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EXPERT INTERVIEW

The Silent Revolution in Clinical Research:

How AI May Reshape the Future of the Pharmaceutical Industry.



The Silent Revolution in Clinical Research: How AI May Reshape the Future of the Pharmaceutical Industry

An interview with Prof. Dr. Erich Bluhmki, Staburo GmbH

Artificial intelligence is transforming many areas of healthcare, from drug discovery to medical imaging and is prone to become a fundamental driver of transformation in clinical research. Beyond improving efficiency, AI has the potential to reconfigure how clinical trials are designed, executed, monitored, analysed and reported.

In this interview, Erich Bluhmki examines the potential implications of AI-driven automation for sponsors, regulators, CROs as well as the broader clinical research ecosystem. He discusses the evolving roles of clinical research professionals, the opportunities associated with increasing automation, and why long-term success will depend on combining scientific knowledge, domain expertise, advanced AI capabilities, and the implementation of intelligent automation.

The future of clinical research will belong to organisations that successfully combine scientific excellence, regulatory rigour, and AI-powered automation to deliver faster, more accessible, and more evidence-driven development while preserving human judgement where it matters most.

1. AI is a major focus across the pharmaceutical industry today. Yet your white paper describes a less visible transformation unfolding in clinical research. What do you mean by that?

When discussions about AI in healthcare arise, attention is typically directed towards high-profile applications such as drug discovery, medical imaging, precision medicine, clinical decision support, and AI-enabled patient engagement. While these innovations are undoubtedly important, they represent only a part of the broader transformation underway. One of the most profound impacts of AI may emerge within the operational and scientific infrastructure of clinical research, where highly standardised, knowledge- and time-intensive processes create unique opportunities for large-scale intelligent automation.

Clinical research is fundamentally a knowledge-driven enterprise. Core activities such as clinical data management, statistical programming, biostatistical analysis, medical writing, clinical trial reporting, and regulatory submissions rely on the systematic generation, interpretation, verification, and communication of very large volumes of structured data, metadata, and scientific documentation.

These processes align closely with the capabilities of modern AI systems. Recent advances in large language models, foundation models, and agentic AI have substantially expanded the ability of machines to understand complex domain-specific

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content, reason across multiple information sources, generate scientifically and regulatorily compliant outputs, and orchestrate multi-step workflows with limited human intervention.

Importantly, clinical research represents one of the most standardised and process-driven domains in healthcare. Over several decades, the industry has established globally harmonised frameworks, including ICH guidelines, CDISC standards, regulatory submission requirements, and highly structured operating processes and procedures. Such environments, characterised by standardised data models, explicit rules, and reproducible workflows, are particularly well suited for intelligent automation.

As a result, AI is evolving from a productivity-enhancing tool that supports individual tasks to an execution layer capable of performing substantial components of end-to-end clinical research workflows. This transition has the potential to fundamentally reshape how clinical trials are designed, conducted, monitored, analysed, and reported. The implications extend beyond incremental efficiency gains, affecting operating models, workforce structures, and the future role of human expertise across sponsors, regulators as well as CROs.

2. Which functions do you think will be affected most by AI?

Data management, statistical programming, and medical writing are likely to be among the functions most profoundly affected by AI in the first place. These disciplines share a common characteristic: much of their work is knowledge-intensive, process-driven, and governed by well-defined scientific, regulatory, and technical standards. Consequently, many activities that currently require substantial manual effort, such as data review, query management, dataset generation, statistical programming, document authoring, and regulatory reporting, are increasingly amenable to AI-driven automation.

Recent advances in Large Language Models and Agentic AI Systems have demonstrated the ability to interpret complex clinical and regulatory information, generate code and documentation, perform quality checks, and execute multi-step workflows with limited human intervention. As these capabilities mature, AI systems will increasingly assume responsibility for routine and repetitive tasks across these functions. This does not imply that these professions will disappear. Rather, their focus will shift towards higher-value activities that require scientific judgement, domain expertise, and accountability.

