

Collaboration In the Medical Device Innovation During the Covid-19 Pandemic in Indonesia: A Network Analysis

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Abstract. *This study identifies social network of medical device innovation during the Covid-19 pandemic in Indonesia. We employed the Social Network Analysis (SNA) from the collected data through semi-structured interview and document analysis. We focused on two case studies of therapeutic devices that have successfully been collaboratively developed and gained marketing license for Covid-19 treatment in Indonesia, i.e. Gerlip HFNC-01 and Covent-20. The study finds that heterogenous actors (university, public research institute, firm, government, society, non-government organization, users) share resources in each stage of the innovation process that demands distinct functions and resources from idea generation, product development, testing and implementation. The relations between actors happen by some means: joint project, resource sharing, and government direction. Key actors should be able to reach as many actors and bridge communication in order to develop network interdependence and to facilitate innovation. Eventually, the government plays a significant role to accelerate innovation through some fruitful policy packages.*

Keywords: *Collaboration, innovation process, medical device, social network analysis*

1. Introduction

The development of medical device demands a long process in a highly regulated system. The developers should meet good knowledge with customers' need in order to deliver a highly valuable innovative product (Durfée & Iaizzo, 2018). The multistep development process requires sufficient financing (Kesavan & Dy, 2020) from development stage, pre-market testing to verify product safety and post-market survey (Guerra-Bretaña & Flórez-Rendón, 2018; Kesavan & Dy, 2020).

Thus, medical device innovation needs collaboration of multi-stakeholder across sectors (De Jager et al., 2017; Kesavan & Dy, 2020; Lander, 2013; Salie et al., 2019) not only for knowledge transfer (De Jager et al., 2017; Salie et al., 2019) but also to divide initial development cost, and to reduce time and risks to market through capacity-based task distribution (Moazzam et al., 2020).

The complexity of medical device innovation has attracted various study to learn how collaboration matters to succeed the process. Moazzez et al. (2020) highlights strategic alliance of bilateral relation as a potential collaboration network for medical equipment research and development (R&D) and production as well as the barriers and challenges in forming and performing the collaboration. Interpersonal relationship is considered as a driver of collaboration in medical device development and that the relationship should be leveraged to enhance the collaborative working (Olubajo et al., 2022).

However, there is few studies looking at the social network of the collaboration along the innovation process of medical device. Network has a significant role in innovation process by transferring knowledge and norms amongst collaborating organizations (Lander,

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2013). Recent studies on network relation are conducted through co-authorship network based on scientific publication of medical device development (Chimhundu et al., 2015; De Jager et al., 2017; de Jager et al., 2019; Salie et al., 2019; Yu & Wang, 2016). This study tries to fill the gap by using empirical cases to learn the social network of medical device innovation process particularly during the Covid-19 pandemic in Indonesia. The collaboration is getting more complex since it is bounded with resource constraints, limited mobilization and quite a short time in order the medical device can be used for Covid-19 treatment. The research question is formulated as: How is the social network of the medical device innovation process during Covid-19 pandemic in Indonesia? It maps the key actors and other involved actors as well as their roles and relation in the collaborative network along the innovation process of medical device.

The study will contribute to research stream of collaboration in medical device innovation since it is one of few to see the social network based on empirical case during the Covid-19 pandemic. The result will also give insight for research organizations, industry, policy maker and other related stakeholders in developing collaborative network on medical device in the near future.

2. Literature Study / Hypotheses Development

2.1. Medical Device Innovation Process

Medical devices are defined as “*any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purposes*” (World Health Organization, 2017). Some of which are lung ventilators and anesthesia equipment (World Health Organization, 2017) such as High Flow Nasal Cannula (HFNC) (Kim & Asai, 2019).

The development of medical device goes through a cyclic stage along the innovation process. There are generally three periods along the innovation process, from new invention to eventual product (Trott, 2017): initiation/idea generation, development, and implementation (Garud et al., 2013; Van de ven et al., 1999; Van de Ven, 2017).

