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Liability and Accountability Under the EU AI Act: Implications for Clinical Trial Sponsors and Contract Research Organizations

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Abstract

Artificial intelligence is moving into clinical trial operations faster than many organizations have fully governed it. As AI tools begin supporting protocol interpretation, operational communications, feasibility assessments, recruitment forecasting, and safety-related workflows, clinical leaders face a growing accountability question: who owns the outcome when AI-informed work affects a regulated process?

This article examines that question through the lens of the European Union Artificial Intelligence Act (Regulation EU 2024/1689), ICH Good Clinical Practice E6(R3), the FDA's draft credibility assessment framework for AI models, the joint FDA-EMA Guiding Principles of Good AI Practice in Drug Development, the revised EU Product Liability Directive, and EMA expectations for computerized systems and electronic data in clinical trials. It argues that AI governance in clinical trials should be treated as an extension of the clinical quality management system rather than as a standalone technology initiative.

For sponsors, CROs, and quality leaders, the practical challenge is no longer awareness of AI adoption. The challenge is operationalizing human-in-the-loop oversight, credibility assessment, data traceability, vendor qualification, and inspection-ready documentation before regulatory expectations tighten further.

Keywords: *artificial intelligence, EU AI Act, clinical trials, ICH E6(R3), Good Clinical Practice, liability, accountability, AI governance, contract research organizations, inspection readiness, risk-based quality management*

Introduction

Artificial intelligence is moving into clinical development at a pace that many operating models were not originally built to support. The EU AI Act now provides a cross-sector legal framework for AI systems in the European Union, while the FDA and EMA have both published recent materials that emphasize credibility, risk, documentation, and human oversight for AI in drug development [1,3,4].

For this discussion, artificial intelligence refers broadly to machine learning models, predictive analytics systems, and generative AI tools that influence operational or analytical processes within clinical trial execution.

The applications of AI and LLMs are tangible and growing. AI systems now support protocol drafting, feasibility modeling, site selection, recruitment forecasting, and operational reporting. These technologies can improve efficiency and strengthen decision support, but they also introduce questions about governance, traceability, and accountability that most clinical quality frameworks were not originally designed to address.

In many organizations, the operational use of AI is already moving ahead of formal governance. Teams are using co-pilot tools for drafting communications, summarizing meeting minutes, and supporting routine administrative work, while related SOPs remain limited, underdeveloped, or in some cases nonexistent. This gap matters. In clinical research even lower-risk use cases are not risk-off, especially if outputs influence protocol interpretation, site behavior, or regulated documentation.

For years, clinical trial execution has been governed primarily through clinical and quality frameworks such as ICH and GCP. As AI becomes embedded in trial operations, a second layer of governance is emerging: technology governance. Clinical organizations will increasingly need to plan governance and operate within both the clinical/quality and technology governance spheres [1,2].

This article will explore the regulatory foundations shaping AI use in clinical trials, examine where AI is already being deployed across trial operations, identify the emerging liability and accountability gaps that clinical leaders need to address, and offer practical governance

recommendations. The shift has already started. AI is being incorporated into clinical operations across the industry. What remains unresolved is whether organizations are preparing proactively enough to deploy these tools in a way that stays compliant, traceable, and inspection-ready. Regulators will eventually ask a direct question: who is accountable when artificial intelligence influences regulated clinical trial activities?

Regulatory Foundations for AI Use in Clinical Trials

Clinical trial operations already function within a well-established regulatory framework designed to ensure quality, transparency, and accountability. Core principles derived from ICH Good Clinical Practice guide how clinical trials are designed, conducted, monitored, and documented [2].

ICH E6(R3), finalized in January 2025 and effective in the EU as of July 23, 2025, places substantially increased emphasis on risk-proportionate quality management, quality by design, and modern approaches to trial conduct. The guideline is explicitly media-neutral, accommodating electronic records, digital health technologies, and decentralized trial elements. Its focus on proportionate oversight grounded in factors critical to quality provides a conceptual framework that extends naturally to AI-enabled processes, even though it does not prescribe specific AI governance requirements [2,5].

