From Synergies to Risks: AI's Impact on Automated Study Build

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Leveraging CDISC Standards for Next-Generation Clinical Trials

Meet the Speakers

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Title: Consulting Technical Director

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Mr. Sagarese brings +25yrs of consultative expertise in eClinical technology platforms, specializing in assisting pharmaceutical companies implement and optimize Oracle Health & Life Sciences cloud services to accelerate drug development and improve patient outcomes.

Sarah Jamal

Title: Strategic Client Advisor

Organization: Oracle Health & Life Sciences

Ms. Jamal specializes in transforming complex clinical research challenges into streamlined solutions for Oracle's top-tier clients. With +15yrs of deep expertise in clinical data management and eClinical technology platforms.

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. Technology Readiness
2. Operational Transformation
3. Risk Management
4. Success Factors
5. Strategic Imperatives

Empowering the Potential of Innovative Applied AI Across Life Sciences Clinical Research, Development, and Operations

Acceleration Opportunity

AI can dramatically accelerate standards-driven study build from protocol to analysis, leveraging USDM as the machine-readable foundation.

Core Benefits

Speed, accuracy, consistency, and seamless cross-system reuse across the entire clinical trial ecosystem.

Critical Risks

Data (sourcing, curation, validation) challenges, reliability concerns, potential bias, governance complexity, and adoption barriers require careful management.

Objective: Deliver a pragmatic blueprint to harness AI safely and effectively with clinical data standards.

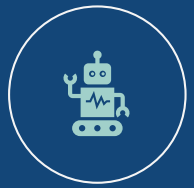
Herein we will explore the synergies and risks of leveraging AI to address pressing industry challenges – from AI's potential to drive synergy and innovation, to the liabilities of failed adoption of this rapidly evolving technology.

Accelerate

Timelines & Improve Quality

Generate

Key Study Artifacts



Harness

Evolving Technology

Manage

Critical Risks

Technology Readiness

Why Now? Industry Context

Convergence Points

Rising Complexity

- Protocol complexity increases while cycle time expectations and cost pressures intensify across the industry.

Standards Maturity

- CDISC standards have reached industry wide submission adoption (SDTM) and Next-Gen enterprise-ready maturity levels (USDM, CT, Biomedical Concepts).

AI Breakthrough

- Transformational advancement in the foundational LLMs capabilities enables sophisticated enterprise automation and orchestration.

The Clinical Trial Automation Revolution

Market transformation at unprecedented scale

AI in clinical trials market	USD 9.17 billion (2025) → USD 21.79 billion (2030) [1,2,3]
19% CAGR	AI driving explosive growth in automation solutions [1,2,3]
Study build time reduction	From 12-16 weeks to 3 weeks with AI automation [4,5]
Cost efficiency improvement	Up to 20% across trial operations [5]
Regulatory momentum	FDA's 2025 AI guidance framework establishing validation pathways [6]

CDISC Advantage: The Foundation for Automation

Enabling the digital groundwork for intelligent study design

- USDM (Unified Study Definition Model)
  - Current version: USDM v3.0 (April 2024), v4.0 (June 2025)
  - Technical capabilities: REST API, OpenAPI 3.0, machine-executable conformance rules
  - Automation scope: Study objectives, endpoints, Schedule of Activities (SoA), biomedical concepts (BCs)

- CDISC 360i Initiative
  - Mission: End-to-end automation from protocol development to study results
  - Phase 1 achievements: significant % of SDTM variables auto-generated, Xx productivity gains
  - AI integration: Protocol-to-study pilot demonstrations

- Study Definition Repository (SDR)
  - Open-source approach: Apache 2.0 licensed reference implementation
  - Industry collaboration: TransCelerate-CDISC, System Integrators (SIs) and Tech consortium

Automated Study Build

Digital Data Flow (DDF) – Progress in Automation Transformation

TRADITIONAL STUDY SETUP	DDF & CDISC 360i	AUTOMATED STUDY BUILD
Setup can often be disparate, time consuming and effort intensive	Promotes automated, dynamic, study setup readiness based on adoption of new study definition standards *e.g. USDM*	Solution developed with DDF and CDISC360 in mind to automate EDC setup
Inconsistencies between systems lead to rework downstream	Facilitates connection of different up/downstream systems	Features automated deployment of study definitions from MDR/SDR into EDC
		Compatible with Open Study Builder, USDM and ODM CDISC study definition standards

EVOLVING EFFICIENCY OPPORTUNITY

The Agentic AI Evolution

Traditional AI
- Rule-based systems requiring explicit programming for each task and scenario.
- Designed to operate within its defined constraints.

