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Leveraging SMEs' Competitiveness Through Innovation and Standardization: Case Study of SMEs in Medical Device

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ABSTRACT

Indonesia's medical devices industry has indicated substantial growth recently. However, domestic products are still seemingly less competitive than imported products. This study aimed to fill the gap by presenting a more robust analysis regarding the collaborative innovation process of new medical devices to support the competitiveness of Small and Medium-sized Enterprises (SMEs) through innovation and standardization. This study employed a qualitative case study approach using a holistic multiple-case design, namely by looking into the innovation process of GLP HFNC-01 and Dharcov-23S medical devices. As the results, we have discovered the activities in the standardization process for each stage of the innovation process and the specific types of standards that SMEs should meet. We have figured out multi-stakeholder cooperation in supporting SMEs in each activity. Furthermore, the role of multi-stakeholder collaboration is also highlighted in supporting SMEs along the innovation and standardization process to gain market competitiveness. Actors involved in each innovation process have disparate backgrounds, capabilities, and knowledge, such as the Public Research Institute (PRI), industries, governments (public testing laboratory, National Public Procurement Agency, Ministry of Health), medical experts, hospitals, and users.

I. INTRODUCTION

Indonesia's medical devices industry has indicated substantial growth recently. Based on data from the Ministry of Health Republic of Indonesia (MoH), the local industry of medical devices has grown by 361.66% in the last five years (2021). The MoH issued around 2,862 commercial licenses in 2016, which increased significantly in 2020 and 2021 by 8,045 and 8,780, respectively.

However, domestic products are still seemingly less competitive than imported products. This is reflected in the total number of commercial approvals granted to medical devices (175,129 as of July 22, 2022), of which 12.7% are local products, and the rest (87.3%) are imported products.

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In this globally competitive world, product competitiveness has become a critical issue. To elevate innovation activities, companies require adequate technological capability in order to develop and improve new products (Valdez-Juárez & Castillo-Vergara, 2021). Furthermore, companies should also maintain the consistency of quality along the innovation process and dissemination to target market in order to achieve product competitiveness (Kutnjak et al., 2019).

Standards and standardization play an important role in the innovation process and, ultimately, product competitiveness. Standards are defined as "commonly agreed reference documents that help to bring order to the world" (Stroyan & Brown, 2012). They constitute important elements of framework conditions for codification and dissemination of knowledge through research, development, and innovation (Blind, 2013; Stroyan & Brown, 2012). Standards ensure the interoperability, compatibility, and reliability of innovative products to meet defined safety and quality criteria, also to reduce risks for users and society (Blind, 2013; Jiang, Liu et al., 2020; Stroyan & Brown, 2012). Thus, standards help companies to elevate both their operational effectiveness and product competitiveness at global scale (Jiang, Liu, et al., 2020).

Furthermore, standardization is interpreted as an official platform utilized by researchers and related actors (Blind, 2013) to "voluntarily develop technical specifications based on consensus among interested parties" in the innovation process. These actors included industry, public authorities, customers, and other relevant stakeholders (European Commission 2008 p.2 as cited in Blind, 2013). Technology standardization supports innovation (Stroyan & Brown, 2012) and development through technological integration into the various aspects of the innovation process (Jiang, Gao et al., 2020). It starts from the supply side (research phase) when the knowledge and idea are generated, including by integrating inputs from heterogeneous sources (implementers of standardized technologies and potential consumers of standardized final product), to the demand side of dissemination as in public procurement (Blind, 2013). Especially in the healthcare sector, new medical devices must be approved by accrediting authorities and funded by stakeholders. Planning, implementing, and controlling the innovation process from initial idea to market launch is a prerequisite to ensure successful life cycle of medical devices (Löschner & Fleßa, 2022). The standardization of activities in each stage of the innovation process is intended to ensure that the new medical devices meet defined safety and quality criteria, also to reduce risks for users and society. In turns, it can increase the likelihood for new medical devices to successfully reach the target market.

Nevertheless, to date, only several studies have investigated the impact of standardization in the innovation process to improve SMEs' competitiveness. Recent study by Efendi et al. (2020) focused on organizational capacity in which learning and imitating capability are important to improve low-technology SMEs' competitiveness in Indonesia. Meanwhile, study by Wagner and Schanze (2018) only focused on the commercialization period, providing an overview of the most relevant and emerging requirements that SMEs need to adapt to sell their medical devices in compliance with European medical device regulations. Another study by Setyawan et al. (2015) highlighted the need for government assistance to develop marketing network and financial institution. It is also revealed from inquiry on empirical studies that there was still no study that discussed the required standard activities for each stage throughout the innovation process and the actors involved in each stage.

This study aimed to fill the gap by presenting a more robust analysis regarding the collaborative innovation process of new medical devices to support SMEs' competitiveness through innovation and standardization. The role of multi-stakeholder collaboration is highlighted in supporting SMEs throughout the innovation process and activities to meet certain standards in order to gain market competitiveness. This study focuses more on standardization at the company level by providing empirical evidence in standard activities throughout the innovation process of new medical devices.

