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Fostering Entrepreneurship and Innovation through a Biomedical Technology PhD Program in Australia*

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The integration of entrepreneurship, innovation and biomedical engineering is a relatively unexplored field of interdisciplinary research and practice, and the aim of this study is to delineate the integration of these disciplines. This paper presents an overview of a unique research and application intervention in the form of a new Doctor of Philosophy (PhD) training program in Technology Innovation, delivered in the context of the Australian Medical Technology industry. The program is administered by the Australian Research Council Training Centre in Biodevices and Diagnostics "BioReactor" at Swinburne University of Technology in Australia. The Swinburne BioReactor program has recently been designed to develop biomedical engineering students to become the next generation of entrepreneurs, industry-ready applied researchers and leaders in the field of biomedical devices and diagnostics. The program provides a paradigm shift from traditional PhDs to industry-oriented PhDs by integrating multi-disciplinary research, entrepreneurship education, design-led innovation training, mentorship, industry partners, collaboration and a unique and innovative stage-gate program structure. The PhD recruitment, program features and associated entrepreneurship and innovation curriculum, as well as program structure, activities and timeline over the duration of PhD study are also described. The program overall provides a contextual approach that can be adopted by other program designers and educators not only in Australia but also more broadly in other counties and locations, especially in areas of biomedical engineering.

Keywords: biomedical engineering; biodevices; entrepreneurship; technology innovation; Ph.D. training program

1. Introduction and background

With the relentless advances in globalisation, the shift towards a knowledge-based economy and the rapidly increasing demands of technological advances in an ever more competitive engineering world, entrepreneurship and innovation are seen as the driving force of long-term productivity, economic growth and wealth, and is a matter of the highest priority in public policy in many countries and locations [1, 2]. Accordingly, it is widely recognised that universities in knowledge-based economies have an important role in contributing to a country's national innovation system. Universities have increasingly become more than institutions of higher learning and education, also involving translation of research and technological development into commercialisation. This has often taken the form of entrepreneurship education and training programs and university-industry collaboration; and thus, fostering knowledge commercialisation and bridging the gap between scientific discovery and practical applications [3–5].

Entrepreneurship education and training has gained increased interest from universities and government worldwide, particularly within the engineering education community over the recent years [6–8]. A current trend in the education literature suggests a move towards educating students 'for' entrepreneurship rather than educating 'about' entrepreneurship. On one hand, educating 'about' entrepreneurship is to teach students predominantly based on the theory of entrepreneurship practices and principles in order to build awareness about how to set up and run a new business. On the other hand, educating 'for' entrepreneurship is more specific with an aim to equip students with both practice skills and personal skills as well as a set of attributes and behaviours needed to be successful entrepreneurs [9].

This trend is fuelled by contentions that the development of students as future entrepreneurs, especially engineering and natural science students, through entrepreneurship education can play a critical role in stimulating levels of entrepreneurial, social and economic activities, including employment and equity [10, 11]. Engineers are seen to have a vital role in the forefront of the development of infrastructure, information and communications

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technologies (ICT), new products and services including new technologies in science and medicine. Yemini and Haddad [1, p. 1221] stated "graduates of the technical and engineering disciplines (more than graduates of other disciplines) are expected to found companies in dynamic, innovative areas that will generate significant economic growth and boost employment".

In the past few decades, technological development in engineering, such as biomedical engineering, has often been characterised as breakthrough innovations that significantly transform the market and/ or the industry. Biomedical engineering is a discipline that advances knowledge through cross-disciplinary activities in engineering sciences, physics, chemistry, biomedical sciences and clinical practice to enhance an overall of health care. The outcome of biomedical applications includes a very broad field such as clinical engineering through to medical device development, bionic eye, and other biomedical disciplines including diagnostic technologies, biomaterials and tissue engineering. In fact, commercialisation of medical research and significant innovation in products, processes and services for health care delivery have a huge impact on a country's health and medical research sector, and more broadly on the nation's competitiveness and economy and the health and wellbeing of people in the communities. It has been predicted that there will be about eight billion people living on the planet by 2025, leading to increased demand in food consumption and water, and hydrocarbons due to climate change, increased ageing population in developed countries and a youth bulge and poverty in many developing countries especially those underdeveloped ones [12]. All these trends are likely to increase global demands for better living standards and advanced health systems; and thus, creating a real and ongoing challenge for biomedical engineers.

Dynamic environment and technological turbulence calls for significant reforms in biomedical engineering education to make it more appealing and valuable to the future needs of health and medical technology market [13]. The capabilities of universities to teach biomedical engineering students in a traditional way are clearly insufficient; the education and training programs must be cultivated to enhance the skills and abilities needed to acquire, create and exploit knowledge and technological innovations. Today a new generation of engineering and science students has a strong interest in entrepreneurship education and training. This is because innovation success requires not only the technical skills in science, technology, engineering and maths, but also requires the focus on building leading qualities, creativity, and sales skills [14, 15]. Students that are equipped with all these skills are therefore able to translate new ideas into successful innovative, entrepreneurial, competitive products and services underpinned by real and viable businesses. They can apply new ideas and technologies to develop new products knowing that there are future market opportunities whilst incorporating optimal management practices in enterprises [5]. As a result, the biomedical engineering discipline has recently become more interdisciplinary with entrepreneurship and innovation disciplines; yet, this continues to create a challenge for universities to develop a new education and training framework and pedagogies of specially designed disciplinary programs that would enable students to solve increasingly complex problems [16–18].