Generative AI
- Requires human prompts for each task, providing recommendations but limited autonomy.
- It learns patterns from vast datasets to generate new content but remains reactive.

Agentic AI
- Autonomous agents that reason, adapt, and make decisions within dynamic clinical workflows.
- Can proactively plan and action multi-step tasks including GenAI as tools.

The Synergy Imperative

AI as an Amplifier of Clinical Excellence

Amplifying Technology

AI/ML enhances human capabilities rather than substituting clinical expertise, creating multiplicative effects beyond simple automation.

Human-in-the-Loop Excellence

High accuracy achieved when AI systems maintain continuous feedback loops with Subject Matter Experts (SMEs) across clinical applications.

Quantified Efficiency

Gains XX% of hours saved per M records, with X^y productivity gains for clinical programmers, data managers, and biostatisticians.

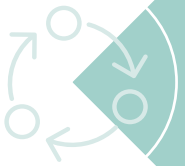
- Efficiency Multipliers
- Clinical Excellence Enhancement
- Innovation Acceleration
- Competitive Advantages

Where AI amplifies human expertise

- Strategic integration creates exponential improvements when AI works as a **force multiplier** for human expertise, not a replacement for clinical judgment.

Standards Enable AI Consistency

Foundation for Scaling Reliable Operations



Semantic Interoperability

Controlled terminology ensures AI systems interpret data consistently across studies.

Cross-Study Standardization

Standards enable AI models trained on one study to work effectively on others.

Regulatory Alignment

FDA and PMDA mandate CDISC standards, creating regulatory-ready AI outputs.

Sampling of Core AI Use Cases

Protocol Mapping

Automated USDM mapping of protocol contents (e.g. study design elements).

CRF Generation

Intelligent eCRF derivations using BC and CDASH, etc.

Validation Rules

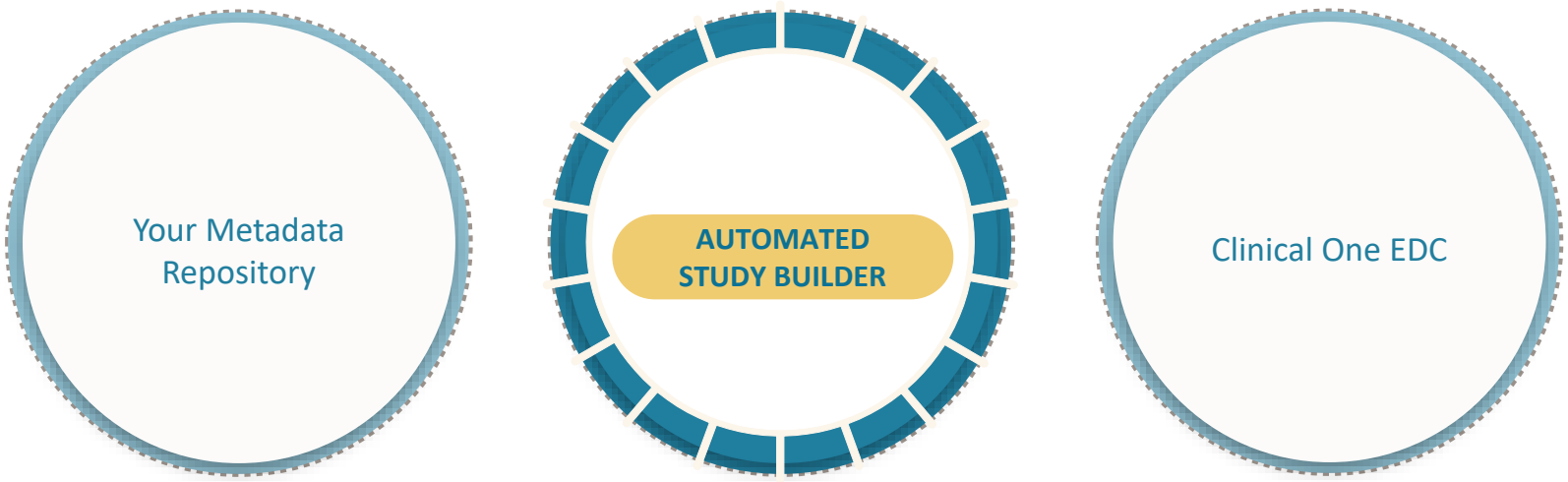
Edit checks and data validation rules generated from standards and historical patterns on top of CDISC CORE.

