

SUMMARY OF THESIS

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**The Paradigm Shift in Clinical Trials in the
Pharmaceutical Industry:
The Economic and Management Implications of Digital
Health Technologies**

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1. Background of the research

The subject of this doctoral thesis is the examination of digital health technologies (DHTs) and other digital solutions applicable in clinical trials involving human subjects within the pharmaceutical industry, with particular regard to their practical, economic and management implications. The research analyses how digital innovations transform the conduct and organisation of clinical trials, and how social, technological, economic and regulatory factors influence their adoption.

The central motivation is an evidence gap: although the benefits and challenges of digital clinical trials (DCTs) are increasingly discussed, their cost-effectiveness and measurable economic consequences remain insufficiently documented through empirical and comparable indicators. The thesis therefore places economic and management questions alongside operational, technological and patient-centred considerations.

Clinical trials represent a major cost and risk component of pharmaceutical research, development and innovation. Rising development costs, longer cycle times, recruitment difficulties and shortages of trial sites and healthcare staff create pressure for operational transformation. DHTs offer alternatives through targeted recruitment, remote participation, automated data collection and real-time monitoring, potentially influencing cost structures, trial duration, resource utilisation and financial returns.

Aim and relevance of the research

The overall aim is to explore and analyse the economic and management impacts of DCTs based on DHTs in pharmaceutical clinical development. Particular attention is paid to cost structure, trial duration, resource use, and the mechanisms and conditions through which economic value and return on investment (ROI) may be realised, as well as to the organisational and regulatory conditions under which DCTs can be implemented in an economically sustainable and operationally feasible manner.

The topic is especially relevant because the COVID-19 pandemic accelerated the digitalisation of clinical trials and exposed the vulnerability of site-centric models. Remote solutions enabled the continuation of research activities while intensifying the need for regulatory adaptation, data protection, organisational learning and new forms of patient engagement. The thesis therefore approaches DCTs as part of a broader socio-technical and managerial transition.

2. Research questions

The literature review identified a limited number of empirical studies with comparable economic data and highlighted considerable uncertainty about the conditions under which DCT efficiencies translate into realised value. On this basis, the research formulated six exploratory research questions. RQ1-RQ3 focus on the main outcome dimensions, while RQ4-RQ6 examine contextual and operational mechanisms.

RQ1. *Do DCTs involve a shorter trial duration compared to traditional clinical trials?*

RQ2. *Is the cost structure of DCTs generally more favourable than that of the traditional clinical trial model?*

RQ3. *Do the quality, reliability and data integration characteristics of data collected during DCTs differ from those of traditional clinical trials?*

RQ4. *Does recruitment efficiency influence the relationship between the trial design and the duration of the trial?*

RQ5. *Does the digitalization of patient communication influence the relationship between the trial design and the cost structure?*

RQ6. *Does the frequency and method of data collection influence the relationship between the study design and data quality?*

In addition to these core questions, the primary research explored the domestic DCT ecosystem from the perspective of stakeholders including sponsors, CROs, clinical investigators and healthcare professionals, patients and patient organisations, service-related experts, and regulatory stakeholders. The exploratory framing reflects the modest domestic quantitative sample and the rapidly changing technological and regulatory environment.

3. Research methodologies

The doctoral research applies a mixed-methods design combining a systematic literature review, semi-structured expert interviews and a quantitative questionnaire. The qualitative-interpretivist component provides contextual depth, while the quantitative component provides structured descriptive indicators for triangulation rather than population-level inference.

3.1 Systematic literature review

The systematic literature review (SLR) examined peer-reviewed empirical studies, financial simulation models and industry benchmark reports addressing DCTs or related DHTs and reporting quantitative, empirical or model-based economic evidence. Relevant outcomes included ROI, OPEX, CAPEX, cost per patient, recruitment and monitoring costs, cycle-time reductions and related measures of economic performance.

The search strategy was intentionally broad and covered Embase, Scopus, EBSCO, PubMed and Web of Science, complemented by citation-network mapping using Litmaps. Screening was conducted in stages using titles and abstracts followed by full-text assessment, with Rayyan used to support the screening process. Publications without an economic dimension, duplicates and secondary commentaries were excluded from the final synthesis.

