

Sustainable Development Research Practices in Philippine Biomedical Devices Innovation: A Case for the Agapay Project

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Abstract: This paper describes the sustainable development research practices under the biomedical devices innovation category. De La Salle University's (DLSU) Agapay Project, funded by the Department of Science and Technology (DOST) through the Philippine Council for Health Research and Development (PCHR), aims to develop an upper limb robotic exoskeleton for stroke and injured patients. This project is a multi-phase collaboration of various academic, industry, and government institutions promoting health research and innovation in the country. The implementation of this project is not without challenge as the research group aims to promote sustainable and environmentally-responsible practices. Among the methods to attain sustainability discussed in this paper include compliance with university and government protocols, research ethics considerations, proper use of resources, and waste management. The project follows the triple bottom line framework for sustainability to ensure a positive social, environmental, and economical research impact. Based on this, criteria on sustainable research was proposed to evaluate proposals in the field. Finally, this framework shall serve as a guide in future biomedical devices research not only in the university but in other institutions.

Key Words: Agapay Project; Robotic Exoskeleton; Sustainable Development; Triple Bottom-line; Upper Limb Rehabilitation

1. INTRODUCTION

The development of biomedical devices in the Philippines is still in its early phase but has already exhibited a lot of potential for its stakeholders. Along with the recent advances in biomedical engineering, interests between researchers in different fields have grown exponentially (Aguiba, 2015). The Department of Science and Technology (DOST) through the Philippine Council for Health Research and

Development (PCHR) has established the Philippine Biomedical Device Innovation Consortium (PBDIC) to support health innovators from all sectors who are venturing into biomedical device research (PCHR, 2015; Acosta, 2016). As part of the founding schools in the consortium, De La Salle University has also established the Biomedical Devices Innovation and E-Health (BDI) Research Group to support this initiative.

One of its pioneering research projects is the Agapay Project which aims to develop a robotic

exoskeleton for the upper limb rehabilitation of post-stroke and injured patients. With the BDI research group aiming to implement sustainable development practices in all of its research projects, a framework for the Agapay Project was created as a model to the group's future endeavors. This paper discusses a brief background on the Agapay Project's story and motivation, how it was implemented, and the sustainable development research practices it follows.

2. AGAPAY PROJECT

The Agapay Project for its first phase aims to develop a 7-degree-of-freedom (DOF) wearable robotic exoskeleton that can perform all the movements of the upper limbs. This includes the 3-dof mobility of the shoulder: abduction-adduction, flexion-extension, lateral-medial rotation; 2 dof of the elbow: flexion-extension, pronation-supination; and 2 dof of the wrist: pitch and yaw. Robotic exoskeletons are wearable devices that parallel the movement of the human extremities. Among the different options for post-stroke and injury therapy, robotic exoskeletons can provide the patient with the kinematic-accuracy it needs during therapy while at the same time records physiological feedback through its biosensors (Cannan and Hu, 2012; Chang and Kim, 2013; Gopura et al., 2011). This project is motivated by the fact that the availability of this device in the Philippines and most of the developing regions is limited and costly (Baniqued et al., 2015). The BDI Research group focused on developing the device for the upper limbs since it directly improves the region where activities of daily-living (ADL) are used.

The project was funded by PCHR-DOST on March 2016 after a series of technical and administrative reviews. Based on experience, the following criteria are assessed by the funding agencies in the approval of biomedical device projects: technical feasibility, clinical significance, social impact, profile of proponents, and plans for sustainability. Most of these criteria can be easily described in the technical proposal, but strategies to implement sustainable research activities are often overlooked. The BDI group presents a framework for its sustainable research practices in the implementation of the Agapay Project.

3. SUSTAINABLE DEVELOPMENT RESEARCH

The World Commission on Environment and Development (WCED) defines sustainable development as the ability to meet the needs of the present without compromising the future generations who have their own specific set of needs as well (WCED, 2011). In the context of organizations and projects, sustainability means "future-proofing" their activities to keep their business going (Wales, 2015). However, research projects unlike businesses are designed to have an end-date, thus, cannot stay in the state of perpetuity. Research projects are instead promoted, transferred, or upgraded according to the needs of their stakeholders. Whatever the case may be, sustainable practices can be applied to research projects by following the WCED definition of future considerations. In most organizations, the triple bottom line (TBL) approach is used as a guide to attain sustainable goals. TBL highlights the following concepts: people, planet and profit (Slaper and Hall, 2011). Following the TBL approach in the evaluation of research projects may provide a clear measure of how sustainable it is executed.