In January 2025, the FDA published draft guidance describing a risk-based credibility assessment framework specifically for AI models used to support regulatory decision-making for drugs and biologics [3]. This scope distinction matters: the framework does not cover AI used purely for operational efficiencies that have no direct impact on patient safety, drug quality, or the reliability of study results. This boundary creates important planning space for organizations. Within its defined scope, the framework introduces a structured seven-step approach for evaluating AI models, covering the question of interest, the context of use, model risk assessment, and the development of a credibility assessment plan [3].

In January 2026, the FDA and EMA jointly published the Guiding Principles of Good AI Practice in Drug Development, a set of ten high-level principles intended to guide the responsible use of AI across the entire medicines lifecycle [4]. These principles emphasize human-centric design, clear context of use, risk-based approaches, multidisciplinary expertise, robust data governance,

and lifecycle management. While voluntary at this stage, the principles are expected to underpin future regulatory guidance and may lead to a global regulatory framework.

The EMA has also been active on multiple fronts. In October 2024, the agency published a Reflection Paper on AI in the Medicinal Product Lifecycle, providing considerations for the safe and effective use of AI and machine learning tools in drug development [7]. The EMA's existing guidance on computerized systems and electronic data in clinical trials further reinforces that AI-enabled systems must be considered within the broader framework for participant protection and reliable trial data [5,6].

The EU AI Act itself introduces a risk-based regulatory framework with four classification tiers. AI systems used within healthcare and clinical research environments are likely to qualify as high-risk, which triggers requirements for enhanced documentation, transparency, data governance, and human oversight [1]. The Act entered into force on August 1, 2024. Prohibited practices became enforceable on February 2, 2025, general-purpose AI obligations took effect August 2, 2025, and full obligations for high-risk systems embedded in regulated products will apply by August 2, 2027 [1,8]. For organizations conducting clinical trials in the EU, that timeline represents regulatory reality, not a distant planning horizon. AI systems influencing study design, patient recruitment strategy, safety-related workflows, or regulatory documentation will likely require clearer governance structures, more traceable documentation, and more explicit human-in-the-loop oversight than many organizations currently have in place [1,5].

Broad industry awareness is not the issue. Most organizations know AI adoption is accelerating. The more challenging part is operationalizing governance at the same pace. Giving teams access to AI tools is easy. Defining how those tools are assessed for credibility, how outputs are validated, how human review is enforced, and how any of it holds up during an inspection? This is where most organizations still have significant work ahead [3,4,5].

Where Artificial Intelligence Is Already Being Used in Clinical Trials

Early adoption of AI within clinical trial organizations is most commonly occurring in administrative and operational support functions. These use cases are often viewed as relatively low risk because they do not directly determine endpoints, safety outcomes, or formal regulatory decisions. Low risk, however, does not mean risk-free.

Generative AI tools are increasingly being used to support routine activities: drafting internal and external communications, summarizing meeting minutes, documenting action items, preparing investigator newsletters, and drafting site-facing clarification messages. Teams may also use AI to assist with operational reports, meeting summaries, or first-draft language for internal tracking records.

This is where it gets dangerous. Administrative use cases feel safe precisely because they seem removed from core scientific decisions. But clinical trial operations are deeply interconnected. In the author's operational experience, AI-generated meeting summaries have misattributed decisions to the wrong stakeholders, omitted critical action items, and subtly reframed protocol requirements in ways that created confusion at both study and site level. One flawed clarification email or operational note, accepted without careful review, can ripple into downstream execution risk.

Large language models produce inaccurate or fabricated outputs at rates that make unchecked use genuinely risky. Research on LLM hallucination across domains has documented error rates that vary widely by task complexity and domain, but consistently show that unsupervised reliance on generated content introduces material risk [12]. This is particularly evident when models are asked to summarize complex source material or generate new content from limited context. On a study I managed, a clinical research associate working under a highly complex protocol used Copilot to help interpret investigator questions and draft a response. The CRA was acting in good faith, working efficiently under operational pressure with a tool that was readily available. The output was not fully accurate. This was immediately identified by the medical monitor team, which then had to contact the site by phone to provide corrected clarification, and the event was documented as a lesson learned for the broader study team [4,5,12].

