CITELINE | A NEW ERA OF CLINICAL INSIGHT

How Citeline Helps Put Good Clinical Practice into Practice

Here are a few ways Citeline can help organizations follow the updated ICH GCP E6(R3) guideline:



Use of digital and AI-enabled insights

Citeline's integration of AI-powered features and advanced analytics supports the guideline's call for proactive, data-driven decision-making. Citeline's **SmartSolutions** products — Protocol SmartDesign and Investigator SmartSelect — leverage AI to offer real-time, actionable intelligence, optimizing and accelerating clinical trial planning and site selection.



Strategic feasibility and trial planning

Citeline's **Feasibility as a Service (FaaS)** offerings meet the need for expert-driven, data-informed feasibility assessments to expedite trial start-up and recruitment planning, a critical component emphasized by the new guideline.



Risk-based quality management

As sponsors need to implement risk-based quality management from trial design through execution, Citeline's data-rich **Trialtrove** and **Sitetrove** platforms provide granular insights into trial design, site feasibility, recruitment benchmarks, and investigator performance. This data and insights are indispensable for planning and risk mitigation as sponsors seek to optimize protocols and conduct trial feasibility assessments. And with **Cohort SmartBuilder**, sponsors can conduct upfront risk assessment in line with ICH E6(R3), ensuring protocols are feasible and aligned with regulatory expectations before handoff to operations.



Advanced data governance and transparency

Sponsors must maintain comprehensive data governance and documentation. Citeline's **Regulatory & Compliance Products & Services** help sponsors navigate evolving disclosure and regulatory expectations efficiently, minimizing risk and maximizing compliance.



Broader stakeholder collaboration

The guideline necessitates clearer roles and accountability involving sponsors, CROs, investigators, and ethics committees. Citeline's comprehensive, multidimensional clinical intelligence — including **Pharmaprojects**, the definitive resource for tracking global pharma R&D — facilitates cross-functional communication and decision-making.



Flexible, patient-centric trials

The guideline emphasizes patient involvement and digital trial components, increasing demand for technology-enabled patient recruitment and engagement solutions. Citeline's trial engagement tools — **Trial Portfolio Websites**, **Community Portals**, and **HCP Awareness** — improve trial awareness, education, and enrollment efficiency, aligning well with this shift. **Cohort Builder** bridges the gap between protocol design and operational execution with patient-centric precision.