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Healthcare Experts' Advisory Unit and Support (HAUS) Program for Medical Device Development in Korea: Introduction of Clinical Unmet Needs-Based Intended Use Establishment (CLUE) Templates

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ABSTRACT

Background: A clear and precise definition of the "intended use" in developing new medical devices can determine the success of entering the healthcare market. For this, practical collaboration between the clinical and engineering experts is necessary, and an appropriate tool is required for effective information collection and decision-making in the process.
Methods: The Korean Academy of Medical Sciences, in cooperation with the Korean Medical Device Development Fund, implemented the Healthcare Experts' Advisory Unit and Support (HAUS) program to match advisory clinical experts in medical device development projects. Three and five collaborative academic conferences were held in 2022 and 2023 to raise awareness of the HAUS program. In the consultation meeting, checklists were used to facilitate communications and satisfaction surveys were conducted afterward. Then, the results of the consultation meetings were compiled to build an integrated document.
Results: The HAUS program was conducted with a gradually increasing number of consultation sessions from 31 in 2021 to 128 in 2023. The medical device development teams (development teams) expressed a higher level of satisfaction (91.4% to 100%) compared to the advisors (clinical experts) (78.6% to 100%) across the survey items. Based on the experiences and observations of the HAUS consultation meetings, the "Clinical Unmet Needs-based Intended Use Establishment (CLUE) templates" were developed, which were

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purposes to improve communication efficiency and to support a systematic approach in establishing the intended use. The CLUE process comprises four main stages for processing: Stage 1, Initial Concept; Stage 2, Expert Consultation; Stage 3, Decision-making; and Stage 4, Intended Use.

Conclusion: The HAUS program seemed to be helpful for the development teams by providing opinions of clinical experts. And the resultant product, the CLUE templates have been proposed to facilitate collaboration between the development teams and the advisors and to define robust clinical intended use.

Keywords: Clinical Intended Use; Clinical Unmet Need; Medical Device Development; Medical Device Innovation

INTRODUCTION

Medical devices encompass a diverse range of equipment designed for medical professionals to home healthcare use, including both hardware and software solutions.[1,2] The purposes of the medical devices are to enable prevention, diagnosis, monitoring, treatment, or alleviation of target diseases or conditions.[3,4] In order for these medical devices to be effectively utilized in healthcare, it is crucial to properly apprehend the clinical unmet needs during the development process.[5-8] The Waterfall Design Process of the Food and Drug Administration also indicates that the starting point of the design process should be user needs.[9] These needs are identified through a thorough analysis of gaps or deficiencies in current medical practices including rigorous assessments, clinical engagements, and filtering procedures to find out the most pressing issues that need innovative solutions.[10-12] By understanding these unmet needs, developers can define specific objectives for their devices, ensuring they address critical healthcare challenges effectively.[5-7] This process involves gathering insights from healthcare professionals, patients, and clinical studies to determine the precise functionalities and capabilities required to meet the identified needs.[5,10,13] The intended use (or intended purpose) should be derived from the viable unmet needs and be utilized as an input component for the development process. This ensures that the design and functionality of the device are optimized according to its intended use, thereby enabling safe and efficient utilization by users and ensure patient safety and clinical effectiveness.[14,15] However, the medical device development process often focuses solely on technological expertise when starting device development, which can lead to overlooking clinical unmet needs. As a result, devices may enter the market without adequately addressing real healthcare challenges, risking a disconnection between their intended use and market acceptance.

Therefore, effective communication between medical device development teams (development teams) and clinical experts is very important. When they collaborate, it ensures to develop medical devices with robust intended use that meet clinical needs. Although this collaborative process is essential, it is not yet familiar to many development teams, who often struggle due to a lack of experience in communication and coordination with clinical experts and vice versa. Education and training are therefore necessary to bridge this gap and providing special tools may facilitate these efforts for communication.

The Korean Academy of Medical Sciences (KAMS) is a legal entity whose members include 194 medical specialty academic societies (academic societies) as of January 2024 in Korea and is in a position to cooperate with expert groups in all academic societies.[16] The Korean

Medical Device Development Fund (KMDF) is a funding program that supports medical device development researchers in Korea.[17] Starting from 2021, the KAMS, in cooperation with the KMDF, has been running the Healthcare Experts' Advisory Unit and Support (HAUS) program to provide tailored clinical advisory support for medical device development projects funded by KMDF, matching clinical experts to the specific needs of the development team when they voluntarily requested. The HAUS program facilitated communication between development teams and clinical experts and tried to promote structured discussions to reduce errors and save time, thereby fostering better inter-team communication and collaboration. And the Clinical Unmet Needs-based Intended Use Establishment (CLUE) templates emerged from these efforts.

The CLUE templates are structured to enable a step-by-step iterative approach to help participants with how to start the conversation, what to discuss, and their roles during the consultation meeting. Additionally, it enhances communication and collaboration by serving as a unified tool among cross-functional teams and facilitating better decision-making. The templates, combining clinical and engineering expertise, could eventually define a robust intended use by identifying unmet needs and ensuring comprehensive data collection. This article reports the three-year experience of implementing the HAUS program and developing the CLUE templates.

METHODS

Organization of healthcare expert advisory unit for the HAUS program

The advisory unit matching process

Organizing an advisory unit was only provided when a medical device development team requested participation in the HAUS program voluntarily to the KMDF and the overall process is described in **Fig. 1**. In this matching process, "Step 6. consent process to assign clinical experts" was included to reflect the development teams' concerns regarding the conflict of interest of clinical experts (or advisors). The number of advisors matched for each development team ranges from one to ten depending on the requirement. After matching, the development teams and the advisors get 10 months for the consultation period. The development teams need to reapply annually to renew the consultation period.

