

Integrating Clinical Trial Evidence into Design Thinking Processes for Healthcare Product Development

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Abstract: Healthcare product development increasingly requires approaches that combine evidence-based healthcare knowledge with human centered innovation. While design thinking has gained significant attention in healthcare innovation, limited research has examined how clinical trial evidence can support design thinking processes in healthcare product development. This study develops and empirically tests a conceptual framework integrating Clinical Trial Evidence (CTE), Design Thinking Processes (DTP), and Healthcare Product Development (HPD) using Type 2 Diabetes clinical trial data. A quantitative research approach was adopted using Partial Least Squares Structural Equation Modeling (PLS-SEM) with Smart PLS. The study utilized a structured dataset comprising 1,000 observations derived from clinical trial evidence. The analysis assessed the direct relationships between Clinical Trial Evidence, Design Thinking Processes, and Healthcare Product Development, as well as the mediating role of Design Thinking Processes. Reliability, validity, and predictive relevance assessments were conducted to ensure the robustness and consistency of the proposed research model. The findings reveal that Clinical Trial Evidence has a significant positive influence on both Design Thinking Processes and Healthcare Product Development. In addition, Design Thinking Processes significantly enhance Healthcare Product Development and mediate the relationship between Clinical Trial Evidence and Healthcare Product Development. These results suggest that integrating structured clinical evidence into design thinking can strengthen innovation capability, improve decision-making quality, and support more effective healthcare product development outcomes. This study contributes to healthcare innovation and entrepreneurship literature by positioning clinical trial evidence as a strategic driver of patient centered innovation. The proposed framework offers a structured approach for integrating evidence-based healthcare knowledge into design thinking and healthcare product development processes. The study also provides practical implications for healthcare organizations, pharmaceutical companies, researchers, and innovation teams seeking to improve the effectiveness and sustainability of healthcare product innovation in evidence driven environments. Overall, the paper argues that combining clinical evidence and design thinking can support more informed, patient centered healthcare product development in chronic disease contexts.

Keywords: Clinical Trial Evidence; Design Thinking; Healthcare Product Development; Type 2 Diabetes; PLS-SEM.

1. Introduction

Healthcare product development now operates in an environment shaped by rapid technological change, rising patient expectations and growing pressure to justify innovation through evidence. Products and services in healthcare must achieve clinical effectiveness, but they must also support usability, accessibility, treatment adherence and meaningful patient experience. These demands are especially pronounced in chronic disease settings, where patients need continuous care support rather than isolated clinical interventions (World Health Organization 2024; Ulrich and Eppinger 2016).

Type 2 Diabetes illustrates this challenge clearly. The disease is long term, behaviourally complex and associated with repeated interactions among patients, clinicians, devices, therapies and digital support systems. Innovation in this area therefore requires more than technical performance. It also requires good understanding of routines of use, barriers to adoption and patient-centred solution design. For this reason, Type 2 Diabetes provides a valuable context for exploring how evidence and innovation can be connected more systematically (World Health Organization 2024).

Design thinking has become one of the most influential human-centred innovation approaches for addressing such complexity. The approach emphasises empathy, problem framing, ideation, prototyping and testing, thereby helping organisations explore problems before converging on solutions (Brown, 2008; Kelley and Kelley, 2013). In healthcare, these features are attractive because innovation problems are often ambiguous, multidisciplinary and deeply shaped by user experience. Previous studies suggest that design thinking can improve healthcare innovation by encouraging stakeholder participation, interdisciplinary collaboration and iterative learning (Altman et al., 2018; Roberts et al., 2021).

At the same time, recent literature warns that design thinking can become superficial when it is disconnected from robust evidence. Bromage et al. (2025) describe the risk of “innovation theatre”, where organisations perform creative exercises but fail to anchor decisions in validated knowledge. In healthcare, this limitation is

serious because innovation should respond to real treatment needs, outcome priorities and clinical constraints rather than to intuition alone.