Analysis Planning

SDTM/ADaM specification pre-population with SAP outlines and TLF shell generation.

Automated Study Builder

EDC metadata flow

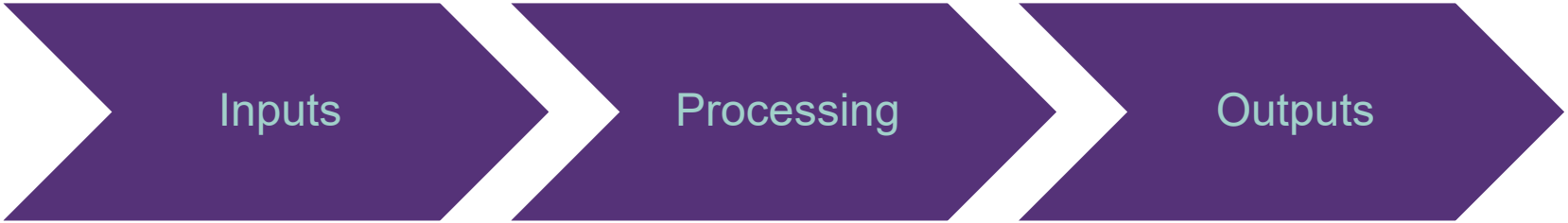


- OpenStudyBuilder is an example of an open-source Metadata Repository
- Other industry repositories are available

- Extract the design from Data Repository
- Compatible with OpenStudyBuilder API, ODM v1.3 and USDM 3.0.
- Review/map design components
- Load to Clinical One EDC

- Trial design is created automatically in Clinical One within minutes!

Protocol-In, Study-Out



- Protocol, USDM foundation, corporate standards, current and archived sources
- AI-driven interpretation, validation, and artifact generations use standards.
- Complete EDC build, validation rules, specifications, TLF, SAPs, DMPs, SDTM mappings, etc.

Cross-system interoperability: EHR, EDC, RTSM, ePRO, DW, Safety, Analytics

Operational Transformation

Strategic Business Value Gains

Operational & innovation for ROI and the benefit of the patient

Faster Trial Execution	Reduction in overall cycle time and faster trial durations.
Cost Reduction	Significant clinical trial cost savings through automation and efficiency.
Patient Recruitment	Enhances recruitment speed and accuracy, reducing screening and enrollment times.
Data Quality & Insights	Automated, real-time data monitoring and analysis for improved data integrity and decision-support.
Protocol Optimization	Predictive analytics and adaptive designs minimize amendments and boost trial success.
Regulatory Compliance	Streamlines documentation and quality control, enhancing regulatory submissions.