"*Entrepreneurship education*" and "*Design thinking*" have been the two emerging themes of educational theory and practice for dedicated educational programs in life science technology innovation in the United States and aboard. Whilst the concept of design thinking supports student learning and creativity to develop an idea for a product or service, entrepreneurship education reinforces the skills and knowledge required to move these ideas through to development and into launch [19, 20]. Although the development and participation in entrepreneurship education programs are typically associated with business and management students, such programs could potentially enhance science technology and engineering design aspects for engineering students in a cross-disciplinary context [21].

Only a comparatively small number of universities have adopted design-led programs that combine technical skills development with market-focussed training in entrepreneurship and innovation. Leading universities in the United States such as Stanford (Biodesign) and MIT (Portugal) offer programs that primarily focus on multidisciplinary medical technology innovation. The programs provide students with education, training, and mentorship for them to become leaders in the biomedical engineering field. Students are to work in teams to assess needs and then take a medical device invention forward from early concept to technology translation and implementation planning. The interdisciplinary programs that centre on medical technology innovation in Europe, such as Ireland's BioInnovate program and the Centre for Technology in Medicine and Health (CTMH) in Sweden, have only recently been established and are closely aligned with the Stanford's Biodesign program and its identify-invent-implement process [20, 22].

Despite the undoubted success of these sorts of programs, biomedical entrepreneurship and innovation is a relatively young field of interdisciplinary education and training. There appears to be a lack of training in entrepreneurship and technology innovation that combines with the rigour of a PhD level research project. An existing PhD program that is closely related to this type of structure is the Engineering Doctorate (EngD) pioneered at the University of Warwick in the UK. The engineering program offers a more industry-oriented PhD; the applied research is nonetheless not specifically tailored to the health and medical sector but also includes other sectors such as automotive, aerospace and construction.

Our aim is to introduce a new Doctor of Philosophy (PhD) training program in Technology Innovation, the Swinburne BioReactor, that has recently emerged through a unique combination of the best and important features which lie in the successes of the existing educational programs from around the world (including Stanford's successful Biodesign program), and collaboration between academics, industry and the Australian government. The program is under the management of the Australian Research Council (ARC) Training Centre in Biodevices and Diagnostics "BioReactor" at Swinburne University of Technology in Australia. The Swinburne BioReactor program caters to the specific needs of the Australian Medical Technology (medtech) industry and directly addresses the skills deficit in the sector by providing a ground-breaking, integrated research and industry-focussed training that reaches beyond science and engineering capabilities to entrepreneurship and innovation skills. The aim of the program is to support the development of the next generation of entrepreneurs, industry-ready applied researchers and leaders in the field of biomedical engineering—specifically, biomedical devices and diagnostics. Despite its distinctiveness, the program offers a contextual approach that can be beneficial for program designers and educators in Australia and also those in other counties and locations, particularly in areas of biomedical engineering education.

2. Presentation

2.1 Biomedical entrepreneurship and innovation education and training in Australia

Australia has been considered as a powerhouse of world class scientific discovery and high quality biomedical research, with a vibrant and defining knowledge-intensive health and medtech industry and a long history of globally recognised breakthroughs in biomedical devices and diagnostics. The country is positioned among the top five countries—well ahead of the UK and US—in relation to its production of scientific articles per capita, by contributing three per cent of the world's medical research publications with only 0.3 per cent of the world's population [23–25]. The Australian biotechnology sector comprises more than 900 biotechnology companies, which include approximately 500 to 900 medtech companies and 400 therapeutics and diagnostics companies [26]. While the majority of the companies in the Australian biotechnology sector are human therapeutics companies, medical devices and diagnostics [medtech] are among other fast-growing opportunities [23, 24]. The medtech industry has revenue of approximately AUD$10 billion per annum and annualised growth estimated as four per cent in 2010–11 (comparable to global growth figures), and amount of exports above AUD$2.1 billion in 2013–2015 [23, 24, 27, 28]. The industry comprises a number of high-performing medical device companies with success stories, such as bionic ear by Cochlear, non-contact sleep system by Resmed, and cervical cancer vaccine namely Gardasil by CSL [29].

The broader commercial potential of the Australian medtech industry is widely recognised, but the future success of the industry in the cutting edge of the global economy remains dependent on a strong innovation pipeline and the development of skilled personnel through entrepreneurship education and training—to facilitate commercialisation of medical research by means of translating fundamental biomedical discoveries or scientific findings into practical and commercially viable outcomes (i.e. products or services to benefit the community) [30, 31]. Although academic programs in biomedical engineering in Australia have grown steadily in recent years, it is recognised that commercialisation skills can be acquired across the thinly spread and fragmented scale of 39 universities, 42 Medical Research Institutes (MRIs) and over 100 hospitals where commercialisation of medical research is being performed [32]. Most Australian universities lean towards the traditional approach where commercialisation—entrepreneurship skills are usually developed and facilitated by business schools, and have only limited industry outreach programs and applied research or support programs that can differentiate the learning outcomes [33, 34]. The Association of Australian Medical Research Institutes (AAMRI), in a submission to the Federal Government-commissioned Strategic Review of Health and Medical Research in 2012, has pointed out a range of key initiatives to increase Australia's capacity to commercialise, including a recommendation for universities to integrate a commercialisation component into PhD programs.