Beyond administrative support, AI is increasingly being applied to analytical and planning activities within clinical development: site feasibility assessments, recruitment forecasting, enrollment modeling, financial planning, and operational performance monitoring. EMA guidance on computerized systems explicitly recognizes the evolution of clinical systems from eCRFs and ePROs toward artificial intelligence, reinforcing that these tools fall within the broader framework for participant protection and reliable trial data [5].

These applications offer meaningful opportunities to improve trial efficiency and support better-informed decisions. They also raise a practical question that clinical leaders cannot afford to leave unanswered: if an AI-supported recommendation contributes to an operational error, who ultimately owns the outcome?

The Emerging Liability Gap

Clinical trials already operate within a defined framework of regulatory accountability. Under ICH Good Clinical Practice, the sponsor retains ultimate responsibility for the conduct of the trial, including oversight of trial execution, participant safety, and the integrity of study data. Sponsors may delegate operational activities to CROs, but regulatory responsibility for the trial remains with the sponsor [2].

CROs, in turn, are responsible for the quality of delegated operational activities, including startup, site management, monitoring, data management, and other clinical operations functions performed on the sponsor's behalf. This sponsor-CRO relationship has long been supported by oversight structures, vendor qualification processes, and quality systems designed to support compliance and inspection readiness.

AI introduces a new dimension to that relationship. AI systems are increasingly supporting operational decisions in areas such as patient recruitment modeling, site selection, protocol feasibility review, risk-based monitoring signal detection, and safety-related data review. As those outputs begin influencing regulated trial activities, the accountability picture becomes more complex, and the reasons go beyond simply adding another party to the chain [1,3,5].

In many organizations, AI tools are technically vetted. They pass IT security reviews, they meet data privacy requirements, and they are approved for general use within the enterprise environment. What often remains undefined is how those tools are actually used in practice across clinical trial functions. A tool may be cleared for deployment without a corresponding SOP that defines acceptable use cases, required review steps, or boundaries on the types of decisions the output should inform. The result is that the tool is available, but the governance around its application is ambiguous.

That ambiguity becomes particularly visible when work crosses functional or organizational boundaries. Clinical trials are inherently cross-functional. A single operational question can involve clinical operations, data management, medical monitoring, regulatory, and the sponsor, sometimes across different organizations and geographies. When AI supports work that spans those boundaries, ownership gets murky. Who validates the output before it gets acted on? A CRA may use an AI tool to draft a response that ultimately requires medical monitor review. A clinical team lead may rely on an AI-generated analysis that informs a sponsor-facing recommendation. In each case, the tool is being used across a handoff point where ownership assumptions can diverge without anyone recognizing it in the moment.

There is also a visibility challenge that clinical operations and project management teams are beginning to recognize. When organizations adopt AI through third-party platforms or enterprise vendor partnerships, the project team executing the trial may not have clear insight into how the underlying model works, how it was trained, what its known limitations are, or how updates and changes to the model are managed. The technology vendor controls the system, but the operational consequences of its outputs fall on the sponsor and CRO teams using it in a regulated context. That gap between who controls the tool and who bears the regulatory accountability for its outputs is one of the less discussed but increasingly important dimensions of AI governance in clinical trials.

When an AI system produces an incorrect recommendation or flawed prediction, responsibility may not be straightforward. It may involve multiple parties: the sponsor, the CRO, the technology provider, and the individual user who accepted or acted on the output. AI does not eliminate responsibility. It redistributes it, often in ways organizations have not yet defined. Building clear ownership and accountability frameworks is essential for governance and inspection readiness.

Practical Scenarios

Consider a scenario that is already realistic in many operational environments. A team member uses AI to review protocol language and draft a site-facing clarification email. The draft appears polished and credible, but one key instruction is inaccurately framed. If that message is sent without careful review, the result may be inconsistent site behavior, avoidable protocol deviations, and a difficult audit trail question later: where exactly did the instruction originate, and who approved it? [5,6]

Now consider a broader operational example. An AI model is used to prioritize investigative sites for activation based on predicted recruitment potential. The model recommends Site A as high potential and Site B as low potential. Based on those predictions, the study team prioritizes Site A. The underlying model, however, contains training bias that undervalues Site B's patient population demographics. In practice, Site B would have enrolled faster while Site A underperforms. Trial timelines are affected as a result.