At the initiation periods, idea is generated as the input for the forthcoming process (Trott, 2017) by identifying problem, technical concept (Durfee & Iaizzo, 2018; Kesavan & Dy, 2020), opportunities and market assessment (Durfee & Iaizzo, 2018; Shaw, 1996, 1998), and potential funding from industry, venture capital and government (Kesavan & Dy, 2020). The development period is characterized with high dynamic between actors following the failure and refinement process of product development as well as the readiness of complements and spare parts for product manufacturing (Garud et al., 2013; Leavy, 2012; Trott, 2017; Van de ven et al., 1999). The product prototype should comply regulation and required standards prior market introduction (Blind, 2013; Jiang et al., 2020). The prototype should pass initial testing, and preclinical and clinical evaluation (depending on the device class). Upon launching, the product should undergo post market surveillance to understand users’ feedback and it might be followed by further development (Durfee & Iaizzo, 2018; Guerra-Bretaña & Flórez-Rendón, 2018).

2.2. Social Network in Innovation Process

Innovation process does not occur in isolation, it involves interaction between heterogenous actors (Chaminade et al., 2018; L. C. Freeman, 1978; Tranos, 2014). The interaction between actors during the innovation process reflects a social process of interactive learning (Chaminade & Randelli, 2020) in a multi-layer social network (C. Freeman, 1995; Shaw, 1996).

Multi-actor network analysis has been fundamental in innovation ecosystem study. The innovation ecosystem perspective

highlights the “dynamic behavioral relationships” among actors (Núñez & Serrano-Santoyo, 2020) and the “pluralism” of heterogeneous actors, governed along the matrix of “fluid and heterogeneous innovation networks and knowledge clusters” (Carayannis & Campbell, 2009).

In this interactive learning, networking is perceived as the “*management of the relationships between the activities, resources, and actors in the creation, development, design, manufacturing, marketing and re-innovation of innovations*” (Shaw, 1996). Networking acts as catalyst (Tranos, 2014) at different stages of innovation process by diffusing cost, adding value through differentiation and developing fusion of inter-organizational learning to gain competitive advantages (Shaw, 1996).

In a multi-actor collaborative network, understanding the position of actors is important to enhance the innovation activities. Key actors contribute to the network development by promoting and establishing communication between involved actors (Núñez & Serrano-Santoyo, 2020). Actors that occupy a central position in the network connect various actors in the network (Woods et al., 2022). Furthermore, composition of actors in the collaborative network is also a vital dimension (Jesu’s et al., 2007).

3. Methodology

The study used empirical cases to identify the social network of collaboration on medical device innovation process during Covid-19 pandemic in Indonesia: Covent-20 and GLP HFNC-01. The Covent-20 and GLP HFNC-01 are medical devices that have successfully been collaboratively developed and gained marketing license in order to address the shortage of therapeutic devices for Covid-19 treatment in Indonesia.

At the first phase, we identify activities and involved actors in each the stages of innovation process. Primary data were collected through semi structured interview

between March 8 – September 16, 2021. The key interviewees were identified for each case and snowballed throughout the research process covering 36 informants from university, public research institutes (PRI), firms, and government institutions. Regarding the Covid-19 pandemic, interviews were conducted online by using Zoom video meeting platform lasting for 1-2 hours/interview with a list of prepared interview questions to ensure data reliability. The interview transcripts were coded to map the activities and involved actors in each stage of the innovation process. The data were then triangulated with secondary data of documentation, archival documents, and videos of events.

