

SM 11 :

Automation and Macros in Clinical Submissions: Challenges, Limits and the Path Forward

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Bharath is a distinguished leader in Life Sciences R&D with deep expertise in Clinical Data Services. He is widely recognized for his strong domain knowledge and strategic vision in managing the end-to-end lifecycle of clinical monitoring and data standards. His core strengths span SDTM, Medical Monitoring, Case Report Tabulation, and Standards Governance.

As a seasoned lead in Medical Monitoring and Standards, Bharath excels at developing high-value monitoring reports using SAS, SQL, and other industry-renowned tools. These reports deliver actionable insights for clinical teams and statisticians, enabling early identification of emerging trends, outliers, and safety or efficacy signals. Bharath has also played a pivotal role in several complex client initiatives, including large-scale EDC platform migrations, cross-platform report transitions, and implementing innovative approaches to clinical monitoring.

Beyond his technical depth, Bharath brings a strong strategic mindset to program and project management. He emphasizes operational metrics, forecasting, and budgeting to enhance efficiency, ensure quality, and drive continuous improvement across clinical data operations.

Foundational Efficiency in Clinical

In the clinical research industry, **automation and macros** are the building blocks of modern data management and statistical programming (often using SAS or R). They transform manual, repetitive data cleaning into standardized, high-speed workflows.



Efficiency gains observed

Clinical Macros




- Parametrized Reusable Code Modules
- Repetitive tasks

Clinical Automations





- Integration of technology to handle data flows.
- Batch Processing
- “intelligent systems” to detect discrepancies



40% Reduction

Data Processing Time



30% Decrease

Error reductions



50% Gains

Statistical programming



15% Savings

Operational Costs

Industry use cases

- SDTM/ADaM Mapping

Automated Quality Control
- Medical Coding

Risk based Monitoring

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Evolution of Automation in Clinical Data

2000 – 2005

2006 – 2012

2013-2019

2020-2025



CDISC (Standards)

- SDS 1.1 released (2000);
- SDTM 3.1 (2004) becomes the foundational submission model.



Macros(Automation)

- High reliance on custom-made SAS macros for one-off data cleaning.



Metadata

- Define-XML 1.0 (2005) provides first machine-readable metadata.



AI (Intelligence)

- Early academic interest; AI-simulated emotions (Kismet, 2000).

- ADaM 1.0 released (2006).

- SAS Clinical Standards Toolkit (2009) centralizes macro frameworks.

- CDASH 1.1 (2009) aligns CRF collection with SDTM metadata.

- Deep learning rise (2012); AlexNet shifts AI toward pattern recognition.

- FDA Mandate (2016) makes CDISC compulsory for all NDAs/BLAs.

- Shift from "simple macros" to standardized global macro libraries.

- SDTM 1.7 (2018) expands metadata to biomarkers and devices.

- AI pilots for patient recruitment and automated medical coding.

- CDISC 360 (2020) proves end-to-end automated metadata flow.
- CDISC 25th Anniversary; focus on "Machine-First" standards.

- Focus on R-integration; macros begin to bridge SAS and open-source.
- Automation replaces up to 50% of manual mapping tasks.

- Digital Data Flow (DDF) (2022) introduces machine-executable rules.
- Metadata-driven automation is standard in top-tier CROs.

- Gen AI (2023) automates CSR.
- Agentic AI (AI 2.0) performs real-time trial design and risk monitoring.

Efficient Automation of Repetitive Tasks

Automation tools reduce time spent on repetitive tasks like SDTM mapping and ADaM derivations through macros and engines.

Template-driven Consistency

Use of templates ensures consistency and high reusability across studies for standardized deliverables.

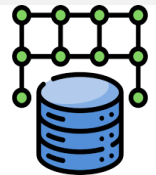
Dependency on Data Quality

Automation success depends on stable standards and uniformity of well-structured data and complete metadata.

Efficiency Gains

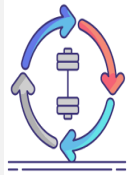
Good efficiency gains for structured, predictable workflows. Ideal for high volume of standardized deliverables

