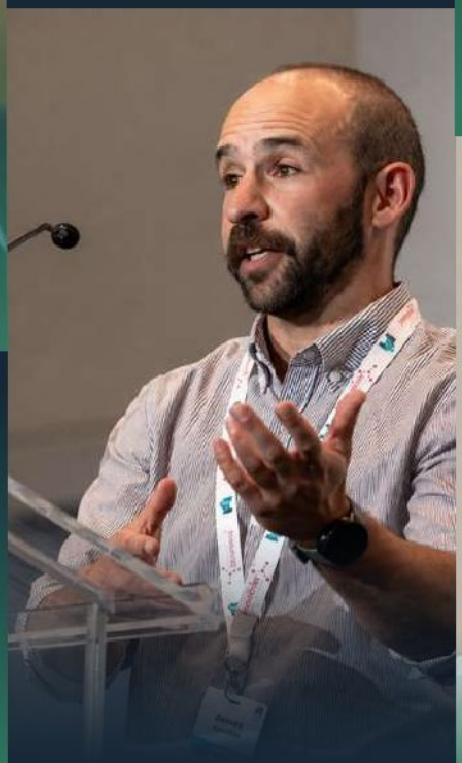


Executive Director,
Cogitars UK

Miguel Pereira



Vijay Vaidya

Independent Contractor,
Clinical Data & AI Automation

Former Director of Statistical Programming, AstraZeneca



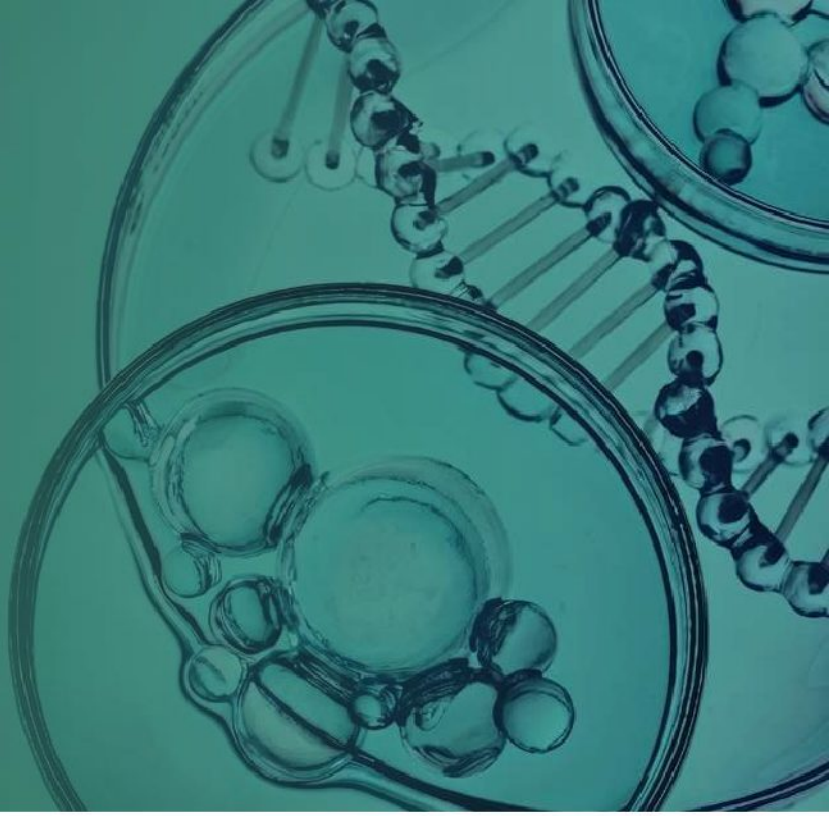
Andrew MacGarvey

CEO & Founder,
Coronado Research

August 2026:
AI in Biometrics

THE BIOMETRICS BRIEF

WELCOME



This inaugural issue of The Biometrics Brief, a digital magazine from Clements Partners, is for professionals at the forefront of biometrics in the life sciences industry.

In each issue, we feature in-depth conversations with people at the leading edge of a topic in this space. It's a platform to speak properly, free from panels, slide decks, or thirty-second soundbites. Just real conversations with people who deeply understand the subject.

