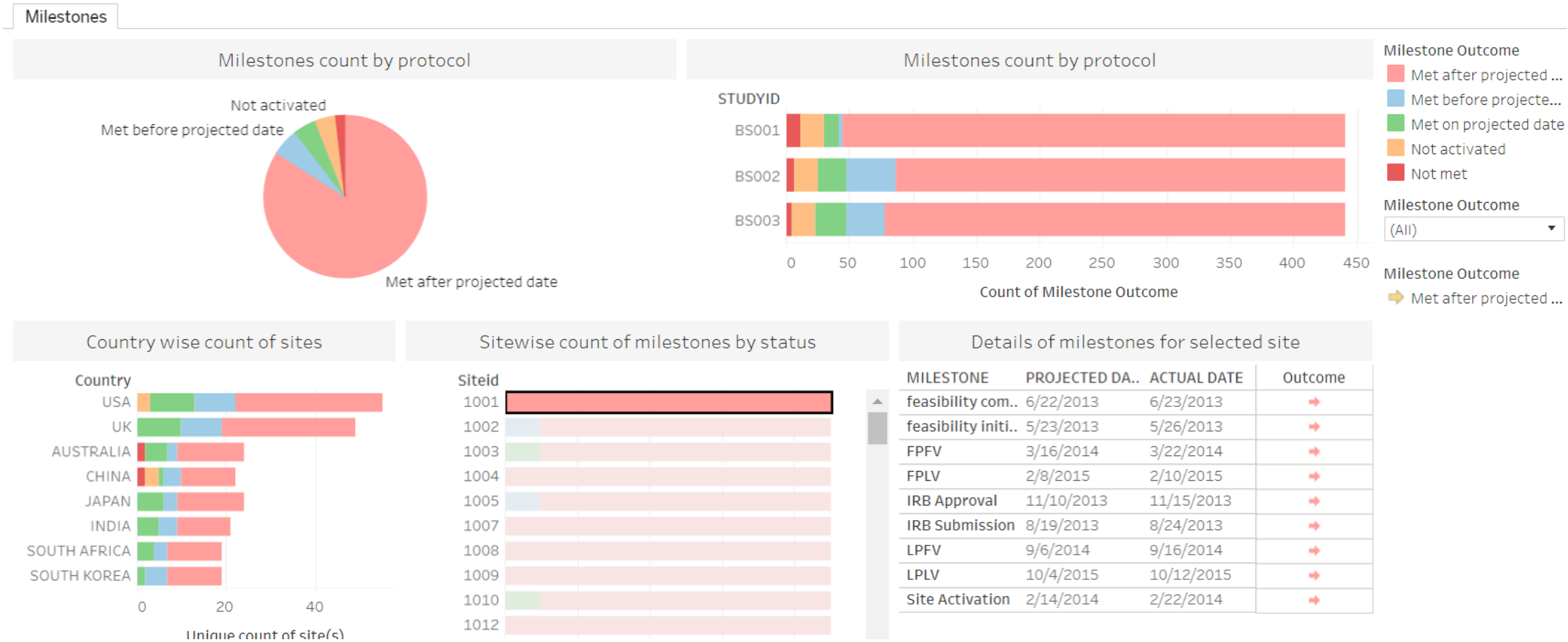
- Improving levels of protocol adherence
- Real time biomarker and safety analysis
- Patient driven site identification
- Improving study design
  - Creating benchmarks based on historical performance
  - Reduction in protocol amendments

