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Single Day Event

Tomorrow's Tapestry: Marvels through the Alchemy of Data Standards, Metadata, Automation, and Cutting-Edge Technology

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Disclaimer

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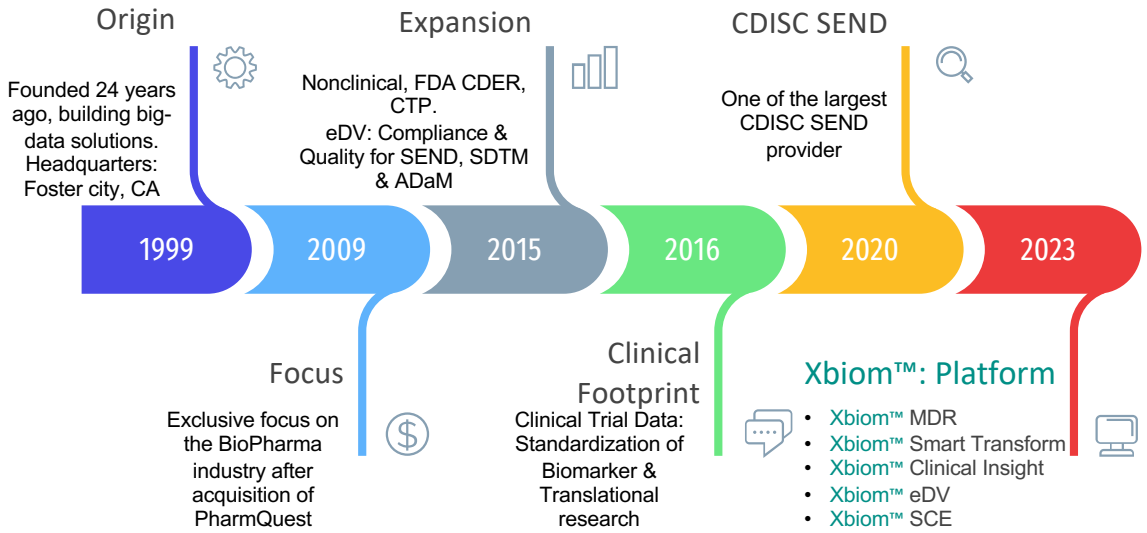
Agenda

- About PointCross
- What Sponsor needs?
- End-to-End Data Life Cycle of a Clinical Trial
- Data Monitoring as Trial Progress
- Data Exploration
- Preparing for Submissions
- Summarization and Q&A