This study looked into the innovation process of GLP HFNC-01 and Dharcov-23S medical device as the case study. GLP HFNC-01 and Dharcov-23S are indigenous therapeutic devices that were developed collaboratively by PRIs and SMEs in Indonesia amidst the COVID-19 pandemic in 2020. GLP HFNC-01 is the first high-flow nassal cannula made by Indonesian company. HFNC is a non-invasive method that can be used to help early-stage COVID-19 patients breathe. Meanwhile, Dharcov-23S is a pneumatic-based CMV (Continuous Mandatory Ventilation) emergency ventilator. The results of this study are expected to contribute in enhancing collaborative innovation by harnessing the role of multistakeholder collaboration to support SMEs' competitiveness, not only through the improvement of innovation capacity, but also through the compliance with the corresponding defined standards.

II. ANALYTICAL FRAMEWORK

A. Standards and Regulations in Medical Device Development

Standards and regulations have become part of our daily lives. They determine whether a plug fits into a socket or whether one mobile phone can be connected to another. It also determines whether the water is fit for human consumption or whether a drug can be marketed (The International Trade Center, 2016). The International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) 2004 formulated the definition of standardization as the activity of establishing, with regard to actual or potential problems, provisions for common and repeated use aimed to achieve the optimum degree of order in a given context. Standardization is implemented through several levels, namely by company, regional, national, and international levels (National Standardization Agency of Indonesia, 2014). An important milestone in the development of standardization in Indonesia was achieved through the passing of Act No. 20/2014 concerning Standardization and Conformity Assessment. Standards are resulted by means of standardization, namely a voluntary technology development process based on consensus among stakeholders (Blind, 2013; Republic of Indonesia, 2014).

The meaning of terms 'standard' and 'regulation' can be vary according to different users. The International Trade Center (2016) defined standards and regulations from the point of view of decision-makers in SMEs:

> *Standard is a required or agreed level of quality or attainment. Public or private entities can set standards. Regulation is a rule or directive made and maintained by an authority, often a government. A standard becomes a regulation when being written into a law.*

Standards and regulations can be applied both to goods and services. Commodity-related regulations are commonly referred to as technical regulations, while service-related regulations are commonly referred to as service regulations (The International Trade Center, 2016).

Medical technology is characterized by a constant flow of innovation through advanced research and development within the industry and cooperation with users (Maresova et al., 2021). MoH classified medical devices into four classes: A, B, C, and D (Regulation of MoH No. 62/2017). This classification is based on their risk class. Bringing a new or innovative medical product to market successfully is largely determined by the developer's capability to meet the complexity of mandatory requirements and, above all, the time and effort required to comply with the conformity assessment by a notified body.

The risk classifications of medical devices, adopted from the Ministry of Health Republic of Indonesia (2017), are described as follows:

a) Class A: low-risk level; Requirements: laboratory test results (Certificate of Analysis / CoA, stability test, sterility test, electrical safety test)
b) Class B, low to moderate risk level; Requirements: laboratory test results (Certificate of Analysis/CoA, stability test, sterility test, electrical safety test)
c) Class C, moderate to high-risk level; Requirements: laboratory test results and results of pre-clinical and clinical trials

d) Class D, high-risk level; Requirements: laboratory test results and results of pre-clinical and clinical trials

Although standards serve as a legitimate directive to facilitate profitable trade, compliance with the existing standards can often be time-consuming and expensive. Besides costs, trade also depends largely on SMEs' support from the immediate business environment, national regulations, and national institutions. The complexity of various standards and regulations can lead to information overload for businesses of all sizes, especially for SMEs. Therefore, SMEs need assistance to strengthen their capacity to be able to compete, connect, and change, also to improve their capability to comply with standards and regulations (The International Trade Center, 2016).

B. R&D, Innovation, and Standard in Medical Device Development

Medical devices will only succeed if their associated technological innovations are capable to overcomes various barriers. In particular, new medical devices in healthcare must be approved by recognized authorities and financed by interested stakeholders. Thus, proper planning, implementing, and controlling the innovation process, from the early idea to the market launch, is a prerequisite to guarantee successful life cycle of the product (Löschner & Fleßa, 2022). Successful product development and dissemination to the market are largely determined by a complex interrelation of equally important factors, namely business strategies, technological solutions, human resources, and end-users involvement (Maresova et al., 2021). Besides, Durfee and Iaizzo (2018) mentioned two additional considerations besides meeting needs and providing value to ensure successful development of new medical devices, namely by establishing regulatory controls and reimbursement policies.

Regulatory issues also impact the whole innovation cycle. They must be considered in the early steps of the medical device design and development, during pre-clinical and clinical evaluation, product regulatory evaluation, manufacturing, and post-marketing surveillance. For this reason, the relationship between medical device developers and national regulation agencies is critical for innovation and competitiveness in this sector (Guerra-Bretaña & Flórez-Rendón, 2018).

With regard to innovation theory, a rigorous interpretation of Porter's hypothesis stated that challenging factors in the form of strict regulation may stimulate innovation as established technologies are gradually replaced by newer, more effective, and safer alternatives (Porter & Van Der Linde, 2017). This is especially true in the highly regulated medical device market, where new entrants must meet certain conditions to be able to proceed. These conditions are primarily concerned with safety regulations, environmental protection requirements, and several aspects of the development process, namely technical, clinical, and biological aspects. Hard conditions can be interpreted as an obstacle, but they can also stimulate innovation (Maresova et al., 2020).

