

# 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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Organization: PointCross Lifesciences

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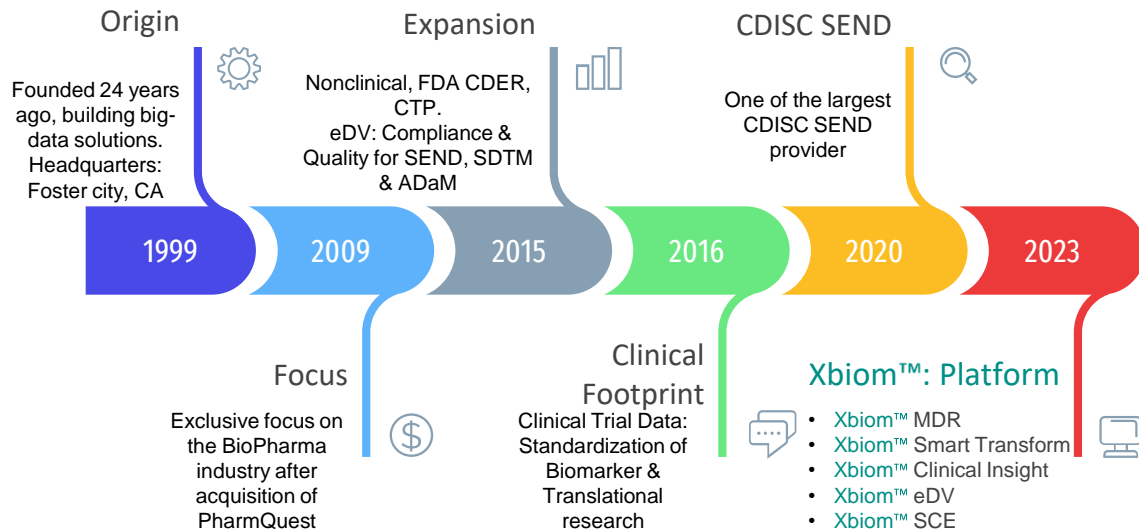