In fact there are only a limited number of Biomedical engineering programs across Australia at PhD level; all these programs however seem to lean towards the traditional doctoral research and thesis rather than an integrated part of an industry-based research program. An industry-oriented PhD qualification carries great prestige as it commands recognition of one's exceptional talents and expertise within the intellectual elite. Such qualification can be considered as a pathway for engineering students to upward social mobility whilst opening up opportunities to work within the industry, within the National science agency or within universities.

2.2 Overview of the Swinburne BioReactor PhD training program

Given that Swinburne pioneered the concept of industry-based learning for undergraduates in Australia and aims to be a leading university of science, technology and innovation, we are keen to lead the way in industry-based research training for the knowledge economy, particularly in relation to the biotechnology sector. In order to achieve this goal, new PhD training program in Technology Innovation is being applied in the context of the Australian medtech industry.

The Swinburne BioReactor program is bringing about a bottom-up cultural change to develop future leaders in medical device and diagnostics segment through industry-led research. The program takes a new look into the 'traditional PhD' especially in biomedical engineering and incorporates concepts of "design-led innovation" into training and "entrepreneurship and innovation" into education [19, 35]. In view of that, the PhD students will not only learn about how to undertake leading edge research and development of new medical devices, but will be equipped to compete more effectively for scarce venture funding for their employers or for their own companies in future.

The development of medical technologies is an intrinsically multidisciplinary endeavour. Correspondingly, the BioReactor focuses on fostering closer collaborations between researchers and industry and addressing industry-specific challenges relating to the multidisciplinary nature of design and development in the medtech industry; technology update and transfer to manufacturing; the composition, maturity and size of local firms in the sector. It is a really new model that involves a diverse group of academic and industry-focussed researchers and companies from across health and manufacturing sector for students to obtain real world experience. With the focuses on developing exceptional university-industry research collaboration and addressing the need to embrace commercialisation, the program is backed by a $1.8 million Australian Research Council Industrial Transformational Training Centre grant for the creation of the "ARC Training Centre in Biodevices and Diagnostics"—a home of participating PhD students and postdoctoral researchers over the course of the program.

2.3 Recruitment of PhD students

In March 2014, a worldwide BioReactor recruitment process was undertaken. Outstanding students from the disciplines of engineering, medicine, science, design and ICT, or recent graduates with relevant business or technology innovation experience were drawn and recruited into a PhD training program. To emphasis diversity amongst the students, residents or fellows in surgery who are interested in applying technology to solve unmet clinical needs were also encouraged to apply. This was done through an international advertisement that aimed to attract the "best and brightest" candidate. A total of 68 highly qualified applicants were listed after the advertisement ended. The application process included a cover letter and response to the key selection criteria and a resume, as well as a three-minute YouTube video that would explain who they are and why they want to enter into the program. Candidates were ranked in terms of their potential to become leaders in medical devices and diagnostics segment, academic records and demonstrated potential for leadership, teamwork, creativity, invention and implementation of healthcare products. Relevant knowledge of medicine and public health, engineering and business and experience in the medtech industry or technology innovation were also considered.

2.4 Program features

The BioReactor program has commenced in February 2015 with 10 scholarship students. All 10 selected PhD students have an interest in research and development and/or starting up their own businesses (entrepreneurship) to make a difference to people's lives and the medical world. Respectively, the program provides them with the opportunity to participate in a structured three year PhD training program that links their core research activities with skills development in areas of biomedical engineering. The program recognises that:

- Creativity and inventiveness are promoted by access to innovation hubs and networks of innovators, while inventors are facilitated by personal motivation, mentorship and strong industry contacts [36];
- Multidisciplinary teams promote innovation through a stimulating mix of viewpoints [37];
- Customer-focussed needs assessment [38] and industry-led development [39] have a strong correlation with eventual market success;
- A stimulating work space is conducive of creative

interaction between students, teachers, mentors, researchers and industry partners.

Therefore, the Swinburne BioReactor employs a structured and systematic approach via educational initiatives of the *PhD research, coursework* and *training* to accelerate the students' research planning and conceptual ability to enable them to successfully undertake the program. In particular, it takes a design-led approach to performing innovative research that focuses on the end-user; initially focusing on a team-based problem solving approach to the identification and evaluation of customer needs, followed by the planning and execution of a solution-focussed and individual research project; engagement of industry partners in the project selection, planning and execution; and the integration of sector-specific, high-level entrepreneurial, product development and commercialisation skills.

The key features of the program include:

- An innovation hub where students, industry partners and academics collaborate to explore end-user needs in hospitals, care homes and other health care environments, identify opportunities and develop platform technologies to underpin new products, systems and approaches to biomedical devices and diagnostics;
- A multidisciplinary team of academic supervisors, drawn from the Science, Engineering, Design and Business Faculties to deliver world leading research;
- PhD students spending at least one third of their time working within industry environments;
- Partner organisations (industry partners) delivering projects, workshops and providing supervision and mentoring as well as accesses to their own specialised facilities, and;
- Training in Entrepreneurship and Innovation as part of the PhD program, including coursework units.

2.5 *Entrepreneurship and innovation curriculum*

Although the BioReactor program is offered in the Faculty of Science, Engineering and Technology (FSET), the coursework units are from Swinburne's Master in Entrepreneurship and Innovation complemented by the Faculty of Business and Law. It must be noted that Swinburne has been recognised as a pioneer in entrepreneurship education in Australia with a substantial number of units concentrating on entrepreneurship from several business viewpoints, and a range of undergraduate and postgraduate programs including vocational education and training and executive development courses for small business owners [40]. The Master of Entrepreneurship and Innovation (MEI), in particular, is a recognised coursework program that ranked top five in the world [41]. The PhD students will be exposed to current experienced and well-qualified faculty members, who are active participants and lecturers in the MEI program.

