

PP05 Redefining the Role of the Statistical Programmer in an AI-Driven World

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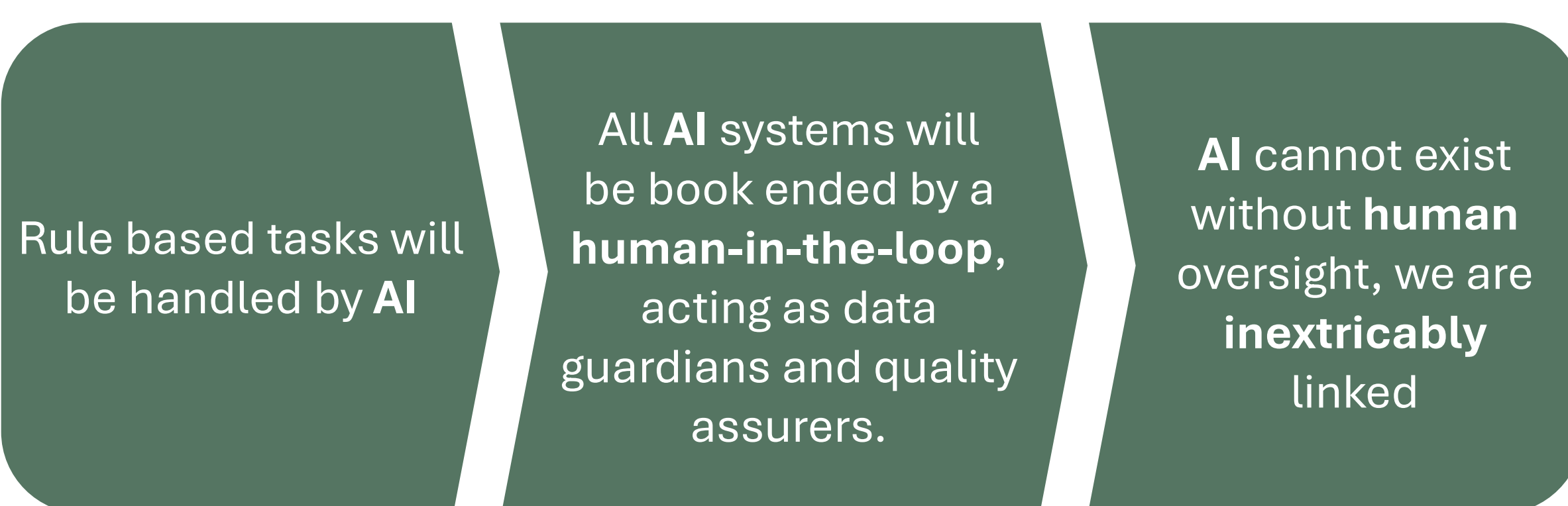
Purpose Led, Data Driven.

With AI adoption on the rise people are questioning what the future has in store. As Statistical Programmers will we become obsolete? This poster showcases how Statistical Programmers will be more relevant than ever in the age of AI. Far from becoming obsolete, there is the opportunity to become technical linchpins, expanding our scope across the drug development lifecycle.