The idea is simple. The people who understand this best rarely get an extended platform to say so, and the people who'd benefit most from hearing them rarely get the chance to hear it, not with everything else competing for their attention. We want to close that gap.

This issue's topic is AI in biometrics.

Everyone in the industry has an opinion on AI by now. Fewer have spent enough time with the tools to know what's actually changed versus what's just noise.

We spoke with statisticians and programming leaders who work with AI daily, not to sell a tool or a trend, but to get a straight, unfiltered read on where things stand.

What became clear across these conversations is that AI is already doing meaningful work in biometrics: automating routine programming, speeding up data checks, and absorbing tasks that once required far more time and people. The harder, less discussed question is what happens to the people learning the job while AI takes on that work. Solving a hard problem yourself, slowly and often frustratingly, was traditionally how junior programmers built the judgement senior people rely on today. If AI is increasingly doing that thinking for them, the industry needs a new way to build that expertise, and right now, there's little agreement on what that looks like.

That's the finding running through this issue. Not whether AI works in biometrics. It does, and our contributors confirm as much. The real question, the one we wanted this issue to answer, is who's coming up behind the people using it well today, and what's being done about it. Read on to see where each of them landed.



Andrew MacGarvey

CEO & Founder,
Coronado Research

I'm the CEO and founder of Coronado Research. We're now in our third year, and we were set up to "join the dots" – that's really how I describe it. We join the dots between regulatory, clinical development, market access and medical affairs, and we do that by understanding the data strategy a company needs to run across the whole lifecycle.

Where AI actually helps.

There are some genuinely good things happening, but there's also a lot of noise, and at the moment the noise is slightly drowning out the good things. Where I think we're underserved is that there's a lot of scepticism, partly because AI became the in thing and everyone tried to get in. There's a lot to work through before you do this well, and that's what Coronado was set up to help people with. From a programming specific perspective, I think automation is probably more powerful than AI from a process point of view. AI copilots supporting programming are hugely valuable too. A lot of it comes down to data standards, then running an automated process on top of that. You've also got tools like Claude Code giving you that classic copilot experience, genuinely helpful for accelerating new code. But a lot of the real work is: if I get my standards right, I can automate through them.

Current challenges?

There are three key problems in AI at the moment. The first is that it's a black box, we don't really understand it. We don't know what the model's doing, how it's been trained, or how the people who built it did what they did. You have to overcome that. The second is that our data isn't in the right form. It's disparate, it isn't put together in a way that lets you put AI tools on top of it. The third is talent, there's a growing gap. Deploying this technology takes a certain type of person: someone who can be the human in the loop and has the skill set to work with the tools. How do we make sure we've got enough of that talent coming through?

Big pharma with deep pockets are the exception, they're bringing in Anthropic, training the whole company. It's much harder to get that traction at mid-size companies.

Fewer programmers, or different work?

It comes down to one thing. Up until two or three years ago, the majority of AI funding in pharma went into discovery, that's where it started, with the protein-folding models. We didn't really invest much in clinical development. The example I always give is Insilico Medicine. They've been working with the FDA on a drug going through development, and they're compressing the discovery-phase timeline from years to months because they're using compute power instead of a lab. You're looking at roughly ten times the number of assets entering the pipeline. I think there will be political pressure on development organisations not to be the barrier. If that Insilico drug gets approved, it opens the floodgates. My guess is it hits a wall in clinical development, where everyone says you can't push ten times the volume through this system, and politically I don't think that'll be accepted. So if the pipe has to stretch to handle many multiples of the current workload, there will be a reduction in programmer numbers, but it might not be as catastrophic as people fear, because you'll still need the human in the loop, especially given the safety stakes. The big question is when that wave hits, and how quickly we can expand the bandwidth. That's the reason I set up Coronado. The programming and data-analytics skill set applies anywhere across the lifecycle, regulatory, market access, medical affairs, all fundamentally about data management. Starting fresh meant I could build a company designed around the technology from day one.

More predictive analysis?

