



C&SP 203X Reinventing Clinical & Statistical programming for the AI -era

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A well-known story but it applies to our world.....



AI-Decade *Vision* for Clinical & Statistical Programming (C&SP)

AI-Driven Data Programming

AI will transform clinical data design, analysis, and submission, embedding programming throughout the clinical lifecycle.

Data and Metadata Focus

Shift from document-centric to metadata-centric operations enables structured protocols and reusable analysis components.

Enhanced Roles for Data programmers

Programmers to focus on insight creation, and being AI users

Trust and Compliance in Data outputs

Human-in-the-loop controls and transparent governance to ensure AI outputs are credible and compliant with regulations.

Only constant is data and our mission is to drive clinical data through every stage of clinical development—and beyond.

External Landscape : Regulatory Expectations Shaping AI Adoption in C&SP

FDA AI Guidance

The FDA's 2025 draft guidance emphasizes risk-based AI credibility, transparency, and performance monitoring in clinical programming.

EMA Risk-Based Approach

EMA's 2024 reflection paper highlights human-centered, risk-based AI use with varying documentation based on risk level.

International Regulatory Standards

ICH guidelines modernize clinical practice with risk management, digital technologies, and structured protocols for AI adoption.

Implications for C&SP Teams

C&SP teams must implement strong governance, validation, and transparency to align AI use with regulatory expectations.

