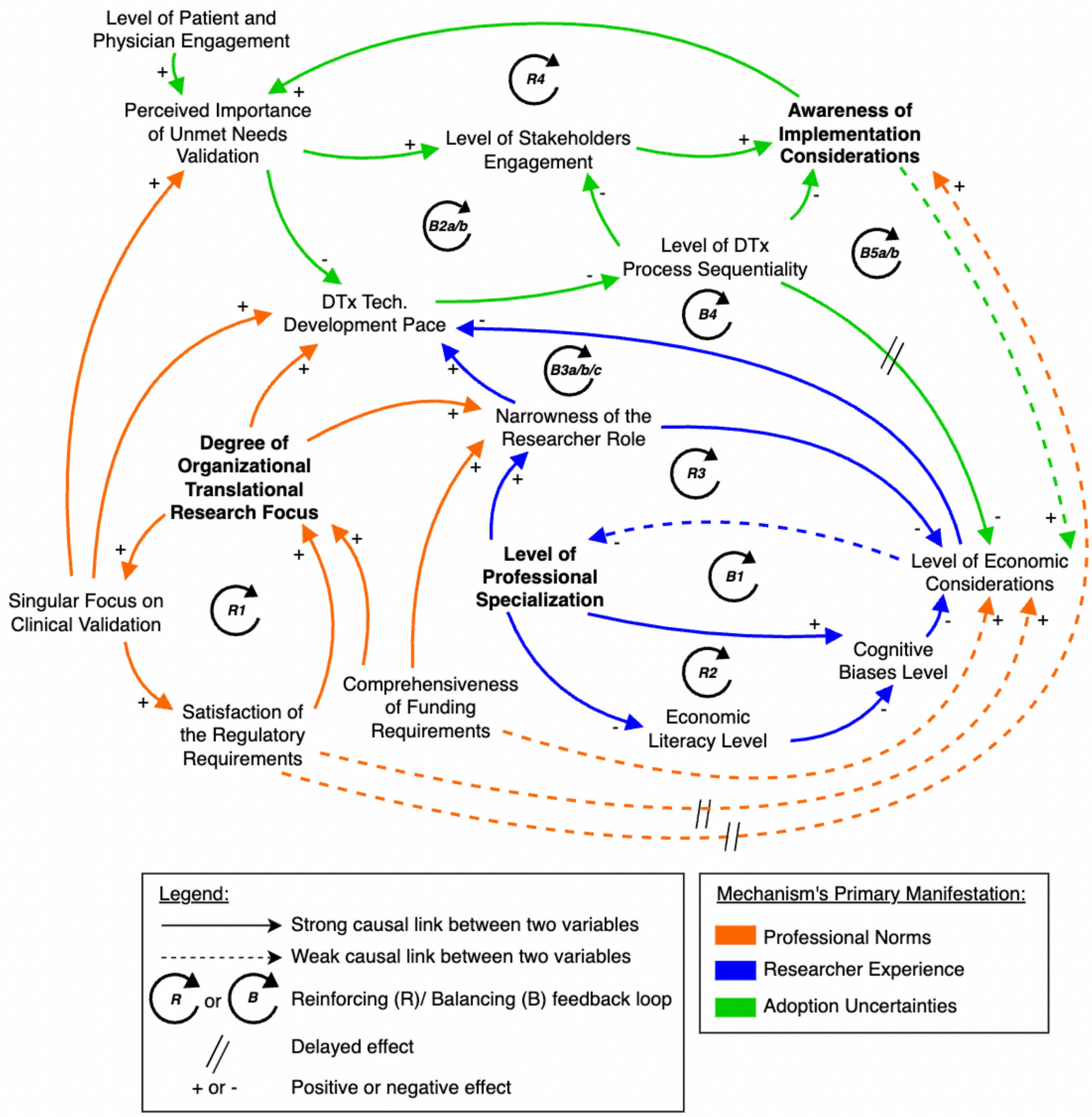
Generative Mechanisms Influencing Economic Decision Making in Digital Therapeutics Development

Yoann Sapanel; L. Martin Cloutier; Alec Morton;
Sapphire Lin; Gyula Seres; Dean Ho.

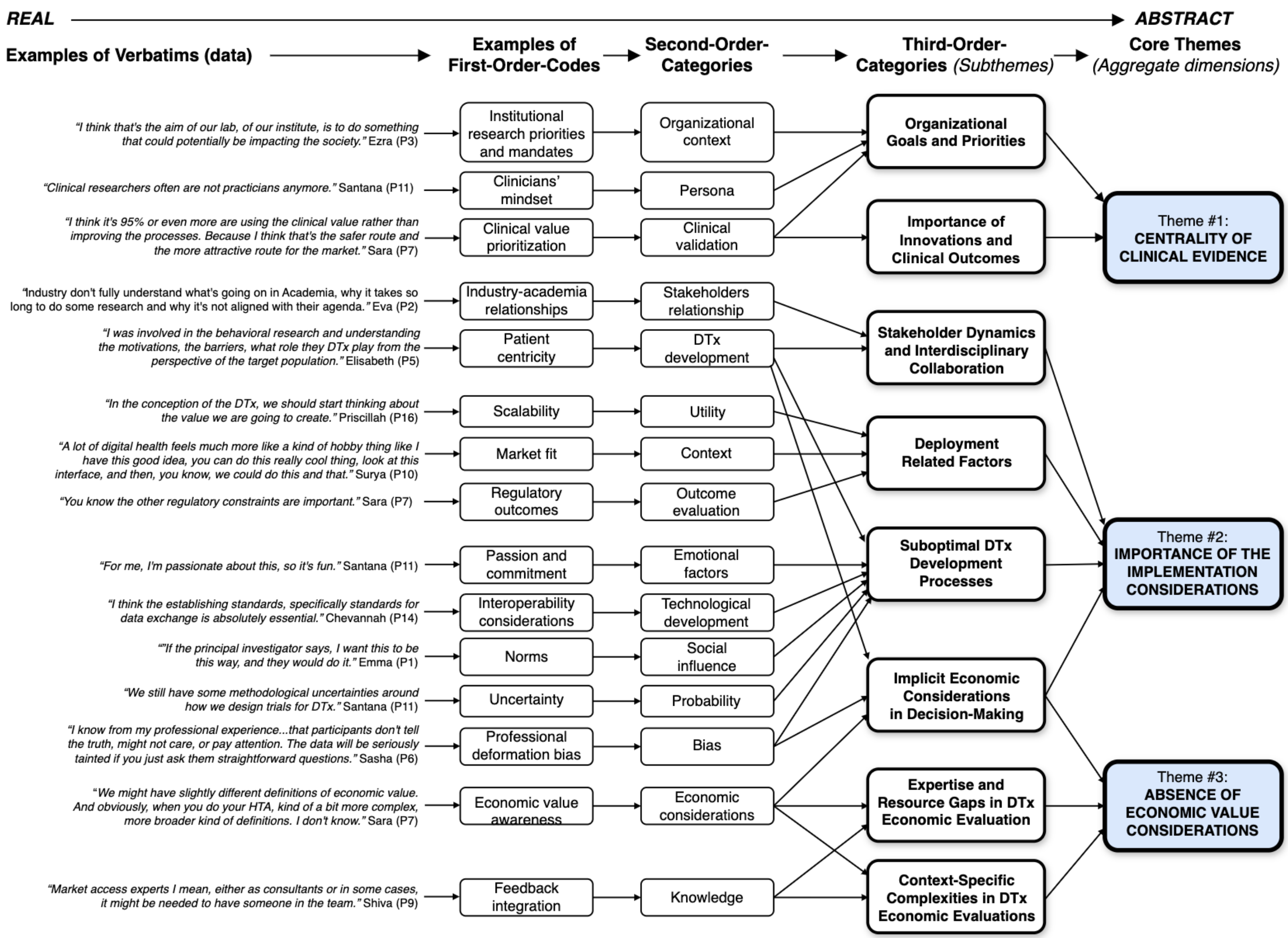
Supplementary Information

Contents (in article order):

Supplementary Fig. 1: Primary within-mechanism and secondary cross-mechanism loops in DTx development. The inclusion of six secondary loops (B3a/b/c, B4 and B5a/b) reflect the contingent effects within the model.



Supplementary Fig. 2: Verbatim to codes, subthemes, and themes. The figure illustrates the methodological progression from participant verbatim through concrete first-order codes to abstract themes, demonstrating Saldaña's "code weaving" principle of integrating empirical data into coherent theoretical constructs[1].



Supplementary Note 1: Integrated theoretical framework.

This supplementary note presents a comprehensive synthesis of the literature review that underpins the proposed theoretical framework guiding this study. The integration of Decision Theory (DT) and Systems Thinking (ST) within a Critical Realism (CR) paradigm provides robust analytical tools for examining complex decision-making processes in DTx development while informing the methodological approach employed in this research.

Critical realism

The study is grounded in CR, which provides a philosophical framework recognizing three interconnected domains of reality[2]:

- **Empirical**: This domain captures the perceptions, feelings and experiences of the researchers as they navigate the DTx development process. It represents only the most surface level of the observable reality.

- **Actual**: This domain refers to events or phenomena that occur, independently of the researchers' awareness or interpretation. While these events are concrete occurrences, they emerge from deeper causal powers.

