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Health Sciences

Disrupt Data Management in our new Multi-Data Source World using Real World Evidence & Patient Centricity initiatives and Machine Learning techniques

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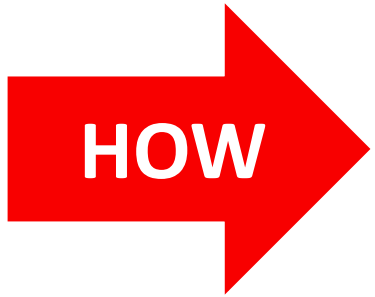
Abstract

In order to disrupt your data management function in this new multi data source world you need to consider various aspects of what you need in a platform to achieve success! Successful disruption here will result in transformation of your approach to manage the explosion of data sources and associated data volumes to run your Clinical Trial Portfolio. This session will discuss the top issues to consider as you are dragged into/embrace this new world.

Research Methodology

August – September 2018



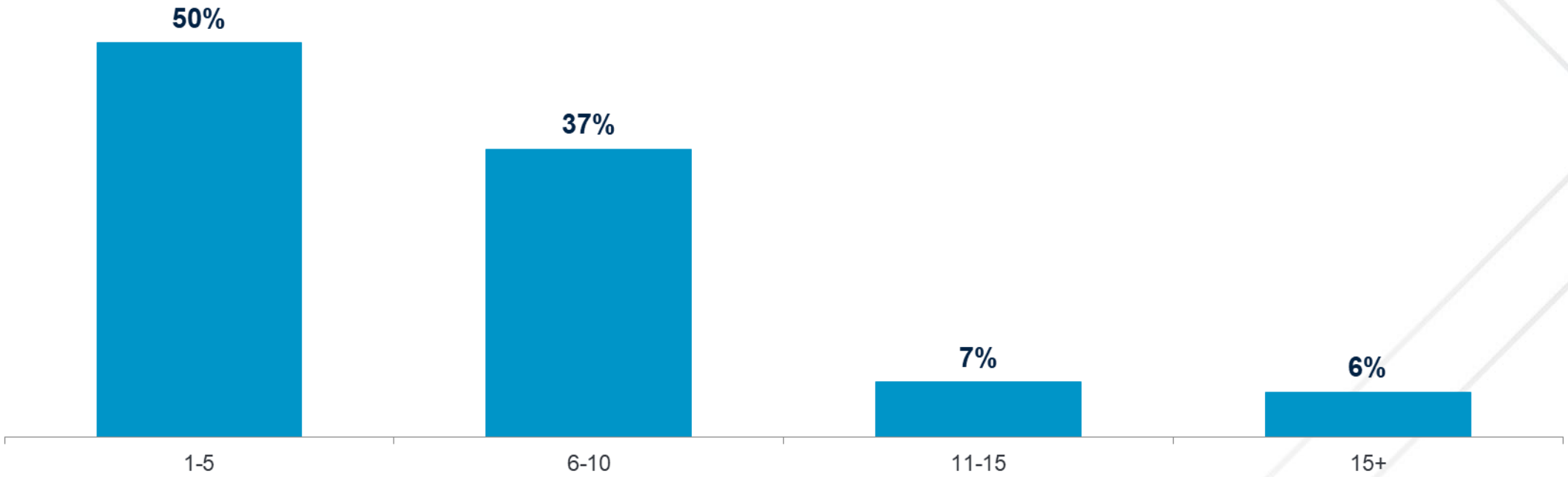
Online survey, 15 multiple-choice questions

155 people involved in clinical data management @ biopharma, CRO, and med device companies