Consultation meeting methods

The operating committee offered no restrictions on the consultation meeting method, such as online meetings or in-person meetings or email, group or one-on-one because the HAUS program was started in 2021 amid the coronavirus disease 2019 pandemic.

Checklist for the consultation meeting

Checklists for medical devices and in vitro diagnostic (IVD) medical devices were provided to support the discussion when the development teams had consultation meetings with the advisors. Questions were derived and modified from selected items of the "Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)" [18] document that are relevant to assist in conceptualizing the clinical use aspect and the intended use. Initially, the HAUS checklist questions were expected to generate inputs for the selected items required by the STED as shown in **Fig. 2**. However, it was found out that the development teams and the advisors did not respond appropriately to the intentions.

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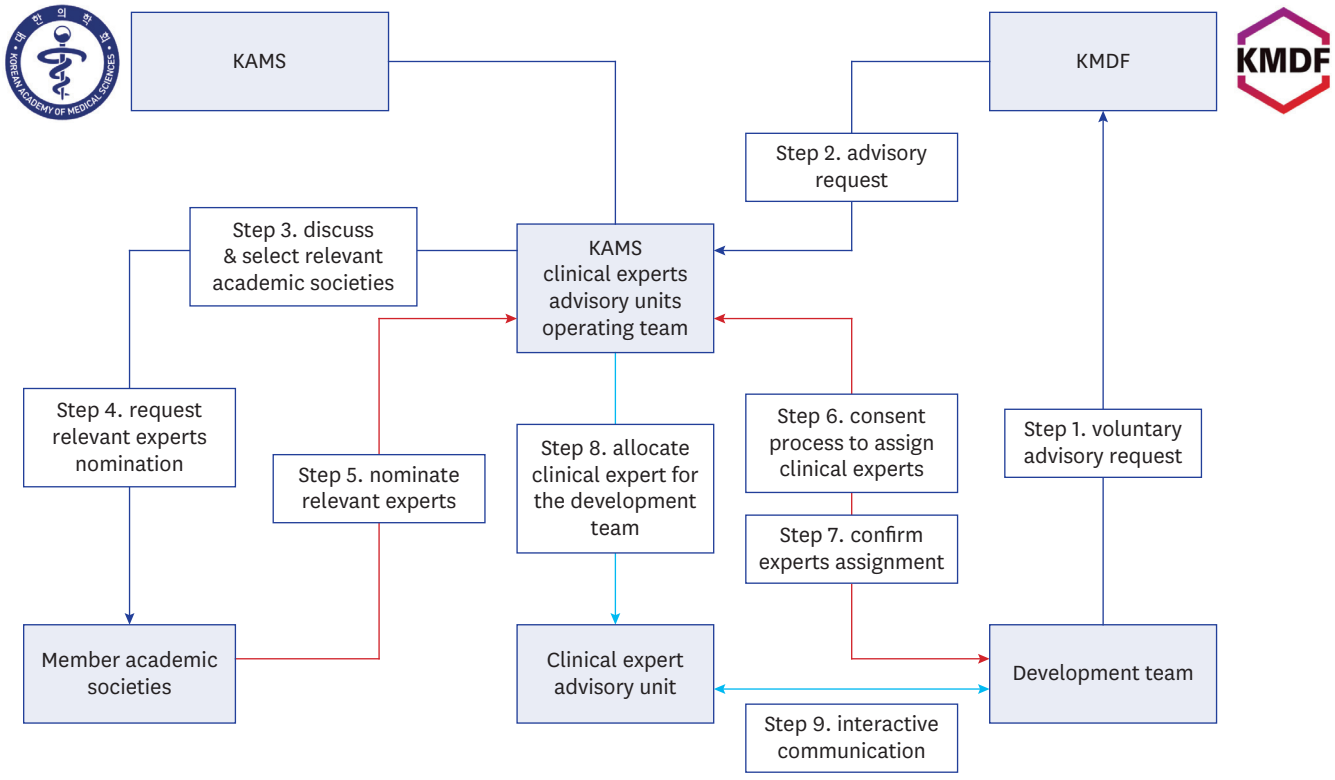

Fig. 1. Healthcare Experts' Advisory Unit and Support matching process.
KAMS = Korean Academy of Medical Sciences, KMDF = Korean Medical Device Development Fund.

Satisfaction survey

Starting from 2022, short satisfaction surveys were conducted on participating development teams and advisors of the HAUS program. The survey items for development teams included satisfaction level of helpfulness of the HAUS program, expertise of the advisors, security of the HAUS program, and friendliness of the advisors. The survey items for advisors include information provided by the development team, the expertise of the development team, the efficiency of the meetings, and openness of the development team. In 2023, an additional item, communication efficiency, was added to the development teams' satisfaction survey. All the survey items were structured in a 10-point Likert scale and the results were grouped as Dissatisfied (1–3 points), Neutral (4–6 points), and Satisfied (7–10 points) (**Supplementary Data 1**).

Collaborative academic conferences

When the HAUS program started in 2021, the academic societies and clinical experts were not aware of this program and the importance of clinical experts' participation in the development process of medical devices. Therefore, relevant academic societies under KAMS were selected and contacted to hold collaborative academic conferences to promote the HAUS program in 2022 and improve awareness of the importance of participation in the development process of medical devices.

