Single Day Events

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From Coder to Architect:
Human–AI Collaboration in Clinical Programming
- Sarita Singh/ 20Jun2026
Veramed
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Abstract

For decades, the value of the statistical programmer has been defined by technical fluency in SAS or R. The rapid emergence of Large Language Models (LLMs) and Agentic AI is fundamentally decoupling manual coding from clinical programming. As AI increasingly automates SDTM mapping, ADaM derivations, and routine validation tasks, the traditional programming role is undergoing a necessary and accelerated transformation. This shift presents both an opportunity and a risk: while automation promises scale and speed, regulatory integrity and clinical nuance must remain uncompromised. We examine how agentic workflows can be integrated into the Pharmaverse ecosystem to automate repetitive tasks while elevating the programmer's responsibility for design, governancae, and oversight. Central to this discussion is the application of Good AI Practice (GAIP, FDA Guideline 2026) —aligned with emerging regulatory expectations—to ensure traceability, validation, and risk-based control in AI-assisted clinical programming environments. Practical examples will illustrate how human-in-the-loop checkpoints are embedded within automated pipelines. The 2026 competency model requires moving beyond technical execution toward agent orchestration and system-level design, empowering programmers to lead the digital transformation of clinical trials.

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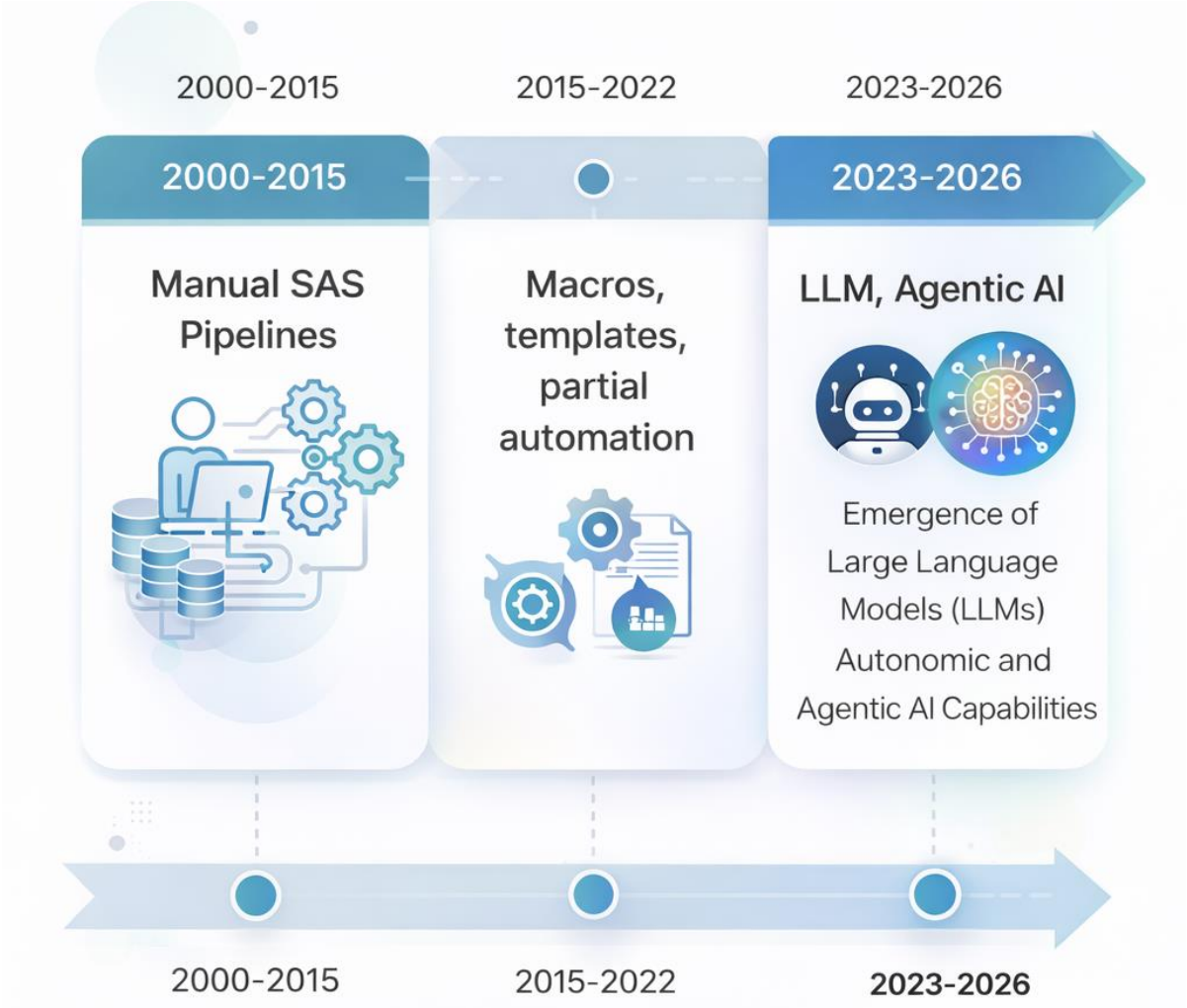
Transforming Programmers Role