# Agenda

- 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

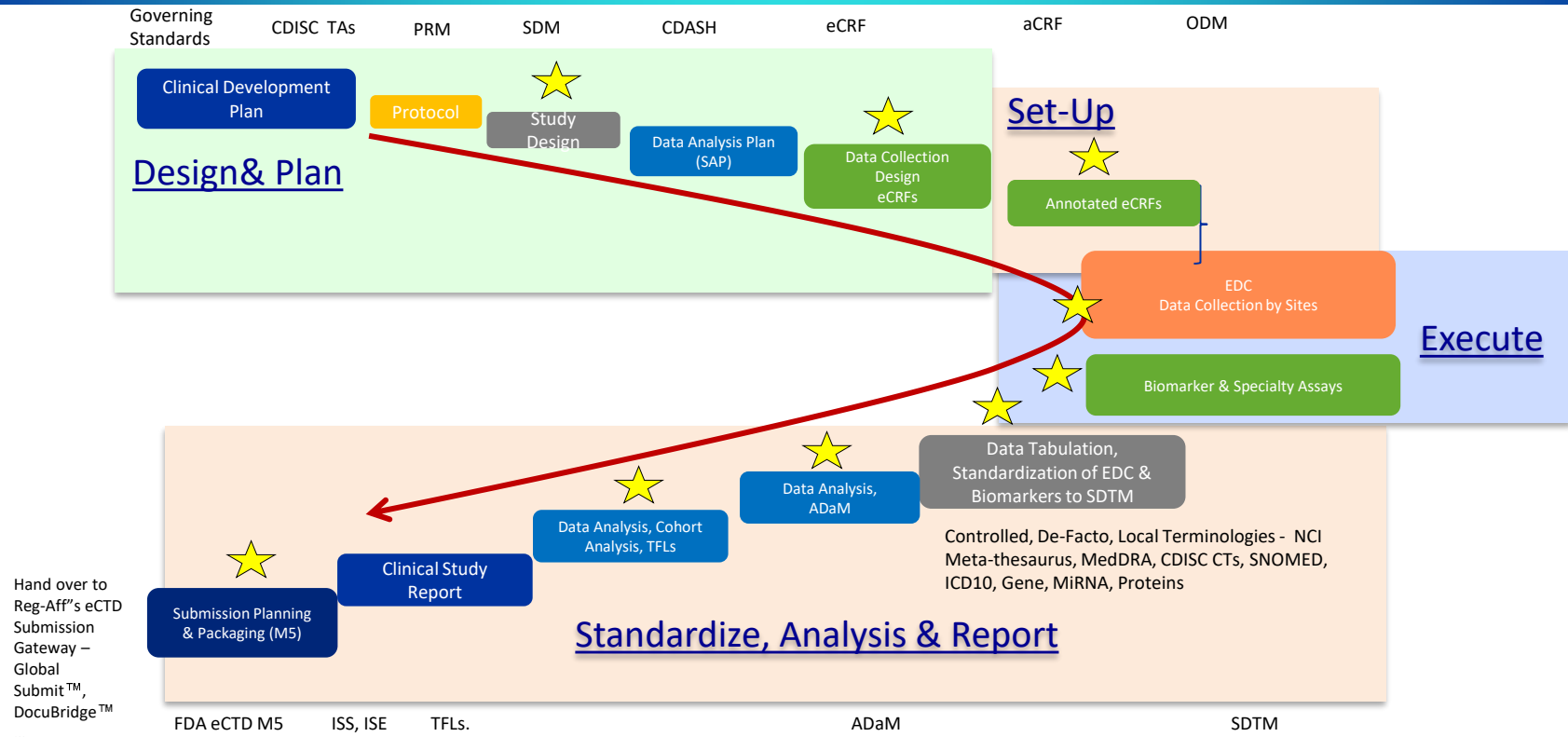


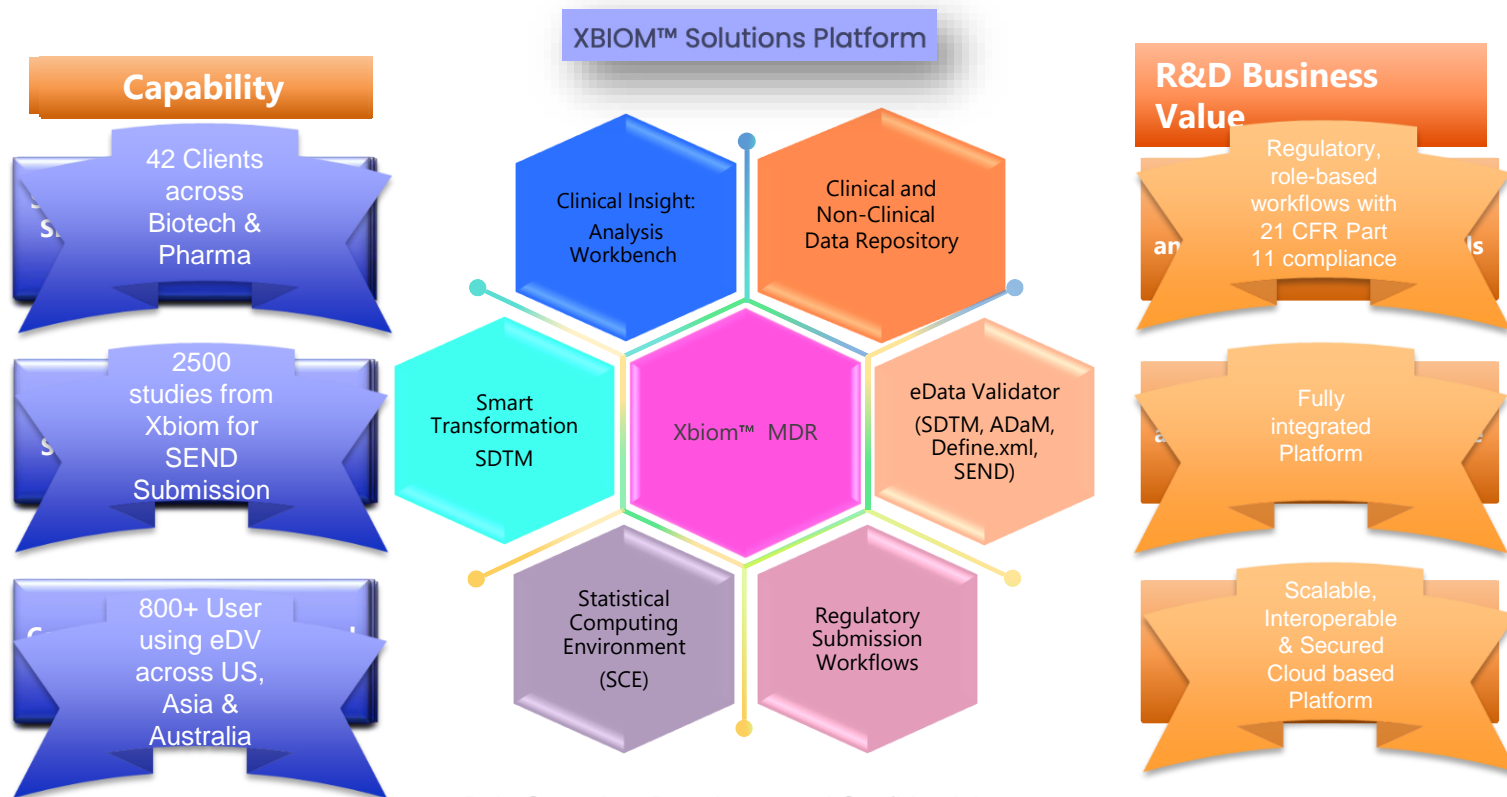
# What Sponsor needs?