Research and development of the CLUE process

Establishing a research and development team for the CLUE process (CLUE R&D team)

The intended users for the CLUE process are researchers or manufacturers who want to develop a new medical device. Therefore, bioengineers, engineers, and clinicians, considered to be a major group of experts involved in developing medical devices, were invited to the

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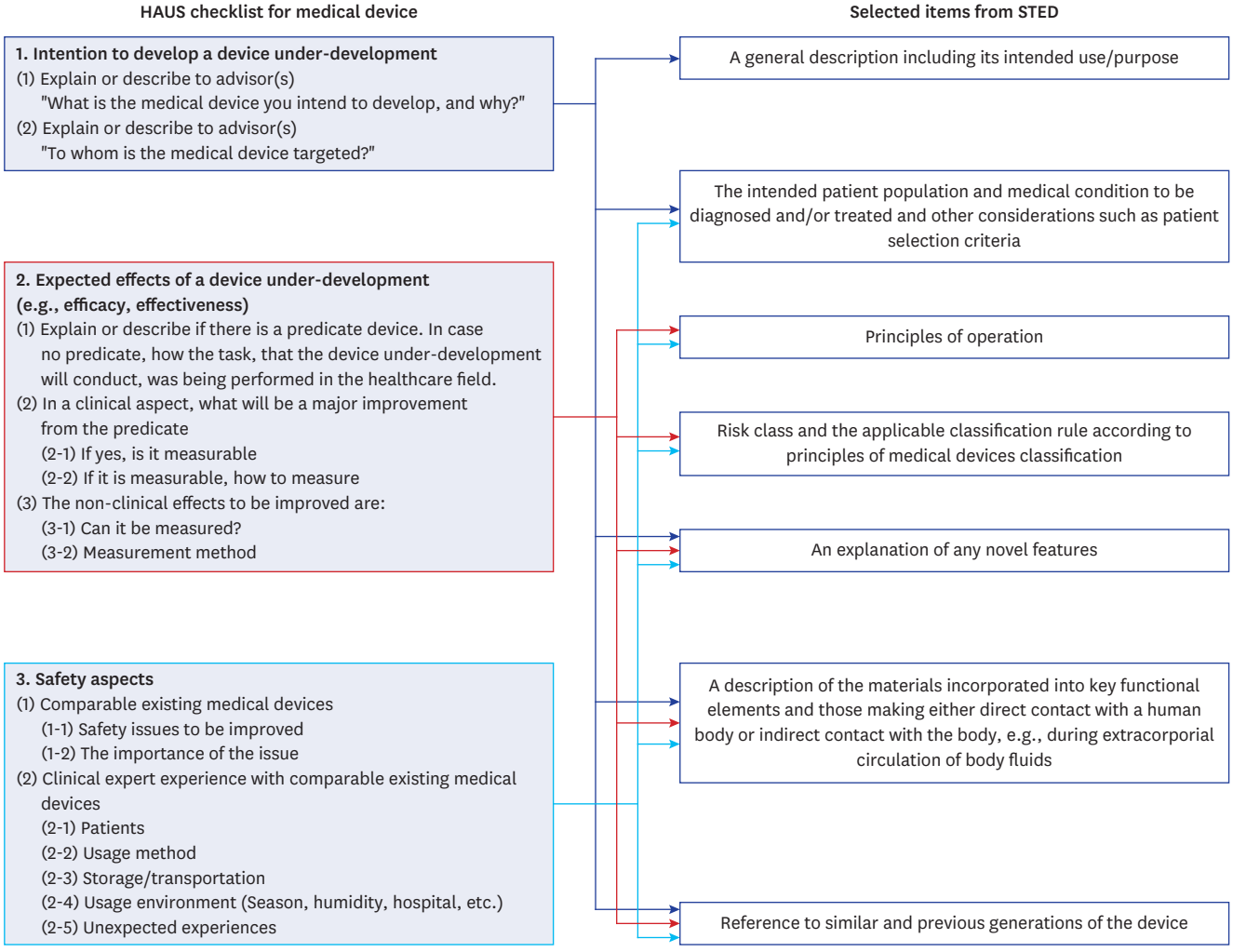

Fig. 2. Mapping between HAUS checklist and STED.
HAUS = Healthcare Experts' Advisory Unit and Support, STED = Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (GHTF/SG1/N011:2008[18]).

CLUE R&D team. Evidence-based medicine methodologists were also involved in the CLUE R&D team to reflect on the relevant requirements of clinical investigation[19] and the new health technology assessment system (nHTA) of Korea.[20]

Identifying necessary components to reflect on the CLUE process

The following conditions were considered as necessary for establishing intended use in the development of new medical devices. The intended use presented by a medical device developer should represent the purpose of utilizing a medical device in clinical practice. The first requirement of the nHTA process is to set clear clinical key questions. The essential component of the clinical key questions is the patient population, intervention, comparator, outcome (PICO) framework.[21] Interestingly, typical composing elements of intended use such as the intended clinical indication, patient population, part of the body or type of tissue interacted with, user profile, use environment, and operating principle are very similar to the components of the PICO framework.[21] Therefore, the CLUE process was designed to focus on defining well-designed clinical key questions for a new medical device. These well-designed clinical key questions reflect the clinical investigation, clinical evaluation, and the nHTA processes.

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International Organization for Standardization (ISO) documents (e.g., ISO 13485, ISO 14971) and International Medical Device Regulators Forum (IMDRF) documents (e.g., IMDRF/GRRP WG/N47) were also reviewed and cross-checked to identify relevant requirements that newly developed medical devices should comply with regulatory authorization.[14,15,22]

Research and development process

There were iterative brainstorming and consultation meetings for the research, development, and improvement of the templates starting from 2021 until the announcement of CLUE templates version 1.0 in 2024. In 2021, the HAUS program was initiated using a checklist to include the clinical aspects in the new medical device development process and facilitate the discussion between the development teams and the clinical experts. Although the questions were based on STED (**Fig. 2**), the users did not fully grasp the purpose. Based on the experience of the HAUS program, especially regarding communication within the program, an initial template was developed in 2022. This initial template was used by research volunteers in 2022 August as a pilot project.