Clinical-trial databases offer a potentially valuable but underused source of structured evidence for innovation. Trial records contain detailed information on interventions, patient eligibility criteria, endpoints, adverse events, treatment limitations and disease-management priorities. Such information can help innovators identify unmet needs, reveal barriers to participation and indicate where healthcare solutions may need to be redesigned. Yet limited research has examined how this type of evidence can systematically support design thinking and product-development decisions (Zarin et al. 2011; Varvara et al. 2025).

This paper addresses that gap by proposing and empirically testing a framework that links Clinical Trial Evidence (CTE), Design Thinking Processes (DTP) and Healthcare Product Development (HPD). Using Type 2 Diabetes clinical-trial data and PLS-SEM, the study asks whether structured clinical evidence strengthens design thinking activities, whether design thinking improves healthcare product development, and whether design thinking mediates the relationship between evidence and product-development outcomes (Hair et al. 2022).

2. Literature Review and Hypotheses Development

2.1 Design Thinking in Healthcare

Design thinking emerged from the design disciplines and later expanded into management, entrepreneurship and public-sector innovation as organisations searched for more user-oriented ways to address complex problems. The method is commonly represented through the stages of empathise, define, ideate, prototype and test. These stages help organisations explore user needs, reframe problems, generate alternatives and refine solutions iteratively (Brown, 2008; Liedtka, 2018).

In healthcare, design thinking is valuable because many problems are socially embedded and involve patients, clinicians, caregivers, managers and technology developers simultaneously. Altman et al. (2018) show that human-centred design can improve healthcare innovation by aligning solutions with lived experience. Roberts et al. (2021) similarly emphasise that design thinking supports healthcare management and innovation by connecting problem exploration with collaborative solution development. These studies suggest that the real strength of design thinking lies not only in creativity, but in structured learning from user contexts.

Recent healthcare literature also links design thinking with co-creation and integrated care. When patients and professionals participate in defining problems and testing solutions, innovations are more likely to be contextually relevant and implementable. This matters for healthcare product development because products often fail not because their technology is weak, but because they do not fit everyday workflows, user abilities or treatment realities (Bogaert et al. 2025; Romero and Rivera 2025).

2.2 Clinical-Trial Evidence as an Innovation Input

Evidence-based healthcare typically treats clinical-trial data as a source of scientific validation, regulatory support and treatment comparison. However, the same data may also have strategic value for innovation. Information on interventions, endpoints, eligibility criteria and treatment limitations can reveal where patients struggle, which groups are underserved and what outcomes healthcare stakeholders consider important. In this sense, clinical-trial evidence can be seen as a structured source of user, disease and system knowledge (Zarin et al. 2011; Varvara et al. 2025).

For healthcare product development, this matters because innovators must often translate scattered clinical knowledge into products, services or support systems that improve care delivery. Clinical evidence can inform decisions about what problems deserve attention and which design requirements are likely to be relevant. Reusing clinical-trial data may therefore strengthen the early stages of innovation, especially problem definition and prioritisation (Varvara et al., 2025).

Nevertheless, evidence alone does not automatically produce innovation outcomes. Structured knowledge needs to be interpreted, reframed and transformed into solution concepts. This observation suggests that design thinking may operate as the mechanism that converts clinical evidence into practical product-development activity (Brown 2008; Liedtka 2018).

2.3 Research Gap, Conceptual Framework and Hypotheses

The reviewed literature supports both the value of design thinking in healthcare and the value of evidence-based decision making, but relatively little research has examined how these domains interact. Most healthcare design studies focus on interviews, workshops or service-improvement initiatives, while evidence-oriented studies concentrate on evaluation, effectiveness or regulation. The intersection between structured clinical evidence and design-oriented innovation remains underdeveloped (Altman, Huang and Breland 2018; Roberts et al. 2021; Varvara et al. 2025).

This paper therefore investigates the following research question: how can structured clinical-trial evidence improve healthcare product development through design thinking processes? The conceptual argument is that CTE may strengthen DTP by helping innovators define healthcare problems more accurately and identify clinically meaningful priorities. DTP should then support HPD by transforming evidence into solution ideas, prototypes and refinement activities. CTE may also influence HPD directly, but the indirect path through DTP is expected to be especially important.

