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NEWSLETTER · IN CONVERSATION WITH ANDY YORK

Eighty percent isn't good enough

Andy York — thirty years in statistical programming, from Roche to VP at Novo Nordisk — on AI's real ceiling in pharma, the guardrails that make it usable, and why the industry's long marriage to SAS is finally loosening.

Andy York has spent more than thirty years deciding how the industry designs, validates and delivers the statistical outputs that go to regulators — from Roche to VP of clinical data science at Novo Nordisk, and now as an independent adviser. I've had the pleasure of working with him twice. He is exactly the person you want puncturing the current AI hype, because he does it with a statistician's arithmetic rather than a vendor's optimism.



Eighty percent of what we need is a twenty percent failure rate.

— Andy York, on Pharma Prescribed

The number nobody wants to hear

The line I keep repeating from this episode is Andy's. When people say AI can already do 80% of a task, he hears a 20% failure rate — and from a Six Sigma view, a process that's wrong one time in five is simply out of control. In an industry where patient safety sits at the centre, he won't call it ready until

accuracy is reliably in the high 90s. Pharma also isn't banking: we work with small, diverse datasets, not decades of uniform records, which makes dependable AI genuinely harder to build here.

Guardrails, not magic

His answer isn't to reject AI but to fence it in. Left unconstrained, a model hallucinates; wrapped in your own standards — for output generation, for ADaM and SDTM — the same tools start hitting far higher accuracy. He's also blunt about theatre: if describing a table to an AI in plain English takes longer than a skilled programmer would take to write it, you've gained nothing. Decide where AI actually earns its place.

Full circle on languages

Andy started when SAS was busy killing off languages nobody remembers now. Today it's SAS itself feeling the push from R and Python, and a generation entering the industry fluent in both. His counsel to tech firms trying to break in is refreshingly unglamorous: talk to the regulators early. Selling the tool is one thing; getting the FDA to understand what you're trying to achieve is the other half of the job.



Listen to the full episode

Andy York on Pharma Prescribed — at pharmaprescribed.com and wherever you get your podcasts.

Andy York is an independent clinical data science consultant with over thirty years' experience, formerly VP of clinical data science at Novo Nordisk.