AI Operating Model Roadmap

Strategic approach to AI adoption in clinical trials

Phase 1: Foundation Building (1-3 months)

Infrastructure assessment	Skills development	Pilot project selection	Governance establishment

Phase 2: Targeted Deployment (3-6 months)

eCRF automation	Validation rule enhancement	Process optimization	Performance measurement

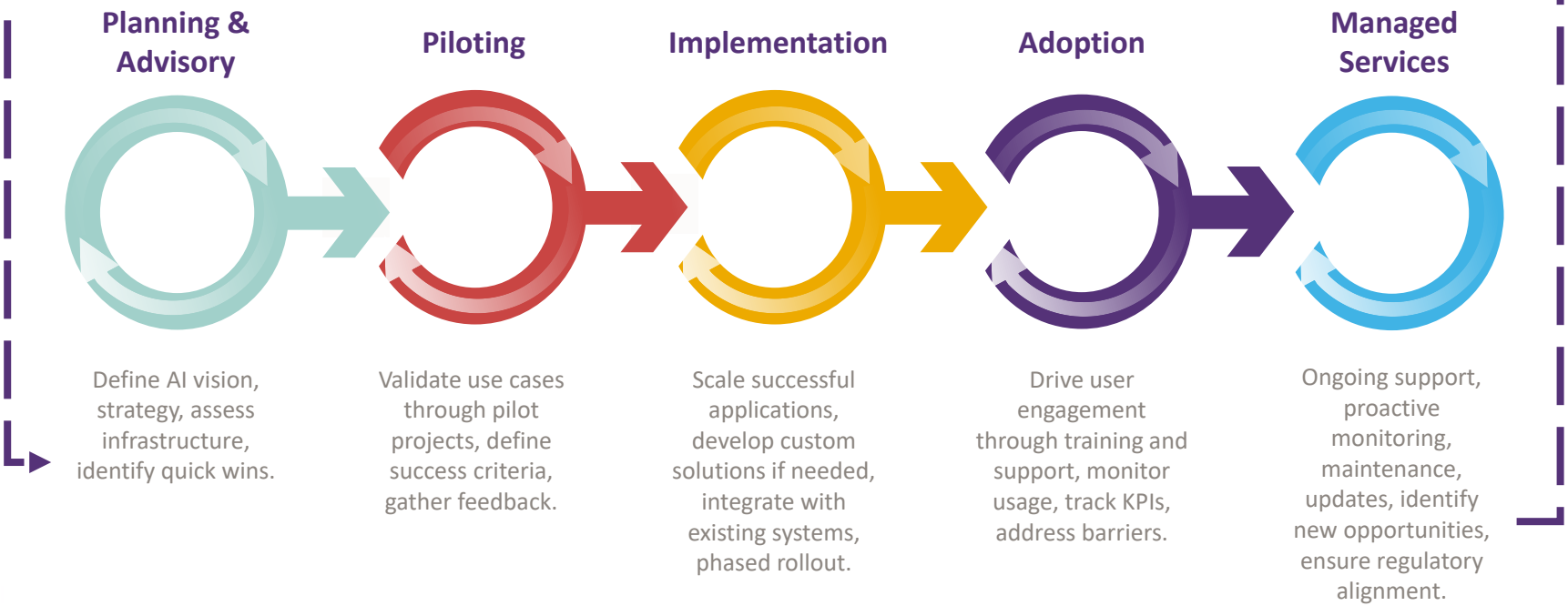
Phase 3: Advanced Integration (6-12 months)

End-to-end automation	Cross-system integration	Adaptive capabilities	Regulatory readiness

Success Factors for Each Phase

- ✓ Executive sponsorship
- ✓ Change management
- ✓ Vendor partnerships
- ✓ Regulatory engagement