About PointCross



Platinum member of CDISC and contributor to PhUSE

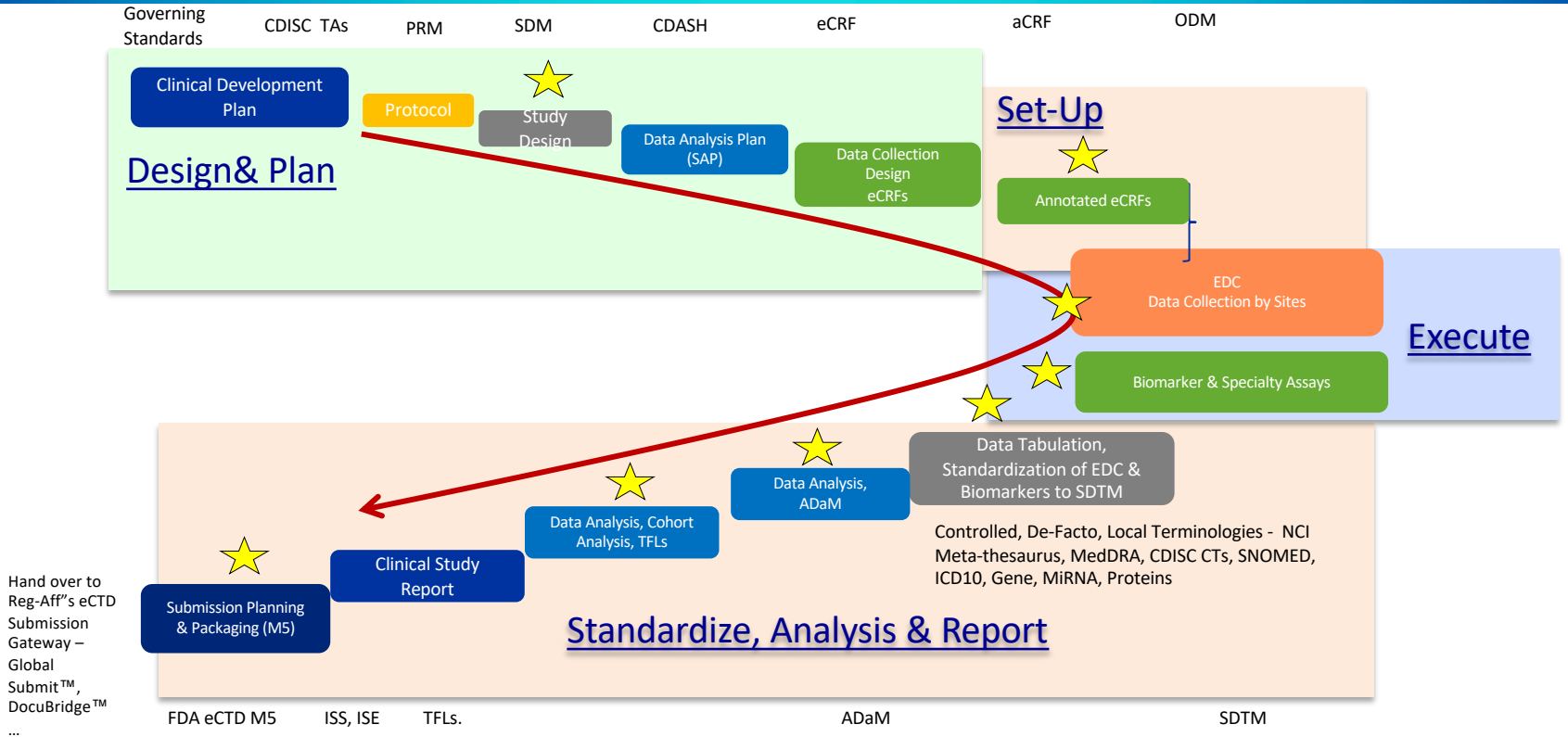
Serving 60+ Biotech/ Pharma
100+ CRO clients

- ✓ Global Team: US, France & India
- ✓ 10000+ no. of users downloaded eDV across US, Asia, Europe & Australia
- ✓ Standardized 7,500+ studies for repository, analysis over 14 years