Pharma intelligence

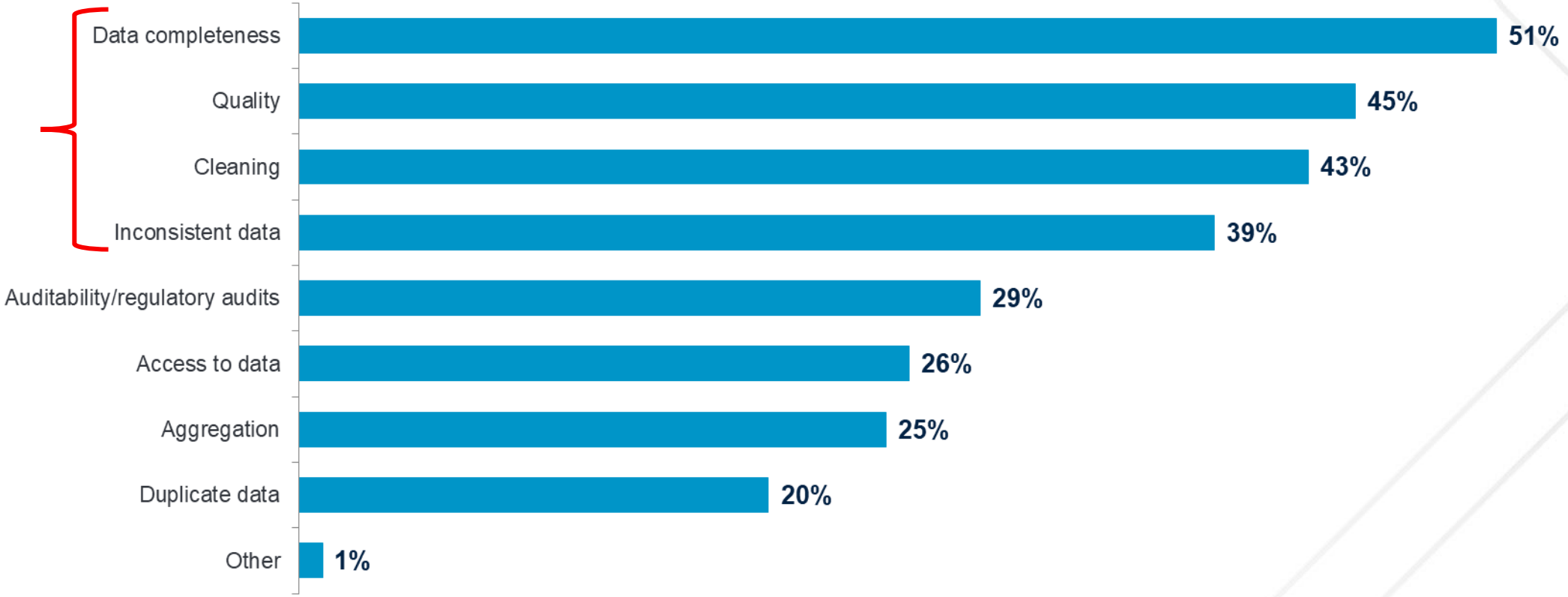
Research Results: Operational Challenges in Clinical Data Management

How many different data sources do you have for a typical clinical trial?



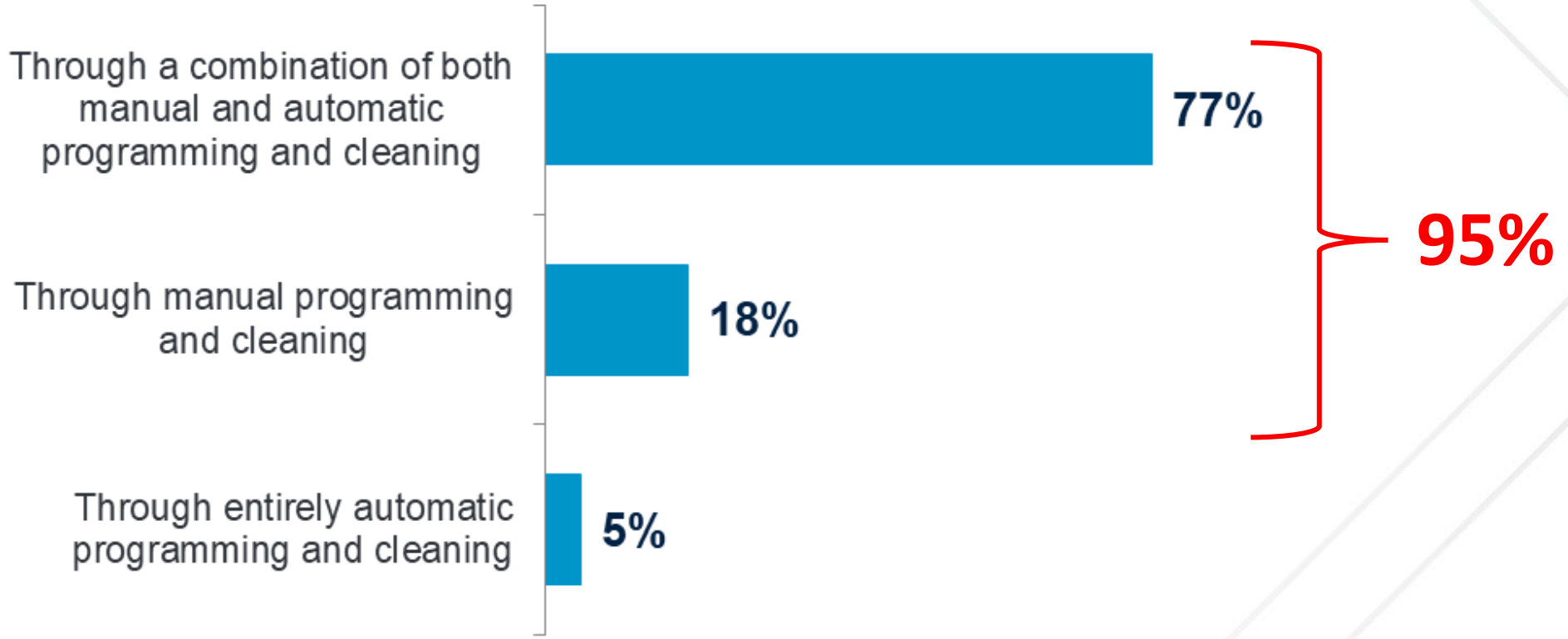
Research Results: Operational Challenges in Clinical Data Management

What are your top three operational challenges with clinical trial data?



