

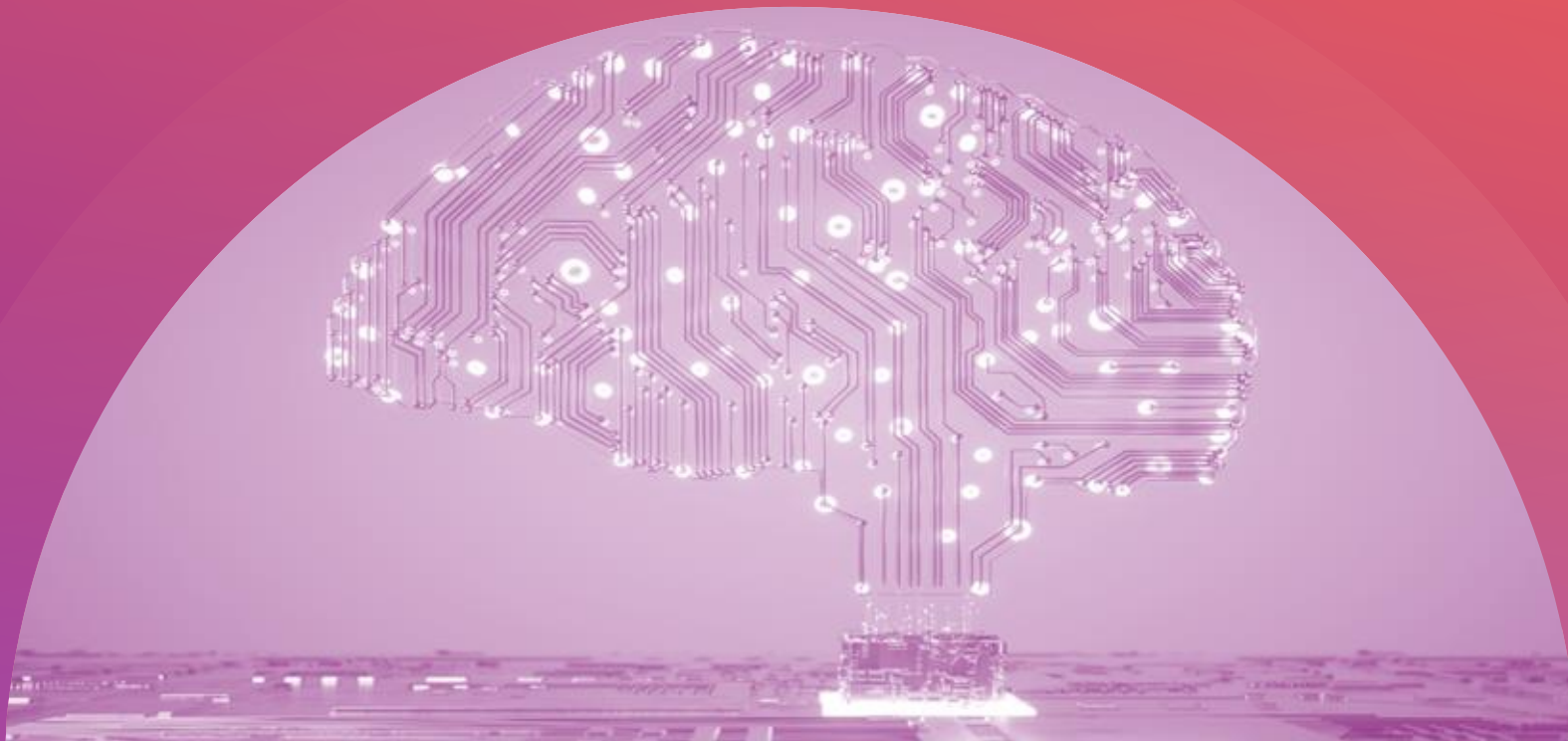
AI AS A COPILOT

EMPOWERING, NOT REPLACING, CLINICAL STATISTICAL
PROGRAMMERS

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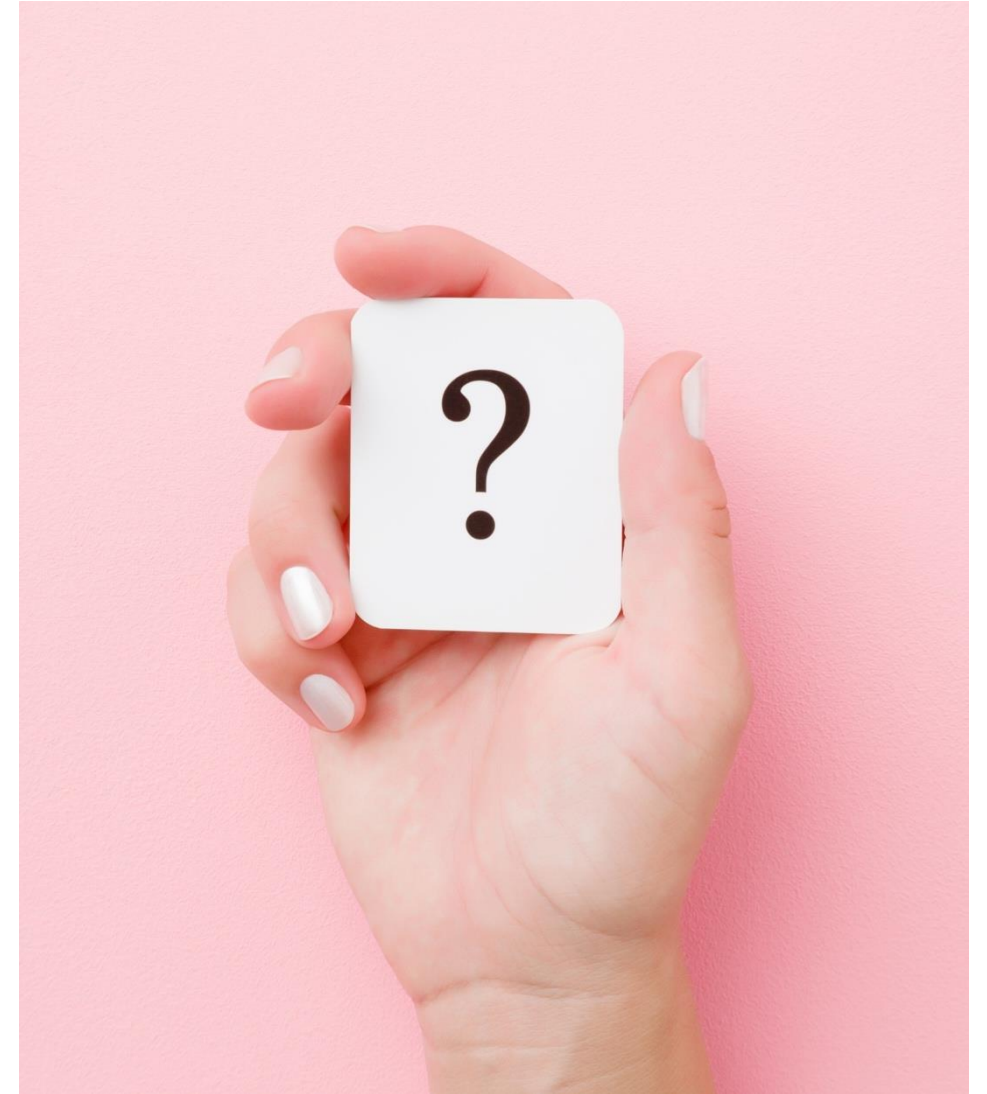
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Why this matters today?

- **Rapid AI adoption** in technical roles
- **Clinical programming** is more than just coding and **subject to regulatory scrutiny**
- **Accountability and judgment** cannot be automated



Clinical Statistical Programmers: Beyond Coding

Clinical statistical programmers play a critical role in transforming raw clinical trial data into structured, analysis-ready datasets and interpretable outputs.

