



saama

#1 in AI Clinical Analytics

SI01

Automate to Accelerate: **Saama's Smart Auto Mapper**

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Agenda

1. Intelligent Clinical Cloud
2. Industry Problem
3. Automation
4. Clinical AI Research Model
5. Clinical AI Success
6. Questions

Saama's Intelligent Clinical Cloud Offering: Life Science Analytics Cloud (LSAC)



Accelerated Clinical Trials

When all your clinical data is in one place and updated in real time, life's much easier for your ClinOps and Medical Review teams.



Automated Data Quality

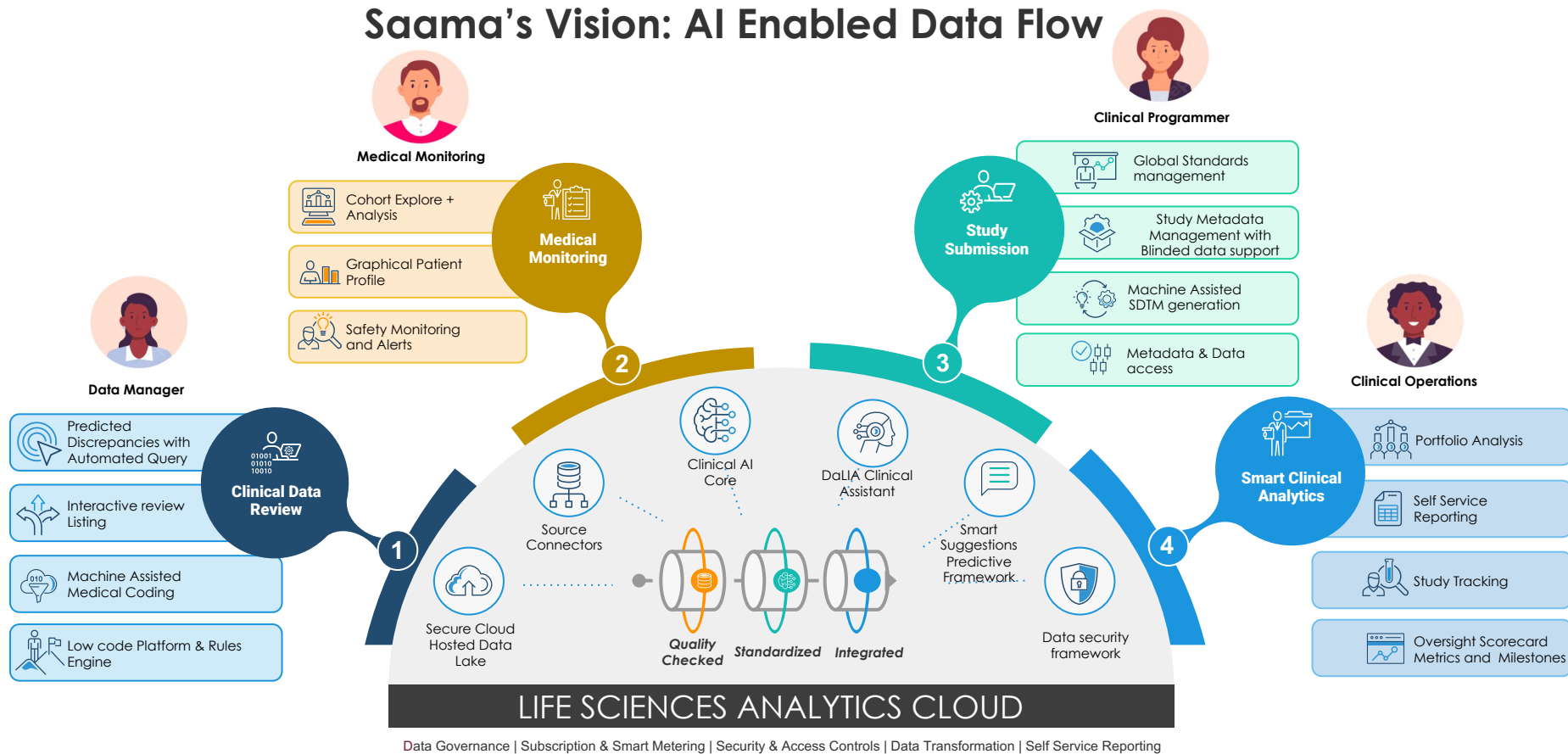
Data Managers have been underappreciated for too long. Eliminate manual work so they can pay attention to the data points that matter most.