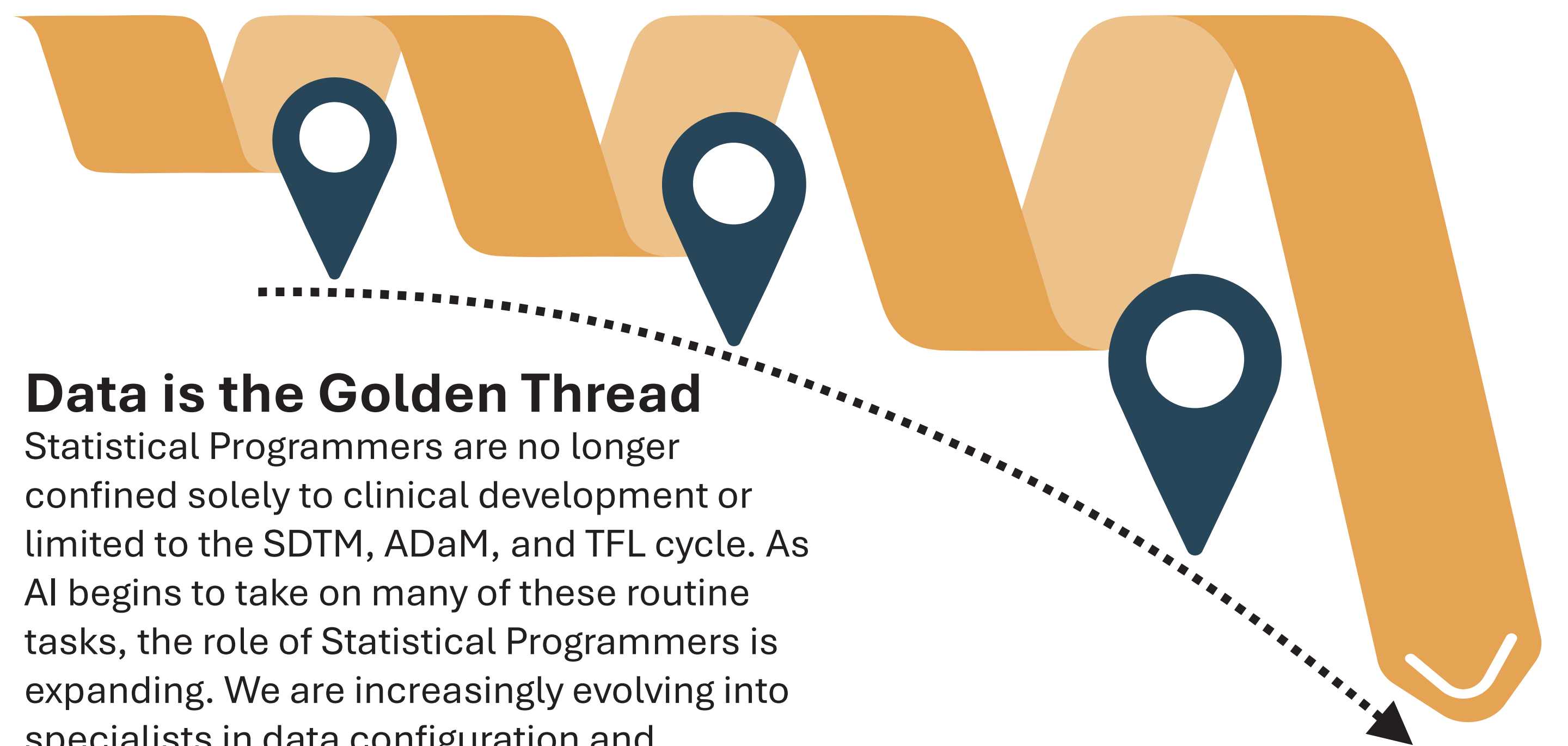
How AI is Changing the Role of the Statistical Programmer

As AI becomes more widely adopted, the way we approach our daily work will inevitably evolve. Many of the tasks that were once routine will be managed by AI systems.

This shift does not make Statistical Programmers obsolete, **it just redefines where our value sits.**



Redefining: The Boundaries



Data is the Golden Thread

Statistical Programmers are no longer confined solely to clinical development or limited to the SDTM, ADaM, and TFL cycle. As AI begins to take on many of these routine tasks, the role of Statistical Programmers is expanding. We are increasingly evolving into specialists in data configuration and transformation throughout the drug development lifecycle. Data is the golden thread that connects every stage of drug development, from early research through post-market analysis.

Statistical Programmers must now engage at multiple points along the data flow, ensuring its **integrity, usability, and transformation**, well beyond the traditional boundaries of clinical development.

Redefining: The Role of the Statistical Programmer

The role and value of the Statistical Programmer is not being diminished, it is being redefined. As AI takes on repetitive, standardised tasks, programmers are freed to contribute where their domain knowledge, critical thinking, and contextual understanding are indispensable.

Moving from the periphery to the centre of drug development, acting as technical linchpins who connect data, insight, and decision-making across functions.



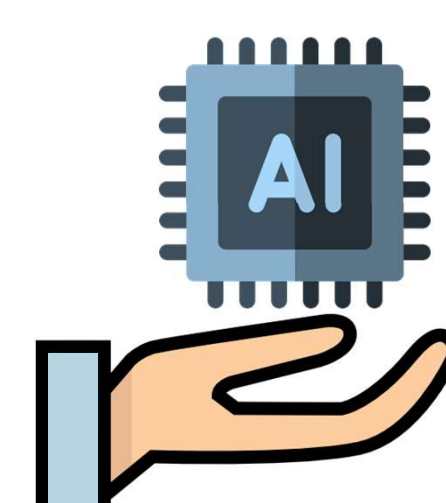
Data Guardian

Safeguard data provenance and integrity

Validate mappings and derived variables

Apply deep domain knowledge to spot anomalies

Ensure outputs comply with regulatory standards



AI System Owner

Own and configure AI platforms for SDTM/ADaM transformation

Apply knowledge of standards (CDISC, ICH) to system setup

Monitor model performance and bias

Oversee change management and integration of AI tools



Critical Reviewer

Review and challenge AI-generated code, datasets, and TFLs

Detect where automated logic fails or lacks context

Safeguard quality of AI generated documents (e.g. aCRF, specs, Define.XML)