The proposed framework therefore treats design thinking as both a process construct and a translation mechanism. CTE provides the evidence base, DTP provides the human-centred innovation process, and HPD represents the development outcome. This distinction is important because healthcare organisations often possess large amounts of evidence but do not always have systematic procedures for converting that evidence into usable products or services (Brown 2008; Liedtka 2018; Zarin et al. 2011).

The hypotheses are intentionally structured to separate direct and indirect effects. H1 tests whether evidence supports design thinking activities. H2 tests whether design thinking supports product-development outcomes. H3 tests whether evidence also has a direct effect on product development. H4 then tests whether the influence of evidence is partly transmitted through design thinking. This structure makes it possible to examine whether design thinking adds explanatory value beyond the direct effect of clinical evidence.

The framework is also consistent with the practical logic of chronic disease innovation. In Type 2 Diabetes, product-development decisions must consider clinical outcomes, daily self-management, treatment adherence and patient experience. A product-development process that relies only on clinical evidence may overlook usability and contextual issues, while a process that relies only on creativity may overlook clinical priorities. The framework therefore argues for an integrated approach (World Health Organization 2024; Ulrich and Eppinger 2016).

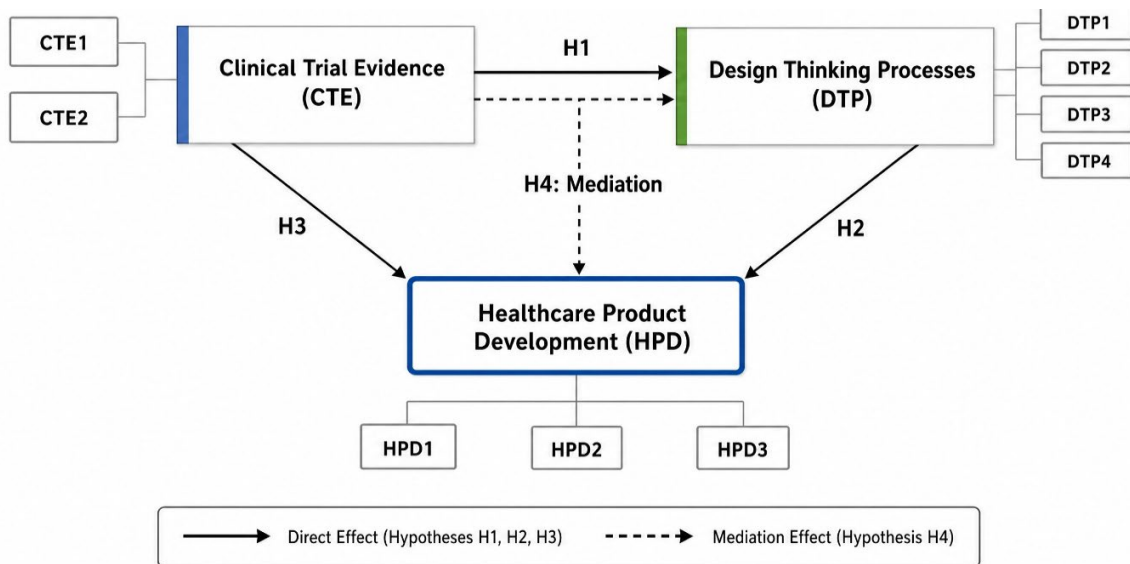


Figure 1: Conceptual framework of the study

- H1: Clinical Trial Evidence positively influences Design Thinking Processes.
- H2: Design Thinking Processes positively influence Healthcare Product Development.
- H3: Clinical Trial Evidence positively influences Healthcare Product Development.
- H4: Design Thinking Processes mediate the relationship between Clinical Trial Evidence and Healthcare Product Development.