What Works Well



Structured Datasets

Information
Organized in
predefined
format



Repeatable Logic

Redundant logic
allows the
standardization



Controlled Terminology

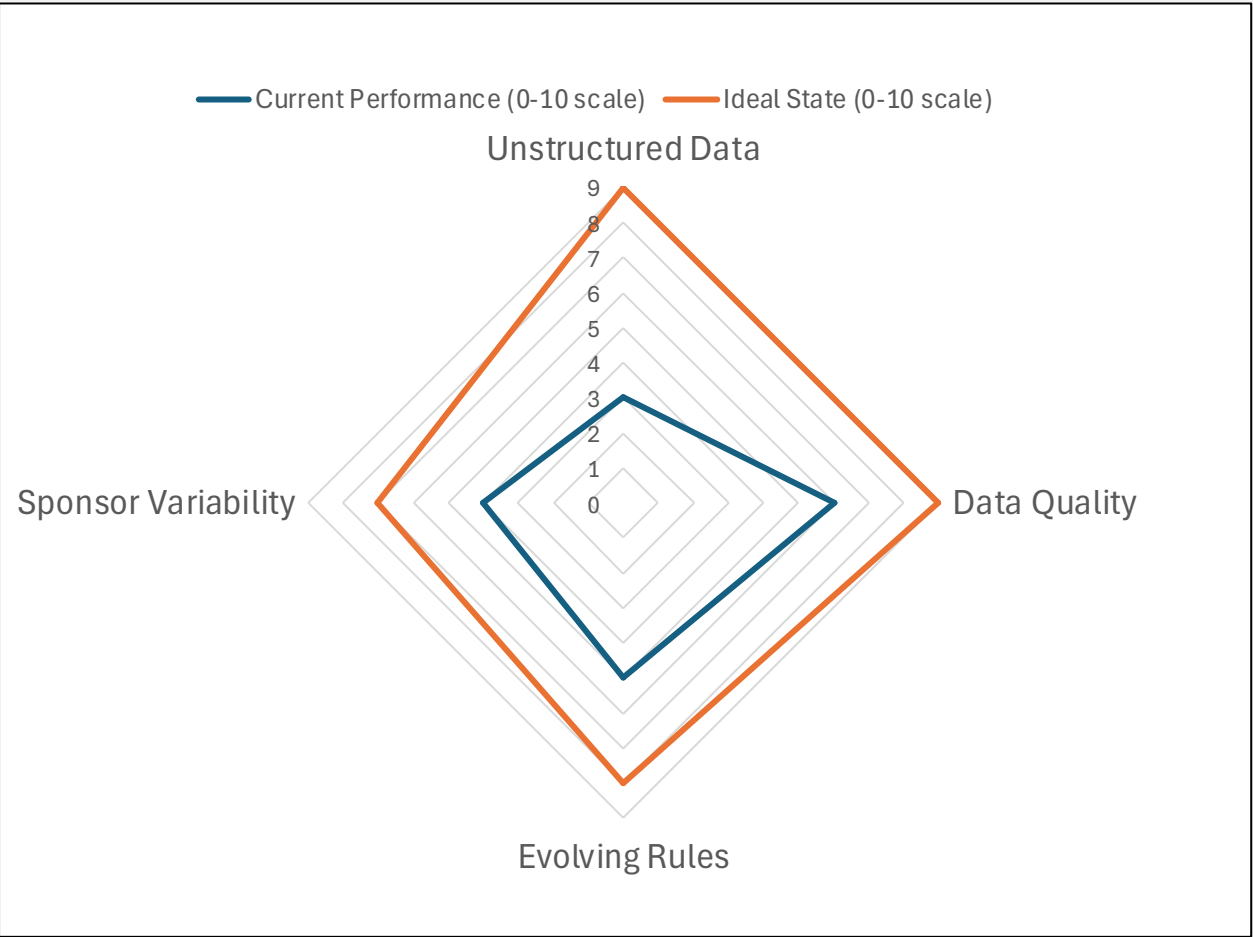
Standard
Controlled
Terminologies
reduces the
variance



Templated Output

Standard
template
formats are
feasible for
alignment
Standardization

Automation Blockers



Unstructured Data Sources

Unstructured data sources introduce variability that standard macros cannot process effectively.

Evolving Regulatory Requirements

Changing regulatory expectations demand nuanced judgment beyond automation's current capabilities.

Need for Manual Validation

Manual review remains essential to ensure accuracy and compliance in deliverables.

Automation Scalability Issues

Inconsistencies in metadata and study-specific exceptions limit the scalability of current automation.

Need for Expert Oversight

Despite automation, expert oversight remains crucial, especially for complex or adaptive trial designs.

Role of Structural Data & Regulatory Challenges



Importance of Structured Data

Foundation for Automation

- Structured data supports scalable, reproducible automation by enabling predictable mappings and standardized derivations.

Metadata-driven Frameworks

- Automation relies on metadata-driven frameworks to transform data and generate compliant outputs consistently.

Challenges of Inconsistency

- Inconsistent data standards, outdated metadata, and sponsor-specific coding create barriers to uniform automation.

Standardization Importance

- Rigorous standardization and centralized metadata management are vital to unlocking automation's full potential.



Regulatory Submission Challenges

Precision and Traceability Requirement

- Regulatory submissions require exact precision and full traceability to meet compliance standards.

Challenges of Complex Trial Designs

- Adaptive studies and non-traditional endpoints introduce variability that automation finds difficult to handle.