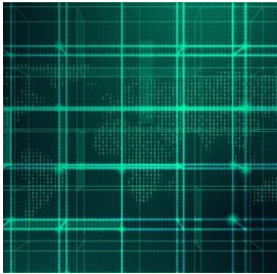


Industry Direction : How Pharma Leaders Are Preparing for AI-First Programming



Open-Source Technology Adoption

Open-source tools like R for regulated clinical programming



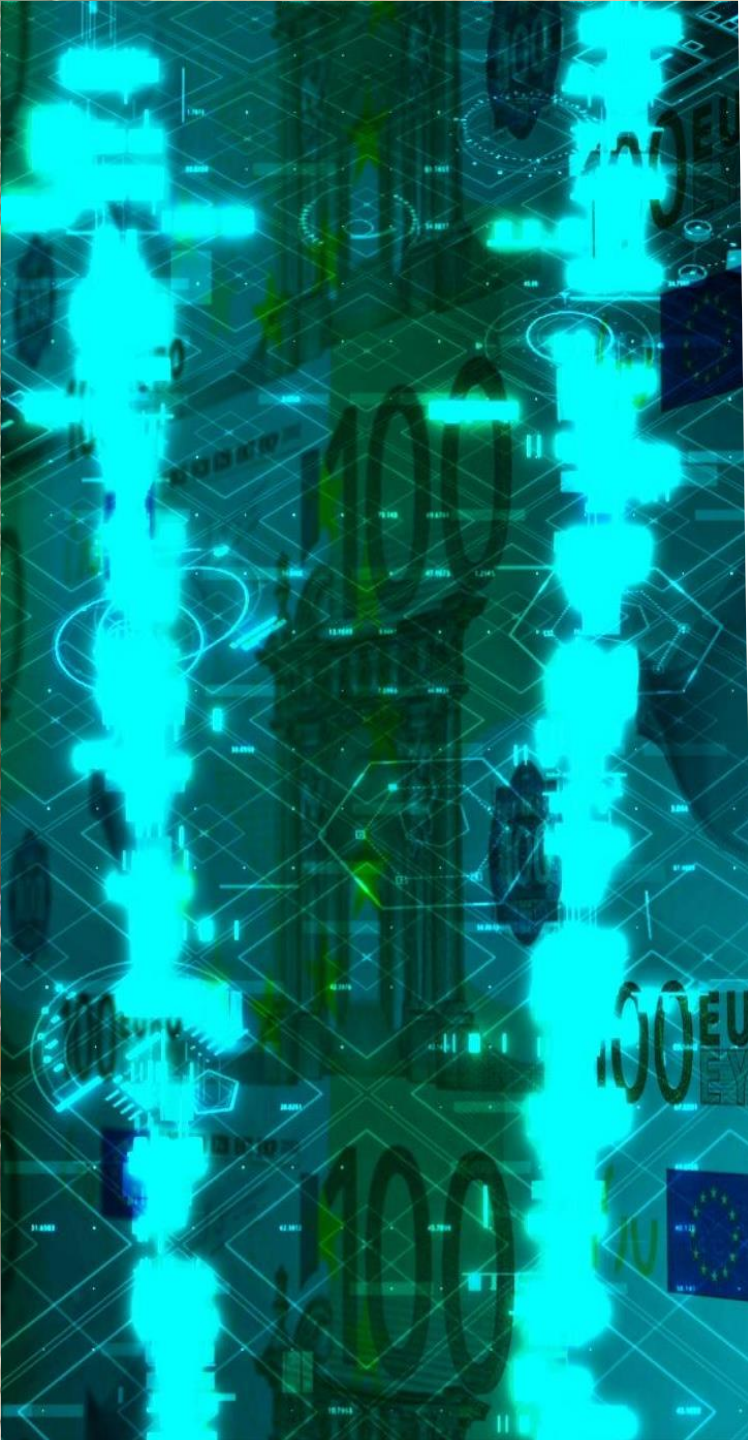
Digital Protocols and Data Flow

Adoption of digital protocols and machine-readable data standards



Reframing Programmer Roles

Focus shifts from code quantity to automation, reusability, and integrated end to end solutions



Delivery Excellence : Defining Measurable North-Star Outcomes

Speed of Delivery

One-working-day delivery of TLF's post database lock
All Visualizations ready at FPI, needed for data review

Reduction in Static Outputs

50% reduction in static tables in favor of interactive, exploratory data review tools

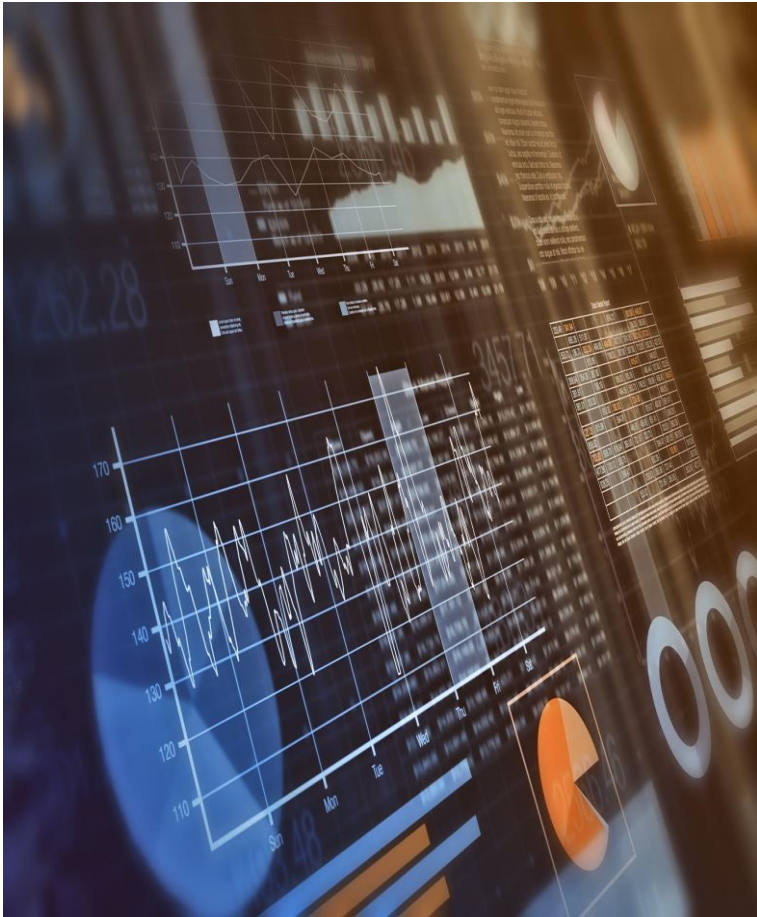
Reusability of Components

Reusing over 80% of programming components either for data review or analysis

Strategic Partnership and Influence

Being recognized as strategic partners internally and industry trailblazers externally

Functional Excellence : The AI-Native Programming Model



A robust Metadata Fabric Foundation with Standards

AI-Augmented Expert Review

A Metric for every deliverable

A partner of choice for every team

A trailblazer across industry

Our Vision is to be a function anchored in Strategic Drug Development, Technology, Critical Thinking, Storytelling, and Influencing Excellence.