Absolutely, I think it's probably here already. Look at predictive analytics and synthetic patient populations, what people call digital twins. We have the compute power to model what would happen to a digital twin, and companies are



using those predictions to inform how a trial will play out. Those technologies are live, though not pervasive yet. I've actually stopped talking about optimisation. I used to say "we can accelerate your development," but now I frame it as getting treatment to patients. A lot of people focus purely on approval, and that's a problem, you may get approval weeks or months earlier but you still have to get the drug into the market. Unless it's a genuine step-change for rare-disease drugs, I think the bigger opportunity is reducing the cost of studies, using synthetic data, predicting where a trial will land, and using predictive analytics for patient recruitment so you carry less risk of a poor site. For me, it's about building the right data from the beginning, so by the time you're ready to go to market, you have everything you need, rather than rushing to approval and discovering you needed a particular piece of data all along. It's more about widening the pipe than pure speed.

Every Cure is a fantastic example: the data has always been there; we just haven't had the power to pull the signal out of it. There's a lot of technology being thrown at the wall to see what sticks, which understandably makes people sceptical. But there is very good technology out there, and the challenge is being thoughtful about how it's positioned. Underneath all of this sits a model, Claude, OpenAI or otherwise, and there's a deep distrust rooted in general media coverage. I think we're coming out the other side of the adoption curve, because people are using these tools personally, and once you use a model yourself, you start to trust it. The hard part isn't the interface, it's how you train and constrain the model, and choose the right one for the job. The companies that succeed will make that an easy decision, showing the protections and the audit trail. I expect some consolidation in the market. Deep domain expertise is going to be the commodity people want in three to five years. Expertise retires out of the top of the industry as people leave, and it isn't coming in at the bottom the same way, because the escalation path that used to build it has been automated away. Twenty years ago, when I hit agenuinely hard problem in SAS, I'd spend half a day on it before escalating to my manager, and I'd learn something in the process. Now you go to Claude Code and it writes the solution. The junior person isn't learning the same way, because it's not their own thinking doing the work. By the time they really need that expertise, they won't have it. We have to work out how we train the people operating the software, or whether it becomes so capable we don't need people at that level at all. The focus should be on talent, how career progression is changing, how people learn under these conditions. Nobody's really talking about that.



Hype vs real.

Because I'm deep in it, I'd say it's a relatively high percentage real in biometrics specifically; people will argue with me though. It's different in broader clinical development, where there's probably a lot more hype. I'm biased, because I'm very pro-AI, but I'd put it at about 80% real. There's maybe 20% claiming they can automate your programming, and when you scratch the surface, it isn't really there. But there's a lot of genuinely good work out there, AI tools that Medidata, Veeva are starting to build into their systems for example. That 20% gets disproportionate attention because it's more interesting to talk about than the boring reality. So biometrics is high on the real side; other parts of clinical development, lower.

43%

of pharmaceutical companies say they struggle to find candidates with the digital literacy skills the workforce now requires.

This comes from the Association of the British Pharmaceutical Industry (ABPI), the UK pharma industry's own trade body, as part of its ongoing skills-gap research. Recruiters covering the sector describe 2026 as a "barbell market": overall job postings are down roughly 8% year-on-year, and layoffs are hitting large pharma hard, Novo Nordisk cutting 9,000 roles, Bayer 12,000 since 2023, while AI-literate specialists are simultaneously the hardest people in the industry to hire, with searches for AI-aware regulatory and quality leads now taking 6–9 months to fill.

Association of the British Pharmaceutical Industry (ABPI), skills-gap research, cited via CSG Talent and Panda International recruitment insights, 2025–2026.



→ *Independent Contractor, Clinical Data & AI Automation*

→ *Former Director of Statistical Programming, AstraZeneca*

Vijay Vaidya

Over the past 20 years, I have built my career in statistical programming and biometrics, including the last decade in leadership roles responsible for delivering high-quality clinical evidence that helps bring safe and effective medicines to patients faster. My role has been to build scalable global teams, strengthen operational excellence, and ensure data standards, reproducibility, and regulatory compliance. As AI transforms biometrics, my focus is on helping evolve the function from a traditional execution model into an AI-enabled evidence generation model, leveraging automation to improve speed and quality while maintaining human oversight, scientific judgment, and regulatory accountability.

The primary focus.

Statistical programming leaders should launch a controlled AI transformation program that modernizes the function while protecting regulatory compliance and scientific integrity. This requires governance, redesigning the operating model, targeted low-risk pilots, strengthening data foundations, and reskilling the workforce. Organizations that act now will actively shape the future biometrics workforce rather than being forced to react to disruption later.