- **Real**: This domain contains the causal mechanisms that generate observable events in the “actual” and shape experiences. These mechanisms operate whether they are activated or perceived, such as institutional pressures for commercialization manifested through performance metrics, underlying power dynamics between academic and commercial interests, or structural economic constraints that influence priorities. These mechanisms, while not directly observable, can be theoretically identified through their manifestation in events and experiences.

This approach enables exploration beyond surface-level patterns to identify deeper explanatory mechanisms shaping researchers' decision-making[3]. Recent research has also demonstrated CR particular relevance for social studies of health, illness, and medical settings[4,5], as well as in information systems research[6,7]. Having established CR as the research study’s philosophical foundation, the theoretical frameworks can now be examined more in-depth to understand how researchers navigate the complexities of DTx development.

Decision theory in healthcare innovation

DT provides a comprehensive foundation for analyzing complex choice-making processes under uncertainty – a central challenge in healthcare innovation. DT helps us understand both the observable patterns in researchers' choices and the underlying mechanisms generating them by drawing on principles from economics[8], psychology[9], statistics[10], and medicine[11]. In healthcare innovation, DT encompasses both normative and descriptive approaches[12].

Expected utility theory (EUT) - The normative component

EUT, developed by von Neumann and Morgenstern[13], offers valuable insights into optimal decision-making under uncertainty—a persistent challenge in healthcare[14,15]. EUT posits that individuals make decisions by evaluating the probability and utility (satisfaction or value) of each possible outcome. The theory expresses rational choice mathematically as the maximization of expected utility, calculated by multiplying the utility of each outcome by its probability, providing a weighted average of utility outcomes while accounting for inherent risks and uncertainties of DTx development. In healthcare, this manifests through structured evaluation frameworks like Health Technology Assessment (HTA), which provides a systematic approach to evaluating new technologies by weighing potential benefits against costs.

Despite its value, EUT faces several limitations in real-world healthcare settings[16]. The assumption of rationality conflicts with bounded rationality, as healthcare professionals often work with incomplete or ambiguous information. Precise utility quantification is challenging in healthcare's multidimensional outcomes. Multiple stakeholders with diverse interests challenge unified utility maximization. The theory also struggles to account for heuristic decision-making in healthcare practice[17]. These limitations suggest that while EUT provides valuable theoretical insights and a structured framework for decision analysis its practical application must be complemented by approaches that account for healthcare decision-making complexities.

Behavioral decision theory (BDT) - The descriptive component
BDT examines how researchers actually make decisions, acknowledging inherent human biases and limitations. Key concepts include bounded rationality[18,19], where decision-makers select satisfactory rather than optimal solutions under cognitive constraints; cognitive biases such as optimism bias[20], pro-innovation bias[21], and selection bias[22]; and heuristics as mental shortcuts used to navigate decisions under uncertainty[23,24].

BDT also has limitations in healthcare contexts. It may not fully capture institutional and systemic factors[25]. Regulatory frameworks often override individual behavioral tendencies. It may also underestimate the value of professional experience and domain expertise in healthcare settings[26].

As Desmond et al. note, decision-making in healthcare innovation encompasses various strategies employed under different circumstances[24]. The integration of normative and descriptive components creates a robust theoretical foundation that captures such complexity by defining optimal decision-making approaches while accounting for human tendencies and real-world complexities in healthcare innovation. This dual perspective is particularly relevant when examining how researchers navigate economic considerations in DTx development, where decisions emerge from an intricate balance between rational analytical approaches (EUT) and the inevitable influence of behavioral and contextual factors (BDT).

The synthesis of these theoretical frameworks informs the research approach by highlighting areas for investigation (Supplementary Table 1).

Supplementary Table 2: Relevance of decision theory in the context of the research question.

Theoretical Foundation	Core principles	Relevance to the Research Question
Expected Utility Theory (EUT)	• Rational decision-making based on utility maximization; • Systematic quantification of utility (e.g., health outcomes) through HTA; • Evaluation of risk and uncertainty.	• Provides a framework for rational decision-making under uncertainty, offering standardized approaches for generating and evaluating evidence; • Guides the evaluation of technological and clinical factors using economic models (such as HTA) to maximize utility and optimize health outcomes; • Informs decision-makers in resource allocation during technology development and validation.
Behavioral Decision Theory (BDT)	• Cognitive biases and decision heuristics; • Bounded rationality; • Contextual dependence of decisions.	• Cognitive biases may lead researchers to overestimate benefits or underestimate risks, skewing development decisions; • Affects how economic risks and clinical uncertainties are perceived, potentially influencing technology development and prioritization; • Highlights the importance of understanding the decision context and available information to distinguish between rational and satisfactory decision-making.

Systems thinking: Extending decision theory

While DT provides valuable insights into individual decision-making processes, it does not fully capture the complex, multi-stakeholder nature of healthcare innovation. ST offers a complementary framework that situates individual decision-making within broader systemic contexts[27].

ST provides, indeed, a robust framework for understanding complex, multi-level systems where technological, individual, organizational, and broader contextual factors interact dynamically, influencing researchers' decision-making processes and ultimately DTx development trajectories[28]. These interactions over time create emergent properties that cannot be understood by examining components in isolation, making ST particularly valuable for comprehending the complexity of researchers' decision-making processes in DTx development.

ST introduces several essential concepts: emergence, where system behaviors arise from interactions between components; non-linearity, where minor decisions can produce disproportionately large effects; feedback loops, where actions produce consequences that influence subsequent decisions; power dynamics, where asymmetries between stakeholders influence which considerations receive priority; and temporal dynamics, where development unfolds across multiple time horizons[29].

ST, particularly through system dynamics (SD) modeling, allows us to identify and analyze the varying temporal scales of feedback loops in DTx development. By incorporating temporal dynamics into the analysis, how the tension between short-term economic pressures and long-term value creation is navigated by researchers can be better understood.

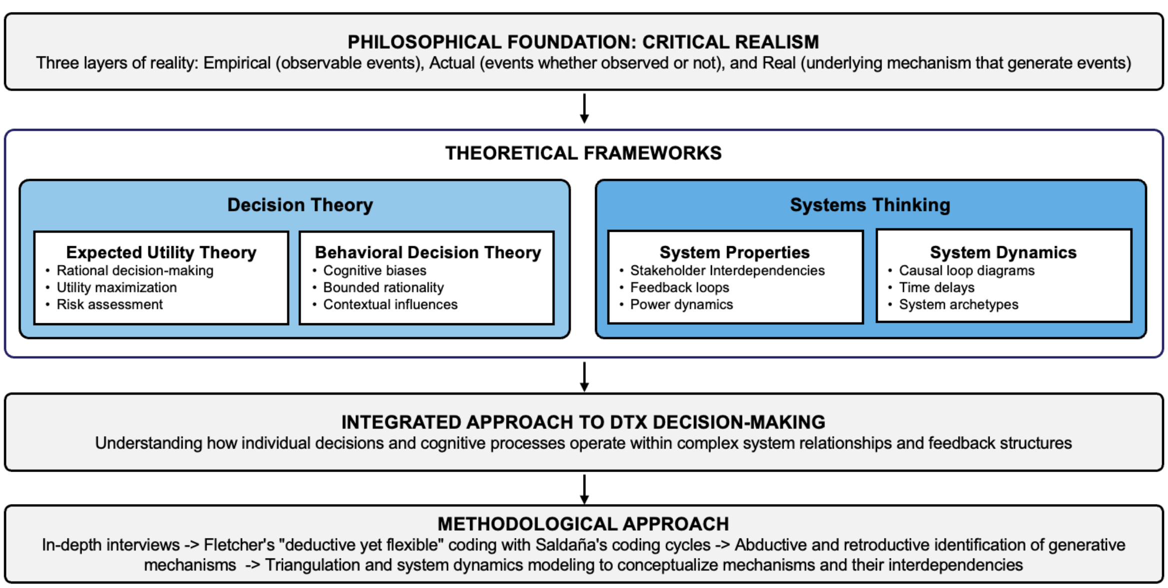
SD, a methodology within ST, offers structured approaches like Causal Loop Diagrams (CLDs) to map relationships and feedback loops between system elements. These tools help capture non-linear mechanisms and identify potential intervention points[27,30].

Theoretical framework synthesis

The complex, multi-stakeholder nature of DTx development requires robust theoretical grounding to understand researchers' decision-making processes. DT, through its dual components of EUT and BDT, provides a comprehensive framework for analyzing both the underlying mechanisms and contextual conditions that influence researchers' decision-making. ST offers a natural extension to DT by providing conceptual tools to understand how individual decisions both influence and are influenced by broader system structures.

As illustrated in Supplementary Fig. 3, this study's integrated theoretical framework combines DT with ST within a CR ontology to comprehend researchers' decision-making processes. This integrated approach enables us to identify not just what economic decisions are made, but how they emerge from complex interactions between individual cognitive processes, organizational structures, and environmental contexts. Such understanding is crucial for identifying potential intervention points and developing more effective strategies for economically sustainable DTx innovations that successfully navigate the complex pathway from concept to clinical implementation.

Supplementary Fig. 3: Integrated theoretical framework for researchers' decision-making in DTx development. This figure outlines an integrated theoretical framework for studying researchers' economic decision-making in DTx development, illustrating how the CR three layers of reality provide the philosophical foundation for combining DT and ST to understand how researchers' decisions operate within complex system relationships, ultimately informing a methodological approach.