The Journey: Our Collaborative Engagement

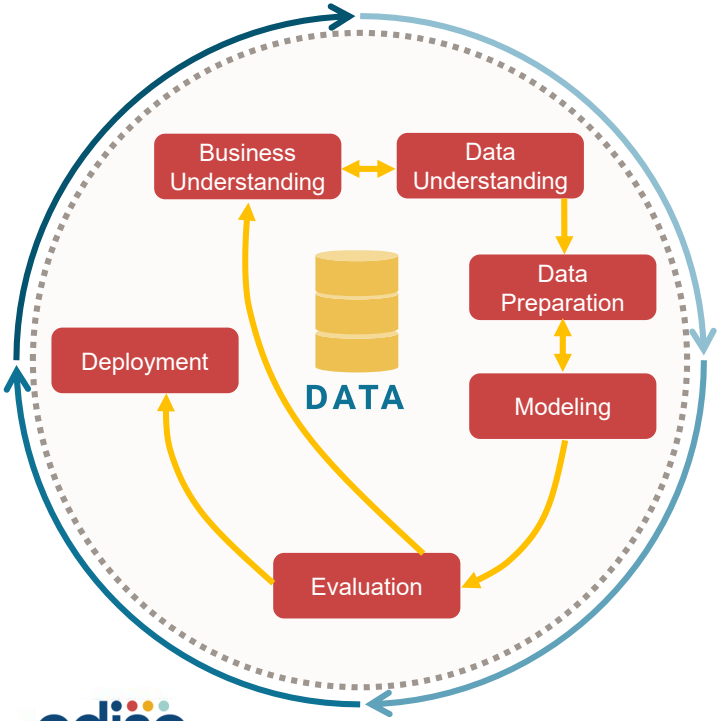


Leveraging Our Expertise

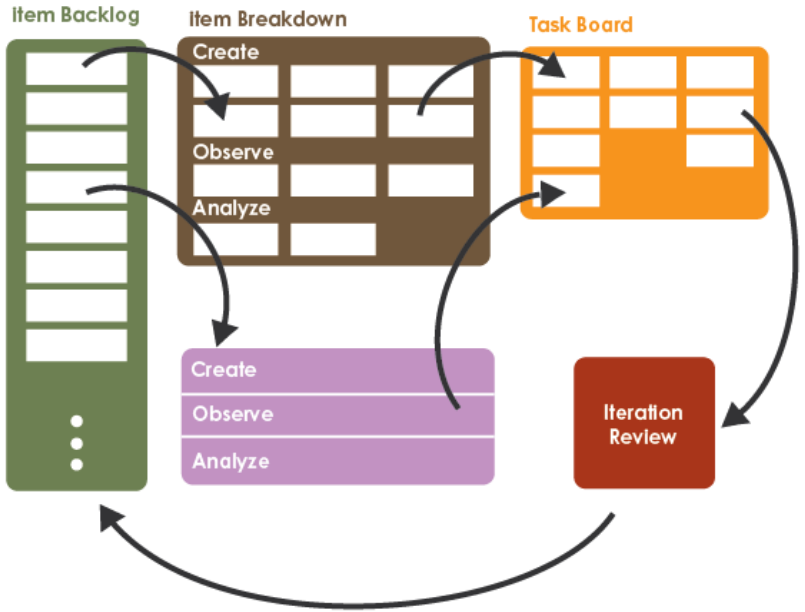
The Agile AI Project: Methodologies & Frameworks

Rethinking for continuous improvement

GenAI Project Lifecycle



Data Driven Scrum



Regulatory Landscape and Validation Framework

Navigating compliance in the AI era

FDA 2025 AI Guidance Framework
International Regulatory Harmonization
Validation Requirements

- Regulatory agencies are establishing comprehensive, risk-based frameworks to ensure AI tools in LS are transparent, validated, and clinically effective before deployment.
- Reference…
  - FDA – GMLP
    - SPIRIT-AI / CONSORT-AI
  - EMA & ICH E6/R3
  - CDER AI Council
  - Etc.

Risk Management

AI Bias and Validation Challenges

Critical risks requiring proactive management

Sources of AI Bias

Training data limitations: Historical underrepresentation of diverse populations

Selection bias: Systematic exclusion of patient groups from training sets

Algorithmic bias: Model assumptions that don't generalize across populations

Representation gaps: Insufficient diversity in clinical datasets

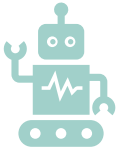
Technical Mitigation Strategies

Diverse dataset curation: Multi-source data collection for enhanced representation

Bias detection algorithms: Fairness metrics including equalized odds and demographic parity

Cross-validation frameworks: External validation using prospectively captured datasets