Provide final quality checks before submission



Coding Expert

Hands-on coding for complex derivations AI cannot automate

Apply logical programming mindset to review of other languages

Tailor evidence to trial objectives and payer needs

Support novel endpoints or adaptive trial designs

Redefining: Where Value Sits

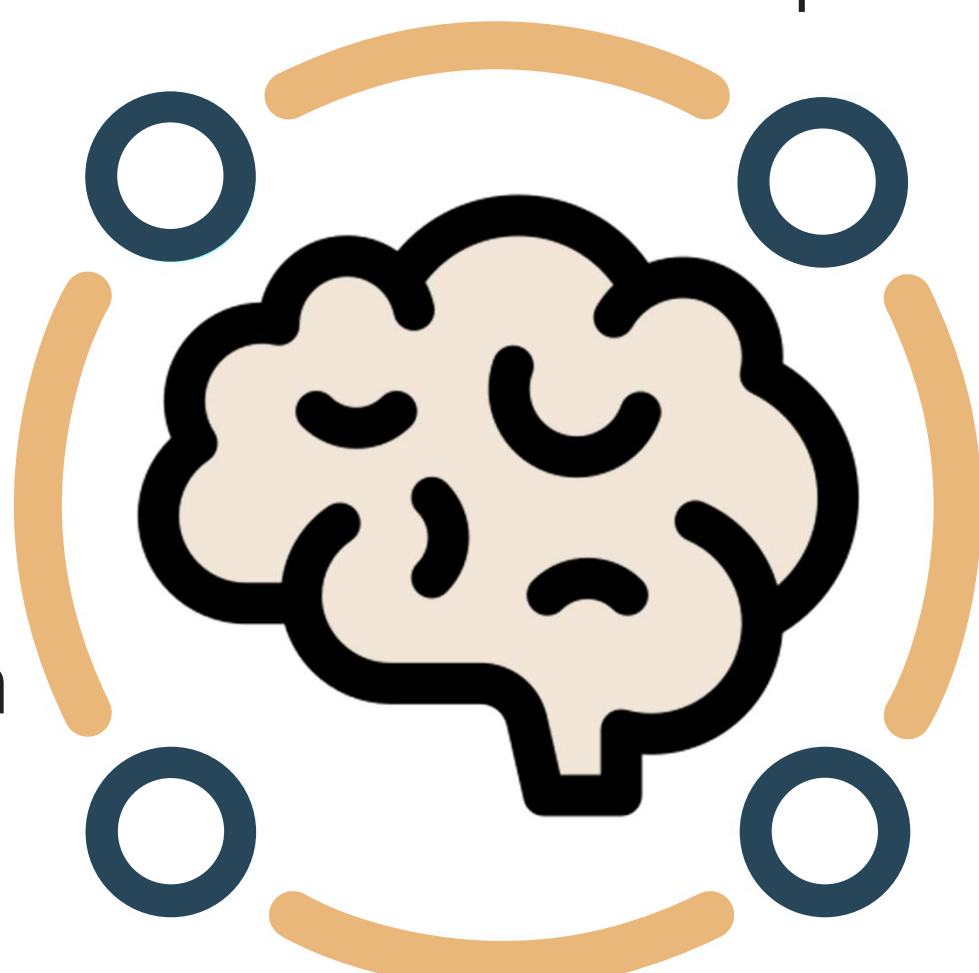
Our enduring value isn't just in what we *do*, but in what we *know*. Our existing strengths become the bedrock for future success, allowing us to broaden our scope and add value across the drug development lifecycle.

