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Key characteristics and role of lead users in medical device innovations: An exploratory study

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ABSTRACT

Developing medical device innovations is a lengthy and costly endeavor, so engaging the right participants early in the process is crucial. While much of the existing literature focuses on procedural aspects of innovation, the human factors that influence success are often overlooked. The Lead User Method is designed to identify key contributors based on their ability to stay ahead of market trends and realize significant benefits. However, it has been criticized for inadequacies in its identification process. To address this gap, our study distinguishes seven key personal characteristics of medical lead users that are essential for successful co-created new product development. Through case studies and semi-structured interviews, we demonstrate that engaging lead users throughout the new product development process—regardless of product complexity—enhances product-market fit and profitability. Their involvement becomes increasingly critical as the process advances, particularly during the market diffusion phase. Our research refines the Lead User Method's identification process and provides actionable insights for decision-makers, reducing uncertainty in medical device innovation while lowering development costs and time and increasing product-market fit and profitability.

Introduction

Innovative companies explore knowledge and develop capabilities to strengthen their competitive position against rivals (Levinthal & March, 1993). To succeed in this value-creation process, companies require resources that are rare, inimitable, non-substitutable, and non-transferable (Barney, 1991). Capabilities are established when these resources are integrated into the firm's value-creation process (Vargo & Lusch, 2004). User knowledge is considered one of the most fundamental resources, and companies aim to identify and involve such relevant users by leveraging open innovation opportunities (Chesbrough, 2003). This collaborative process, termed *co-creation*, enables organizations to introduce radical innovations, enhancing their market competitive advantage (Perks et al., 2012; Ramaswamy & Ozcan, 2018).

Firms that innovate successfully collaborate with a specific type of user, known as a *lead user*, in their new product development (NPD) process (de Jong et al., 2024; Dean et al., 2024), as these *leading-edge users* (von Hippel, 1986) are a critical source of breakthrough innovations that are commercially attractive (Baldwin et al., 2006; Fleming, 2007; Lettl et al., 2006; Lilien et al., 2002; Sawyer & Henriksen, 2024). Although a significant percentage of users (10 to 40 %) independently modify or develop products across various industrial and consumer sectors (Baldwin & von Hippel, 2009; Herstatt & von Hippel, 1992; Lettl, 2007; Lüthje, 2004; Lüthje et al., 2005; Morrison et al., 2000; Urban & von Hippel, 1988), lead users typically prefer to collaborate with firms to drive innovation through co-creation (Dean et al., 2024). This preference is particularly pronounced in complex product development requiring specialized knowledge and tools (Globocnik & Faullant, 2021), such as medical device innovations. Consequently, lead users become central to firms' value-creation processes (Cooper, 2001; O'Hern & Rindfleisch, 2010), contributing to various stages of NPD, from idea generation to market diffusion and post-launch activities (Hoyer et al., 2010).

The academic literature provides theoretical frameworks that emphasize the engagement of external users in firms' innovation processes. The user-centered design approach advocates for learning about users' needs, behaviors, and preferences by involving them in the NPD process. User-centered design ensures the final product is intuitive, easy to use, and effective at addressing user problems. Thus, users are no longer passive consumers but active participants in developing new products or services (Ramaswamy & Ozcan, 2018).

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Although lead users play a crucial role in co-created innovation, identifying and selecting them remains a significant challenge. Research emphasizes the importance of personal attributes in successful collaboration, yet comprehensive studies on this aspect remain limited. For instance, Boer et al. (2006) state that innovation synergy can only be achieved when the right individuals are prepared to collaborate. Moreover, selecting appropriate user profiles enables developers to prioritize and design for the most relevant user groups (Abrell et al., 2018). Identifying suitable leading-edge users for a co-created NPD process is particularly difficult due to variations in individual contributions (Füller et al., 2012) and the diverse personal attributes of users (Lettl, 2007; Mi et al., 2024).

The Lead User Theory and method, developed by von Hippel (1986), provide a foundational framework for identifying lead users likely to develop innovative products or services. It highlights two primary attributes: being ahead of market trends and experiencing significant expected benefits. However, empirical studies suggest that the identification process is more complex and requires additional factors (Lüthje et al., 2005). Trend assessment often relies on subjective judgments, which may lack consistency over time. Moreover, major innovations—such as the X-ray machine, stethoscope, antibiotics, and cardiac defibrillator—emerged without clear preceding trends. Similarly, measuring expected benefits can be challenging and open to varied interpretations, raising concerns about reliability.

While some studies address specific personal characteristics of lead users, they often lack a comprehensive approach. For instance, Pham et al. (2012) emphasize the necessity of expert-level knowledge for suitable collaborators, while Preißner et al. (2024) and Shane (2000) highlight the importance of domain-specific expertise, and Hogarth (2005) underscores the role of intuitive judgment. However, these studies do not apply established theories or models to determine adequate knowledge levels. In contrast, our study addresses this gap by applying the *Five Stages Model of Skill Acquisition* (Dreyfus, 2004) to gain deeper insight into the knowledge levels required of co-creators. Given that most knowledge is tacit (Nonaka, 1994; Polanyi, 1958) and consists of intangible *know-how*, it is essential to explore the process of identification and transfer among collaborators effectively.

Despite extensive research on lead users, there is a lack of comprehensive models addressing the personal attributes necessary for successful co-creation, particularly in the context of medical device innovations. Medical technology (Medtech) NPD processes are characterized by their complexity, their regulatory requirements, and the need for specialized knowledge. Our study aims to fill this gap by focusing on the following research questions:

- RQ1: What personal characteristics of lead users contribute most effectively to the success of co-created NPD processes in medical device innovation?
- RQ2: Which stages of the co-created NPD process require the active engagement of lead users to maximize the market success of medical device innovations, and how do their personal characteristics influence this involvement?
- RQ3: How do the intensity and nature of lead user involvement differ across the various stages of a co-created NPD process in the Medtech sector?

By applying *systematic combining* (Dubois & Gadde, 2014)—an approach that iteratively matches theory with empirical data—alongside principles of abductive reasoning, our research seeks to answer these questions within the context of medical device innovations for clinical use. Specifically, we focus on the personal characteristics of lead users and their impact on success at different stages of the co-created NPD process. Additionally, our investigation considers the implications of the European Union's Medical Device Regulations (MDR), which have been in effect since 2017. This study is particularly relevant for NPD decision-makers identifying and selecting appropriate lead users for the firm's co-created NPD process.

We propose seven key characteristics that medical lead users must possess to succeed in the co-created NPD process and conclude that lead users should be involved throughout the entire process. Furthermore, this research advances theory by refining the Lead User Method, linking the identified personal characteristics to the two primary attributes of lead users. It also contributes to existing theories in user-centered design, co-creation, and open innovation.

The managerial implications of our study offer competitive advantages for decision-makers by providing strategic guidance on selecting appropriate lead users. This approach reduces development time and costs, accelerates time-to-market, and maximizes profitability. This paper also provides valuable insights for lead users, helping them understand firms' selection processes and assess their suitability for co-created NPD before approaching companies with innovative ideas.

The study is structured as follows:

- Section 1 (this section) presents our research questions and overarching concepts.
- Section 2 reviews the theoretical background of the research and develops research propositions.
- Section 3 describes this paper's research methodology.
- Section 4 presents the findings.
- Section 5 contains a discussion of the findings.
- Finally, the Conclusion outlines the theoretical, practical, and managerial contributions and the study's limitations and recommendations for future research.

Literature review

As a starting point, we reviewed academic literature on the personal characteristics of lead users to establish our initial propositions. This study follows an exploratory approach with an open-ended design, aligning with a proposition-based methodology.

Theoretical foundation of the applied methods

According to Stebbins (2001), exploratory studies often focus on areas with limited or no prior research. Levinthal and March (1993) argue that organizations—and, by extension, research endeavors—must balance *exploration*, "the search for knowledge of facts," and *exploitation*, "the use and development of well-known facts." Our study aligns with the exploration dimension, prioritizing the discovery of new insights and potential theories over established frameworks. In this context, our exploration-oriented study seeks to advance the understanding of lead users' personal characteristics within medical device innovations, a relatively unexplored area.

As Levinthal and March (1993) discussed, the iterative nature of exploratory research encourages researchers to continuously refine their understanding and adapt to new data rather than being constrained by existing theories. This adaptability is crucial for examining complex phenomena—in our case, the context-specific personal characteristics of lead users.

Understanding complex phenomena, such as medical device innovations (particularly when lead users are involved throughout the entire NPD process), the relationship between a lead user and a firm, and the interplay of technological, human, and cultural factors, requires a comprehensive exploratory approach. This approach emphasizes open-ended methods capable of capturing the dynamic nature of these systems. It allows our study to adapt to emerging findings and evolving research questions and propositions. Additionally, it invites diverse perspectives and analytical methods, leading to deeper insights that a fixed research design might overlook. This methodology also supports a systematic exploration of interconnections within dynamic contexts (Eisenhardt, 1989; Yin, 2018).

Our proposition-based study aligns with an exploratory and open-ended research design by using propositions as initial indicators rather than strict hypotheses. In exploratory research, propositions provide a flexible framework that guides investigation without imposing constraints, allowing us to refine our propositions and research questions based on emerging findings.

Domain-Related knowledge and expert-level understanding

Lead users possess domain-specific knowledge, often referred to as *need knowledge*, which significantly shapes the ideas and solutions they develop (Lettl, 2007; Lüthje et al., 2005; Marzouki & Belkahla, 2020; Schreier & Prügl, 2008). This knowledge, refined through years of practical experience, experimentation, and learning, enables lead users to effectively identify and address emerging needs within their domain (Globocnik & Faullant, 2021; Lüthje & Herstatt, 2004). As a result, lead users contribute novel and highly relevant solutions to the NPD process (Cooper & Kleinschmidt, 2007; Ernst, 2002; Hoban, 1998).

Deeply embedded within their fields, lead users exhibit a strong capacity to interpret and adapt innovation-related information, further enhancing their contributions to NPD (Cohen & Levinthal, 1990; Lüthje & Herstatt, 2004). Recognized as domain experts (de Jong et al., 2024; Faullant et al., 2012; von Hippel, 1986), their expertise facilitates the transformation of complex ideas into meaningful inputs that drive value co-creation (Hervas-Oliver & Sempere-Ripoll, 2015).

