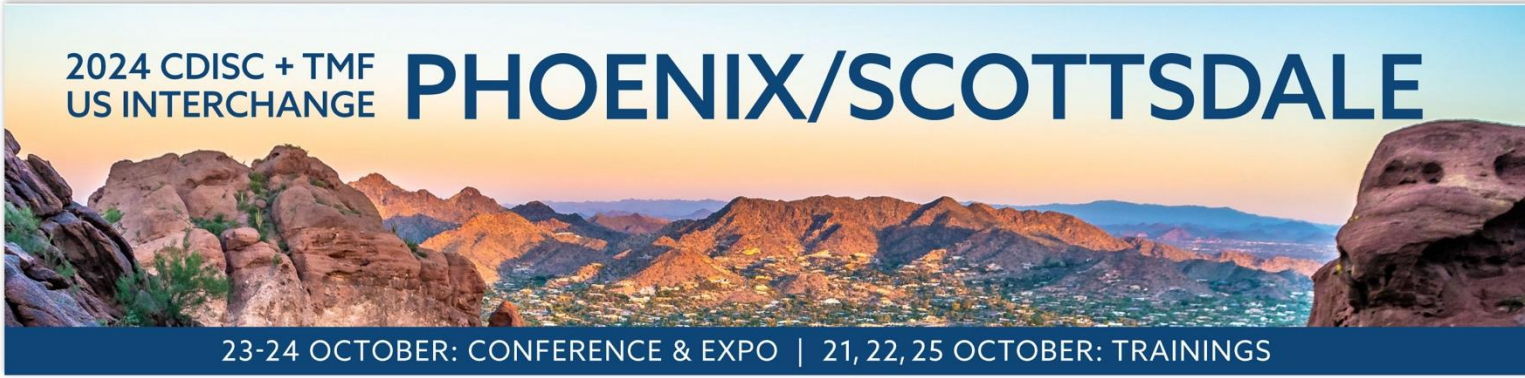


SDTM as Single Source of Clinical Data

Presented by Michael Goedde, President, Bioforum
and Bremer Louw, VP Operations, BionData

Meet the Speakers

Michael Goedde

Title: President

Organization: Bioforum

Michael is an industry veteran with 30+ years of experience ranging from working at biotech and big pharma companies to leading large global biometrics teams at CROs. His background is computer science and mathematics. In his current position he enjoys his role as President at Bioforum – The Data Masters.

Bremer Louw

Title: VP Operations

Organization: BionData

Bremer has been in the Clinical Research industry for 18 years, serving as SAS programmer in Data Management and Statistical Programming departments. He has been leading teams in Data Management and Statistical programing for more than a decade. Currently he is the Vice President of Operations at BionData, the technology department of Bioforum.

Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

- *The author(s) have no real or apparent conflicts of interest to report.*

Agenda

1. Problem
2. How can SDTM help?
3. Roadblocks
4. Solutions
5. Benefits

SDTM as Single Source of Clinical Data

Clinical Data are managed in Silos

Collected Clinical Data

Frequent

REPORTING

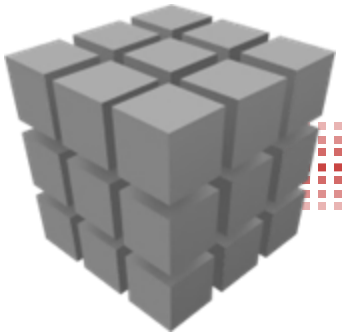
- Medical Monitoring
- Safety Review
- Data Management Review
- RBQM

