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AI in Clinical Trials:
Regulatory & Guidance Reference Guide

AI-supported activities in clinical trials increasingly fall within existing expectations around GCP, computerized systems, data integrity, human oversight, and AI literacy. Organizations using AI within regulated workflows should ensure personnel understand the responsibilities, limitations, and governance expectations that apply.

For: Clinical Operations, QA, centralized monitoring, medical monitoring, data management, RBQM, IT, digital innovation, and capability-development teams responsible for implementing, governing, or overseeing AI-supported activities within regulated clinical trial environments.

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AI use in clinical trials is increasingly intersecting with existing expectations around GCP, computerized systems, data integrity, privacy, validation, and human oversight. While regulations continue to evolve, organizations already have responsibilities when AI-supported workflows influence **regulated activities, records, or decisions**.

This reference guide brings together key regulatory and guidance sources that help clinical trial teams understand the current landscape and support more **controlled, accountable, and inspection-ready AI use**.

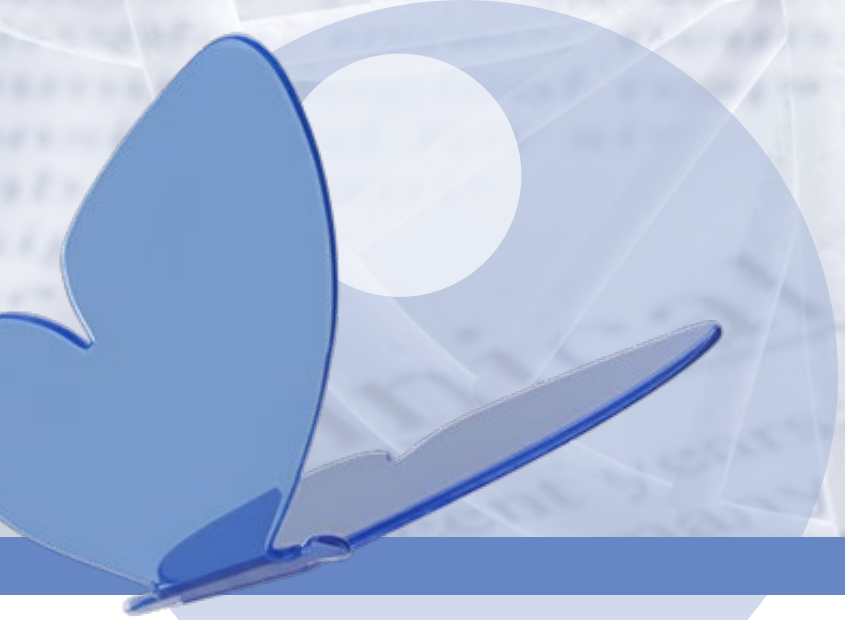
Layer	Regulation / Guidance	Official Source	What it covers	Implication for AI use in clinical trials
Data Foundation	**GDPR (EU)**	https://eur-lex.europa.eu/eli/reg/2016/679/oj	Processing of personal data; privacy, security, lawful use	**Do not enter personal or sensitive study data into unapproved AI tools**
	HIPAA (US)	https://www.hhs.gov/hipaa/index.html	Protection of PHI; privacy, security, breach rules	**Ensure AI use complies with PHI protection requirements**
Clinical Trial Framework	**ICH E6(R3) – Good Clinical Practice**	https://www.ema.europa.eu/en/ich-e6-good-clinical-practice-scientific-guideline	Conduct of clinical trials; qualified personnel; data governance; computerized systems	**AI-supported trial activities require appropriate oversight, accountability, and controlled use**
Computerized Systems & AI	**EMA Guideline on Computerised Systems and Electronic Data in Clinical Trials**	https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-computerised-systems-and-electronic-data-clinical-trials_en.pdf	Computerized systems, electronic data, validation, user responsibilities, training, and explicit inclusion of AI within the computerized systems landscape	**AI-supported systems in clinical trials require trained users, controlled processes, and documented oversight**
AI Literacy & Governance	**EU AI Act – Article 4 (AI Literacy)**	https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai	AI literacy obligations for providers and deployers of AI systems	**Organizations using AI should ensure personnel understand AI risks, limitations, and responsible use**
AI/ML Governance	**FDA / MHRA / Health Canada – Good Machine Learning Practice (GMLP)**	https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles	Principles for AI/ML lifecycle management, validation, transparency, and human oversight	**AI systems should be fit-for-purpose, validated, transparent, and used under human oversight**
AI Governance in Medicines	**EMA Reflection Paper on AI in the Medicinal Product Lifecycle**	https://www.ema.europa.eu/en/use-artificial-intelligence-ai-medicinal-product-lifecycle-scientific-guideline	Governance and scientific considerations for AI across medicines development and regulation	**Expect increasing regulatory scrutiny of AI-supported activities within regulated environments**
Data Integrity & Oversight	**MHRA GxP Data Integrity Guidance**	https://www.gov.uk/government/publications/guidance-on-gxp-data-integrity	Data governance, audit trails, risk-based controls, integrity expectations	**AI-supported outputs affecting GxP records or decisions should remain reviewable, traceable, and controlled**

AI Essentials for Clinical Trials

MyRBQM® Academy's **AI Essentials for Clinical Trials (GCP-Compliant)** certification helps clinical teams understand how AI can be used responsibly in GCP-regulated environments.

The 70-min, self-paced e-course is designed for professionals in Clinical Operations, QA, Data, Central Monitoring, Medical Monitoring, and study leadership who need a practical baseline before AI use becomes broader, faster, or harder to control.

Access the eCourse on MyRBQM Academy →



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