In either case, regulators and auditors may reasonably ask who validated the tool, whether the system was sufficiently transparent for its intended use, whether human oversight was applied before the recommendation was acted on, and whether the decision was traceable and inspection-ready. Under the EU AI Act, these questions move beyond operational inconvenience and into the domain of regulatory governance [1,5,6].

Additional Complexity in CRO Environments

These scenarios become more consequential when the organizational structure itself is layered. Accountability becomes more complex when AI tools are deployed by CROs on behalf of sponsors. A CRO may implement AI-enabled tools to support site selection, risk monitoring, operational forecasting, or startup planning. In those situations, two accountability layers exist simultaneously: the sponsor retains regulatory responsibility for the conduct of the trial under ICH GCP, while the CRO executes operational activities using tools that may incorporate AI-driven decision support [2].

If an AI-enabled tool contributes to an operational error or flawed decision process, responsibility may involve the sponsor, the CRO, the technology vendor, and potentially multiple levels of oversight. The question is not simply who used the tool. It extends to who qualified it, who approved its use in a regulated context, what governance was defined around it, and how human judgment remained in control of the final decision [1,5,6].

The Evolving EU Liability Landscape

The liability framework surrounding AI in Europe is itself still developing. In September 2022, the European Commission proposed an AI Liability Directive intended to harmonize rules for non-contractual civil liability when AI systems cause harm [9]. Following prolonged disagreement

among member states and increasing industry pressure for regulatory simplification, the Commission officially withdrew the proposal in October 2025 [10]. This withdrawal has practical consequences. Without the AI Liability Directive, civil liability for AI-related harms in clinical trials is now governed by national tort regimes that vary across EU member states. For a global CRO or sponsor running trials across multiple European countries, that fragmentation introduces real legal uncertainty regarding liability allocation and dispute resolution.

What does remain operative is the revised EU Product Liability Directive (Directive EU 2024/2853), adopted in 2024, which explicitly extends strict product liability to standalone software, including AI systems [11]. Under this directive, if an AI system used in a clinical trial context is found defective, for example because it produced systematically biased recruitment predictions due to flawed training data, the provider of that AI system could face strict liability. The revised directive also introduces rebuttable presumptions of defectiveness where AI systems fail to meet safety expectations [11].

For sponsors and CROs evaluating AI vendor partnerships, the practical implication is clear: contractual allocation of liability for AI-related failures needs to be addressed explicitly. Existing master service agreements may not account for these evolving obligations, and organizations would benefit from reviewing vendor contracts with this regulatory evolution in mind. It is imperative to qualify and define the scope of oversight to ensure safety, security, and privacy.

Clinical trials are already one of the most tightly regulated environments in industry. The EU AI Act introduces a technology-focused governance layer on top of that. For sponsors and CROs alike, the question is whether they can adopt AI in a way that strengthens operational capabilities without weakening the accountability structures regulators expect [1,2].

Inspection Readiness and Audit Risk

The integration of AI into clinical trial operations introduces new considerations for inspection readiness and regulatory audit risk. Clinical trials already operate under established expectations for traceability, documentation, accountability, and system validation. Any technology influencing trial conduct needs to be implemented in a way that preserves those principles [2,5,6].

When AI systems begin supporting operational or analytical activities within a regulated trial environment, organizations need to be prepared to explain how those systems are governed, validated, and monitored. Regulators and auditors are unlikely to be satisfied with a general statement that AI was used only to support efficiency. They will want to understand ownership, intended use, oversight, and the controls surrounding the system [1,3,5].

Process ownership is often the first question. Traditional clinical trial workflows usually have clear ownership within clinical operations, data management, safety, quality, or regulatory functions. When AI contributes to those processes, organizations need to determine which function retains responsibility for oversight and accountability, and that determination needs to be documented.