Human Oversight Necessity

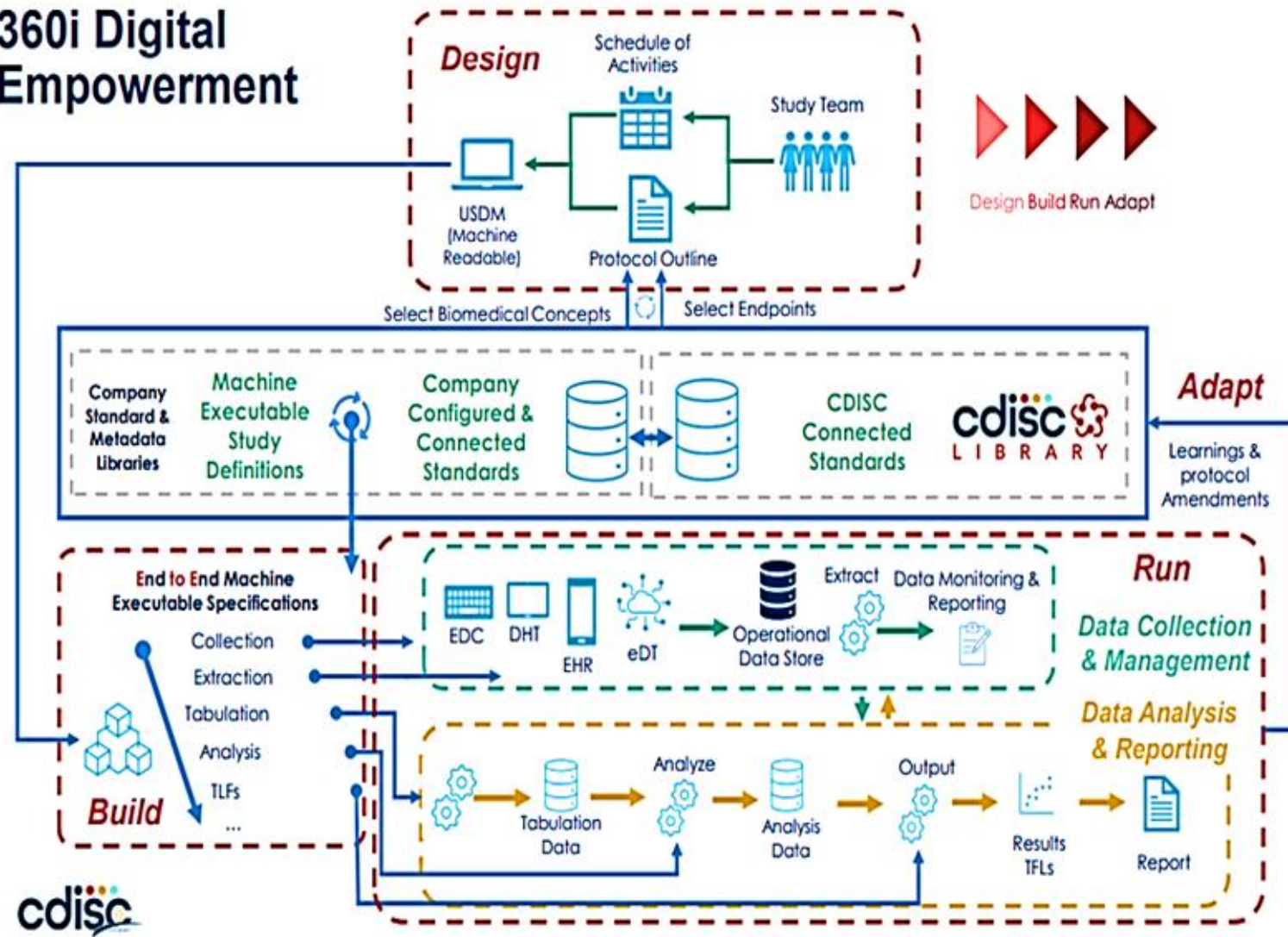
- Human expertise is essential for defensible metadata and auditable derivations in regulatory submissions.

Hybrid Automation Approach

- Combining automation with expert review addresses current limitations and ensures regulatory compliance.

Future: AI and Metadata Integration

360i Digital Empowerment



1

Study Design

The core idea is to shift from documents to digital, machine-readable content. With protocol, technical, and standards information digitized, study setup in an EDC system can be automated, transforming how studies are designed and executed.

2

Data transformations

Move transformation logic into metadata so programs can automatically interpret and transform data. With logic stored in metadata, audits and inspections become easier, and any needed changes require updating only the metadata—not the transformation programs.

3

Full Adoption with Metadata Approach

This approach can be applied through all transformation steps—from ADaM to TLFs and ultimately to submission—each producing metadata that preserves full data lineage. When compiling the submission package, this maintained metadata can be used to automatically generate hyperlinks in the eCTD.

Role of Human Expertise

Automation enhances workflows but human expertise remains essential for accurate clinical decisions and quality.