3.2 Expert interviews

The qualitative component comprised 13 semi-structured interview sessions involving 14 individual participants. Purposive sampling was used to achieve stakeholder diversity in the Hungarian clinical trial ecosystem. Interviews lasted approximately 60-90 minutes, were conducted via Microsoft Teams and recorded with verbal consent.

Interviews were transcribed using Alrite speech recognition software and analysed in MAXQDA Analytics Pro using thematic analysis with a hybrid inductive-deductive coding logic. Predefined DCT dimensions were complemented by practice-based codes, and thematic saturation was reached after 13 sessions.

3.3 Quantitative questionnaire

A self-developed questionnaire was completed by 11 of 13 response units (84.6%). Nineteen impact areas were rated on a four-point Likert scale and analysed descriptively.

4. Research results

The empirical findings indicate that DHTs have the potential to reshape clinical trial operations, but their effects are conditional rather than automatic. The strongest positive signals concern data-related outcomes, while effects on trial duration appear more context-dependent. Human, organisational, regulatory and data-security factors constrain the realisation of technological potential.

4.1 Systematic literature review

The SLR identified a substantial research gap in the economic evaluation of DCTs. Conventional database screening identified only two studies that met the predefined quantitative eligibility criteria. Citation-network mapping using Litmaps identified 19 additional relevant publications that broadened the contextual and methodological evidence base. The evidence base therefore remains relatively small compared with the volume of general DCT literature.

The review also showed that terminology is fragmented: decentralised, virtual, siteless, hybrid and digitally enabled trials are often used inconsistently. This limits search precision and comparability. A second structural limitation is the scarcity of transparent cost data. Detailed trial budgets are commercially sensitive, leading the literature to rely heavily on industry benchmarks, vendor reports and simulation models.

Overall, the available evidence suggests that potential economic benefits are closely connected to recruitment efficiency, monitoring optimisation and cycle-time reduction. At the same time, implementation costs, organisational change, platform onboarding, legacy-system integration and cybersecurity can offset theoretical savings. Economic estimates should therefore be treated as context-dependent rather than universally transferable benchmarks.

4.2 Expert interviews

The qualitative analysis generated nine main themes: economic and business impacts; clinical operations and trial organisation; strategy, innovation and vision; stakeholder impacts and burden; regulatory environment; data management and quality; patient-centred care and access; disruptive digital technologies; and social and demographic challenges.

A strong cross-cutting pattern was the time-delayed interpretation of ROI. Interviewees commonly described DHT adoption as cost-increasing in the short term because of infrastructure, system integration and training, while longer-term value was associated with operational efficiency, time savings and greater organisational flexibility. However, these benefits were rarely tracked through

formal KPIs, meaning business decisions were often based on strategic expectations and practical experience rather than robust economic measurement.

Digitalisation also redistributed work rather than simply reducing it. Paper-based documentation and some site activities declined, but new tasks emerged around technology use, monitoring and troubleshooting. For physicians and sites, administrative and technical workload could increase; for patients, continuous data collection and device use could create additional burden. Stakeholder-reported patient experience emerged as an operational factor linking human acceptance, retention and data quality.

Technological maturity differed across solutions. EDC and ePRO were described as more routinely integrated, whereas AI-based analyses and virtual reality were more future-oriented and experimental. Mature tools were associated with more stable operational experience, while emerging technologies involved greater uncertainty and expectation.

4.3 Quantitative questionnaire

The descriptive questionnaire results broadly supported the qualitative findings. DHT applicability/acceptability received a mean score of 3.36 on a four-point scale. The highest mean scores were observed for the amount and quality of collected data (both 3.45), while data security received the lowest mean (2.27) and the highest standard deviation (1.01).

The table below presents selected key indicators from the 19-item questionnaire.