3. Methodology

3.1 Research Design and Data Source

The study adopted a quantitative design because the objective was to test a predictive framework connecting three latent constructs and a mediating relationship. PLS-SEM was selected because it is appropriate for exploratory and prediction-oriented models and performs well when the research focus is on explaining variance in endogenous constructs (Hair et al., 2022). The model was estimated using SmartPLS.

The empirical context was Type 2 Diabetes. A structured dataset of 1,000 observations was developed from clinical-trial information relating to this disease area. The disease context was selected because Type 2 Diabetes requires sustained treatment support, self-management, monitoring and product or service innovation over long periods. Trial-derived information offered a consistent evidence base from which indicators could be formed (World Health Organization 2024; Zarin et al. 2011).

The model included three constructs. Clinical Trial Evidence (CTE) represented the availability and usefulness of structured evidence derived from trials. Design Thinking Processes (DTP) represented retained activities aligned with defining, ideating, prototyping and testing. Healthcare Product Development (HPD) represented development-oriented outcomes associated with the translation of knowledge into healthcare solutions.

3.2 Measurement and Analytical Procedure

Reflective indicators were used for all three constructs. After model refinement, CTE was measured by CTE1 and CTE2, DTP by DTP1_Define, DTP2_Ideate, DTP3_Prototype and DTP4_Test, and HPD by HPD1, HPD2 and HPD3. Indicators with weaker loadings were removed in order to improve reliability and construct quality in line with common PLS-SEM assessment practice (Hair et al. 2022).

The analysis followed standard PLS-SEM stages. First, the measurement model was assessed using outer loadings, Cronbach's alpha, composite reliability and average variance extracted (AVE). Second, discriminant validity was examined. Third, the structural model was evaluated using path coefficients, bootstrapped significance testing, coefficients of determination (R^2), effect sizes (f^2), predictive relevance (Q^2) and mediation testing. This procedure allowed both measurement quality and explanatory performance to be assessed systematically.

4. Results

4.1 Measurement-Model Assessment

Table 1 presents the retained outer loadings. All indicators exceed or closely approach the commonly used 0.70 threshold, indicating acceptable indicator reliability. CTE1, CTE2 and HPD3 are particularly strong, while DTP4_Test is the weakest retained item but remains acceptable. The results suggest that the retained indicators adequately represent the three latent constructs (Hair et al. 2022).

Table 1: Outer loadings of the measurement model

Construct	Indicator	Outer loading
Clinical Trial Evidence	CTE1	0.903
Clinical Trial Evidence	CTE2	0.886
Design Thinking Processes	DTP1_Define	0.815
Design Thinking Processes	DTP2_Ideate	0.879
Design Thinking Processes	DTP3_Prototype	0.857
Design Thinking Processes	DTP4_Test	0.709
Healthcare Product Development	HPD1	0.816
Healthcare Product Development	HPD2	0.818
Healthcare Product Development	HPD3	0.937

Source: Author's work

The reliability and convergent-validity results in Table 2 also support the adequacy of the measurement model. Cronbach's alpha values range from 0.751 to 0.833. Composite reliability values exceed recommended cut-offs, and all AVE values are above 0.50. Together, these statistics confirm satisfactory internal consistency and convergent validity for CTE, DTP and HPD (Hair et al. 2022).

Table 2: Reliability and convergent validity

Construct	Cronbach alpha	rho_a	rho_c	AVE
CTE	0.751	0.754	0.889	0.801
DTP	0.833	0.851	0.889	0.668
HPD	0.820	0.829	0.894	0.738

Source: Author's work

Discriminant validity was assessed primarily by the Fornell-Larcker criterion shown in Table 3. The square roots of AVE on the diagonal are greater than the inter-construct correlations, which indicates acceptable construct separation. However, HTMT diagnostics from the full analysis showed a high overlap between DTP and HPD. This implies that the two constructs are theoretically and empirically close in the present dataset. Accordingly, the structural findings are interpreted cautiously as evidence of a strong relationship rather than complete conceptual independence (Hair et al. 2022).