Assessing the sustainability of a project proposal may provide an insight into the success of its implementation. For the Agapay Project, it was an initiative for researchers to follow such practices to ensure a successful outcome. It is suggested that funding agencies looking into the development of biomedical devices evaluate the sustainability of a research proposal. Table 1 presents the suggested criteria in evaluating the sustainability of a research proposal in the biomedical devices field. This was based on the triple bottom-line approach discussed earlier. Take note that the weight of each criterion was still unspecified because of the diversity of research proposals under the biomedical devices category.



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 De La Salle University, Manila, Philippines
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Table 1. Proposed Sustainability Criteria for Evaluating Research Proposals in Biomedical Devices

Category	Criteria	Score	Remarks
People	Compliance with Government Regulations	1	Proposal lacks discussion on compliance with government regulations
		2	Proposal vaguely discusses compliance with government regulations
		3	Proposal aims to include compliance with government regulations
		4	Proposal details the categories of compliance with government regulations
		5	Proposal includes a detailed and specific discussion of compliance with government regulations
	Ethical Considerations	1	Proposal has no ethics clearance
		2	Proposal has poor ethics clearance
		3	Proposal has yet to be cleared from the ethics board
		4	Pending requirements from the ethics board
		5	Proposal has approval from the ethics board
	Medical Collaboration	1	No collaboration with any medical expert
		2	With little participation of a medical expert
		3	A medical expert is part of the team
		4	A medical expert is actively involved
		5	A medical expert is one of the project leaders
Planet	Waste Management	1	Proposal did not declare any waste management methods
		2	Proposal has poor declaration of any waste management methods
		3	Proposal has declared their waste management methods
		4	Proposal has a sound plan for their waste management methods
		5	Proposal follows the university/institution's policies on waste management methods
Profit	Resource Management	1	Proposal has no budgeting and personnel hiring plans
		2	Proposal has poor budgeting and personnel hiring plans
		3	Proposal has provided a simple LIB and personnel hiring plans
		4	Proposal has provided a detailed LIB and personnel hiring plans
		5	Proposal has provided a complete LIB and personnel hiring plans

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Below are some of the research practices (criteria) of the Agapay Project team in an effort to achieve sustainability during its implementation and future phases.

A. Compliance with Government Regulations

Every device has an intended purpose and must be considered as a clinically effective after undergoing and passing regulatory compliance (WHO, 2003). A good indicator for device performance is its clinical effectiveness which is achieved by following ISO standards. Standards are published documents that establish the technical specifications such as rules, guidelines and precise criteria for ensuring materials, devices and process are fit for their intended purpose. These assure users about reliability on goods and services provided in the marketplace.

Some of the important ISO Standards regarding medical devices that were followed during the development process as suggested by FDA-CDRRHR were ISO 14971: Application of risk management to medical devices; ISO 13485: Quality management systems - Requirements for regulatory purposes; and ISO 14155: Clinical investigation of medical devices for human subjects - Good clinical practice. These standards were purchased through Bureau of Philippine Standards (BPS), an affiliated body of ISO.

However, there are instances wherein regulations are not properly implemented, thus resulting to problems involving not only the users but the government as well. The lack of clarity in the regulation poses as one major factor that affects compliance. Offering wide range of interpretations of important regulatory elements such as guidelines and examples can be means of solution (Field and Behrman, 2002). Promoting compliance through ways that'll encourage rather than to burden enforcement can also serve as a key. Taking into consideration that medical device users, such as patients, are people for whom medical devices are designed since device safety and performance will directly impact them (WHO, 2003; Marcus et al., 2016; Johnson, 2016).

The Food and Drug Administration (FDA) indicated that the level of control is necessary for ensuring its safety and effectiveness. The risk a device poses to the patient or user becomes a major factor in determining which of the three (3)

regulatory classes I, II and III a specific medical device is assigned to (WHO, 2003; CBER, 2006).

The Agapay Project, on the other hand falls under the Class II category. These are medical devices that require greater regulatory controls for guaranteeing safety. Compared to Class I, it poses a higher risk of harm if not properly regulated. Assuring the safety of medical device includes several essential elements. Absolute safety is not guaranteed. It greatly affects performance and effectiveness. It is a risk management issue that must be considered throughout the device's the operating life. Responsibility must be shared among the stakeholders.