In data management, professionals will increasingly act as architects and governors of data ecosystems. Their responsibilities will expand beyond traditional data cleaning and query management towards data quality strategy, metadata governance, cross-system integration, AI-enabled surveillance of data integrity, and the oversight of automated data review processes.

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Statistical programmers will evolve from code developers into analytical workflow architects. Rather than manually producing datasets, tables, listings, figures, and analysis programmes, they will design, validate, monitor, and govern AI-generated analytical workflows while ensuring methodological rigour, reproducibility, and traceability.

Medical writers will increasingly become scientific communication strategists and content governors. Their primary role will shift from drafting documents to directing AI-assisted content generation, ensuring scientific consistency across documents, verifying the accuracy of interpretations, integrating evidence from multiple sources, and maintaining regulatory and medical credibility throughout the submission process.

More broadly, we are likely to witness a transition from human execution of operational tasks to human supervision of intelligent systems. The future value of these professions will increasingly lie in scientific judgement, quality oversight, process governance, and the ability to ensure that AI-generated outputs are reliable, compliant, and fit for decision-making in a highly regulated environment.

3. What about the other areas, such as biostatistics, medical review, and data disclosure?

I think the impact of AI will extend across virtually the entire clinical research value chain.

In biostatistics, AI is already capable of supporting routine analyses, generating tables, figures, and listings, and producing first drafts of statistical outputs and reports. As these tasks become increasingly automated, the statistician's role will shift towards scientific leadership as a methodological evidence strategist, including defining the most relevant clinical questions, selecting appropriate analytical strategies, evaluating potential sources of bias, and ensuring the validity and robustness of study conclusions.

Medical review functions will undergo similar changes. AI can already support safety surveillance, signal detection, literature assessment, medical data review, and the synthesis of large volumes of clinical information. However, the interpretation of complex safety findings and, most importantly, the final assessment of benefit/risk profiles will remain closely under human oversight. These activities require clinical judgement, contextual understanding, and accountability, making them unlikely to be fully delegated to AI in the foreseeable future.

Data disclosure is also prone to substantial transformation. Documents such as clinical study reports, plain-language summaries, and disclosure packages that currently require extensive manual effort will increasingly be generated with AI assistance. Consequently, disclosure professionals will evolve into scientific and regulatory stewards, responsible for ensuring the accuracy, consistency, transparency, and regulatory compliance of AI-generated content.

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4. Does this mean that fewer people will be needed to conduct clinical trials?

Most likely, yes. For individual clinical trials, significantly fewer personnel may be required than today, particularly for highly standardised, repetitive, and document-intensive activities that are well suited for automation.

However, it would be overly simplistic to view this transformation solely as a reduction in workforce requirements. An equally important consequence is that organisations will be able to conduct more studies with the same workforce and at lower cost. By automating routine activities and accelerating key processes, AI has the potential to substantially improve productivity across the clinical development lifecycle, enabling sponsors and CROs to increase study throughput while reducing operational burden.

At the same time, entirely new functions and new areas of expertise will emerge. Organisations will require professionals with specialised capabilities in AI governance, model validation, agent orchestration, and process architecture. Their role will be to ensure that AI-driven systems operate transparently, reliably, securely, and in full compliance with regulatory expectations. In highly regulated environments such as clinical research, establishing appropriate oversight and accountability frameworks will be just as important as the underlying technology itself.

As a result, the workforce will not simply become smaller; it will become different. Routine execution will increasingly be automated, while human expertise will shift towards strategic oversight, scientific judgement, quality assurance, and the governance of increasingly complex AI-enabled processes.

Basically, the greatest impact of AI may not be a reduction in headcount, but a dramatic increase in the efficiency of clinical research, enabling more studies to be conducted, faster and more cost-effectively, with the same or even fewer resources. This evolution is likely to redefine both the skill sets and the professional profiles that will be most valuable in clinical research over the coming decade.