During the pilot project, some areas for improvement were found. The users had difficulties in filling the initial template properly. Many users were unaware of the need for a series of consultations between the development teams and the clinical experts. Nor did they regard that the initial template should be repeatedly used to collect, analyze, and revise it until a robust intended use could be defined. Accordingly, the initial template was modified and structured into a stage-based step-by-step approach in 2023. The summary development process of CLUE templates from HAUS checklist is illustrated in **Fig. 3**.

RESULTS

The HAUS consultation meetings

Among applied development teams, 68% to 80% conducted consultation meetings with the advisors. The number of participating academic societies was around 30 each year. The number of participating advisors has decreased in 2022 and substantially increased in 2023 and 2024. Also, the number of consultation meetings continuously increased after the collaborative academic conferences that were held by KAMS in 2022 and 2023. The 2024 data showed a further increase in the number of applied development teams, participating academic societies, and advisors (**Table 1**).

Satisfaction survey

The survey data from 2022 and 2023 reflect overall high satisfaction levels across various attributes related to usability and effectiveness. The development teams expressed a higher level of satisfaction (91.4% to 100%) compared to the advisors (78.6% to 100%) across the survey items. The number of respondents increased in 2023 for both groups, indicating growing engagement and interest in the HAUS program (**Table 2**, **Supplementary Data 2**).

The qualitative aspect of the survey from 2023 also revealed much positive responses from the development teams where 20 out of 30 responses indicated that the development teams would like to continue participating in the consultation program. The rest of the responses were suggestions to improve some aspects of the consultation process such as expansion of the advisor pool, follow-up management, advocacy, and communication (**Supplementary Table 1**).

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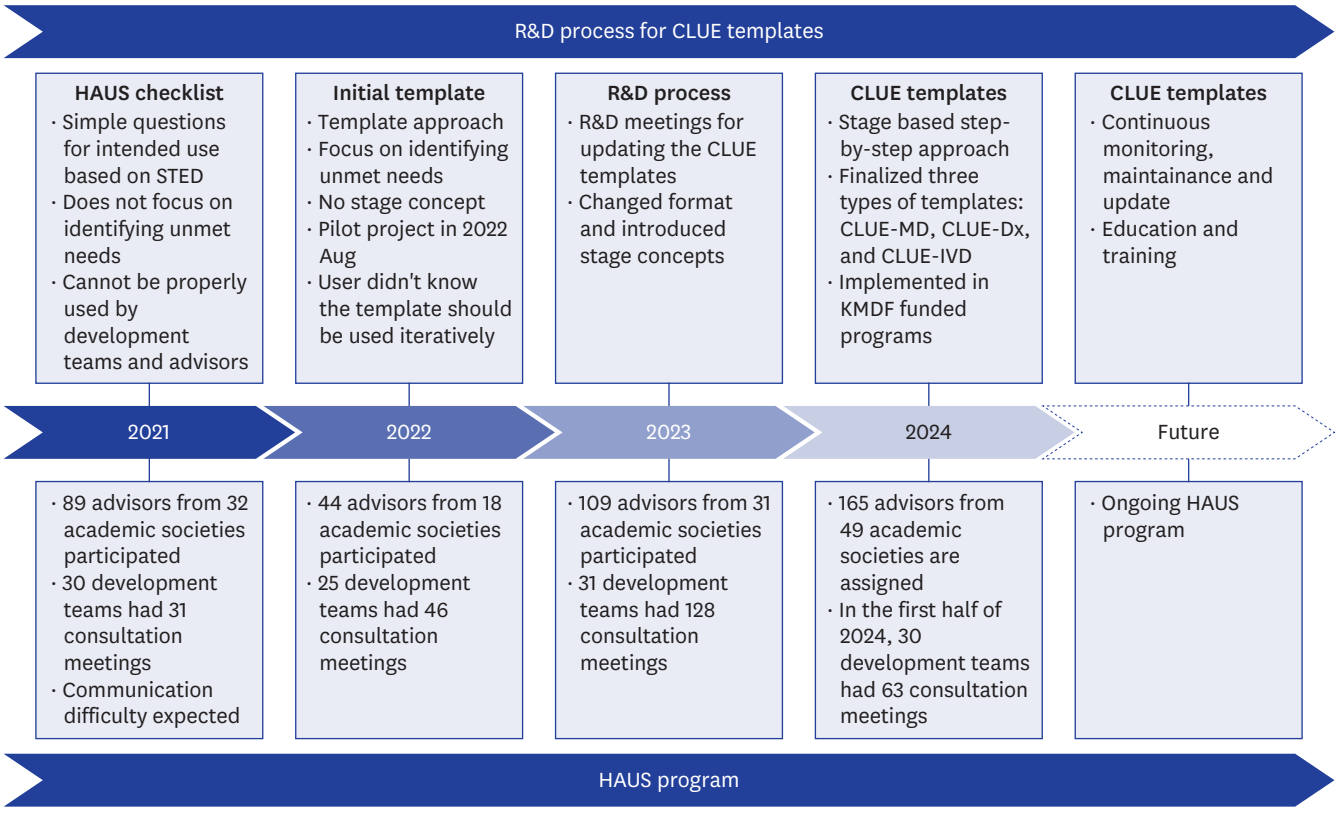

Fig. 3. Evolution of HAUS program and CLUE templates.
HAUS = Healthcare Experts' Advisory Unit and Support, STED = Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (GHTF/SG1/N011:2008[18]), CLUE = Clinical Unmet Needs-based Intended Use Establishment, R&D = Research and Development, CLUE-MD = Clinical Unmet Needs-based Intended Use Establishment template for interventional medical devices, CLUE-Dx = Clinical Unmet Needs-based Intended Use Establishment template for diagnostic medical devices, CLUE-IVD = Clinical Unmet Needs-based Intended Use Establishment template for in vitro diagnostic medical devices, KMDF = Korean Medical Device Development Fund.