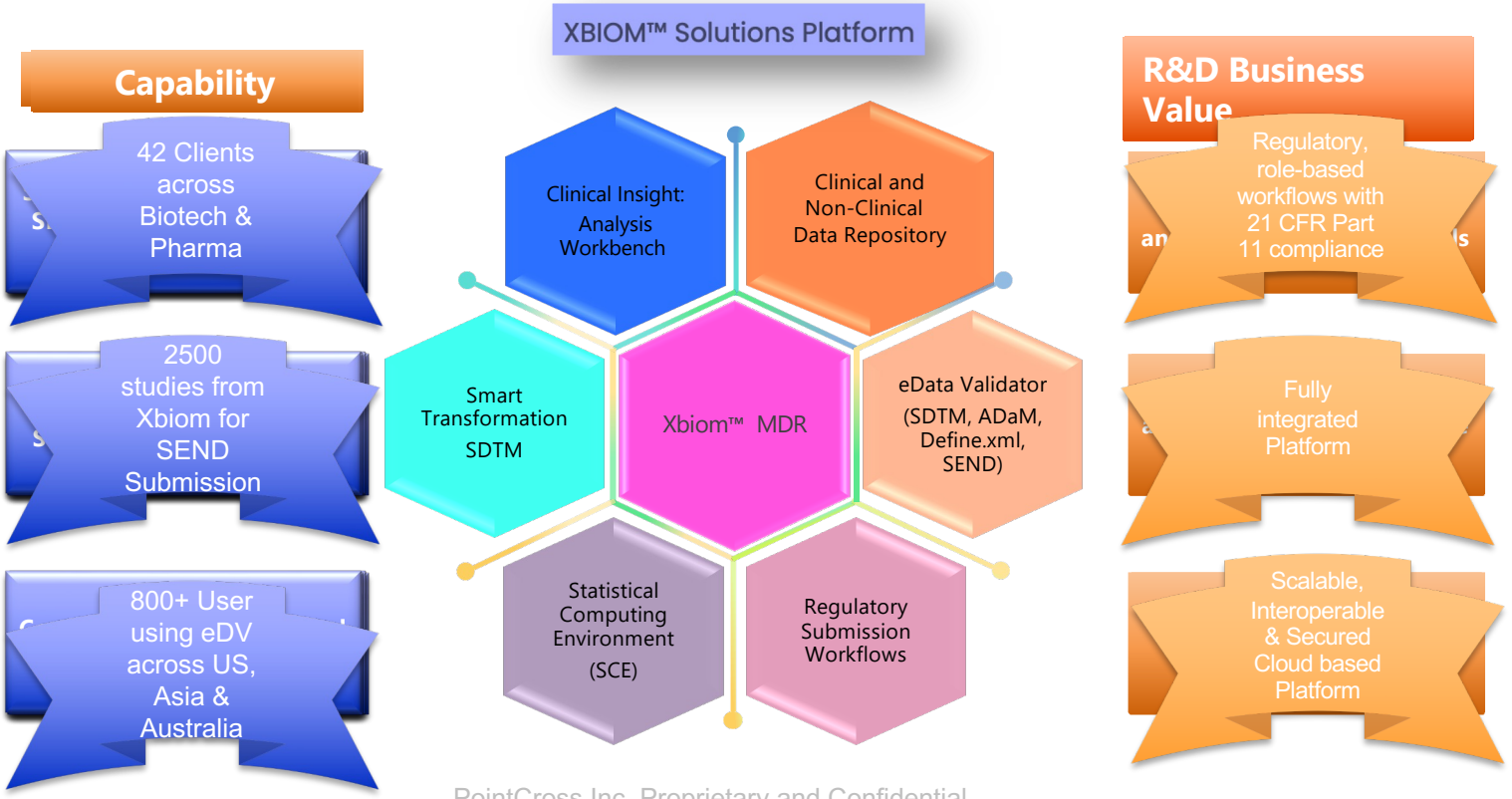
What Sponsor needs?

- Real time access to the data to understand the progress of the trial with respect to time, patient enrolled per cohort/site, with the important endpoints/events.
- Qualified and effective workflows for end-to-end planning, preparation, analysis, and packaging.

