



Let's Talk Future: Automated
Solutions for Standards-
Compliant Data, Mock Shells, and
TFL Generation Using Open-
Source Platforms with AI

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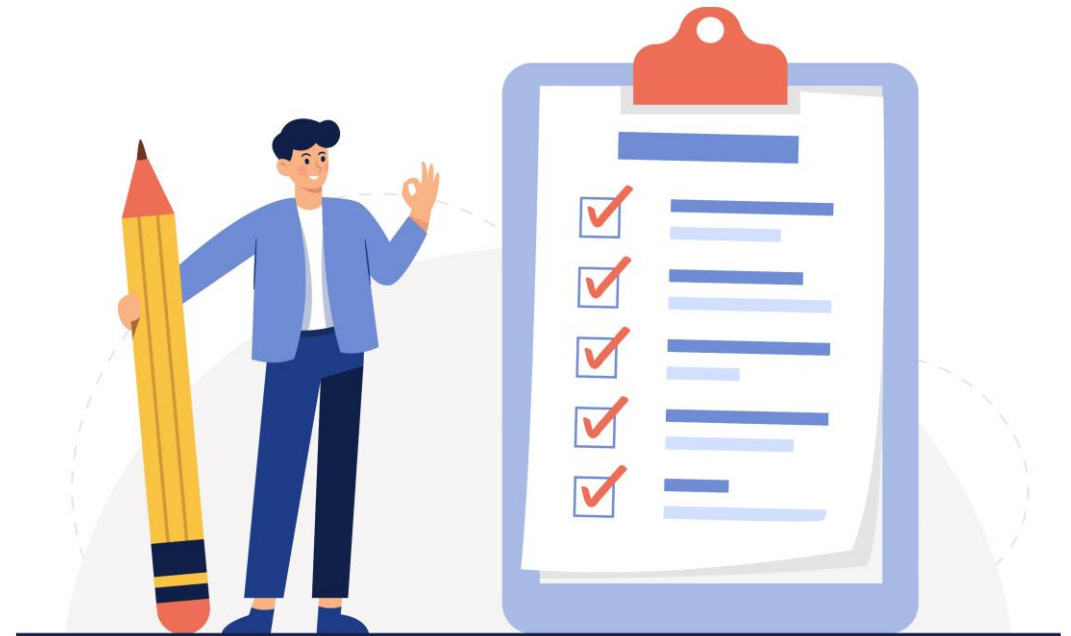
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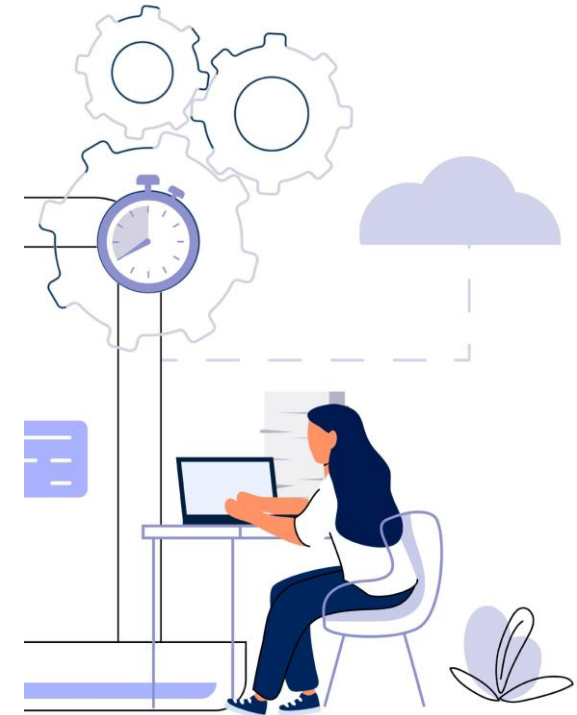
Agenda

- Introduction
- Advantages of using Open source
- Traditional Data Transformation & Reporting Pipelines
- Challenges in Manual Approaches
- The Need for Automation
- Open-Source & AI-Driven Automation
- Implementation Architecture
- Benefits & Use Cases
- Conclusion & Future Outlook



Introduction

- Clinical trials generate vast amounts of data that require transformation into regulatory-compliant formats such as CDISC-SDTM and ADaM.
- Generating Tables, Figures, and Listings (TFLs) is a critical yet labor-intensive process.
- Manual processes introduce inefficiencies, delays, and risks of non-compliance.
- Open-source platforms (R, Python) and AI-driven solutions can automate and standardize these workflows while ensuring compliance and auditability.



