

Medical Monitoring in Clinical Research in 2026: Transformation Toward Intelligent, Risk-Based, and Real-Time Oversight

Paul Khoueiry^{1*}, Cynthia Lehouiller² and Maxim Belotserkovskiy³

¹Associate Director Medical Monitoring and Consulting, PSI CRO AG, France

²Senior Medical Writer, PSI CRO AG, USA

³Head Medical Affairs, PSI CRO AG, Germany

***Corresponding author:** Paul Khoueiry, Associate Director Medical Monitoring and Consulting, PSI CRO AG, France

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ABSTRACT

Medical monitoring is undergoing a profound transformation driven by the integration of artificial intelligence (AI), decentralized clinical trials (DCTs), digital health technologies, and the implementation of ICH E6(R3). Traditionally focused on adverse event review and protocol compliance, medical monitoring is increasingly evolving toward a proactive, data-driven, and risk-based governance function. This narrative review explores the emerging role of medical monitors in 2026, highlighting AI-assisted safety surveillance, risk-based quality management, centralized monitoring, predictive analytics, and AI governance frameworks. The review also discusses regulatory expectations, ethical considerations validation requirements, and the continued necessity of medical monitor oversight within increasingly automated clinical ecosystems. Current evidence suggests that AI will augment rather than replace medical monitors, shifting their role from reactive oversight to active anticipation and risk prevention.

Abbreviations: AI: Artificial Intelligence; DCTs: Decentralized Clinical Trials; SDV: Source Data Verification; RBM: Risk-Based Monitoring; FDA: Food and Drug Administration; AEGIS: Augmented Ethical Governed Intelligent Surveillance

Introduction

Medical monitoring in clinical research entered a transformative new phase in 2026. What was once a predominantly site-based, manual process centered on periodic visits and retrospective review has evolved into a highly interconnected ecosystem driven by artificial intelligence (AI), risk-based methodologies, decentralized technologies, and continuous real-time surveillance. Regulatory authorities, sponsors, contract research organizations, investigators, and technology developers are collectively redefining how clinical trials are supervised to improve patient safety, strengthen data integrity, accelerate operational efficiency, and maintain regulatory compliance in increasingly complex research environments.

Evolution of Medical Monitoring

Historically, clinical monitoring focused heavily on verification of on-site activities. Clinical research associates routinely traveled to investigative sites to perform source data verification (SDV), confirm protocol compliance, and review adverse events. The underlying objective of monitoring has remained constant: protecting trial participants while ensuring the reliability and credibility of clinical data. However, the rapid expansion of precision medicine, adaptive trial designs, genomic therapies, immuno-oncology, and multinational decentralized studies exposed the limitations of conventional monitoring models. Traditional approaches became increasingly difficult to sustain due to escalating operational costs, delayed detection of safety signals, excessive manual review processes, inefficient SDV

practices, and the overwhelming growth of digital clinical data. As trials became more technologically sophisticated and geographically distributed, pharmacologic companies and research organizations recognized that conventional monitoring methods were no longer sufficiently agile or scalable to meet expanding demands.

Risk-Based Monitoring Becomes the Standard

As of 2026, risk-based monitoring (RBM) has emerged as the dominant operational paradigm in clinical research oversight. Rather than uniformly scrutinizing all data points, modern monitoring strategies prioritize critical variables and focus attention on areas that pose the greatest risk to participant safety and trial integrity. Centralized statistical monitoring, key risk indicators, remote review workflows, and trigger-based interventions now form the core of contemporary oversight programs. This evolution allows monitoring teams to concentrate on clinically meaningful issues such as patient safety risks, protocol deviations, recruitment anomalies, fraudulent patterns, and unexpected data inconsistencies. Regulatory support from agencies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency accelerated the widespread adoption of RBM, particularly following the operational disruptions experienced during the COVID-19 pandemic. Remote oversight capabilities that were initially implemented as emergency measures have now become foundational elements of modern clinical trial infrastructure.

Artificial Intelligence Redefines Clinical Oversight

AI has become one of the defining forces of reshaping medical monitoring in 2026. AI-driven systems are increasingly integrated into clinical operations to identify safety signals in real time, detect inconsistent data patterns, predict protocol deviations, prioritize alerts, and monitor operational drift across global clinical trial networks. These AI-driven technologies are shifting medical monitoring from a retrospective activity into a proactive and predictive discipline. One of the most significant developments has been the introduction of AI-assisted real-time oncology monitoring pilot programs supported by the U.S. FDA. These initiatives aim to substantially shorten trial timelines by using continuous data surveillance and automated analytics to detect emerging issues earlier than traditional review processes allow. Such efforts exemplify a broader industry shift toward continuous oversight models capable of identifying risks before they escalate into clinically significant issues. However, expert human review of AI-generated outputs remains essential to avoid so called “hallucinations” and misinterpretation of the AI-derived data and findings.

Continuous Monitoring of Artificial Intelligence Systems in Clinical Trials

As AI becomes integrated into monitoring workflows, healthcare delivery, and clinical decision support systems, researchers and regulators have increasingly recognized the need to monitor the AI algorithms in addition to the clinical trials they support. In 2026, several

publications introduced governance frameworks designed specifically for adaptive medical AI systems. Among these, the Augmented, Ethical, Governed, Intelligent, Surveillance (AEGIS) framework proposed mechanisms for continuous model evaluation, post-market surveillance, algorithmic drift detection, conditional deployment approval (depending on fulfilling certain requirements and ensuring specific safety measures), and automated escalation pathways for safety concerns. These governance frameworks closely align with emerging regulatory expectations, including Predetermined Change Control Plans and the evolving requirements of the European Union AI regulatory framework. Investigators have demonstrated that continuous oversight systems can identify degradation in AI model performance before clinically meaningful failures occur. This represents a profound conceptual shift in clinical monitoring: oversight responsibilities now extend beyond patients, sites, and data collection processes to include the ongoing governance of adaptive algorithms.