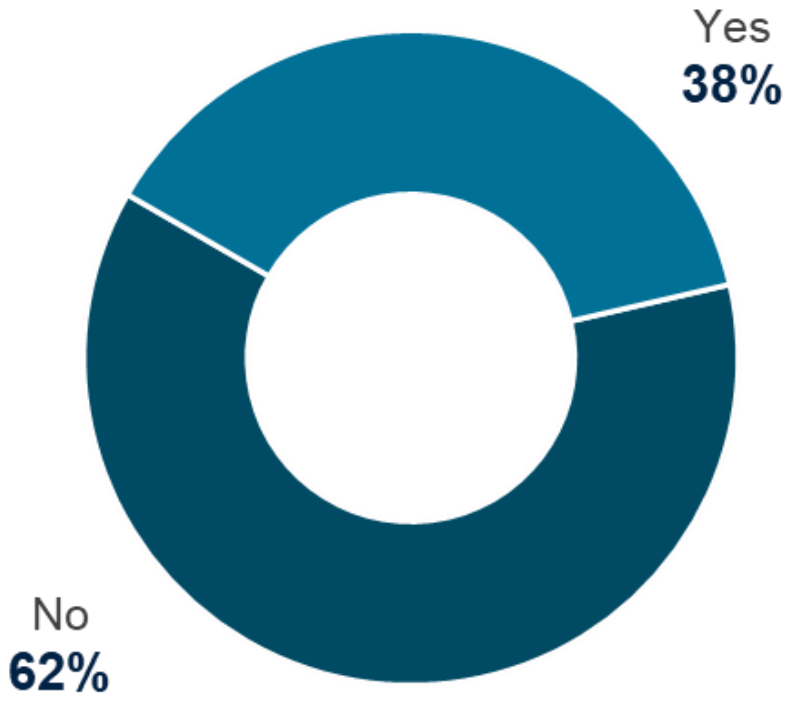
Research Results: Operational Challenges in Clinical Data Management

How is your clinical trial data aggregated, cleaned and transformed for use?



Research Results: Lack of Timely Access to Clinical Data

Do you have real-time access to ALL of your clinical trial data?



Technology Disruption Definition

- Meriam Webster
  - Disrupt: to cause (something) to be unable to continue in the normal way : to interrupt the normal progress or activity of (something)

- Investopedia
  - Disruptive technology significantly alters the way businesses operate…often forces companies to change the way they approach their business…

Your Data Management Platform needs the capability to…

- …be extendable to manage new Data Sources
- …support EHR & Device/Sensor eSource Data Sources to support your Real World Data & Evidence strategy
- …define automated pipelines for supporting downstream processes at lower cost with real time access
- …provide Data Managers (either internal or partners) tools for the complexities of each data source type
- …ingest, combine, align, aggregate an unlimited number of Data Sources to support an unlimited number of target data formats (proprietary & industry standard)required for downstream processes
- …support full traceability and one button push audit meeting preparations
- …support robust archival of completed Trials/Studies in a comprehensive CDR
- …serve as an Artificial Intelligence platform to support new Trial/Study Design & Automated Setup, Enhanced Risk Based Monitoring, etc.
- …support your Patient Centricity strategy with roundtrip Site notification for high value add patient outreach
- …support effective collaboration and management of partners

…be extendable to manage new Data Sources

Top 3 Biopharma Head of Data Management "~24% of our Trial data comes from EDC, remaining comes from other data sources" -> EDC is just another data source!