1 Duplicate Normalization

Standardize

2 Discrepancies & Quality Issues

SDTM



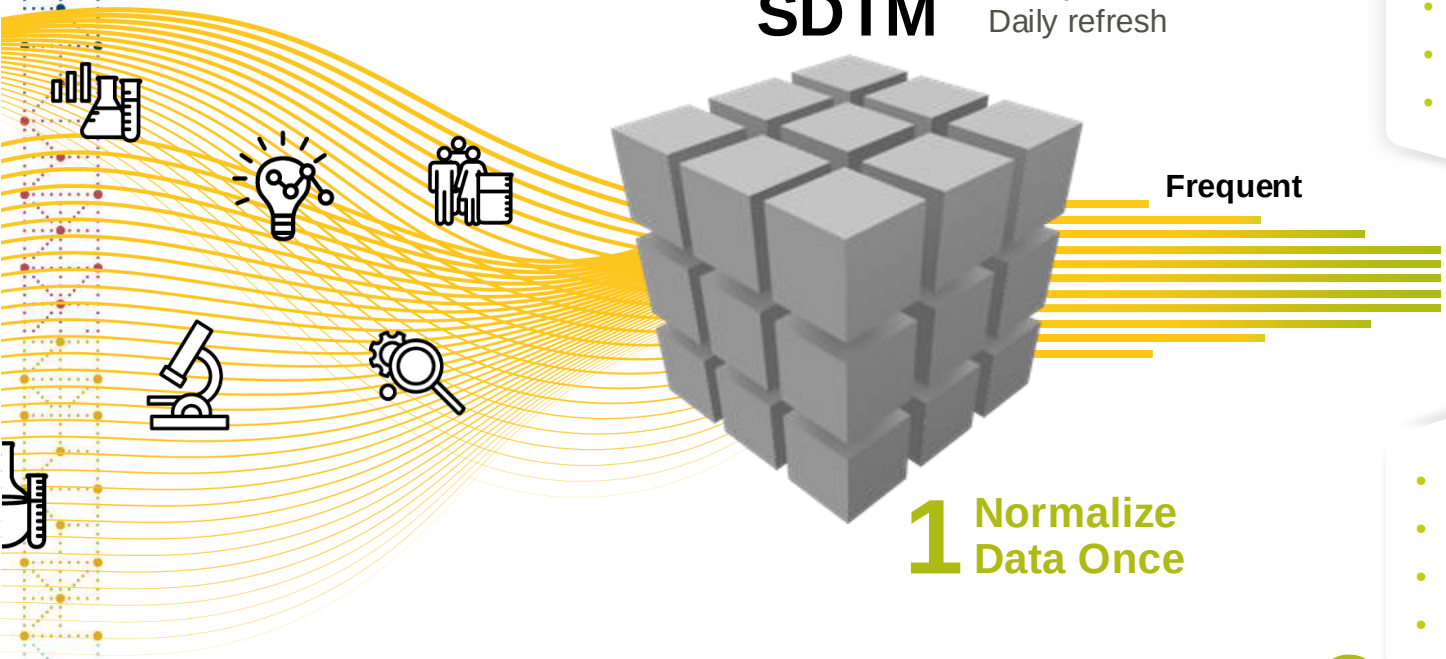
Infrequent

- Statistical Analysis
- Regulatory Submission
- Cross Study Analysis
- Future Study Design

3 Limited Reusability

SDTM as Single Source of Clinical Data

How can SDTM help?



REPORTING

- Medical Monitoring
- Safety Review
- Data Management Review
- RBQM

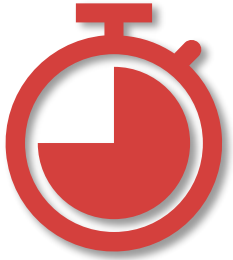
2 Complete Alignment

- Statistical Analysis
- Regulatory Submission
- Cross Study Analysis
- Future Study Design