At the second phase, we conducted the Social Network Analysis (SNA) per case to identify the key actors, position of other involved actors and the network relation based on actors mapping in the first phase. SNA is relevant for multi-actor network analysis because it emphasizes the identification of multiple actors and their relationships (Núñez and Serrano-Santoyo, 2020). It explains the relationship between and the system among nodes by pointing out the structure and characteristics of the network (Lee & Yoon, 2018). Nodes represent actors; ties are lines connecting nodes that represent relationship between actors. The relationship can be knowledge transfer, resource sharing or joint projects (Núñez & Serrano-Santoyo, 2020). UCINET and VOSviewer software were used to analyze and visualize the network. The key actors are the actors with the highest degree and/or betweenness centrality of the network. Degree centrality indicates number of connections by an actor while betweenness centrality represents the link in the connection between different pairs of actors (Wellington Ribeiro et al., 2022).

4. Findings and Discussion

4.1. Findings

1) Case 1: GLP HFNC-01

The GLP HFNC-01 is a high flow nasal cannula, developed by Gerlink, a small and

medium enterprise (SME), by collaborating with the Indonesian Institute of Science (LIPI), a PRI, in 2021 to contribute for Covid-19 handlings. The collaboration grows bigger along the innovation process by involving multi-actors (Table 1).

Table 1.

Innovation process of GLP HFNC-01

Innovation process	Activities	Lead actors	Other actors
Initiation period	Ideation	Gerlink	LIPI
	Funding (Industry)	Gerlink	
	Medical consultation	Unpad	RSHS; Gerlink; LIPI
Development period	Reverse engineering	Gerlink	LIPI
	Software development	Gerlink	LIPI
	Hardware development	Gerlink	LIPI
	Internal testing	P2TP-LIPI	Gerlink; LIPI
	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; LIPI
	Manufacturing	Gerlink	Suppliers
	Donations	Gerlink	LIPI; RSHS; Dr. Sutomo Hospital Surabaya; Persahabatan Hospital
Implementation/termination	Direct sales	Gerlink	Distributors
	IP Licensing	PPII-LIPI	Gerlink; LIPI
	Public Procurement	LKPP	BRIN; PPII-LIPI; Gerlink
	Users' feedback	Panti Wilasa Hospital Semarang	Gerlink, LIPI
Coordination		LIPI	MoH; BPFK; MoSOE; BRIN; Gerlink

At the initiation stage, Gerlink invites LIPI for collaboration to fill the firm's technological gap. Idea generation through product development are conducted by consulting with medical practitioners from Unpad (university) and RSHS (hospital) as a potential user. At the development stage, collaboration is getting more complex which involves the Health Facilities Security Center (BPFFK), for product testing to issue the marketing license. Gerlink manufactures the product with support from both local and global spare parts suppliers. The product is introduced to the society through donation and procurement. During the pandemic time, the Government facilitates several policy packages to encourage indigenous medical devices innovation through regulation flexibility in product testing and production license (Indonesia Guideline for Evaluation of Medical Device and Supplies during Covid-19 pandemic), tax incentives (e.g. MoF decree No. 28/PMK.03/2020; MoF decree No. 149/PMK.04/2020), and public procurement. In the social network analysis (see App. 1), Gerlink has the highest degree centrality (18) and betweenness (87.833), followed by LIPI with degree and betweenness centrality of 14 and 39.167 in respective. Gerlink initiates the collaboration by providing the funding for the whole innovation process. It looks for partners such as medical practitioners for consultation, conducts market research, and handles the commercialization and after sales service following users' feedback. On the other hand, LIPI provides resources (researcher, laboratories) for R&D. Also, it bridges coordination between public institutions including during the product testing, license issuance and public procurement process through its technology

transfer office (TTO). The government direction on the Covid-19 handlings to public institutions accelerate the coordination between the entities along the innovation process.

2) Case 2: Covent-20

The Covent-20 is a transport ventilator, with two operating modes: continuous mandatory ventilation (CMV) and continuous positive airway pressure (CPAP). Covent-20 is developed through collaboration initiated by the Faculty of Engineering, Universitas Indonesia (FTUI/University) at the onset of Covid-19 pandemic in Indonesia amidst the ventilator shortage.