There are several MEI units that PhD students can undertake during their first year to increase their knowledge and skills in entrepreneurship and innovation, and support a series of activities associated within the PhD training program. These units include, but are not limited to: (1) *creativity and innovation*, which focuses on creative/design thinking and idea generation during the front end of innovation and overall effectiveness of the innovation process (from invention to innovation) including entrepreneurship; (2) *opportunity discovery*, which focuses on discovery and development of entrepreneurial opportunities and startup business model such as the use of lean startup [42]; (3) *opportunity evaluation,* which focuses on business planning process, tools and research techniques for analysing and evaluating entrepreneurial opportunities (feasibility approach) such as growth impact analysis and customer validation, financing and investment decision-making as well as legal structures; and (4) *product innovation* which focuses on typical activities and best practices for managing the various stages of developing a new product and service innovation, particularly in regards to the cross-functional and outsourced activities in technology start-up firms, as well as appropriate tools and structured methods for achieving the best outcomes, some of which include product design and prototype development.

Such theory, tools and techniques taught in these MEI units can facilitate PhD students to learn and apply their knowledge and skills to develop new medical device innovations as part of the requirement of the PhD program. While the MEI coursework units have specified outcomes, they are primarily designed to provide PhD students with a general theoretical framework that informs their structured approach to opportunity identification and evaluation in their specific technology field and forms the basis of their research project development. This differs significantly from the goals of coursework within Professional Doctorate programs.

2.6 *Program structure*

The structure of the BioReactor PhD training program is summarised in the Fig. 1. It enables participating PhD students to acquire a range of entrepreneurial skills, research expertise and innovation strategies that can be used to lead applied research in high-tech industries.

Progress is closely monitored by means of standard project management tools applied in industry. The use of the "Licenced to Cure" and "Wrike" software tool, for instance, allows remote oversight of project progress by multiple stakeholders and facilitates communication between research and development teams, no matter where the team member is located.

With the exception of a series of three major reviews, formal progress reviews are conducted by the interdisciplinary supervisory panel/team and by mentors with relevant industry experience on a monthly or bimonthly basis during the Identification and Evaluation phases and on a quarterly basis during the Implementation phase. The major reviews are conducted at the end of the Evaluation phase (confirmation of candidature), which is generally prior to 12 months elapsed candidature, at 21 months and at 30 months. The rationale for the panel approach is that it can provide a range of expertise during the Identification and Evaluation phases, especially when students are working in multidisciplinary teams and require a flexible supervision structure to address any subject or knowledge specific areas of expertise that need to be supported. The multi-disciplinary team-based approach itself is widely regarded as the best practice in systematically identifying opportunities and inventing and implementing new technology solutions. During the Evaluation phase, a suitable project-specific supervisory team with relevant specialist skills and knowledge is also identified for individual student projects occurring in the Implementation phase. In addition to the conventional PhD setting, the supervisory team therefore includes an academic supervisor, industry consultant, PhD coach-psychologist, business strategy analyst and a mentor.

2.6.1 *Process map, activities and timeline*

More specifically, the structure of the BioReactor

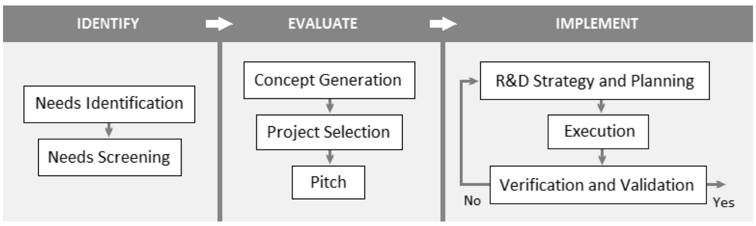

Fig. 1. Three major phases of the BioReactor PhD training program.