Fewer or different roles?

AI is going to redefine excellence in biometrics by shifting how teams create value. Automation will absorb routine execution, enabling professionals to focus on innovation, scientific interpretation, and regulatory strategy. Organizations will become leaner in standardized delivery while demand increases for experts who can design, validate, and govern AI-enabled systems. The opportunity is to reskill the workforce, moving people away from repetitive activities and into roles centered on judgment and accountability.

Accountability.

As biometrics evolves into an AI-enabled function, accountability becomes even more critical, not less. AI will accelerate execution, but responsibility remains anchored to the individuals who design, govern, and approve these workflows. Regulators like the FDA and EMA maintain a clear baseline: sponsors remain accountable for the integrity and traceability of clinical evidence. This requires updated SOPs that explicitly define human oversight, decision rights, and audit trails.

What's overhyped.

Some current claims are ahead of what operating models and regulatory expectations can realistically support. We should expect an initial period of inflated expectations followed by practical adoption where AI creates measurable value within strict regulatory guardrails. Claims based on technology alone underestimate the need for clinical judgment, statistical explainability, and human oversight in a heavily regulated environment. The real transformation comes from modernizing data architecture, governance, and workforce capabilities, not from AI alone.

The FDA issued its first dedicated AI drug-development guidance on January 6, 2025.

Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products" introduces a risk-based credibility assessment framework for AI models used in nonclinical, clinical, postmarketing, and manufacturing phases.

FDA, fda.gov





The question nobody's asking.

Talent sustainability. How do we develop the next generation of biometrics experts when AI automates the very foundational activities through which expertise has traditionally been built? Organizations must intentionally redesign career pathways, for example through structured rotational review roles where junior staff develop judgment by evaluating AI-generated outputs against first-principles logic. The shift is from "what can AI automate" to "how do we build a function where human judgment keeps growing alongside it.

Hype vs real.

I think AI in biometrics is currently 40% hype and 60% real. The 60% reflects AI's power as a force multiplier for statistical programmers and biostatisticians. The hype represents claims that collide directly with regulatory realities and complex scientific oversight.

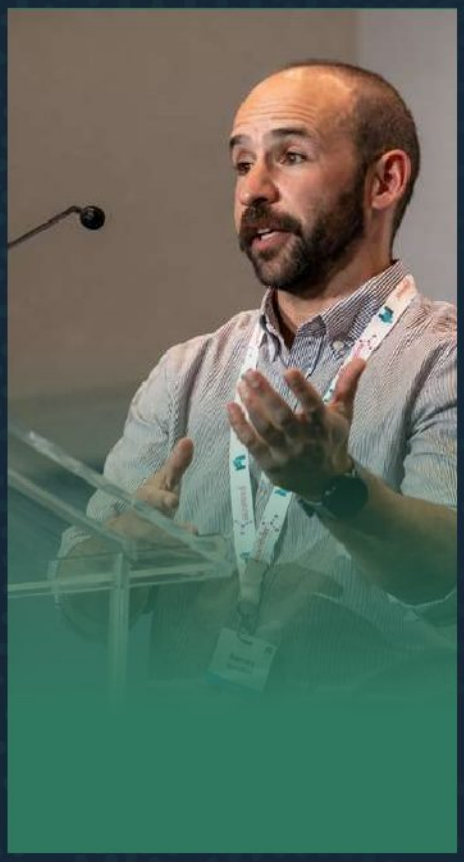
The FDA has logged

500+

drug and biologic submissions containing AI components between 2016 and 2023.

This is the agency's own stated figure, used to justify why it moved to issue formal guidance.

FDA Center for Drug Evaluation and Research (CDER), "Artificial Intelligence for Drug Development," fda.gov



Miguel Pereira, MD PHD

Executive Director, Cogitars UK

I'm a biostatistician with expertise in Bayesian statistics and some programming experience. AI has quickly integrated into my workflow, mainly supporting programming tasks like writing code for statistical outputs and helping me better understand various methodologies.

The future of AI.

I think the real question is: what won't be AI? I believe AI, especially in programming for SDTM, ADaM, and TLFs, will mostly automate the workflow with a few exceptions. It's not about the activities themselves, but how we oversee and validate them. The challenge shifts from doing things quickly to ensuring the output is correct. Validation becomes the new bottleneck.

