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NEWSLETTER · IN CONVERSATION WITH ADAM BAUMGART

Fewer surprises at database lock

Adam Baumgart — 35 years across CROs and pharma — on making risk-based quality management make sense, and why a clinical trial is best understood as a people-based process.

Adam Baumgart has spent 35 years in and around clinical trials and has, by his own admission, lost count of the roles. For the last decade and a half his passion has narrowed to one unglamorous but consequential thing: risk-based quality management. If your eyes glaze at the phrase, this episode is the antidote — he explains it in plainer English than any guidance document manages.



A clinical trial is a people-based process.

— Adam Baumgart, on Pharma Prescribed

RBQM without the jargon

Adam traces it back to total quality management on Toyota's production lines, then asks the obvious question: how do you apply that to a people-based process — patients, clinicians, sponsors — rather than a factory? His answer is four pillars: quality by design (build quality in), quality risk management (de-risk and manage it), and the quality control and quality

assurance we always had. Nothing exotic; just applied earlier and more deliberately.

The point is fewer surprises

The real shift, he argues, is doing meaningful risk assessment at the very start of every study rather than discovering problems downstream. Standardise what you can, design quality in, then watch the risks that matter as data comes in and gets cleaned and analysed. Do that and the trial throws up fewer nasty surprises when it counts — a quieter database lock being its own reward.

Where AI fits

He's constructive about AI as a way to sharpen RBQM, clinical data review and site monitoring — provided it's pointed at genuine risk and efficiency rather than adopted for its own sake. The consistent thread is judgement: the technology serves the risk framework, not the other way around.



Listen to the full episode

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Adam Baumgart is a biometrics and risk consultant with 35 years in pharma and CROs, advising at ZedE Associates and CDO Consulting.