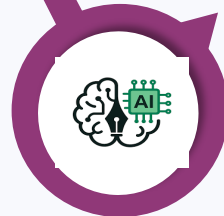
Importance of Structured Data

Structured data is the foundation for scalable automation and ensures consistency in clinical workflows.



AI and Metadata Integration

Combining AI with metadata-driven frameworks boosts automation efficiency and regulatory compliance.



Automations by Adhering CDISC

Integrating CDISC standards advancements with open-source tech to drive intelligent automation and enhance regulatory deliverables.



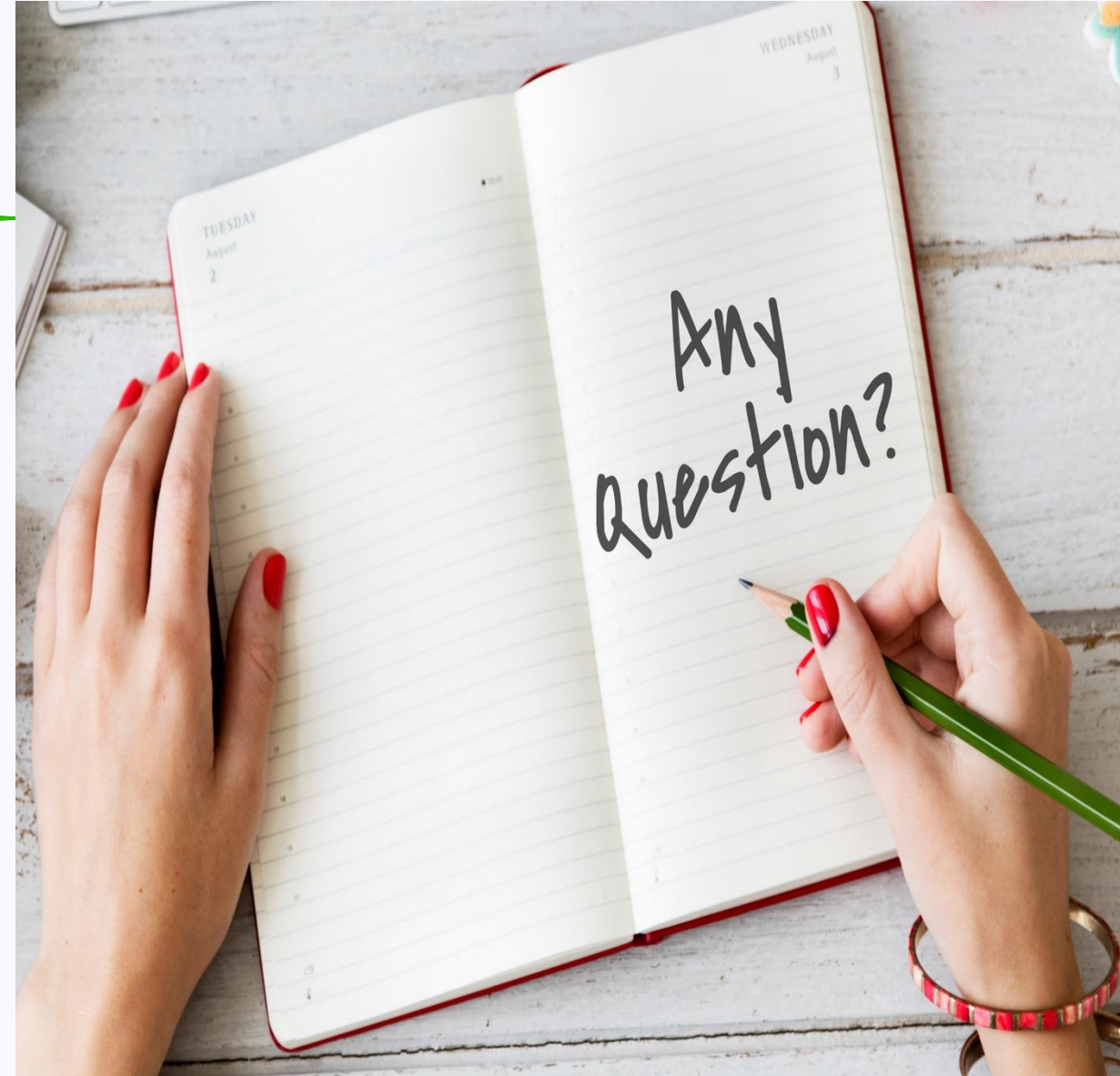
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TAKEAWAYS**

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- Automation: From Protocol Definition To Submission : [Automation From Protocol Definition To Submission](#)
- CDISC 360i : <https://www.cdisc.org/cdisc-360i>
- Copilot (Jan 13, 2026, release) and Gemini AI : Gemini 3 in Chrome extension





Thank you