



From System Exports to Standards: Will Standardisation of External Vendor Data Redefine Clinical Data Management/Analysis?

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Meet the Speaker



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***Sai Sri Sravya Deevi** is a Clinical Consultant at Zifo Technologies, Inc., with over 8 years of experience in clinical data management and standardisation. She specializes in external vendor data integration, CDISC standards implementation, and clinical database programming across diverse therapeutic areas. Her work focuses on transforming vendor data acquisition from reactive, manual processes into systematic, automated workflows that ensure regulatory compliance and operational efficiency. Her expertise spans the full lifecycle of vendor data integration from specification development and Data Transfer Agreement negotiation to automated validation and production monitoring consistently delivering analysis-ready datasets that meet stringent CDISC requirements and accelerate study timelines.*

Agenda

- Challenges in External Vendor Data Integrations
- Vendor Data Integration Framework
- Methodology
- Results and Impact
- Case Study
- Conclusion

Abstract

In the rapidly evolving field of clinical research, integrating external data sources is crucial for enhancing clinical trial data and gaining insights into patient treatments. Diverse data sources like patient assessments, lab results, genomics, images/videos, and real-world evidence hold significant potential to advance drug development. However, orchestrating these data presents challenges in clinical data management. To successfully integrate external data, it is essential to address challenges in standardization, quality assurance, governance, and project management. Our strategies include adopting CDISC standards, enforcing stringent quality control, establishing clear governance frameworks, and ensuring timely data transfers. This approach allows us to standardize diverse data sources and provide study data for integrated review and analysis in under two months from contract sign-off. Through case studies and lessons learned from various projects, we will explore how to harness the full potential of external data to drive innovation and improve patient care.

Challenges in External Vendor Data Integrations



Vendors
delivering
non-CDISC
compliant
data formats



Missing or
incomplete
data
dictionaries



Inconsistent
quality
standards
across
vendors



Extended
timelines for
data
transformati
on and
reconciliation



Lack of
standardized
governance
processes

Vendor Data Integration Framework

Technical Infrastructure

- Data Destination Architecture
- Ingestion framework
- Quality Control Automation
- Integration capabilities

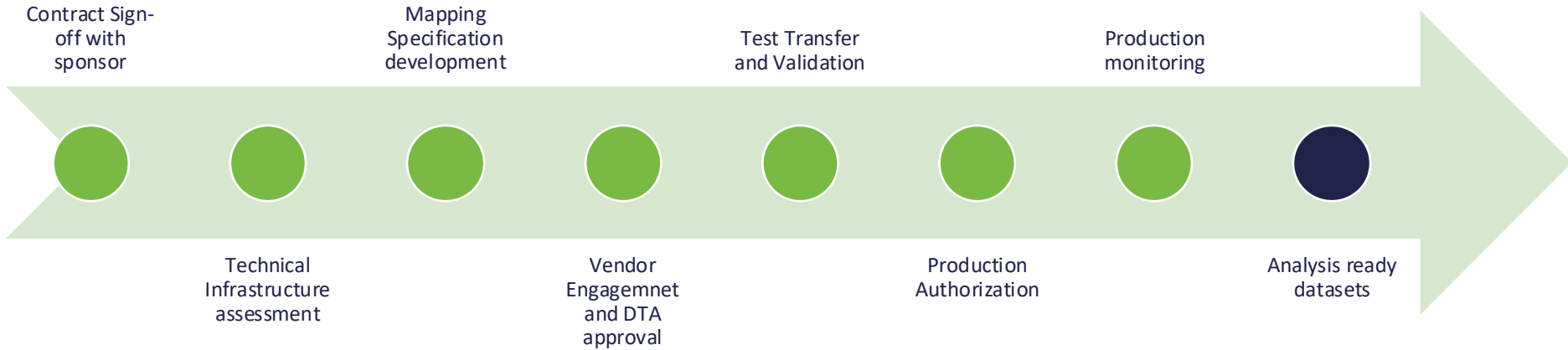
Data Governance

- Data Standards Adoption
- Data Management Process
- Organizational Structure

Domain Scalability

- Therapeutic area adaptability
- Domain Coverage expansion
- Continuous evolution

Methodology



RESULTS

Integration Efficiency

- Reduced integration timelines
- Enables earlier identification and resolution of data quality issues

Data Quality

- CDISC compliant data
- Elimination of post delivery correction cycles

Scalability

- Application of framework across multiple therapeutic areas
- Successful Implementation in complex datatypes such as biomarker and imaging data

CASE STUDY

Study Context

- Global Phase III oncology study
- External Data – Central lab, Imaging core lab, EPRO and Biomarker analysis

Challenges

- Proprietary XML format
- Non-standardized data dictionaries
- Variable mapping
- Project management challenges

Framework application

- Standardized ingestion pathways
- CDISC aligned DTAs
- Mapping Specifications for Biomarker analysis

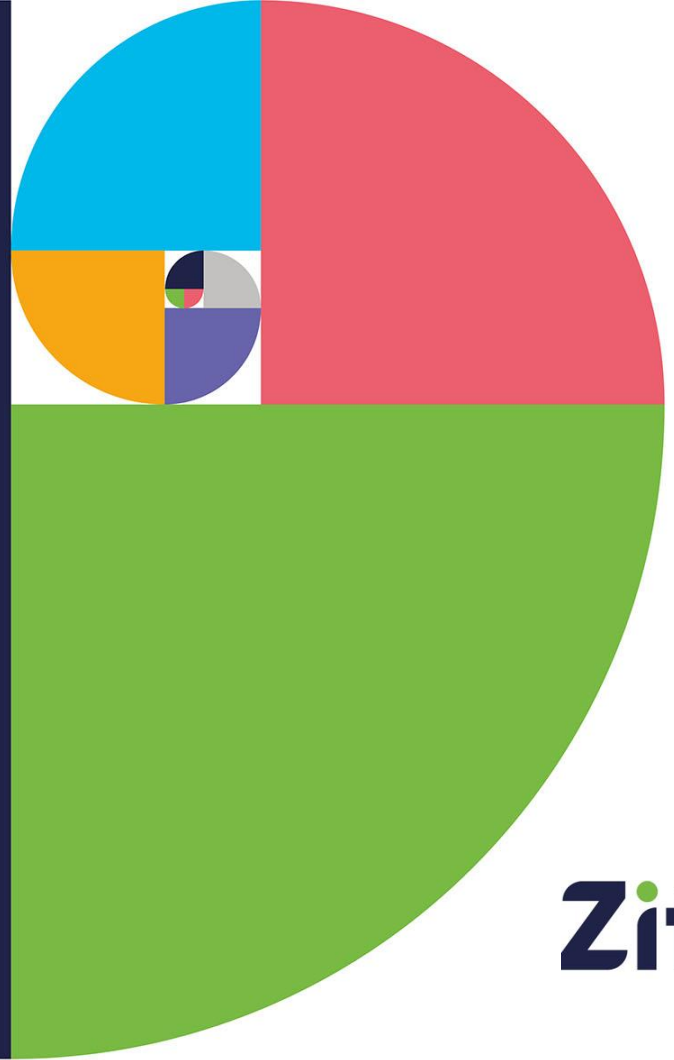
Outcomes

- CDISC Compliant test transfers
- Automated validation eliminated inconsistencies
- Analysis ready datasets

CONCLUSION

- Eliminated post-delivery data transformation
- Compressed database lock timelines
- Achieved first-transfer compliance
- Scalable across data modalities

Thank you



Zifo.