5. Why could Agentic Workflows become a game changer for clinical research?

I believe this is where the most profound transformation of clinical research will occur.

Today, most AI applications are used to support individual tasks. Agentic Workflows take a fundamentally different approach by orchestrating multiple specialised AI agents that collaborate across entire clinical development processes. Rather than optimising isolated activities, they enable the automation and coordination of complex end-to-end workflows.

For example, one AI agent could interpret a study protocol and identify key design requirements, while others generate data standards, create analysis datasets, perform statistical analyses, draft study reports, prepare disclosure documents, and support

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regulatory submissions. Information can be transferred seamlessly between agents, minimising manual handoffs and reducing operational inefficiencies.

The significance of this approach extends far beyond productivity gains. Clinical research is currently characterised by fragmented processes, functional silos, and extensive manual coordination. Agentic Workflows have the potential to integrate these activities into a more connected, efficient, and adaptive operating model.

Importantly, this does not eliminate the need for human expertise. Rather, it shifts human involvement towards areas where scientific judgement, clinical insight, ethical considerations, and strategic decision-making are essential. While AI agents execute and coordinate operational tasks, experts provide oversight, challenge assumptions, interpret findings, and remain accountable for critical decisions.

In the long run, Agentic Workflows are not simply about performing existing tasks faster. They represent an opportunity to redesign how clinical research is conducted, potentially reducing development timelines, lowering costs, improving quality, and enabling organisations to execute a greater number of studies with the same resources. This is why many believe that the transition from isolated AI tools to coordinated AI agent ecosystems may become the most transformative step in the evolution of clinical research.

6. What does this development mean for CROs, particularly small and medium-sized organisations?

For CROs I believe, this transformation though AI represents both a significant challenge and a substantial strategic opportunity.

Historically, CRO business models have been built around providing highly qualified professionals and generating revenue through billable project hours or full-time equivalent (FTE) resources. As AI increasingly automates activities along their entire value chain, this labour-based model is likely to face growing pressure. The ability to scale by simply adding personnel may become a less important competitive advantage.

At the same time, entirely new service models are beginning to emerge. Rather than primarily supplying individual experts, CROs could evolve into operators of validated, AI-enabled clinical development platforms that deliver integrated, technology-driven services across the clinical research lifecycle. In this model, value creation shifts from workforce capacity to scientific expertise, process excellence, and the effective deployment and governance of AI.

This transformation may also expand the addressable market for CRO services. AI-enabled operating models could make high-quality clinical development support more accessible and affordable for academic research institutions, non-profit organisations,

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MedTech companies, and emerging biotechnology firms that have traditionally faced resource constraints.

Thus, the most successful CROs may not be those with the largest workforce or the lowest FTE rates, but those that can combine scientific excellence, regulatory rigour, and AI-enabled scalability. Their competitive advantage will increasingly depend on the ability to deliver faster, more cost-effective, and regulatorily compliant clinical research solutions while maintaining the quality and reliability expected in a highly regulated environment.

7. Could AI also make clinical research more accessible to smaller research organisations?

Absolutely. In fact, this may be one of the most transformative consequences of AI in clinical research.

Today, many academic research groups, university spin-offs, non-profit organisations, and emerging biotechnology companies face significant barriers when attempting to advance promising innovations into clinical development. The challenge is often not a lack of scientific ideas, but the complexity, cost, and specialised expertise required to design, conduct, analyse, and report clinical trials in a regulatory-compliant manner.

Regulatory expectations for data quality, statistical rigour, documentation, and quality management are largely independent of organisational size. As a result, smaller organisations frequently struggle to build and maintain the multidisciplinary capabilities required across areas such as data management, biostatistics, medical writing, quality assurance, and regulatory affairs.

AI has the potential to substantially lower these barriers. By automating routine activities and providing access to sophisticated capabilities through integrated platforms and services, AI can reduce both the cost and complexity of clinical development. This could enable smaller organisations to access expertise and operational capabilities that were previously affordable only for large pharmaceutical companies.