Table 3: Fornell-Larcker criterion

Construct	CTE	DTP	HPD
CTE	0.895		
DTP	0.731	0.817	
HPD	0.762	0.894	0.859

Source: Author's work

4.2 Structural-Model Assessment

Table 4 reports the path coefficients. All three direct hypotheses are supported. The strongest direct path is from CTE to DTP ($\beta=0.731$), indicating that structured clinical-trial evidence substantially strengthens design thinking processes. The path from DTP to HPD is also strong ($\beta=0.724$), which confirms that design-oriented innovation activity contributes positively to healthcare product-development outcomes. The direct effect of CTE on HPD remains positive and significant, but is notably smaller ($\beta=0.232$), suggesting that evidence alone has a more limited effect unless it is translated through a design process.

Table 4: Structural-path and mediation results

Path	Beta	Mean	STDEV	t-value	p-value
CTE → DTP	0.731	0.732	0.013	54.439	0.000
DTP → HPD	0.724	0.724	0.017	41.908	0.000
CTE → HPD	0.232	0.232	0.020	11.436	0.000
CTE → DTP → HPD	0.529	0.530	0.014	36.634	0.000

Source: Author's work

The model-quality results are presented in Table 5. CTE explains 53.5% of the variance in DTP, which indicates moderate explanatory power. CTE and DTP together explain 82.4% of the variance in HPD, which indicates strong explanatory power for healthcare product development. Effect-size results show that CTE has a very large effect on DTP, while DTP has a very large effect on HPD. The direct effect of CTE on HPD is meaningful but comparatively small. Positive Q^2 values for DTP and HPD confirm predictive relevance (Hair et al. 2022).

Table 5: Explanatory power, effect size and predictive relevance

Assessment	DTP	HPD	Interpretation
R ²	0.535	0.824	Moderate for DTP; strong for HPD
Adjusted R ²	0.534	0.823	Stable explanatory power
f ² (CTE effect)	1.149	0.143	Large effect on DTP; small direct effect on HPD
f ² (DTP effect)	–	1.382	Large effect on HPD
Q ² predict	0.534	0.580	Predictive relevance confirmed

Source: Author's work

At the indicator level, the prediction-oriented assessment also remained positive. Q²_predict values ranged from 0.274 to 0.503 for the retained DTP indicators and from 0.395 to 0.447 for the retained HPD indicators, which provides additional support for predictive relevance. Finally, the mediation result confirms that DTP plays a central translating role between structured evidence and product-development outcomes.

Table 6: Hypothesis-testing summary

Hypothesis	Relationship	Result
H1	CTE positively influences DTP	Supported
H2	DTP positively influences HPD	Supported
H3	CTE positively influences HPD	Supported
H4	DTP mediates the relationship between CTE and HPD	Supported

Source: Author's work

4.3 Predictive Assessment and Robustness

The prediction-oriented results provide an additional check on model usefulness. Table 7 summarises indicator-level predictive assessment for retained DTP and HPD indicators. All Q²_predict values are positive, indicating that the model has predictive relevance at the indicator level. Some PLS-SEM prediction errors are close to the linear-model benchmark, which suggests that the model is useful but should not be overstated as uniformly superior for every indicator. This interpretation is consistent with the exploratory nature of the study (Hair et al. 2022).

Table 7: Summary of indicator-level predictive assessment

Indicator Group	Q ² Predict Range	PLS-SEM RMSE Range	PLS-SEM MAE Range	Interpretation
DTP indicators	0.274-0.503	0.677-0.832	0.560-0.706	Positive predictive relevance
HPD indicators	0.395-0.447	0.590-0.833	0.473-0.678	Positive predictive relevance

Source: Author's work

Taken together, the structural and predictive results indicate that the model has both explanatory and practical relevance. The strongest empirical pattern is not simply that clinical-trial evidence is related to healthcare product development, but that the relationship becomes much stronger when design thinking processes are included as a translating mechanism. This finding supports the central argument of the paper and gives the model a clear managerial interpretation.