To better analyze the levels of expertise that lead users bring, we apply the *Novice to Expert* model (Dreyfus & Dreyfus, 1980; Dreyfus, 2004), which suggests that experts not only possess a rich body of tacit knowledge but also demonstrate an intuitive and holistic understanding of problems, enabling them to make creative, rule-breaking decisions. This intuitive approach and flexibility in complex situations are particularly valuable in NPD, where lead users are well-positioned to tackle complex, real-world challenges in innovative ways. Thus, we propose:

- Proposition 1 (P1): Expert-level professional knowledge in lead users positively impacts the success of co-created NPD.

Technical knowledge and solution development

In addition to domain knowledge, lead users bring high-level technical knowledge—termed *solution knowledge*—which enables them to creatively reassemble and integrate their expertise to solve complex challenges (von Hippel, 2005). Their extensive technical and professional expertise has led to numerous breakthroughs, including the development of the first gas chromatography device, biocompatible implants for hernia surgeries, and innovative healthcare robots (Lettl et al., 2006; Riggs et al., 1994). These examples illustrate how lead users' technical knowledge allows them to push beyond conventional methods, developing novel solutions that address specific unmet needs.

Technical knowledge becomes even more critical in prototype development, where lead users leverage their expertise to create and test prototypes, enabling rapid iterative improvements (Søberg & Chaudhuri, 2018). This prototyping process accelerates the NPD timeline and enhances the final product's relevance and functionality. Moreover, technical knowledge allows lead users to approach NPD with high creativity, fostering cross-functional insights essential for innovative solutions (Boden, 1994; Fleming, 2007; Larkin et al., 1980).

Based on these considerations, we propose:

- Proposition 2 (P2): High-level technical knowledge in lead users positively impacts the success of co-created NPD.

Experimentation and prototyping in problem-solving

Lead users adopt a hands-on, experimental mindset that emphasizes iterative prototyping and continuous adaptation, positively influencing the effectiveness and speed of the NPD process (Thomke, 1998). Unlike traditional development approaches, where manufacturers rely on static customer requirements, lead users engage in real-time prototype testing and modification, often based on immediate feedback and contextual needs. This iterative approach enables lead users to refine products rapidly, ensuring closer alignment with actual user needs and enhancing the practical utility of the final product.

Furthermore, the experimental mindset of lead users provides firms with a strategic advantage, as an accelerated development timeline facilitates faster market entry and enhances the competitiveness of the resulting product (Thomke et al., 1998; Thomke & von Hippel, 2002). This continuous refinement of prototypes allows lead users to effectively identify and address functional and usability concerns, which is particularly beneficial in medical device innovation.

Based on these insights, we propose:

- Proposition 3 (P3): An experimental mindset in lead users contributes to the success of co-created NPD.

Tacit and explicit knowledge transfer in collaborative product development

Knowledge transfer is critical in co-created NPD, particularly for synthesizing tacit and explicit knowledge into actionable insights. *Explicit knowledge*, which is structured and easily documented, forms the foundation of collaboration, ensuring that information is readily accessible and consistently applied across project teams (Dahan & Hauser, 2002; Mascitelli, 2000; Nonaka, 1994; Smith, 2001). In contrast, *tacit knowledge*, acquired through experience, provides deep insights and unique cognitive frameworks essential for addressing complex, innovative challenges (Polanyi, 1966; Zhang et al., 2015). This knowledge is more difficult to articulate but remains crucial for solving ambiguous and intricate challenges in the NPD process (Polanyi, 1966; Thomke & Fujimoto, 2000).

Nonaka's (1994) knowledge conversion model identifies two primary processes for integrating tacit knowledge: *externalization* and *socialization*. Through externalization, tacit ideas are articulated using storytelling, metaphors, and analogies, enabling complex concepts to be communicated effectively to a broader team (Lakoff & Johnson, 2003; Srivastava et al., 2020; Stewart et al., 2006). Additionally, physical prototypes and artifacts facilitate tacit knowledge transfer by providing a visual and tangible representation that enhances collective understanding and fosters collaboration (Chaudhuri et al., 2023).

On the other hand, socialization involves transferring tacit knowledge through direct interaction, practice, and physical proximity, fostering a shared knowledge base among collaborators (Nonaka, 1994; Sakellariou et al., 2017). This form of knowledge transfer strengthens team alignment and enables the continuous refinement of ideas through shared experiences.

To effectively engage in these processes, lead users must possess advanced communication skills to convey complex concepts clearly and a collaborative attitude to facilitate knowledge-sharing. These interpersonal competencies are essential for successful knowledge transfer, particularly in environments that demand high levels of collaboration and iterative development.

Based on these insights, we propose:

- Proposition 4 (P4): A collaborative attitude in lead users positively impacts the success of co-created NPD.
- Proposition 5 (P5): Advanced communication skills in lead users positively impact the success of co-created NPD.

Conceptual framework development

The literature review highlights five critical characteristics of lead users—expert-level domain knowledge, high-level technical knowledge, an experimental mindset, a collaborative attitude, and advanced communication skills—as essential to the success of co-created NPD, particularly in medical device innovation. These attributes enable lead users to engage effectively in knowledge generation and transfer, creative problem-solving, and collaborative development, which are fundamental to value co-creation in NPD.

These propositions form the foundation of our conceptual framework, synthesizing the core attributes that empower lead users to contribute meaningfully to NPD. By leveraging explicit and tacit knowledge and adopting an experimental approach, lead users bridge the gap between domain expertise and practical application, fostering innovative solutions that address emerging needs. Our framework, informed by an abductive reasoning approach, not only serves as a basis for testing these propositions but also facilitates further exploration of additional lead user attributes in NPD contexts.

Fig. 1 presents a conceptual framework for analyzing the personal characteristics of lead users as success factors in co-created NPD within medical device innovation. P1 (Proposition 1) represents the foundation, enabling recognition of solution gaps (*need knowledge*), while P2 addresses the transformation of these gaps into actionable solutions (*solution knowledge*). This foundational expertise allows lead users to identify unmet needs and drive value creation.

Supporting P1, the framework includes P2, P3, P4, and P5, which interact to translate explicit and tacit knowledge into an innovative product effectively. These attributes facilitate creative problem-solving, iterative prototyping, collaboration, and the exchange of complex knowledge within co-creation processes.

Additionally, two emergent characteristics, C6 (*Characteristic 6*) and C7, were identified through abductive reasoning. C6 emphasizes the role of relational networks in fostering collaboration and knowledge exchange, while C7 highlights the importance of positional credibility in influencing outcomes and ensuring the adoption of innovative solutions. These characteristics serve as enablers of market success.

The integration of P1–P5 and C6 and C7 facilitates the co-created NPD process by bridging technical and market needs. The framework illustrates how lead user characteristics contribute to co-created NPD, driving success in innovation.

In the following sections, we define key terms and outline each phase of our methodology, ensuring clarity and rigor in our approach to studying the impact of lead user characteristics on NPD success.

Material and methods

Conceptual clarity and definitions

To ensure conceptual clarity, the key terms in this paper are defined as follows. These terms have been selected because they represent foundational concepts central to our research. Precise definitions are essential for establishing a shared understanding and minimizing ambiguities in interpreting our findings.

1. NPD: it refers to the process by which firms transform ideas into marketable products. This process encompasses various stages, including idea generation, concept formulation, product development, product testing, and market diffusion.
2. Innovation: We adopt the definition of innovation from the *Oslo Manual of Innovation* (OECD & Eurostat, 2018):

An innovation is a new or improved product or process (or combination thereof) that differs significantly from the unit's previous products or processes and that has been made available to potential users (product) or brought into use by the unit (process).

Additionally, we introduce a further criterion for innovation: the product must be new to the world, regardless of its complexity or whether it represents an incremental or radical change.

3. Success of co-created NPD: Success in co-created NPD is defined as the point at which the development process attains innovation status and begins generating reported profits, as indicated by the company's chief executive officer.
4. Personal Characteristics of a Lead User: The personal characteristics of a lead user encompass traits, attributes, skills, knowledge, attitudes, mindset, formal status, and other individual-specific features.
5. Co-Creation: Co-creation occurs when lead users participate in various or all stages of a firm's NPD process (Cooper, 2001) rather than being involved solely in the idea exchange phase (Füller et al., 2012). This form of collaboration differs from the broader concept of co-creation, which includes co-creation experiences. The broader concept involves the entire interaction between the customer and the

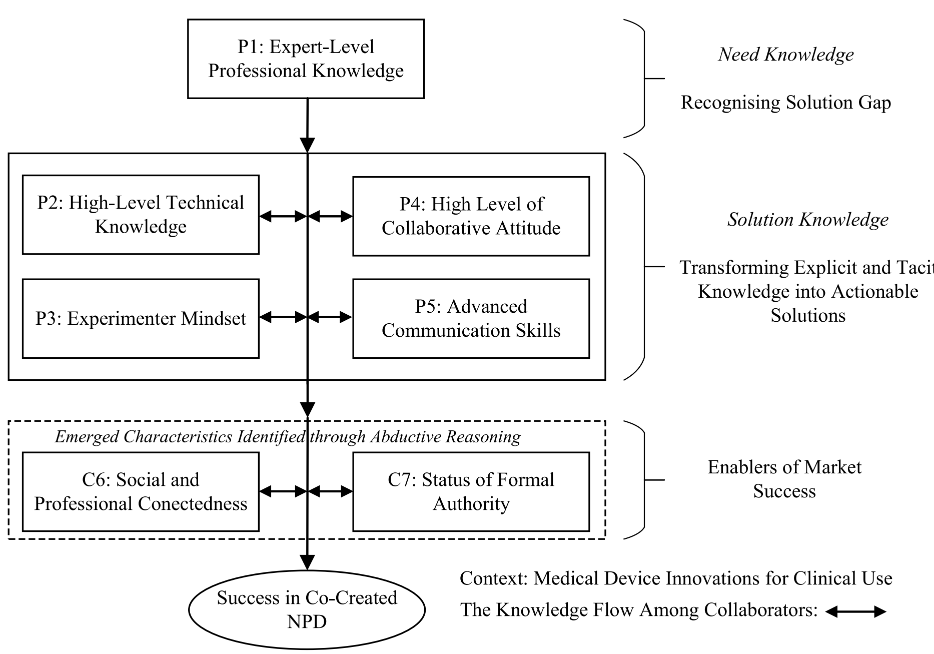

Fig. 1. Conceptual framework for lead user co-created NPD in medical device innovation.

firm, focusing on "creating an experience environment in which consumers can engage in active dialogues and co-construct personalized experiences" (Prahalad & Ramaswamy, 2004, p. 8).