Where senior talent comes from.

This is a common question across coding industries. AI can automate many mainstream activities, but there will still be complex tasks it can't handle, and new drugs will always present unique challenges. Senior personnel will be essential for oversight. We need to keep training

Open-source statistical programming now has a working regulatory track record.

The R Consortium's Regulatory Submission Working Group has completed five successful R-language pilot submissions to FDA CDER since 2021, testing whether R-based packages can meet the same review and reproducibility standards as SAS.

R Consortium, r-consortium.org

Only

10.7%

of drug developers have fully implemented AI/ML in clinical development.

A peer-reviewed 2025 survey of 302 respondents across 79 pharmaceutical companies, biotechs, CROs, and technology vendors found 36.9% weren't using AI/ML at all across the 36 clinical activities studied, 30.3% were beginning or piloting, 22.1% were partially implementing, and only 10.7% had fully implemented it in a repeatable way.

Lamberti et al., "The Adoption and Use of Artificial Intelligence and Machine Learning in Clinical Development," Therapeutic Innovation & Regulatory Science (Springer), Vol. 59, published May 2025. Peer-reviewed, conducted by Tufts CSDD with the Drug Information Association.

junior programmers so they can become the senior people capable of overseeing AI. Without understanding it, you can't verify its accuracy.

Fewer roles, or different roles?

I don't necessarily see this as a reduction in roles. If we use AI across the whole clinical development space, we achieve more in less time. I don't foresee a reduction in roles, rather an increase in productivity. If fifty people are needed for twenty trials and AI makes them significantly more productive, what typically happens is those fifty people start doing forty trials instead. Look at the pandemic: lockdown began March 2020, and by December we had a vaccine with efficacy shown in tens of thousands of people. Just nine months. There's a middle ground between that and the usual a normal five-to-ten-year development cycle.

Accountability.

I think accountability stays the same. It's mainly the sponsor that takes responsibility, regardless of what tool you use. In the short term there might be some loosening of standards, and then a scandal because somebody predicted something wrong. That's naturally what enforces things, it's the reason we have a lot of regulations in the first place.

Hype vs real.

About ten to fifteen percent hype, and probably around thirty percent real. Everything else is still in development, there are a lot of companies, including ones I work with, still building things that aren't public yet. Especially since the beginning of this year, the models have become a lot better. But we still need time for people to develop it.

CLOSING THOUGHTS

Most of us will find that if you ask people in this industry about AI, you'll get a different opinion, perspective, and concern. Across our three contributors in this issue, we got real variation in opinions and talking points. But some consistent themes run through their reasoning.

We can all see it: tasks that used to take a day to work through, and taught you something in the process, now get solved in a minute by an AI assistant. Nobody's arguing that's not a win on speed. But it means junior people aren't building the same judgment the senior people in this industry relied on to get where they are. Talent sustainability kept coming up as the question nobody's actually asking. And everyone made some version of the same point: if you don't understand what the AI's doing, you can't check its work, and somebody still has to be senior enough to do that.

So as we close this month's issue, the finding from our conversations with Andrew, Vijay, and Miguel is clear. AI is working in biometrics, and with the right infrastructure, compliance, and tools, we can be optimistic about the industry's ability to produce effective new drugs faster. But as the industry gets good at doing the work faster, figuring out how to develop the next generation of people qualified to oversee it in ten years becomes the real issue. It's not a new problem, just one nobody's fixed yet.

STAY IN TOUCH

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NEXT ISSUE »

Bayesian statistics used to be the "rare" exception. Today, it's rapidly gaining ground as a serious option for complex and adaptive protocols, backed by the FDA's 2026 guidance on Bayesian methodology. Next issue, we talk to the biostatisticians at the forefront of this shift to explore exactly what this means for protocol design, regulatory submissions, and trial simulation.

Meet us at PHUSE EU Connect

We're exhibiting 15–18 November in Glasgow. Come find us at our stand, or book a slot below and we'll grab time together.

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Prefer a Virtual Chat

Introductory call with Clements Partners

Got a topic you want us to cover, or can recommend someone we should talk to? Get in touch and let us know.