5. Discussion

5.1 Theoretical Implications

The results make three main theoretical contributions. First, they show that clinical-trial evidence can be treated as an innovation input rather than only as a clinical or regulatory resource. This extends the evidence-based healthcare perspective by suggesting that structured trial information has value in the earliest stages of

innovation, particularly for problem definition and opportunity identification (Zarin et al. 2011; Varvara et al. 2025).

Second, the findings strengthen the argument that design thinking can serve as a mechanism for evidence translation. The large and significant indirect effect of CTE on HPD through DTP indicates that structured evidence becomes more useful for innovation when it is processed through define, ideate, prototype and test activities. In this sense, design thinking does not replace evidence; it operationalises it.

Third, the high explanatory power for HPD indicates that the joint consideration of evidence and design activity offers a useful way to understand healthcare product development. The study therefore contributes to the innovation and entrepreneurship literature by connecting evidence-based reasoning with human-centred problem solving in a single empirical model (Brown and Katz 2011; Ulrich and Eppinger 2016).

5.2 Practical Implications

For practitioners, the findings suggest that healthcare organisations and pharmaceutical or med-tech innovation teams should not treat clinical-trial databases as resources relevant only to researchers or regulatory specialists. Trial data can be used earlier in the innovation process to reveal unmet needs, user barriers and clinically meaningful priorities. This can improve the quality of innovation briefs and guide more targeted concept development (Zarin et al. 2011; Varvara et al. 2025).

The results also imply that innovation teams benefit from combining evidence with structured design activity. Evidence alone produced only a modest direct contribution to healthcare product development, whereas the mediated effect through DTP was substantially stronger. Practically, this means that teams should create routines for translating evidence into design workshops, concept generation, prototype evaluation and user testing rather than keeping evidence separate from innovation practice.

This implication is especially important in chronic disease contexts. In areas such as Type 2 Diabetes, solutions must fit both clinical requirements and long-term patient behaviour. Evidence-informed design thinking can therefore help organisations develop products and services that are not only novel, but also clinically grounded and more likely to be accepted in real use environments (World Health Organization 2024; Roberts et al. 2021).

5.3 Limitations and Future Research

This study focuses on one disease context, Type 2 Diabetes, which may limit the generalizability of the findings to other therapeutic areas. Second, the analysis is based on a structured dataset derived from clinical-trial information; future research could complement this approach with organizational data, interviews with healthcare innovators, or case studies of product-development teams. Third, the constructs examined in this study are conceptually related, particularly design thinking processes and healthcare product development, so future studies could further refine the measurement items and test the framework in different healthcare settings (Hair et al. 2022).

Future research could extend the framework to other chronic disease areas, compare different forms of healthcare evidence, and examine how evidence-informed design thinking influences product-development outcomes over time. Longitudinal studies would be especially useful for understanding whether early design decisions based on clinical evidence led to stronger implementation, adoption, and patient-centered innovation outcomes (Roberts et al. 2021; Varvara et al. 2025).

6. Conclusion

This paper set out to examine whether clinical-trial evidence can support healthcare product development through design thinking. Using Type 2 Diabetes clinical-trial data and PLS-SEM, the study found that structured evidence strongly supports design thinking processes, that design thinking strongly supports healthcare product development, and that design thinking mediates the relationship between evidence and product-development outcomes.

Overall, the findings indicate that evidence-informed design thinking provides a promising pathway for more effective healthcare innovation. The framework offers a practical and theoretical basis for integrating structured clinical knowledge with human-centred innovation activity, while remaining sufficiently concise for conference discussion and further development.

The expanded version of the paper therefore presents the research as a complete conference contribution: it defines the problem, positions the theoretical gap, presents the conceptual framework, tests the model empirically and acknowledges the methodological limits of the data. This balance is intended to meet the conference requirements while still preserving the strongest elements of the full doctoral research paper.

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Ethics Declaration

Ethical clearance was not required for this study because the analysis used secondary structured clinical-trial data and did not involve direct contact with human participants or the collection of new personal data.

AI Declaration

AI-based language assistance tools were used in a limited way to support drafting and language refinement. The research design, conceptual development, data analysis, interpretation of findings and final verification of the manuscript were undertaken by the author.

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