Credibility assessment comes next. Just as computerized systems used in clinical trials must be shown to perform as intended, AI-enabled systems require comparable assessment based on their intended use and the associated level of risk. Organizations should be able to explain how they evaluated output reliability, what use case the tool was approved for, and what limitations were identified. The FDA's seven-step credibility framework provides a structured approach for AI models supporting regulatory decision-making, though organizations will also need proportionate approaches for operational AI tools that fall outside that guidance's explicit scope [3,5,6].

Traceability is equally critical. Clinical trial documentation must support a clear audit trail linking decisions and outputs to their underlying inputs. When AI systems generate recommendations, summaries, or predictive outputs, organizations should be able to demonstrate the data sources used, how those data were processed, the provenance and lineage of inputs and outputs, and the retention of relevant logs or records. Those capabilities are essential for maintaining transparency and reproducibility in an inspection setting [1,5,6].

Organizations also need to define the scope of AI influence within their decision-making processes. In practice, that means documenting what the AI system is doing, what type of decision it informs, where qualified personnel review the output, and how human-in-the-loop oversight is enforced. Fully automated decision-making is unlikely to be acceptable in most clinical trial contexts. Human judgment must remain central [1,3,4].

Ongoing monitoring matters as well. AI systems can change behavior over time due to model drift, retraining, updates, or evolving source data. Effective governance should include defined

performance thresholds, monitoring for drift or degradation, and structured processes for approving updates or retraining activities [3,4].

Many organizations will adopt AI through external platforms rather than building systems internally. In those cases, vendor oversight processes need to go beyond standard procurement reviews. They should evaluate system credibility, transparency, audit trail availability, retention controls, cybersecurity, data privacy, and the vendor's ability to support regulated use and inspection needs. Emerging standards such as ISO/IEC 42001 for AI management systems and the extension of ISPE GAMP 5 principles to AI-enabled systems provide useful frameworks for structuring vendor qualification and ongoing oversight in regulated environments [13,14]. Given the revised Product Liability Directive's extension of strict liability to AI software, contractual agreements should also address liability allocation with greater specificity than many organizations currently use [1,5,6,11].

Recommended Governance Approaches for AI in Clinical Trials

As AI becomes more integrated into clinical trial operations, organizations will need governance frameworks that keep AI-enabled processes aligned with regulatory expectations for quality, traceability, and oversight. AI governance should not be treated as a purely technical initiative. It works best when approached as an extension of the existing clinical quality management system [2,4,5].

Standardized AI Credibility Documentation

Each AI system used within regulated clinical trial activities should have a standardized, inspection-ready credibility summary that clearly describes the system and its intended use. A concise document covering intended use, trial processes supported, validation or credibility assessment results, data sources and known limitations, performance thresholds, human-in-the-loop review requirements, and monitoring procedures for drift or degradation can go a long way toward demonstrating governance maturity during an inspection or audit [3,4].

Building the Inspection Narrative Early

Organizations should begin building the inspection story during initial deployment, not after widespread implementation. Governance artifacts should be created as part of the system's

introduction and embedded into SOPs, validation activities, training programs, and quality documentation from the start. Cross-functional AI governance committees spanning clinical operations, quality, regulatory, data science, and information technology can help ensure that governance expectations are applied consistently and that proposed use cases receive appropriate scrutiny before deployment [5,6].

AI as an Enabler of Quality by Design

AI should be positioned as a tool that supports quality by design and strengthens risk-based oversight, not as a replacement for professional judgment. This aligns with the direction of ICH E6(R3) and with the FDA-EMA Guiding Principles, which emphasize human-centric design, clear context of use, risk-based performance assessment, and lifecycle management [2,3,4]. AI can help teams identify operational risks earlier, analyze complex datasets more efficiently, and improve decision-making consistency. Those benefits, though, depend on maintaining clear human oversight at every point where AI outputs influence regulated decisions.

Risk-Based Classification of AI Use Cases

Not all AI applications carry the same degree of regulatory risk, and governance frameworks should reflect that. Use cases should be classified by the role of the AI within the trial lifecycle, the degree of influence on regulated decisions, and the potential impact on participant safety, data integrity, or regulatory submissions. Higher-risk applications, such as safety signal detection, patient eligibility screening, and enrollment predictions that drive site activation decisions, should trigger more robust validation, documentation, and oversight. Lower-risk applications may warrant lighter governance, but they are never risk-free [1,3,4,5].