Traditional Data Sources

- EDC
- Central Labs
- PK/PD
- Safety
- …

Recent Data Sources

- eCOA/ePRO
- Direct Data Entry
- EHR
- Devices/Sensors
- Genomics & Proteomics

Upcoming Data Sources

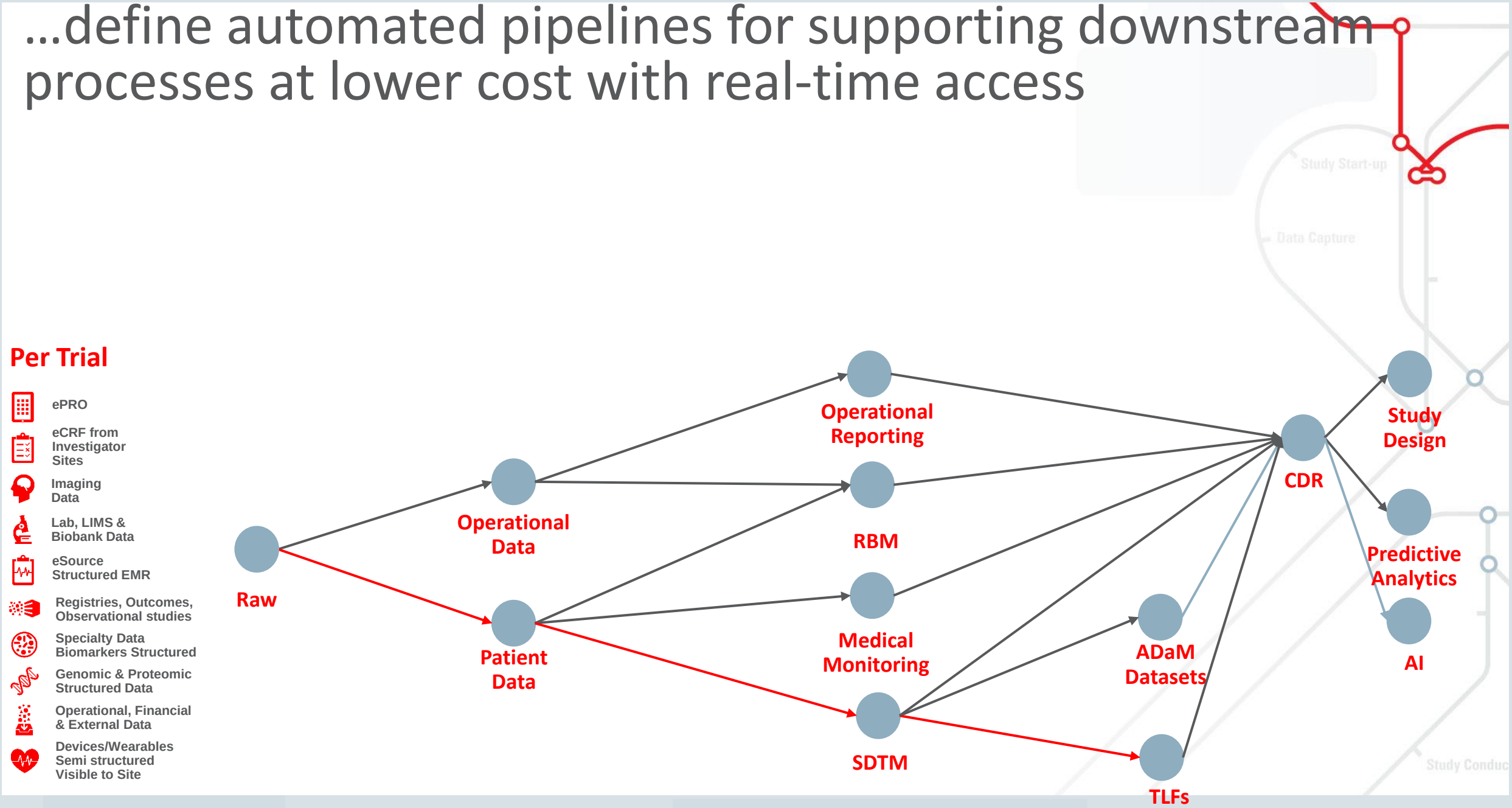
- Metabolomics
- Scientific Literature
- Social Media
- Census
- Weather

New Data Sources we're talking about now we weren't talking about 3-5 years ago.

What new Data Sources will we be talking about 3-5 years from now??

…support EHR & Device/Sensor eSource Data Sources to support your Real World Data & Evidence strategy

…define automated pipelines for supporting downstream processes at lower cost with real-time access



Traceback to Source

…provide your Data Managers (either internal or partners) tools for the complexities of each data source type

- EHR Data Source: Terminology Mediation
  - Initial Site EHR system terminologies include SNOMED, LOINC, etc mapped to terminology representations in Clinical Research applications
  - Ongoing maintenance of Site EHR system new terminology versions and/or Clinical Research application terminology versions
- EHR Data Source: Industry Standards
  - Typically industry standards like HL7 FHIR help, but as the saying goes “when you’ve seen one Epic HER implementation you’ve seen…ONE!!”
- EHR Data Source: Unstructured portion requires Natural Language Processing
- Device/Sensor Data Source: Patient Provisioning
  - track provisioning of 1..n devices/sensors to each patient in the Clinical Trial while maintaining blinding
- ‘Omics Data Source
  - Manage complexity of loading multiple industry standard formats (e.g. .vcf, etc.)
  - Manage multiple levels of computing ‘Omics data results for analysis