- Interpret analysis plans and specifications
- Handle ambiguity and edge cases
- Ensure traceability, QC, and audit readiness



**Interpretation
Decisions
Accountability**

**Draft narrative
Structure
Summarization
Iteration
Tailored messaging**

**AI ASSISTS THE FLIGHT.
HUMANS LAND THE PLANE.**

The Right Role of AI: A Copilot Approach



**Supports well-
defined tasks**

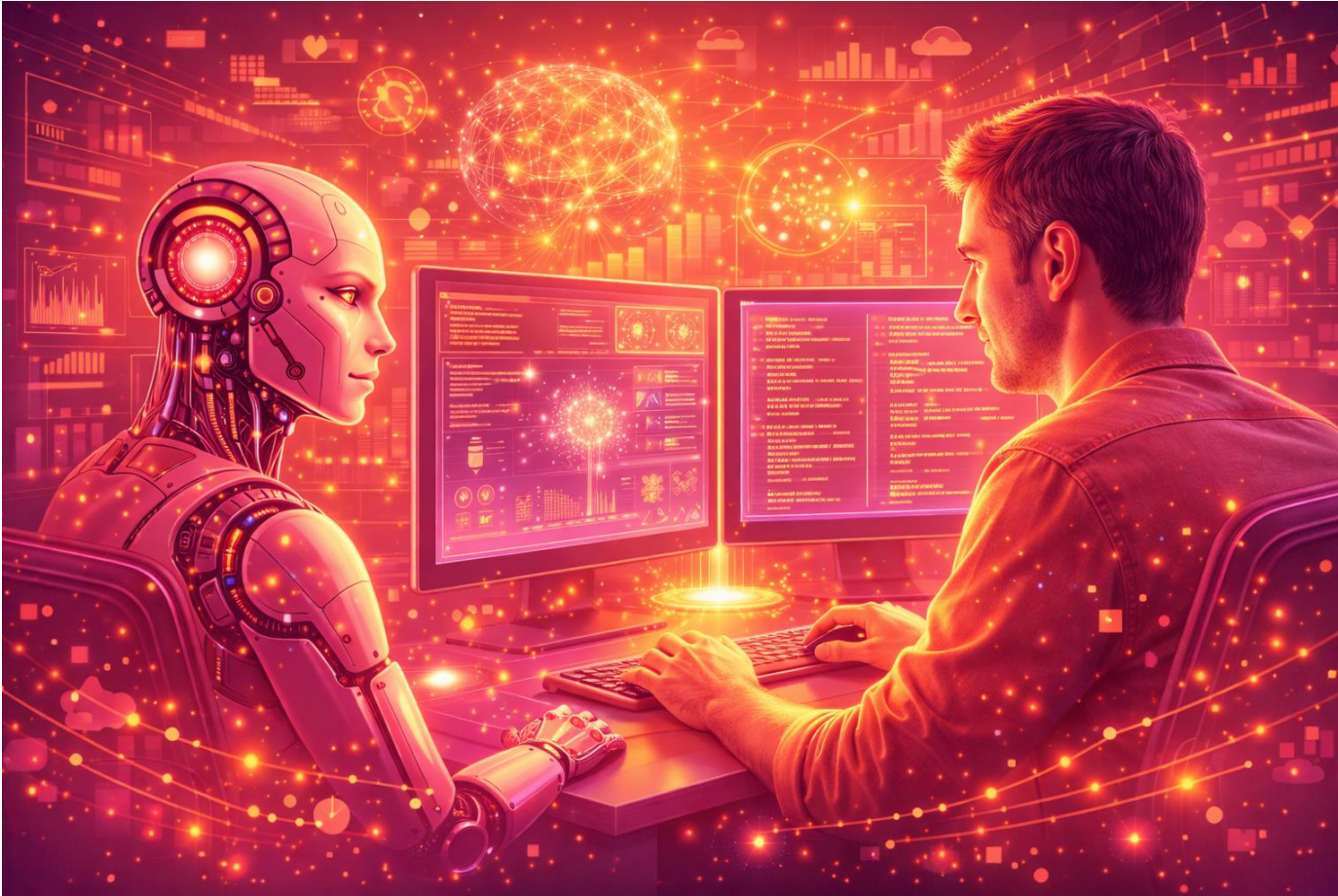


**Accelerates development
and understanding**



**Final decisions
remain human**

PRACTICAL AI USE CASEs FOR CLINICAL STATISTICAL PROGRAMMING



AI as a SAS®
knowledge assistant

Automated
generation of
repetitive code

AI-assisted creation
of complex data
step logic

AI support for
complex Code block
and merge logic

AI-assisted pre-
validation QC and