The innovation process goes through several stages. Trott (2017) defined innovation as activities ranging from new inventions to eventual products. It involves the process of "idea generation, technological development, product manufacturing, and marketing of a new (or improved) product, manufacturing process, or equipment". Furthermore, Van de Ven et al. (1999) divided this process into three periods: the initiation period, the developmental period, and the implementation/termination period. The initiation period highlights how the idea and innovation are generated, including identifying the resources required in order to proceed to the subsequent process. The developmental period involves the interaction among various elements, namely technological collaboration, competition, and conformity with the government regulations to obtain "legitimacy" status for the innovative product. In this period, the developers will determine whether the implementation of the innovation is possible to be continued, or has to be halted due to running out of resources.

It has been established that each stage of the development process exhibits its own challenges, and each stage is equally essential to guarantee

overall success. This includes pre-stage funding, partner acquisition, partner recruitment, and setting development milestones. Furthermore, success in medical device innovation process is also determined by developer's capability to conduct clinical trials, obtain regulatory approval, launch the products to target market, and do post-marketing surveillance. Nonetheless, various barriers can hamper the progress. These include issues related to external costs, such as lack of funding, high implementation costs, and verification or certification costs. Further obstacles can emerge from unethical regulators and difficult access to acquire information (Maresova et al., 2021).

The research framework of this study was built based on the concept of the innovation process and the standards that must be met at each stage (Figure 1).

III. METHODOLOGY

This study employed a qualitative case study approach using a holistic multiple-case design to answer the research questions. The study adopted a replication framework in order to produce a robust analysis. Case studies were selected carefully at the beginning of the study by considering the potential results they might lead to. The results of the selected case study were expected to generate a literal replication (similar results) (Yin, 2003).

Furthermore, the case study protocol was designed to structuralize the research framework. Data were collected between March 8, to September 16, 2021. A good case study should use as many reliable sources as possible, as the various sources are highly complementary (Yin, 2018). The primary data were complemented with extensive secondary data. The primary data were collected through semi-structured interviews that lasted 1–2 hours each and were performed online using Zoom platform. The questions for the interview were designed based on the conceptual framework. As many as 43 respondents were interviewed in 32 different occasions. They were researchers, engineers, related deputy/directors of the PRIs, medical practitioners, the firms' managers (PT. Gerlink and PT. Dharma), related government officials, and policymakers. The primary data were complemented with extensive

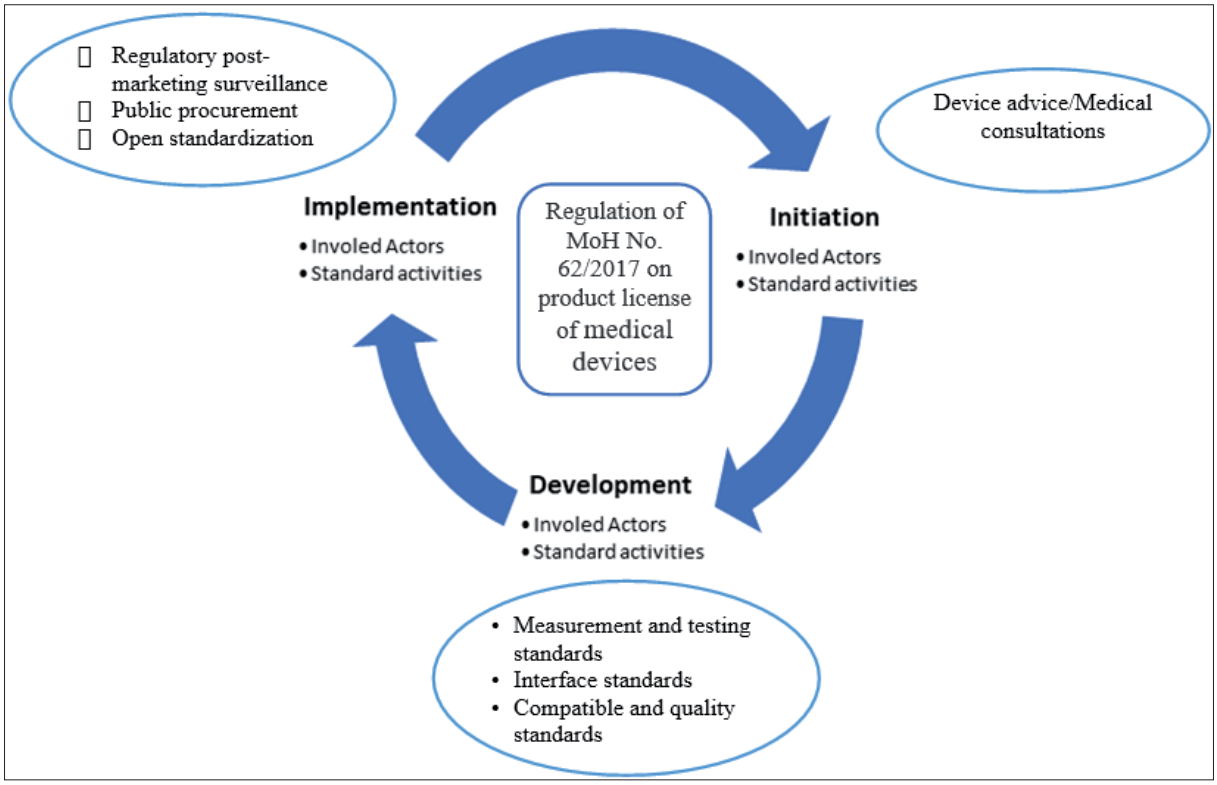


Figure 1. Research Framework

secondary data, namely in the form of documentation, archival documents, and interview videos.

