Decision Criteria for Technology Commercialization of Medical Devices

A THESIS

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Dedication

This thesis is dedicated to my parents and my husband. Thank you to the family and friends for immense mental support and encouragement.

Abstract

This paper provides a brief review of the current literature on technology commercialization factors for heterogeneous medical devices. It intends to propose some technology commercialization factors focused on three novel medical devices. Technology commercialization factors provide a means for a company to prioritize which technologies to commercialize so that an organization's resources are used most effectively. A survey was arranged in order to provide feedback for the proposed technology commercialization factors. The results of the survey are analyzed after getting feedback from a number of personnel involved in medical device industry. Based on the response of the participants, relative weightings of the proposed technology commercialization factors are calculated. Finally, the relative weightings are used to score the three novel medical device technologies. A brief statistical analysis of the proposed technology commercialization factors is also discussed here.

Table of Contents

List of Tables

List of Figures

1 Introduction

To foster innovation, it is essential for an organization to commercialize its technologies. Technology commercialization aims to transform technology innovation into products or services to create commercial benefits [1]. In other words, commercialization attempts to render market value by generating profit from innovations through incorporating new technologies into products or services. Many factors drive a firm's decision to commercialize one new technology over another. Manufacturing companies must assess the likelihood of funding of the innovation from internal and external sources. Companies must estimate the profitability of the new venture, the ability to protect the intellectual property of the innovation, the size of the target market etc. [2].

Technology commercialization includes various actions and components such as acquiring ideas with complementary knowledge, implementing the ideas, developing prototype, manufacturing saleable goods, and converting the goods into economic benefits by selling them [3]. Successful commercialization strategies are contingent on the technology's source, the availability of organizational resources and technological complexity [4].

For successful technology commercialization, it is crucial to document technological feasibility and market requirements in the initial investigation [5]. Effective commercialization depends on research on how the diverse sources of technology (e.g., university, research institute, industry) impact technology commercialization outcome [6]. With more applied research there's a chance of higher marketability of the

innovation, which leads to higher rates of technology commercialization [7]. Therefore, extent and quality of research concerned with the technology fortifies the dimension of feasibility of that innovation.

Strategic technology transfer plays a vital role in technology commercialization. Eldred and McGrath [8] suggested that technology transfer is a very important concept while linking the technology development process and product development process. Duhm and Wielockx [9] stated that successful technology commercialization depends on a gradual technology development process. Design development process also depends on the universities which developed the technologies at universities [10] [11]. Protecting the patent of a new technology is also essential to commercialize it. To prevent imitation of extremely innovative technologies, the startups can follow the pathway of patenting and commercializing it [12]. Extremely innovative technologies can attain commercial success when the inventor of the technology contributes to the further development of the technology [13]. In that case, addition of new aspects to the existing technology would be more facilitated.

A firm's decision-making for a technology innovation is greatly influenced by weighting the technology commercialization factors. A firm shouldn't follow all potential technologies, because not all technologies would render the desired market values and the firm has limited resources. A company must estimate all possible variables, which would affect an innovation's relative advantage over other technologies of that company [14]. All possible consequences for each technology must be assessed to get a comparative

picture of feasibility and possible added-values. A systematic way of choosing which technology to commercialize will lead to the ultimate economic success for a company. That's why weighting the commercialization factors are critical for an effective pathway from a business perspective.

Based on literature review on technology commercialization and medical device innovation, this article intends to identify some technology commercialization factors (TCF) of heterogeneous medical devices. A survey via Qualtrics.com is conducted to provide feedback on the proposed TCFs. The feedback is then used to assign relative weights to the proposed TCFs. The results of this effort have been applied to three proposed medical devices: high pressure water jet craniotome, peripheral lung biopsy and glioblastoma tumorID. The main contribution of this paper is to provide a weighted scoring of several technology commercialization factors for these devices after performing a SWOT analysis. A novel decision matrix is proposed from the SWOT analysis. The prospect of successful commercialization is represented from the reflection of the overall score of the medical device technologies.

The rest of this article is structured as follows. Section 2 presents literature background of technology commercialization factors and their weightings for medical device technologies. Section 3 depicts the research methodology of this study. Section 4 discusses the proposed technology commercialization factors (TCF). Section 5 introduces an overview of three medical device technologies and a decision matrix of these technologies based on the proposed TCFs of Section 4. Section 6 presents the survey

methodology. The survey was conducted to provide relative weightings to the proposed technology commercialization factors. Section 7 includes discussion of the results of the survey and an implementation of the results on the mentioned medical device technologies. Finally, section 8 concludes the entire study.

2 Literature Review

2.1 Technology Commercialization Factors and their weightings for medical devices

The literature review of this study includes discussion of technology commercialization (TC) factors and their weightings. Many prior studies have paid attentions to decision criteria for successful technology commercialization. An overview of these factors summarized in a study by Kirchberger [6] is reproduced in Table 1:

Table 1: List of Coded TC factors [6]

Final Factors	Initial factors
Potential Market size	Potential market growth rate, adoption of technology
Property rights	Licensing, patent availability, patent scope, reimbursement requirements, fairness of property rights distribution
Technology suitability for commercialization	Feasibility, age of innovation, competition in target market segment, development stage of technology, expected time to market, innovation scope, projected market share, pioneering nature

Final Factors	Initial factors
Technology application value	Customer satisfaction, product development time, technology Customer satisfaction, product development time, technology assessment, technology carve-outs, technology complexity, technology importance.
Technology transfer strategy	Experimenting with technology in value networks, choice of strategy, innovation strategy, overcoming bottlenecks, project management of the transfer
University policy and structure	Autonomy of technology transfer office, degree of support, entrepreneurial orientation, design of process, quality of research, number of researchers, university size, organizational ambidexterity, type of university, previous spin outs
Resource availability	Access to finance, access to incubators, funding at university, internal human and technology-based manufacturing sources, availability of venture capital
Researchers' individual characteristics	Commercialization capability, faculty quality, marketing skills, motivation, risk taking aptitude, nationality, star scientists, time allocation, willingness to engage in transfer.

The decision criteria for technology commercialization centers around early stage impediments, which would influence the process of transforming a technology to market. Patent scope, target market research, technology transfer from startups, potential

resources, etc., are important deciding factors for commercializing a new technology.

Kim et al. [15] demonstrated two technology commercialization capability-related factors: the manufacturing function (MFF) and the marketing function (MKF). Kim et al. [15] also introduced the learning function (LF) and the external networking function (ENF), both functions measure the R&D (Research and Development) capability of a company. Here, R&D capability is related to a dynamic capability to implement acquired knowledge of research and development on technology innovation performance. MFF relates to continuous improvement of manufacturing system. MKF refers to marketing ability and knowledge about the target market.