The collaboration grows as the innovation process evolves and requires new functions and resources (Table 2). The involved actors represent heterogenous backgrounds and resources to offer. There are academicians from higher educations (FTUI, Poltekkes-Jakarta-2) and medical practitioners from university (FKUI) and its hospital (RSUI) involved in generating idea and R&D. The University provides the financing. A calibration company shares its calibration equipment for product development and self-assessment prior to product testing in BPFFK. The government through the Ministry of Health (MoH) gives relaxation in clinical trials during emergency condition by making preclinical trial as optional and reducing the number of human patients. After passing the preclinical and clinical evaluation, manufacturing companies scale up the product to be commercialized through donation and public procurement. In this collaboration, one actor can support in several functions along the innovation process.

Table 2.
Innovation Process of Covent-20

Innovation process	Activities	Lead actors	Other actors
Initiation period	Ideation	FTUI	FKUI
	Funding (Government grant)	DISTP-UI	FTUI
	Medical consultation	FKUI	RSUI; FTUI

Table 2. (Continued)

Innovation process	Activities	Lead actors	Other actors
Development period	Reverse engineering	FTUI	Poltekkes-Jakarta-2
	Software development	FTUI	
	Hardware development	FTUI	Poltekkes-Jakarta-2
	Internal testing	PT.Medcalindo	FTUI; Poltekkes-Jakarta-2
	Product Testing: safety (electrical and mechanical), performance and reliability	BPFK	PT.Medcalindo; Poltekkes-Jakarta-2; FTUI; ILUNI-FTUI
	Pre-clinical trial	Imeri-UI	RSUI; ILUNI-FTUI; FTUI
	Clinical trial	MoH	RSCM; Persahabatan Hospital; FKUI; ILUNI-FTUI; FTUI
	Marketing License	MoH	PT.Enesers; PT.GTM; BUMA
	Manufacturing	FTUI	PT.Enesers; PT.GTM; PT.Pindad; PT.Daruma; PT.Chemco; ILUNI-FTUI
Implementation/termination	Donations	ILUNI-FTUI	Society; BRIN-Consortium; FTUI
	IP licensing	DISTP-UI	BUMA; FTUI
	Public Procurement	LKPP	BUMA; FTUI
	Users' feedback	RSUI	FTUI
	Tax incentive	MoF	BNPB; ILUNI-FTUI; PT.Chemco; FTUI
Coordination		ILUNI-FTUI	BPFK; MoSOE; BRIN; FTUI; ILUNI-FTUI; Poltekkes-Jakarta-2

The relation of the multi-actors forms a social network (see App. 2). Based on the SNA, FTUI and ILUNI-FTUI perform the highest degree and betweenness (see App. 2) centrality

of 19 and 11 respectively. They also have the highest betweenness of 157.167 (FTUI) and 98.750 (ILUNI-FTUI). FTUI initiates and manages the collaboration by making strategic

decisions, distributing tasks, and coordinating the whole actors from idea generation, through product development, testing and implementation. ILUNI-FTUI, an NGO that consists of an alumni network of FTUI, connects many actors to collaborate. They arrange a crowd funding program for ventilator donation and delivery to users, coordinate with public institutions (Ministry of State Owned Enterprises (MoSOE), Ministry of Finance (MoF) etc.), support the clinical trial, invite ventilator spare parts suppliers (PT.Daruma, PT.Chemco) and manufacturing companies (PT.Enesers, PT.GTM, PT.Pindad), and looking for partner (BUMA, an SME) to license the product patent.

B. Discussion

1) Multi-stakeholder's roles in medical device innovation

Network plays an important role in innovation. It considers the relationship between activities, resources and actors along the process of innovation (Shaw, 1996). The actors involved in the innovation collaboration operates different roles and responsibilities (Cappellano & Makkonen, 2020). In this study we identify actors and their roles in each stage of the innovation process (Table 3).