Human in loop of Agentic Workflow

Traditional Role of the Statistical Programmer

"If SDTM mapping can be automated, what is the programmer still accountable for?"

Disruptive Shift: Emergence of LLMs and Agentic AI



- **Until 2015:** Manual SAS pipelines
- **2015- 2022:** Macros, templates, partial automation.
- **2023–2024:** Context, Tools, Compound systems
  - RAG, open-source models (Llama)
  - API calling, workflows
- **2024–2026:** Agentic AI
  - Multi-agent platforms, memory
  - Interoperability networks
  - Autonomous decisioning

Agentic Workflows in Clinical Programming

Multiple AI Agents, Human Checkpoints, Orchestrated Systems

Coordinated AI Workflow with Human Oversight

Pharmaverse Integration

Standard Control

Instance of Human –AI Collaboration

Agent Orchestration

<ROLE>
You are a clinical programmer highly skilled in R clinical programming and proficient with Pharmaverse packages, particularly for SDTM and ADaM dataset derivations in a regulatory-compliant context.
</ROLE>

<TASK>
Create R code to derive a Treatment-Emergent Flag (TRTEMFL) for an ADAE dataset using Pharmaverse packages. The flag must be derived according to the following specification:
- If `ADSL.TRTSDT` ≤ `ADAE.ASTDT` and both dates are non-missing, then set `TRTEMFL = "Y"`.
- Otherwise, leave as missing (`NA`).

Ensure:
1. Correct merging logic between `ADAE` and `ADSL` based on `USUBJID`.
2. Handling of missing values without errors.
3. Use of Pharmaverse functions for date handling and variable derivation where appropriate (e.g., `admiral` functions).
</TASK>

<SOURCE>
Assume you have access to ADSL and ADAE data frames compliant with ADaM standards.
</SOURCE>

<RULES>
- Use **Pharmaverse packages** (e.g., `admiral`, `dplyr`) for implementation.
- Code must be reproducible and readable: include library calls, joins, and flag derivation.
- Incorporate proper NA handling safeguards.
- Final output: ADAE dataset with newly added `TRTEMFL` variable.
Provide the full R code as a fenced block.
</RULES>

<VALIDATION>
- Verify logic by demonstrating an example with sample data for 2–3 subjects.
- Confirm that only records meeting the date condition have `TRTEMFL = "Y"`.
- Explicitly state any assumptions you made (e.g., date formats, dataset structure).
</VALIDATION>

AI - Implementation

✅ R Code Implementation

```r
22  # Derive TRTEMFL
23  #-----------------------------
24  adae_final <- adae %>%
25    # Merge ADSL TRTSDT into ADAE using admiral helper
26    derive_vars_merged(
27      dataset_add = adsl,
28      by_vars = exprs(USUBJID),
29      new_vars = exprs(TRTSDT)
30    ) %>%
31    # Derive TRTEMFL
32    derive_var_trtemfl(
33      start_date = ASTDT,
34      trt_start_date = TRTSDT
35    )
36
```

Human Oversight Instance

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Admiral R package Documentation

Details

For the derivation of the new variable the following cases are considered in this order. The first case which applies, defines the value of the variable.