Streamline Regulatory Submissions

Pharmacovigilance teams can generate regulatory submissions in minutes, and actively monitor drug safety signals after drugs get approved.

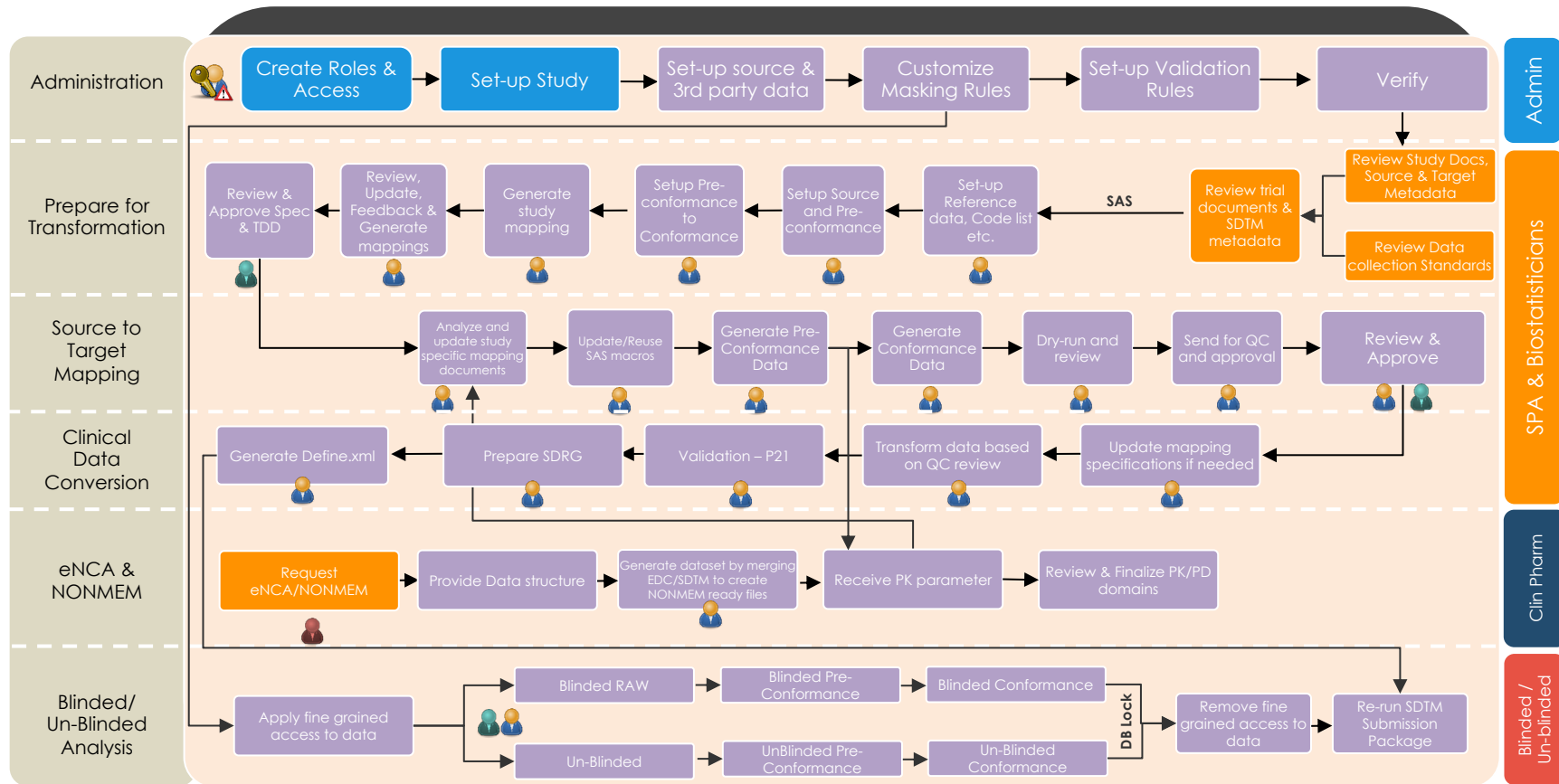
Saama's Vision: AI Enabled Data Flow



Context: Current Clinical Development Business Processes



Traditional SDTM Mapping Process



Current Challenges in Mapping Process



Current Challenges

- Manual and laborious task of mapping each SDTM domain column
- Manual task to perform unit conversions, codelist maps etc.
- Manual errors related to correctness and completeness of maps
- Increase in lead time of SDTM generation
- Manual task to understand raw data/metadata as a precursor to manually mapping
- Inconsistency of maps across studies
- Lack of version control of maps
- SDTM conversion is not real time i.e. mapping effort aligned to study milestones



Solution Need

- Automation of map creation