The collected data were analyzed to find out the multi-stakeholders role in supporting the SMEs' competitiveness through innovation and standardization using the innovation ecosystem-based conceptual framework. The first analysis was conducted for each case (within-case analysis). The analysis process in the first case was replicated in the second case to explicate the replication logic. The second analysis of the cross-case was then conducted based on the results of each case. The cross-case analysis was intended to draw the final findings and to conclude the study.

IV. RESULTS

A. The Innovation Process of GLP HFNC-01

PT Gerlink Utama Mandiri initiated the production of its innovative device, GLP HFNC-01, with aim to contribute in handling the COVID-19 pandemic. This company, whose main business is manufacture of geotechnical technology, invited The Indonesian Institute of Sciences (LIPI), a PRI, through its researchers, to collaboratively develop the technology and to fill the gaps in Gerlink's limited technical capabilities.

Gerlink identified market potentials and arranged medical consultations with medical experts from the Faculty of Medicine, Padjadjaran University (Fac. Medicine, Unpad) and Hasan Sadikin Hospital (RSHS), a regional hospital, to deal with users' demand. This medical consultation also helped Gerlink to understand the specific product type and its use in the human body. The idea generation has changed three times, from developing an emergency ventilator into an ICU ventilator and, finally, a high flow nasal cannula (HFNC) by considering several aspects: institution's direction, medical consultation, and market potentials. The small team growed, and more actors joined the ecosystem to develop HFNC.

The product prototype was tested internally in the PRI's laboratory first, followed by product testing at the Health Facilities Safety Center of MoH (BPFK) to obtain a marketing license. During this time, regulations and standards for product testing for HFNC and ventilators in Indonesia have not been established. The government, through BPFK and MoH, responsively prepared the emergency regulation to support product competitiveness by adopting global standards of the Medicines and Healthcare Products Regulatory Agency UK (MHRA). Gerlink then proposed production and distribution certification due to its new line production on medical devices. PRI significantly influenced inter-public institution coordination during proposal licensing and product dissemination.

GLP-HFNC-01 was disseminated through several ways, including donation, direct sales and distributors, and e-procurement. Gerlink provided training to medical practitioners and after-sales service to guarantee product quality and to ascertain the product's safety for the users. It also conducted several incremental improvements to the product based on users' feedback.

> "There was a doctor from Panti Wilasa Hospital who encouraged us. The heater was too hot for patients, then it broke. The product was recalled two times. We tried to improve, and the third improvement was successful. I deployed teams in Surabaya, Bandung, and Jakarta to get valuable input from users. The important process is how we responded to and accepted their input." (Director of Gerlink)

B. The Innovation Process of Dharcov-23S

PT Dharma Precision Tools (DPT), a manufacturing company producing precise cutting tools, added a new line of production for ventilators amidst the COVID-19 outbreaks in Indonesia. The willingness to make social contributions and to support the government's policy in prioritizing locally produced medical equipment has encouraged PT DPT to develop a pneumatic-based emergency ventilator, namely the Dharcov-23S.

PT DPT initiated the idea generation to develop the process on its own until the product testing in BPFK, which required significant improvement. The Agency for the Assessment and Application of Technology (BPPT), a PRI, assisted PT DPT in further development by filling a gap in its technological capacity.

Table 1. Actors in the innovation process of GLP HFNC-01

Innovation Process	Stage	Lead Actor	Actor 1	Actor 2	Actor 3	Actor 4	Actor 5
Initiation	Idea generation	Gerlink	LIPI				
	Funding (Industry)	Gerlink					
	Medical consultation	Fac. Medicine Unpad	RSHS	Gerlink	LIPI		
Development	Reverse engineering	Gerlink	LIPI				
	Software development	Gerlink	LIPI				
	Hardware development	Gerlink	LIPI				
	Internal testing	P2TP-LIPI	Gerlink	LIPI			
	Coordination	LIPI	MoH	BPFK	MoSOE	BRIN	Gerlink
	Product Testing: safety (electrical and mechanical), performance, and reliability	BPFK	Gerlink	LIPI			
	Marketing License	MoH	Gerlink	LIPI			
	Production and distribution certification	MoH	BKPM	MoI	Gerlink		
	Manufacturing	Gerlink	Suppliers				
Implementation	Commercialization – Donations	Gerlink	LIPI	RSHS	Dr. Sutomo Hospital, Surabaya	Persahabatan Hospital	
	Commercialization – Direct sales	Gerlink	Distributors				
	IP Licensing	PPII-LIPI	Gerlink	LIPI			
	Commercialization Public – Procurement	LKPP	BRIN	LIPI's TTO	Gerlink		
	Users feedback	Panti Wilasa Hospital, Semarang	Gerlink	LIPI			