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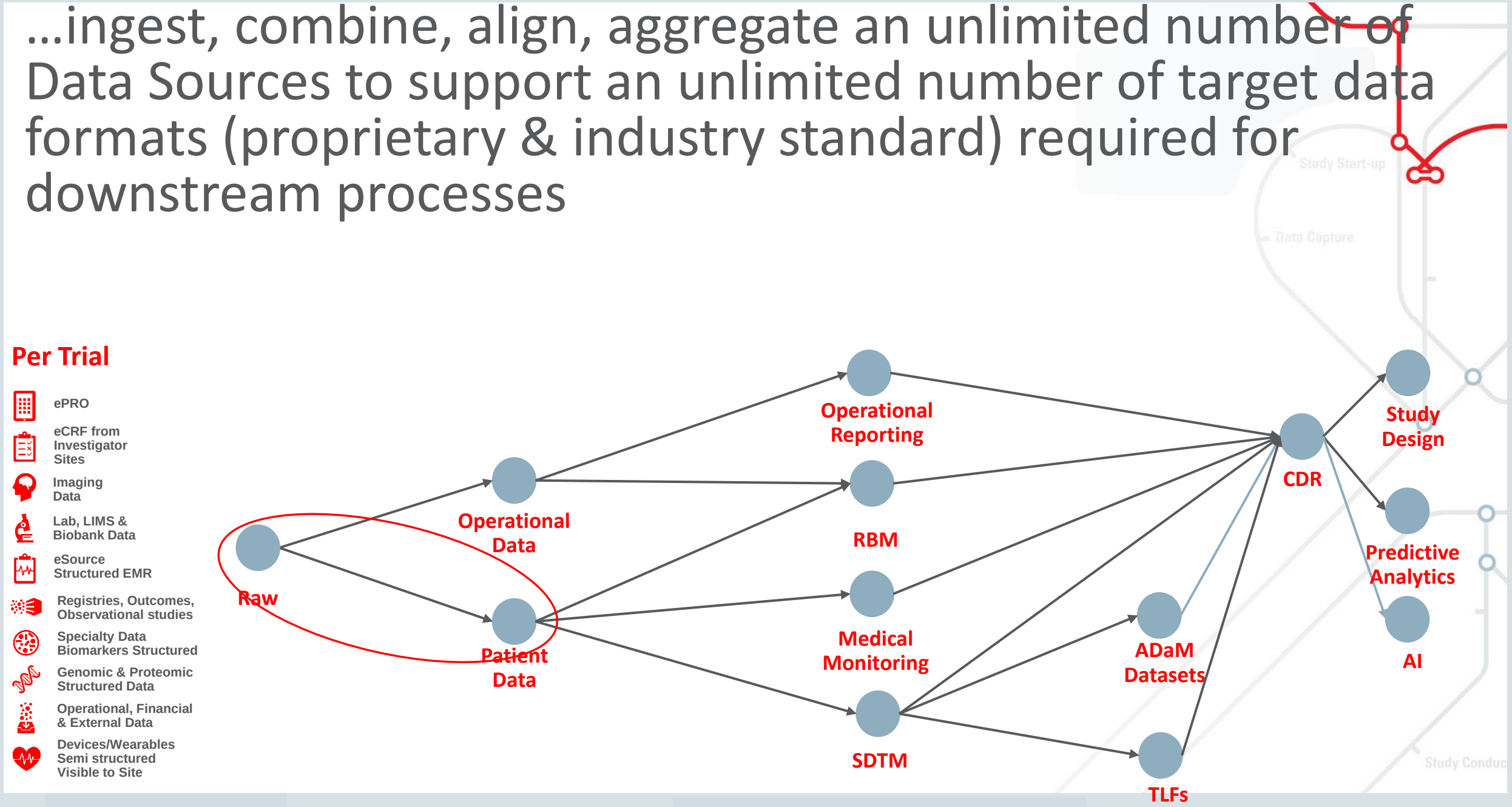