A useful analogy is the transformation of the software industry through cloud computing. Start-ups no longer need to build and operate their own data centres to develop and scale innovative products. Similarly, future biotech companies, for example, may no longer need to establish fully staffed clinical development organisations before initiating clinical programmes. Instead, they could leverage AI-enabled platforms that provide scalable access to many of the capabilities required for modern clinical research.

Essentially, AI has the potential to broaden access to high-quality clinical research capabilities across the entire research ecosystem. By reducing operational complexity and lowering resource requirements, it could enable a wider range of organisations to

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participate in clinical research while maintaining the scientific and regulatory standards that are essential for generating reliable evidence and improving patient care.

8. Will regulatory authorities such as the FDA and EMA also be transformed by AI?

Almost certainly, I believe.

Regulatory authorities face many of the same challenges as pharmaceutical companies and CROs. Their experts review vast volumes of study documentation, evaluate datasets, assess statistical analyses, and identify potential regulatory, methodological, benefit/risk and safety concerns. Much of this work is highly structured, data-intensive, and document-driven, making it well suited for AI-assisted review.

In the coming years, regulators are likely to increasingly deploy AI to support the assessment of submission packages, verify data consistency, reproduce analyses, identify anomalies, and prioritise areas that require deeper scientific scrutiny. Such capabilities could improve efficiency, enhance review quality, and help authorities manage growing workloads without compromising regulatory standards.

An especially interesting development is the potential emergence of a digitally enabled sponsor-regulator ecosystem. AI may be used by sponsors to generate components of clinical documentation and by regulators to review and evaluate those same materials. As a result, AI-supported processes are likely to become integrated throughout the entire lifecycle of regulatory interactions.

Of course, this does not diminish the role of regulatory scientists and reviewers. On the contrary, their expertise may become even more valuable. As routine verification and document review activities become increasingly automated, human reviewers will be able to focus much more on complex scientific questions, medical assessment, methodological challenges, and areas where expert judgement is essential.

Basically, the greatest impact of AI on regulatory authorities may not be faster document review alone, but a shift towards a more efficient, data-driven, and science-focused regulatory decision-making. As with the pharmaceutical industry, the goal will not be to replace human expertise, but to augment it and allow experts to concentrate on the issues that matter most for patient safety and public health.

9. Looking ahead, what do you think will determine which research organisations succeed in this new AI environment?

I think the decisive factor will be the ability to combine three capabilities: scientific & AI excellence, regulatory expertise, and intelligent automation.

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While AI will undoubtedly automate many activities that are currently performed manually, the more important question is how value creation within clinical research will evolve. Competitive advantage will increasingly shift away from the production of documents, datasets, statistical outputs and clinical reports towardss scientific judgement, regulatory accountability, and the effective orchestration of AI-enabled processes and digital ecosystems.

Organisations that succeed will be those that can seamlessly integrate advanced technologies into scientifically rigorous and regulatorily compliant development frameworks. In a highly regulated environment, technological capabilities alone will not be sufficient. AI-generated outputs must remain transparent, traceable, reproducible, and suitable for regulatory scrutiny.

An interesting consequence of this transformation is that it may simultaneously increase both efficiency and accessibility within clinical research. Pharmaceutical companies may be able to conduct more development programmes with fewer resources and greater speed, while smaller biotechnology companies, academic institutions, and emerging biotech organisations may gain access to capabilities that were previously beyond their reach.

Ultimately, success in the future is unlikely to be determined by the organisational size primarily. Instead, the leading organisations will be those that can use AI to accelerate development, improve operational efficiency, and maintain the highest standards of scientific quality and regulatory compliance. Those that successfully combine human expertise with intelligent automation will be best positioned to thrive in the next generation of clinical research.

MEET THE EXPERT



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He explores the impact of AI-driven technological developments on the future of traditional teaching at schools and universities, as well as clinical research in drug development.
His white paper, *"The Silent Revolution of Clinical Research,"* was published by Staburo on 24 November 2026.

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