Supplementary Note 2: Detailed results from steps 1 and 2 of data analysis.

This supplementary note summarizes the results from step 1 (Coding and identification of demi-regularities) and step 2 (Abductive reasoning process), as outlined in the data analysis methodology summary (Supplementary Table 2). These results informed the generative mechanisms retroduced in step 3, which are detailed in the Results section of the main paper.

Emerging core themes (step 1)

First, the centrality of clinical evidence emerged as the most prominent demi-regularity, quantitatively corroborated by the highest coding frequency for the "Clinical Validation > Clinical value prioritization" code across the transcript corpus. Despite EUT's prediction that researchers would systematically evaluate all value components, participants consistently steered discussions toward clinical considerations. The predominance of clinical considerations became particularly evident through researchers' implicit interpretations of key terminology. When participants employed terms, such as "validation" and "generating evidence," these consistently referenced clinical trials and clinical evidence generation rather than other forms of validation (technical or economic).

This clinically driven perspective extended to researchers' conceptualization of "value" of a DTx, which they predominantly viewed through the lens of clinical needs and safety/efficacy evidence. This pattern, which emerged consistently across clinician-researchers, was exhibited by most health systems and social science researchers and was frequently observed by practitioner-researchers. Notably, interviews with research engineers revealed a more nuanced pattern. Within this group, technological "performance" of the DTx, and what one participant termed "shiny engineering innovations" emerged as equally significant factors in their decision-making frameworks. This variation suggests a potential disciplinary influence on value assessment approaches within DTx research and development.

Second, implementation factors played a crucial role in development decisions, revealing tensions between rational planning and behavioral responses to uncertainty. Participants emphasized factors like "manpower utilization", "workflow integration," "care pathway changes", clinical team "productivity" impacts, and "acceptability" from both patients and care teams. As Cheah (P13) articulated, "*when you implement a [DTx] solution in a clinical setup, most likely it's not going to work out. Implementation is an issue, such as adherence and adoption of a technology*". Emma (P1) elaborated on this perspective: "*There's obviously the medical value of the DTx, but it's also the workflow fit, and the human factors more broadly considered. What is the patient journey, where the solution is going to fit, understand the physician's decision making, their involvement, are the nurses involved?*" Uncertainties surrounding implementation and adoption may foster risk-averse decision-making, potentially limiting innovation in traditionally conservative healthcare settings. Elisabeth (P5) emphasized the importance of balancing internal constraints to avoid "*overburdening some of the early thinking point*" and maintaining an innovative culture. This risk-aware approach could also drive more rigorous pre-implementation planning during early DTx development, including new frameworks for risk assessment and controlled experiments. The study findings revealed that researchers typically employ multiple validation approaches to address implementation uncertainties, including physician and patient consultations to comprehensively evaluate needs and perspectives as well as pilot studies and usability testing.

Third, the absence of economic value considerations in early development stages emerged as a consistent pattern, reflecting the BDT's concept of bounded rationality. With a single exception (Cheah, P13), both clinician-researchers and research-engineers consistently indicated that economic factors fell outside their priorities or perceived responsibilities. Researchers also expressed uncertainty about incorporating economic considerations into their DTx development processes. Cheah (P13) stood as the sole exception, noting: "*In our ongoing study, the cost-effectiveness of our model of care is the primary endpoint, and the secondary endpoints are actually the efficacy and safety to supplement prior evidence we have on those aspects.*" This systematic de-prioritization of economic considerations in the sample deviates from the EUT's prediction of comprehensive utility maximization, creating potential blind spots in decision-making.

These demi-regularities suggest a complex interplay between rational decision-making frameworks and behavioral influences, with interesting tensions between EUT predictions and BDT observations, shaping how researchers approach DTx development decisions.

Puzzling facts and plausible explanations (step 2)

The second step, following Sætre and Van de Ven four-step abductive reasoning approach[31], identified puzzling facts and provided plausible explanations for them. As discussed above, a key empirical finding was researchers' predominant focus on clinical evidence, either as a single priority or combined with technological performance considerations in DTx development. Surprisingly, researchers focused almost exclusively on clinical benefits, leaving little room for other forms of value evidence, particularly economic considerations or process-oriented categories (e.g., DTx that enhance self-management capabilities, support informed decision-making, or reduce healthcare access barriers). This finding contrasts with researchers' acknowledged importance of such factors for successful implementation[32], as well as with healthcare systems' evolution since 2006—from the "triple aim" of improving care, health, and cost to the "Quadruple Aim" framework that adds meaning at work[33]. Modern healthcare frameworks recognize that, given limited resources, the economic aspects of healthcare delivery cannot be separated from clinical considerations. Germany's Digital Health Applications (DiGA) framework exemplifies this integrated approach, legitimizing "*patient-relevant improvements in structure and process*" alongside direct medical benefits when evaluating DTx for market approval[34].

The dominance of clinical evidence permits multiple theoretical interpretations. At its core, it likely reflects a deeply embedded institutional logic within healthcare, where clinical outcomes have historically served as the foundation of medical decision-making. Organizational structures and research priorities—whether oriented toward pure or translational research—may also influence researchers' decision-making patterns.

Participants viewed economic considerations as outside their domain of expertise, expressing uncertainty regarding economic evaluations and their inherent complexity for DTx. This represents a form of constrained utility maximization where researchers optimize within familiar domains rather than across all value dimensions (clinical, technical, and economic). This selective optimization contrasts with EUT's prediction of comprehensive value assessment and maximization but aligns with BDT's concept of bounded rationality. While researchers wanted "their" DTx to be of use, their tendency toward "familiarity" was observed —defaulting to clinical metrics rather than pursuing comprehensive value assessments—and “satisficing behavior,” choosing the first option that meets minimum acceptability levels. As articulated by Camirah (P15): “*We tried doing some form of costing analysis, but we are not sure whether we are holistic enough in presenting the project costings to higher management. So that's something we are still struggling with. We may be throwing money into the ocean…*”

The systematic deprioritization, or absence, of economic considerations throughout DTx development, may be attributed to a lack of awareness of their importance at individual and/or institutional levels, especially in later stages of the DTx process, for implementation, adoption and for potential reimbursement decision. It can also be hypothesized that researchers were led back to more familiar domains by a certain level of economic literacy limitations in the interview sample. Moreover, most researchers conceptualized the DTx process as linear and chronological or sequential, with a stepwise approach. This sequential decision-making framework may explain the deferral of economic considerations to later stages, further supporting the use of heuristic decision-making strategies outlined in the BDT framework.

Researchers consistently reported uncertainty surrounding DTx implementation and adoption as a potential “barrier” or “complexity,” which led to the second major theme discussed above. Their acknowledgment of these aspects as significant threats to DTx success was surprising (to the research study team). Although researchers reported that economic elements did not enter their decision-making process, many of the implementation-related aspects they did consider correspond to direct and indirect medical and non-medical costs associated with DTx in HTA terminology. Indeed, the pattern of implementation prioritization aligns with important domains in HTA frameworks[35–37]. Although researchers reported limited consideration of economic factors throughout DTx development, the findings suggest, therefore, that certain aspects of DTx economic value may be more thoroughly integrated throughout DTx development than either articulated by the researchers or previously evidenced[32].

In conclusion, the abductive analysis revealed key puzzling facts in DTx researchers' decision-making processes, suggesting a complex interplay between institutional logics, individual expertise boundaries, and conceptual frameworks. This abductive step provided plausible explanations for these phenomena, which are further examined in the retroductive step (step 3) of the analysis (see Results section) to develop a deeper understanding of the underlying mechanisms and structures influencing DTx researchers' decision-making patterns.

Supplementary Note 3: Saldaña's cycles of coding methodology.

The first coding cycle employed descriptive and in vivo coding methods to identify first-order codes that preserved participants' original language and captured basic descriptive elements of the data. This process led to the development of new codes, while some existing codes were combined or refined to better reflect participants' experiences. For example, “Knowledge > Patient Feedback Integration” was broadened to “Knowledge > Feedback Integration” to reflect participants' frequent reports of consulting physicians, nurses, and specialists. The notion of DTx adoption emerged early as a potentially important factor throughout the DTx process, leading to the creation of the “Implementation > Adoption” code. Through this iterative coding process, the framework expanded from 58 provisional codes to 78 distinct codes (Supplementary Table 7), demonstrating the iterative nature of the coding process[38]. Throughout this process, detailed notes for each interview transcript were maintained, documenting key discussion points, interpretations, potential participant quotes and changes to the codebook.