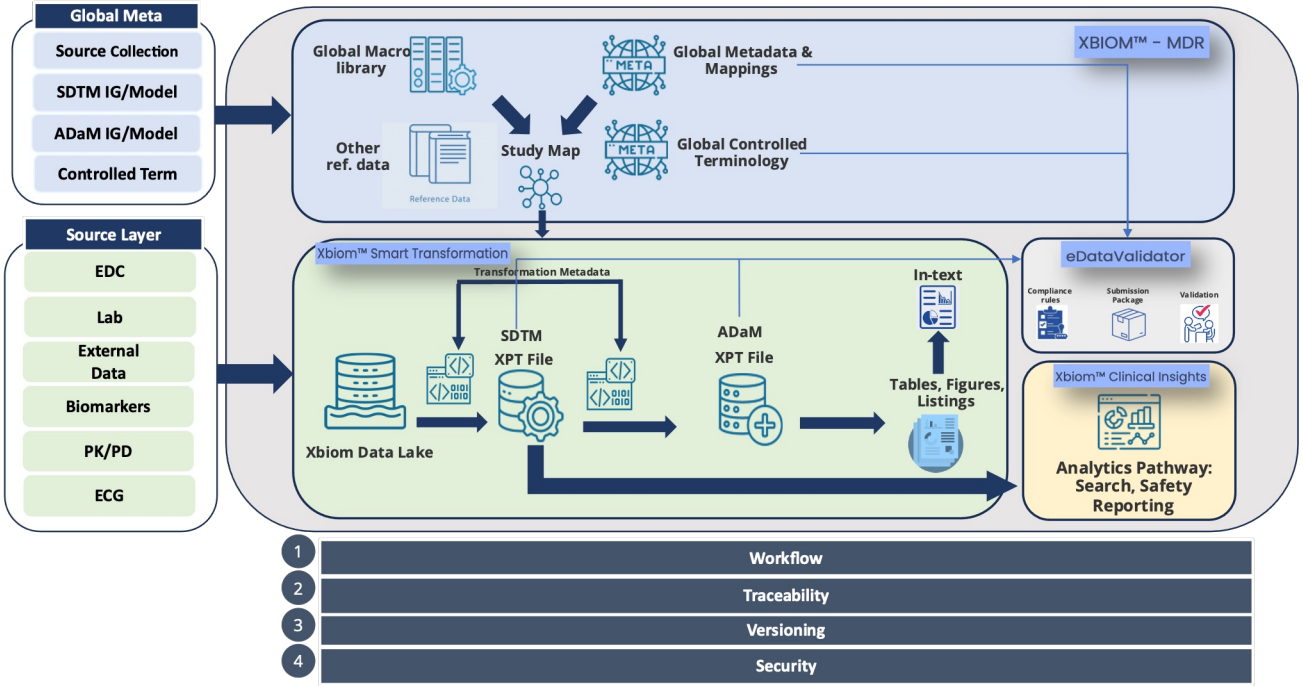
End-to-End Data Life Cycle of a Clinical Trial



Xbiom™ Solutions Platform



Xbiom™: End-to-End SDTM Submission



Data Monitoring as Trial Progress

- Understanding response of trial subjects to treatment or disease
- Uncover, relate and gather insights on subject end-points or Adverse Events to biomarkers
- Insights & clues from stratified cohort analysis on disease response

Data Exploration

14.3 Safety Data Summary figures and tables.

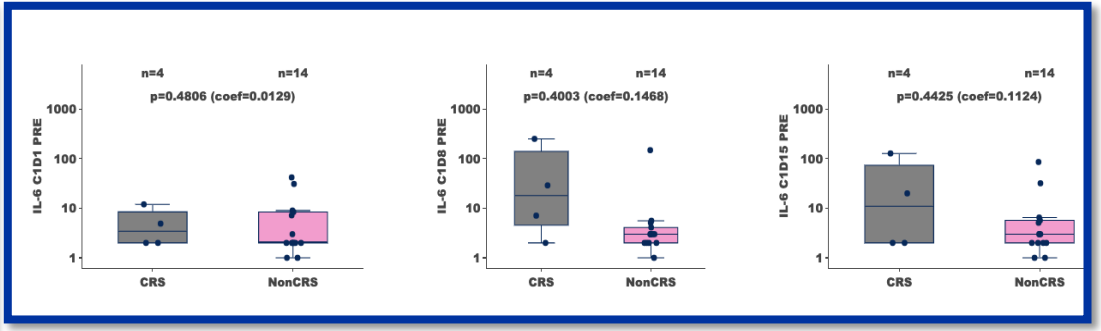
14.3.2 Overview of Adverse Events, Safety Population