- Auto-verify & test maps
- Re-usability of maps across studies
- Reduce time to understand raw data/metadata
- Support for near real time conversion
- System enforced version control
- Implement maps as a configuration



Business Outcomes

- Reduction of lead time for generating SDTM
- Reduction of time & resource
- Realtime SDTM generation
- Real Time analytics & data visualisation possible

SDTM Development, Quality & Issue Remediation



**Preconfigured Global Library, Ingestion
APIs, Custom Connectors and Standards,
Study Set-up & Registration**

Initialization through global standards

1

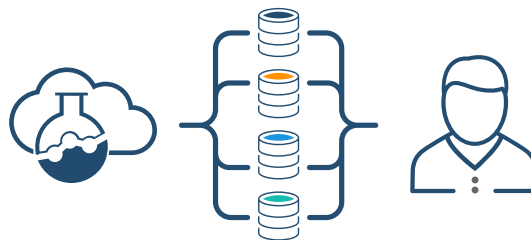
Finalize SDTM Development
Perform Dry Run | Approve & Promote Maps

2

Ensure SDTM Dataset Quality
Verify Vendor SDTM & Raw Data in Programing
Environment

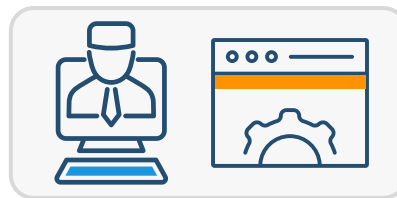
3

SDTM Error & Issue Remediation
Review QC Reports in SAM | P21 Reports
Approve Metadata Transformations