The learning function (LF), mainly monitoring trends of R&D, proved to have a significant positive influence on both technology commercialization capability factors. Additionally, the external networking function (ENF) had a significant positive influence on the manufacturing function (MFF). Here, ENF relates to new market entry through external technology cooperation. Both of the technology commercialization capability-related factors, the manufacturing function (MFF) and the marketing function (MKF) had a significant positive influence on innovation performance [15].

Mehta [16] presented a linear roadmap of commercialization plan for a biomedical invention including its components. Their proposed plan outlines several important technology commercialization factors. The roadmap is portrayed below [16]:

Plan	Position	Patent	Product	Pass!	Production	Profits
Industry context	Market research	Intellectual property rights	New product development (NPD)	Regulatory plan	Manufacture	Reimbursement
Technology positioning and strategy, industrial value chain context	Market need, market size, profitability	Intellectual property and licensing strategy, Business models	Stage-gate new product testing and development plan, budget	Regulatory Strategy-working with FDA towards approval	Production planning	Coverage, Coding, Payment, Distribution, Marketing and sales planning

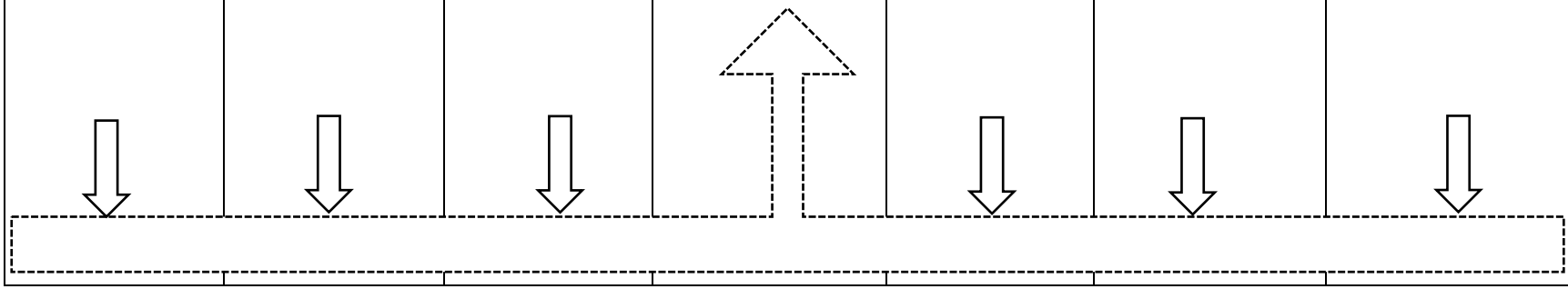


Figure 1: Components of a commercialization plan and roadmap

This roadmap emphasizes various stages required to commercialize an innovation marketed in a competitive and regulated marketplace. This roadmap supports the conclusion that the biomedical technology commercialization process depends on the factors such as market research, licensing strategy, intellectual property search, regulatory and reimbursement plans etc.

To introduce a scoring methodology of innovation capacity, a set of guidelines on [17] incorporating results of an online survey with a goal to better understand the values regrading innovation has referenced. The study suggested that the challenges and opportunities can be identified and prioritized through a thorough interpretation of survey results, which would lead to focused corrective action [17].

A weighting of some critical factors for technology commercialization process was developed by M. Jung et at. [18]. Their weighting was based on relative variable importance (RVI) using the classification tree (CT) method. RVI is the relative order of priority among the factors considering the interaction between input factors [18]. In this CT, the most influential factor was assigned as marketing capability, RVI value of 1. The following Table 2 is reproduced from the study of TC factors by CT process [18].

Table 2: Technology commercialization Critical Factors with RVI dimensions by CT (classification tree) process [18]

Critical factors	**RVI Dimension**
Marketing capability	1.0000
Cooperation with developer	0.7217
Effort for technical improvement	0.5633
Willingness and capability of adopter	0.5376
Supply of complementary technology	0.5334
Financial capability	0.5288
Market condition	0.5077
Excellence of technology	0.2420
Technical capability of adopter	0.2341

S. Kumar et al., [19] used the Analytical Hierarchy Process (AHP) to weight the critical technology transfer and commercialization factors. The result of the AHP methodology was utilized to evaluate critical factors of effective technology transfer process in India. A summary of their results [19] are shown in the following table:

Table 3: Summary of results showing weight of Critical Factors of technology transfer (TT) by AHP [19]

Dimensions of Critical factors of TT	**Weight of dimensions**
Regulatory concerns	0.48159
Relative advantage in economic terms	0.19505

Dimensions of Critical factors of TT	Weight of dimensions
Technical features	0.14384
Marketing related benefits and forces	0.10065
Managerial and strategic issues	0.07886

Here, 'Regulatory concerns' indicates the significance of legal and regulatory barriers at the national and international levels. 'Relative advantage in economic terms' relates to cost effectiveness, profitability etc. 'Technical features' includes technological abilities of suppliers, local suitability of technology, compatibility etc. 'Marketing related benefits and forces' refers to entry to new market, market requirements etc. Finally, 'Managerial and strategic issues' indicates strategic implications, resources etc. [19].

The literature review from the above studies summarizes previous efforts to identify technology commercialization (TC) factors and efforts to weight them. Inquiries into the relative weighting of technology commercialization factors, for medical device innovations in particular, have been especially rare. This study aims to identify several TC factors for medical device innovations. The proposed factors for the current study are discussed in the Section 4.

3 Research Methodology

The research methodology of this study includes proposing technology commercialization factors for medical device innovations, a SWOT analysis and a decision matrix for the proposed medical devices, a survey to weight the proposed TCFs

and apply the weighted TCFs to get overall score for the proposed medical devices. A flowchart of these activities is shown below:

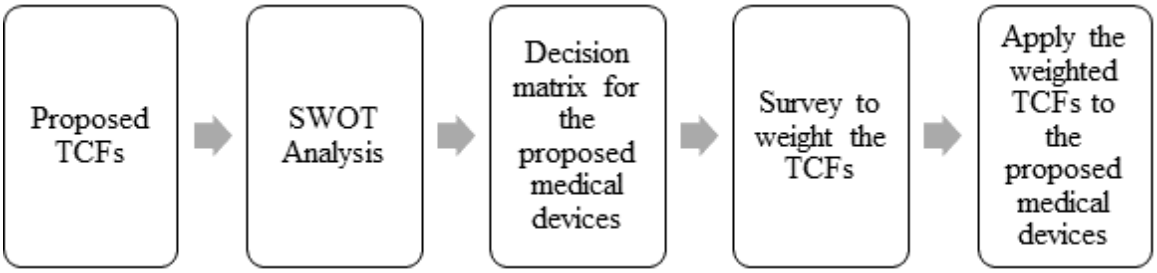


Figure 2: Flow chart for the research methodology of the study

SWOT analysis and decision matrix were discussed in Section 5.4 and 5.5. The analysis and implementation of the decision matrix will be discussed in Section 7.1.