The study confirms that the composition of actors in the collaborative network is important (Jesu's et al., 2007). There should be heterogenous actors to offer required resources in order to succeed the innovation. Despite initiated by different types of actors, understanding users' perspective through knowledge sharing with medical practitioners

is dispensable prior the idea generation as well as looking at the internal firm's technological capacity. The presence of knowledge source, either university or PRI, is significant to fill the gap of firm's technological capacity (GLP HFNC-01).

At the development stage, product scale up considers not only the capacity of manufacturing companies, but also the readiness of the complementarities (Adner, 2006), such as spare parts suppliers and compliance to regulation. During this time, the government plays a vital role by enhancing coordination between public institutions and facilitating policies and regulation flexibilities so that the innovative products can be implemented to the market safely and competitively.

The innovative products are introduced to market through some schemes, i.e., donation, public and direct procurement. Donation is considered a potential strategy considering humanity aspect. The government facilitates donation as an initial market for the emerging innovative products. Also, the NGO through its wide network bridges societies through crowd funding for product donation (Covent-20). In order to broaden the market, the firm demands distributors to participate in the procurement chain (GLP HFNC-01). Finally, post market survey is compulsory to look at users' response for further improvement (Durfee & Iaizzo, 2018).

Table 3 gives overview of the cross-case findings on multi-stakeholder's role in medical device innovation.

Table 3.
Multi-stakeholders' Roles in Medical Device Innovation

Innovation process	Activities	Actors		Potentially Required Actors
		GLP HFNC-01	Covent-20	
Initiation period	Generating ideas by considering users' demand, technological capacity, and market potential	Firm; PRI; University; Medical Practitioners	University (cross faculty); Medical Practitioners	Firm; University; PRI; Users
	Arranging funding source	Firm	TTO; University	Firm; University/Government
Development period	Developing idea to create innovative products through R&D and doing internal testing	Firm; PRI; Public lab	University; Higher Education; Private calibration lab	Firm; University; PRI; testing laboratory (public/private)
	Product testing to ensure ethical standards and safety compliance	Public testing laboratory; Firm; PRI	Public testing laboratory; Private lab; University; NGO; hospital; Public Institution	testing laboratory (public/private); hospital (Ethical clearance); Firm; university; PRI; NGO; Public Institution
	Manufacturing process - product scale up; production and marketing license	Firm; Suppliers; Public Institution	Firms (manufacturing companies); Suppliers; NGO; Public Institution	Manufacturing companies; Suppliers, Public Institution; NGO
Implementation period	Commercializing innovative products, donations	Firm; PRI; TTO; Users; Distributors; Public Institutions	NGO; university; Society; Users; TTO; Firm; Public Institutions	Firm; Distributors; University/PRI; TTO; Public Institutions; NGO
	licensing innovative products	Firm; TTO; PRI	Firm; TTO; University	Firm; TTO; University/PRI
	Users' feedback for product development/improvement	User; Firm; PRI	User; University	Users; Firm; PRI/University
Coordination & facilitation: Regulation setting, policy direction, policy coordination, competitive R&D funding, marketing license, production certification, tax incentives		Government		

2) Social network in medical device innovation

Regarding the complex multi-stakeholder relation in the medical device innovation, this

study identifies the key actors that have significant contribution to the network development and how the relations facilitate

the innovation.

Building network of multistakeholder can accelerate the process of innovation (Tranos, 2014). The key actors can improve the innovation performance by utilizing the resources shared within the collaboration (Woods et al., 2022). During the Covid-19 pandemic, developing indigenous medical device demands support from the whole system. It is not limited to the role of university/research institute, public institute and firms solely, but also demand the participation of a wider complementarities including society, testing agency and NGO. The findings indicate that the relation between actors happen by some means: joint project (Gerlink-LIPI), knowledge transfer (as in medical consultation), resource sharing

(funding, human resource, infrastructure), and government direction.