Advantages of Open-Source Technology



CUSTOMIZATION



SCALABILITY



INTEROPERABILITY



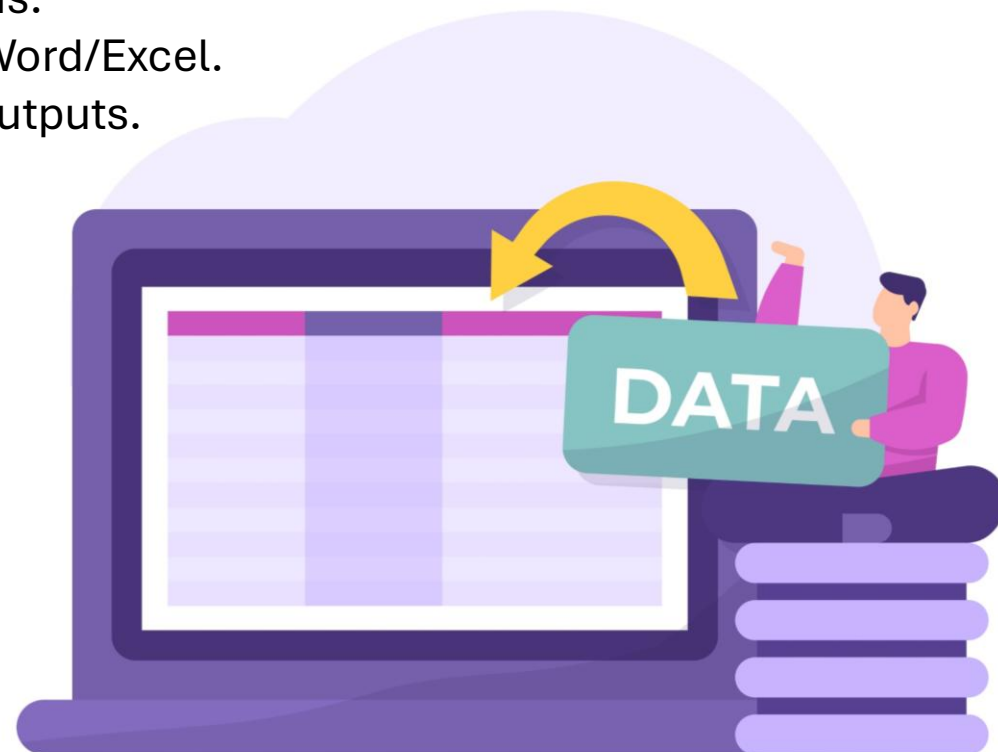
COST



TRANSPARENCY

Traditional Data Transformation & Reporting Process

- Raw Data: Collected from various sources (EDC, external labs).
- SDTM Mapping: Manually maps raw data into CDISC-compliant SDTM format.
- ADaM Derivations: Further transformations for statistical analysis.
- Mock Shells Creation: Defines structure, manually designed in Word/Excel.
- TFL Generation: Statistical programmers manually create final outputs.



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Challenges in Manual Approaches



Challenges in Standards-Compliant Data Transformation

- Manual SDTM mapping struggles with **complex data structures, missing data, and ambiguous CRF designs**.
- **Lack of scalability** makes frequent data updates cumbersome.
- **Compliance risks** arise due to manual validation.

Challenges in Mock Shell Generation

- **Inconsistencies across studies** due to lack of standardization.
- **Protocol amendments** require multiple iterations, slowing approvals.
- **Version control issues** lead to confusion and inefficiencies.

Challenges in TFL Generation

- **Heavy programming expertise required** for manual table creation.
- **Reproducibility concerns** with inconsistent metadata handling.
- **Errors lead to rework**, delaying regulatory submissions.

The Need for Automation

⚡ Why Automate?

- ✓ Reduces manual effort and speeds up study execution.
- ✓ Ensures **consistent, standardized outputs** across studies.
- ✓ Enhances **regulatory compliance** and auditability.
- ✓ Reduces risk of human errors in statistical reporting.