The next chapter describes the proposed TCFs, how these proposed TCFs were chosen, and importance of these TCFs for successful commercialization.

4 Proposed Technology Commercialization Factors

Successful technology commercialization is imperative for survival in the competitive markets [20]. An organization cannot commercialize all potential technologies due to limited resources. The organization must decide which technology would exhibit most potential positive aspects in terms of economic success. Therefore, factors affecting decision criteria for technology commercialization hold immense interest.

Commercialization of medical devices is part of medical device design and development activities. This study focuses to identify deciding factors for commercializing medical devices in particular. To know these deciding factors, activities for commercializing new medical devices need to be addressed**. S**teps of medical device design for innovation of medical devices are provided below [21]:

Table 4: **S**teps of medical device design for commercialization [21]

Phases	**Stages**	**Activities**
Identify	Need Finding	Strategic focus Need statement
	Need Screening	Market analysis Stakeholder analysis
Invent	Concept generation	Ideation Initial concept selection
	Concept screening	Intellectual Property basics Regulatory basics Reimbursement basics Business models Concept exploration and testing Final concept selection

Phases	Stages	Activities
Implement	Strategy development	IP strategy R&D strategy Clinical strategy Regulatory strategy Quality management Reimbursement strategy Marketing and stakeholder strategy Sales and distribution strategy Competitive advantage and business strategy
	Business planning	Operating plan and financial aid Strategy integration and communication Funding approaches Alternate pathways

At this point, several activities in the medical device innovation process require concepts from the previous discussion on technology commercialization factors. After reviewing the above literature background this paper identifies a number of deciding factors which lead to successful commercialization.

From the literature overview, a summary of some major factors that are significant for successful technology commercialization are: technology transfer strategy/ property rights [6], feasibility [6] [16], resource availability [6] [18], manufacturing and marketing

functions [15], market entry strategy [15] [18], market size [6] [21], technology positioning [16], licensing strategy [6] [16], regulatory strategy [16] [19] [21], reimbursement strategy [16] [18] [21], effort for technical improvement [18], technical capability [19], regulatory concerns [19], market research [16] [21]. After combining all of these factors, this study intends to generalize them and propose a novel list of technology commercialization (TC) factors, especially in the context of medical device technology innovation.

Hence, in light of literature review along with study of medical device innovation activities, the following six TC factors are proposed after summarizing the major TC factors. Following is a table showing how these six TC factors were proposed after summarizing the major TC factors from literature background. The corresponding references of literature, where these TCFs were mentioned, are also mentioned here.

Table 5: Proposed TCFs based on literature review

Major TC factors from literature background	**Proposed TCFs: summarizing the major TCFs from literature reviews**
Market research [16] [21], market entry strategy [15] [18], market size [6] [21], marketing functions [15]	Market size
Effort for technical improvement [18], feasibility [6] [16], technical capability [19], technology positioning [16]	Technology feasibility

Major TC factors from literature background	Proposed TCFs: summarizing the major TCFs from literature reviews
Regulatory concerns [19], regulatory strategy [16] [19] [21]	Regulatory pathway
Reimbursement strategy/potential [16] [18] [21]	Reimbursement potential
Transfer strategy/ property rights [6], licensing strategy [6] [16]	Technology transferability/ Licensing
Resource availability [6], financial capability [18]	Resource availability

The discussion for each proposed TC factor is presented below.

4.1 **Market size**

Market analysis along with projection of the segment market is one of the most important initial steps for commercializing a new technology. A strategic and systematic market plan plays a vital role in technology commercialization, with an emphasis on profiling and finalizing the target market. Market orientation and understanding the customers are the key factors for successful commercialization [6]. Innovators should perform an efficient market analysis, which includes market prediction along with the identification of end users [22]. They also need to estimate the target market size as well.

Per Slater and Mohr (2006) [23], the ability to identify appropriate target markets also supports the successful commercialization of technologies. Per M. Eyring et al. [24], early identification of emerging markets by detecting the unmet needs helps the startup to grow profits. Strategic market analysis may also identify a low-end solution or a disruptive innovation. This analysis will be based on the target market landscape followed by a need statement in the initial stage of commercialization. The market landscape may include competitive dynamics of segment market and opportunities of potential expansion of market [21].

A well-planned market analysis will reflect needs from the customers' perspective, which would lead to an effective estimate of projected market size. Hence, market size analysis is a significant contribution to the development of commercialization.

4.2 **Technology Feasibility**

The factor of technology feasibility relates to the features of the technology which support or hinder its commercialization [6]. This introduces the idea of how much invention necessary for market introduction of the technology. In other words, technology feasibility is the likelihood of economic success with improvement of existing technology. Prototyping is helpful to identify how much invention will be needed in later stages in marketing. The driving factors that stipulate technology feasibility are, the quality of the technology, scope, pioneering nature (type of innovation), and expected time to market growth. Analysis of technology feasibility can help lead research toward

the scope of cost reductions of the technology innovation [25]. A strategic feasibility study will prevent problems later in design verification and validation activities of the commercialization process [26].

Technology feasibility can also be reflected by technology readiness level (TRL). TRL is related to technology capabilities. When upgrading from technology development to product development, the risk is higher for a lower-TRL technology [27]. To reduce risks for medical technologies in order to increase the scope of feasibility certain steps are essential such as, initial market analysis, hypothesis test of prototype, design review, Premarket Notification or 510(k) (for class II device) or Pre-Market Approval (for class III device) [27].

4.3 **Technology transferability/ Licensing**

Technology transferability mainly focuses on strategies for early stage impediments in commercialization. Research through universities helps foster technology-based economic growth nationwide. The diffusion of university-developed intellectual property (IP) is therefore a vital and dynamic process. To protect the patents of these research work, proper licensing activities are essential. Research conversion to IP leads to academic start-ups or external entrepreneurial companies. Most major U.S. research universities have set up technology transfer office (TTO) to patent the IP and manage the development and commercialization of their innovations [28].

The TTOs use a metrics-based index that assess the relative position among peers and in distinguishing best practices. From a study of 2012 to 2015 [28], the index is measured as four indicators of technology transfer success: how many patents issued, how many licenses issued, amount of licensing income, and number of start-ups formed. This data was collected by the Association of University Technology Managers (AUTM) through the AUTM's Annual Licensing Activity Survey [28]. Another study by Galbraith et al. (1991) [29] suggested that successful technology transfer is subject to the incorporation of the requirements of the end users of the technology when choosing the R&D projects.

Gans and Stern [30] claimed that startups would have a higher chance of successful product development if they have strong intellectual property. With appropriate patenting/licensing, they can collaborate with other cooperative firms to commercialize their technologies [30]. Companies intending to commercialize a new product, should pursue to secure their freedom to operate (FTO), which is to ensure that the manufacturing, marketing and use of their new product or service does not infringe the IP rights of others [21].