During assessment of medical device benefits, there are factors that need to be prioritized regarding compliance and enforcement efforts. These includes the type, magnitude, likelihood of patients experiencing one or more benefits, the duration of effects, patient preference, benefit factors for healthcare professionals or caregivers, and its medical necessity. FDA summarized the factors for the assessment of medical risks (CDRH, 2016; Johnson, 2016). One is severity of risk. It is the amount of harm that can be expected to occur under a duration component. Another is the likelihood of risk or the probability of risk occurrence. Nonconforming product risks include whether nonconforming product has been distributed and if so, how many nonconforming devices are on the market. In addition, the duration of exposure to population is the length of time between initial patient exposure to the device with the identified risk of harm and the point at which the risk of harm is successfully addressed. False-positive or false-negative results are important risk factor for diagnosis. Patients should be concerned on the potential harm that can be introduced to the through the device. Risk factors for health care professionals or caregivers must also be considered when the risk may have an adverse impact on the clinician or caregiver.

Overall, the Agapay Project follows not only the regulations issued by the government by those of the university as well.

B. Code of Ethics

Research ethics focuses mainly on the responsibilities of researchers concerning living subjects of the research process (DRE, 2011). This is a critical step often overlooked as some of the

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De La Salle University, Manila, Philippines
November 24 & 25, 2016

research activities may provide harm to one's health. At De La Salle University, all research projects particularly in the biomedical devices category must undergo a series of ethical reviews from based in an ethical review mechanism regulated by the DLSU Research Ethics Office (REO) (DLSU ITS-STRATCOM, 2013). The DLSU Code for the Responsible Conduct of Research serves as guidelines for the conduct of research in the University. Basically, the ethical principles comprise integrity and professionalism, cooperation, accountability, and zeal and growth in general common sense. There are 2 types of ethical review in the University, namely, the full review and the expedited review. Researches are subject to a full review if it involves vulnerable groups, such as the elderly, youth-at-risk, special children, or individuals who are in inequitable relationships. Projects qualifying for expedited review includes research where informed consent is needed from the subjects and the informed consent process will be correctly and appropriately applied, and that the researchers will be taken appropriate measures to protect the privacy of the subjects. Since the Agapay Project is still in its first phase, wherein the study only intends to fabricate a working prototype that is tested in a controlled environment, the DLSU REO has exempted the project for the ethical review. In its second phase, the necessary clearances must be made since it will already deal with actual patients during its clinical trials.

C. Medical Collaboration

It is important to find a suitable collaborator from the medical field for the success and effective development of new devices to ensure optimum use of resources such as material, labor, financial, etc. (Bennet, 2014). The Department of Rehabilitation Medicine of the Philippine General Hospital (UP-PGH) is the Agapay Project's medical collaborators for the prototype development phase. One example of the necessity of consultation is in clarifications of clinical importance of certain features. The importance of allowing spastic movements on stroke patients was clarified with medical collaborators to verify why most researches uses back-drivable DC motors than servo motors which could have been much easier to control (Gopura et al., 2011).

Another consideration that needs medical consultation is the possible use of smaller motors. Though literature already recommended motor specifications, the actual motors to be used can be tailored fit to the project's scope. One example is the exoskeleton for shoulder rehabilitation which recommends each motors to be capable of 46 lbs. and be able to mimic the resisting strength of a therapist (Liszka, 2006), but considering that commercial therapy bands only typically has a maximum resisting force of 14 lbs. and the product is more assistive than resistive then a smaller motor can be chosen, this after also considering the weight of the exoskeleton which the motors also need to bear. Being able to use a smaller motor means the whole exoskeleton will be lighter and cost-effective.

D. Waste and Resources Management

The line-item budget (LIB) is a detailed breakdown of funds generated early in the project proposal stage. This includes consideration of human resources, material and operating resources, capital outlay and other expenses that would support the implementation of the project.

Personnel – The research team plays a vital role in attaining sustainable research practices. It is important to provide adequate trainings and seminars to learn new and further techniques to improve skills and efficiency of the team (WHO, 2005). Building strong relationship in the team will also contribute to the performance and success of the research project.