Industry Expertise

- Deep domain knowledge
- Comprehensive CDISC/ICH knowledge
- Good understanding of clinical endpoints and statistical intent

Logical Thinking

- Apply critical reasoning to validate AI outputs and catch edge-case errors
- Provide objective, reproducible checks to safeguard quality and compliance



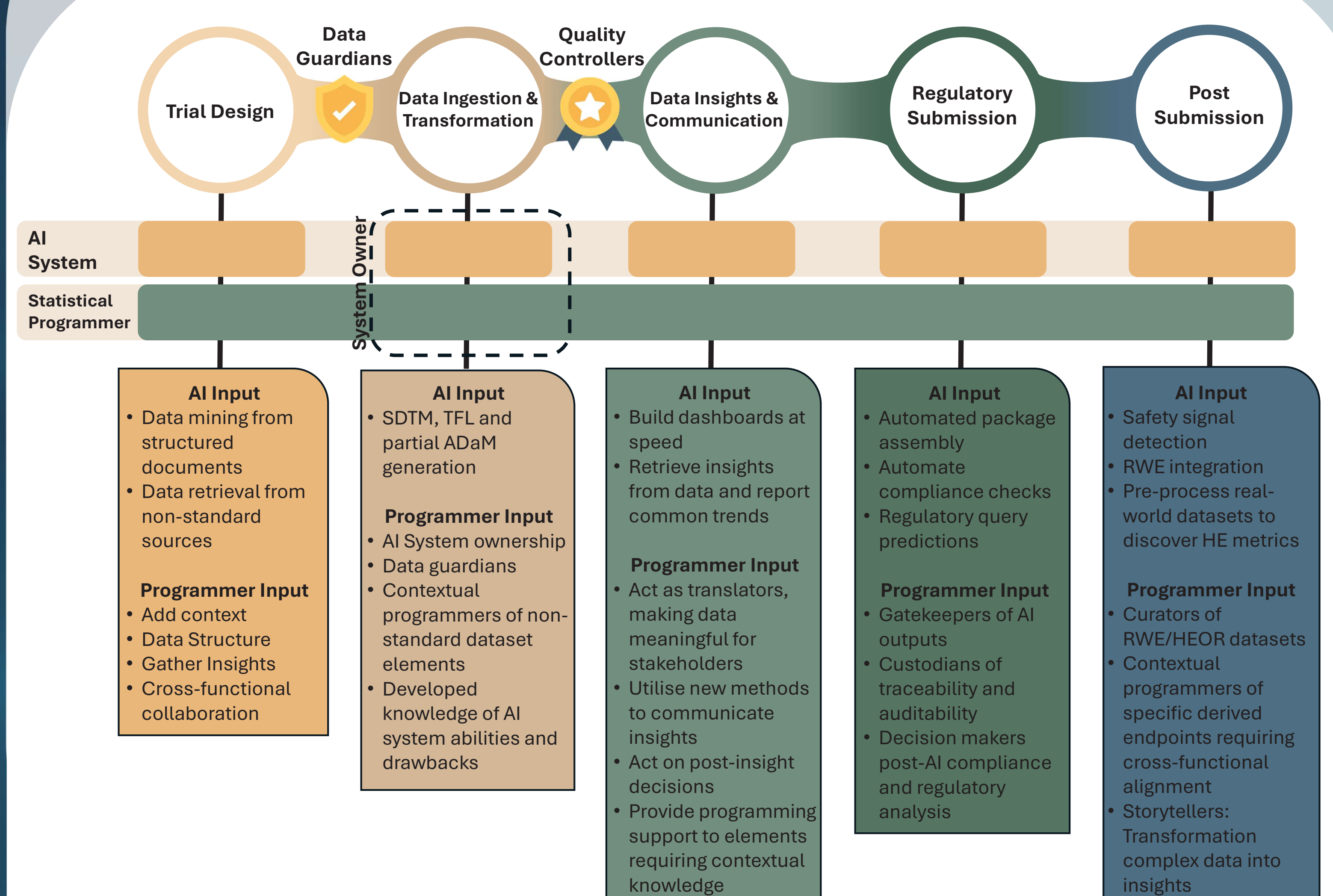
Data Translation

- Storytelling
- Add meaning and structure to data
- Utilise new methods and tools to further data exploration
- Communicate insights to help decision-makers

Adaptability

- Keep pace with new/emerging and changing technology.
- Be AI literate, understand prompt engineering, and limits of model certainty.
- Shift from "doing the coding" to system ownership and oversight roles

Redefining: The Model



AI automation accelerates core data transformations (yellow lane), but statistical programmers remain the linchpins (green lane), acting as system owners, guardians, and translators across the lifecycle. Programmers work with Regulatory Affairs and Market Access from study design through submission and commercialisation, ensuring aligned endpoints, trustworthy transformations, and structured evidence for both regulators and payers.



SCAN ME

For more information and to see how you can become a future-proof programmer, scan the QR code to read our PHUSE EU Connect 2025 Paper:

Code, Collaborate, Conquer: The Future-Proof Programmer in an AI World

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