Impact of Automation on Efficiency & Accuracy:

- ⚡ **60-80% time reduction** in data standardization.
- ⚡ **Improved compliance** with automated validation checks.
- ⚡ **Enhanced collaboration** with cloud-based mock shell approvals.

Open-Source & AI-Driven Automation

Key Technologies Enabling Automation:

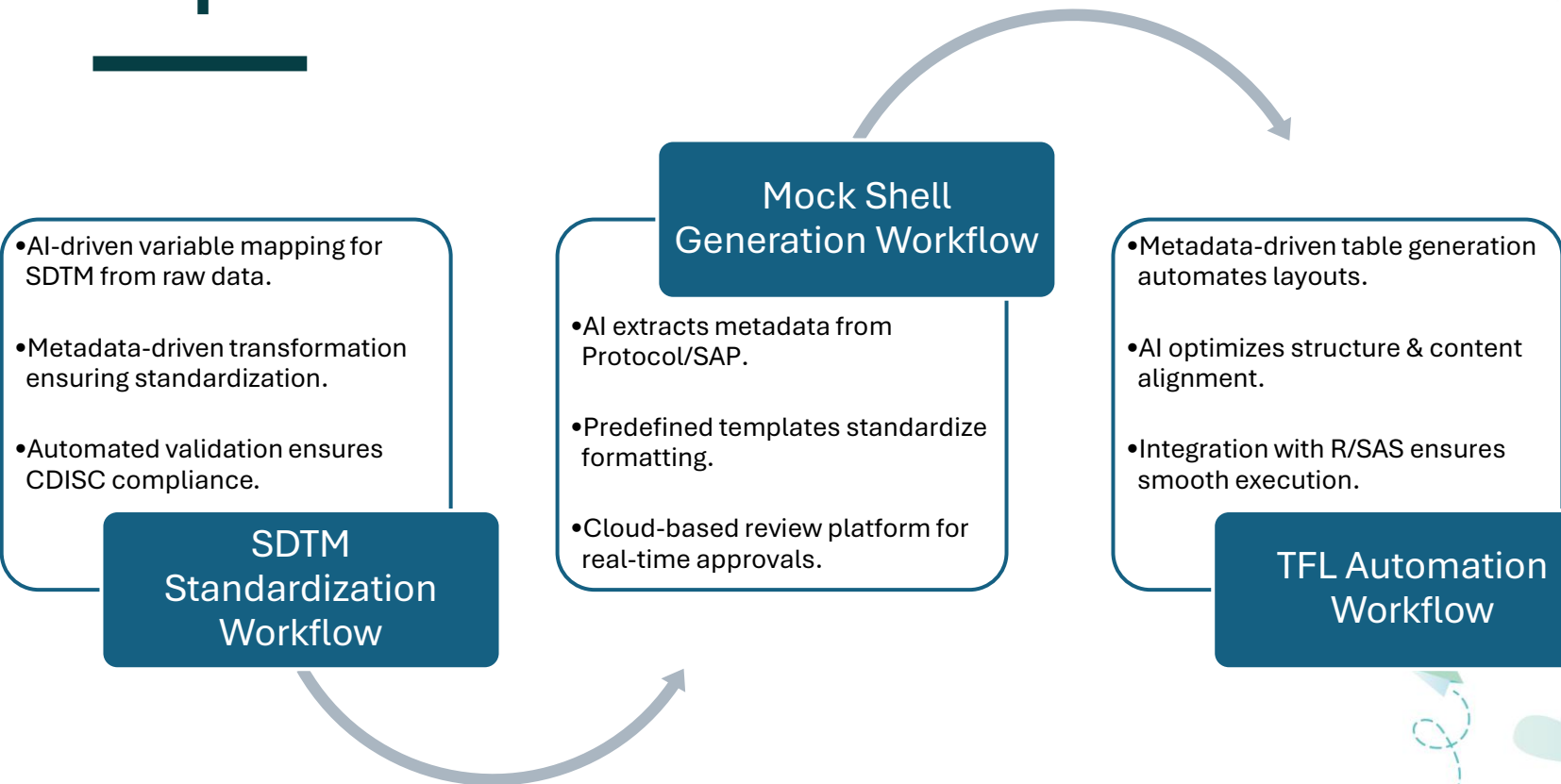
- **R & Python:** Metadata-driven transformations & automated table generation.
- **AI/NLP:** Extracts protocol metadata for variable mapping and mock shell creation.
- **Machine Learning:** Predictive algorithms for SDTM and ADaM mapping.