Our study defines co-creation as a process in which multiple stakeholders, including users and firms, collaborate to create value through active involvement in shaping experiences, products, or services. This approach fosters innovation and mutual benefits, leading to a more interactive and participatory relationship that enhances user satisfaction and drives organizational growth (Ramaswamy & Ozcan, 2018).

Method and theoretical framework

We studied five firms developing and manufacturing medical implants, prostheses, and devices. Of these, three produced low-complexity products, while two focused on high-complexity products. These case studies were selected to provide rich, contextual insights into co-created NPD processes and the unique challenges these firms face.

Employing an abductive reasoning approach, the case studies iteratively navigate between empirical observations and theoretical insights. This method is particularly effective for identifying patterns and refining initial propositions, offering advantages beyond purely inductive or deductive approaches. Case studies are well suited to this research as they enable an in-depth exploration of complex phenomena within their real-world context.

An exploratory case study design was chosen for its suitability for investigating complex, context-specific phenomena, such as identifying the personal characteristics of lead users that contribute to success in co-created NPD within the medical device industry. This design aligns with the research goal by facilitating an in-depth examination of the under-explored attributes of lead users in a real-world setting. This approach allows the study to uncover patterns and relationships critical for understanding the interplay between lead user characteristics and successful product development outcomes by prioritizing exploration.

Adopting a systematic combining approach supports the iterative matching of empirical findings with existing theories. Systematic combining, characterized by a dynamic interplay between data collection, theoretical frameworks, and case analyzis, ensures that the research remains flexible and responsive to emerging insights. This process facilitates the validation and refinement of existing theories related to lead users and co-creation and fosters theory development by revealing new dimensions or interactions unique to the medical device development context. Thus, systematic combining is essential to achieving the dual objectives of theoretical alignment and advancing knowledge in this specialized domain.

The selection of case companies followed the principles of theoretical sampling, as outlined by Eisenhardt and Graebner (2007). This approach ensured the selection of cases highly relevant to the research objectives, facilitating robust pattern recognition and theory development. Five companies were chosen based on the following criteria:

1. Primary focus on developing and manufacturing medical devices.
2. Active participation in global markets, indicating a significant international footprint.
3. Collaboration with lead users during the NPD process.
4. Alignment with the specific innovation-related criteria discussed in Section 3.1.

These criteria were fundamental to capturing the dynamics of the focal phenomenon under study. Interviews were conducted with decision-makers directly involved in lead user selection and co-creation activities within NPD processes, ensuring relevant and context-specific insights for theory building.

The case studies focus on the characteristics of lead users and their impact at different stages of the co-created NPD process. Additionally, they aim to determine the required level of lead user engagement across various stages of this process. Given the exploratory nature of the case study method, the interviews are designed to explore in depth the experiences and insights related to lead users. This qualitative approach enables researchers to uncover detailed, context-specific information crucial for understanding lead users' key roles throughout the NPD process.

The interviews were conducted in four phases:

1. Phase 1: Data were collected and analyzed from the interviewees.
2. Phase 2: Interpretations were verified, and the impact of each identified lead user characteristic at different stages of the co-created NPD process was assessed.
3. Phase 3: The results were validated with medical lead users.
4. Phase 4: The validation data were visualized.

Phase 1. Collecting and analyzing data

The decision to use case studies and semi-structured interviews as the primary data collection methods was driven by the study's goal of understanding complex phenomena within specific contexts. These methods were selected for their ability to provide rich, context-specific insights into interviewees' experiences. Case studies allowed for an in-depth examination of real-world instances, while semi-structured interviews offered the flexibility to explore emergent themes and gain a deeper understanding of participants' perspectives.

Alternative approaches, such as surveys, longitudinal studies, or mixed methods, were considered but deemed less suitable. Surveys could have provided broader quantitative data but lacked the depth necessary for this study. Longitudinal studies, while valuable for tracking changes over time, were not feasible due to time and resource constraints. Though potentially enriching, mixed methods would have exceeded the project's scope and resources.

The chosen methods provided the best balance between in-depth understanding and practical feasibility, aligning with the study's objectives. This rationale will be further clarified in the manuscript. Data collection, documentation, analyzis, and validation were carried out in four sub-steps.

In the first step, the authors familiarized themselves with the organizational context to establish criteria for selecting suitable interviewees (Patton, 2015). These criteria included:

1. Holding a decision-making position regarding the entire co-created NPD process.
2. Playing a leading role in identifying and selecting lead users.

Given the flat organizational structure of the firms involved, the interviewees were typically general managers and heads of development departments, chosen to minimize bias in the retrospective sense-making process (Eisenhardt & Graebner, 2007; Weick et al., 2005).

A detailed field procedure and schedule for data collection were established in advance to ensure accuracy and conceptual clarity. Before the interviews, participants received an explanation of key terms based on an interview protocol (Yin, 2018). This explanation included the purpose of the interview, definitions of essential terms, and five initial propositions regarding lead users' characteristics, which were presented as semi-structured interview questions. The analyzis of the interview transcripts employed qualitative data analyzis methods, including coding and thematic analyzis, to ensure a systematic approach.

First, interviewees were asked to retrospectively assess the personal characteristics of lead users who had successfully contributed to the co-created NPD process, leading to innovation. They were also encouraged to suggest additional characteristics not covered in the interview protocol (Appendix A) that they believed were relevant to the process's success.

In the second step, all interviews were transcribed to facilitate data analyzis and support theory development (Yin, 2018). To validate the accuracy of the transcripts, they were sent to the interviewees for review, and any discrepancies or inconsistencies in interpretation were resolved collaboratively.

In the third step, a within-case analyzis (Eisenhardt & Graebner, 2007) was conducted to extract and analyze the distinctive characteristics of lead users within each case. This process involved an iterative approach to coding and thematic identification, ensuring a thorough exploration of the data. The analyzis began with a detailed, line-by-line reading of each transcript to build familiarity with the content. Key segments of text representing lead user characteristics were systematically identified and manually coded.

Distinctive colors were applied to each characteristic within the transcripts to organize and differentiate emerging themes. This manual method was chosen to capture the finer details of context-specific expressions, idiomatic language, and metaphors that might be overlooked by automated software. Throughout this process, reflective memo writing was used to document insights and interpretations, enhancing the depth and rigor of the analyzis.

To ensure reliability and reduce bias, the analyzis was conducted independently by a co-author who performed a separate review of the transcripts. Once both analyzes were completed, the results were compared to identify commonalities and resolve discrepancies. This collaborative process facilitated the triangulation of findings, ensuring a robust and consensual interpretation of the data. The final within-case analyzis synthesized the independent insights into a coherent framework, identifying the key characteristics of lead users as a foundation for subsequent cross-case comparisons and thematic integration.

The fourth step involved a cross-case analysis, in which the findings from the five case companies were compared and synthesized. The coded data from the interviews were grouped into themes, identifying seven categories: five aligning with predefined characteristics and two representing new insights.

In total, seven interviews were conducted for Companies A and C, while eight interviews were conducted for Companies B, D, and E, with durations ranging from one to three hours. This structured process, integrating coding and thematic analyzis, provided a rigorous framework for identifying patterns and insights essential for theory building. The detailed data collection process for each company is presented in Table 1.

Each company's product complexity level was evaluated based on the definition provided by Senders (2006). According to this definition, a product is classified as highly complex if its operation requires programmatic logic; otherwise, it is categorized as low complexity.

Phase 2. verification of our interpretations

During the verification process, interviewees were asked to review our interpretations and provide feedback, including any additional information or corrections for omissions.

Each case company organized a focus group to gather additional insights from the original interviewees, allowing immediate interaction and responses to others' perspectives (Morgan, 1997). This interactive format enhanced the reliability of our findings, as participants could clarify and expand on ideas in real time (Stewart et al., 2006). During these sessions, participants reviewed seven key categories derived from our case summaries (Yin, 2018) and discussed the impact of each on the product's market success, as well as on different stages of the co-created NPD process.

To quantify the perceived influence of each characteristic, participants rated each category on a five-point Likert scale, where one indicated strong disagreement, and five indicated strong agreement with the characteristic's importance. Ratings were collected for each stage of the NPD process: (1) idea generation and concept formulation, (2) product development, (3) prototype testing, and (4) market diffusion. This approach enabled us to capture specific insights regarding the relevance of each category at each stage of NPD.

Each focus group discussion generated an average numerical score (one to five) for each category per stage. Companies were assigned a letter grade (A, B, C, D, or E) to facilitate cross-company comparison. An average (AVG) score was calculated for each category by aggregating individual ratings from all companies, reflecting a broader consensus on the category's importance across different organizational contexts.

For clearer visualization, we categorized the influence levels of each characteristic in Table 2 according to three impact thresholds. Fields highlighted in green indicate essential characteristics, where the AVG score ranged between four and five, signifying a high perceived impact. Blue-highlighted fields represent characteristics of moderate importance, with AVG scores between 3.0 and 3.9, while unhighlighted fields denote a low impact, with scores below three.

The focus group scores contribute to the overall conclusions by providing a quantitative basis for assessing each characteristic's impact on NPD success. This structured scoring process validates the qualitative insights from interviews, offering clear and comparable data. Key contributions include cross-company comparisons, as the aggregated AVG and AVG1 scores highlight which characteristics consistently have a high impact across companies, confirming their broader significance. Additionally, the scores provide stage-specific insights by rating each characteristic at different NPD stages, revealing when each factor is most influential and adding depth to the conclusions.

The visual representation of impact levels, as shown by the highlighted scores in Table 2 (essential, moderate, low), makes identifying the most critical factors easy, reinforcing the study's main findings. These scores translate qualitative insights into measurable results, underscoring which elements are essential for market success.

The results, supported by focus group scores and qualitative feedback, confirmed the validity of the five initial propositions, providing a strong foundation for identifying the key personal characteristics essential for a successful co-created NPD:

1. Expert-level professional knowledge
2. High-level technical knowledge
3. An experimental mindset
4. A collaborative attitude

Table 1
Data collection sources.