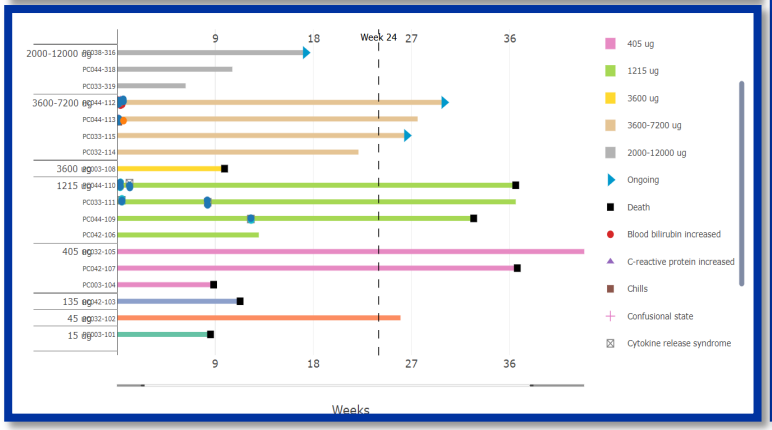
SEV	15 ug	45 ug	135 ug	405 ug	1215 ug	3600 ug	3600-7200 ug	2000-12000 ug
SAE	2	0	1	3	3	2	1	2
Grade 3	1	0	1	2	2	1	1	1
Death	1	0	0	1	0	1	0	0
Life-Threatening	0	0	0	0	1	0	0	1

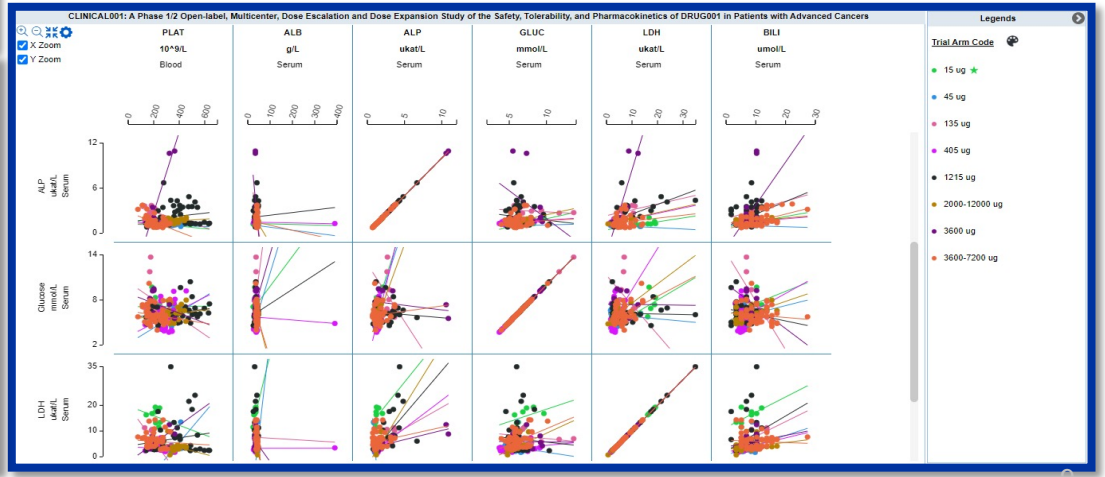
14.3.2 R script

14.3.3 Patients With Serious Adverse Events1 by System Organ Class and Preferred Term, Safety Population

DECOD	15 ug	45 ug	135 ug	405 ug	1215 ug	3600 ug	3600-7200 ug	2000-12000 ug
-Accidents and injuries (SMQ)	0	0	0	1	0	0	0	0
Fall	0	0	0	1	0	0	0	0
-Arthritis (SMQ)	0	0	0	0	1	0	0	0
Osteoarthritis	0	0	0	0	1	0	0	0
-Biliary system related investigations, signs and symptoms (SMQ)	0	0	0	0	0	0	1	0
Blood bilirubin increased	0	0	0	0	0	0	1	0
-Cardiac failure (SMQ)	0	0	1	0	0	0	0	0
Cardiac failure congestive	0	0	1	0	0	0	0	0
-COVID-19 (SMQ)	0	0	0	0	0	0	1	0
SARS-CoV-2 test positive	0	0	0	0	0	0	1	0