Governance Framework

Risk-based Validation

Continuous Monitoring

Human-in-the-Loop Control

Process Excellence : AI
Governance, Validation, and
Risk Management



Workforce Transformation : Evolving Skills and Roles for the AI Era

Build a future ready Workforce

Traditional coding roles evolve toward curation, oversight, and strategic problem-solving in AI-enabled environments.

AI Literacy and Training

Upskill-workforce, Tiered training programs develop AI literacy

Emergence of New Roles

New roles like metadata engineers, AI product owners, and model validators complement traditional expertise.

Talent Development Strategies

Re-evaluate current work-force, reporting structure, and geographic locations to develop efficient future workforce plans, shifting from transactional to AI-driven tasks

Balancing Upfront Investment with Long-Term Value

Initial Foundational Investments

First-year investments focus on governance, training, architectures, and pilot funding

Scaling and Incremental Investment

Years two and three involve investing in platform hardening, automation, and partner capacity

Measuring Value Realization

Value emerges through efficiency gains, improved data quality, faster decisions, and enhanced regulatory credibility.

Linking Investment to Outcomes

Connecting investments to clear metrics sustains executive support and drives durable AI adoption returns.



Driving Adoption Through Structured Change Management

Clear Communication

Structured Learning Support

Celebrating Early Wins

Transparency and Trust





Anticipating and Mitigating Key Risks

Regulatory and Data Risks

Technical Risks and Monitoring

Talent and Workforce Challenges

Managing Organizational Change

CALL TO ACTION

The Leadership Moment Is Now

The question isn't whether AI will transform Clinical & Statistical Programming—it already has.



Individuals

- Build AI literacy
- Launch pilot projects
- Develop data product thinking



Teams

- Create playbooks for AI-enabled workflows
- Build reusable, AI-ready data assets
- Establish model validation checklists and governance frameworks



Leaders

- Redesign operating models around insight facilitation
- Invest in upskilling programmers
- Partner strategically with Biostatistics, Safety, and Medical Affairs

The question is whether you'll lead the transformation or follow it. Data remains constant.

Your expertise is irreplaceable.

This is your moment to expand, to orchestrate, to lead.....



BACK-UP



IS THIS DECK
AI
GENERATED?

O Yes! But with human in the loop.

THE HUMAN



THE PROMPT



This is the 203X vision for Clinical & Statistical Programming in J&J. Now based on information on how all pharma companies are preparing for advent of AI, create a new slide deck that highlights the action plan for Clinical & Stats programming for next decade

Copilot said:

Reasoning completed in 30 steps

This is great context, Sangeeta—thank you for sharing the 203X vision. I've built a new, ready-to-present slide deck that translates that vision into a concrete, externally-anchored action plan for Clinical & Statistical Programming over the next decade.

Download the deck:

CSP_AI_Decade_Action_Plan_2026-2035.pptx

Protocol-to-Planning Automation

AI automates drafting study planning documents from structured protocols, reducing manual effort and accelerating study initiation.

AI-Supported Data Mapping

AI enables efficient SDTM mapping from electronic data capture, guided by metadata and rules for transparency and reviewability.

ADaM and TLF Generation

AI assists in code assembly and reviewer guide generation, ensuring traceability and reducing cycle times for analysis outputs.

Quality and Compliance Support

AI aids code review, SOP creation, and inspection package assembly, improving consistency without raising patient risk.

Interactive Data Review Tools

Replacing static reports with AI-powered dashboards enhances insight while reducing overall output volume.

Examples: High-Impact Use Cases for the First 18 Months

Phased AI Transformation Roadmap for Clinical & Statistical Programming

ROADMAP PHASE	TIMEFRAME	PRIMARY FOCUS	KEY OUTCOMES
Foundation	2026	Governance, AI literacy, validation, baseline metrics	Trusted AI pilots, human-in-the-loop controls, inspection-ready documentation
Scale & Standardize	2027–2028	Metadata-driven automation, reusable standards, interactive-first delivery	25–50% reduction in static outputs, broader 24 hours post-DBL delivery, and all review methods available at FPI
Embed & Integrate	2029–2031	End-to-end AI integration across lifecycle and functions	,real-time data review, unified CP/SP operations
Transform & Lead	2032–2035	Real-time submissions, adaptive AI ecosystem	Global reusability, real-time regulatory engagement,