Note:

P2TP-LIPI = Research Center for Testing Technology, Indonesian Institute of Sciences

MoI = Ministry of Industry, Republic of Indonesia

LKPP = The National Public Procurement Agency

BRIN = The National Research and Innovation Agency

TTO = Technology Transfer Office

> "Our technological capability is limited; we relied on literature study, we watched YouTube. We were confused with the technology and the procedure. Then we met BPPT, we talked, then they helped us." (Director of DPT)

During the innovation stages, the PRI facilitated medical consultation, product testing in BPFK, clinical trials, public procurement, and a post-marketing survey. The clinical trial after product testing was conducted through several relaxation of the newly developed regulation, including using mannequins instead of humans.

For strategically introducing its product, PT DPT leveraged its parent company, which comprised several companies, and corporate social responsibility (CSR) for product procurement and donation.

> "We are currently conducting a post-marketing testing. Therefore, after distributing it to hospitals, we want feedback from them.… LPDP funding will be used for post-marketing testing. We use it to monitor and purchase materials during post-marketing testing." (Team Leader-BPPT).

V. DISCUSSION

A. Technology Standardization Throughout the Innovation Process of Medical Devices

Standardization is a voluntary technology development process based on consensus among stakeholders. The standardization process generates standards (Blind, 2013). Standards (regulatory) issues affect the entire stages of the innovation process. Standards should be obeyed from the early stages of the medical device design, to development stages and post-marketing surveillance. For this reason, the relationship between medical device developers and national regulators is critical to ensure continuity of innovation and competitiveness in this area (Guerra-Bretaña & Flórez-Rendón, 2018).

The innovation process of GLP HFNC-01 and Dharcov-23S medical devices is empirically carried out by activities related to specific standards. Activities at each stage of the innovation process are carried out through multi-stakeholder collaboration to support SMEs along the technological innovation and standardization process.

Standardization along the innovation process of medical devices is conducted at the company

Table 2. Actors in the innovation process of Dharcov-23S

Innovation Process	Stage	Lead Actor	Actor 1	Actor 2	Actor 3	Actor 4
Initiation	Idea generation	DPT				
	Funding (Government grant)	BPPT	BRIN-Consortium	LPDP		
	Funding (Industry)	Dharma Group Foundation				
	Medical consultation	PERDICI	Hermina Hospital Serpong	BPPT	DPT	
Development	Reverse engineering	DPT				
	Software development	DPT				
	Hardware development	DPT	BPPT			
	Internal testing	P2TP-LIPI	BPPT	DPT		
	Coordination	BPPT	MoSOE	BPFK	DPT	
	Product Testing: safety (electrical and mechanical), performance, and reliability	BPFK	BPPT	DPT		
	Clinical trial	MoH	RSSA	BPPT	DPT	PERKI
	Marketing License	MoH	DPT			
	Production and distribution certification	MoH	BKPM	MoI	DPT	
	Manufacturing	DPT	Suppliers			
Implementation	Tax incentive	MoF	BNPB	BPPT	DPT	
	Commercialization-Donations	BPPT's TTO	CSR-Dharma Group	DPT		
	Commercialization Public Procurement	LKPP	BRIN	BPPT's TTO	DPT	
	Users feedback	BPPT	Kab.Tangerang Hospital			

Note:
LPDP = Indonesia Endowment Fund for Education
PERDICI = Indonesian Society of Intensive Care Medicine
MoSOE = Ministry of State Owned Enterprises
RSSA = dr. Saiful Anwar Hospital, Malang
PERKI = The Indonesian Association of Cardiovascular Specialists
BKPM = Ministry of Investment/Indonesia Investment Coordinating Board
MoF = Ministry of Finance
BNPB = National Agency for Disaster Countermeasures

level. Each stage comprises several standard activities to meet certain standards from government regulations. Regulation of MoH No. 62/2017 on product licensing of medical devices specifically provides mandatory standards as the directive at the development and implementation periods. Through standardization along the innovation process, Indonesian SMEs have managed to create innovative medical device products that have never been created before.

The Initiation Period

The main activity during this period is device advice/medical consultation. In this activity, medical experts' involvement can compensate for technical and knowledge lack regarding specific types of medical devices in SMEs. Medical device developers are often considered lacking of technological insights or scientific understanding of a specific type of product and its use in the human body, requiring them to seek medical consultation (device advice) with medical practitioners and national regulation agencies (Guerra-Bretaña & Flórez-Rendón, 2018). Medical consultation was carried out at the beginning of developing the GLP HFNC-01 and Dharcov-23S medical devices. GLP HFNC-01 medical consultation was conducted with medical experts from the Faculty of Medicine, Padjadjaran University (Fac. Medicine, Unpad) and Hasan Sadikin Hospital (RSHS). As for Dharcov-23S, the medical consultation was conducted with the Indonesian Society of Intensive Care Medicine (PERDICI) and Hermina Hospital, Serpong.