Table 1. HAUS consultation meetings

Year	Applied DT			Assigned for HAUS consultation		Conducted HAUS consultation	
	New	Continued	Total	No. of academic societies	No. of advisors	No. of DT	No. of sessions
2021	44	0	44	32	89	30 (68%)	31
2022	19	13	32	18	44	25 (78%)	46
2023	27	17	44	31	109	35 (80%)	128
2024	53	20	73	49	165	30 (41%)[a]	63[a]
Total	143	-	193	130	407	120	268

HAUS = Healthcare Experts' Advisory Unit and Support, DT = development teams.
[a]First half of 2024.

Collaborative academic conferences

Collaborative academic conferences were held within three academic societies in 2022 and five academic societies in 2023 to increase awareness of the domestic medical device development activities and the importance of participation of academic societies in the HAUS program for the quality development of medical devices to improve patient health and safety. During these conferences, 24 development teams presented their projects to the academic societies (**Supplementary Table 2**). After these advocacy events, the number of participating advisors increased substantially from 44 in 2022 to 109 in 2023 and 165 in 2024 (**Supplementary Table 3**). The conferences fostered greater collaboration and engagement among the development teams and the advisors, encouraging more of them to participate in the HAUS program.

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Table 2. Satisfaction survey results by development teams and advisors

Year	Survey item	Dissatisfied (1–3)	Neutral (4–6)	Satisfied (7–10)	No. of responses
Development teams' satisfaction survey results					
2022	Helpfulness	0 (0)	0 (0)	27 (100)	27
	Expertise	0 (0)	0 (0)	27 (100)	27
	Security	0 (0)	1 (3.7)	24 (96.3)	25
	Friendliness	0 (0)	1 (3.7)	26 (96.3)	27
2023	Helpfulness	1 (2.7)	2 (5.4)	34 (91.9)	37
	Expertise	0 (0)	2 (5.4)	35 (94.6)	37
	Security	0 (0)	2 (5.6)	34 (94.4)	36
	Friendliness	0 (0)	0 (0)	38 (100)	38
	Communication efficiency	1 (2.9)	2 (5.7)	32 (91.4)	35
Advisors' satisfaction survey results					
2022	Provided information	0 (0)	5 (13.5)	32 (86.5)	37
	Expertise	1 (2.7)	2 (5.4)	34 (91.9)	37
	Efficiency	0 (0)	4 (10.8)	33 (89.2)	37
	Openness	0 (0)	4 (10.8)	33 (89.2)	37
2023	Provided information	2 (4.8)	7 (16.7)	33 (78.6)	42
	Expertise	1 (2.3)	2 (4.7)	40 (93.0)	43
	Efficiency	0 (0)	1 (2.3)	42 (97.7)	43
	Openness	0 (0)	0 (0)	42 (100)	42

Values are presented as number (%).

The CLUE process and templates

Three types of CLUE templates have been developed: "CLUE-MD" for interventional medical devices (**Supplementary Data 3**), "CLUE-Dx" for diagnostic medical devices (**Supplementary Data 4**), and "CLUE-IVD" for IVD medical devices (**Supplementary Data 5**). The three CLUE templates are fundamentally similar but vary depending on the type of device being developed. For example, the CLUE-IVD and CLUE-Dx include steps for considering a reference standard and estimation of clinical impact by erroneous results while CLUE-MD does not need to consider these steps. The CLUE-IVD includes the consideration of specimens where CLUE-Dx and CLUE-MD are not needed. In CLUE-IVD, the development team needs to consider the clinical impacts of each possible result (true positive, false positive, true negative, and false negative) to estimate the performance goal of the new IVD medical device. Minimizing false positive and false negative results is a balancing process that needs to consider different factors including the intended use to reduce potential harm to the patient. The CLUE-Dx shares common characteristics of both CLUE-MD and CLUE-IVD. **Fig. 4** describes the step-by-step approach of the CLUE process to generate the necessary components of the intended use as well as the similarities and differences between the three templates.

The process of utilizing the CLUE templates to establish the clinical intended use was named as the CLUE process. The CLUE process comprises four stages: Stage 1 Initial Concept, Stage 2 Expert Consultation, Stage 3 Decision-making, and Stage 4 Intended Use. In Stage 1, the reasons for new device development are summarized and initial unmet needs are outlined by the development team. Stage 2 involves gathering and documenting opinions from the clinical experts. Stage 3 focuses on defining core features and final unmet needs based on the previous stages. In Stage 4, the development team can finally define the "intended use" based on the previous stages for operating principle, target population, health effect, user, usage environment and indications. This process can be utilized as a tool to determine the intended use of the new medical device (**Fig. 4**). This structured methodology aims to enhance the precision and effectiveness of establishing the intended use of new medical devices, improving their relevance and impact in the healthcare market. The four stages of each