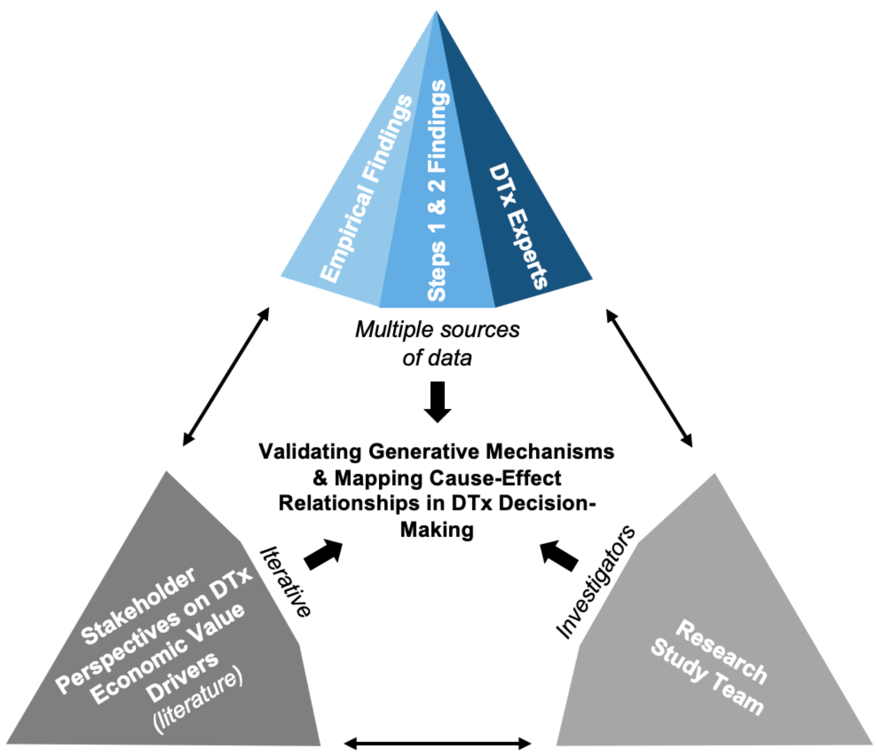
These first-order codes were then aggregated during the second coding cycle using pattern coding and focused coding techniques to develop more conceptual second-order categories that represented broader analytical groupings. For example, several first-order codes, such as “Economic value awareness,” “Business model,” and “Clinical validation costs” were synthesized into the second-order category, “Economic considerations.”

This progression from participant verbatim, through concrete first-order codes, to abstract themes followed Saldaña's principle of “code weaving”, where codes were integrated into a coherent analytical narrative that connected empirical observations with theoretical constructs[1] (Supplementary Note 3 and Supplementary Fig. 2).

Supplementary Note 4: Triangulation approach to validating mechanisms and mapping cause-effect relationships in DTx decision-making.

To conceptualize these mechanisms and elucidate their interdependencies through a CLD, an iterative three-step process was implemented to: (1) identify influencing variables, (2) map relationships and assign polarity, and (3) validate and refine the model. Throughout each phase, three distinct categories of unit triangulation were incorporated[39], as shown in Supplementary Fig. 4 and detailed below.

Supplementary Fig. 4: Implementation of triangulation methodology for CLD construction in DTx decision-making. This figure illustrates the approach combining multiple sources of data, iterative, and investigator triangulation to systematically validate the generative mechanisms and their relationships throughout the three-phase CLD construction process.



Step 1: Variable identification

The data triangulation involved comparing **multiple sources of data**, including the study's empirical findings from both steps 1 and 2, to identify potential variables and their relationships influencing researchers' decision-making processes. The extraction of variables and their relationships from the research data incorporated both explicit participant statements about causal relationships and pattern analysis across interviews to ensure comprehensive relationship mapping. Each potential relationship was systematically evaluated against three evidence criteria: (1) explicit mention in participant interviews, (2) support in existing literature, and (3) logical consistency with decision-making theory. Relationships meeting at least two criteria were included in the model.

Step 2: Relationship mapping and polarity assignment

In parallel with variable identification, **iterative triangulation** was employed through systematic comparisons with literature findings, including the authors' previous work, which had established both variables and causal relationships among eight clusters of factors influencing DTx economic value[32]. This methodological approach enabled critical comparative analysis between existing literature and refined conceptualization of variables influencing researchers' decision-making processes, and their interdependencies, leading to a CLD for each of the three generative mechanisms (Figs. 1 to 3).

Relationship polarities (positive or negative) were established by analyzing directional influence between variables, supported by literature citations and participant quotes. Positive relationships indicate that variables move in the same direction—both increasing or both decreasing together. Negative relationships indicate opposite movements. Relationship strength (strong or weak) was determined by analyzing the frequency and emphasis of these connections within the data.

Feedback loops were identified through manual loop tracing—specifically by tracing paths through the causal network diagram and identifying where variables connect back to themselves through a series of relationships. Common system archetypes that appear frequently across different domains were also sought, such as "limits to growth" or "fixes that fail," with consideration given to the characteristics of their feedback structures[40–42]. Each loop was categorized as either reinforcing (R) or balancing (B) based on the product of polarities along the loop. Reinforcing loops amplify change in a consistent direction, creating exponential growth or decline patterns, while balancing loops counteract change and tend toward stability or equilibrium. Each loop was named according to its primary function within the system, with documentation of its constituent variables and potential impact on system behavior.

Step 3: Model validation and refinement

To validate and refine the model, as new versions of the CLDs emerged, they were discussed with the research study team through **investigator triangulation** to analyze and interpret findings, including reviewing codes when needed to ensure convergence. As part of the iterative process, discussions with three DTx experts who met the study inclusion criteria but were outside the original sample were scheduled at different time intervals to interpret, validate, and refine emerging versions of the individual mechanisms CLD (Figs. 1 to 3), which over time converged into a single integrated refined CLD (Fig. 3), illustrating the generative mechanisms and their manifestations shaping economic considerations in DTx development.

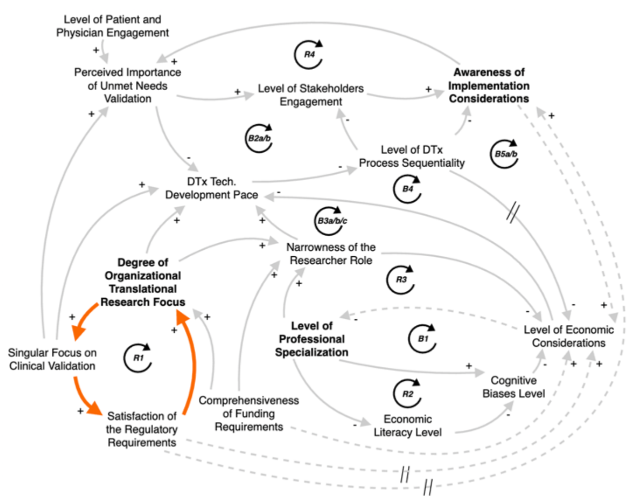
Supplementary Table 2: Data analysis methodology summary.

Step	Description	Results
1. Coding and identification of demi-regularities	• Creation of a "deductive yet flexible" coding framework combining DT concepts with DTx literature, while effectively capturing CR's stratified ontology[38]. • Application of both deductive and inductive coding using ATLAS.ti software. • Implementation of Saldaña's cycles of coding methodology for systematic data analysis[1]. • Adoption of Fletcher's approach to identify recurring patterns (demi-regularities) at the CR real level[38].	• Expansion of the initial codebook from 58 to 78 distinct codes, as detailed in Supplementary Table 7. • Identification of three core themes as illustrated in Supplementary Fig. 2. and Supplementary Table 8: (1) centrality of clinical evidence, (2) importance of implementation considerations, and (3) absence of economic value consideration.
2. Abduction	• Implementation of Sætre and Van de Ven four-step abductive reasoning approach[31]: (1) observing puzzling facts in researchers' decision-making patterns, (2) confirming these anomalies with empirical evidence, (3) formulating explanatory hypotheses, and (4) evaluating alternative explanations.	• Iterative analysis of empirical data and theoretical literature revealed two puzzling patterns in researchers' decision-making: (1) strong prioritization of clinical evidence while consistently deprioritizing economic considerations (despite acknowledging their importance), and (2) significant focus on implementation factors that actually align with economic value domains in HTA frameworks, despite researchers' claims of neglecting economic considerations.
3. Retroduction	• Investigation of causal mechanisms using Danermark's framework[8]. • Analysis of dependencies and interactions between the identified mechanisms, validated via three complementary triangulation methods (data, iterative, and investigators). • Visualization of complex relationships through SD and CLDs.	• Recognition of three primary generative mechanisms: (1) the *Professional Norms*, (2) the *Researcher Experience*, and (3) the *Adoption Uncertainties*. • Developed CLDs for each mechanism (Figs 1 to 3), mapping the variables and potential causal links, which ultimately converged into an integrated single model (Fig. 3) explaining the interactions between identified mechanisms and their influence on DTx decision-making.

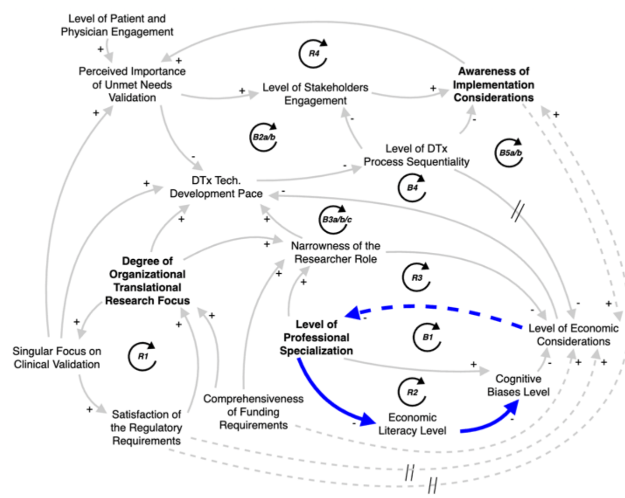
Supplementary Table 3: Overview of individual primary and secondary balancing and reinforcing loops in the CLD.