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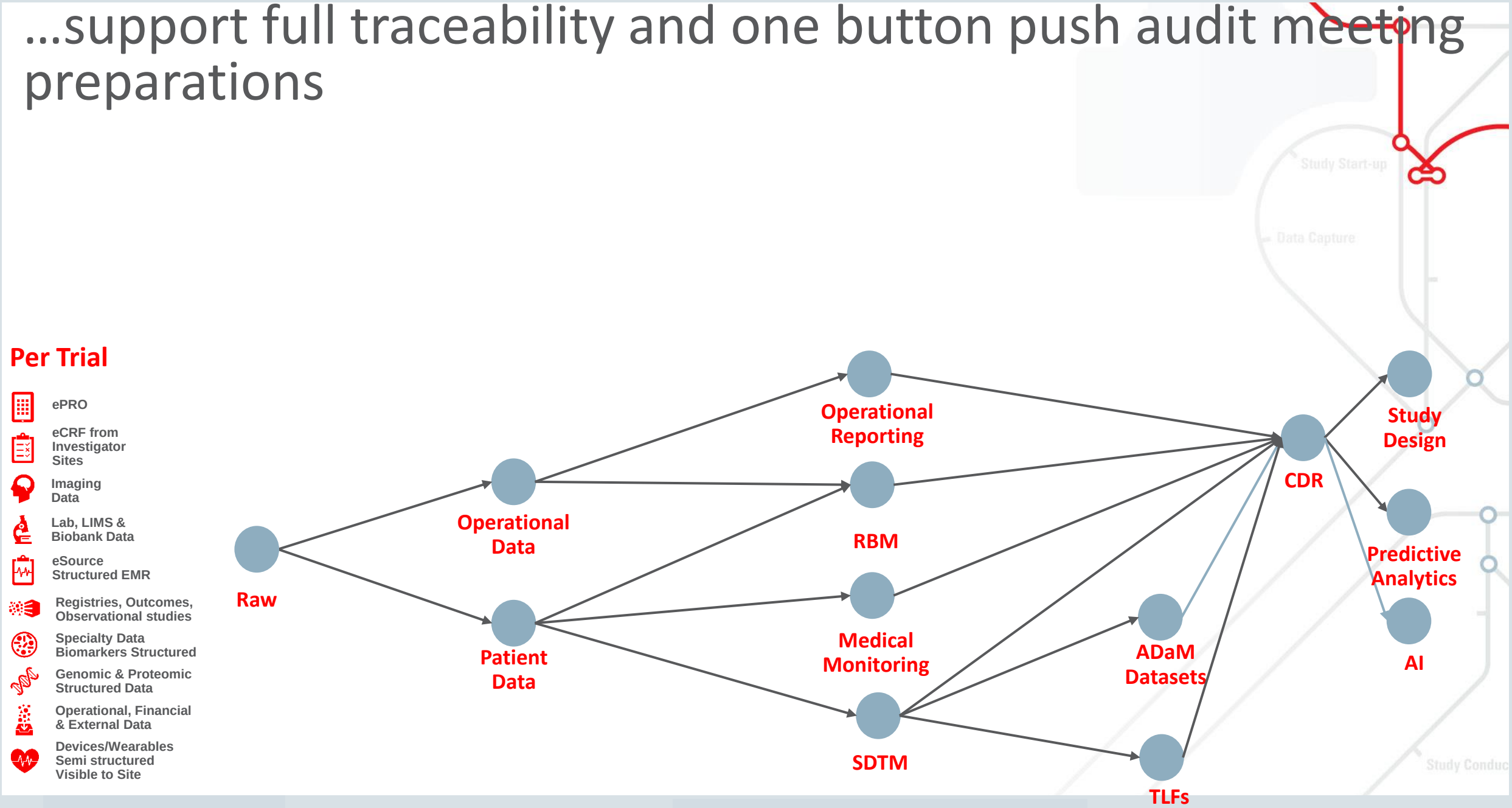
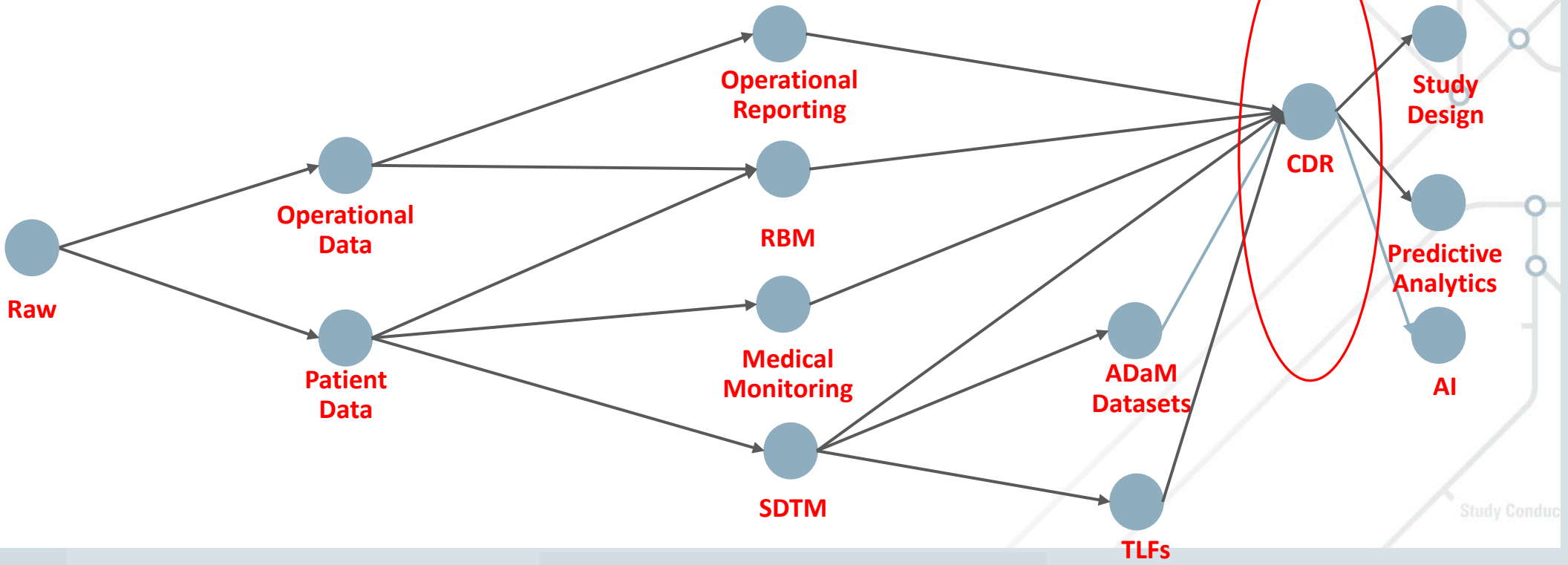


…support robust archival of completed Trials/Studies in a comprehensive CDR

Per Trial

- ePRO
- eCRF from Investigator Sites
- Imaging Data
- Lab, LIMS & Biobank Data
- eSource Structured EMR
- Registries, Outcomes, Observational studies
- Specialty Data Biomarkers Structured
- Genomic & Proteomic Structured Data
- Operational, Financial & External Data
- Devices/Wearables Semi structured Visible to Site