Cross Study Reporting – Step #3

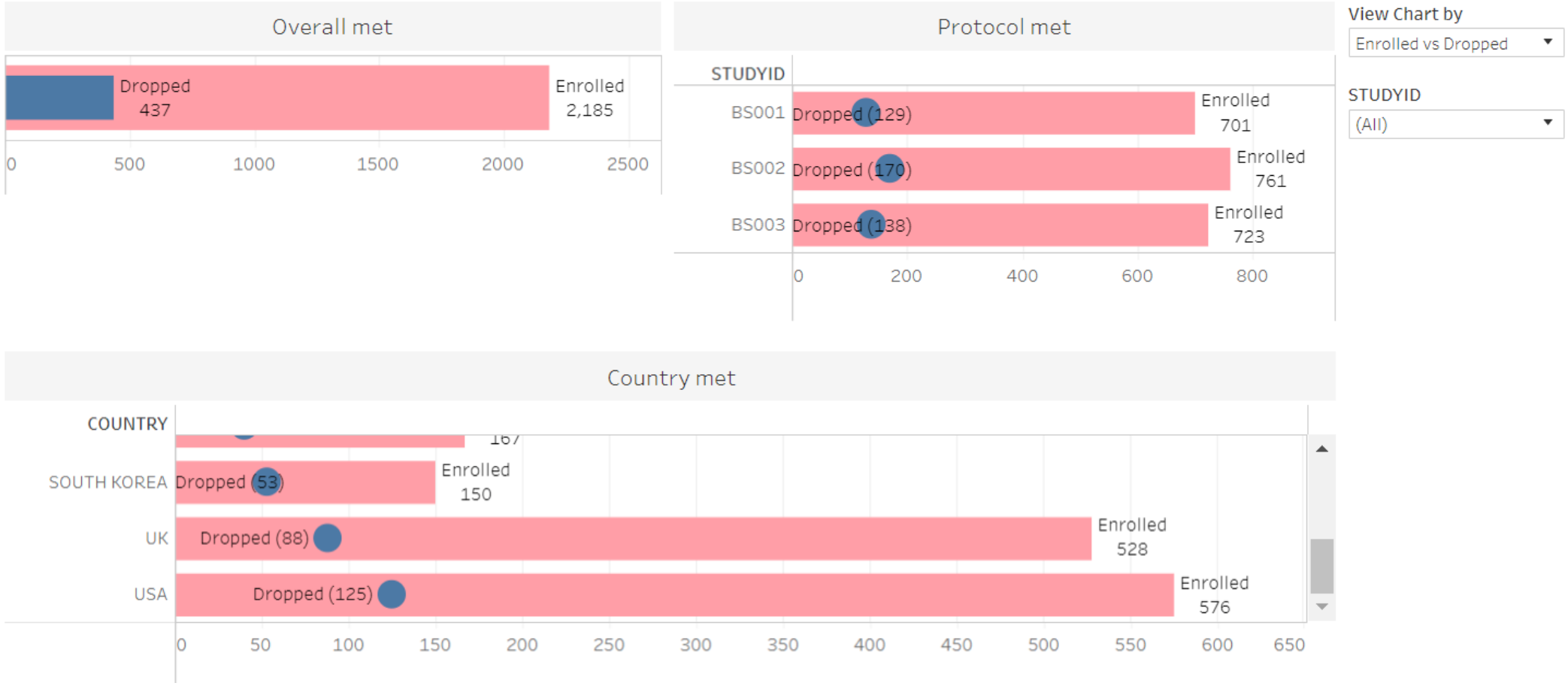
Reusability of Data

- Milestones
  - Portfolio Management
- Study Startup
  - Site Initiation
  - Activation
  - Recruitment Analysis
- Study Conduct
  - Protocol Deviation
  - Data Quality
  - Monitoring Rate
- Scientific Analysis
  - Safety Events
    - AE/SAE
  - Lab Outcomes
  - Vital Outcomes
  - Abnormal Trends