Primary within-mechanism loops

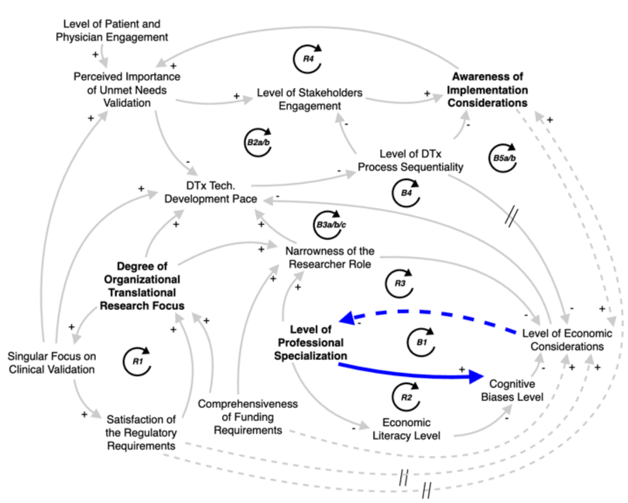
R1. Clinical Value Loop



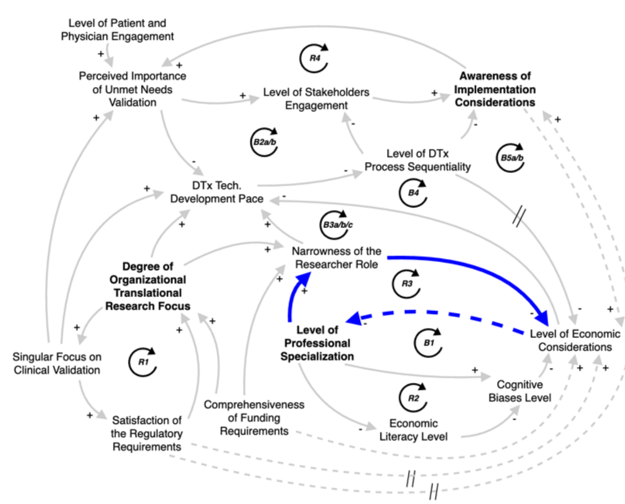
R2. Literacy Loop



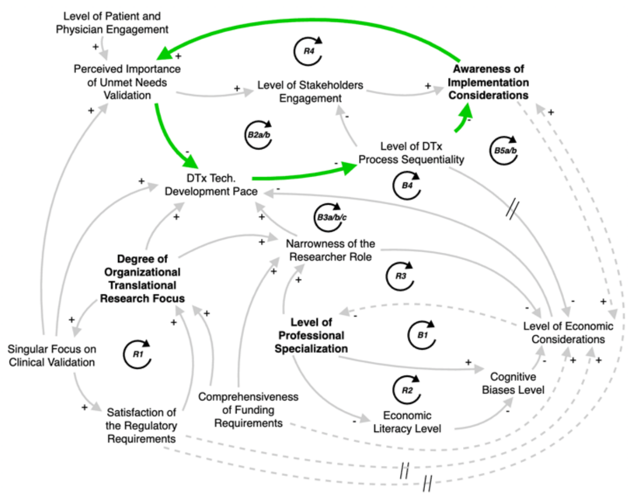
B1. Bias Loop



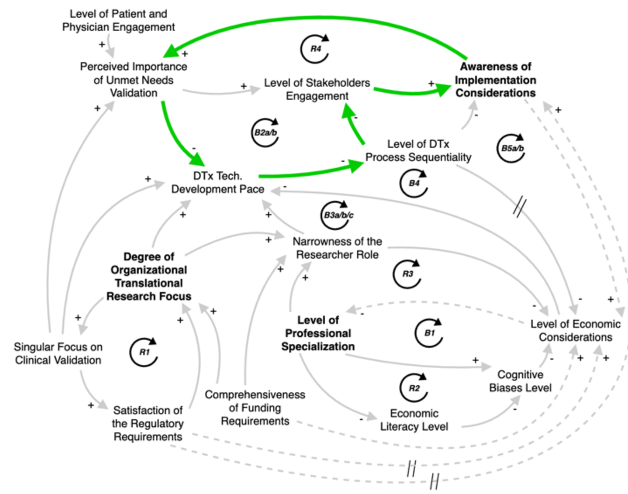
R3. Role Boundary Loop



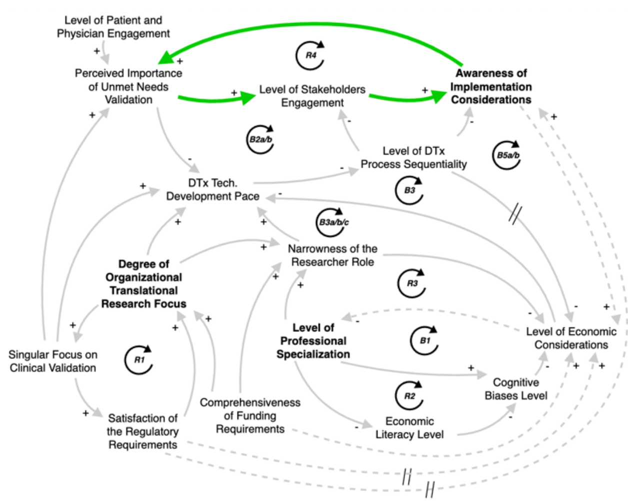
B2a. Implementation-Driven Development Loop



B2b. Stakeholder-Driven Development Loop

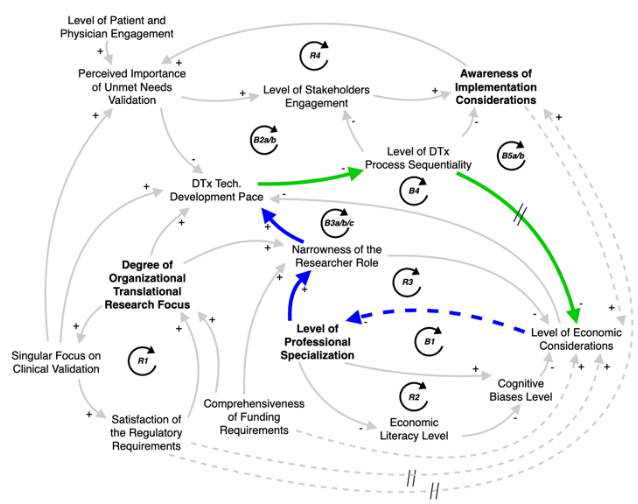


R4. Collaboration Loop

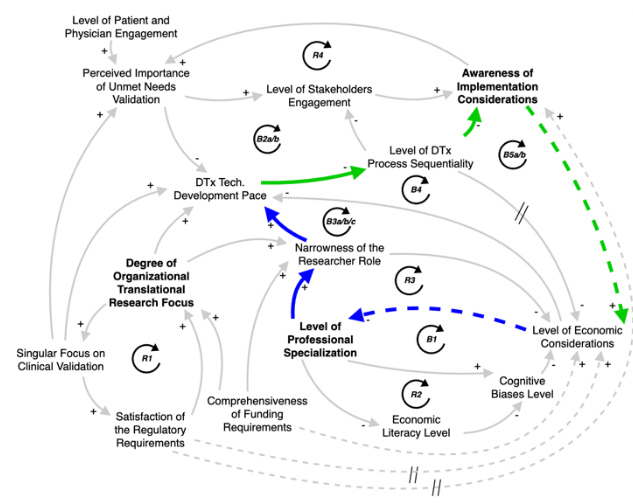


Secondary cross-mechanism loops

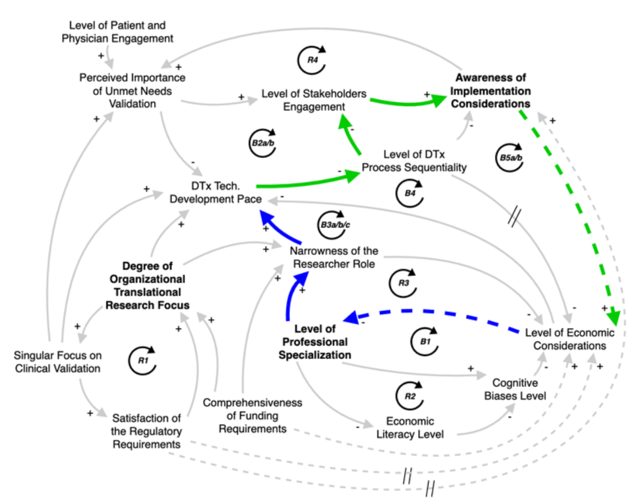
B3a. Specialization-Technology Loop



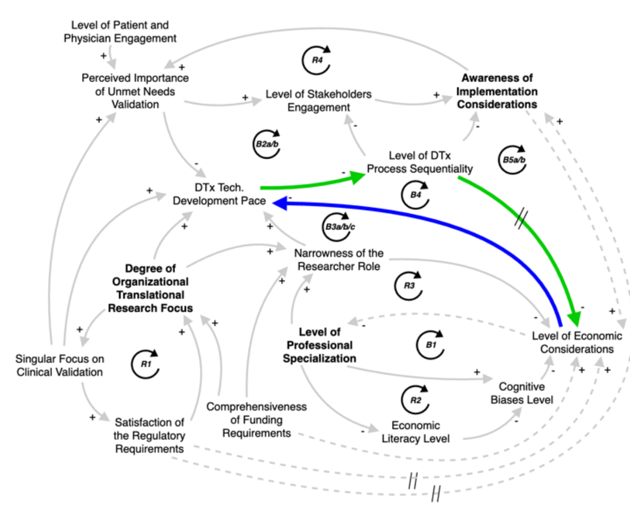
B3b. Implementation-to-Specialization Loop