Material and Operating Resources – This includes supplies and materials needed in the implementation of the project. The PCHRD-DOST, which is the funding agency of the project, ensures the proper purchasing of materials and disbursement of funds aligned within the LIB. The DLSU Procurement Office facilitates every purchase of materials in the university. The Materials Requisition Form (MRF) should be accomplished detailing the requested items. As shown in Figure 1 below, supplies, production materials and laboratory equipment had an average procurement processing time of six (6) weeks to eleven (11) weeks from the requisition up to the delivery depending on some factors such as source (local or import), stock availability from suppliers and document processing of the materials based on samples (n).

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De La Salle University, Manila, Philippines
November 24 & 25, 2016

It is recommended to describe the items clearly with attachments including picture, specification, required quantity, web link, and other necessary information to mitigate the procurement canvassing. Choosing locally available early for immediate attention of the procurement staffs. The team request items beforehand to anticipate the deadline and work plan. Proper coordination between the researchers and procurement staff is also important for the process. Sales invoice, delivery receipt, purchase order, reference guide, CD drivers and warranty cards should be properly stored for file and reference.

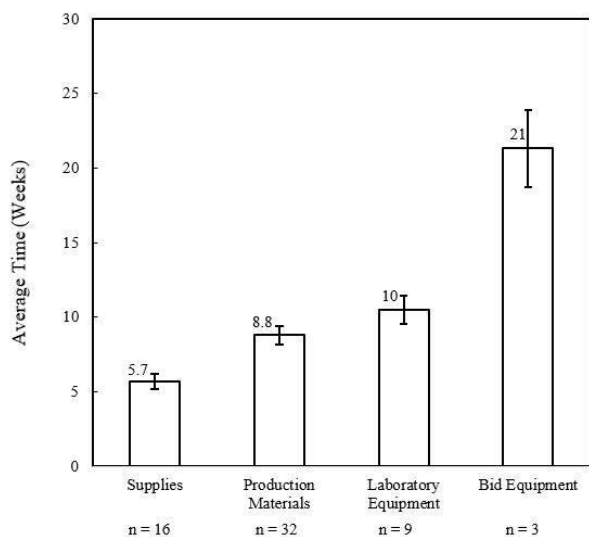


Fig. 1. Agapay Project Procurement Processing Time

As with the compliance to the RA 9003, otherwise known as the "Ecological Solid Waste Management Act of 2000" and the DLSU Waste Management System, waste materials should be properly segregated into biodegradable, non-biodegradable, Polyethylene Terephthalate (PET) bottle, aluminum can and scrap papers. Observing the proper waste management system will ensure the protection of human health and the environment (DLSU, 2005).

Capital Outlay – This details the budgetary requirement of the research for equipment items needed for the project (PITAH, 2015). The actual choice of equipment is based upon the scientific requirements for accuracy, precision, robustness and technology (WHO, 2005).

research materials rather than imported ones lessens the procurement process time but if inevitable, available potential distributors of the required materials may be identified. Unexpected urgent purchases of materials must be incorporated Bid equipment with item cost amounting to Php 300,000.00 and above had an average procurement processing time of twenty two (22) weeks from the requisition up to the delivery depending on some factors such as coherent specification, local or import source, stock availability from suppliers and document processing of the materials (Refer to Figure 1). Unlike with the process for supplies and materials requisitions, bid equipment usually undergo the bidding process which increases lead time. This includes bidding invitation, pre-bidding conference, evaluation and awarding. Acquired research equipment should be properly handled and maintained including its generated wastes. According to the Biomedical Waste Management and Handling Rules, 1998, bio-medical waste shall be treated and disposed of in accordance with Schedule I – Categories of Bio-medical Waste and in compliance with the standards prescribed in Schedule V – Standards for Treatment and Disposal of Bio-medical Wastes (MEF, 1998).

4. CONCLUSION

In this paper, the sustainable development research practices of the Agapay Project were discussed. As the pioneering venture of the DLSU Biomedical Devices Innovation and E-Health Research Group, the Agapay Project framework towards organizational sustainability shall be used in future research projects dealing with health innovation and device development. This framework is based on the triple bottom line approach to achieve sustainable goals which includes consideration of three key elements: people, planet and profit. Among the major research practices discussed are the medical collaborations, code of ethics, compliance with government regulations, and waste and resources management. Finally, a sustainable development criterion was proposed to serve as a guide for research proposal evaluators in the biomedical devices fields. The developed framework may not only be used in the future research projects of the university, but as well as other institutions that are into biomedical devices research.

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November 24 & 25, 2016

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