Digital innovation in Healthcare : challenges and possibilities

29th October 2025

Amsterdam

European
University Hospital
Alliance

Evolution of the clinical trial landscape ?

Trends

•More complex, competitive, and global / Europe losing ground vs. US, Asia, LATAM / Expansion beyond oncology → neurology, immune-mediated, chronic & rare diseases / Recruitment delivery = key success factor

Challenges

•Heavy regulatory & admin burden (CTR, GDPR, MDR, contracts) / Insufficient funding for early-stage & investigator-initiated trials / Reduced time/opportunity for clinicians to do research / Data ownership & sharing hurdles

Risks

•Industry dominance threatens independence, open science, & neglected-disease research / Medical devices often lack robust clinical validation

EUHA Clinical trials questionnaire summary

Evolution of the clinical trial landscape ?

Positives

•National initiatives (e.g. SweTrial, Austria's accelerated approvals) / New translational hubs & precision medicine centers / Stronger academic–industry collaborations / Growth of professionalized Clinical Trial Units (CTUs) / Registry-based research opportunities

Future Needs

•More funding for investigator-initiated & early-stage trials / Harmonized contracts & frameworks across Europe / Stronger evaluation requirements for medical devices / Balanced funding aligned with societal/healthcare impact

EU Clinical Trial Regulation (CTR) & CTIS

Facilitations

•Harmonization across EU → consistency for multi-country trials / CTIS central database → transparency & accountability / Single entry point with templates → higher quality submissions/ Stronger patient safety monitoring

Challenges

•CTIS usability & reliability issues (log-in, workflows, no alerts) / Long timelines vs. non-EU countries / Divergent national interpretations & ethics committee practices / Heavy admin burden (strict deadlines, 25-year retention, costs) / MDR/IVDR in parallel → added complexity, esp. for devices / Academic trials disproportionately affected

EU Clinical Trial Regulation (CTR) & CTIS

Suggestions for Improvement

•Enhance CTIS usability, workflows & reliability / Introduce email notifications & deadline reminders / Streamline fast-track amendments (esp. translations/consent forms) / Harmonize ethics review & provide EU-wide templates / Reduce costs & simplify for IITs/academic trials / Reassess long documentation retention & SUSAR reporting process

AI & GDPR – practice and gaps

- Common controls: DPIAs, registers, ethics approvals, secure platforms, DTAs, consent governance
- Key tension: GDPR purpose limitation vs. exploratory AI needs for large-scale data
- Divergent GDPR interpretations hinder collaboration & secondary use
- Unclear legal basis for training on third-party data; risk of AI leaking personal data
- Need EU-level guidance on GDPR × AI Act; standardized anonymization/consent/secondary-use protocols
- Maturity varies: some sites have limited hands-on AI experience

Cross-Cutting Themes – Clustered Overview

Regulation:

- CTR, CTIS, MDR, GDPR add delays and costs
- Divergent national interpretations block harmonization

Resources:

- Funding gaps for early-stage and IITs; industry better resourced
- Shortages of trained staff: nurses, coordinators, data managers

Data & Digital:

- Frequent data-sharing/GDPR challenges; unclear AI–GDPR interplay
- Platforms/tools lack interoperability; AI/ML slowed by regulation

Opportunities:

- Streamline regulatory pathways & SOPs
- Invest in people, infrastructure, Centres of Excellence
- Strengthen patient engagement & recruitment support

AI & Digitalisation in Clinical Trials – Overview

- AI and digitalisation are transforming trial design, conduct, and analysis.
- Academic hospitals (e.g. UZ Leuven, HUS) already pilot multiple tools from NLP-based patient finding to digital consent.
- Focus on efficiency, patient-centricity, and real-world data integration.

Core domains:

1. Patient identification & recruitment
2. Decentralised / hybrid trial operations
3. AI-supported analysis & data management
4. Digital infrastructures for secure data use
5. Regulatory alignment & workforce readiness

Current AI Use Cases Supporting Clinical Trials

- Patient identification – NLP on EHRs (CTcue, Monsana) to match trial criteria
- Trial design & conduct – ML models predicting drop-out, adaptive trial design
- Imaging & genomics – AI analysis of CT/MRI, pathology, WGS to find biomarkers / responders
- Data quality – Automated data cleaning & extraction from free text
- Synthetic / digital models – Digital twins & synthetic controls for model validation
- Decentralised components – eConsent, ePRO, remote monitoring, mobile apps

Implemented & Piloted Systems in Hospitals

Implemented:

- eConsent + ePRO devices + remote monitoring platforms
- NLP-based patient screening (CTcue, Monsana pilot)
- AI-driven imaging & pathology (Contextflow, Neonatology echo AI)
- Model-informed precision dosing (vancomycin)
- Administrative AI: billing (Elise AI), cost estimation, quality (Qubuz)
- RAG chatbots & Copilot tools for research support

Piloted / In progress:

- AI-based pre-operative summarisation (Anesthesiology)
- Allergy verification LLMs, AI triage in ER
- NLP for trauma registry data extraction
- Patient matching for feasibility (AstraZeneca + Monsana)

Challenges & Regulatory Needs

Key barriers:

- Unclear validation rules for AI used in patient selection / decision support
- Overlap and conflict between CTR ↔ MDR ↔ AI Act
- Lack of standardised framework for AI performance & transparency
- Data ownership & liability issues in multi-centre AI use
- Ethical concerns: bias, explainability, reproducibility

Regulatory support needed:

- EU-level guidelines for AI in clinical trials
- Joint validation framework across CTR–MDR–AI Act
- Streamlined data-use agreements & secondary-data legislation

Enablers & ACT EU Collaboration Opportunities

Technical enablers:

- Interoperable data standards & secure federated platforms
- Shared AI training and testing infrastructures (e.g. HUS Data Lake, UZL Google Cloud)

Organisational enablers:

- Data stewards & AI-literate research staff
- Central AI governance and research support desks
- Strong IT-research collaboration

Enablers & ACT EU Collaboration Opportunities

Opportunities under ACT EU:

- Central validation platforms for AI tools
- Federated data infrastructure for multi-country AI research
- Joint training & capacity building programmes
- Public–private partnerships to scale AI in decentralised trials

Curewiki - Belgium

- The Patient Expert Centre and Curewiki launched a platform that connects patients to clinical research promoters
  - tool looks at all the studies in Europe, (particularly in Belgium) , and their protocols.
  - Via AI , complex study criteria are translated into an understandable and patient-oriented pathway.
  - Patients on the platform only need to answer a series of questions about their profile (weight, age, type of condition, geographical area, etc.) to receive selection of personalised studies. The patient then decides which study they want to participate in or whether they want to discuss it with their doctor. The entire process is fully compliant with the GDPR.
- 16,000 registered patients - aim 1 million Belgian patients
- endorsements from BioWin, BioVia, Pharma.be, Hospitals.be and patient associations. The Alzheimer's League has placed a direct link on its website.
- Access to be funded by pharma and biotech. Patient associations and academia will have free access