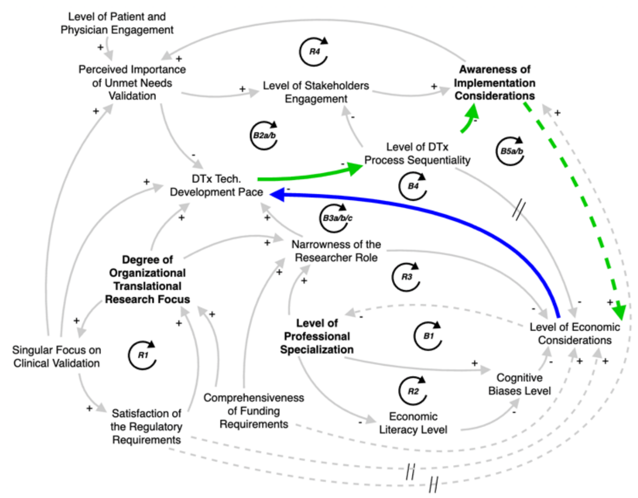
B3c. Stakeholder-Guided Implementation-to-Specialization Loop



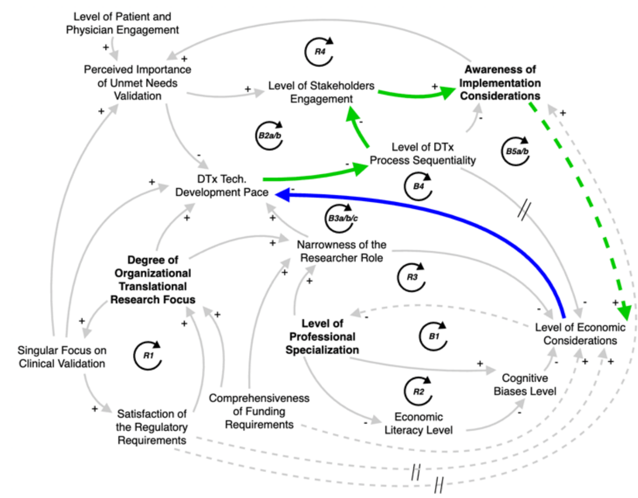
B4. Development Efficiency Loop



B5a. Implementation-Economic Development Loop



B5b. Stakeholder-Informed Implementation-Economic Loop



Supplementary Table 4: Demographic data of study participants.

Pseudonym[a] *(participant number)*	Field of practice	Experience across the DTx lifecycle[b]			Years of experience	Setting *(country)*	Gender	Education
		1	2	3				
RESEARCH-ENGINEERS								
Emma *(P1)*	Biomedical engineering	x	x	x	> 10	Public academic institution *(Singapore)*	F	Ph.D.
Eva *(P2)*	Biomedical engineering	x	x	x	> 10	Public academic institution *(USA)*	F	Ph.D.
Ezra *(P3)*	Biomedical engineering	x	x		> 5	Public academic institution *(Singapore)*	M	Ph.D.
Eisa *(P4)*	Biomedical engineering	x	x		> 5	Public academic institution *(Singapore)*	M	Ph.D.
Elisabeth *(P5)*	Neuroengineering	x	x	x	> 10	Private healthcare organization *(Switzerland)*	F	Ph.D.
HEALTH SYSTEMS AND SOCIAL SCIENCE RESEARCHERS								
Sasha *(P6)*	Behavioral sciences			x	> 10	Public academic institution *(Singapore)*	M	Ph.D.
Sara *(P7)*	Healthcare management			x	> 10	Public academic institution *(Germany)*	F	Ph.D.
Senna *(P8)*	Health policy		x	x	> 5	Public academic institution *(United Kingdom)*	M	Ph.D.
Shiva *(P9)*	Health policy	x	x		> 5	Public academic institution *(Singapore)*	M	Ph.D.
Surya *(P10)*	Health economics	x	x	x	> 20	Public academic institution *(United Kingdom)*	M	Ph.D.
Santana *(P11)*	Health economics		x	x	> 10	Public academic institution *(Germany)*	M	Ph.D.
CLINICIAN-RESEARCHERS								
Christoph *(P12)*	Neuropsychology		x	x	> 20	Private healthcare provider *(Australia)*	M	Ph.D.
Cheah *(P13)*	Ophthalmology	x	x		> 10	Public healthcare provider *(Singapore)*	M	Ph.D.
Chevannah *(P14)*	Cardiology	x		x	> 10	Private healthcare organization *(Germany)*	F	Ph.D.
Camirah *(P15)*	Nursing	x	x		> 5	Public healthcare provider *(Singapore)*	F	Ph.D.
PRACTITIONER-RESEARCHERS								
Priscillah *(P16)*	Technology implementation	x	x	x	> 20	Public healthcare provider *(Canada)*	F	M.Sc.
Priyah *(P17)*	Technology implementation	x	x	x	> 15	Public healthcare provider *(Singapore)*	F	Ph.D.

[a] The pseudonyms are designed to convey key information about each participant. The first letter indicates their role: 'E' for research-engineers, 'S' for health systems and social science researchers, 'C' for clinician-researchers, and 'P' for practitioner-researchers. The last letter denotes their current work setting: 'A' for academic organization, and 'H' for healthcare providers or organizations (either private or public). The gender of the pseudonym corresponds to the participant's sex. For instance, the pseudonym "Christoph" (P12) signifies a male clinician-researcher working in a healthcare organization or provider.

[b] Phase 1 encompasses the technological development of the DTx intervention, followed by phase 2, the clinical validation of the DTx intervention through clinical trials, and finally phase 3 corresponds to the implementation of the DTx intervention in a real-world environment.

Supplementary Table 5: COREQ checklist.

Item No	Guide Questions/Description	Comment
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Interviewer/ facilitator	Which author/s conducted the interviews?	YS conducted the semi-structured interviews.
2. Credentials	What were the researcher's credentials?	YS holds an M.Sc. in Entrepreneurship and Strategic Management and is a doctoral student researching economic value drivers for DTx. LMC has a Ph.D. in Strategic Management and Applied Economics and conducts research in Information Technology management. AM holds a Ph.D. in Management Science, specializing in decision analysis and operations research, with expertise in healthcare decision-making and health economics. DH holds a Ph.D. in Biomedical Engineering, SL in Communication and Information, and GS a Ph.D. in Economics.
3. Occupation	What was their occupation at the time of the study?	YS served as a Director at the Institute of Digital Medicine (WisDM), National University of Singapore, while LMC was a Professor in the Department of Analytics, Operations, and Information Technologies, School of Management Sciences, at the University of Quebec at Montreal, Canada. DH was the Provost's Chair Professor, Director of the Institute for Digital Medicine (WisDM), Director of the N.1 Institute for Health, and Head of the Department of Biomedical Engineering at the National University of Singapore. AM holds joint appointments at the National University of Singapore, Duke-NUS and the University of Strathclyde. SL and GS are both research fellows at the Institute of Digital Medicine (WisDM), National University of Singapore.
4. Gender	Was the researcher male or female?	One woman-identifying researcher and five male-identifying researchers.
5. Experience and training	What experience or training did the researchers have?	YS, LMC, AM, SL, GS, and DH have extensive experience in conducting qualitative health research. Additionally, YS, LMC, and DH have recently published relevant papers to the research question. LMC teaches research methods in the areas of information technology. AM focuses on developing methodologies for supporting complex healthcare resource allocation and policy decisions, having made significant contributions to health technology assessment and healthcare prioritization. SL and GS specialize in decision-making and behavior changes in health and public policy.
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	YS and DH had varying relationships with the health community at large, while LMC, AM, SL, and GS had no relationships with participants prior to the study. All were perceived as unbiased researchers rather than persons with a particular stake, stance or opinion about the topic.
7. Participant knowledge of the interviewer	What did the participants know about the researcher?	The interviewers introduced themselves to participants and describing the context, scope and purpose of the research, going through the different sections of the consent form. The contents followed the exact guidelines as certified by ethics review boards for research with human beings of all institutions involved.
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator?	The participants were informed of the knowledge gap and corresponding research question as context for the interview, highlighting the interviewers' interest in addressing this gap without presenting specific assumptions or potential biases. The contents followed the exact guidelines as certified by ethics review boards for research with human beings of all institutions involved.
Domain 2: study design		
Theoretical framework		