Developing a medical device with FTO and IP protection is a significant route to technology transfer. In order to assure FTO, an extensive patent search is required. A patent is a legal document that gives an inventor the right to prevent others from commercial use of that invention. Criteria for obtaining a patent are utility, novelty and obviousness. Strong IP can be a source of potential revenue through licensing agreement. Strong IP is also a barrier for market entry for other competitors [21].

Some factors that lead to a high rating for technology transferability are good patent coverage, business friendly IP policies at universities and support of the inventors when transferring from university. Protecting inventions by licensing with a strategic IP landscape has a big positive impact on technology commercialization.

4.4 **Regulatory pathway**

Developing an effective, strategic approach to regulation is of critical importance in the medical device development process. Regulatory approval or clearance must be approved by the FDA. The manufacturer must learn about the medical device classification system. The definition of medical device quoted from FDA [31] is stated below:

"A machine, implement, implant, in vitro reagent, apparatus, instrument, or other similar article, including any component part which is:

1. envisioned for the diagnosis of disease or other conditions, or to lessen or treat, or prevent disease, in man or other animals, or
2. intended to impact any function of the body of man or other animals, and which does not attain any of its primary intended purposes through chemical action on the body of man or other animals and which is not reliant on being metabolized for establishing its primary intended purposes" [31].

Following are the detailed regulatory activities required to commercialize a medical device innovation.

4.4.1 Device classification

Once a new product is considered as a medical device, the innovator determines its risk profile in accordance with the FDA safety classification system. Following is a brief discussion of each class of medical device and the regulatory pathway for each class of medical device [21]:

Class I medical devices are typically simple in design. There is no need for clinical trials or proof of safety or efficacy. Examples of Class I medical devices are bandages, bedpans, examination gloves, hand-held surgical instruments, etc.

Class II medical devices are often non-invasive, but more complicated in design than class I devices. Examples of Class II medical devices are X-ray machines, powered wheelchairs, surgical needles, infusion pumps, and suture materials.

Class III medical devices are high-risk devices. Typically, they are implantable, therapeutic, or life-sustaining devices. Examples of Class III medical devices are replacement heart valves, implantable pacemakers, and implanted cerebellar simulators.

Regulatory pathway for class I device must follow the ‘general controls’: registration of the establishment with the FDA, medical device listing, general FDA labeling requirement, compliance with quality system regulation (QSR). Most of the Class I devices are exempt from premarket clearance. Class II devices must meet all class I

requirements, in addition to ‘special controls’ including: special labeling requirements, mandatory performance standards, design controls, and post market surveillance. Class II devices are generally cleared to market via the 510(k) processes. Class III devices must meet Class I and Class II requirements, in addition to stringent regulatory approval requirements that necessitate valid scientific evidence to demonstrate their safety and effectiveness. Class III devices are generally approved by the PMA regulatory pathway [21].

4.4.2 510(k) Approval and Substantial Equivalence to the new device

The three medical device concepts to be analyzed in this study are class II devices (see section 5). So, 510 (k) approval from FDA is compulsory for marketing and commercial distribution.

It is mandatory that applicants compare their intended 510(k) device to one or more similar existing devices currently in the US market. The device cannot be commercialized until FDA approves a 510(k)-clearance stating that the device has been determined to be substantially equivalent (SE) [32].

A device is substantially equivalent (SE) if it verifies the same technological characteristics and the same intended use as a legally marketed device, which is known as the predicate. A device that was legally marketed prior to May 28, 1976 is a legally marketed device (or pre-amendments device). Once the submitter gets SE clearance, the

device can start the marketing process. The SE determination usually takes 90 days and is made based on the information by the submitter [33].

Per the FDA, “applicants must compare their device to one or more similar legally marketed devices to support their SE claims. If the device is SE to a predicate, it is placed in the same class. If it is not SE, it becomes non-SE and is placed into Class III” [34]. Only one predicate device is required, when manufacturers would consider comparing substantial equivalence. Identifying a single predicate device to simplify and facilitate the decision-making process is encouraged by the FDA [35]. Pre-clinical data is necessary to validate that the new device performs equivalent to the predicate. This will prove that the device’s safety is equivalent to that of the predicate. Thus, technological characteristics of the new device are authenticated.

There might be some situations where the new device has the same intended use as an existing marketed device, but the new device’s technological characteristics resemble a second marketed device, which has a different intended use. In this case, manufacturers will attempt to adopt the 510-k pathway with a split predicate for the new device to demonstrate substantial equivalence [32]. The split predicate will account for one existing marketed device for the same intended use and another device for same technological aspects.

The above discussion on regulatory pathway depicts the detailed regulatory activities and hurdles to commercialize a Class II medical device. The extent of regulatory hurdles,

which mostly depends on the device classification, must be considered by the innovator to commercialize the device. For example, Class III devices are high-risk devices, which would require the most stringent regulatory approval.

4.5 **Reimbursement Potential**

After receiving approval to market, next stage of the product success depends on good reimbursement potential, which relates to the market adoption of the medical device within medical community, market growth and sales growth [36]. Reimbursement for medical devices is handled by both public and private insurance programs. Innovators will achieve reimbursement faster and more easily if they can utilize existing reimbursement pathways (existing CPT code) for a new technology, rather than pursuing new coding [21].

Coverage, coding and payment are the three most important concepts for reimbursement of a product [36]. These three concepts are briefly discussed below:

4.5.1 Coverage

Coverage refers to the terms and conditions for payment. Coverage will be applicable for new medical procedures and technologies that are not presently defined in the regulatory system [36]. It is also possible that the devices will be covered under existing codes.

4.5.2 Coding

Innovators will achieve reimbursement faster and more easily if they can use existing coding for the invention rather than pursuing a new code [21]. CPT (Current Procedural Terminology) codes are used to define the evaluations and any other medical procedure performed by a healthcare provider on a patient. [37]. CPT codes indicate for what procedures the healthcare provider would be reimbursed from the insurance payer. The coding landscape is different for inpatient and outpatient medical procedures. Coding also differs depending on whether the medical procedure is performed by physician or technician [36]. Hence, a manufacturer must assess the potential coding scenario of the new invention before commercializing it.

4.5.3 Payment

Payment is the remuneration by health insurance plans or government-funded programs, such as CMS (Centers for Medicare & Medicaid Services). In other word, payment describes who is paid, and how much. Medicare payment to hospitals is made under separate payment systems: inpatient and outpatient settings. Inpatient is the case of hospital stay of more than 24 hour and outpatient is the setting where patients are discharged from hospital on the same day [33].