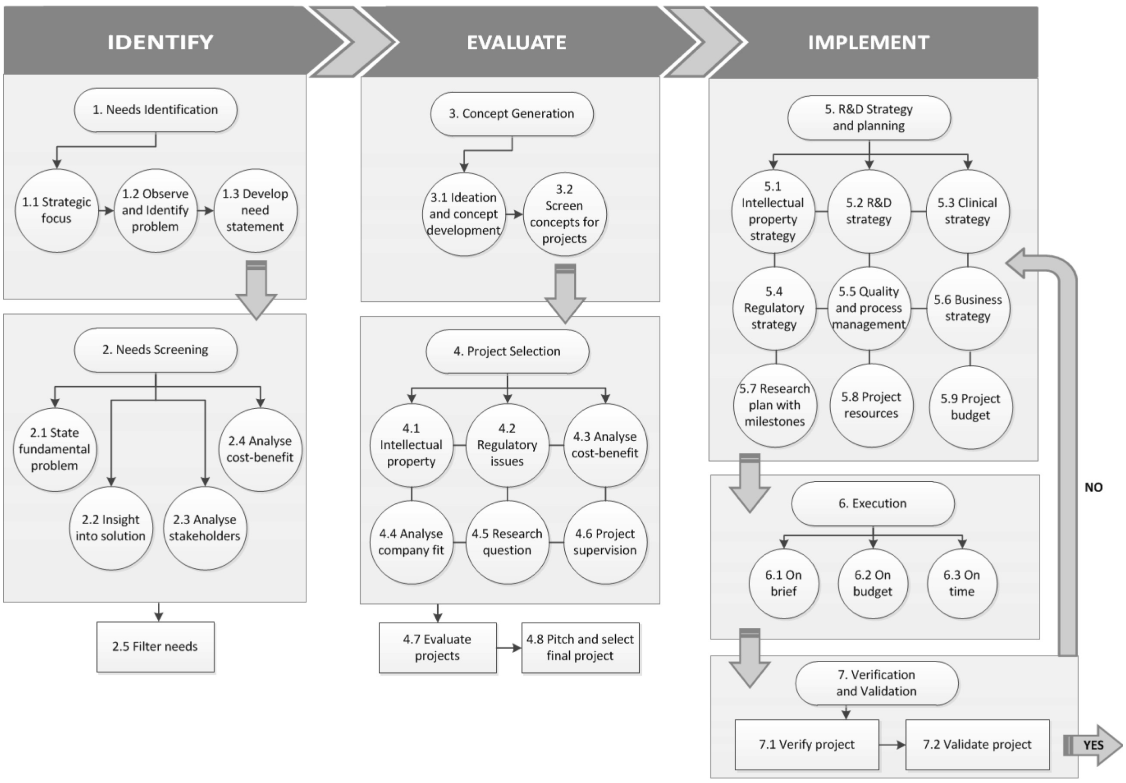

Fig. 2. Map of the BioReactor PhD training process (adapted from [19]).

Table 1. Timeline for PhD training

Activity	Description	Year 1				Year 2				Year 3			
1	Needs identification												
2	Needs screening												
3, 4	Concept generation, project selection												
	MEI coursework units	=======											
5	R&D strategy and planning												
	MEI coursework units			=======									
6, 7	Execution, verification and validation												
8	Thesis and reporting												

Note: major progress reviews are indicated by the heavy bars.

program is broken up into a process with series of distinct phases and activities in Fig. 2, and is shown in a timeline over the three year period in Table 1.

Each activity on the timeline is briefly described in detail below:

Activity 1. Needs identification (Months 1– 2)
On commencement, students can take the coursework unit such as opportunity discovery to gain fundamental knowledge on real world innovations and the practice of entrepreneurship. While the industry partners pitch key areas they have capability in or want to develop further, the academic team discusses key research capabilities (1.1 Strategic focus). The students are then be divided into multidisciplinary teams of 3–4 students and assigned academic and industry supervisors, before being immersed in end-user and Partner Organisation (PO) environments. During this period, the students observe and identify problems (1.2) before developing needs statements (1.3). End-user environments include hospitals, pathology labs, clinics, nursing homes and aged care facilities, as appropriate to the POs. To encourage a creative, open-minded process of opportunity identification, each team is expected to identify a large number of opportunities (regarded as an essential feature of the program). There are also personality tests and team building exercises including weekly meetings with the supervisory team to monitor progress.

Milestone 1: each team must identify at least 100 needs.

Activity 2. Needs screening (Months 3–4)
Building on Activity 1, students then learn how to develop metrics for screening needs/opportunities. After defining the fundamental problem for each opportunity (2.1), students have to identify a key insight into the problem that opens up the potential for a new solution (2.2). These insights might arise from a variety of sources, including recent advances in clinical science; emerging materials, technologies or processes; recognising inefficient, costly or difficult workflow; or observing the patient experience. In addition, students also assess the match with the interests and skills of the industry, academic and student stakeholders (2.3) and perform a cost-benefit analysis to develop an understanding of the potential return on investment (2.4). The large number of opportunities force students to adopt a disciplined approach to the filtering process (2.5), rather than just latching on to the first interesting problem that comes along. The supervisors then continue to monitor progress and ensure that all stakeholders are adequately catered for between the teams.

Milestone 2: each student must identify 2–3 individual projects to take forward to Activity 3.

Activity 3: Concept generation (Months 5–6)
Students continue to work in teams to generate multiple possible conceptual solutions for each project (3.1). All the 10 PhD students and postdoctoral researchers also work together as a group where each student present his/her own projects and receive comments through a "Post-It notes" exercise. In some instances, there might be a person within the group who takes on the heavy or devil's advocate role in order to cultivate creativity and best possible ideas. Methodologies are adopted from design teaching and the MEI unit such as creativity and innovation in order to facilitate brainstorming that draws on multiple areas of expertise in the team. Once a large number of concepts are generated, a further filtering process will occur, largely based on technical feasibility within the constraints of a PhD training program (3.2).

Milestone 3: the most promising conceptual solutions are identified for each project opportunity.

Activity 4: Project selection (Months 7–8)
Students undertake a more detailed study of the

selected opportunities at this phase. To support this activity, available relevant subjects from the MEI units that students can take are, for instance, opportunity evaluation and product innovation. This phase involves analysis of factors relating to intellectual property (IP) (4.1), regulatory requirements and associated issues (4.2), cost-benefit analysis (4.3), company fit analysis (PO strategic interests) (4.4), fundamental research questions (4.5) and confirming availability of appropriate academic supervision (4.6). The students are supported by targeted seminars on IP, medical device regulatory frameworks, business models and presentation skills. These seminars draw on guest lecturers from bodies such as the Therapeutic Goods Administration (TGA) and IP Australia, as appropriate. If necessary, students have to conduct some practical evaluation (proof-of-concept) during this period (4.7). At the end of this period, students pitch their project proposals to a "Dragon's Den" of the partner organisations, each of which then selects the project that they want to pursue (4.8).