	Company A	Company B	Company C	Company D	Company E
Core Products	Medical Implants and Prostheses	Medical Implants and Prostheses	Medical Implants and Prostheses	Medical Instruments	Medical Instruments
Core Activities	Development and Manufacturing	Development and Manufacturing	Development and Manufacturing	Development and Manufacturing	Development and Manufacturing
Interviewee Positions	General Manager and Head of R&D	General Manager and Head of R&D	General Manager and Head of R&D	General Manager and Head of R&D	General Manager and Head of R&D
Engineering Complexity of the Products	Low Complexity	Low Complexity	Low Complexity	High Complexity	High Complexity
Total Number of Interviews	7	8	7	8	8
Interview Duration Interval (Shortest - Longest)	1:30–3:00	1:20–2:55	1:00–1:35	1:15–2:40	1:10–2:50

Table 2
Focus group scores and results.

Characteristics / scores by firms and average	IMPACT on the idea generation and concept formulation stage						IMPACT on the product development stage						IMPACT on the prototype testing stage						IMPACT on the market diffusion stage					
	firm					*AVG*	firm					*AVG*	firm					*AVG*	firm					*AVG*
	A	B	C	D	E		A	B	C	D	E		A	B	C	D	E		A	B	C	D	E	
Expert-level professional knowledge	5	5	5	5	4	*4,80*	4	1	4	2	3	*2,80*	4	5	5	4	4	*4,40*	5	5	5	4	2	*4,20*
High-level technical knowledge	3	2	3	4	4	*3,20*	4	1	2	2	3	*2,40*	4	5	4	5	4	*4,30*	5	5	2	3	2	*3,40*
Experimenter mindset	4	5	5	5	3	*4,40*	4	1	3	3	4	*3,00*	4	5	5	3	4	*4,20*	5	1	5	1	1	*2,60*
Collaborative attitude	5	5	5	4	4	*4,50*	5	5	2	2	4	*3,50*	5	5	5	3	4	*4,40*	5	5	5	4	5	*4,80*
Advanced communication skills	4	4	5	4	4	*4,10*	5	4	4	4	4	*4,10*	5	5	5	4	4	*4,60*	5	5	5	5	5	*5,00*
Social and professional connectedness	4	3	4	4	5	*4,00*	4	1	2	3	4	*2,80*	4	1	2	3	4	*2,70*	5	2	5	4	4	*4,00*
Status of formal authority	5	1	3	3	1	*2,60*	5	1	1	2	2	*2,10*	5	3	1	4	1	*2,80*	5	5	5	5	4	*4,80*
Average 1 (AVG1)						***3,94***						***2,96***						***3,91***						***4,11***

5. Advanced communication skills

Additionally, through abductive reasoning, two further characteristic elements emerged during the verification process, as participants' feedback and focus group discussions revealed patterns and insights that extended beyond the initial propositions:

6. Social and professional connectedness
7. Formal authority

By incorporating these two additional elements and confirming all initial propositions, the study provides a more comprehensive understanding of the personal characteristics required for lead users to achieve success in co-created NPD, particularly in the context of medical device innovations. This extended framework highlights the importance of adopting a holistic perspective on essential lead user characteristics and underscores the complexity of the research problem.

In the next step, all identified personal characteristics of lead users were validated to ensure the accuracy, reliability, and credibility of the research data. This process also aimed to enhance transparency and reduce biases.

Phase 3. validation of research results

To ensure the validity of the findings, a primary strategy known as *triangulation* (Creswell & Creswell, 2022) was employed. This process involved using two different data sources to build coherent evidence regarding the personal characteristics of lead users and their impact at various stages of the NPD process. The first data source included the case companies (as described in Steps 1 and 2), while the second data source consisted of medical lead users.

The following validation criteria were established: A characteristic was considered essential and thus validated if the empirical research results (from case companies) and the subsequent validation (with medical lead users) corroborated its essential role in at least one stage of the entire NPD process. It was rejected if the research findings or the validation process did not support the characteristic's essentiality.

In the first step of the validation process, medical doctors were identified based on von Hippel's lead user criteria, which include being ahead of market trends and experiencing significant expected benefits. These criteria were explained in detail to the doctors, who then conducted a self-assessment, indicating whether both attributes applied to them with a yes or no response. Additionally, lead users were required to have a history of successful innovation. The validation process continued only with those who met these criteria.

In the second step, these lead users were informed about the seven characteristic elements identified in Phases 1 and 2. They were then asked to assess the impact of each characteristic on success at different stages of the co-created NPD process using a rating scale from one (strongly disagree) to five (strongly agree). This assessment was conducted through semi-structured interviews.

All responses were aggregated into a table, and the average (AVG) score for each characteristic element at each NPD stage was calculated. A secondary average (AVG2) was also computed from the average scores across all NPD stages (see Table 3).

The marking criteria were consistent with those used in Phase 2. Specifically, three impact levels were established for each characteristic at different stages of the co-created NPD process. Characteristics were designated as essential (highlighted in green) if the average (AVG) score ranged from four to five (inclusive), moderate (highlighted in blue) if the AVG score ranged from three to 3.9 (inclusive), and low (no highlight) if the score was three or below.

Based on the validation process results, all seven characteristic elements identified through abductive reasoning were found to be essential in at least one stage of the NPD process, contributing to the success of the co-created innovation. Consequently, all seven characteristic elements met the acceptance criteria for validation.

Phase 4. visualization of validation data

The data are visualized in Fig. 2 to represent the validation results better. This figure visually illustrates the data from Table 3, showing how each identified personal characteristic impacts the co-created NPD process.

Table 3
Validation process scores and results.

	IMPACT on the idea generation and concept formulation stage							IMPACT on the product development stage							IMPACT on the prototype testing stage							IMPACT on the market diffusion stage						
	lead users							lead users							lead users							lead users						
Characteristics / scores by lead users and average	A	B	C	D	E	F	*AVG*	A	B	C	D	E	F	*AVG*	A	B	C	D	E	F	*AVG*	A	B	C	D	E	F	*AVG*
Expert-level professional knowledge	5	4	5	5	5	4	*4,67*	5	5	5	5	5	4	*4,83*	4	5	5	5	5	5	*4,83*	5	5	5	4	3	5	*4,50*
High-level technical knowledge	4	4	4	5	2	3	*3,67*	5	5	4	5	2	4	*4,17*	5	5	3	5	3	5	*4,33*	5	5	4	4	2	5	*4,17*
Experimenter mindset	5	5	5	4	3	5	*4,50*	5	5	4	4	4	5	*4,50*	5	5	2	4	3	5	*4,00*	5	5	2	3	1	3	*3,17*
Collaborative attitude	5	5	4	4	2	5	*4,17*	3	5	4	4	5	5	*4,33*	5	5	4	4	5	5	*4,67*	5	5	4	4	5	5	*4,67*
Advanced communication skills	4	5	4	4	1	3	3,50	4	5	3	4	4	4	4,00	5	5	3	4	5	5	4,50	5	5	4	5	5	5	4,83
Social and professional connectedness	5	3	3	4	1	2	*3,00*	3	3	2	3	2	3	*2,67*	3	4	2	3	3	4	*3,17*	5	4	4	4	5	5	*4,50*
Status of formal authority	5	1	3	3	1	2	*2,50*	3	1	2	3	2	4	*2,50*	3	2	2	3	3	4	*2,83*	5	5	3	3	4	5	*4,17*
Average 2 (AVG2)							***3,71***							***3,86***							***4,05***							***4,29***

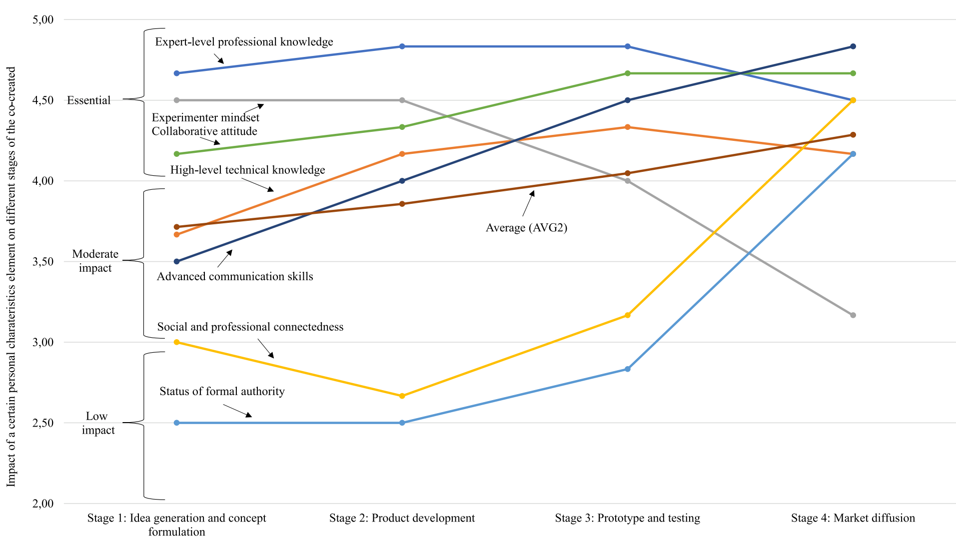

Fig. 2. Visualized validation data.

The X-axis delineates the stages of the co-created NPD:

- Stage 1—Idea Generation and Concept Formulation
- Stage 2—Product Development
- Stage 3—Prototyping and Testing
- Stage 4—Market Diffusion

The Y-axis indicates the impact of each personal characteristic on these stages, categorized as *Essential, Moderate Impact*, or *Low Impact.*

In the subsequent section, we elaborate on our findings, including the seven personal characteristics of effective medical lead users.

Results

One of this study's key findings is the identification of seven personal characteristics essential for lead users to succeed in the co-created NPD process, addressing Research Question 1 (RQ1). Medical lead users must possess all seven characteristics to effectively engage in collaborative innovation, as depicted in Fig. 2.

Five of these characteristics were derived from our initial propositions, which were grounded in academic literature:

- Proposition 1—Expert-Level Professional Knowledge
- Proposition 2—High-Level Technical Knowledge
- Proposition 3—Experimental Mindset
- Proposition 4—Collaborative Attitude
- Proposition 5—Advanced Communication Skills

Additionally, two further characteristics emerged through abductive reasoning:

- Proposition 6—Social and professional connectedness

- Proposition 7—Formal authority

Another major finding of our study indicates that medical lead users must be involved throughout the entire NPD process, as each characteristic element is essential at least in one stage of the co-created NPD. The full engagement of lead users significantly contributes to the success of the co-created NPD process, answering Research Question 2 (RQ2). This conclusion is supported by the fact that all interviewees who participated in the study confirmed their involvement across the entire NPD process. Additionally, the importance of different lead user characteristics was particularly emphasized during the validation interviews with medical doctors.

