The Evolving Role of the Statistical Programmer

-- Navigating the Future with GenAI and Open Source Tools

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Why This Topic Matters?

Clinical trials are more complex

GenAI & open source are reshaping how we work

Sponsors want faster, smarter delivery

Staying relevant means evolving with the role

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Traditional Role of Statistical Programmer

Creating SDTM, ADaM datasets

Programming TLFs in SAS

QC, validation, regulatory submissions

Often manual and siloed

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What's Changing Now?

Growing data complexity

Agile and real-time models

More client demands on innovation, speed & quality

Rise of GenAI, open-source tools

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Open-Source Tools

Why They're Gaining Ground?

R, Python: more flexible & innovative

Growing Regulatory acceptance

R-Shiny: interactive dashboards

Strong community support

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How is the Role Evolving?

Execution-focused

Manual workflows

Reactive programming

Siloed work

THEN

NOW

Insight-driven

Automated & adaptive

Proactive, risk-aware

Cross-functional **collaboration**

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LLM in Action : Examples

Development of Robust Statistical Analysis Plans (SAPs)

Protocol Alignment

LLMs can analyze protocol and extract key objectives, end points, methodologies, to ensure SAP aligns with protocol

Standardization

LLMs can refer guidelines internal as well as industry standards and draft SAP which adheres to Best practices, this ensure regulatory compliance and reproducibility of results

Template Creation

LLMs can assist creation of templates for TLFs based on SAP and shell specs ensuring output is structured and in predetermined format.

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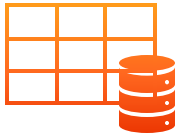
LLM in Action : Examples



Data Transformation from Raw data to SDTM and ADaM

Automated Mapping

Data Science tools can automate conversion of raw data to SDTM and subsequently to ADAM, reducing the manual effort and errors

Compliance with Standards

It can utilize CDISC Open-Source Alliance (COSA) like standards to ensure data transformation is consistent with industry standards

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LLM in Action : Examples

Validation of Outputs

Consistency Checks

LLMs can perform consistency checks between SAP, Protocol and generated output to ensure final deliverable accuracy

Automated Validation tools

Platforms like Beaconcure's "Verify" – can utilize ML and NLP to automate validation of Stats Analysis outputs. It converts Static Outputs into Dynamic structured Database ensuring efficient QC.

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GenAI in Statistical Programming:
Real Use Cases

- Code generation (e.g., macros)
- Auto-documentation from SAPs
- Natural language queries
- Risk detection, QC automation
- AI as co-pilot, not replacement

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What the Future Could Look Like?

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How Can You Prepare?

Learn

R, Python,
AI basics
etc

Explore

“WHY” are
you doing
the analysis?

Join

Open-source
communities
(e.g. PHUSE, R
consortium)

Adopt

A growth
mindset

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Call to Action: Don’t Get Left Behind!

Tools are changing - and so are expectations

Be curious, adaptable, and proactive

Don’t aim for perfection - just progress

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Thank you !

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