Based on SNA, Gerlink and LIPI (GLP HFNC-01) (Fig. 1) and FTUI and ILUNI-FTUI (Covent-20) (Fig. 2) exhibit the highest degree and betweenness centrality. A node/actor with the highest degree centrality does not indicate the power, instead the actor's capacity to reach as many other nodes/actors in the network to access various resources. Meanwhile, betweenness emphasize on communication capacity, in which node/actors are able to mediate communication or bridge coordination between pairs of actors to build interdependence within the network (Núñez & Serrano-Santoyo, 2020).

Five Actors with the highest degree and betweenness centrality in GLP HFNC-01 innovation	
Actors Degree	
Gerlink	18.000
LIPI	14.000
MoH	6.000
LKPP	3.000
PPII-LIPI	3.000
Actors Betweenness	
Gerlink	87.833
LIPI	39.167
MoH	31.000
LKPP	3.333
Unpad	1.333

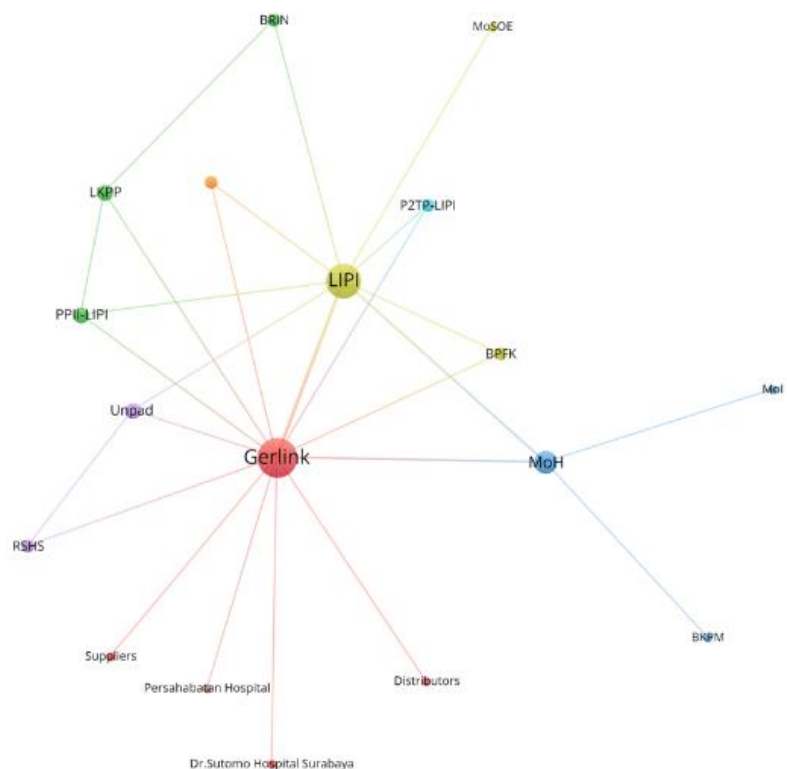


Figure 1.
Social Network of GLP HFNC-01

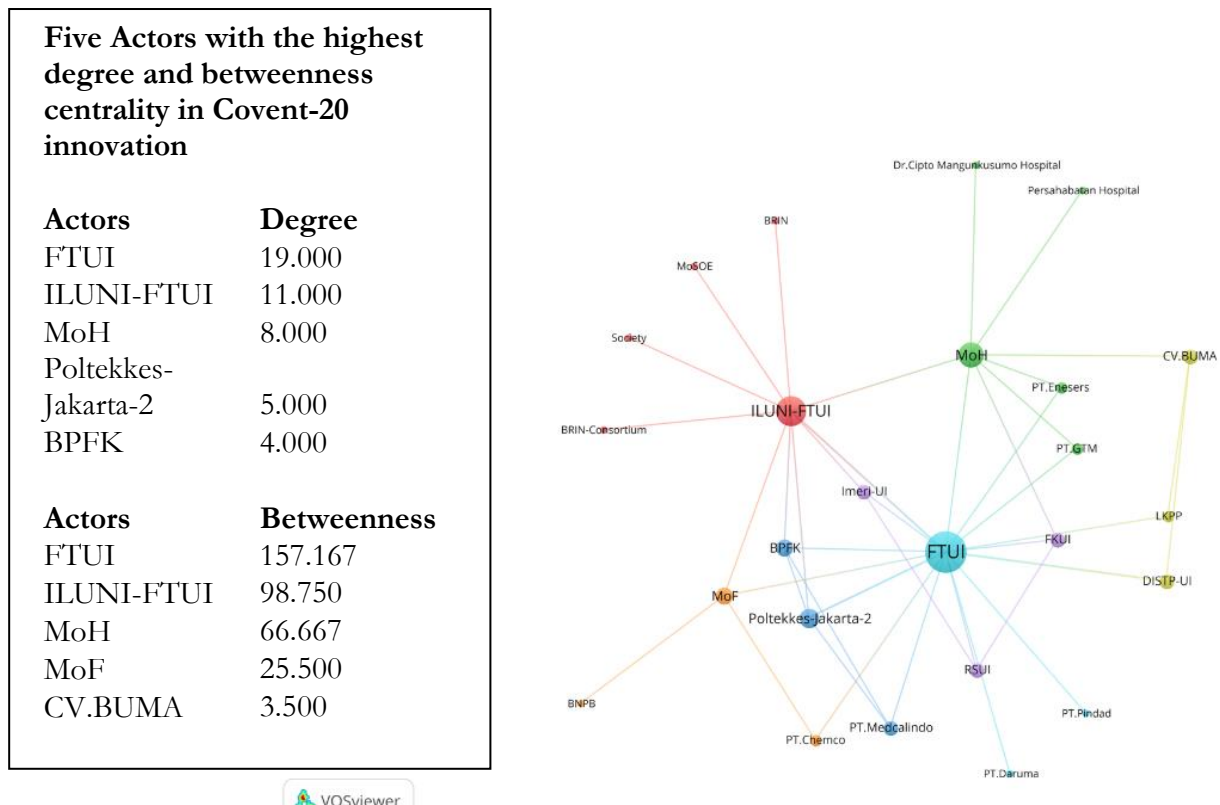


Figure 2.
Social Network of Covent-20

The findings indicate that Gerlink (Firm) (GLP HFNC-01) and FTUI (University) (Covent-20) are the key actors of each collaboration. Both the Firm and the University deserve an advantageous position reaching as many other actors in the network. They initiate the collaboration, looking for partners, and managing the collaboration and making strategic decision along the innovation process. In spite there are lead and other actors supporting each function in innovation activity, both key actors always present for coordination.