Milestone 4: research projects are identified; students are matched to industry and academic partners.

Activity 5: R&D strategy and planning
(Months 9–11)
The individual students are now embedded with the POs to develop their detailed project plans. Particular attention are paid to developing a strategy for managing IP (5.1), priorities for the R&D program (5.2), defining the pathway to clinical trials (5.3), may be post PhD, managing the regulatory requirements (5.4), aligning the program with quality and process management requirements (5.5) and defining the business case for the PO (5.6). Based on these considerations, the students then produce a project Gantt Chart with clearly articulated milestones (5.7). Students are also expected to identify resources needed for the project, including access to specialised research facilities and expertise (5.8), together with a project budget (5.9). During this period, students meet up with their academic supervisor on a fortnightly basis to discuss progress. Industry specific project management software tools may be used to document and manage this and subsequent phases of each project.

Milestone 5: detailed project plan document is submitted; students undertake confirmation of candidature.

Activity 6: Execution (Years 2 and 3)
The students are expected to execute their project plan. Regular meetings are held with the supervisory team to monitor progress and provide specialist technical advice. Overall the focus is based on ensuring that students remain on brief (6.1), on budget (6.2) and on time (6.3) in terms of delivering the agreed research outcomes. In addition to making an original contribution to the field of scholarship during this phase, students must also demonstrate the independence, initiative, responsibility and accountability that are expected of a PhD student (AQF Level 10 attributes). While this implementation phase is primarily an individual endeavour, a range of enrichment activities are to be continued to maintain the collegial and supportive environment that was developed during the initial team-based activities. Students are then expected to make regular presentations on their project to the Centre participants. In addition, quarterly workshops are held with guest speakers and "challengineering" events, where teams are formed to tackle short term challenges nominated by industry. All students are to attend a major international conference combined with a study tour of a medical device hub in the USA, Europe or Asia. During this period, students continue to spend at least 1/3 of their time undertaking research with the PO.

Milestones will vary according to research plan.

Activity 7: Verification and validation (to completion: **Activity 8: Thesis and reporting**)
To meet the agreed milestones, students firstly need to demonstrate that their output (experimental results, prototype, system, etc.) complies with the requirements defined in the project plan (7.1 Project verification). Secondly, the output of the project needs to be validated (7.2) by the identified stakeholders to show that it meets their needs. These steps are critical components of a quality management system and are necessary for a disciplined approach to medical device development. If it is not possible to verify or validate an output, the project plan can be revised by reconsidering the factors addressed in Activity 5 (R&D strategy and planning). This allows an iterative and adaptable approach that is often needed to address the uncertainties that unavoidably arise in fundamental research.

Final Milestone: submission of a thesis equivalent to 70,000 to 100,000 words and any other required project documentation for examination.

3. ARC training centre in biodevices and diagnostics

3.1 The Australian research council

The Australian Research Council (ARC) itself is a Commonwealth entity of the Australian Government that operates the Industrial Transformation Training Centres (ITTC) scheme. The ARC ITTCs scheme provides support funding for collaborative research of university-based researchers with industry or another partner organisation outside the Australian university sector in order to transform research into an opportunity at the project level. The partner organisation must however provide financial support or make in-kind contribution equivalent to or more than the ARC contribution. This type of scheme is considered highly valuable as it offers opportunities for Higher Degree by Research candidates including postdoctoral researchers to participate in innovative training that supplement the needs of industries and other research end-users vital to the future of Australia. In August 2014, the ARC has also updated its policy to fund health and medical research such as bioengineering and natural sciences in responding to specific Australian Government health and medical research priorities [43].

3.2 Swinburne bioreactor centre

The mission of the Centre is to improve Australia's innovative capacity and entrepreneurial activity in the medtech industry through understanding all aspects of the processes for turning ideas into products. The approach of the ARC Training Centre addresses the National Research Priority on "Frontier technologies for building and transforming Australian Industries" [44]. This also includes the three priority areas in the Manufacturing focus of the ITTC scheme through a postdoctoral research program and a PhD training program. The postdoctoral research program focuses on broader sectoral issues in terms of how product design can better meet customer needs (i.e. aesthetic response of customers to medical devices and biology at the interface), as well as assessing the broader impact of the Centre activities on the entrepreneurial and innovative attitudes and skills of the PhD students and the *firm organisation and management* of partner organisations. The latter is seen as a first step in a longer term program to understand the factors which contribute to the success of biomedical device and diagnostics companies in the Australian context. The PhD training program identifies and addresses the most critical needs of the partner organisation in terms of *product design and development* and *improvements in manufacturing techniques.* In turn, this provides support to the industry partners, the Australian medical device and diagnostics companies, to develop the next generation of innovative and profitable products to deal with community healthcare needs.