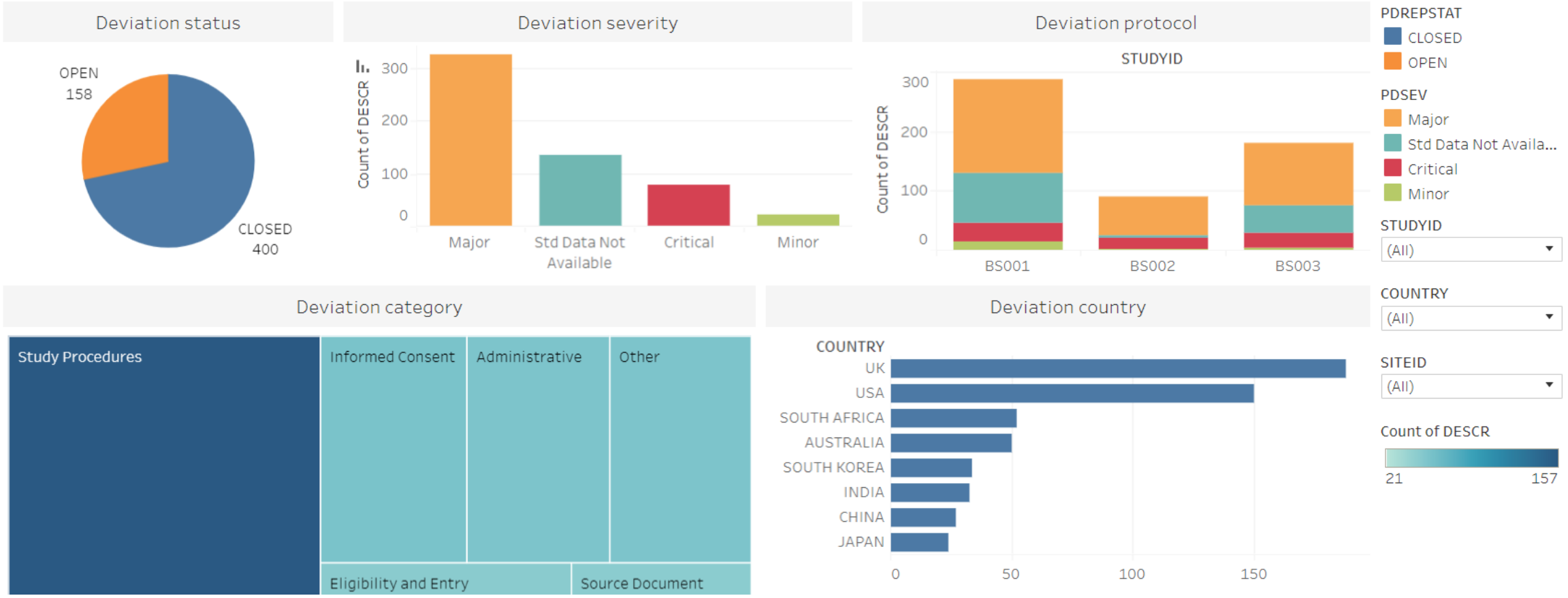
Key Milestones – Benchmarking



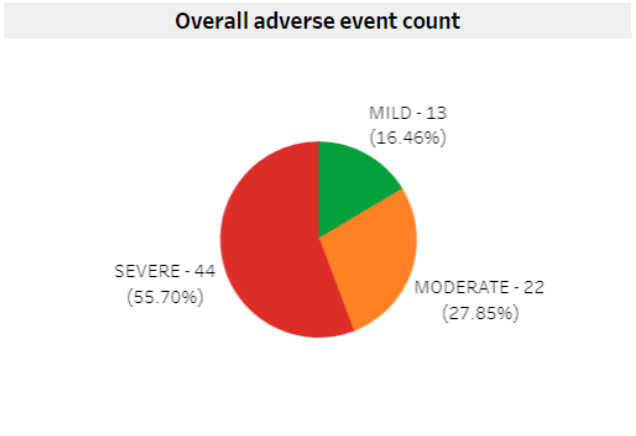
Recruitment – Benchmarking, Ratio Analysis