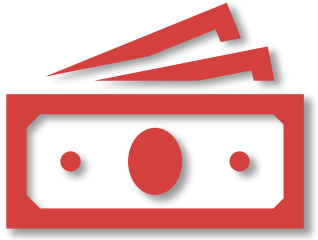
3 Reusable

SDTM as Single Source of Clinical Data
Roadblocks to Adoption

Standardized & analysis ready data is…



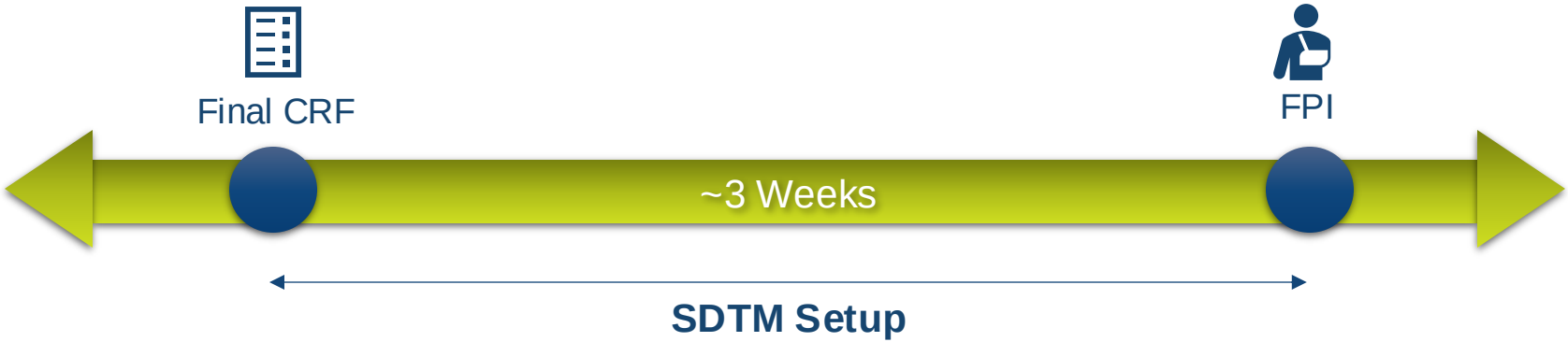
Available **LATE** in the study



COSTLY to keep LIVE

SDTM as Single Source of Clinical Data

Solution - Available LATE in the study



Short Timeline

Technology & Processes
Reduce manual effort through technology and streamlined processes