Data Lifecycle Controls and System Integrity

AI-enabled systems should operate within the same data governance expectations applied to other computerized systems supporting clinical trials: validated controls, secure access, audit trails, retention requirements, and traceability of inputs and outputs. AI governance in clinical trials will mirror earlier expectations surrounding computerized systems validation. The key difference is that AI introduces adaptive behavior and probabilistic outputs, so governance needs to extend beyond traditional validation models to account for that variability [5,6].

Governance of Third-Party AI Vendors

Where organizations rely on third-party AI vendors, vendor qualification processes should be expanded to include AI-specific oversight. This includes model credibility assessment, change management protocols, decision-logic transparency where relevant, audit trail retention, privacy protections, and the vendor's ability to support regulated use and inspection needs. Standards such as ISO/IEC 42001 and GAMP 5 guidance on AI-enabled systems offer structured approaches to vendor assessment that align with existing GxP qualification expectations [13,14]. Contracts should define responsibilities for governance, system support, data protection, and liability allocation with greater specificity than many organizations currently use, particularly given the revised Product Liability Directive's treatment of AI software [1,5,6,11].

Conclusion

AI is becoming part of the operational infrastructure of clinical development. From administrative workflow support to predictive modeling and broader decision support, AI-enabled tools are already influencing how clinical trials are planned, managed, and executed. Over time, that influence will continue to expand and we must start preparing for this now.

AI implementation does not arrive on its own. It brings governance expectations, and the regulatory environment is actively building around those expectations. The EU AI Act, ICH E6(R3), the FDA's credibility assessment framework, the joint FDA-EMA Guiding Principles, and the revised Product Liability Directive collectively signal a convergence in regulatory thinking: organizations deploying AI in regulated environments need to demonstrate that those systems are governed, validated, and overseen with the same discipline applied to any other process influencing clinical trial integrity [1,2,3,4,11].

For clinical trial organizations, this means the regulatory lens needs to expand beyond traditional GCP to include technology governance. The withdrawal of the proposed AI Liability Directive leaves civil liability for AI-related harms governed by national regimes that vary across EU member states, which adds legal complexity that organizations should factor into their risk planning [10].

Clinical leaders do not need to become technical experts in AI systems. They do need to understand how those systems are governed, how outputs are reviewed, where human judgment remains

central, and how the resulting processes can be clearly explained within a compliant operational framework [3,4,5]. There is real opportunity here. When implemented thoughtfully, AI can strengthen quality by design, improve risk-based oversight, and support better operational decision-making across the trial lifecycle. Realizing that opportunity, though, depends on governance keeping pace with adoption [2,4].

This article has focused on operational and analytical AI applications within clinical trial conduct. Patient-facing AI, including AI-enabled recruitment tools, digital therapeutics, symptom-tracking chatbots, and patient-facing decision support, represents an additional and distinct layer of regulatory complexity involving medical device classification, informed consent requirements, and direct safety implications. That domain warrants dedicated analysis beyond the operational governance scope addressed here.

Many organizations are already experimenting with AI tools across their operational environments. Most are not moving too fast on adoption. They are moving too slow on governance. Strategic operations teams are well positioned to define governance models early and align AI use with the principles of ICH, GCP, and emerging technology regulatory guidance. The window for proactive positioning is narrowing.

Priority Actions for Clinical Operations Leaders

For organizations looking to move from awareness to action, four near-term priorities stand out.

First, conduct an AI use inventory. Most organizations do not have a complete picture of where AI tools are already being used across their clinical operations teams. Before governance can be built, the current landscape needs to be mapped, including informal use of generative AI tools that may not yet be captured in any SOP or system qualification record.

Second, develop a standardized AI credibility summary template. Even a one-page document covering intended use, credibility assessment, known limitations, human oversight requirements, and drift monitoring procedures gives organizations a repeatable, inspection-ready artifact that can be deployed across use cases as adoption scales.