Accomplishing a strong reimbursement landscape is quite challenging for a startup company. The startup or innovator has to ensure that they are adequately paid for providing the technology to end customers. Startups have to prove the economic value of their offerings as well as their clinical benefits [21]. Strong reimbursement strategies with

knowledge of appropriate and strategic coding landscape will then have a positive impact on commercialization.

4.6 **Resource Availability**

Per Boardman and Ponomariov [38], resource availability relates to the extent of resources for the commercialization of the product. The resources include venture capital, suitable consultant or professional personnel, sources of funding, supporting structure, etc. And availability of these resources impacts the technology commercialization process from the initial to final stages. Although funding from industry grants might positively influence the interaction between university and industry, it does not necessarily increase the prospect of university researchers to initiate a company.

The organizational resources and innovative capabilities are important driving forces for new ventures to achieve successful commercialization [39]. Organizational resource is the entity in which the new venture possesses human, tangible, and intangible resources. A well-trained labor force with proper manufacturing knowledge act as an effective catalyst for strong prospect of technology commercialization. Research and marketing for new venture requires adequate financial sources to aid successful commercialization. Strong intellectual property landscape and innovative manufacturing schemes can act as intangible resources, which facilitate new product development and help to maintain a competitive edge in the market [39].

In addition, the combination of proper and skilled resources helps accelerate a TC process. Human or technological resources with manufacturing skills enhance the company's knowledge on advancing commercialization [40]. Here, human resources comprise the expertise and skills of manufacturing personnel of an organization. Unique skills of human resources can offer competitive advantage for a firm. A well-organized and skillful labor force can lead to an innovative environment for an organization. Knowledge of new employees opens a new window of expedited innovative activities, which ultimately triggers speedy technology commercialization. Modern manufacturing technologies facilitate a firm's flexibility to increase its variety of the products, where multiple products can be manufactured at lower cost than a single product. This incremental and innovative product development with appropriate manufacturing skills help to achieve successful technology commercialization of new products [40]. Furthermore, skilled manufacturing personnel help eliminate wastes throughout the product development cycle and enhance the firm's manufacturing capability by adjusting the new product specifications. This ultimately helps expedite the technology commercialization process.

Following are the discussions of the proposed medical device innovations, to which relative weighting of the mentioned technology commercialization factors will be applied.

5 Concepts to be Weighted: Overview of three projects of medical device

5.1 High pressure water jet Craniotome

The high-pressure water jet Craniotome intends to reduce the incidents of dural tear during craniotomy by attaching a fluid discharge nozzle to a dura guard which discharges a high pressure sterile saline solution. The invention includes an elongate leg, a guard, and a fluid discharge channel with a port connected to a craniotome [41] [42].

This device introduces a way to reduce the incidence of dural tear in craniotomies by at least half while not increasing the time it takes to remove the bone flap, as compared to current methods. In approximately 20-30% of craniotomy procedures, there's an occurrence of dural tears. Dural tears increase the risk of a cerebrospinal fluid leak after the craniotomy procedure and increase the procedure time [42].

The proposed tool is a modification of the existing craniotomes. It acts like a dura guard protecting dura from the cranium. It intends to facilitate separation of dura from cranium ahead of the craniotome. Water separation by waterjet dissection has been demonstrated in the literature [43].

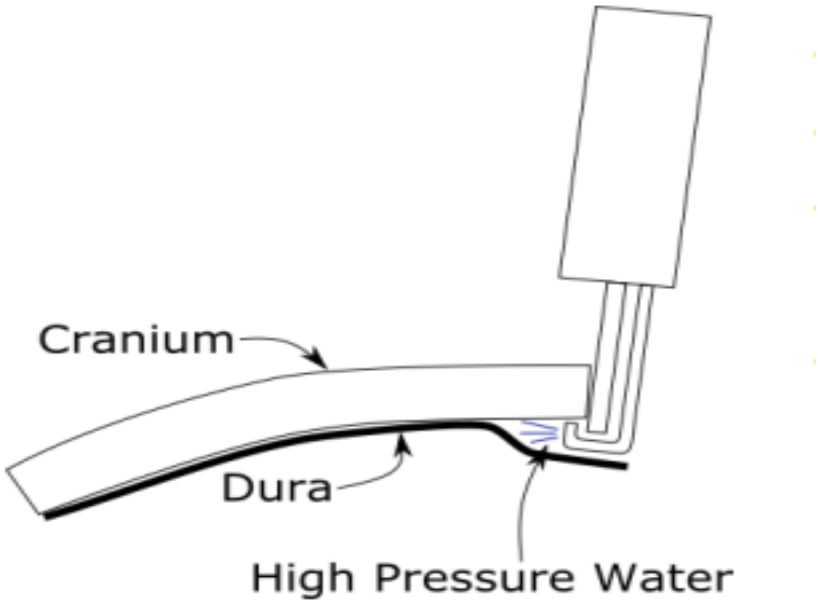


Figure 3: Proposed High pressure water jet Craniotome

F. Barker et al. conducted a study [44] of statistics of brain tumor procedures between 1988 and 2000. In this timeframe, craniotomies were performed at 98% of the 955 hospitals in the study. It was also found that the 100 highest-caseload U.S. hospitals performed about 41% of the total U.S. surgical primary brain tumor caseload in 2000 [44].

The global neurology devices market size was valued at USD 6.2 billion in 2014 [45]. The global market for powered surgical instruments in 2014 is estimated to be around $1.5 to 1.6 billion [46]. During the forecast period of 2014 to 2019 this market is estimated to grow at a moderate CAGR (compound annual growth rate). A CAGR of 9.42% is estimated as a forecast for the global neurosurgery market to grow during the period of 2016 and 2020 [46]. The estimate was delivered after inputs from industry

experts and in-depth market analysis. Key vendors to operate this market are DePuy Synthes, Integra LifeSciences, Medtronic, Stryker, Abbott Laboratories etc. [47].

According to research by Grand View Research, Inc. the global neurology device market is expected to reach USD 10.8 billion by 2022 [48]. Approximately 160,000 craniotomies performed per year in the United States [41]. A Craniotomy drill set costs about $(900-1500) [62].

There are a few challenges for the high-pressure water jet craniotome. Patient outcomes may not change significantly. Target market may be small for this device and more research is desired. There is large number of established competitors for this device.

Opportunities for this proposed device include a clear need from neurosurgeons, possibility of application of this device in other neurological procedures (e.g. laser), and a large number of potential licensing partners. [41].

5.2 **Peripheral lung biopsy**

Lung cancer is one of the leading causes of cancer deaths worldwide [49]. Tasneem Lokhandwala et al. [50] stated that total lung cancer diagnostic cost was $38.3M in a study sample, of which 43.1% was accounted for by biopsied patients without a lung cancer diagnosis. The study was conducted to assess the diagnostic costs leading up to a lung cancer diagnosis in patients in the timeframe from January 1, 2009 to December 31, 2011 [50].