3.2.1 Centre's industry partners

The Centre is focussed on small Australian companies that often play a major role in research and development of new medical devices as partner organisations. The industry partners boast a diverse range of specialised med-tech technologies and products. They meet the contribution requirement set by the ARC and also provide mentorship to the PhD students for them to gain insights into unmet/under-met needs of medical device innovation. Above and beyond, the industry supervisors generally have a PhD, while industry consultants have equivalent experience in an R&D environment. Additional mentoring is also provided by a network of experienced volunteers—generally senior industry professionals, including semi-retired alumni of the University who see this as a way of "giving back" to the profession. The partner organisations themselves have experienced personnel with a wide range of technical and business skills specific to the biodevices and diagnostics market. They can therefore provide adequate training and supervision for researchers at the Centre to gain exposure to manufacturing processes and industry R&D activities that are appropriate to the highly regulated medical device market. The industry partners and mentors can add significant value in connecting students and the Australian biomedical industry and associated collaborations and networks.

3.2.2 Swinburne University involvement

As for Swinburne, the Centre fits firmly into the University's 2020 aim and its five areas of focus: future manufacturing, sustainable futures, digital frontiers, personal and societal wellbeing, and inspirational science and technology. The University aims to produce outstanding research that is relevant and internationally recognised, focussing on outcomes and impact through close engagement with industry and the communities. Consequently, the Centre has received strong support from all areas of the University, including significant cash and in-kind contributions. The Office of Graduate Studies, for instance, offers the PhD students a variety of training opportunities, providing information and guidance throughout their candidature. Through the Higher Degree by Research Communications Lab, students and postdoctoral researchers are offered additional support in proposal and report writing, working with industry, media skills and research supervision.

3.2.3 Advisory board

Both external and internal advisory board with considerable knowledge and experiences in medtech industry, particularly medical device development, were appointed. Their roles are to review process for the selection of PhD students and postdoctoral researchers and provide consultancy on the direction and delivery of the program as well as monitoring the overall operation of the Training Centre in accordance with the ITTC funding agreement.

3.2.4 Research facilities

The PhD students and postdoctoral researchers are able to access a comprehensive range of research facilities at Swinburne, including the Biointerface Engineering Hub with its extensive surface modification and characterisation suite, PC2 Labs for both bacterial and cell culture, and the Nanofabrication Lab (e-beam lithography, focussed ion beam milling, sputter coater, dry etcher, surface profilometer and mask aligner). Additional facilities include a scanning electron microscope, spectroscopy instrumentation, live cell imaging facility and an X-ray photoelectron spectrometer (currently being commissioned).

Further both the academic and industry participants in the Centre have a number of well-established national and international linkages that will be used to support and promote the Centre activities. Academic collaborations are leveraged to gain access to specialised facilities, research capabilities or expertise that is not readily available within Swinburne, and to facilitate the PhD students gaining access to multiple "customers" in the clinical environment. The University also has an extensive network of contacts in the Biomedical Engineering Departments at Victorian hospitals through several graduates and industry-based learning students from Swinburne, including links to the Therapeutic Goods Administration to improve the students' understanding of the regulatory framework for medicines, biological and medical devices.

Significantly for the BioReactor Centre, the recently established Swinburne's Advanced Manufacturing and Design Building features a "Factory of the Future" where advanced visualisation tools, computer-aided design, rapid prototyping and fabrication equipment are linked together in a series of studios. A "Biodevice Innovation Studio" is established in this space and will be the focal point of the Training Centre activities. The Studio provides versatile workbenches for device development and testing. The space includes rooms for meetings, brainstorming sessions and presentations, as well as a kitchen facility for informal interactions between researchers and industry visitors. This style of research facility is in keeping with the "Design Factory" philosophy as a result of the relocation of Swinburne's Faculty of Design to this new building in early 2014.

The official launch of the Centre was coincided with the opening of the AMDC building at the Factory of the Future in July 2015. A federal minister, both Chancellor and Vice-Chancellor of Swinburne, together with all of the industry partners, academics and the PhD students were involved in the launch.

4. Discussion

4.1 Program benefits and challenges

As the primary aim of the Swinburne BioReactor program is to develop future entrepreneurs, industry-ready researchers and leaders in industry-research links within the medtech industry, the program offers both direct and indirect benefits to a number of entities whilst posing some challenges particularly to those associated within.

With regard to Swinburne's strategic direction, the program is aligned with Swinburne's aim to increase Australia's capacity in science, technology and innovation as the drivers of modern, internationalised economies and workplaces. The industry focus of the program contributes to Swinburne's strength in developing industry-ready graduates and is viewed as a postgraduate extension of the successful industry-based learning program for undergraduates. Although there are somewhat similar programs offered elsewhere in the world (e.g. Engineering Doctorates in the UK), the BioReactor has its own unique features that are different to the "traditional PhD" and supports Swinburne's progressive approach to education. Having profiled the program as a Research Doctorate to retain the PhD title in an industry-based training environment differentiates the program from other offerings in the education market and internationally carries more weight than a Professional Doctorate or Engineering Doctorate. The approach of the program is an unorthodox start to a PhD and is reshaping the traditional ways and what it means to do research.

The BioReactor also provides a means of collaboration between different faculties ranging from engineering, science to business in order to achieve the prime objective and shared goal in education and training. While the program is currently being offered within the Faculty of Science, Engineering and Technology, it has attracted interests from other faculties and challenges the University with a view of rolling it out across faculties and later emulates within Australia and around the world. According to Yock, Brinton and Zenios [19], one of the challenges facing innovation programs are the requirements for commitment and provision from universities for such programs and the alignment of program structures to stimulate interests and drive the performance of faculty and schools. There is often a difficulty to ascertain a genuine interest of faculty and develop proficiency in technology transfer and translational education. It is therefore important that the benefits and value of engaging in research and translational activities, collaboration and alignment of faculty performance and promotional metrics are encouraged by universities leaders both internally and publicly.