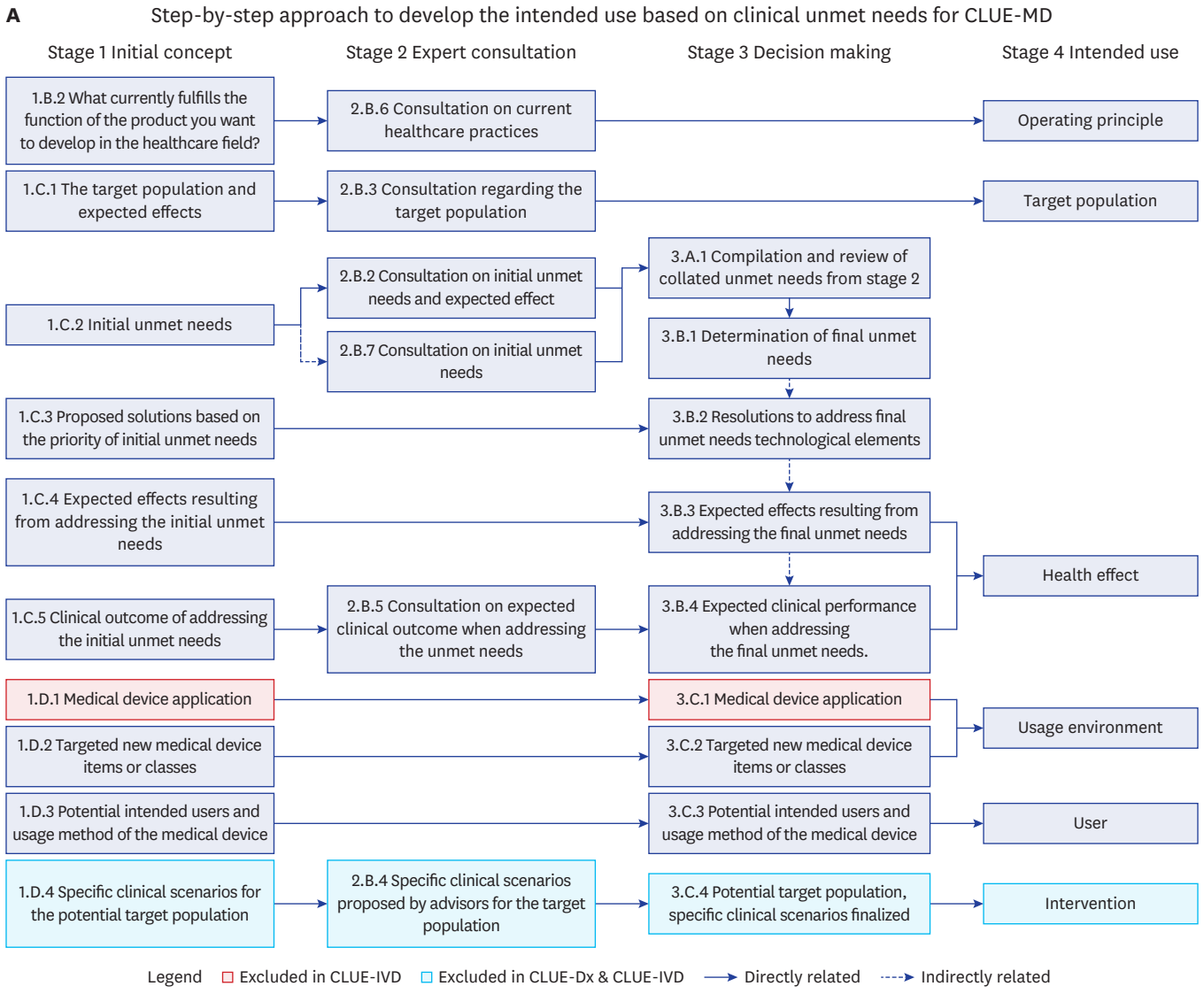

Fig. 4. Step-by-step CLUE process of developing the intended use based on clinical unmet needs using CLUE templates.
CLUE = Clinical Unmet Needs-based Intended Use Establishment, CLUE-MD = Clinical Unmet Needs-based Intended Use Establishment process for interventional medical devices, CLUE-Dx = Clinical Unmet Needs-based Intended Use Establishment process for diagnostic medical devices, CLUE-IVD = Clinical Unmet Needs-based Intended Use Establishment process for in vitro diagnostic medical devices, IVD = in vitro diagnostic.

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template interconnect, some items across the templates are repetitive, aiming to refine and identify the clinical unmet needs iteratively. The contents filled in the tables will evolve as each stage progresses. The order of the tables in Stage 2 is not in line with Stage 1 and Stage 3 because Stage 2 is designed to follow the usual process of the clinical expert consultation.

DISCUSSION

The HAUS program has helped the developers to address the above challenges, yet challenges remain in the consultation process. The development teams do not have a structured idea on how to get input from the advisors. On the other hand, the advisors are also not familiar with this kind of consultation process and have limited experience of medical device development.