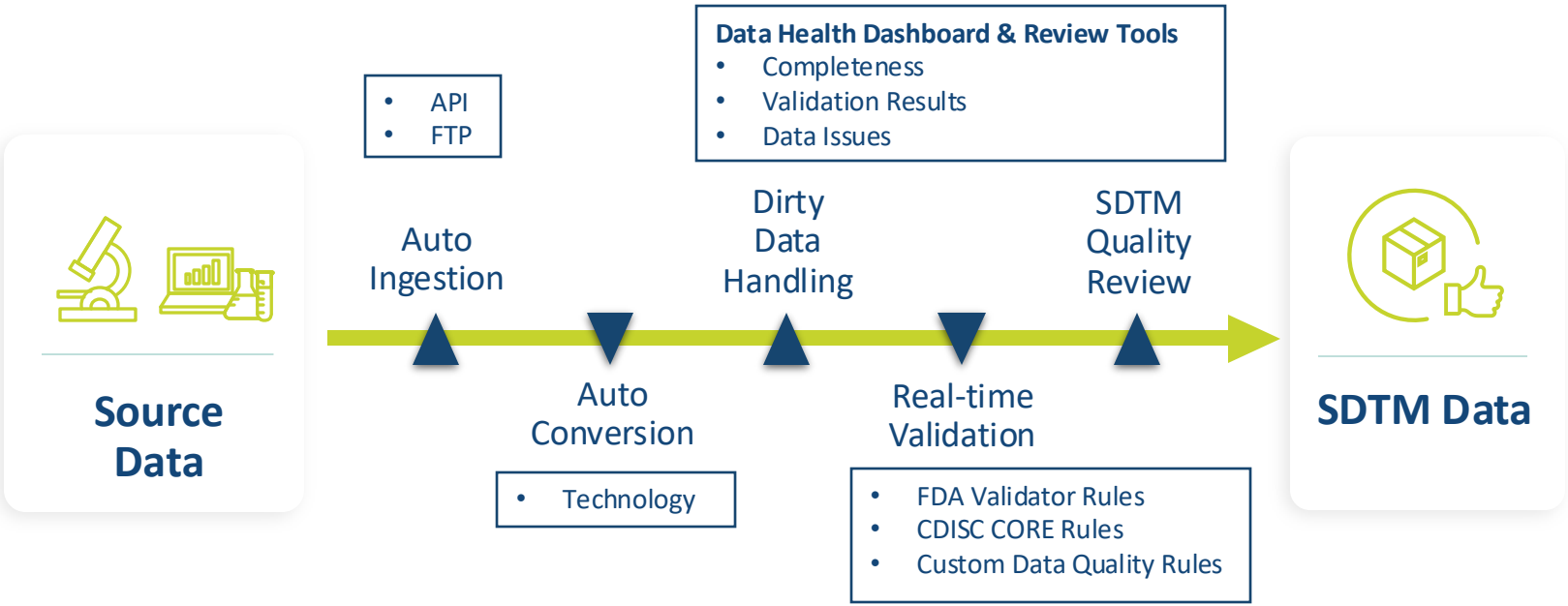
Lack of Data

Synthetic test data
Generate test data from source system Metadata

SDTM as Single Source of Clinical Data

Solution – Costly to keep LIVE

No human intervention – Only monitoring



SDTM as Single Source of Clinical Data
Benefits

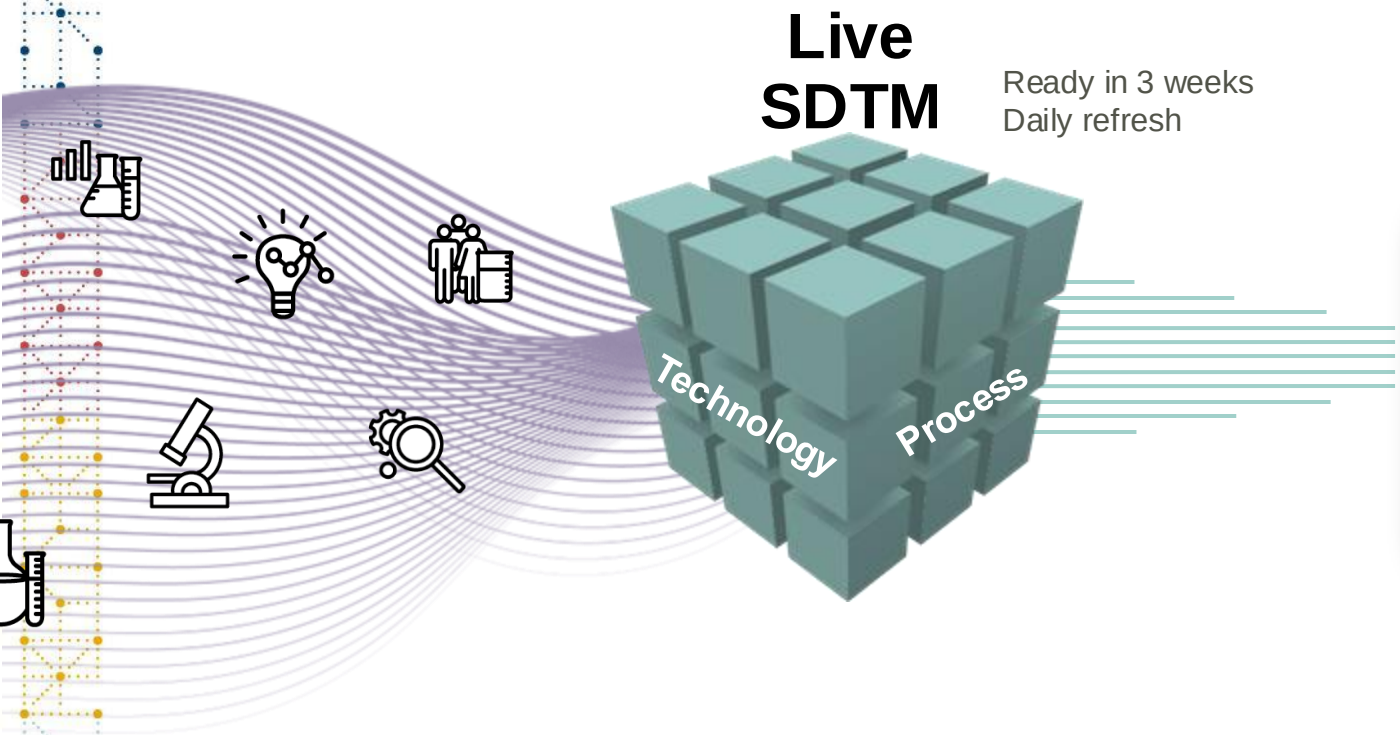
Cost Saving
- ✓ Normalize your data only once
- ✓ Reuse visualizations, reports, listings
- ✓ Automated Reruns

Time Saving
- ✓ Avoid lock delays with proactive issue detection and resolution
- ✓ SDTM within 24 hours from lock
- ✓ Standardized visualizations and reporting available at FPI

Quality Improvement
- ✓ Unified decision making - Avoid reporting discrepancies
- ✓ Monitor data quality against FDA requirements
- ✓ Avoid downstream quality surprises with continuous data validation

SDTM as Single Source of Clinical Data

Conclusion



REPORTING

- Medical Monitoring
- Safety Review
- Data Management Review
- RBQM
- Statistical Analysis
- Regulatory Submission
- Cross Study Analysis
- Future Study Design

Thank You!

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Bremer Louw

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