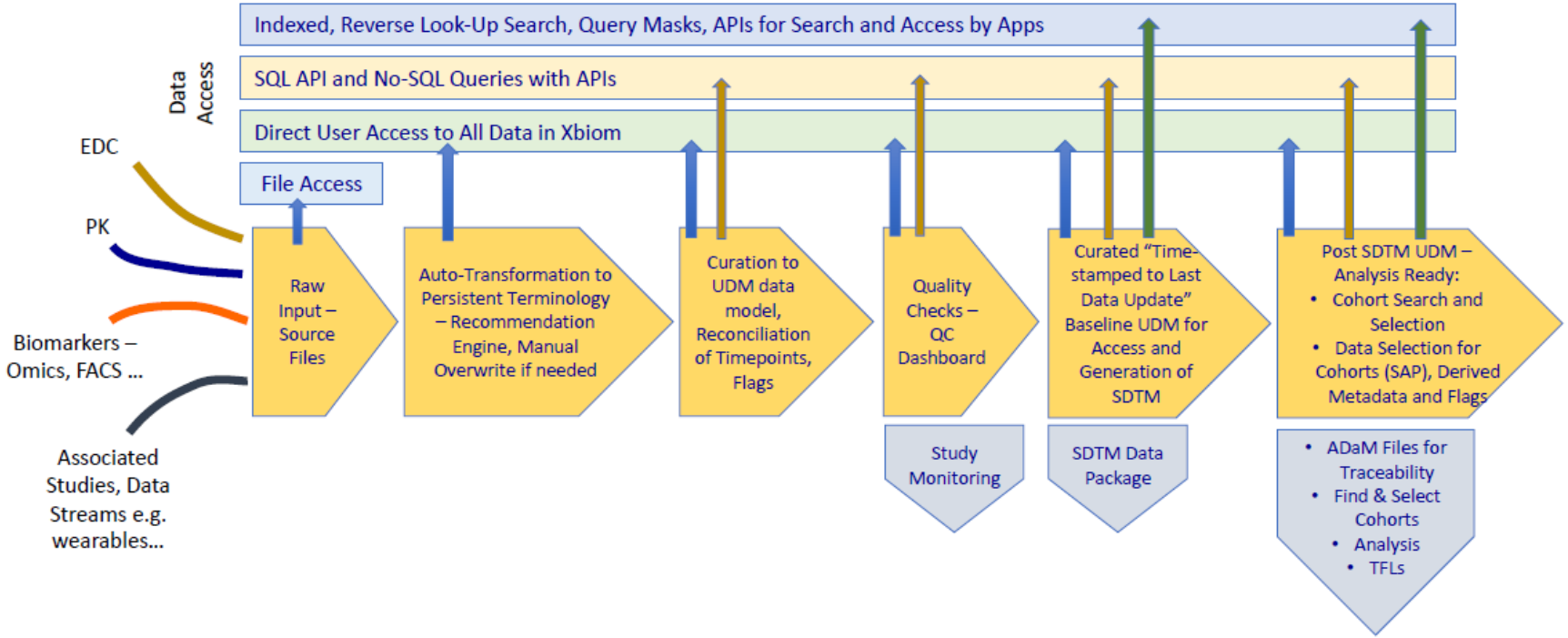




Preparing for Submissions

- Effective workflows to accelerate time to submission
  - Global Library & Standards Management
  - Streamlined Data ingestion & transformations
  - Standardized methods to enhance the data review and compliance process for improving data quality and submission deliverables

Data Curation and Standardization Stages to SDTM and Beyond



In Summary

Sponsor/CRO Objectives

- Enhanced Data ingestion & transformation
- Reduce effort for Metadata Change Management
- Faster Time to create Submission Deliverables
- Learning model, Automation & Accelerators

Xbiom Significant Accelerators

- Data Ingestion / Custom Connectors
- Global Library & Standards Management
- Macros and Derivation Library
- ML Based Mapping
- Self Service UI & Data pipelines

Solution Value

- 20% - 40% TCO Reduction
- 25% - 50% Accelerated Turn-around Time
- Drive Automation & Innovation entire clinical data pipeline
- Industrialization Scale up via standardized harmonization processes

Thank you

Xbiom™ makes data useful

Quality is never an accident. It's always the result of intelligent effort- John Ruskin

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The Global Healthcare Data Science Community

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