self-review

AI-assisted
understanding and
reuse of inherited
programs

PRACTICAL AI USE CASEs FOR CLINICAL STATISTICAL PROGRAMMING



Risks, Limits, and Governance

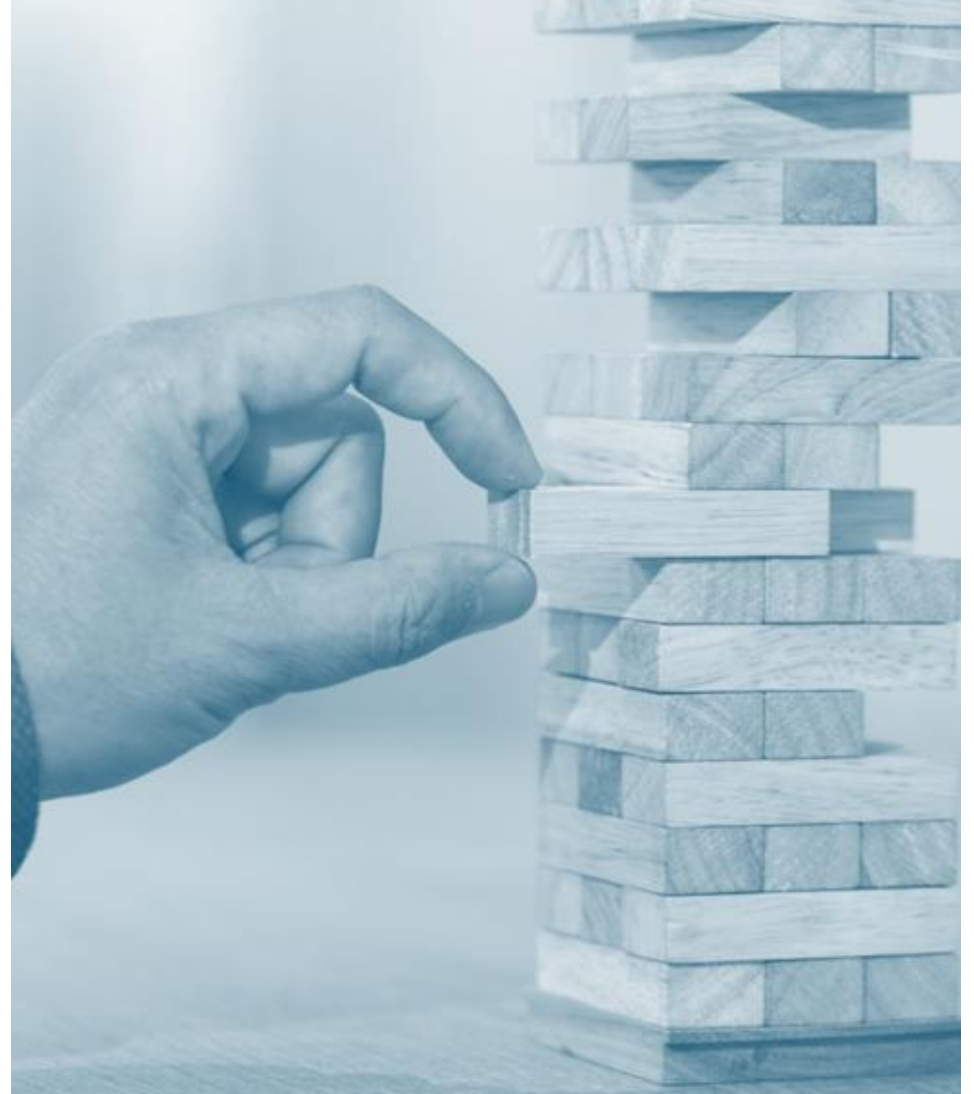
Treat AI output as draft only

Overreliance on AI suggestions

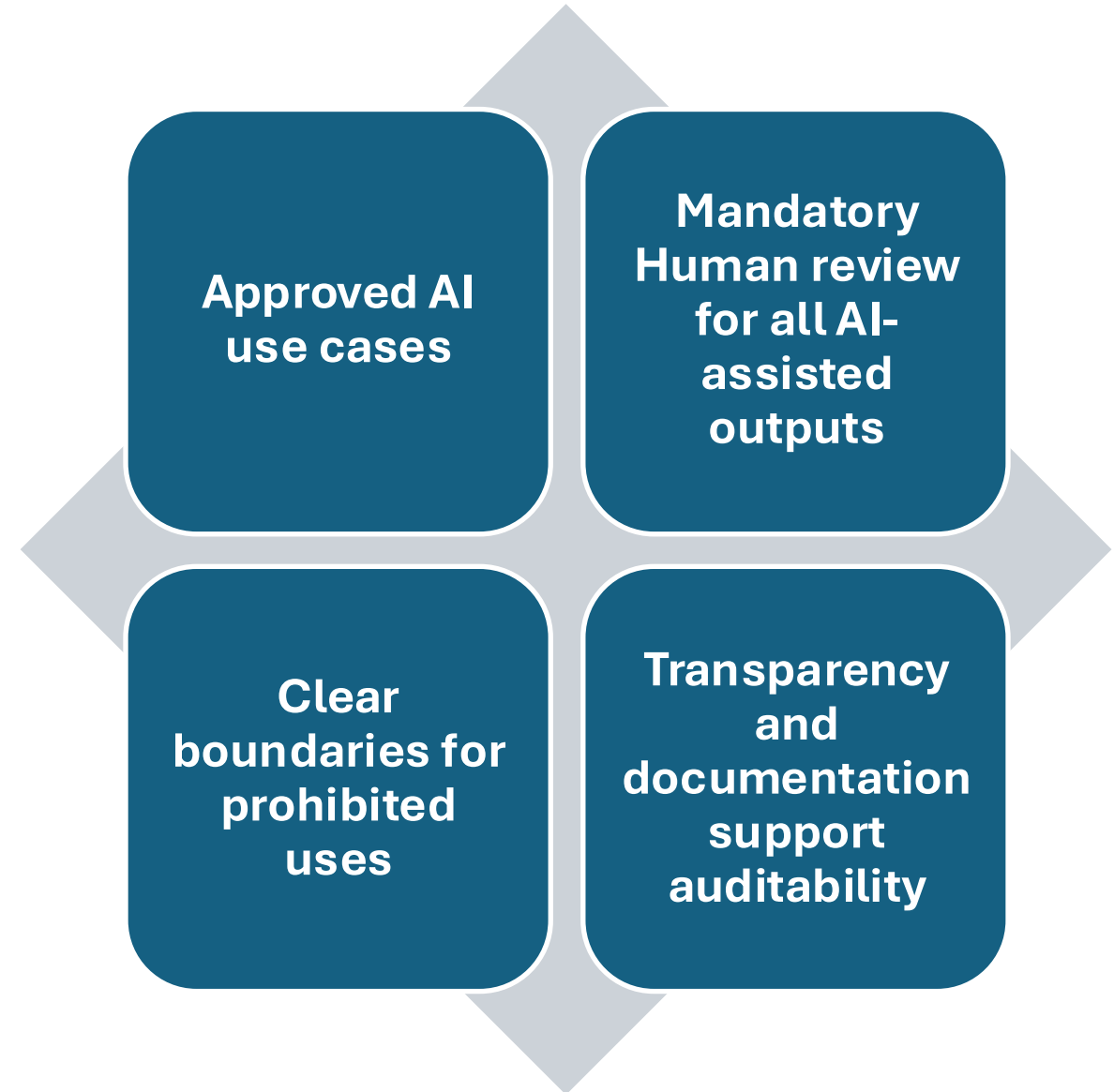
Requires thorough QC

Data privacy concerns

Organizational Governance



RESPONSIBLE INTEGRATION FRAMEWORK





Future Outlook

AI role in statistical programming is likely to **expand in depth rather than breadth**.

AI assistance will be more **predictable & easier to implement**

Fundamental **need for human judgment, contextual understanding, and accountability** will remain unchanged

Near term adoption is expected to focus on areas that are already well understood and procedurally defined

Organizations will develop **formal standards** and tooling to support AI-assisted development

AI is **unlikely to replace clinical statistical programmers** in clinical research. Instead, it will increasingly serve as a copilot

Conclusion



AI is best viewed not as a replacement for human expertise, but as a copilot that supports programmers by reducing repetitive effort, accelerating understanding, and assisting with well-defined technical tasks.

However, **effective use of AI depends on strong governance and disciplined integration, clear boundaries** around acceptable use, mandatory human review, and explicit exclusion of AI from validation and approval activities.

Q & A



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