An increasing trend was observed in the overall average scores from the focus groups (AVG1 in Table 2) and the validation process scores (AVG2 in Table 3). Based on these findings, we conclude that the involvement of lead users in co-created NPD becomes increasingly crucial in the later stages, particularly during the *market diffusion* phase of the innovation process, addressing Research Question 3 (RQ3). This finding represents a significant and novel contribution to the literature, as previous research largely overlooked the role of lead users in these later stages. Our findings underscore the critical importance of lead users' engagement throughout all phases of the NPD process, offering new insights that could reshape the application of the Lead User Method in innovation management practices.

In our analyzis, lead users consistently demonstrated successful contributions to the NPD process. These contributions were evidenced by their possession of all seven characteristic elements, indicating alignment with lead user attributes and a proven track record in previous co-created innovation processes.

Detailed results on the seven characteristics of lead users

Characteristic 1: expert-level professional knowledge (need knowledge)

All companies in our case studies emphasized that professional knowledge is a key characteristic of lead users. To better understand these external contributors, we classified lead users as individuals at the expert level based on the Novice-to-Expert model (Dreyfus & Dreyfus, 1980; Dreyfus, 2004).

According to this model, expert-level individuals demonstrate several key attributes:

- Authoritative knowledge, meaning they deeply understand their field and rely on accumulated experience rather than just theoretical learning.
- High work standards enable them to make intuitive decisions based on past experiences.
- Managing complexity, as they have a holistic understanding of intricate systems.
- Contextual awareness allows them to see their work's broader implications and focus on the most critical aspects of a given problem.
- Autonomy, enabling them to think creatively, challenge conventions, and develop innovative solutions.

The responses from interviewees reinforced these attributes:

- Quote 1: "They are specialists in their field and have no less than ten to fifteen years of professional experience." (Company A)
- Quote 2: "They are active academic researchers with considerable scientific results." (Company D)
- Quote 3: "Innovation with practitioners with less than ten years of experience usually comes to a dead-end." (Company E)
- Quote 4: "They possess a deep level of product and use-knowledge and can identify significant problems with the product and create an innovative vision for the solution." (Company A)
- Quote 5: "They see the overall picture of the system and focus on the most important aspects." (Company D)
- Quote 6: "They act and decide intuitively." (Company B)
- Quote 7: "They can think outside the box and break rules." (Company D)

While experience accumulates over time, our findings indicate a threshold age at which individuals become less motivated and contribute less efficiently to innovation. This decline typically occurs around 60 to 65 years old.

- Quote 8: "Even though extensive experience accumulates over many years, there is a threshold age, typically around 60–65, when practitioners become less motivated, and their contributions become less efficient." (Company B)
- Quote 9: "At this age, they primarily occupy decision-making roles on professional committees and advisory boards and are less inclined to innovate." (Company D)

The interview quotes strongly support the proposition that expert-level knowledge in lead users positively impacts co-created NPD success. These findings also align with the Novice-to-Expert model developed by Dreyfus and Dreyfus (1980), which describes how individuals progress from novice learners to experts through accumulated experience and deep domain knowledge.

Each interview quote reinforces key attributes associated with expert-level knowledge acquisition:

1. Extensive Experience – Quote 1 highlights that lead users typically have 10 to 15 years of professional experience, demonstrating the importance of deep, accumulated tacit knowledge. This depth of expertise enables them to create advanced solutions and effectively contribute to innovation.
2. Authoritative Knowledge – Quote 2 shows that lead users are often exceptional academic researchers with significant scientific achievements. Their authoritative knowledge and extensive domain expertise allow them to tackle highly complex fields such as medical device innovation.
3. Accumulated Learning – Quote 3 suggests that innovation is often limited among practitioners with less than 10 years of experience. This finding underscores the model's emphasis on long-term learning as a critical component of expert performance.
4. Holistic Understanding of Complex Systems – Quote 4 describes how lead users develop deep product and usage knowledge, enabling them to identify significant problems and create innovative solutions. Experts can see beyond immediate issues and approach problems with a holistic perspective.
5. Contextual Awareness and Prioritization – Quote 5 indicates that lead users can see the "overall picture," linking to an expert's ability to perceive context, prioritize key aspects, and navigate complex systems efficiently.
6. Intuitive Decision-Making and Innovation – Quotes 6 and 7 demonstrate that lead users rely on intuitive decision-making and rule-breaking thinking, which allows them to make non-linear, innovative choices based on accumulated tacit knowledge. These abilities distinguish experts from less experienced practitioners who rely on rigid frameworks.

Finally, the age-related decline in motivation and efficiency observed in practitioners between 60 and 65 (Quotes 8 and 9) suggests that while expertise remains deep, its impact on innovation may diminish over time. This finding reinforces the idea that although extensive experience fosters expertise, its practical contribution to innovation has inherent limitations.

The focus group data (Table 2) show that expert-level professional knowledge has a high impact (AVG $\geq$ 4) on three key stages: idea generation (4.80), prototype testing (4.40), and market diffusion (4.20). This alignment supports Proposition 1, as the high ratings at these stages suggest that expertise is particularly influential in generating ideas, validating prototypes, and launching products. The strong scores indicate that expert knowledge is essential for interpreting complex information and driving success in NPD processes, as theorized in the proposition.

In sum, the focus group results and quotes linked to expert attributes in Dreyfus & Dreyfus's model illustrate how deep domain knowledge enables lead users to contribute significantly to NPD success. Their expertise facilitates advanced problem-solving, intuitive insights, and a comprehensive understanding of complex systems, ultimately leading to the acceptance of Proposition 1.

Characteristic 2: high-level technical knowledge (Solution knowledge)

The following quotes were collected regarding high-level technical knowledge:

- Quote 1: "High-level technical knowledge is a significant advantage, as it broadens the range of possible solutions and introduces a wider perspective." (Company B)
- Quote 2: "Technically savvy individuals present better-developed and more feasible ideas." (Company E)
- Quote 3: "Individuals with technical knowledge are more likely to understand engineers' reasoning and avoid pushing for technically unfeasible ideas." (Company D)
- Quote 4: "The best technical contributors have a technical mindset, are passionate about technical solutions, often have a small workshop at home, and engage in informal learning." (Company D)
- Quote 5: "They can convince potential future users or decision-makers by providing sound technical reasoning." (Company C)

The interview quotes support Proposition 2 by illustrating how the high-level technical knowledge of lead users positively influences co-created NPD outcomes.

- Quote 1 suggests that technical expertise broadens the range of potential solutions, reinforcing the idea that a combination of knowledge fosters creativity and introduces new perspectives.
- Quote 2 indicates that individuals with technical expertise generate feasible ideas, underscoring that technical knowledge is key to developing practical solutions.
- Quote 3 demonstrates that understanding engineering constraints helps avoid unfeasible ideas, highlighting the importance of specialized skills in refining an initial idea or product.
- Quote 4 describes technically knowledgeable individuals who engage in informal learning, reflecting the role of ongoing technical engagement in driving innovation.
- Quote 5 stresses that technical knowledge is crucial in persuading decision-makers, emphasizing the importance of comprehensive technical reasoning in validating innovative solutions.

Additionally, focus group data indicate that high-level technical knowledge had a moderate impact (AVG between 3.0 and 3.9) across all stages of NPD, except for product development, where it had the highest impact during prototype testing (4.30). This finding partially supports Proposition 2, suggesting that technical knowledge is particularly valuable during prototyping, where specialized skills help refine and validate product functionality.

The moderate scores in other stages imply that while technical knowledge contributes to NPD, it is not as crucial as expert-level professional knowledge or other characteristics, such as a collaborative attitude, across all stages.

Together, the interview quotes and focus group results confirm Proposition 2 by demonstrating how high-level technical knowledge contributes to NPD success through creativity, feasibility, and proper technical reasoning.

Characteristic 3: experimenter mindset

Our research data reveal two key findings regarding the experimenter mindset in lead users.

1. The iterative process of experimentation during idea testing and prototype problem-solving significantly improves the initial idea or prototype, thereby positively impacting the NPD process.
2. The willingness to experiment reflects the strong motivation of lead users to develop their ideas into new products.

The following quotes illustrate these findings:

- Quote 1: "The initial 'trial-and-error' testing process helps practitioners refine their ideas using materials such as plasticine, metals, and wood. The ability to draw, manual skills, and an experimenter mindset significantly contribute to the success of a co-created NPD." (Company E)
- Quote 2: "Such a person demonstrates high motivation throughout the NPD process." (Company B)
- Quote 3: "Practitioners with an experimenter mindset can also be characterized by a high level of commitment, as well as technical and manual skills." (Company D)
- Quote 4: "The process of experimentation requires advanced domain-specific knowledge and technical competencies." (Company A)

These quotes emphasize the importance of Proposition 3, which asserts that an *experimenter mindset* in lead users contributes to the success of co-created NPD.

- Quote 1 highlights the trial-and-error testing process and the use of plasticine, metals, and wood, demonstrating how experimentation and immediate adjustments accelerate the NPD process.
- Quote 2 points to high motivation throughout the NPD process, illustrating how lead users' persistence in refining solutions positively impacts product success.
- Quote 3 mentions commitment, technical skills, and manual skills, reflecting the practical problem-solving approach of lead users and the value of iterative experimentation.
- Quote 4 emphasizes that advanced domain-specific knowledge and technical competencies enable rapid prototyping, enhancing product success and competitive advantage.

Focus group data (Table 2) support Proposition 3 by demonstrating that an experimenter mindset has a high impact on critical NPD stages, particularly in idea generation (4.40) and prototype testing (4.20). These phases are essential for iterative refinement, aligning with Thomke et al. (1998), who argue that experimentation accelerates NPD through rapid adjustments.

Additionally, strong scores in collaborative attitude and communication skills further complement the experimenter mindset, enabling effective co-creation. Together, these factors confirm that an experimenter mindset is crucial to NPD success, reinforcing the claims made in Proposition 3.