Decentralized Clinical Trials and Remote Monitoring

Decentralized clinical trials (DCTs) have fundamentally altered the operational landscape of medical monitoring. Modern DCT models frequently incorporate telemedicine consultations, electronic consent platforms, wearable biosensors, remote patient-reported outcomes, home nursing visits, digital biomarkers, and cloud-based data capture systems. These technologies generate unprecedented volumes of continuous, real-world patient data that require sophisticated centralized oversight infrastructures capable of real-time signal detection and automated alert prioritization. As a result, the role of the medical monitor has substantially evolved from primarily a reviewer of site-based adverse event reports to a hybrid clinical-data strategist responsible for interpreting centralized analytics dashboards, evaluating AI-generated risk signals, and coordinating multidisciplinary surveillance activities across decentralized ecosystems.

Remote Patient Monitoring and Autonomous Clinical Triage

Remote patient monitoring technologies have advanced substantially in 2026, particularly with the emergence of autonomous AI triage systems. One notable study described an AI monitoring agent designed to continuously evaluate patient vital signs, perform contextual clinical triage, and escalate emergencies with minimal human intervention. The system demonstrated high sensitivity in detecting emergencies while maintaining operational consistency and cost-efficient deployment. Such technologies may address one of the most persistent challenges in remote monitoring programs: the substantial burden placed on human reviewers (medical monitors) responsible for evaluating continuous streams of patient alerts. Autonomous triage systems have the potential to improve scalability across oncology studies, cardiology trials, chronic disease programs, post-marketing surveillance initiatives, and long-term safety follow-up in decentralized research environments.

Regulatory Modernization in 2026

Regulatory authorities are rapidly adapting to ongoing technological transformations. Modern regulatory frameworks increasingly emphasize centralized oversight, AI-assisted review, integration of real-world evidence, remote inspections, digital endpoint validation, and continuous risk evaluation. Expectations surrounding explainable AI, i.e. AI capable of being understood by humans, human oversight, cybersecurity resilience, and data traceability are becoming central to compliance strategies. The regulatory model is evolving from episodic inspection toward continuous compliance supported by ongoing digital surveillance.

The New Role of the Medical Monitor

As of 2026, the professional identity of the medical monitor is undergoing significant transformation. Medical monitors are expected to possess not only strong clinical expertise, but also to demonstrate literacy in data analytics, digital systems, operational risk management, and AI governance. Responsibilities now include evaluating decentralized workflows, assessing digital biomarkers, participating in adaptive risk management programs, overseeing algorithmic safety systems, and collaborating closely with statisticians, data scientists, informaticians, and cybersecurity specialists. Despite these advances, substantial challenges remain unresolved. Continuous wearable monitoring and decentralized trial infrastructures generate vast quantities of data that can overwhelm traditional review systems without intelligent filtering mechanisms. Concerns about AI transparency persist, particularly when black-box algorithms influence clinical decision-making without fully explainable reasoning pathways. Bias and fairness issues remain critical, as AI systems may exhibit inconsistent performance across underrepresented patient populations. Cybersecurity threats also continue to grow as remote trial ecosystems expand and become increasingly interconnected.

In parallel, the clinical research workforce must adapt to this changing environment. Clinical operations personnel now require competencies that extend beyond traditional trial management into data analytics, digital health technologies, remote surveillance systems, and AI-enabled decision support platforms. Education and workforce development will play a critical role in ensuring successful implementation of next-generation monitoring systems.

Future Outlook

Medical monitoring is undergoing a clear transition from periodic oversight toward continuous surveillance, from reactive oversight toward predictive intervention, and from manual review toward intelligent automation. Clinical trials are becoming increasingly patient-centric rather than site-centric, with human expertise progressively augmented, rather than replaced, by AI-driven analytics. Future monitoring ecosystems are expected to incorporate real-time adaptive surveillance architectures, federated analytics platforms which

are software platforms used to analyze data across different locations, predictive safety modeling, digital twins (virtual data representation of an individual or a population in a clinical trial or even a disease process), AI-assisted clinical decision support, and fully integrated decentralized infrastructures capable of continuous learning. These innovations may ultimately allow clinical trials to become safer, faster, more efficient, and more inclusive.

Conclusion

The year 2026 represents a pivotal turning point in the evolution of clinical research oversight with an expansion in medical monitoring far beyond traditional adverse event review into a sophisticated discipline encompassing predictive analytics, AI governance, decentralized surveillance, digital health integration, and continuous regulatory compliance. As clinical trials become more digital and data-intensive, the future of medical monitoring will depend on successfully balancing automation, human expertise, ethical oversight, and regulatory trust. These changes will necessitate the development and implementation of continuing medical education programs to ensure that medical monitors, as representatives for the drug-development industry, maintain up-to-date skills and expertise. A clear consensus is emerging across academia, regulators, and industry: effective medical monitoring in the future will not simply observe clinical trials but will actively anticipate, interpret, mitigate and prevent risk in real time.

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Paul Khoueiry . Biomed J Sci & Tech Res



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