

BIOGRAPHY

Michael Roberson is VP Business Development at MaxisIT. Michael has worked in customer facing roles in the clinical research and development market at SAS Health and Life Sciences, Oracle Health Sciences, OminComm Systems, Aris Global, and several startup companies.

Michael helps companies select and implement new systems across the life-cycle of clinical trial execution and reporting. Michael enjoys connecting with business leaders and subject matter experts to improve the process of planning, executing, documenting and analyzing clinical trials, with the ultimate goal of bringing new therapies to patients.

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The 80/20 Rule: How AI-Driven Automation Improved Efficiency and Quality for Operational Data

A case study of a top-10 sponsor's adoption of an AI-driven approach to gaining greater control, consistency and value by creating an operational data repository.

Question?

Can clinical trials data be truly standardized?

~~Yes~~

No

Why?

Because clinical trials are scientific experiments.

What can be Achieved?

While we can't achieve 100.0% data standardization, we can,

- Define core data standards across programs and therapeutic areas**
- Consistently use our standards with our partners and CROs**
- Consistently validate data *received* against our standards**
- Create a historical single source of truth repository**
- Move to automated, AI-driven systems to remove manual error prone processes**

Case Study

- **Top 10 pharmaceutical company**
- **Business Owners aligned with Clinical Operations**
 - **VP, Clinical Information Sciences**
 - **Senior Director, Clinical Information Management**
 - **Director, Clinical Information Management**

Lack of Consistent Operational Data

- **Study conduct outsourced to CROs**
- **Study setup done with *internal CTMS***
 - **not well suited to maintain data standards across studies/programs**
- **Inconsistent data for ClinOps teams impacted quality, slowed decision making and delayed reporting**
- **Desire to retire CTMS**
- **Desire for an operational single-source-of-truth**

Strategy (1 of 2)

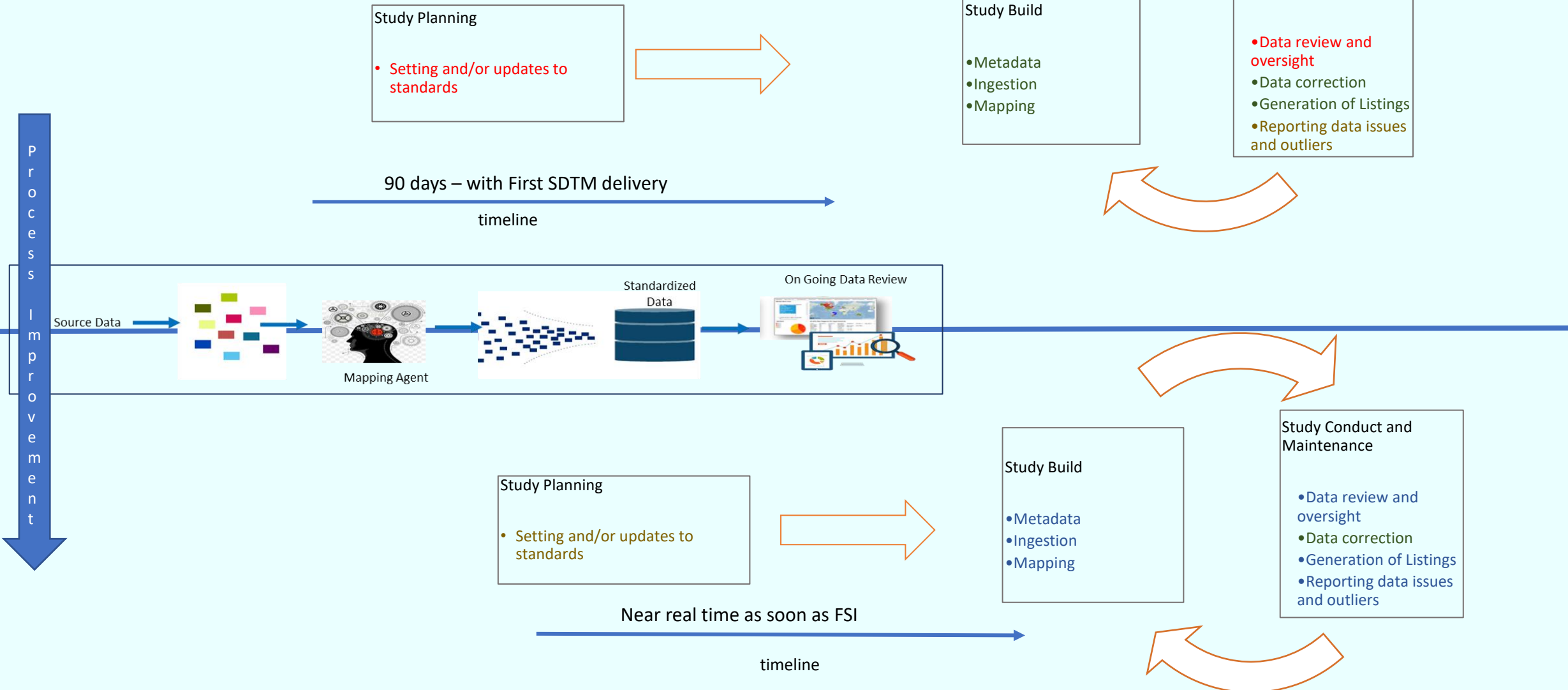
- **Standardize data definitions, ensure data consistency within and across programs**
- **Create an operational data repository to,**
 - **Support on-going trials**
 - **Allow historical comparisons**
- **Make data readily available for,**
 - **Operational oversight**
 - **Faster decision making and problem solving**
 - **Timely regulatory reporting**

Strategy (2 of 2)

- **Replace CTMS with metadata-driven bi-directional operational data repository**
 - **Share study designs with CROs**
 - **Automate mapping and validation of data receipt**
- **Increase automation, reduce manual processes, and improve data quality / consistency**
 - **In exchanging study design data w/ CROs**
 - **When receiving study conduct data from multiple eClinical systems across multiple CROs**

Case Study – Process Improvement

- ✓ Outsourced process
- ✓ Inhouse automated process
- ✓ Inhouse manual process
- ✓ **Manual process**



Lessons Learned

- **Data governance needs strong management support**
- **Agreeing to data standards requires organizational collaboration**
- **Maintaining data standards requires consistent training**
- **Use the 80/20 rule to reduce manual intervention, increase efficiency and improve moral**
- **Automation is possible and yields results – e.g. AI-driven data mapping did reduce errors and allowed staff to focus on actual problems**

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