Characteristic 4: high level of collaborative attitude

In the context of collaborative attitude, the following quotes were collected during the interviews:

- Quote 1: "Users with a high collaborative attitude regularly involve product engineers in real operations to demonstrate the context and express themselves through the 'learning by doing' process. They showcase their work and provide valuable insights into the context." (Company D)

- Quote 2: "Practitioners engage engineers in actual surgical operations, reflecting their commitment to implementing ideas through co-creation." (Company A)

These interview quotes reinforce Proposition 4, which argues that a collaborative attitude enhances NPD by enabling tacit knowledge transfer.

- Quote 1 highlights how users involve engineers in real operations, using learning by doing to share contextual knowledge. This aligns with Nonaka's (1994) concept of socialization (tacit-to-tacit transfer), where knowledge is transmitted through direct, practical interaction.
- Quote 2 demonstrates how engaging engineers in surgical operations fosters socialization, transferring tacit knowledge through close collaboration.

The focus group data further support Proposition 4, showing that a collaborative attitude is critical for effective tacit knowledge transfer in NPD. Scores are consistently high across all stages, particularly in idea generation (4.50), prototype testing (4.40), and market diffusion (4.80).

Both the interview quotes and focus group results demonstrate that a collaborative attitude promotes tacit knowledge transfer, supporting Proposition 4′s claim that a high level of collaboration is essential for success in NPD.

Characteristic 5: advanced communication skills

Only users with advanced communication skills can articulate their ideas and solutions using a common language with product engineers. These users are adept at formulating clear and concise statements, focusing on the core aspects of a problem or solution.

The following quotes illustrate this finding:

- Quote 1: "Good communication skills are essential for sharing ideas, collaborating with engineers during the co-created NPD process, and effectively communicating product advantages during the market diffusion phase." (Company A)
- Quote 2: "Practitioners with excellent communication skills can significantly enhance the efficiency of co-creation by formulating clear statements and emphasizing the core aspects of their insights throughout the NPD process." (Company C)

The interview quotes support Proposition 5 by illustrating how advanced communication skills in lead users positively impact co-created NPD.

- Quote 1 highlights the role of effective communication in sharing ideas, collaborating with engineers, and promoting products. This aligns with the need to transfer both explicit and tacit knowledge effectively. Clear communication aids in externalizing tacit knowledge, making complex insights understandable and actionable (Polanyi, 1966).
- Quote 2 further emphasizes the importance of articulating insights clearly, facilitating efficient co-creation. By focusing on "clear statements" and "core aspects," this quote demonstrates how communication helps convert tacit knowledge into explicit, shareable forms.

Together, these quotes validate the proposition that communication skills enhance knowledge transfer and collaboration, both of which are essential for successful NPD.

The focus group data (Table 2) also support Proposition 5, highlighting the high impact of advanced communication skills at each NPD stage:

- Idea Generation (4.10): Clear communication is essential for sharing knowledge effectively.
- Product Development (4.10): Strong communication skills help align teams and ensure consistency.
- Prototype Testing (4.60): Communication is crucial in refining insights and facilitating adjustments.
- Market Diffusion (5.00): Effective communication is critical for conveying product value and engaging stakeholders.

The interview quotes and focus group data confirm that communication skills are essential for NPD success, supporting Proposition 5, which is therefore accepted.

Additional characteristics

Through abductive reasoning and systematic combining, we identified two additional characteristics of lead users essential for successfully executing the co-created NPD process.

Abductive reasoning involves iteratively moving between empirical observations and theoretical insights to identify patterns and refine propositions. Systematic combining is an iterative approach that integrates theory and practice through a continuous dialogue between empirical data and theoretical frameworks (Dubois & Gadde, 2014).

These methodologies revealed two critical characteristics:

1. Social and professional connectedness
2. Formal authority

Characteristic 6: social and professional connectedness

The data analyzis revealed two key findings regarding social and professional connectedness in lead users.

1. Socially connected users refine ideas and enhance creativity

Socially connected users gain valuable input from other practitioners, helping to improve innovative ideas and solutions. Additionally, social and professional networks enhance users' creativity by providing access to diverse knowledge bases, which are essential for generating new ideas. This connectedness plays a crucial role in the market diffusion stage of the co-created NPD process by facilitating product promotion.

The following interview quotes illustrate this point:

- Quote 1: "It helps refine initial ideas by obtaining immediate feedback from experienced practitioners and potential future users." (Company E)
- Quote 2: "Socially connected users are well-informed about the real demands of users, which helps reduce the time-to-market ratio and develop products based on actual market needs." (Company D)

2. Social connectedness improves market awareness and strategic decision-making

Social connectedness allows users to gather valuable information about market trends, user needs, and existing solutions, increasing their familiarity with the competitive landscape.

The following quotes highlight this finding:

- Quote 3: "A well-performing contributor is familiar with competitors and available products in local and global markets." (Company E)
- Quote 4: "They understand how to leverage product advantages in their practice and are aware of the commercial potential of the market." (Company C)
- Quote 5: "It is challenging if a practitioner is not acquainted with the global market and leading trends and attempts to develop a product that cannot be sold." (Company B)

- Quote 6: "International work experience positively influences one's perspective, allowing for a broader view of the same problem." (Company A)
- Quote 7: "Each market has its specialties, regulations, medical standards, and culture; therefore, a thorough understanding of the target market and its context is crucial." (Company D)

The quotes emphasize that social and professional connectedness is crucial in the idea generation and market diffusion stages. This is supported by focus group results (Table 2), where *social and professional connectedness* received relatively high scores for these stages (4.0 for idea generation and 4.0 for market diffusion). Quotes 1 and 2 illustrate how social connectedness helps participants understand market needs and obtain immediate feedback, facilitating market validation and product promotion.

The interviews indicate that social connectedness is limited during product development and prototype testing. The focus group results corroborate this, as *social and professional connectedness* received lower scores (2.8 and 2.7, respectively) in these phases, reflecting its reduced influence on these more technical aspects.

Quotes 3 through 7 highlight the importance of understanding market trends, competition, and a global outlook for successful market entry. The focus group scores for *status of formal authority* (4.8) and "Social and professional connectedness" (4.0) in the market diffusion stage further support the interpretation that familiarity with the market and global experience is essential during product launch and market expansion.

Based on the data analysis and focus group results, social and professional connectedness is central to the co-created NPD process's idea generation and market diffusion stages. The focus group findings confirm that this characteristic is particularly important in these phases for achieving successful co-created NPD.

Characteristic 7: status of formal authority

Our data analyzis indicates that the formal authority status of lead users plays a crucial role in changing existing medical protocols and guidelines, influencing the market during the promotion phase of a new product, and driving mindset shifts. Formal authority is derived from an individual's job position and academic achievements. However, the formal authority required may vary across different sales territories, as its influence might be limited to specific regions or products.

The following interview quotes illustrate these findings:

- Quote 1: "The credibility of practitioners is derived from their job positions and academic achievements. The status of formal authority is necessary for changing existing medical protocols and guidelines." (Company E)
- Quote 2: "The market is more receptive to a radically new product when a formal authority endorses it." (Company D)
- Quote 3: "The influence of formal authority may be limited to specific countries or regions; therefore, different authorities might be needed in various sales areas." (Company D)
- Quote 4: "A formal authority is highly influential at conferences, where they promote innovative products and drive changes in mindset." (Company C)

The interview quotes align with the focus group results (Table 2).

- Quotes 1 and 2 emphasize that formal authority, derived from job positions and academic achievements, is essential for changing medical protocols and gaining market acceptance for new products. This finding aligns with focus group data, where status of formal authority received a high average score (4.8) in the market diffusion stage, highlighting its importance in influencing and endorsing product acceptance.
- Quote 3 notes that the impact of formal authority varies by region, requiring different authorities in different sales areas. The focus group results support this, showing that the status of formal authority is important but context-dependent, especially in the market diffusion phase, which is critical in specific territories, market segments, or medical regulations.
- Quote 4 describes how formal authorities promote innovations at conferences and drive mindset shifts. The high score (4.8) for status of formal authority in Table 2 reflects this role, emphasizing its impact in settings where authority figures advocate for and legitimize new products.

Our data analyzis and focus group results indicate that the formal authority status of lead users is essential for successfully implementing the co-created NPD process, particularly in:

1. Influencing medical protocols
2. Gaining market acceptance
3. Driving mindset changes during the market diffusion stage

Discussion

The findings presented above are based on interviews with key decision-makers and managers involved in the NPDprocesses of five case companies focused on medical device innovations. Additionally, six validation interviews were conducted with lead user medical doctors. This empirical work confirmed the crucial role of seven personal characteristics of lead users in the success of co-created NPD.

The medical doctors who participated as lead users are medical professionals with specialized knowledge and practical experience in medical device development. They play an active role in the development process, from product design through prototyping and testing. These doctors provide critical feedback to ensure the devices meet user needs and are suitable for various clinical settings. Their contributions are essential in the early development and market diffusion phases, where they influence clinical protocols and persuade others of the innovation's appropriateness.

In the following section, we will discuss these findings and examine the generalizability of our results.

Level of lead users' involvement in the co-created npd process

Most scholars emphasize the engagement of lead users primarily during the idea generation stage at the fuzzy front end of co-created NPD. However, only a few studies examine the necessity of lead user involvement in the later stages of the process.

Our findings provide new insights specific to our context, demonstrating that lead users must be engaged throughout every stage of co-created NPD, thereby addressing Research Question 2 (RQ2). Specifically, our research reveals that:

- Lead users generate valuable ideas during the ideation stage.
- They provide critical feedback and insights throughout development, testing, and commercialization.
- Their continuous engagement ensures that the product remains aligned with user needs and market demands, ultimately enhancing innovation and overall success in the NPD process.

Furthermore, lead users must possess all seven identified personal characteristics to succeed in co-created NPD. Based on our results, we emphasize that the same lead user should participate in all stages of the co-created NPD process to maintain continuity and maximize the chances of success.

Expert-Level domain-related knowledge (need knowledge)

Our findings align with existing literature emphasizing the critical role of lead users' domain-related knowledge in identifying innovation opportunities and developing solutions (Faullant et al., 2012; Piller et al., 2006; Preißner et al., 2024; Riggs et al., 1994). Concepts such as *in-depth knowledge* (Lettl et al., 2006) and "real-world understanding" (von Hippel, 1986, p. 797) highlight the necessity of expertise in innovation. We use the *Novice to Expert* model (Dreyfus & Dreyfus, 1980; Dreyfus, 2004) to illustrate how expert-lead users effectively navigate complex challenges.