Continuous monitoring: Real-time assessment of algorithmic fairness



Human Oversight Requirements

Multi-level review process: Technical, clinical, and regulatory validation stages

AI Oversight Committee: Multi-disciplinary governance with clear escalation procedures

Performance surveillance: Ongoing model accuracy assessment and drift detection

Quality control protocols: Systematic review against established standards

Implementation Barriers and Adoption Challenges

Overcoming obstacles to widespread adoption

Technical and Infrastructure Barriers

Organizational and Cultural Barriers

Regulatory and Compliance Concerns

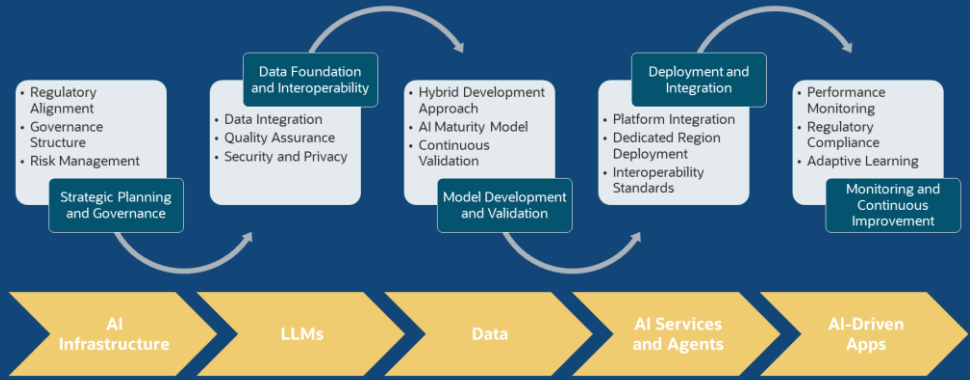
Strategic Solutions

Risk Management Framework

Essential safeguards for AI implementation

- Technical Risk Controls
- Clinical Safety Safeguards
- Data Governance and Privacy
- Regulatory Compliance Framework

Equip every facet of the enterprise AI lifecycle



Success Factors

Industry Best Practices and Lessons Learned

Insights from successful implementations

IMPLEMENTATION SUCCESS PATTERNS

COMMON PITFALLS TO AVOID

LESSONS FROM INDUSTRY LEADERS

KEY PERFORMANCE INDICATORS

Strategic Imperatives

Call to Action and Next Steps

Moving from awareness to piloting & implementation

Take Action

Strategic Planning

Partnership Opportunities

Long-term Vision

Summary and Key Takeaways

Essential insights for AI-enabled study automation

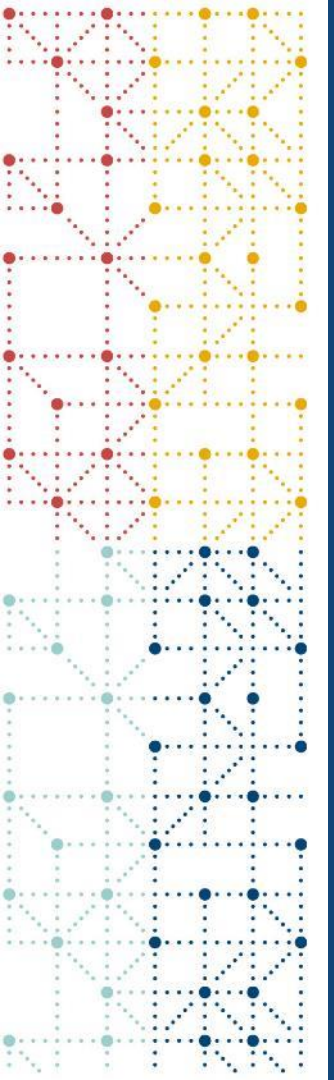
TECHNOLOGY READINESS

BUSINESS IMPACT

RISK MANAGEMENT IS CRITICAL

IMPLEMENTATION SUCCESS FACTORS

STRATEGIC IMPERATIVES



Questions

Thank You!

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