Extract SDTM Datasets with SAM

Raw Data from 3rd Parties & Vendor SDTM Data



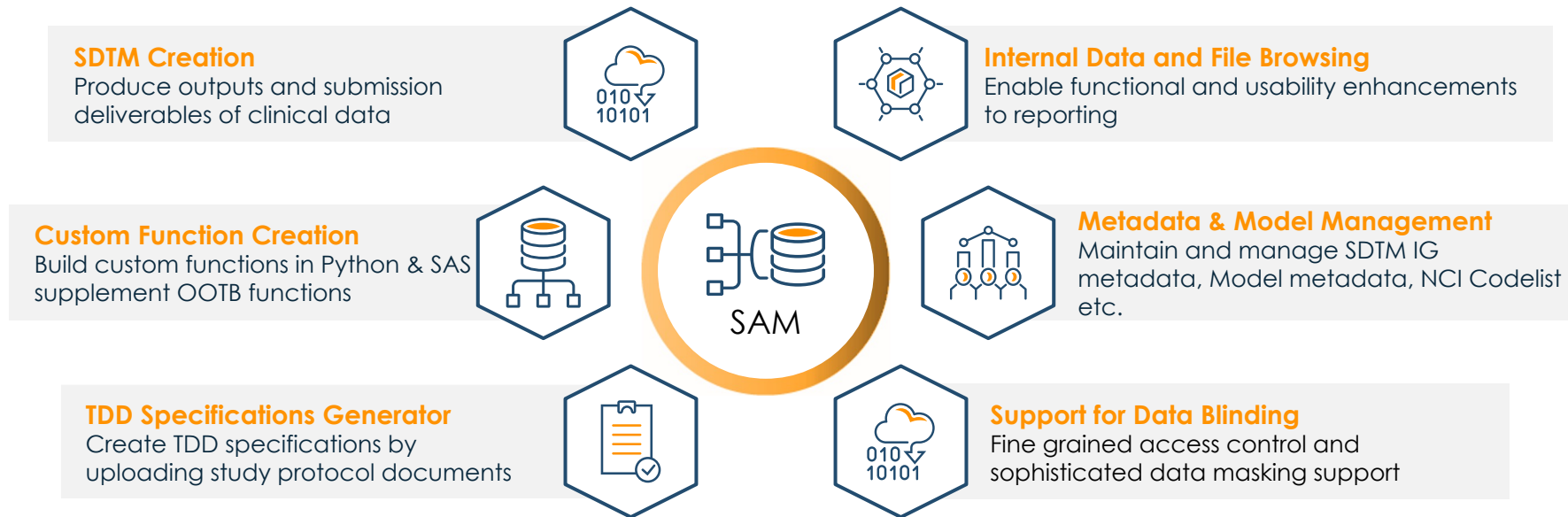
Human Review

Update Transformation Maps & Metadata
Finalize Custom Functions



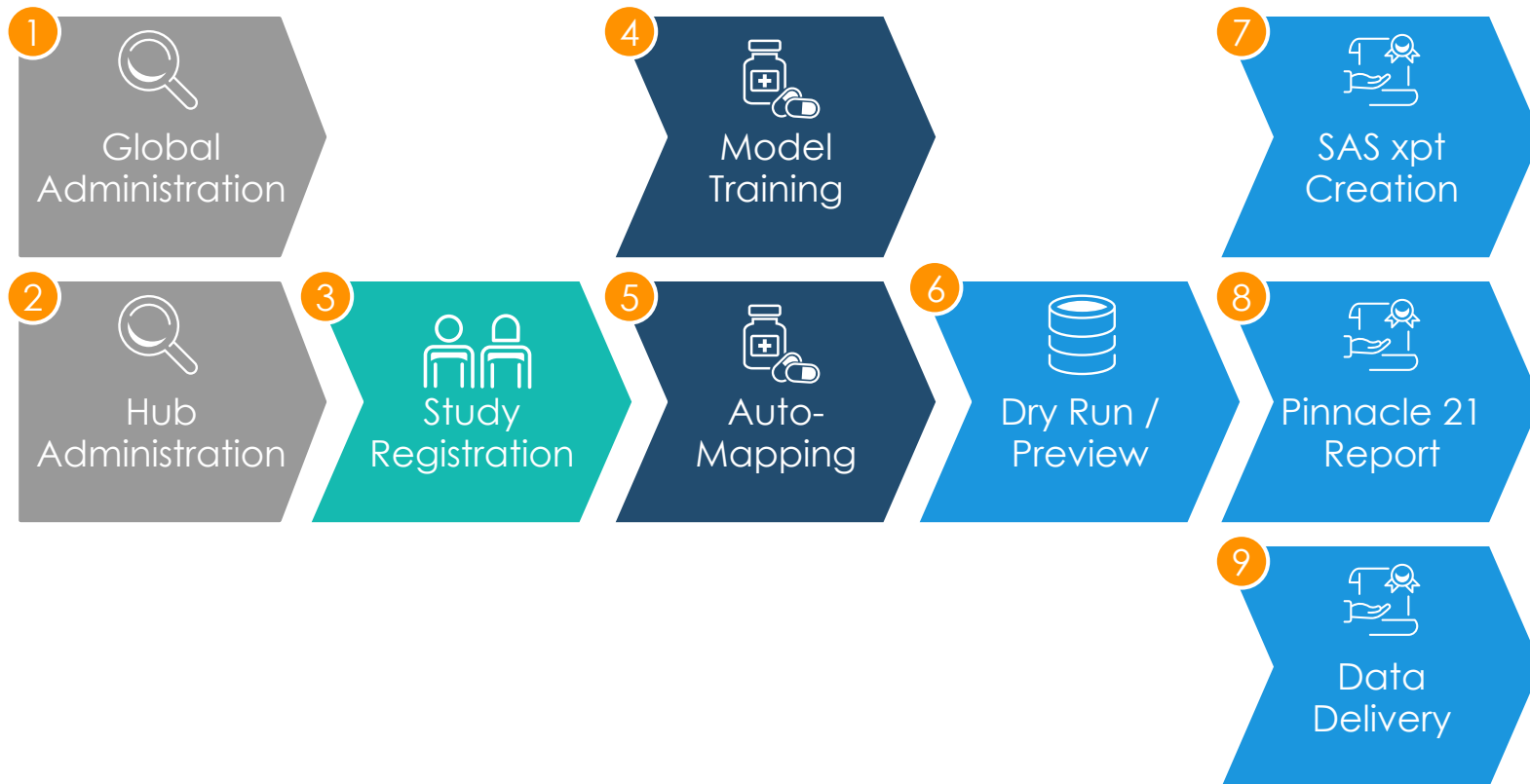
Smart Auto Mapper: Automation

Automation of Deliverables Through Machine Learning



Clinical Data Transformation with Smart Auto Mapper

Metadata Management, Model Training and Submission Deliverables



Smart Auto Mapper: Key Functions



Integration
with Clinical
Data Hub

Raw data is safely stored in Clinical Data Hub, and can be easily compared to transformed data in a single environment



Raw to SDTM
Data Mapping

Automap Raw Data to SDTM standard with AI.

Complete most tasks with codeless, out-of-the-box functions



Human-in-the-
Loop Review

Human involvement in AI mapping ensures traceability (no 'black box')

SME feedback helps improve AI mappings over time



Flexible &
Scalable
Architecture

SAM is not reliant on specific source systems or data

Enabling new transformations (eg. for new therapeutic areas) is a breeze



Reduced Time
to Data
Access

Allow clinical team members quick access to the specific data they need with fine-grained data access permissions

AI Application Implementation

From Use Case Identification to Quantifying Benefits



Data Discovery

- Identify & Prioritize Use Cases
- Identify Data with Sufficient History
- Digitize Data for Machine Accessibility (ex. pdf, scanned data, etc.)
- External Data Ingestion & Curation (Dictionaries + Libraries)
- Assess Data Quality & Quantity for ML Opportunities to Create Labeled Data