- 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.

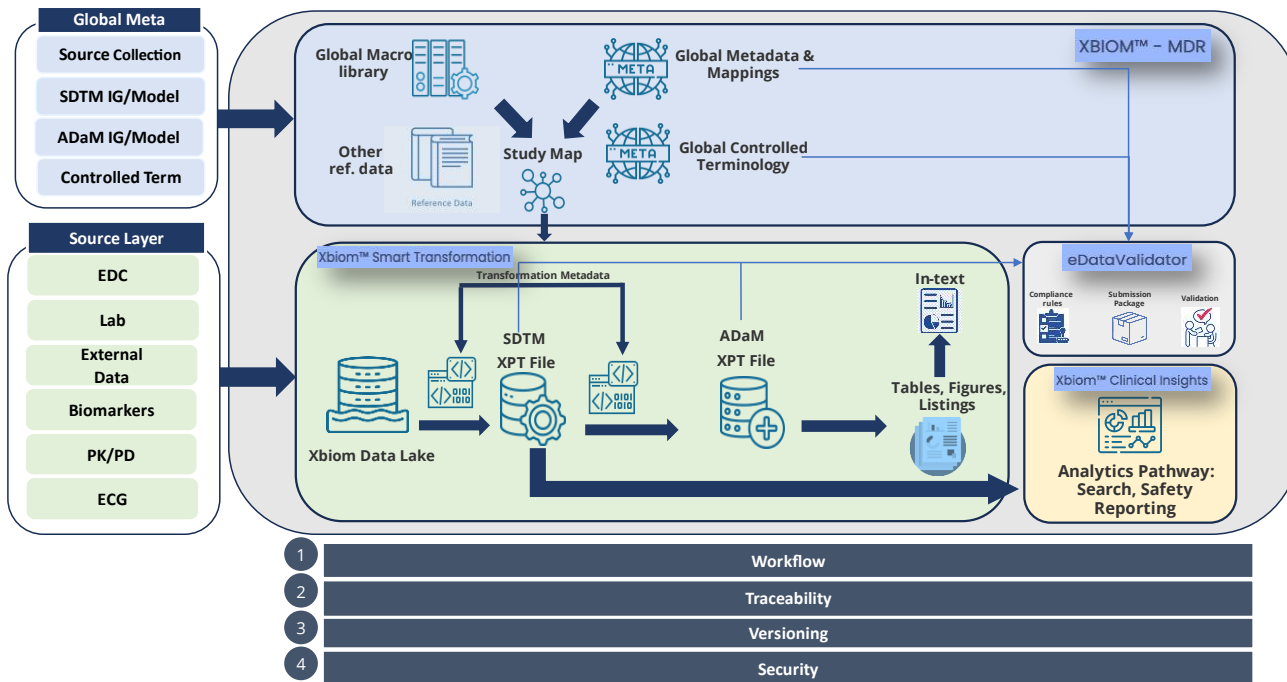


# End-to-End Data Life Cycle of a Clinical Trial





## Xbion™: 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.

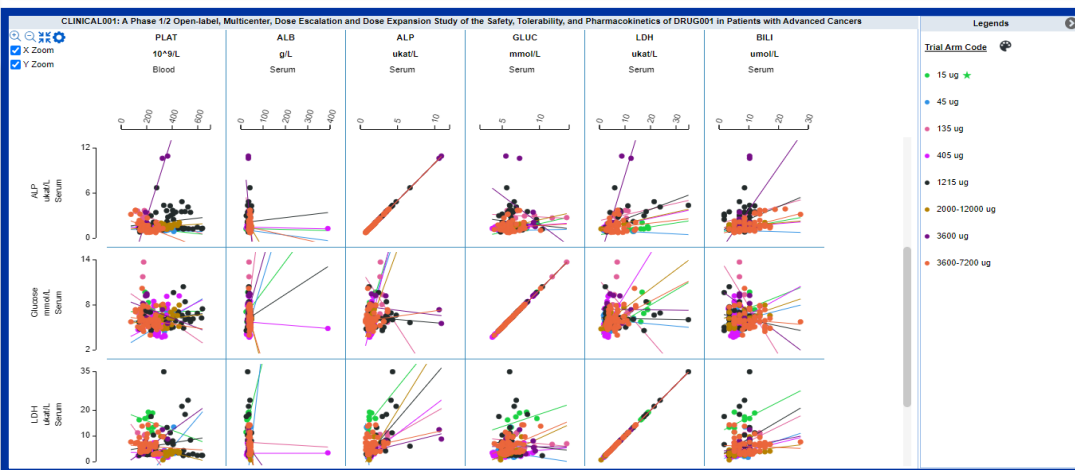
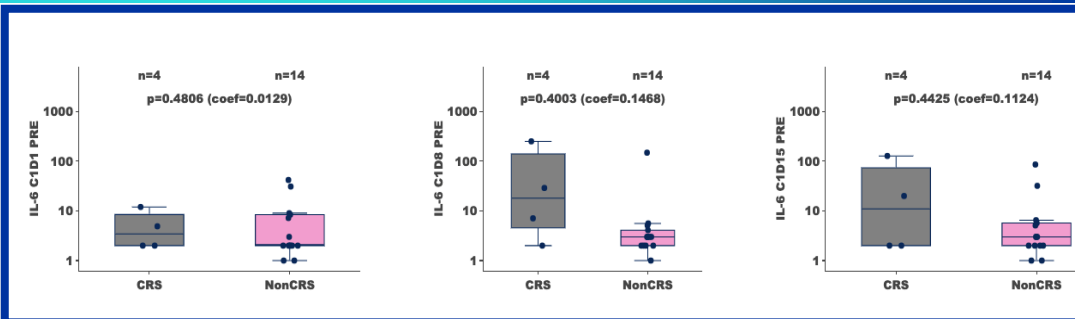
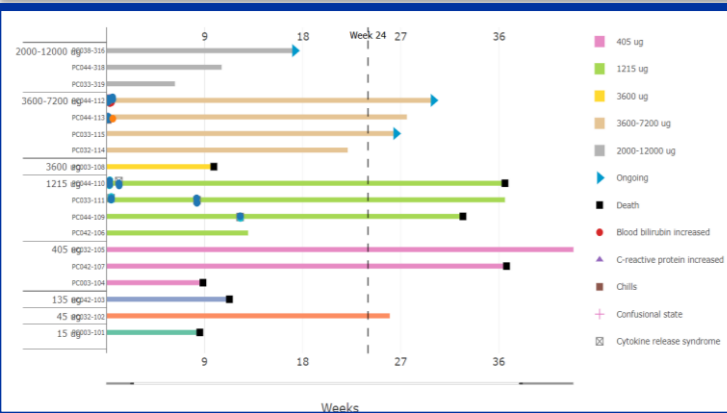
### 14.3.2 Overview of Adverse Events, Safety Population