- *not treated*: If `trt_start_date` is `NA`, it is set to `NA_character_`.
- *event before treatment*: If `end_date` is before `trt_start_date` (and `end_date` is not `NA`), it is set to `NA_character_`.
- *no event date*: If `start_date` is `NA`, it is set to `"Y"` as in such cases it is usually considered more conservative to assume the event was treatment-emergent.
- *event started during treatment*:
  - if `end_window` is not specified: if `start_date` is on or after `trt_start_date`, it is set to `"Y"`,
  - if `end_window` is specified: if `start_date` is on or after `trt_start_date` and `start_date` is on or before `trt_end_date` + `end_window` days, it is set to `"Y"`,
- *event started before treatment and (possibly) worsened on treatment*:
  - if `initial_intensity`, `intensity` is specified and `group_var` is not specified: if `initial_intensity < intensity` and `start_date` is before `trt_start_date` and `end_date` is on or after `trt_start_date` or `end_date` is `NA`, it is set to `"Y"`;
  - if `group_var` is specified: if `intensity` at treatment start < `intensity` and `start_date` is after `trt_start_date` and `end_date` is on or after `trt_start_date` or `end_date` is `NA`, it is set

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Opportunities vs Risk

AI-Driven Automation

Opportunity vs Risk in AI-Driven Automation

Benefits of Automation

- Increased Efficiency
- Scalability & Consistency
- Focus on Higher-Value Tasks

Risks of Ungoverned Automation

- Subtle Errors
- Hallucinated Results
- Loss of Traceability
- Regulatory Challenges

Need for Governance

- Governance Frameworks
- Human Oversight
- Ensuring Accountability & Control

Guiding Principles of Good AI Practice in Drug Development

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The 10 principles are tailored to the drug development cycle and emphasize the importance of:

- Human-centric by design
- Risk-based approach
- Adherence to standards
- Clear context of use
- Multidisciplinary expertise
- Data governance and documentation
- Model design and development practices
- Risk-based performance assessment
- Life cycle management
- Clear, essential information

https://www.fda.gov/about-fda/artificial-intelligence-drug-development/guiding-principles-good-ai-practice-drug-development

Human-in-the-Loop: Preserving Oversight

Role of Human Judgment

Humans interpret AI results, accept risks, and provide documented justification beyond automated outputs.

Examples of Oversight Tasks

Reviewing AI-generated mappings and validating derivations ensure clinical and analytical appropriateness.

Increased Importance of Expertise

AI presence heightens need for senior expertise to evaluate system behavior and data outputs.

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Advancing Competency

Accelerating Programmers Role

Advancing Competency

Foundational Technical Execution

- Core coding and programming skills for clinical tasks

Advanced Skill Differentiation

- Agent orchestration
- Workflow design
- AI Risk Assessment

Leadership & Strategic Role

- Leadership
- Accountability
- Strategic Thinking

Evolving Role of the Clinical Programmer

Beyond Coding to Strategy & Leadership

Key Takeaways

AI Automates Technical Tasks

Handles automation in clinical programming, enhancing efficiency and precision.

Human Responsibility and Governance

Despite AI automation, accountability, judgment, and governance remain essential human roles.

Future of Human-AI Collaboration

Crucial for advancing clinical trial innovation.

Leadership and Adaptation

Embracing AI governance and architectural thinking empowers leaders to drive innovation and responsibility.

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