Machine Learning Experiments

- Create Hypothesis & Outcome Expectation
- Feature Engineering
- Choose ML Algorithm
- Perform Machine Training Using Labeled Data
- Run & Evaluate Model
- Iterate & Fine Tune Models to Improve Accuracy
- Continue to Improve Accuracy until Expectations are Met

Embedding AI in Operations

- Scaling, Compliance and Model Performance
- Embed in Workflow (Change Management)
- Improve Machine's Knowledge with Experience
- Track and Measure AI Benefits
- Continuous Learning and Model Reuse



Saama's Clinical AI Research Model

Saama's AI research work and open source contributions are well-published

Graph Convolutional Networks

Multi-Label Classification

An Attentive Sequence Model for Adverse Drug Event Extraction from Biomedical Text

Attentive Sequence Model

Biomedical Text

Introduction

Abstract

Keywords

1. Introduction

2. Related Work

3. Methodology

4. Results

5. Conclusion

6. Acknowledgments

7. References

8. Appendix

9. Bibliography

10. Index

11. Glossary

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282.



Top of the Leaderboard

Negation Scope Resolution on *sem 2012 Shared Task: Sherlock Dataset



Clinical AI Success

Clinical AI Success Requires Collaboration and Identifiable Business Value

Collaborate with Sponsor to Identify Use Case and Business Value

Maximize Machine Training Using Labeled Data and Sponsor Experience



Leverage Existing AI Assets and Iterate with Sponsor to Identify Optimal Approach

Continuously Improve with Feedback and Training Cycles



Thank You