Example: AI in TFL Generation

- **AI-assisted layouts** optimize table formatting dynamically.
- **Natural Language Processing (NLP)** extracts study parameters from protocols.

Implementation Architecture

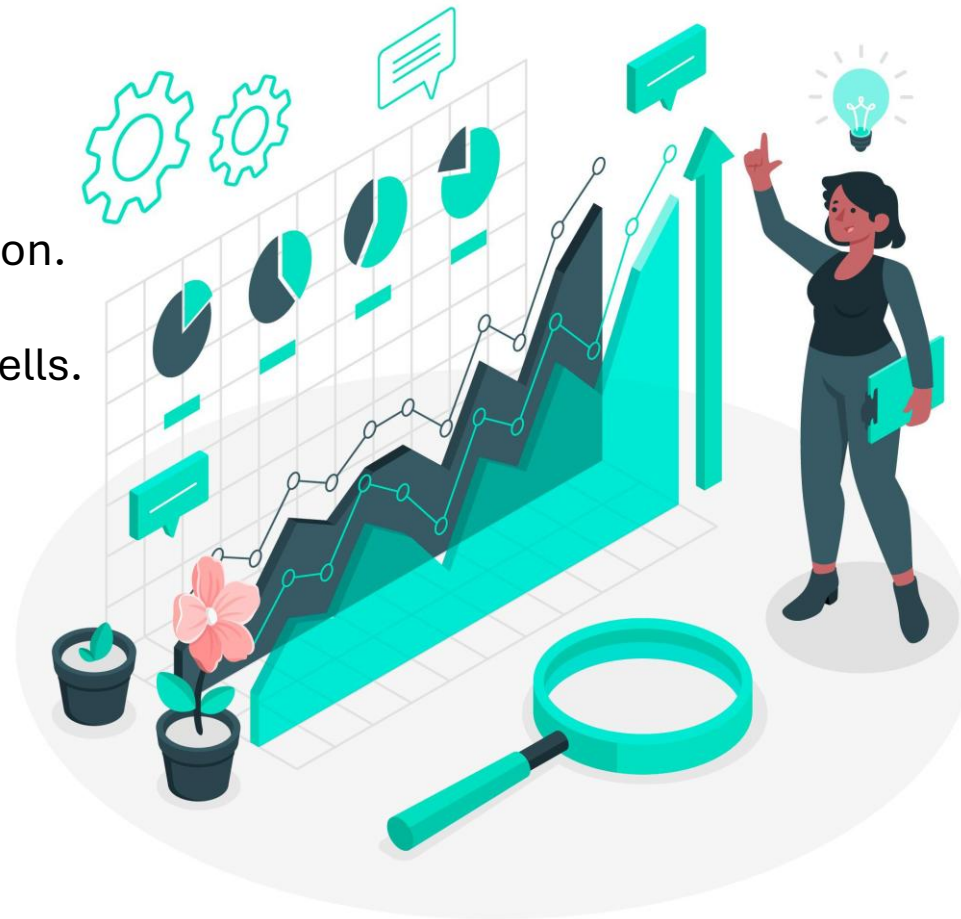


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Benefits

Key Benefits of Automation:

- ✓ **Time Efficiency:** Reduces effort in SDTM mapping & TFL creation.
- ✓ **Scalability:** Adaptable across different therapeutic areas.
- ✓ **Improved Collaboration:** Cloud-based approvals for mock shells.
- ✓ **Regulatory Compliance:** CDISC adherence with audit trails.



Conclusion & Future Outlook

- Manual SDTM, mock shell, and TFL generation processes introduce inefficiencies and compliance risks.
- Open-source platforms like R & Python, combined with AI-driven automation, streamline clinical data standardization.
- Organizations adopting metadata-driven workflows gain significant efficiency, accuracy, and compliance benefits.
- Future Outlook: Integration of AI-powered regulatory compliance and automated decision support systems will further enhance automation in clinical data management.





Ideas
Delivered
Intuitively

Thank You!

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