Consistent with Pham et al. (2012), our study shows that expert knowledge is crucial in the idea-generation phase, allowing lead users to predict market needs accurately. Additionally, our findings support the idea that lead users' ability to grasp "the essence" of a problem (Dörfler & Eden, 2019) significantly enhances their contributions during prototype testing, as their expertise fosters quick iterative adjustments, aligning with Thomke et al. (1998) on the importance of experimentation in successful NPD.

Interestingly, we observed a decline in motivation and effectiveness among lead users over 65, challenging the assumption that more knowledge always leads to greater innovation. This finding aligns with Magnusson (2009), who discusses the inverted U-shaped relationship between creativity and knowledge, suggesting that increased expertise may inhibit radical idea generation beyond a certain age. Furthermore, our findings indicate that older practitioners often occupy decision-making roles, which may limit their involvement in innovation.

Our findings underscore the importance of expert-level knowledge throughout the co-created NPD process. While expertise enhances strategic insights, the identified threshold effect highlights that knowledge accumulation does not always equate to increased innovation potential, emphasizing the need to balance expertise and creative openness in NPD contexts.

High-level technical knowledge (solution knowledge)

Our study builds on the established understanding that lead users' technical knowledge is critical in the NPD process (Enkel et al., 2005; Lüthje et al., 2005; Urban & von Hippel, 1988; von Hippel et al., 1999), with a particular focus on how this *solution knowledge* supports medical device innovation.

Aligned with findings from Riggs et al. (1994) and Lettl, Herstatt, and Gemuenden (2006), our research shows that technically skilled users contribute through early experimentation and rapid prototyping, helping to refine ideas and reduce costly revisions. Additionally, users with technical competencies extend the range of possible solutions and incorporate broader perspectives.

Furthermore, lead users' capacity to reorganize and apply specialized knowledge aligns with the expert-level knowledge of the Novice to Expert model (S. E. Dreyfus & Dreyfus, 1980). Their expert-level skills enable them to broaden the scope of solutions and offer diverse insights during prototype development. As Cohen and Levinthal (1990) noted, this expertise helps lead users to provide useful, context-specific feedback, accelerating development and supporting a more efficient NPD process.

Although Gruner and Homburg (2000) suggest that an overemphasis on technical perspectives may limit broader input, our findings indicate that technical knowledge plays a positive role across all stages of development, particularly in prototype testing and market introduction. Lead users effectively communicate the technical value of innovations to potential customers, which aligns with Søberg and Chaudhuri (2018), enhancing product credibility and supporting successful market adoption.

Experimenter mindset

Thomke et al. (1998) define experimentation as an iterative process involving building, testing, analyzing, and refining prototypes—typically led by firms. However, in medical device development, strict regulations on human testing mean that lead users often perform early experimentation, either independently or in partnership with firms. This process includes idea testing, early prototyping, and animal testing, aligning with Thomke & von Hippel's (2002) emphasis on user-driven innovation.

Our findings show that an experimenter mindset in lead users is closely connected to their technical knowledge, supporting Lettl, Herstatt, & Gemuenden (2006) and Lüthje & Herstatt (2004), who argue that specialized knowledge strengthens the ability to experiment. Lead users with this mindset bring valuable skills to prototyping and are also highly motivated, aligning with Levinthal & March's (1993) concept of continuous adaptation as crucial for solving complex challenges.

The experimenter mindset provides two main benefits:

1. It requires advanced knowledge of the field, which enables lead users to make quick, informed adjustments (S. E. Dreyfus & Dreyfus, 1980; Polanyi, 1966).
2. It drives strong user engagement in the co-created NPD process, which is essential for innovation.

While Gruner and Homburg (2000) caution that a technical focus may limit broader input, our findings indicate that technically skilled lead users improve the NPD process through iterative testing in medical technology. Their contributions help reduce development costs, enhance innovation, and ensure prototypes meet practical needs, making these users valuable collaborators.

Social and professional connectedness

In the context of medical device innovations, our results highlight the critical importance of social and professional connectedness for successful innovation, aligning with findings from Dahl & Moreau (2002) and Kratzer & Lettl (2008). These studies emphasize that collaboration among users and professionals enhances the quality of innovative ideas. Our research confirms that such connectedness is vital for generating and refining ideas and obtaining feedback from experienced practitioners and potential users.

Our findings indicate that a network of connections enhances the effectiveness of lead users in the NPD process. These social ties allow lead users to gather diverse insights, aligning with Vargo & Lusch (2004) and their view on the importance of relational resources in value creation. Moreover, social connectedness is crucial during the market diffusion phase, as medical practitioners are more likely to adopt solutions from lead users who share their professional backgrounds, particularly those with notable achievements and authority.

Finally, the extensive social connections of lead users improve their market awareness, enabling them to anticipate future needs and trends. This aligns with Lettl (2007) and Lüthje et al. (2005), who argue that well-connected users are better positioned to understand emerging demands. Overall, our findings emphasize the significance of social and professional connectedness in driving successful medical device innovations throughout the NPD process.

Status of formal authority

Our findings reveal a critical extension of the lead user concept, which has traditionally emphasized lead user involvement primarily in the idea generation and concept formulation phases (von Hippel, 1986). In contrast, we assert that lead user participation during the market diffusion stage is essential for the success of new medical products. This is particularly important because only individuals with formal authority can change existing clinical protocols and integrate innovations into practice—a point strongly emphasized by our medical doctor lead user interviewees.

Moreover, accepting new medical technologies often depends on endorsement from credible practitioners, highlighting the role of authority and trust in innovation adoption. Our research results indicate that lead users with formal authority significantly facilitate market diffusion, increasing the likelihood of acceptance.

This perspective is novel, as the role of lead users in the market diffusion phase is often overlooked in the literature. Prior studies, such as von Hippel (1986), Cohen & Levinthal (1990), Lüthje et al. (2005), and Bird et al. (2021), primarily focus on earlier stages of product development, neglecting the importance of lead users in translating innovations into practice. Our findings suggest that these authoritative individuals are crucial for generating innovative ideas and bridging the gap between innovation and practical application.

Additionally, we highlight the vital role of lead users with formal authority in the market diffusion phase, emphasizing that their engagement can enhance the successful integration of innovations into healthcare practice.

High level of collaborative attitude and advanced communication skills

Expert lead users possess a significant amount of tacit knowledge, which is often described as *sticky* (Lüthje et al., 2005) and difficult to articulate (S. E. Dreyfus, 2004; Polanyi, 1958). Our findings indicate that the most effective lead users adeptly employ both methods of tacit knowledge conversion: tacit-to-explicit and tacit-to-tacit (Nonaka, 1994).

The conversion from tacit to explicit knowledge requires advanced communication skills to articulate insights through storytelling and clear statements. In contrast, tacit-to-tacit conversion necessitates a highly collaborative attitude, demonstrated when lead users engage product engineers in real surgical operations to convey complex concepts that cannot be easily expressed verbally. This aligns with literature emphasizing the importance of communication and collaboration in knowledge-sharing (Nonaka, 1994). Other scholars have also noted that effective knowledge conversion is crucial for innovation.

However, while previous studies have acknowledged the significance of tacit knowledge in innovation, they often overlook the dual methods of knowledge conversion employed by lead users. Our research underscores that communication skills and collaborative efforts are vital for effectively leveraging tacit knowledge in the development process.

In summary, our findings emphasize the critical role of lead users' high-level collaborative attitude and advanced communication skills in successfully converting tacit knowledge into actionable insights for NPD.

Conclusions

Although the original Lead User Method defines lead users by two criteria—being ahead of market trends and experiencing significant expected benefits—empirical studies suggest that its identification process remains unreliable (Lüthje & Herstatt, 2004). This finding highlights the need to refine the method and improve the selection of co-creators, particularly in medical device innovations for clinical use.

Theoretical contribution

Selecting lead users based on their ability to stay ahead of market trends first requires identifying the underlying trend in which they hold a leading position. Although formal methods exist (ranging from expert judgment to simple trend extrapolation), "trend identification and assessment remain something of an art, and perceptions may fluctuate over time" (von Hippel, 1986, p. 798). Empirical studies further highlight the challenge of finding reliable information sources and prioritizing data, particularly when expert knowledge and experience vary widely (Lüthje et al., 2003; Lüthje & Herstatt, 2004).

Moreover, relying on trend identification can mislead management, particularly in cases of breakthrough innovations. Historically, radical innovations such as the X-ray machine, stethoscope, antibiotics, and cardiac defibrillator emerged without any identifiable preceding trends, challenging the applicability of trend-based methods for selecting lead users.

To reduce the uncertainty associated with trend prediction, we propose an alternative approach to identifying trends and, consequently, lead users, following this line of reasoning:

- Pham et al. (2012) suggest that individuals with expert-level knowledge in a specific domain tend to make highly accurate intuitive predictions.
- Hogarth (2005) argues that intuitive judgment often outperforms analytical processes in highly complex environments where no single formal rule has strong predictive validity.
- Preißner et al. (2024) and Shane (2000) assert that individuals who develop domain-related knowledge through education and work experience are more likely to discover innovation opportunities.

Based on this reasoning, we argue that lead users with:

1. Expert-level professional knowledge (a credible source of need knowledge),
2. High-level technical knowledge (solution knowledge), and
3. Market familiarity (derived from social and professional connectedness)

are better equipped to predict market trends than traditional trend assessment methods or internal/external market researchers. The presence of these elements determines a lead user's capability for innovation (see Fig. 3).

The second defining characteristic of lead users is a strong anticipated benefit, referring to the advantage gained from acquiring a solution (von Hippel, 1986). This incentive motivates users to develop early prototypes and engage in iterative experimentation.

The conversion of tacit-to-tacit knowledge (Nonaka, 1994) requires a high willingness to collaborate with product engineers, while tacit-to-explicit conversion demands personal effort to share ideas informally through discussions and storytelling (Collins, 2001). Additionally, the status of formal authority and social and professional connectedness can act as facilitators in achieving high expected benefits.

Based on this reasoning, we conclude that the high expected benefit of lead users is closely linked to their personal characteristics, including:

1. An experimenter mindset
2. Social and professional connectedness
3. Status of formal authority
4. A collaborative attitude
5. Advanced communication skills

The presence of these characteristics determines the motivation of lead users for innovation (see Fig. 3).