About 234,030 new cases of lung cancer are estimated in the U.S. in 2018. Among them 121,680 are men and 112,350 are women [51]. The estimate is from research of The American Cancer Society.

S. Leong [52] found that in 2013, electromagnetic navigation bronchoscopy (ENB) was used for 3,371 bronchoscopic lung biopsy procedures and endobronchial ultrasound (EBUS) was used for 15,293 of these biopsy procedures. Both EBUS and ENB are bronchoscopic techniques to diagnose lung cancer. The overall diagnostic yield for ENB ranges from 59% to 77.3% [52]. M. Anastasia De Roza et al documented that the diagnostic yield of ENB has been recorded at only 67 to 73% [53]. Another bronchoscopic biopsy tool, transthoracic needle biopsies, is found to have the risk of pnuemothorax between 9 and 54% [54]. These scenarios, of low yield and high risk associated with the existing lung biopsy tools, lead to a promising peripheral lung biopsy tool, which is proposed here.

The proposed tool of peripheral lung biopsy has the potential to reduce the risk of pneumothorax and improve patient comfort. It would perform bronchoscope based peripheral lung biopsy without the need for an ENB (electromagnetic navigation bronchoscopy) system. It has improved capabilities of existing ENB systems [56]. A SuperDimension electromagnetic navigation bronchoscopy (ENB) system costs $193,000 [55].

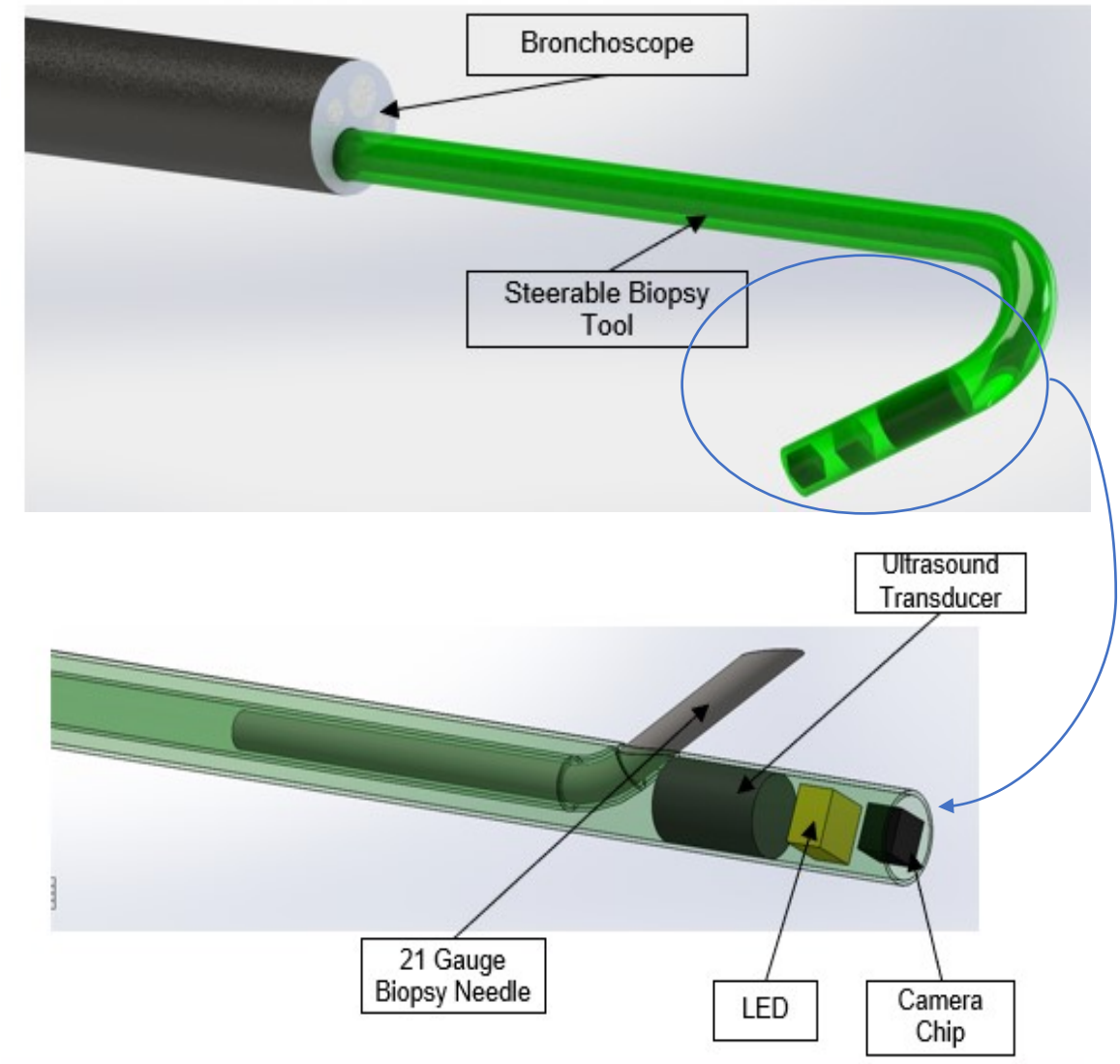


Figure 4: Proposed Peripheral Lung Biopsy Tool

The peripheral lung biopsy tool includes a camera chip, an EBUS (endobronchial ultrasound) sensor, and biopsy capabilities all in one tool. It is sized to be deployed through the 2mm tool port of a traditional bronchoscope. The biopsy tool is steerable. [56]. For estimating the target market for the proposed lung biopsy tool, primarily we consider that this tool would be used in 40% of the lung cancer patients. In 2011, 43.1%

of the lung cancer patients were accounted for lung biopsy [50], that's why we primarily choose to consider 40% of the new lung cancer cases would use the proposed lung biopsy tool. The estimated number of new cases of lung cancer is 234, 030 in 2018 [51]. Therefore, the potential market size for the proposed peripheral lung biopsy tool per year would be approximately 93,600 (i.e. 40% of the 234,030 new cases of lung cancer).

5.3 **GBM TumorID**

In the U.S. there are approximately 700,000 people with a primary brain and central nervous system tumors. About 80,000 new cases of primary brain tumors are likely to be diagnosed in 2018 [58].

According to an estimate of the National Cancer Institute, 22,850 adults were diagnosed with brain and other nervous system cancer in 2015. Among them 12,630 were men and 10,280 were women [59]. The study showed that two to three persons per 100,000 adults per year has GBM (Glioblastoma), and 52% of all primary brain tumors are GBM. Overall, about 17 percent of all brain tumors (including primary and metastatic) are found as GBM [59].

The proposed tool of Glioblastoma (GBM) TumorID is a handheld device, which intends to measure differences in the tissues electrical impedance levels to identify tumor margins for optimal tumor resection. It has demonstrated proof of concept on mice with glioblastoma. Favorable results indicate the ability to distinguish intraoperatively

between tumor tissue and normal brain tissue for maximum resection of brain tumors with minimal damage to normal tissue [57].