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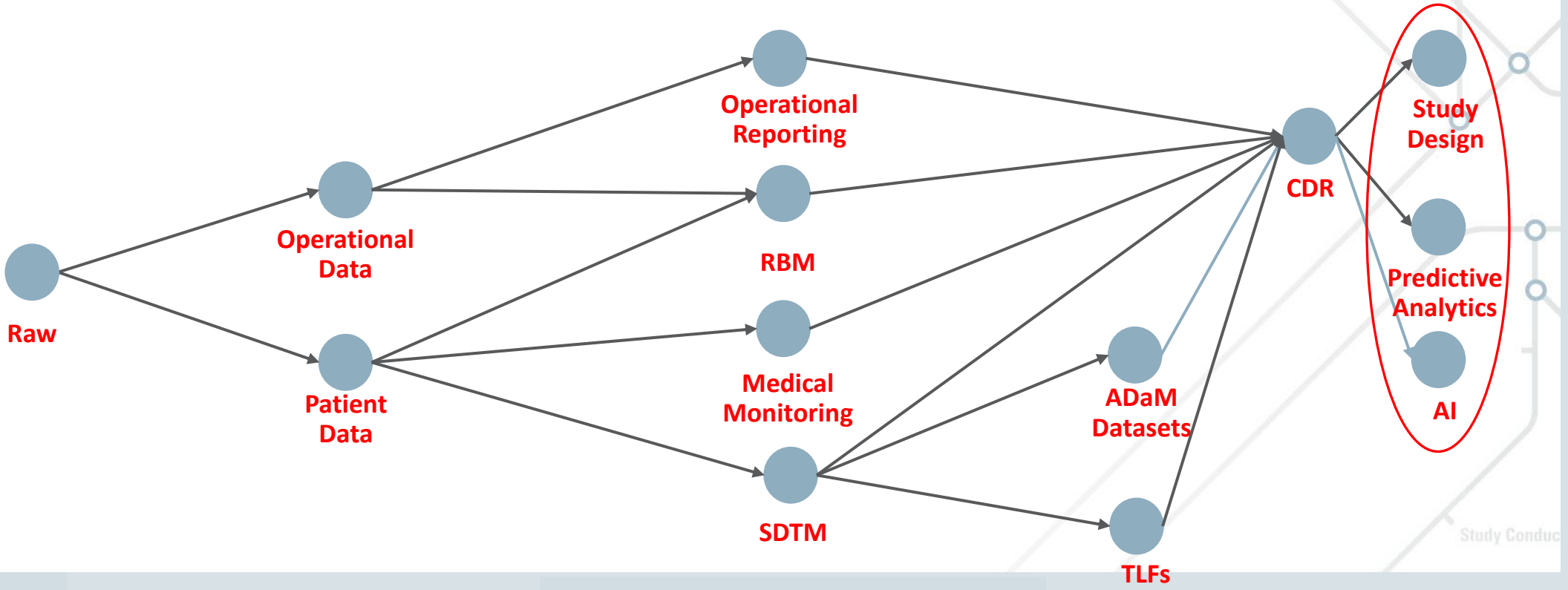

Traceback to Source

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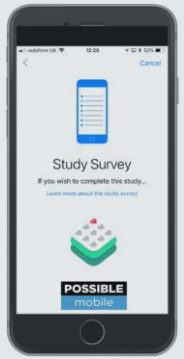


Integration: Bluetooth / Mobile App / Apple Health

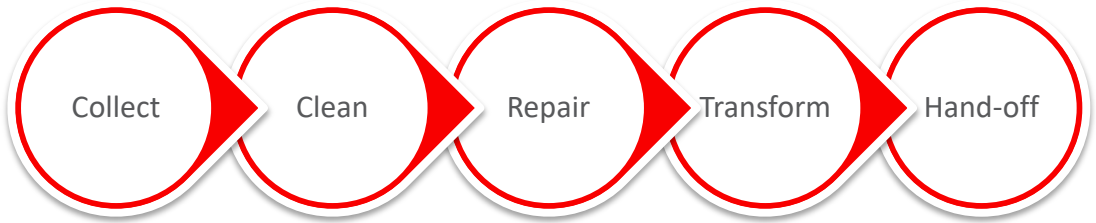
Integration: Vendor Cloud to Oracle mHealth

…support effective collaboration and management of partners

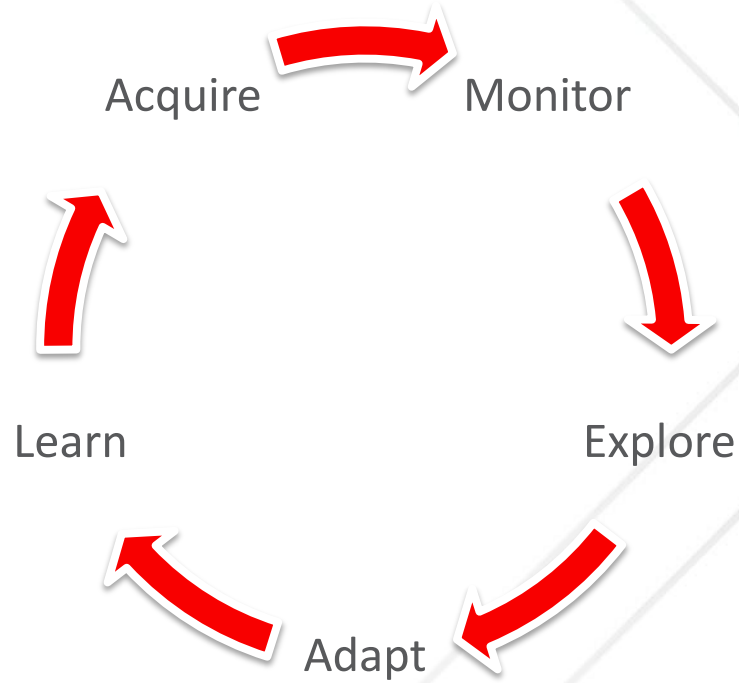
- Consume Partner/CRO services on your owned and operated Data Management Platform to maintain full control, transparency and real-time access
- Provide secure access to Partners/CROs on a Trial by Trial basis
- Maintain flexibility in managing and changing Partner/CROs over time
  - A direct benefit of making the black box, transparent and into a white box