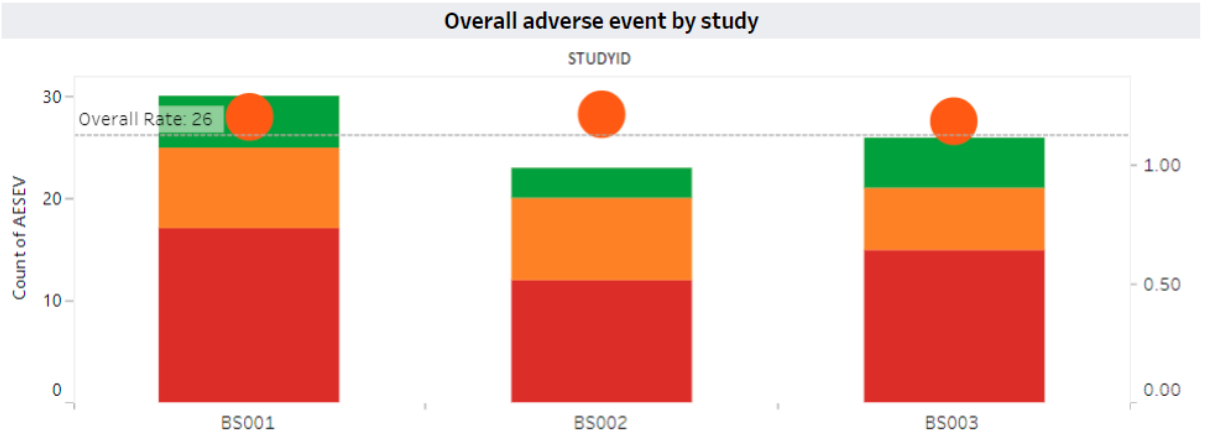


Protocol Deviations – Progress, Severity, Patterns



SAE – Patterns/ Incidence Rate/ Geographical Trends





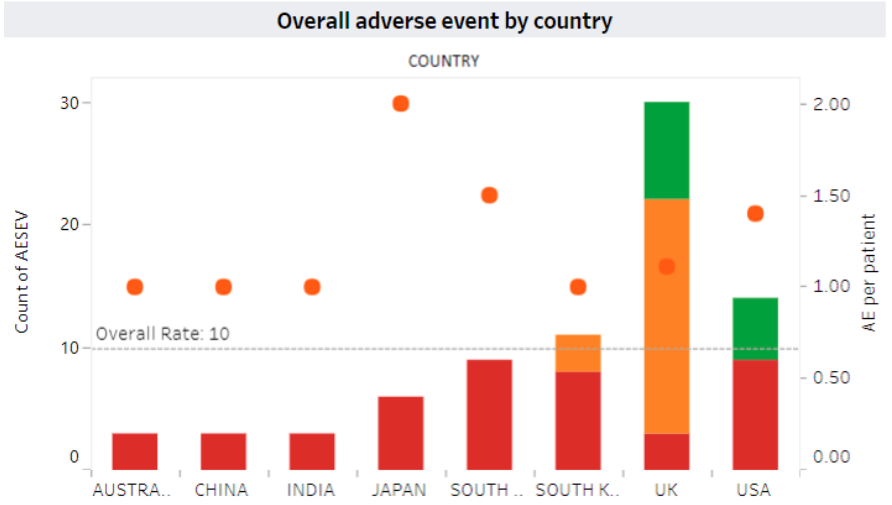
AESEV
MILD
MODERATE
SEVERE

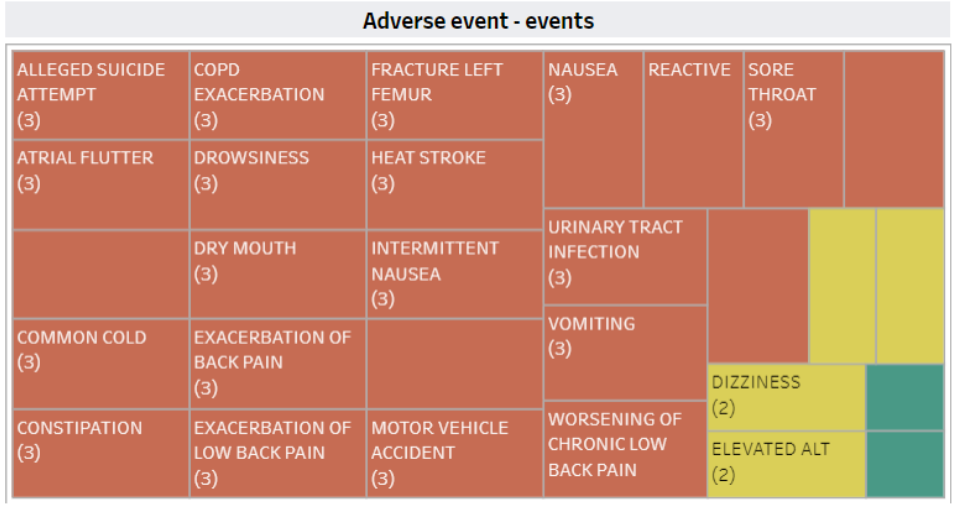
STUDYID
(All)

COUNTRY
(All)

SITEID
(All)