Step three of the method was further refined to enhance the efficiency of the Lead User Method's identification process. This advancement involves integrating the research findings into the identification step by linking specific personal characteristics to the general attributes of lead users, such as being ahead of market trends and providing a high expected benefit (see Fig. 3).

Based on their characteristics, appropriate lead users are well-positioned to be ahead of market trends and to demonstrate a high expected benefit, thereby significantly contributing to the success of co-created NPD. Moreover, these co-creators can be objectively identified and selected by assessing their key personal characteristics.

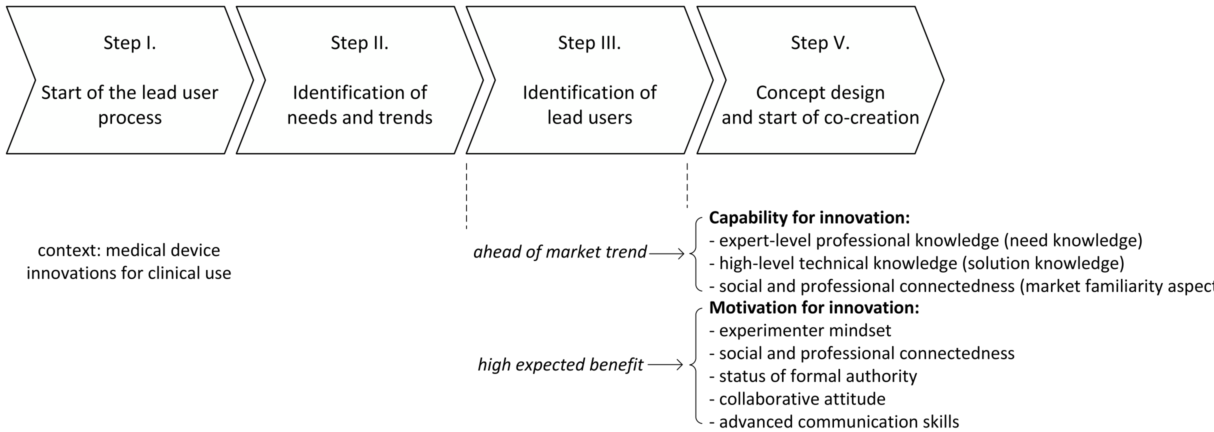

Fig. 3. Further development of the lead user identification process.

This study also contributes to open innovation theory, the user-centered design method, and collaborative innovation by providing specific insights and novel research findings.

Managerial implications

Engaging lead users across all stages of the NPD process—beyond just the 'fuzzy front end'—is essential for market success. Unlike prior studies that suggest limited early-stage involvement (e.g., Brockhoff, 2003; Enkel et al., 2005), our findings—supported by AVG1 and AVG2 data in Table 2—reveal that lead user engagement should intensify as the process advances, particularly in the market diffusion stage (answering Research Question 2). This continuous involvement helps reduce uncertainty, shorten development time, lower costs, and ensure a competitive product-market fit.

For effective selection, decision-makers should prioritize lead users with all seven identified characteristics, as these collectively drive successful co-created NPD. Each characteristic provides distinct advantages:

- Domain expertise helps anticipate market trends,
- Technical knowledge ensures solution feasibility, and
- Social connectedness fosters idea diversity and market adoption.

These characteristics remain critical across all NPD stages, regardless of product complexity.

Lead users with deep domain expertise can understand market needs and provide a strategic product vision. Managers should identify these users by assessing key indicators, such as extensive experience (e.g., 10–15 years), patents, and academic achievements, which signal the ability to address complex challenges holistically. Technical expertise is equally essential for ensuring prototype feasibility, with indicators including:

- Proficiency in technical terminology,
- Engagement in informal learning, and
- An engineering-oriented perspective.

These technically skilled lead users provide rapid, grounded feedback, streamlining testing and minimizing costly revisions.

The experimenter mindset among lead users enhances prototyping efficiency, particularly in regulated fields. Managers should prioritize lead users with prior prototype experience, as these individuals proactively refine ideas in practical settings.

Additionally, lead users who are well-connected within professional networks contribute diverse insights and facilitate product adoption by leveraging their central role to promote innovation among peers. Formal authority is particularly valuable in the market diffusion stage, where senior lead users can influence product acceptance and integration. Managers should focus on selecting users in decision-making positions, as their credibility accelerates market uptake, particularly in fields like healthcare, where authority plays a crucial role.

Communication skills and collaboration are also essential for effective knowledge transfer. Lead users who can articulate complex insights and work closely with development teams to enhance knowledge exchange, leading to practical improvements. Indicators of strong communication skills include clarity in language, simple metaphors, and a hands-on approach in real-world settings.

The authors created a guideline (Appendix B) to provide an overview of the essential characteristics of suitable lead users in co-created NPD. This guide details key attributes, contributions, and identification signals to assist decision-makers. Each characteristic is organized to help identify appropriate lead users for the entire value-creation process.

The guide outlines the main attributes under each characteristic element that contribute significantly to the NPD process. It explains how each characteristic positively impacts idea generation, product development, prototype testing, and market diffusion stages. Additionally, it includes signals for decision-makers to help select suitable lead users based on objective indicators.

This guideline supports decision-makers in identifying and selecting appropriate lead users with specific skills and abilities for co-created NPD, thereby optimizing external resources throughout the development lifecycle.

Limitations and further research

Our study has several limitations that may impact the research findings. First, it is based on case study research with a limited number of cases and employs an exploratory qualitative approach, utilizing theoretical sampling, systematic combining, and abductive reasoning. The investigation was conducted individually, focusing on single lead users within the co-created NPD process. The study did not explore scenarios involving multiple lead users participating simultaneously in NPD, which could introduce different dynamics and potentially require additional characteristic elements and varying levels of engagement.

Another limitation is that we focused exclusively on individuals meeting the lead user criteria of being ahead of market trends and offering high expected benefits (von Hippel, 1986). Additionally, our study is confined to medical device innovations, which may limit the generalizability of the findings.

Applying quantitative methods and alternative approaches could validate our findings and further refine the Lead User Method for future research. Exploring the engagement of multiple lead users within the co-created NPD process presents an opportunity to identify additional characteristic elements and examine the necessary levels of engagement.

One particularly promising direction is to investigate further how different lead users influence the diffusion phase of innovation and their interactions with development companies. Future research could also broaden the definition of external contributors, moving beyond the two general attributes established by the lead user concept (von Hippel, 1986). Examining other types of innovations could reveal distinct personal characteristics and different engagement dynamics, offering a valuable research agenda for innovation management and co-creation strategies.

CRediT authorship contribution statement

Béla Venesz: Writing – review & editing, Writing – original draft, Visualization, Validation, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Tibor Dőry:** Writing – review & editing, Validation, Supervision, Methodology, Conceptualization.

Appendix A. - Interview protocol

Interviewee(s):
Position(s):
Company:
Date:
Start Time:
End Time:
Interviewer(s):
Introduction:

At the beginning of the semi-structured interview, the interviewer will introduce the research background, objectives, and definitions of key terms, including lead user, NPD, innovation, successful NPD, product complexity, personal characteristics, and co-creation.

Interview Questions:

The interview will proceed with the following semi-structured questions:

1. How do you perceive the impact of expert-level professional knowledge in lead users on the success of the co-created NPD process?
2. How do you perceive the impact of high-level technical knowledge in lead users on the success of the co-created NPD process?
3. How do you perceive the impact of an experimenter mindset in lead users on the success of the co-created NPD process?
4. How do you perceive the impact of a collaborative attitude in lead users on the success of the co-created NPD process?
5. How do you perceive the impact of advanced communication skills in lead users on the success of the co-created NPD process?
6. Do you believe any additional personal characteristics of lead users influence the success of the co-created NPD process, which we have not yet discussed?

Appendix B. Main attributes of each characteristic: their contributions and signals for practice

Characteristic	Main Attributes	How It Contributes to NPD Success	Signals for Decision-Makers
Expert-Level Professional Knowledge	Possesses deep tacit understanding of their field. Switches between analytical and intuitive processes. Sees the big picture and grasps complex situations holistically. Focuses on key aspects of a problem and creates an innovative vision for solutions. Uses intuition to solve problems without consciously applying specific principles or theories.	Identifies market trends and significant problems. Recognizes real market needs ("need knowledge"). Provides professional feedback on solutions. Facilitates market diffusion through professional credibility.	Minimum of 10–15 years of experience. Under age 65. Scientific publications or patents. Academic researcher status and achievements. Ability to think outside the box and challenge norms.
High-Level Technical Knowledge	Strong technical competencies. Expands the range of possible solutions. Accepts and understands engineers' reasoning. Avoids pushing technically unfeasible ideas. Maintains a technical mindset.	Proposes technically feasible solutions ("solution knowledge"). Provides feedback considering the technical aspects of the problem and solution. Offers sound technical reasoning.	Uses correct technical terminology. Has a strong interest in technical solutions. Demonstrates a technical mindset. Engages in informal learning regularly.
Experimenter Mindset	Highly committed and motivated. Possesses advanced manual skills.	Tests initial ideas and builds prototypes. Advances ideas through experimentation. Produces detailed sketches or drawings. Conducts prototype testing and provides expert feedback.	Has engaged in initial experimentation. Has built early prototypes. Owns a personal workshop or lab.
Social and Professional Connectedness	Holds a central position in relevant social or professional networks.	Gains valuable feedback from experienced practitioners. Promotes access to diverse knowledge bases. Facilitates market promotion of the product. Stays informed about market trends and user demands.	Has an extensive professional network. Actively maintains professional relationships. Recognized as a leader in professional communities.
Status of Formal Authority	Holds a position of authority within an organization. Influences professionals nationally and internationally.	Uses credibility to influence professionals. Changes existing clinical protocols and guidelines. Plays a key role in product promotion and mindset shifts.	Holds a decision-making position. Has academic credentials and achievements. Occupies a high-level job position.

(*continued on next page*)

(*continued*)

Characteristic	Main Attributes	How It Contributes to NPD Success	Signals for Decision-Makers
Collaborative Attitude & Advanced Communication Skills	Converts tacit to explicit knowledge. Converts tacit to tacit knowledge. Persuades and convinces others.	Shares ideas and insights clearly. Uses simple and understandable language and metaphors. Provides engineers with contextual knowledge through hands-on collaboration. Demonstrates clear communication during market diffusion.	Expresses strong motivation to demonstrate real-world challenges. Uses clear, simple, and effective communication. Applies easy-to-understand metaphors in exp

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