Involving patient experts and patient organizations earlier in the initiation period also increases the likelihood that innovations will achieve the values that are considered beneficial for patients. To achieve this, technology developers and researchers need to collaborate closely with patient experts and patient organizations from the very beginning of initiation period (Tummers et al., 2020).

The initiation period covers idea generation (Garud et al., 2013) as input for the subsequent processes (Trott, 2017). As the study cases indicate, the success of this period is not solely determined by single player. Instead, it involves several actors from various backgrounds to facilitate the emergence of innovative ideas. It is typically followed by system shock and arrangement to transform the tacit ideas into the innovative ones, including the allocation of necessary resources (Van de Ven et al., 1999).

The Development Period

The development period is characterized by failure and refinement following the assessment and progress of development. The relationship among actors is as dynamic as the fluidity of engagement (Garud et al., 2013; Van de Ven et al., 1999). To guarantee successful development, the feasibility of all supporting factors should be ascertained, like manufacturing elements, spare parts, and the others that can lead to value generation (Garud et al., 2013; Leavy, 2012; Van de Ven et al., 1999).

Before being implemented, innovative products must meet the required standards (Blind, 2013; Jiang, Gao et al., 2020). This means testing activities in advance, such as bench testing and pre-clinical (animal) testing, are necessary to find out whether the products are capable to meet the established criteria. Bench testing might be performed on a first small-scale prototype and scaled-up model (Durfee & Iaizzo, 2018). In these two case studies, two standard activities were performed as bench testing: internal and production testing. Medical device developers (Gerlink-LIPI and BPPT-PT DPT) were involved in PRI's laboratory (P2TP-LIPI) for internal testing. Measurement and testing standard is used as type standard for internal testing activity. This standard aims to optimize a medical device's engineering function through metrology, measurement, and testing standards (Blind, 2013; Durfee & Iaizzo, 2018).

Regarding product testing, medical device developers are coordinated by the public testing laboratory (BPFK), particularly in developing new regulations to ensure product safety. In addition to meeting measurement and testing standards, product testing activities must meet interface standards. The standard is intended to ascertain the medical device's interoperability between components and save customization costs. It is especially used in the manufacture of

domestic and foreign medical parts to ascertain their compatibility (Blind, 2013).

If the device seems feasible and passed the review screens, it proceeds to the first step of human testing, namely first-in-human tests (Durfee & Iaizzo, 2018). The GLP HNFC-01- innovation process only required product testing, and did not perform clinical trials. This is because GLP HNFC-01 belongs to Class B medical device category. In contrast to HNFC-01 GLP, the Dharcov-23S medical device belongs to Class C category. Therefore, clinical trials were needed. The Government of Indonesia has allowed a relaxation of medical device approvals amidst the pandemic. Standard requirements for preclinical studies are not mandatory, and clinical trials were allowed to be performed using mannequins, given the risky and highly contagious condition. Clinical trial activities must meet compatibility and quality standards with aim to improve quality, to reduce health, safety, and privacy risks, also to build critical mass (Blind, 2013).

Further, bigger clinical trials are necessary for regulatory clearance (Durfee & Iaizzo, 2018). This period demands coordination with a wider actor, including the government, to obtain institutional support and legitimacy for the innovation (Garud et al., 2013; Van de Ven et al., 1999). During standard activities for clinical trials, medical device developers were involved and coordinated by MoH, the Hospital for Ethical Clearance (RSSA), and Indonesian Cardiovascular Specialists Association (PERKI).

The Implementation Period

The implementation period in innovation process should adapt to the current condition and institutional setting to be able to properly and safely accepted by end-users (Garud et al., 2013). Both case studies fulfilled domestic component level (TKDN) certification throughout the implementation period. This activity aims to comply with the requirements stated in tender specifications of public procurement operations. One strategy to create a market for domestic products is by establishing certification and implementing public e-procurement standards. Acquisition of intellectual property rights is also important for SMEs in this activity. Protecting the intellectual property of new concepts and innovations is very important in medical devices development and innovation. This is because developing medical technology, especially medical devices that require large-scale clinical trials, is quite costly by any means (Durfee & Iaizzo, 2018). Therefore, collaboration with National Public Procurement Agency (LKPP) and Technology Transfer Office (TTO) are nesessary in this activity.

Many innovation processes has managed to proceed after implementing incremental improvements by responding users' feedback or developing other innovative products (Rong et al., 2020). During the implementation period, another activity conducted as part of the GLP HNFC-01 innovation process was acquiring users' feedback regarding the compliance of standard's open standardization process. The standard is intended to answer the users' need for incremental improvements and to facilitate early users' adoption of new products (Blind, 2013). To further develop and improve its medical device, the SME (Gerlink) collaborated with the user (Panti Wilasa Hospital Semarang) to collect feedback and obtain the necessary information. All stakeholders, including patients, should be involved to participate in the co-creation process of medical devices. Collaborative research helps medical device developers formulating the right questions and better perspectives through new insights from everyone involved (Tummers et al., 2020).