Impact area	Mean	Median	SD
DHT applicability / acceptance	3.36	3	0.50
Patient engagement / trust	2.91	3	0.94
Data security	2.27	3	1.01
Amount of data collected	3.45	4	0.93
Data quality / reliability	3.45	3	0.52
Patient-centred care	3.09	3	0.94
Doctor-patient communication	2.55	3	0.82
Study duration / cycle time	3.00	3	1.18
Cost-effectiveness	2.91	3	0.83
Return on research costs	2.82	3	0.75

4.4 Integrated findings and conditional impact model

Answers to the research questions

RQ	Evidence base	Answer
RQ1	SLR, interviews; questionnaire: study duration / cycle time mean 3.00, SD 1.18.	DCT elements can contribute to shorter trial duration, but the effect is highly context-dependent rather than universal.

RQ2	SLR and interviews; questionnaire: cost-effectiveness mean 2.91 and return on research costs mean 2.82.	DCTs do not necessarily reduce costs immediately. Initial CAPEX and implementation costs may offset savings, while longer-term value can arise through efficiency and time-to-market effects.
RQ3	Questionnaire: data quantity and data quality / reliability both mean 3.45; data security mean 2.27. Interviews provide contextual interpretation.	Digital approaches are perceived to strengthen data generation and quality, but data security remains a major constraint; direct population-level comparison with traditional trials is not established by this study.
RQ4	SLR, interviews on targeted recruitment and pre-screening; questionnaire indicators for screening/recruitment and retention.	More targeted recruitment and screening can contribute to shorter timelines, but the magnitude of the effect depends on the study design and target population.
RQ5	Interviews and economic evidence on communication, travel, patient burden and workload; questionnaire: doctor-patient communication mean 2.55.	Digital patient communication can alter the cost structure by reducing some site and travel burdens while creating technology, integration and support costs; the net effect is conditional.
RQ6	Questionnaire: data quantity mean 3.45, data quality / reliability mean 3.45, usability / processability mean 3.36; interviews on real-time and continuous data collection.	Higher-frequency digital data collection can increase data volume, timeliness and informational value, but improved data quality is not automatic because security, usability and participant burden also matter.

These answers are exploratory interpretations based on mixed-methods triangulation; they should not be read as results of formal statistical mediation or hypothesis testing.

The integrated interpretation indicates that DCT outcomes emerge through an operational pathway rather than through technology alone. Structural conditions such as technological development, regulatory reform and cost pressure influence operational mechanisms such as patient recruitment, continuous communication and remote data collection; these mechanisms then affect trial duration, cost structure and data quality.

The conditional impact model identifies human and regulatory factors as mediating conditions. The realisation of technological potential depends on acceptance, implementation quality and organisational readiness. Important contextual moderators include trial phase, therapeutic indication and procedural complexity, organisational and site digital readiness, and the regulatory and data-governance landscape.

From an economic perspective, the model distinguishes immediate “hard money” investments (software, hardware, validation, onboarding and related CAPEX) from delayed “soft money” returns, such as cycle-time acceleration, fewer dropouts, improved data quality and potential portfolio-level eNPV effects. The thesis therefore treats DCT adoption as an ecosystem-level transition rather than a series of isolated software implementations.

5. Conclusions and recommendations

The research indicates that DCTs are in a transitional stage. Digital solutions are broadly recognised as valuable, but economic, organisational and human conditions do not always enable that value to be fully realised. The central conclusion is therefore conditionality: the impact of DCTs depends on study design, trial phase, therapeutic complexity, organisational preparedness, patient needs and the regulatory environment.

For clinical operations, DHTs should be considered early in protocol design and selected according to the therapeutic area and target population. Large, geographically dispersed Phase II-III populations can offer stronger opportunities for digital and hybrid approaches, while early-phase studies requiring intensive in-person oversight may remain more site-centric.

For economic decision-making, initial CAPEX and implementation costs should be evaluated together with delayed operational and portfolio benefits. ROI should not be reduced to immediate direct savings; cycle-time acceleration, time-to-market, retention, data quality and risk reduction can create indirect value. However, these benefits should be measured rather than assumed.

For patients and sites, patient-centred design, usability testing, training, device support and hybrid participation can mitigate digital exclusion. For investigators, implementation should include workload redesign, structured training and operational support. For regulators, technology-neutral and adaptable frameworks, together with controlled environments for testing new digital solutions, can support innovation while maintaining patient safety and data integrity.