Third, review vendor contracts for AI-specific liability and governance provisions. Many existing master service agreements were drafted before AI-enabled tools became part of routine

delivery. Given the revised Product Liability Directive's extension of strict liability to AI software, contractual language around accountability, performance monitoring, and data governance warrants a fresh review.

Fourth, establish a cross-functional AI governance forum. AI governance cannot be owned exclusively by IT or by clinical operations. It requires coordination across quality, regulatory, data science, and operational functions. Even a lightweight governance committee that reviews proposed AI use cases against a risk-based classification framework is a meaningful step forward.

The planning window is open, and the organizations that operationalize governance early will be the ones best positioned to lead.

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[Extended bio for editorial reference:]

Ashley Essick, MBA, PMP, is a Project Manager at ICON PLC, where she leads oncology and plasma-derived therapy studies across 23 countries and all major global regions, managing cross-functional teams of 100 to 250. With 7 years driving global clinical trials across Phase I–III, built on 13+ years of progressive healthcare project management spanning site operations, regulatory compliance, and enterprise strategy, Ms. Essick brings a full-spectrum perspective on drug development. She is the architect of a portfolio of 18 enterprise AI solutions that address operational gaps traditional delivery models were not designed to solve, presented to SVP/EVP leadership with executive sponsorship secured. Solutions are designed for regulatory compliance (ICH E6(R3), 21 CFR Part 11, EU AI Act) with human-in-the-loop governance. Ms. Essick is a direct operational contributor to three FDA-approved therapies: Inlexzo (TAR-200/SunRISe-1, first-in-class bladder cancer), Zepbound (tirzepatide/SURMOUNT-1, obesity), and the Wegovy cardiovascular indication (semaglutide/SELECT). The views expressed in this article are those of the author and do not necessarily represent the official position of ICON PLC.

References

1. European Union. Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence (Artificial Intelligence Act). *Official Journal of the European Union*. Published 12 July 2024. Entered into force 1 August 2024.

2. International Council for Harmonisation. ICH Harmonised Guideline E6(R3): Guideline for Good Clinical Practice. Step 4 Final Version, adopted 6 January 2025. Effective in the EU 23 July 2025. Published by FDA in the *Federal Register* 9 September 2025.

3. U.S. Food and Drug Administration. Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products: Draft Guidance for Industry and Other Interested Parties. January 2025. Docket No. FDA-2024-D-4689.

4. U.S. Food and Drug Administration, Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research, with the European Medicines Agency. Guiding Principles of Good AI Practice in Drug Development. Published 14 January 2026.

5. European Medicines Agency. Guideline on Computerised Systems and Electronic Data in Clinical Trials. EMA/INS/GCP/112288/2023. Effective 10 September 2023.

6. European Medicines Agency. Notice to Sponsors on Validation and Qualification of Computerised Systems Used in Clinical Trials. EMA/INS/GCP/467532/2019.

7. European Medicines Agency. Reflection Paper on the Use of Artificial Intelligence in the Medicinal Product Lifecycle. EMA/CHMP/764436/2023. Published October 2024.

8. Busch F, Kather JN, Johner C, et al. Navigating the European Union Artificial Intelligence Act for Healthcare. *NPJ Digital Medicine*. 2024;7:210. doi:10.1038/s41746-024-01213-6.

9. European Commission. Proposal for a Directive on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive). 2022/0303(COD). September 2022.

10. European Commission. Commission Work Programme 2025. COM(2025) 45. February 2025. Proposal officially withdrawn October 2025 (*Official Journal of the European Union*, C/2025/5423, 6 October 2025).

11. Directive (EU) 2024/2853 of the European Parliament and of the Council on liability for defective products (revised Product Liability Directive). *Official Journal of the European Union*. 2024.

12. Ji Z, Lee N, Frieske R, et al. Survey of Hallucination in Natural Language Generation. *ACM Computing Surveys*. 2023;55(12):1-38. doi:10.1145/3571730.

13. International Organization for Standardization. ISO/IEC 42001:2023. Information Technology: Artificial Intelligence: Management System. Published December 2023.

14. International Society for Pharmaceutical Engineering. GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems. Second Edition, 2022.