As part of their risk management system and to fulfill the regulatory post-marketing surveillance, medical device developers must collect post-marketing information, including clinical data (Guerra-Bretaña & Flórez-Rendón, 2018). These clinical trials are often needed to provide data for reimbursement considerations (Durfee & Iaizzo, 2018). At the same time, PRI, through the Medical Device Development Team (BPPT) leader, conducted Dharcov-23S post-marketing surveillance to the hospitals that use Dharcov-23. This study was conducted to comply with MoH regulations, specifically regulatory post-marketing surveillance (post-marketing requirements). The purpose of this standard is to document and control adverse events and complaints. BPPT will

also use the results of this study to further develop Dharcov-23S.

Based on empirical evidence from two case studies, the similarities and differences in standardized activity types to meet specific standards at each stage of the innovation process are presented as follows.

- Both case studies carried out device advice/ medical consultation activities during the initiation period, internal testing, and product testing activities during the development period, and domestic component level (TKDN) certification fulfillment activities for tender specifications of public procurement during the implementation period.
- Clinical trial activity in the development period was only carried out in Dharcov-23S innovation process because it was included in the class C medical device category, namely possessed a moderate to high risk.
- In the implementation period, the activities of acquiring users' feedback to make incremental improvement were only carried out in GLP HNFC-01 innovation process. Meanwhile, clinical trial activities for post-marketing surveillance were only carried out in Dharcov-23S innovation process.

B. Multi-Stakeholders Involvement in Technological Innovation and Standardization

Standards and regulations, such as in technological development and procurement activities, are essential to facilitate international trade and improve company's internal value chains. Therefore, SMEs must make more efforts to comply with standards and regulations to be more competitive (The International Trade Center, 2016).

Standardization is the platform used by researchers and other stakeholders throughout the innovation process. Standards are directives that provide legitimate framework conditions for implementing research, development, and innovation. The standardization process is conducted by compile specific knowledge with aim to establish a generally accepted consensus to facilitate actors with disparate backgrounds, capabilities, and knowledge, such as researchers, industries, governments, and social interest groups (such as consumers) (Blind, 2013). Collaboration among critical stakeholders, namely academia, health institutions, industries, and regulatory agencies, aims to establish coordinated efforts in order to overcome the barriers in medical devices development and innovation (Guerra-Bretaña & Flórez-Rendón, 2018).

Through the results in this study, we have discovered the activities in the standardization process for each stage of the innovation process and the specific types of standards that SMEs should meet. We have also figured out multi-stakeholder cooperation in supporting SMEs in each activity. These results are summarized in Table 4.

SMEs must meet certain standards and regulations in developing innovative products, such as medical devices. These standards and regulations must be met at each stage of the innovation process. The standard type for each activity serves a specific purpose. To make SMEs more capable to comply with these standards and regulations, also to guarantee SMEs' market competitiveness, adequate support through multi-stakeholder collaboration should be maintained

Table 3. Standard activities in GLP HFNC-01 and Dharcov-23S innovation process

Innovation Process	GLP HFNC-01	Dharcov-23S
Initiation	Device Advice/Medical Consultations	Device Advice/Medical Consultations
Development	Internal testing	Internal testing
	Product testing	Product testing
		Clinical trial
Implementation	Domestic component level (TKDN) certification for tender specifications of public procurement	Domestic component level (TKDN) certification for tender specifications of public procurement
	Users' feedback for incremental improvement	Clinical trial for post-marketing surveillance

Table 4. Multistakeholders collaboration in supporting SMEs along the innovation and standardization process

Innovation process	Activity in the standardization process	Type of standards	Purpose	Involved actors	
				GLP HFNC-01	Dharcov-23S
Initiation	Device Advice/ Medical Consultations	Device Advice/ Medical Consultations	Understanding the specific type of product and its use in the human body	SME, PRI, Medical experts	SME, PRI, Medical experts
Development	Internal testing	Measurement and testing standards	Optimizing the engineering function of a medical device	PRI, SME	PRI, SME
	Product testing	Interface standards	Ascertaining interoperability between components; reducing the adaption and customization cost	Public testing laboratory, SME, PRI	Public testing laboratory, SME, PRI
	Clinical trial	Compatibility and quality standards	Increasing the quality Reducing the health, safety, and privacy risks Building critical mass	-	MoH, Hospital (Ethical clearance), PRI, SME, Association
Implementation	Domestic Component Level (TKDN) certification for tender specifications of public procurement	Domestic component level (TKDN) certification	Ensuring the product is available and usable by the public sector, notably in tender specifications	National Public Procurement Agency, TTO, SME	National Public Procurement Agency, TTO, SME
	Clinical trial for post-marketing surveillance	Regulatory post-marketing surveillance (post-marketing requirements)	Documenting and managing the adverse events and complaints	-	PRI, Hospital
	Users' feedback	Open standardization processes	Reflecting user's needs for incremental improvement Promoting the diffusion of new products by early adopters	User/hospital, SME, PRI	-

along the innovation and standardization process. This is mainly important because various actors involved in each stage of the innovation process activity have disparate backgrounds, capabilities, and knowledge, such as PRI, industries, governments (Public testing laboratory, National Public Procurement Agency, MoH), medical experts, hospitals, and users.