Item No	Guide Questions/Description	Comment
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study?	Critical realism was established as the study's philosophical foundation. Theoretical frameworks such as DT and ST were introduced to examine and interpret how researchers navigate the complex choices involved in DTx development.
Participant selection		
10. Sampling	How were participants selected?	Purposive sampling was used. Initial recruitment occurred through the research team's professional network, with participants encouraged to refer qualified colleagues through snowball sampling.
11. Method of approach	How were participants approached?	Email invitations were sent to individuals who could potentially meet the following inclusion criteria: (1) a minimum of five years of experience in DTx development or clinical validation, (2) current involvement in the technological development or clinical validation of a DTx, (3) fluency in English or French. The recruitment process followed the exact guidelines as certified by ethics review boards for research with human beings of all institutions involved.
12. Sample size	How many participants were in the study?	17 Participants. For details of the study participants' demographic data, please refer to Supplementary Table 4.
13. Non-participation Setting	How many people refused to participate or dropped out? Reasons?	While several individuals did not respond to the invitation, nobody explicitly declined the invitation. All those who agreed to participate remained committed throughout the study. This followed the exact guidelines as certified by ethics review boards for research with human beings of all institutions involved regarding participants' informed consent and right to withdraw without justification.
14. Setting of data collection	Where was the data collected?	Data were collected through either Zoom or face-to-face interviews and analyzed using ATLAS.ti software (ATLAS.ti Scientific Software Development GmbH).
15. Presence of nonparticipants	Was anyone else present besides the participants and researchers?	None.
16. Description of sample	What are the important characteristics of the sample?	Fully presented in Supplementary Table 4.
Data collection		
17. Interview guide	Were questions, prompts, and guides provided by the authors? Was it pilot tested?	A semi-structured interview guide with key questions was designed to explore topics including: (1) participants' roles as DTx researchers, (2) their priorities and key considerations throughout the DTx lifecycle, and (3) day-to-day prioritization and decision-making processes. Please refer to Table 3 for details of the topics discussed.
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	No.
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	All interviews were audio-recorded and later transcribed. This followed the exact guidelines as certified by ethics review boards for research with human beings of all institutions involved in data management procedures during the research, during the analysis, and post-reporting.
20. Field notes	Were field notes made during and/or after the interview or focus group?	Following each interview, the interviewer documented brief notes highlighting the interview's nature and key themes emphasized by the interviewee.
21. Duration	What was the duration of the interviews or focus group?	Interview duration varied but typically ranged from 45 to 60 minutes.
22. Data saturation	Was data saturation discussed?	Yes.

Item No	Guide Questions/Description	Comment
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No.
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	The interviewer coded and described the data, regularly discussing the resulting codes with the research study team. The analysis combined deductive and inductive coding, followed by abductive and retroductive processes, to identify generative mechanisms underlying observed decision-making patterns.
25. Description of the coding tree	Did the authors provide a description of the coding tree?	Yes. Please refer to Supplementary Fig. 2 for the verbatim to codes, subthemes, and themes developed through Fletcher's "deductive yet flexible" coding[38] with Saldaña's coding cycles[1].
26. Derivation of themes	Were themes identified in advance or derived from the data?	Derived from the data.
27. Software	What software, if applicable, was used to manage the data?	ATLAS.ti software (ATLAS.ti Scientific Software Development GmbH).
28. Participant checking	Did participants provide feedback on the findings?	Discussions were scheduled with three DTx experts at different time intervals who met the study inclusion criteria but were outside the original sample to interpret, validate, and refine emerging versions of the CLD.
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified?	Yes.
30. Data and consistent findings	Was there consistency between the data presented and the findings?	SD modeling was applied to visualize causal relationships through triangulated data sources, ultimately aiming to achieve a higher degree of internal and external validity, strengthening confidence in the findings.
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes, major themes are clearly identified in the paper, as well as the generative mechanisms underlying observed researchers' decision-making patterns.
32. Clarity of minor themes	Is there a description of diverse cases or a discussion of minor themes?	No.

Supplementary Table 6: Interview topic guide.

Topics	Guiding topics for discussion
Background and Opening Topics	• Professional background and role in DTx development • Current DTx project(s) context and stage • Professional training influences on economic decision-making approaches
Understanding of Economic Value *(Real to Actual Domain)*	• Personal understanding of DTx economic value • Experience with economic decision-making in DTx projects • Key considerations, priorities and decision-making drivers that guide DTx development • Organizational context and constraints
Contextual Conditions *(Actual Domain)*	• Market and regulatory environment • Resource availability and limitations • Stakeholder collaboration, influences and pressures • Organizational incentives and their influence • How uncertainty affects decision-making processes
Practical Implementation *(Empirical Domain)*	• Specific examples of economic decisions made • Implementation challenges and solutions • Success metrics and evaluation methods • Lessons learned from past decisions • Trade-offs between competing priorities • Balancing clinical versus economic considerations • Role of experience in decision-making • Group decision-making dynamics
Reflection on Practice	• Perceived effectiveness of current decision-making approaches • Challenges in translating economic considerations into practice • Tools or support needed for better decision-making • Recognition of potential biases or limitations • Evolution of the decision-making approach over time
Closing	• Additional thoughts on economic value considerations • Recommendations for other researchers • Reflections on ideal versus actual decision-making processes

Supplementary Table 7: Final codebook.

Number	Code Category	Code	Frequency	Short description	Primary Sources
1	Bias >	Anchoring	7	Anchoring to initial estimates, that is, researchers' tendency to rely potentially too heavily on the first piece of information they encounter when making decisions.	DT > BDT based CR > Cognitive constraints
2	Bias >	Availability heuristic	2	Related to the tendency to overestimate the likelihood of events based on how easily they come to mind.	DT > BDT based CR > Cognitive constraints
3	Bias >	Confirmation bias	7	Researchers' tendency to search for, interpret, and recall information in a way that confirms existing beliefs.	DT > BDT based CR > Cognitive constraints
4	Bias >	Cultural	1	Influence of cultural background and values on research decisions and interpretations.	Code emerged from Chevannah's (P14) transcript analysis
5	Bias >	Loss aversion	-	Related to the tendency to prefer avoiding losses over acquiring equivalent gains.	CT > BDT based CR > Cognitive constraints
6	Bias >	Other	7	Miscellaneous cognitive biases affecting research decisions that do not fit into other specific categories.	Code emerged from Eisa's (P4) transcript analysis
7	Bias >	Overconfidence	14	Related to the tendency to overestimate one's own abilities, knowledge, and accuracy of predictions.	DT > BDT based CR > Cognitive constraints
8	Bias >	Professional training	21	Impact of professional education and experience on DTx development processes and related decisions.	Code emerged from Eva's (P2) transcript analysis
9	Clinical validation >	Clinical value prioritization	150	Focus on generating evidence of DTx safety, efficacy, and health benefits.	Literature Review CR > Actual Domain
10	Clinical validation >	Clinical trial results	37	Documented outcomes demonstrating DTx safety and efficacy from trials.	Literature Review CR > Empirical Domain
11	Clinical validation >	Participant selection	5	Criteria for choosing appropriate study participants for clinical validation.	Literature Review CR > Actual Domain
12	Clinical validation >	Study design decisions	20	Methodological choices for validation, including outcome measure selection.	Literature Review DT > EUT based CR > Actual Domain
13	Context >	Healthcare system characteristics	10	Structural aspects of healthcare systems affecting DTx implementation.	Code emerged from Cheah's (P13) transcript analysis
14	Context >	Market fit	42	DTx's ability to address significant clinical needs in the target market.	Literature Review
15	Context >	Regulatory influence and considerations	67	Impact of potential (or the absence of) guidelines, standards, and requirements on DTx development.	Literature Review CR > Real Domain
16	Context >	Reimbursement considerations	42	Planning for payment and coverage mechanisms.	Literature Review DT > BDT based
17	Context >	Resource-related considerations	102	Constraints in funding, time, expertise, and other development resources (e.g., missing information or expertise needed for	Literature Review DT > BDT based CR > Cognitive constraints

				development Knowledge gaps). Defined as constraints on Agency, under CR.	
18	Context >	Decision-making >	28	Environmental and situational factors influencing decision processes.	Code emerged from Ezra's (P3) transcript analysis
19	DTx development >	Access	7	Considerations related to ensuring equitable access to the DTx solution across user populations.	Code emerged from Chevannah's (P14) transcript analysis
20	DTx development >	Diversity of stakeholders	104	Involvement of varied stakeholders in the DTx development process.	Code emerged from Emma's (P1) transcript analysis
21	DTx development >	Patient centricity	45	Focus on incorporating patient needs, preferences, and experiences throughout the DTx development process, ensuring the solution addresses real patient challenges and promotes engagement.	Code emerged from Emma's (P1) transcript analysis
22	DTx development >	Patterns	4	Recurring approaches in development processes and decision-making.	CR > Empirical Domain
23	DTx development >	Process	142	Stages of technological innovation and development.	Code emerged from Emma's (P1) transcript analysis
24	Eco. consideration >	Long-term costs	10	The long-term impact of DTx onto society.	Code emerged from Christoph's (P12) transcript analysis
25	Eco. consideration >	Business model	70	Strategy for DTx monetization and market deployment.	Literature Review
26	Eco. consideration >	Clinical validation costs	6	Expenses for trials, recruitment, data collection, and analysis.	Literature Review
27	Eco. consideration >	Development costs	14	Expenses for initial creation and iterative improvements of the DTx.	Literature Review DT > EUT based
28	Eco. consideration >	Direct medical and non-medical costs	54	Including costs of pharmaceutical treatment, of the DTx, health resource utilization, intervention-specific training, and participants' time spent on the DTx.	Literature Review DT > EUT based
29	Eco. consideration >	Eco. prioritization	94	Emphasis on economic considerations in development.	Code emerged from Eva's (P2) transcript analysis
30	Eco. consideration >	Economic value awareness	145	Researchers' understanding of the concept of economic value (e.g., strategies implemented to ensure economic viability of the DTx)	Literature Review
31	Eco. consideration >	Economic evaluation methods	66	Approaches for assessing DTx cost-effectiveness and value, such as cost-benefit analysis (CBA), cost-effectiveness analysis (CEA), or cost-utility analysis (CUA).	Literature Review DT > EUT based > HTA
32	Eco. consideration >	Funding sources	15	Available financial resources for DTx development.	Literature Review CR > Real Domain
33	Eco. consideration >	Implementation related	114	Awareness of practical deployment considerations, such as clinical workflow integration, provider training needs, or support requirements.	Literature Review DT > EUT based
34	Eco. consideration >	Indirect medical and non-medical costs	37	Including costs related to the productivity impact and DTx maintenance.	Literature Review DT > EUT based