Count of AETERM
1
3



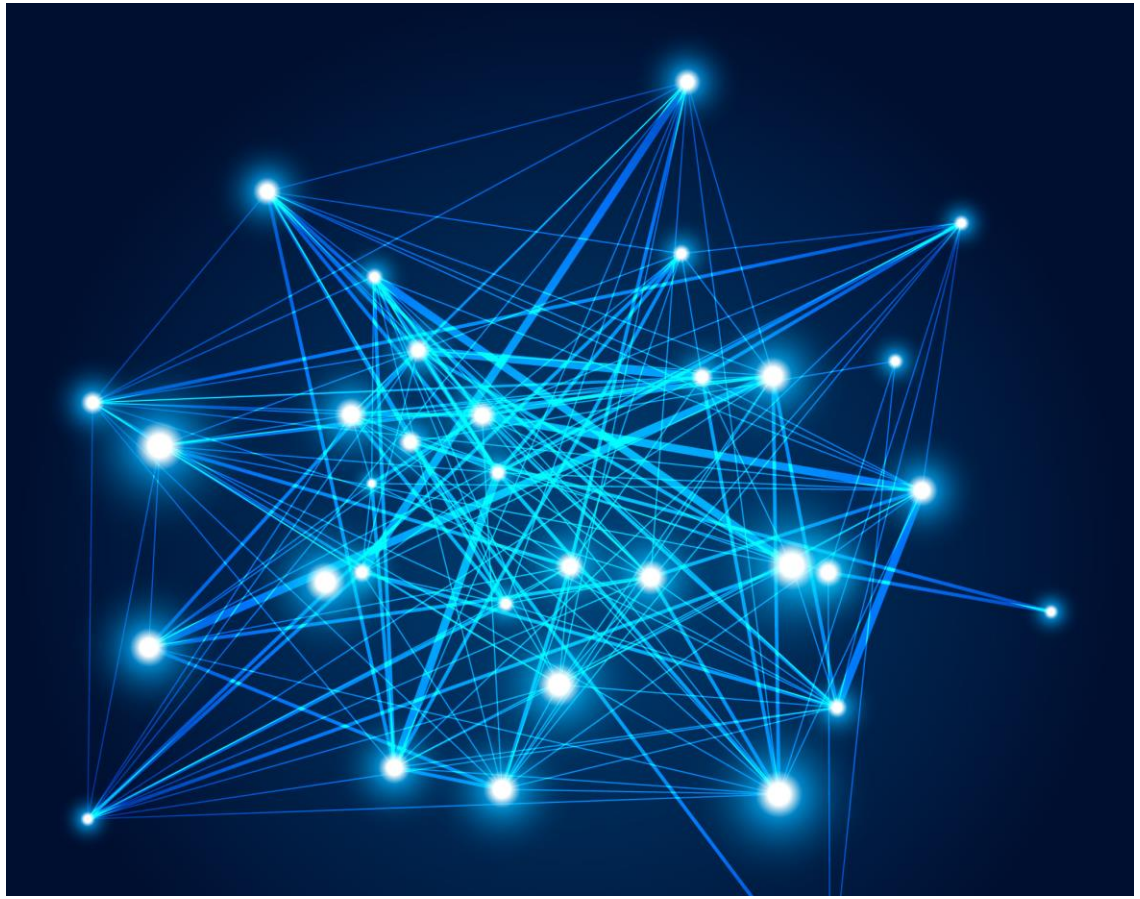


Cross Study Reporting – Step #4

Decision Support enablement

- Process must include minimum
  - Data reliability (GIGO)
    - Change in data environment
  - Monitoring of operational environment
    - Absolute vs Relative risks
  - Investigation of risks
    - outlier incidents, trends
  - Compliance with quality tolerance limits
    - Potential non-compliance with regulatory standards
  - Continuous Improvement
    - Feedback Loop

Value of automation



- **Timeliness** - Real time flow of data
- **Scalability –** Intelligence applied over large volumes of data can be significant
- **Objectivity** - Automation makes decisions taken less vulnerable to bias (objective)
- **Reduced Cost** - Continuous integration of KRI reduces significant manual efforts on monthly basis
- **Compliant** - Recording decisions with timestamp allows future audit readiness

Thank you

For questions please contact
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