VI. CONCLUSION

This study has managed to fill the gap by presenting a more robust analysis regarding the collaborative innovation process of new medical devices to support SMEs' competitiveness through innovation and standardization. By looking into the innovation process of GLP HFNC-01 and Dharcov-23S medical devices as the case studies, we have discovered the activities in the standardization process for each stage of the innovation process and the specific types of standards that SMEs should meet. We also figured out multi-stakeholder cooperation in supporting SMEs in each activity.

Furthermore, the role of multi-stakeholder collaboration is also highlighted in supporting SMEs along the innovation and standardization process to gain market competitiveness. Actors involved in each innovation process activity have disparate backgrounds, capabilities, and knowledge, such as PRI, industries, governments (public testing laboratory, National Public Procurement Agency, MoH), medical experts, hospitals, and users. The results of this study will contribute to enhance collaborative innovation by harnessing the role of multi-stakeholder collaboration to support SMEs' competitiveness, not only through the improvement of innovation capacity, but also

through the compliance with the corresponding defined standards.

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REFERENCES

Blind, K. (2013). *The impact of standardization and standards on innovation.* Nesta Working Paper No. 13(15), 3-28. Manchester Institute of Innovation Research.

Durfee, W. K., & Iaizzo, P. A. (2018). The medical device innovation process. In *Engineering in medicine: Advances and challenges* (pp. 495–509). Elsevier. https://doi.org/10.1016/B978-0-12-813068-1.00019-1

Efendi, S., Sugiono, E., Guritno, E., Sufyati, E., & Hendryadi, E. (2020). Building innovation and competitiveness for low technology manufacturing SMEs through imitating capability and learning: The case of Indonesia. *Cogent Social Sciences*, 6(1). https://doi.org/10.1080/23311886.2020.1803515

Garud, R., Tuertscher, P., & Van De Ven, A. H. (2013). Perspectives on innovation processes. *Academy of Management Annals*, *7*(1), 775–819. https://doi.org/10.1080/19416520.2013.791066

Guerra-Bretaña, R. M., & Flórez-Rendón, A. L. (2018). Impact of regulations on innovation in the field of medical devices. *Research on Biomedical Engineering*, *34*(4), 356–367. https://doi.org/10.1590/2446-4740.180054

Jiang, H., Gao, S., Zhao, S., & Chen, H. (2020). Competition of technology standards in Industry 4.0: An innovation ecosystem perspective. *Systems Research and Behavioral Science*, *37*(4), 772–783. https://doi.org/10.1002/sres.2718

Jiang, H., Liu, W., Zhao, S., & Chen, Y. (2020). Technology standardization, competitive behavior, and enterprises' innovation performance: A conceptual model. *Library Hi Tech*, *38*(1), 251–269. https://doi.org/10.1108/LHT-11-2017-0249

Kutnjak, G., Miljenović, D., & Mirković, A. (2019). Improving the competitiveness of small and medium-sized enterprises by applying a quality management system. *Pomorstvo*, *33*(1), 11–21. https://doi.org/10.31217/p.33.1.2

Leavy, B. (2012). Ron Adner: Managing the interdependencies and risks of an innovation ecosystem. *Strategy and Leadership*, *40*(6), 14–21. https://doi.org/10.1108/10878571211278840

Löschner, U., & Fleßa, S. (2022). Essentials of innovation theory for medical devices. In C. Boccato, S. Cerutti, & J. Vienken (Eds.), *Medical devices improving health care through a multidisciplinary approach* (pp. 35–51). Springer Nature Switzerland AG.

Maresova, P., Hajek, L., Krejcar, O., Storek, M., & Kuca, K. (2020). New regulations on medical devices in Europe: Are they an opportunity for growth? *Administrative Sciences*, *10*(1), 1–18. https://doi.org/10.3390/admsci10010016

Maresova, P., Rezny, L., Peter, L., Hajek, L., & Lefley, F. (2021). Do regulatory changes seriously affect the medical devices industry? Evidence from the Czech Republic. *Frontiers in Public Health*, *9*(April), 1–13. https://doi.org/10.3389/fpubh.2021.666453

National Standardization Agency of Indonesia. (2014). *Introduction to Standardization 2nd Edition* (Jakarta).

Porter, M. E., & Van Der Linde, C. (2017). Toward a new conception of the environment-competitiveness relationship. *Corporate Environmental Responsibility*, *9*(4), 61–82. https://doi.org/10.1257/jep.9.4.97

Republic of Indonesia. (2014). *Act No. 20/2014 concerning Standardization and Conformity Assessment*.

Rong, K., Lin, Y., Yu, J., Zhang, Y., & Radziwon, A. (2020). Exploring regional innovation ecosystems: An empirical study in China. *Industry and Innovation*. https://doi.org/10.1080/13662716.2020.1830042

Setyawan, A. A., Isa, M., Wajdi, W. F. M., Syamsudin, & Nugroho, P. S. (2015). An assessment of SME competitiveness in Indonesia. *Journal of Competitiveness*, *7*(2), 60–74. https://doi.org/10.7441/joc.2015.02.04

Stroyan, J., & Brown, N. (2012). *Using standards to support growth, competiveness and innovation*. https://doi.org/10.2769/42198

The International Trade Center. (2016). *SME Competitiveness Outlook 2016: Meeting the Standard for Trade*. http://www.intracen.org