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



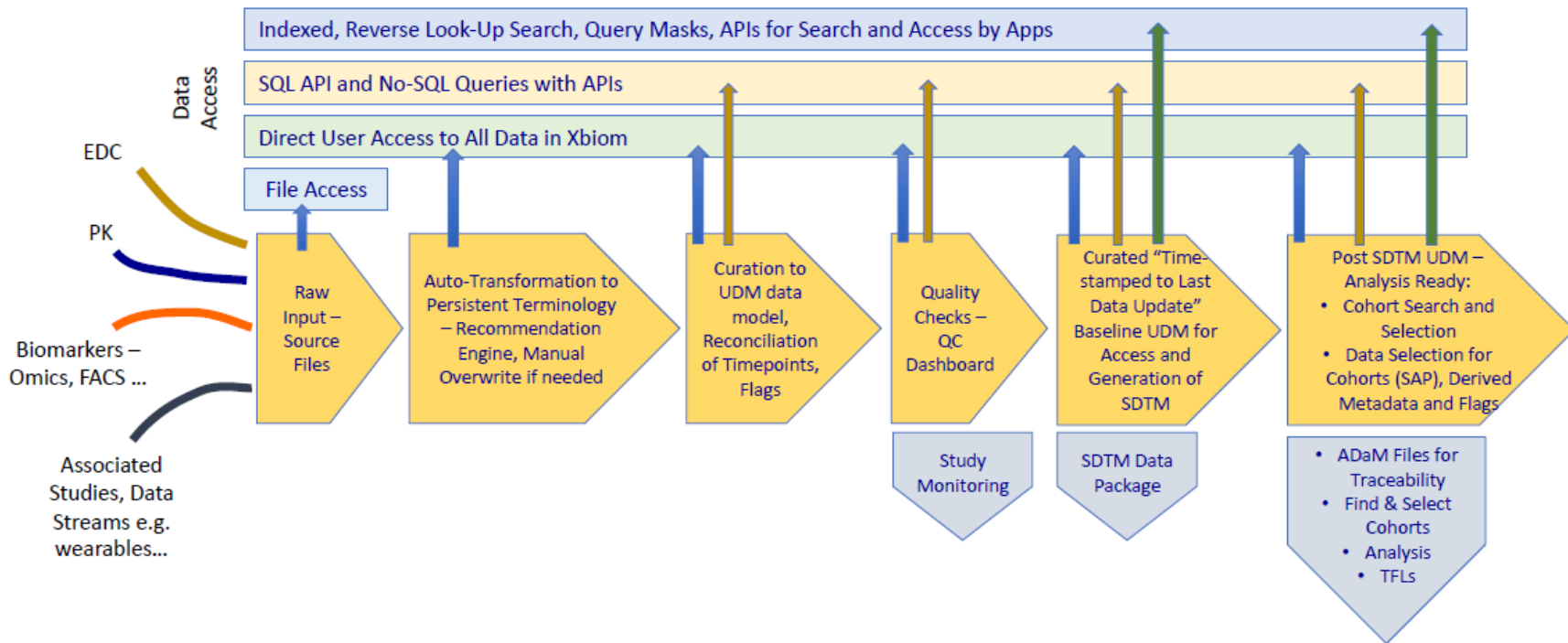


# Preparing for Submissions

- 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<sup>TM</sup> makes data useful

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



### The Global Healthcare Data Science Community

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