



Smart Clinical Trial Technologies

Drug development faces formidable challenges!

In 2024, the average cost to bring a drug to market reached \$2.2 billion, with clinical trials alone consuming a significant 68% of that. This is compounded by a 90% trial failure rate, largely due to efficacy and adverse events. Operational hurdles further complicate matters, including widespread recruitment issues (80% of trials), high dropout rates (25%), and patient non-adherence (40%).

As clinical trials grow increasingly complex and expensive, **innovative solutions are critical**. This short report explores smart technologies and novel approaches designed to boost trial efficiency, reduce costs and timelines, and ultimately increase success rates.

Smart Clinical Trial Technologies



Optimise Patient Recruitment, Engagement & Retention

Streamline patient selection and enrolment. Enhance patient experience and prevent dropouts. Reduce trial costs and timeline.

- **Precision recruitment:** [TrialGPT](#) and [Deep 6 AI](#) streamline patient-trial matching through artificial intelligence (AI)-driven analysis of medical records; [Antidote.me](#) and [Carebox](#) provide online platform that connects patients with trials/sponsors.
- **Patient stratification:** [PrecisionLife](#) recruits super responders using mechanistic biomarkers; [Sonrai Analytics](#) identifies patient subgroups based on multi-modal data using machine learning (ML).
- **Patient diversity:** [Acclinate](#) improves diversity through community-focused, data-driven approaches; [Science 37](#) advances diversity through decentralised trials.
- **Patient engagement:** AI-powered digital platforms from [AiCure](#) and [Spencer Health Solutions](#) enhance patient engagement and reduce dropouts.
- **Site selection:** Through AI, [Citeline](#) and [ICON](#) optimise site and investigator selection by evaluating capability, experience, and historical performance.



Adaptive Trial Design & Predictive Simulation

Optimise trial design and enable real-time adjustments. Enhance patient safety and benefits. Improve trial efficiency and success rates.

- **Protocol development:** [Phesi](#) optimises trial design by leveraging data from 70 million patients and trial/site information, while [Medidata](#) draws on data from 11 million patients and 36,000 historical trials.
- **Adaptive trial designs:** More efficient, ethical, and flexible than traditional designs ([PhaseV](#) and [Cytel](#)); [Berry Consultants](#) and [Cogitars](#) apply Bayesian methods to reduce sample size, accelerate timelines, and boost clinical trial success.
- **Digital Twins/Synthetic Control Arms:** [Unlearn.AI](#) and [Medidata](#) create virtual patients using AI and ML models trained on patient and clinical trial data.
- **Trial outcome prediction:** [QuantHealth](#) predicts treatment response through in-silico simulations, trained on data from 350 million patients; [Insilico's InClinico](#) predicts trial success rate; [VeriSIM Life](#) and [Altis Labs](#) leverage AI to predict drug efficacy in clinical studies.



Decentralised Trials & Remote Patient Monitoring

Enhance trial accessibility and engagement. Capture real-world data for deeper insights. Reduce burden on patients and sites.

- **Decentralised clinical trials (DCTs) and hybrid trials:** Patient-centric approach leveraging digital platforms, electronic consent, telehealth virtual visits, wearables/biosensors, patient training/education, at-home/outpatient sampling, and home visits ([THREAD](#) and [Signant Health](#)).
- **Remote Patient Monitoring (RPM):** [ObvioHealth](#) and [ICON](#)'s systems enable efficient data collection, real-time health issue/adverse event alerts, and improve patient engagement and communication.
- **Wearables and digital endpoints/biomarkers:** [ActivInsights](#) and [Koneksa Health](#) provide medical-grade wearables or devices with integrated mobile apps to capture patient physiological and behavioural data, e.g., cardiac, respiratory, motor functions, sleep.
- **Medication adherence:** [AARDEX Group](#) and [Schreiner Group](#)'s smart packaging technologies monitor medication-taking behaviour, providing patients with reminders and alerts.



Efficient Data Collection, Management & Analysis

User-friendly electronic systems streamline data capture and simplify workflows. Enable real-time data access and insight discovery.

- **Electronic clinical data solutions:** Digital platforms such as Electronic Clinical Outcome Assessment (eCOA), Electronic Case Report Form (eCRF), and Electronic Data Capture (EDC) replace paper-based systems, streamline data collection and storage, enhance data quality, and reduce errors ([Castor](#), [Milo Health](#), [OpenClinica](#)).
- **Real-time data insight and analytics:** [Quanticate](#) and [SGS/Tableau](#) provide data visualisation tools to monitor study progress, identify potential issues (e.g., patient safety and non-compliance), and facilitate decision making.
- **Real-World Data (RWD) and Evidence (RWE):** RWD are routinely collected healthcare data, including electronic health records (EHRs), medical claims, patient registries, and digital health data. RWD and the resulting RWE can support clinical trial operations, post-market surveillance, and the development of external control arms ([IQVIA](#) and [Flatiron Health](#)).



Implementation Consideration

Smart clinical trial technologies, powered by AI/ML and digital platforms, have the potential to transform clinical trial operations, bringing safe, effective, and high-quality treatments to patients faster. However, their adoption requires careful consideration and assessment:

Evolving landscape – As AI/ML and digital tools continue to advance, it demand agile implementation strategies and a commitment to ongoing adaptation.

Technical hurdles – Interoperability, integration into existing workflows, and adequate personnel training.

Assessment aligned with regulatory guidance – The FDA uses a risk-based approach to regulate AI/ML in drug development, focusing on three key areas:

1. Human-Led Governance, Accountability, and Transparency

Ensure adherence to legal and ethical values; Have a risk management plan to identify and mitigate risks.

2. Quality, Reliability, and Representativeness of Data

Ensure data integrity, relevance, replicability, reproducibility, privacy, and security; Identify and manage biases and errors.

3. Model Development, Performance, Monitoring, and Validation

Consider model risk and credibility; Address issues of accuracy and explainability; Consider model re-training based on real-world performance; Ensure the model is reliable, relevant, and consistent over time.

Contact Information



Cindy Maddrell, PhD, DVM

cindy@lifescienceconsultant.co.uk

+44 7929 930051

<https://www.lifescienceconsultant.co.uk/>

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