Opportunities for this device include ease of use and potential time savings compared to current methodologies. But there are some challenges including low impact on outcomes, low marketability and access, comparatively small market etc. Market size is estimated as 12,760 per year [60]. The global glioblastoma multiforme (GBM) market size is predicted to reach USD 1.15 billion by 2024 [61]. Estimated 10-year NPV for this project is $8,207,000 [57].

Figure 5: Preliminary CAD design of TumorID

The proposed TumorID device could be considered as FDA Class II device (performance standard) as long as it provides only measurements that a physician interprets as part of making a diagnosis. In this scenario, the “measurement only” device could provide the

physician with an impedance measurement (or other measurement), which the physician could then check against published literature.

5.4 SWOT analysis of the projects

A SWOT (Strength, Weakness, Opportunity and Threat) analysis is a strategic planning method. It is carried out to evaluate internal strengths and weaknesses, along with its external opportunities and threats of an organization or a project. It helps identify the objective of the project, in this case, potential aspects of commercialization of medical device innovations.

Based on the literature review and overview of the proposed medical devices of this study, a SWOT analysis was performed. It is displayed in Table 6.

Table 6: SWOT analysis of the proposed medical devices

Name of the proposed medical devices	Strength	Weakness	Opportunity	Threat
High-pressure water jet Craniotome	Comparatively less expensive than the existing modified craniotomes, since it acts as a dura guard	Market for dura guard may be small (more research needed)	Technology may be applied to other neurosurgical applications	Competition in target market segment
			Considerable number of potential licensing partners- Good Patent scope	
	Potential ease in Technology transfer		Resource availability	
	Clear need from neurosurgeons		160,000 craniotomies performed per year in the United States.	
Peripheral lung biopsy	Perform bronchoscope without the need for an ENB system	Low potential venture capital	Improved capabilities of existing ENB systems	Increased adoption of ENB system

Name of the proposed medical devices	Strength	Weakness	Opportunity	Threat
Glioblastoma TumorID	Selective tumor type application	High cost of technology development and possible clinical trials [57]	Low technology complexity	Very small market size- approximately 12,000 per year
		Potential licensing hurdles		

5.5 Proposed Decision Matrix for Heterogenous Technologies

Based on the SWOT analysis and discussion of the proposed tools (see Section 5.1, 5.2 and 5.3), a decision matrix for the mentioned projects is proposed here.

Scoring: Scale range for the proposed decision matrix is considered from 1 to 5.

Potential market size range: 10,000-20,000 = score 1; 20,000-50,000= score 2; 50,000-100,000= score 3; 100,000- 150,000= score 4; over 150,000= score 5.

Technological Feasibility range: prospect of improvement of existing technology (how much invention needed)- 1= poor, 2= fair, 3= good, 4= very good and 5= excellent.

Reimbursement Potential: 1= No code, but more expensive. 2= No code, costs the same, 3= costs the same, there's an existing code, 4= existing code, costs the same, effective, 5 =existing code, more effective than existing, cheaper, better.

Regulatory pathway range: 1 = significant regulatory hurdles (Class III device with a large human trial required for FDA clearance), 3= Moderate regulatory hurdles (Class II device), 5 = minimal regulatory hurdles (Class I device).

Technology transferability/ Licensing range: Strategies for early stage impediments including intellectual property protection: 1= poor, 2= fair, 3= good, 4= very good and 5= excellent.

Resource availability range: Based on venture capital availability and access to finance: 1= poor, 2= fair, 3= good, 4= very good and 5= excellent.

Rationale for selection of score for different decision criteria of the proposed medical devices

Potential market size for high-pressure water jet craniotome, peripheral lung biopsy and glioblastoma tumorID are around 160,000, 93,600, and 12,000 approximately (Section 5.1, 5.2 and 5.3). Therefore, market size for these devices are assigned as 5, 3 and 1 for high-pressure water jet craniotome, peripheral lung biopsy and glioblastoma tumorID respectively.

Prospect of improvement of existing technology is very good for each of the proposed medical devices, since they all are modifications of the existing medical device technologies. Hence, technology feasibility score for the three medical devices are assigned as 4 according to the scoring range.

Both high-pressure water jet craniotome and glioblastoma tumorID have existing codes, which cost the same and effective as the existing code. That's why we assigned the reimbursement potential score of 4 to these devices. Peripheral lung biopsy has existing code, which is more effective than existing, cheaper, better. Hence, according to the scoring range, the reimbursement potential score of 5 is proposed for peripheral lung biopsy.

All three proposed medical device technologies mentioned here are class II device [63]. Innovators would have to face moderate regulatory hurdles for commercializing these devices. The regulatory pathway score for the three devices in this study is 3.

High-pressure water jet craniotome has an excellent scope of licensing with considerable number of potential licensing partners (see section 5.1). That's why we assigned technology transferability score of 5 as per the scoring range of this study. IP scope for peripheral lung biopsy is less than that of the high-pressure water jet craniotome, technology transferability score of 4 is proposed for lung bipsy tool here. Licensing hurdles for glioblastoma tumorID are potentially highest (see the SWOT analysis)

compared to the other two medical devices discussed here and so transferability score of 3 is proposed for the tumorID.

Potential of venture capital availability for high-pressure water jet craniotome is found to be higher than that of the other two devices. The scope of resource availability for glioblastoma tumorID is found to be a little higher than peripheral lung biopsy. Weaker IP for the lung biopsy tool may lead to less investment, because of the complexity of the device. TumorID requires more testing to get to market and potentially would need to raise more capital. Therefore, resource availability score for high-pressure water jet craniotome, peripheral lung biopsy and glioblastoma tumorID are proposed as 5, 3 and 4.

As per above discussion, the decision matrix for the proposed medical devices is shown in Table 7. The values of decision matrix itself do not provide a complete picture of decision criteria. In order to obtain data of relative importance of each deciding factor for technology commercialization, a survey is conducted. The survey results are shown in the next sections.

Table 7: Proposed decision matrix for the proposed medical devices

Decision Criteria	**High-pressure water jet Craniotome**	**Peripheral lung biopsy**	**Glioblastoma TumorID**
Market Size	5	3	1
Technological Feasibility	4	4	4
Reimbursement Potential	4	5	4
Regulatory pathway	3	3	3
Technology transferability/ Licensing	5	4	3
Resource availability	5	3	4
Total Score	26	22	19

In the next section, the calculation is described for overall score of the proposed medical devices, considering the relative weights of the proposed TCFs.

6 Survey Methodology:

A survey was conducted via Qualtrics.com, an online survey tool of the University of Minnesota. A determination was made by the U of M that this study did not constitute human subjects research. The survey intended to weight decision criteria for technology commercialization factors, relative to each other. Now, the survey details along with discussion of the result are presented below.