Data Management may change...

From Clinical Data Management….

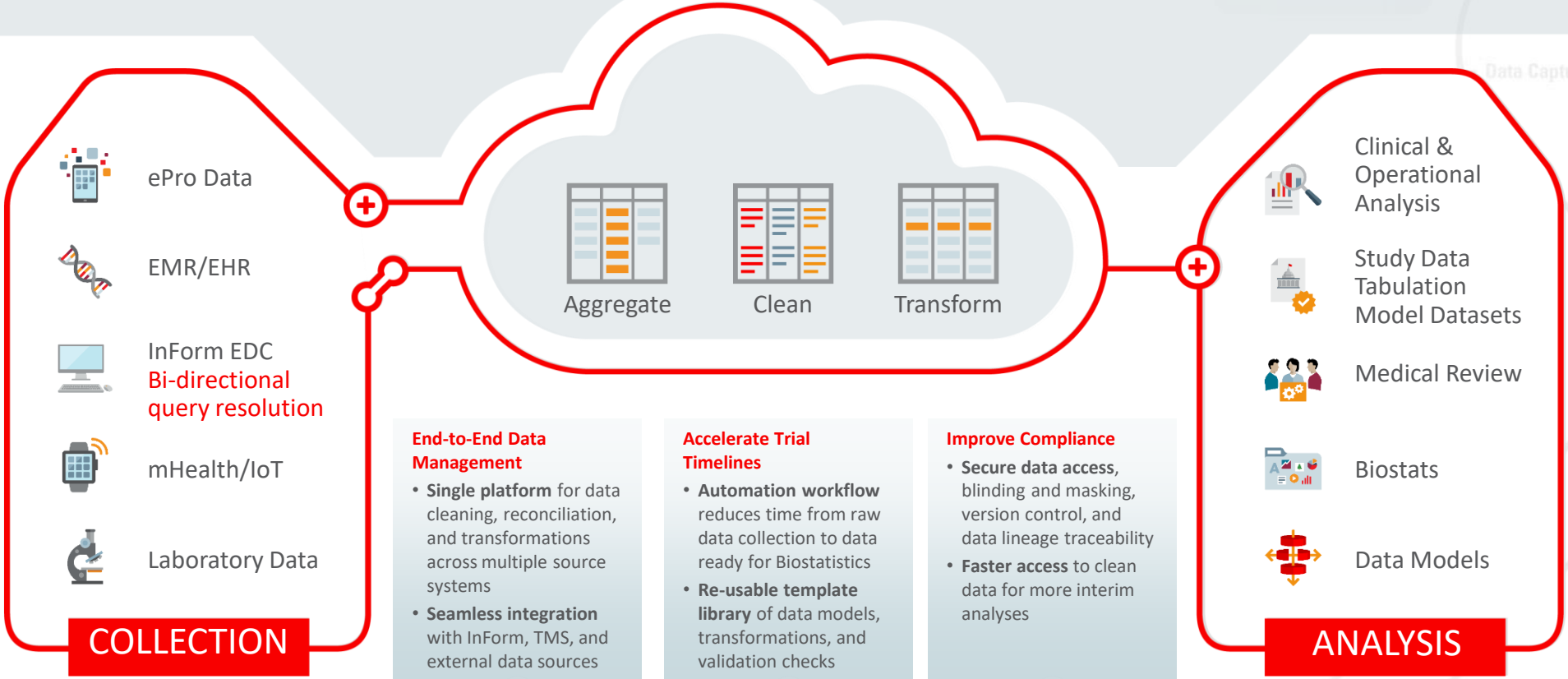


…to Clinical Data Science



Data Management

Oracle Health Sciences Data Management Workbench (DMW) provides you with the information you need to identify and respond to trial issues early and fast.



Key Benefits

End-to-End Data Management

- **Single platform** for data cleaning, reconciliation, and transformations across multiple source systems
- **Seamless integration** with InForm, TMS, and external data sources

Accelerate Trial Timelines

- **Automation workflow** reduces time from raw data collection to data ready for Biostatistics
- **Re-usable template library** of data models, transformations, and validation checks

Improve Compliance

- **Secure data access**, blinding and masking, version control, and data lineage traceability
- **Faster access** to clean data for more interim analyses

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Integrated Cloud

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