Today, universities and their entrepreneurship and innovation training programs can tremendously influence the ability of individuals to seize control of tomorrow's market and industry, by means of learning to become innovators and entrepreneurs. Primarily, the BioReactor program incorporates leading methods in entrepreneurship and innovation through industry-led research and training that promotes an innovation culture and knowledge economy. This is also driven by the emerging trend that industry people are changing their view of research and development by seeing universities as sources of innovation.

The companies that involve as partner organisations in the program such as the BioReactor can expect to receive multiple benefits, such as exposure to a diverse range of expertise and potential employees, new intellectual property and patents, tax credits, new sources of revenue, an independent analysis of current and new business opportunities. The Swinburne BioReactor Centre promotes business-to-business commercial opportunities amongst the participants by bringing together a number of firms with complementary rather than competitive technology capabilities. Each partner organisation is assisted in rigorously evaluating and ranking a range of opportunities relevant to their business interests. While larger companies can support dedicated R&D divisions that support this function, the small-to-medium companies that represented the majority of businesses in Australia are often unable to afford this amenity. The Centre serves to enhance leading edge, collaborative research between Swinburne and the partner organisations. On one hand, the university investigators bring an established track record of successful fundamental research. On the other hand, the partner organisations have portfolios of proprietary and competitive technologies and domain specific knowledge of the market. This creates challenges for small-to-medium sized companies to engage in this type of industry-focussed program that can ultimately give the Australian centre a stage to compete globally and the opportunity to build brand Australia in R&D.

In addition, partner organisations are provided with a PhD student, supported by academic experts and a postdoctoral researcher, whose focus is to address the fundamental research questions that need to be answered in order to establish feasibility of a new product, manufacturing process or service. For smaller companies, it is difficult to justify this level of resourcing for an opportunity that requires fundamental questions to be addressed. The program can therefore provide them with an opportunity to make significant advances in terms of technology development, while minimising the risk of failure through rigorous cost-benefit analysis, project planning and project management.

Having students embedded in the partner organisations for a significant fraction of the time creates an opportunity (and challenge) for the students to transfer their knowledge to company employees, as well as sharing the technical capabilities that they are exposed to in the University environment. The academic participants will also derive similar reciprocal benefits from this relationship. On completion of the program, partner organisations may invite students to continue their relationship with the company, having had the opportunity to observe their capabilities at close quarters. However, graduating students and postdoctoral researchers will also have hands-on experience of the end-to-end processes involved in product research and development including evaluation of project opportunities and management of venture capital funding. This can thereby stimulate them to build their own start-up companies.

In terms of the National Research Priorities, the Centre has a direct impact on the development of cutting edge technologies for stimulating the profit and growth of Australian biodevice and diagnostics manufacturing; thus, achieving economic and employment benefits. This is possible through a combination of breakthrough science relating to fundamental processes (e.g. biological surface interactions, light-tissue interactions), frontier technologies in areas such as photonics and nanotechnology, application of advanced materials (biomaterials and colloids) and smart information use through interactive service systems (agent-based software).

Together with the partner organisations, the Centre has an indirect impact on promoting and maintaining good health for all Australians, by contributing to technologies that support the mental and physical capacities of ageing people, and technologies that allow more effective point-of-care monitoring and treatment, adoption of healthier lifestyles and new health care products. These can result in social benefits not only for Australia nationally but also internationally around the world through improvements in healthcare such as reduced costs for medical testing, reduced hospital stays and prolonging the ability of the elderly to remain independent.

5. Conclusion and future research

The overall value of the framework of the PhD training program in technology innovation provides a contextual approach for program developers/leaders and educators to design and develop an entrepreneurship and innovation education and training program in the field of biomedical engineering. While the majority of the biomedical engineering degrees often include industry internships and/or industry-based projects, enhancing an industry engagement and collaboration for all researchers is increasingly challenging and is the key enabler to drive innovation that allows industry to develop higher value product/service combinations. This paper offers best practice guidelines for Australian university-industry research collaboration and commercialisation in the form of a PhD training program (Higher Degree by Research) in technology innovation, particularly relating to biomedical devices and diagnostics. Together with partner organisations, the Centre also identifies best practices for global competitiveness in product innovation, including opportunity identification, product design and development, quality systems and manufacturing techniques. These implications for university-industry collaboration and the advancement of product innovations may apply not only to Australia and the biotechnology sector, but also more broadly to other countries and sectors.

We contribute to the literature by adding the body of knowledge in an interdisciplinary field across education and training, engineering, and entrepreneurship and innovation disciplines and bridging the gap in the traditional PhDs to industry-oriented PhDs. Research implications, however, call for empirical studies to evaluate the effectiveness of this new entrepreneurship and innovation education and training program that illuminates the supply of future PhD graduate leaders and entrepreneurs in Australia. At this stage it is not well known what parts of the innovation training curriculum will have the most impact on the future profitability and success of the Australian medical technology industry. Further research is recommended to empirically test the conceptual model of the PhD training program, its three major phases of identification, evaluation and implementation and their relationships between components as well as the parameters of each activity. In addition, it is important to evaluate the impact of the PhD training program on the changes in the beliefs and intentions of participating students to start and launch a new medical device or diagnostic company. Such research is presently being conducted by the authors to provide an empirical analysis and a more comprehensive evidence of best practices for this conceptual paper.

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