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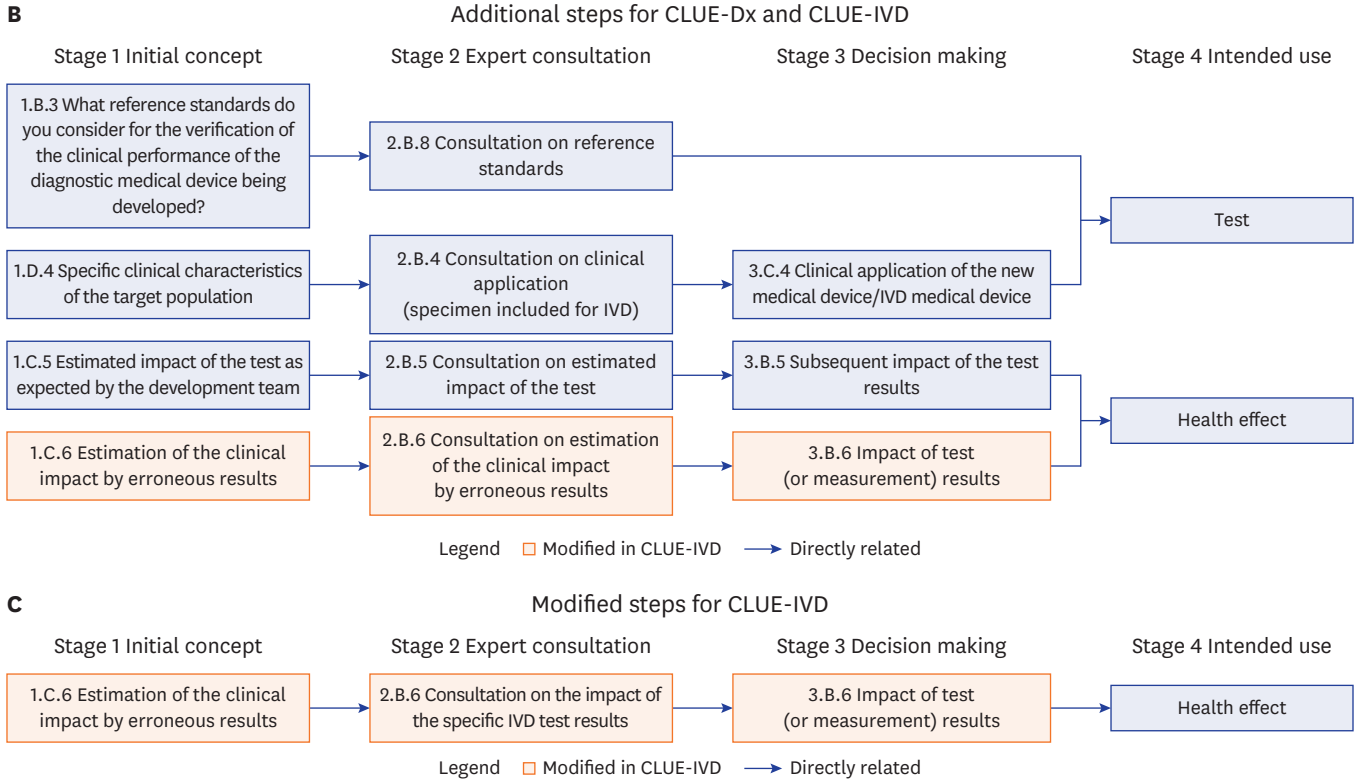

Fig. 4. (Continued) Step-by-step CLUE process of developing the intended use based on clinical unmet needs using CLUE templates.
CLUE = Clinical Unmet Needs-based Intended Use Establishment, CLUE-MD = Clinical Unmet Needs-based Intended Use Establishment process for interventional medical devices, CLUE-Dx = Clinical Unmet Needs-based Intended Use Establishment process for diagnostic medical devices, CLUE-IVD = Clinical Unmet Needs-based Intended Use Establishment process for in vitro diagnostic medical devices, IVD = in vitro diagnostic.

Also, collaboration was difficult due to the differences in background, professional culture, and benefits of interest often resulting in the two parties not being on the same page. Some development teams reported the need for improvement in communication with advisors and follow-up management in the satisfaction survey. The development teams and the advisors had to build a collaborative culture among various specialized fields and require an enabling environment that promotes collaboration. There were also some suggestions to provide a template to facilitate these consultation meetings in the satisfaction survey. Therefore, the KAMS and KMDF put much effort to develop the CLUE templates and to create an enabling environment.

The innovation pathway of a new medical device can be influenced by the dynamic between "technology push" and "market pull" concepts.[5,23,24] The "technology push" approach is where the developer finds and promotes a solution for a clinical need that users may not recognize, creating demand for the product. Conversely, the users (clinician and patient) identify a need, and the developers respond with a solution tailored to fulfill that need based on the users' input and requirements in the "market pull" approach.[5,23] The CLUE process is the integration of both approaches where the development team puts down their ideas in Stage 1 and consults with the users (advisors) in Stage 2.

Realizing the clinical unmet needs is the foundation of the Stanford Biodesign model, one of the most well-known and comprehensive approaches for medical device innovation, and the identification of unmet needs can be done by needs finding and needs screening

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processes.[5,10,24,25] Also, the clinical intended use is the starting point of Good Manufacturing Practice.[2] If clinical intended use is not established, the subsequent impact is enormous in the regulatory approval process as it can impact on designing, validation, and manufacturing process, and possibly negative impact on patient safety. According to ISO 13485, the designing and manufacturing of medical devices should be aligned with the clinical intended use.[22] One of the challenges in risk analysis of medical devices is the diversity of use scenarios based on intended use. ISO 14971, Risk Management of Medical Devices, requires that risk analysis begin with a clear understanding of the intended use and reasonably foreseeable misuse. Analysis of the intended use and potential misuses provides the appropriate context and a framework for the subsequent risk analysis.[15]

The CLUE process was created to guide and facilitate the identification of clinical unmet needs through an iterative step-by-step process where the inputs from the clinical experts can be received through a few consultation meetings in Stage 2. The identified unmet needs can then be linked to define a robust clinical intended use for the new medical device in Stage 4. This intended use is essential and is mandated by medical device regulatory requirements from ISO and International Electrotechnical Commission (IEC), such as ISO 13485, ISO 14971, IEC 62366-1, and IEC 62304 (**Table 3**).[15,22,26,27] Therefore, the CLUE template, by deriving the intended use of medical devices from unmet clinical needs, holds significant value for scalability and applicability.