35	Eco. consideration >	Influencing factors	16	Including participants' baseline characteristics, reimbursement rate, treatment adherence, attrition rate, degree of clinical inertia and sustained DTx clinical effectiveness.	Literature Review
36	Emotional factors >	Confidence	6	Self-assurance in development decisions and approaches.	Code emerged from Surya's (P10) transcript analysis
37	Emotional factors >	Fear and anxiety	5	Concerns, worries, or anxieties influencing decision-making processes.	DT > BDT based
38	Emotional factors >	Optimism and hope	7	Expressions of positive expectations or confidence influencing choices and strategic decisions.	DT > BDT based
39	Emotional factors >	Passion and commitment	24	Indications of personal investment, dedication, or emotional attachment which drive decision-making and persistence.	DT > BDT based
40	Emotional factors >	Pressure and stress	11	Mentions of time constraints, workload, or external demands affecting decision-making behavior.	DT > BDT based
41	Knowledge >	Best practices	22	Proven effective methods, techniques, and approaches in DTx development and implementation.	Code emerged from Eva's (P2) transcript analysis
42	Knowledge >	Expert consultation processes	26	Methods for incorporating subject matter expertise.	Literature Review
43	Knowledge >	Feedback integration	73	Incorporation of stakeholder perspectives and input, such as patients and HCPs.	Literature Review CR > Empirical Domain
44	Knowledge >	Market intelligence utilization	13	Use of market data in decision-making.	Literature Review
45	Knowledge >	Talent development	4	Strategies and processes for building and maintaining necessary expertise and skills within the development team, including training and knowledge transfer.	Code emerged from Cheah's (P13) transcript analysis
46	Organizational context >	Institutional research priorities and mandates	73	Formal organizational goals directing research focus.	Literature Review
47	Organizational context >	Organizational culture toward commercialization	48	Institutional attitudes and practices toward research commercialization.	Literature Review
48	Organizational context >	Strategic alignment	3	Alignment between DTx goals and broader organizational objectives (e.g., level of leadership support).	Literature Review
49	Outcome evaluation >	Market potential evaluation	19	Assessment of commercial opportunities, market size and potential, and therefore of the DTx potential value.	Literature Review DT > EUT based
50	Outcome evaluation >	Regulatory outcomes	5	Considerations related to obtaining regulatory approval in order to commercialize a DTx in specific markets.	DT > EUT based CR > Empirical Domain
51	Persona >	Adoption related	91	Considerations (and concerns) related to DTx uptake by target users.	Code emerged from Surya's (P10) transcript analysis

52	Persona >	Clinicians' mindset	45	Unique perspectives and decision-making approaches that distinguish clinicians-researchers in their work.	Code emerged from Eva's (P2) transcript analysis
53	Persona >	Engineer's mindset	34	Unique perspectives and decision-making approaches that distinguish engineers-researchers in their work.	Code emerged from Eva's (P2) transcript analysis
54	Persona >	Researcher's mindset	34	Insights and perspectives that characterize researchers' general approach and thought processes.	Code emerged from Eva's (P2) transcript analysis
55	Persona >	Researchers' priorities	108	Day-to-day priorities of researchers, and therefore key considerations in decision-making processes.	Code emerged from Emma (P1) transcript analysis
56	Persona >	Researchers' role	95	Interviewee's involvement and contributions across different stages of DTx development and technical lifecycle. It also captures the personal experiences of the researchers with DTx development.	Code emerged from Emma (P1) transcript analysis CR > Empirical Domain
57	Probability >	Probability calculations	10	Objective and subjective probability calculations.	Literature Review DT > EUT based
58	Probability >	Uncertainty	13	Acknowledgment of potential uncertainty.	Literature Review DT > EUT based
59	Social influence >	Competitive pressure	8	Impact of market competition on decisions.	DT > BDT based
60	Social influence >	Norms	30	Established practices, standards, and unwritten rules that shape behavior within the DTx ecosystem.	DT > BDT based
61	Social influence >	Peer pressure	3	Direct and indirect influence exerted by professional peers and industry colleagues on decision-making.	DT > BDT based
62	Social influence >	Status and reputation concerns	2	Decision-making influenced by considerations of professional standing and organizational reputation.	DT > BDT based
63	Stakeholder relationships >	Communications	17	Related to the communications between the different stakeholder groups.	Code emerged from Shiva's (P9) transcript analysis
64	Stakeholder relationships >	Cross-disciplinary collaboration structures	72	Formal and informal arrangements for working across different fields of expertise, encompassing collaborative networks that facilitate knowledge exchange.	Literature Review CR > Actual Domain
65	Stakeholder relationships >	Group and power dynamics	12	Distribution and exercise of authority in decision-making (e.g., stakeholder alignment issues). It includes the "network effects", i.e., the impact of existing relationships and connections on researchers' decision-making and development choices.	Literature Review CR > Actual Domain
66	Stakeholder relationships >	Industry-academia relationships	21	Connections and interactions between academic researchers and industry partners.	Literature Review CR > Actual Domain
67	Stakeholder relationships >	PPP dynamics	6	Public-private partnership interactions and relationships.	Literature Review CR > Actual Domain
68	Tech. development >	Features prioritization	10	Decisions about which features or capabilities to develop first.	Literature Review
69	Tech. development >	Interoperability considerations	16	Ability to integrate with other systems and platforms.	Literature Review

70	Tech. development >	Security and privacy features	8	Measures for protecting data and ensuring privacy.	Literature Review
71	Tech. development >	Tech. architecture	5	Choices and decisions about technological structure and components.	Literature Review
72	Tech. development >	Tech. limitations	3	Constraints imposed by technology or infrastructure.	Literature Review CR > Real Domain
73	Tech. development >	Tech. prioritization	67	Focus on technological capability development. It could also be considered as a “pro-innovation bias”.	Code emerged from Emma’s (P1) transcript analysis
74	Tech. development >	User interface	12	Choices affecting how users interact with the DTx (e.g., decisions related to the end-user experience).	Literature Review
75	Utility >	Resource	2	Resource allocation-related decisions and considerations.	DT > EUT based CR > Actual Domain
76	Utility >	Risk	10	Notions of risk and uncertainty evaluation.	DT > EUT based
77	Utility >	Scalability	31	Scalability potential of the future DTx intervention.	DT > EUT based
78	Utility >	Time	1	Time-value considerations (e.g., specific deadlines).	DT > EUT based

Supplementary Table 8: Illustrative quotes for the three generative mechanisms.

Mechanisms	Representative Quotes	Context	Interpretation
Professional Norms	"*As a researcher, my KPIs are focused on publications and clinical validation... economic considerations aren't part of our metrics.*" (Emma, P1) "*The priorities would be focused on technical performance and the clinical value this solution can have.*" (Elisabeth, P5) "*We were too focused on the clinical service delivery team [and did not engage some of the stakeholders'. So we developed that and then went through a couple of trials. One was a pre-test, post-test study first, now a randomized controlled trial to see whether it really works. At this point, we still have not done cost-benefit analysis. So it may be a money-losing intervention, we don't know, but we may be throwing money into the ocean. So this is one downside.*" (Camirah, P15)	Discussion of research priorities	Demonstrates how institutional structure and dynamics shape decision-making focus
Researcher Experience	"*From my engineering background, I naturally focus on technical performance... economic aspects weren't part of my training.*" (Ezra, P3) "*I don't really consider myself an expert in this area at all. I have some knowledge, partly during training, there are specific components of our examinations that cover things like cost effectiveness.*" (Cheah, P13) "*It's safer to follow guidelines. That's what we're trained to do throughout our training.*" (Surya, P10)	Reflection on professional training	Shows the influence of educational background on decision frameworks
Adoption Uncertainties	"*Implementation is always the biggest unknown... you can have perfect clinical results but fail completely in real-world adoption.*" (Christoph, P12) "*The kind of the end goal is really about the adoptions, basically, the deployment and the adoptions of these technologies.*" (Priyah, P17) "B*esides economics, it's the implementation part, like how do we assess or evaluate the fidelity or the adoption of this kind of program, how do we do stakeholder engagement, how to analyze their responses, how to overcome barriers and facilitators when you look at the big picture.*" (Camirah, P15)	Discussion of development challenges	Illustrates how adoption uncertainty shapes Dtx development-related decisions

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