Furthermore, LIPI (PRI) (GLP HFNC-01) and ILUNI-FTUI (NGO) (Covent-20) arise with the second highest degree and betweenness centrality to bridge communication in each collaboration. The PRI has much to do with inter public institution coordination to support Gerlink as the focal firm. Likewise, the NGO, has a wide alumni network. It facilitates the network development by bridging FTUI as the key

actor with other potential partners, including those involve in product testing (hospital, public institutions), manufacturing (firms, suppliers), and implementation (societies, firm).

5. Conclusions

Heterogenous actors collaborate in each stage of medical device innovation process that demands distinctive functions and resources. With the complexities of multistakeholder relation along the innovation process, the role of key actors is significant in developing, coordinating and facilitating the collaboration. Key actors are defined as those who have highest centrality and betweenness centrality in the collaborative network of innovation. Key actors are not merely defined by who initiates the collaboration and does not refer to power. Instead, the actors should have capability to reach as many other actors in order to access resources to facilitate the

innovation. Key actors are also able to communicate and bridge information between groups of actors in building network interdependence to succeed the innovation.

So, as the implication of the study, regarding capacity in the network development, the key actors can be represented by any entities: a firm, university, PRI, or NGO. Eventually, the role of government is ultimately valuable to facilitate the innovation activities through supportive policies.

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