The CLUE process is particularly valuable because it guides the development of medical devices to closely align with the actual clinical needs, by enhancing awareness of their clinical relevance and impact in the healthcare field. By engaging clinical experts directly in the early stages of medical device development, the CLUE process not only identifies precise clinical unmet needs but also enables the integration of expert opinions into the design and functionality of the device. This coordination is critical because it leads to the development of medical devices with innovative features, practical utility, and compliance with regulatory standards.

The regulatory standards ISO 13485, ISO 14971, IEC 62366-1, and IEC 62304 provide a comprehensive framework for the quality management, risk management, usability engineering, and software lifecycle processes of medical devices.[15,22,26,27] By applying the intended use derived from the CLUE process to these standards, this process is expected to enhance the likelihood of regulatory approval and market success. Therefore, the CLUE template's extension beyond initial identification to include regulatory alignment demonstrates its comprehensive utility in the medical device development lifecycle.

Neither prolonged nor in-depth pre-training is required to perform the CLUE process. This is a significant advantage where any interested clinicians can easily participate in the consultation process without committing much of their time. The shortage of clinicians as innovators[28] is also addressed by the CLUE process since the advisor does not need to be a clinician innovator, and the advisor pool can easily be expanded without specific training or commitment. Nevertheless, having clinicians as innovators is still valuable, and by participating in the HAUS program and CLUE process, some clinicians may discover their hidden talent as innovators.

One prominent feature of the CLUE process is the iterative approach. The recommendation for an iterative approach to stakeholder engagement and the need identification process by Markiewicz[29] and Weigl et al.[13] is in alignment with the CLUE process. The CLUE process is

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Table 3. Contents related to intended use in ISO and IEC standards for medical devices

Regulatory standards	Contents
ISO 13485:2016 Medical devices—Quality management systems—Requirements for regulatory purposes[22]	3.8 Labelling 3.10 Manufacturer 3.12 Medical device family 3.13 Performance evaluation 4.2.3 Medical device file 7.2.1 Determination of requirements related to product 7.2.3 Design and development inputs 7.3.6 Design and development verification 7.3.7 Design and development validation 7.3.9 Control of design and development changes 8.3.2 Actions in response to nonconforming product detected before delivery
ISO 14971:2019 Medical devices—Application of risk management to medical devices[15]	Introduction A.2.1 Scope 3.6 Intended use/Intended purpose 3.9 Manufacturer A.2.3 Terms and definitions 5.2 Intended use and reasonably foreseeable misuse A.2.5.2 Intended use and reasonably foreseeable misuse A.2.5.3 Identification of characteristics related to safety 5.4 Identification of hazards and hazardous situations A.2.5.4 Identification of hazards and hazardous situations 7.4 Benefit-risk analysis 8 Evaluations of overall residual risk 10.3 Information review
IEC 62366-1:2015 Medical devices—Part 1: Application of usability engineering to medical devices[26]	(Annex A) Clause 1: Scope 3.9 Normal use (Annex A) Definition 3.9: Normal use 3.23 Use specification 5.1 Prepare use specification (Annex A) Subclause 5.1: Prepare use specification 5.6 Establish user interface specification
IEC 62304:2006 Medical device software—Software life cycle processes[27]	3.13 Problem report (Annex) B.4.4 Legacy software 5.3.3 Specify functional and performance requirements of SOUP item (Annex) B.5.7 Software system testing 6.2.1.1 Monitor feedback 6.2.1.3 Evaluate problem report's affects on safety 6.2.3 Analyze change requests

ISO = International Organization for Standardization, IEC = International Electrotechnical Commission.

not a tool to magically solve all the challenges faced by the developers. However, it can help to align the thought process of the development team and the clinical experts in exploring and identifying the unmet needs and realizing the relationship between the unmet need and the intended use. Active participation of the academic societies is also important to successfully implement the CLUE process and to advance the innovation of medical devices for better health outcomes.

The CLUE templates were announced publicly in 2024 April and implemented in KMDF funded medical device development programs in 2024. The CLUE process and templates are still in the very early stage of implementation and need to gather experience and feedback from the users. Analyzing user feedback from developers and clinical experts can provide insights into the challenges and benefits of the process. Continuous monitoring and maintenance efforts are needed to improve usability. In the future, the CLUE R&D team aims to advocate the use of CLUE templates in the designing stage of medical devices to relevant academia, industry, research institutes and international stakeholders. The CLUE R&D team

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plan to continue advocating the importance of the clinical intended use in the medical device development field internationally.

The CLUE templates focus on medical devices and IVD medical devices innovation. Other areas of innovation such as pharmaceuticals, advanced therapies, or convergence medical products are also important for advancing the capabilities of the healthcare field. Future research can utilize similar approaches to facilitate other areas of innovation. Additionally, exploring the possible relations with existing regulatory frameworks can harmonize with health authorities' standards. Addressing these limitations and focusing on these research areas will help evolve the CLUE process into a more robust, efficient, and widely accepted framework for medical device development.

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SUPPLEMENTARY MATERIALS

Supplementary Data 1
Survey questions

Supplementary Data 2
Survey results

Supplementary Data 3
CLUE-MD v1.0

Supplementary Data 4
CLUE-Dx v1.0

Supplementary Data 5
CLUE-IVD v1.0

Supplementary Table 1
Opinions collected from research and development teams participating in 2023 advisory units (qualitative aspect)

Supplementary Table 2
Cooperative academic meetings within clinical societies and project titles

Supplementary Table 3
Academic societies and the number of participated advisors

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