6. Scientific and practical contributions

The thesis makes three principal scientific contributions. First, it provides a structured overview of the principal cost drivers associated with DCT implementation and explains how digitalisation alters traditional trial cost structures. Second, it synthesises and critically evaluates the available evidence on recruitment efficiency, monitoring costs, retention and cycle-time acceleration. Third, it proposes an integrated conceptual framework that connects economic and operational mechanisms with patient experience and pharmaceutical R&D portfolio management.

Decision-making framework

The practical decision framework reframes DHT adoption from a binary technology choice into a staged governance process. The first step is protocol and therapeutic-area feasibility: managers assess whether trial design, participant geography, endpoints and the target population provide a meaningful basis for digital components. The second step is financial alignment, balancing immediate “hard money” expenditures against delayed “soft money” returns. The subsequent stages concern organisational and site readiness, participant support, regulatory compliance and controlled implementation.

Integrated KPI matrix

To capture value across the trial life cycle, the thesis proposes a KPI matrix combining sponsor-level financial measures with process and human indicators. This is intended to complement traditional post-trial cost assessment with continuous monitoring of operational drivers.

Dimension	Illustrative KPI	Purpose
Portfolio & financial	eNPV	Connect DCT outcomes to portfolio capital value
Portfolio & financial	Cost per enrolled patient	Compare digital recruitment efficiency with baseline costs
Portfolio & financial	Time-to-market acceleration	Monetise cycle-time effects
Portfolio & financial	OPEX reallocation ratio	Track shifts from site overheads to digital services
Process quality	Screen failure rate	Assess recruitment targeting and efficiency
Patient	Retention / dropout rate	Monitor continuity and protocol completion risk
Technology & data	Data latency / missingness	Monitor data flow and data-quality risk
Human factors	Investigator Burden Index	Track usability and administrative workload

The matrix is designed as a three-phase monitoring routine: baseline setting before the trial, operational monitoring during recruitment and active execution, and post-trial valuation. This enables management to connect operational effects to financial models and future capital-allocation decisions.

7. Limitations of the research

The study is exploratory and its findings should be interpreted in light of several limitations. The qualitative sample was purposive and non-probability based, and the quantitative component included only 11 completed questionnaires. The results therefore support contextual understanding and triangulation rather than population-level statistical generalisation.

Stakeholder coverage was also constrained. Formal regulatory perspectives could not be incorporated into the primary research because of institutional data-availability constraints, and direct access to active trial participants was limited by data-protection requirements. Patient organisation representatives provided valuable perspectives, but direct patient evidence remained limited.

The evidence base itself is heterogeneous. Terminological fragmentation may have resulted in relevant publications being missed despite the use of citation-network mapping. In addition, a substantial share of available economic evidence comes from commercial reports, vendor materials and simulation models. Such evidence may reflect favourable implementation scenarios and often provides limited visibility into onboarding, change management, legacy integration and cybersecurity costs.

The transferability of international findings to Hungary is also constrained by differences in infrastructure, labour costs, funding, governance and regulatory arrangements. The thesis specifically notes that the potential of Hungary's EESZT may remain underused for clinical research because of interoperability, legal and technical constraints. These contextual factors reinforce the need for phase-, indication- and geography-specific economic evaluation.

8. Future research directions

Future research should move towards structured, longitudinal and empirically grounded economic evaluation. The thesis proposes the following directions:

- expand primary data collection through sponsor, CRO and site-level cost data;
- introduce standardised definitions for fixed/variable, direct/indirect, one-off and recurring DCT costs;
- conduct stratified analyses by trial phase, therapeutic area, geography and regulatory environment;
- apply quantitative cost-benefit and life-cycle analyses to assess when initial digital investment is recouped;
- integrate data quality, patient safety and retention outcomes into economic evaluation;
- use longitudinal and portfolio-level datasets to examine scalability and institutional learning;
- apply sensitivity analyses and compare conventional, hybrid and fully decentralised designs;
- incorporate parallel sponsor, CRO, site, patient and regulatory perspectives.

A strengthened methodology of this kind could transform the cost structure of DCTs from a largely conceptual topic into a more robust decision-support domain for clinical development strategy.

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