The survey requests were sent to 42 people involved in medical device industry. 18 people responded to the survey. Therefore, the response rate was recorded as 42.86%.

Screenshots of the survey questions and a sample survey response are attached in the 'Appendix' section.

Following are the proposed decision criteria for commercialization of medical devices:

- Market Size - Potential market size for the projected medical device
- Technological Feasibility- Prospect of improvement of existing technology (how much invention needed)
- Reimbursement Potential- Utilizing existing reimbursement pathways for a new technology, rather than pursuing new coding
- Regulatory pathway- Extent of regulatory hurdles to be faced
- Technology transferability/ Licensing- Strategies for early stage impediments
- Resource availability- Venture capital availability and access to finance

For Question 1, participants were asked to assign weights on each of these factors in terms of importance as decision criteria for commercialization of medical devices on a scale of (1-3). 3= Most important, 2= Important, 1= Least important.

The responses for Question 1 of the survey is shown in Table 8:

Table 8: Percentage of the respondents assigning the relative importance of TC (Summary of results for Question 1 of the survey)

	Relative Importance		
Proposed Technology Commercialization Factors	Most Important	Important	Least Important
	3	**2**	**1**
Market size	55.6%	44.4%	0.00%
Technological Feasibility	72.2%	27.8%	0.00%
Reimbursement Potential	55.6%	44.4%	0.00%
Regulatory Pathway	22.2%	72.2%	5.6%
Technology transferability/ Licensing	22.2%	55.6%	22.2%
Resource availability	22.2%	44.5%	33.3%

The desired proportion for the factor 'market size' was 55.6% as most important (=3) and 44.4% as important (=2) (Results' screenshots are provided in the Appendix section, named as Q11 for market size, Q12 for Technological feasibility and so on). 'Technological feasibility' was marked as most important (=3) by 72.2% participants and important (=2) by 27.8% of the participants. Similarly, 55.6% participants chose the factor 'Reimbursement Potential' as most important (=3) and 44.4% as important (=2). 'Regulatory pathway' was marked as important (=2) by 72.2% participants and most important (=3) by 22.2% of the participants and least- important (=1) by 5.6% participants.

55.6% participants chose the factor ‘Technology transferability/ Licensing’ as important (=2), 22.2% as important (=2), and 22.2% as least- important (=1). The desired proportion for the factor ‘Resource availability’ was 44.5% as important (=2), 33.3% as least- important (=1) and 22.2% as most important (=3)

For Question 2, participants were asked if they have any recommendation to add any Technology Commercialization Factors (TCF) other than the mentioned ones. 55.6% of the participants said ‘Yes’ and they recommended their opinion as directed in Question 3. 44.4% of the participants said ‘No’ to Question 2, which means they agree with the proposed with the Technology Commercialization Factors.

Participants were requested to mention any recommendation to add any TCF in Question 3. Following is the table of the response (original quote of the respondents) of the list of recommendation of additional Technology Commercialization Factors (TCF).

Table 9: List of recommendation of additional technology commercialization factors (TCF)

Respondents	Feedback
1	Clinical unmet need (current solution is poor or with poor outcomes), competitive activity in the space, IP position, knowledge or know how of the people introducing the new technology.
2	Clear path to profitability. Even if you have all the other factors, if it doesn't make business sense it won't be successful. Include clinical utility with technological feasibility. Just because you can build it doesn't mean anyone will want to use it.
3	Patient impact (of the disease/condition on quality of life as well as the ability of the technology to remedy) Potential for cost savings to payors and providers Patent landscape (available whitespace and freedom to operate)
4	Patent landscape & competitors in the market.
5	Strong Intellectual Property, Strong and Diverse Team
6	Competitive position (is there one or more competing products)
7	Amount of capital required to get to the market? Have other technology startups been acquired? If yes, for how many dollars and at what stage i.e. post FIM, FDA approval or after demonstration of reimbursement?
8	Team composition and expertise Freedom to operate and IP protectability
9	Appropriate technical and business staff

Respondents	Feedback
10	Evidence exists to supports a claim that the device delivers better outcomes at a lower cost than existing solutions.

The participants were requested to provide any feedback to the proposed Technology Commercialization Factors list. There were four feedbacks recorded for this question. The quoted response is listed below in Table 10:

Table 10: Feedback to proposed technology commercialization factors list:

Respondents	Feedback
1	I see you wanted to rank the top technology commercialization factors, however this is probably not how people would look at it, rather they would look at each factor on a pass/fail basis. i.e. you need to have all these factors as considerations and they all need to be feasible or "green lights". You can have "yellow lights" that you still need to develop or work out the strategy, but any one factor that is "red" would likely kill the project if it is truly a "red light". For example, if the market is too small, or the reimbursement is lower than cost of technology to solve it, or regulatory pathway is $$$ in clinical studies and years to marketability with a small market potential etc... none of the factors outweigh the others, as you need them all to at least be reasonable.
2	More just a comment, that how I think about these issues is less of a

Respondents	Feedback
	weighted factor and more of a threshold. E.g. is the market 100 million or more? Can it be built? Can you get paid for it? Can it be FDA approved? If yes to all then proceed. If not, then find a new project. The trick is that you won't get all the needed information to say Yes to each one at the same time, so you will need to iterate and investigate each one. Usually, I look to see what the market potential is first because that is fairly easy. If it is more than $100 million it might be worth it. Then do a quick assessment if the technology is feasible. Then check the regulatory and reimbursement pathways because those depend on the technology. Finally, how much will it take to get it to market. Usually, along the way the idea will change e.g. an idea for a different tech that is actually a different market, so the process will start again.
3	In my opinion, technology transferability (potential ability to license as I'm understanding it) is the combined result of the other factors.
4	The level of importance is difficult to ascribe to each of these factors, since any one could potentially lead to failure of commercialization efforts.

Finally, participants were asked to mention their roles in medical device industry in Question 5. The result is shown below in Table 11:

Table 11: Roles of the respondents in medical device industries

Roles in medical device industries	Engineering	Management	Academic researcher	Investor
Percentage of respondents	36.8%	29%	26.3%	7.9%

Respondents chose more than one roles in medical device industries if applicable. 36.8% participants indicated that they are in Engineering role, whereas 29%, 26.3% and 7.9% of the participants mentioned that they are in Management, Academic Researcher and Investor roles in medical device industries.

7 Discussion of Results

7.1 Data Analysis

This section presents all data analysis and calculation of the relative weightings of the proposed technology commercialization factors (TCF). At first, the assigned relative importance to the TCFs from the response of the survey is tabulated and analyzed. The distribution of the relative importance is also analyzed for statistical analysis later. The calculation for weighted scoring is also demonstrated in this data analysis section.

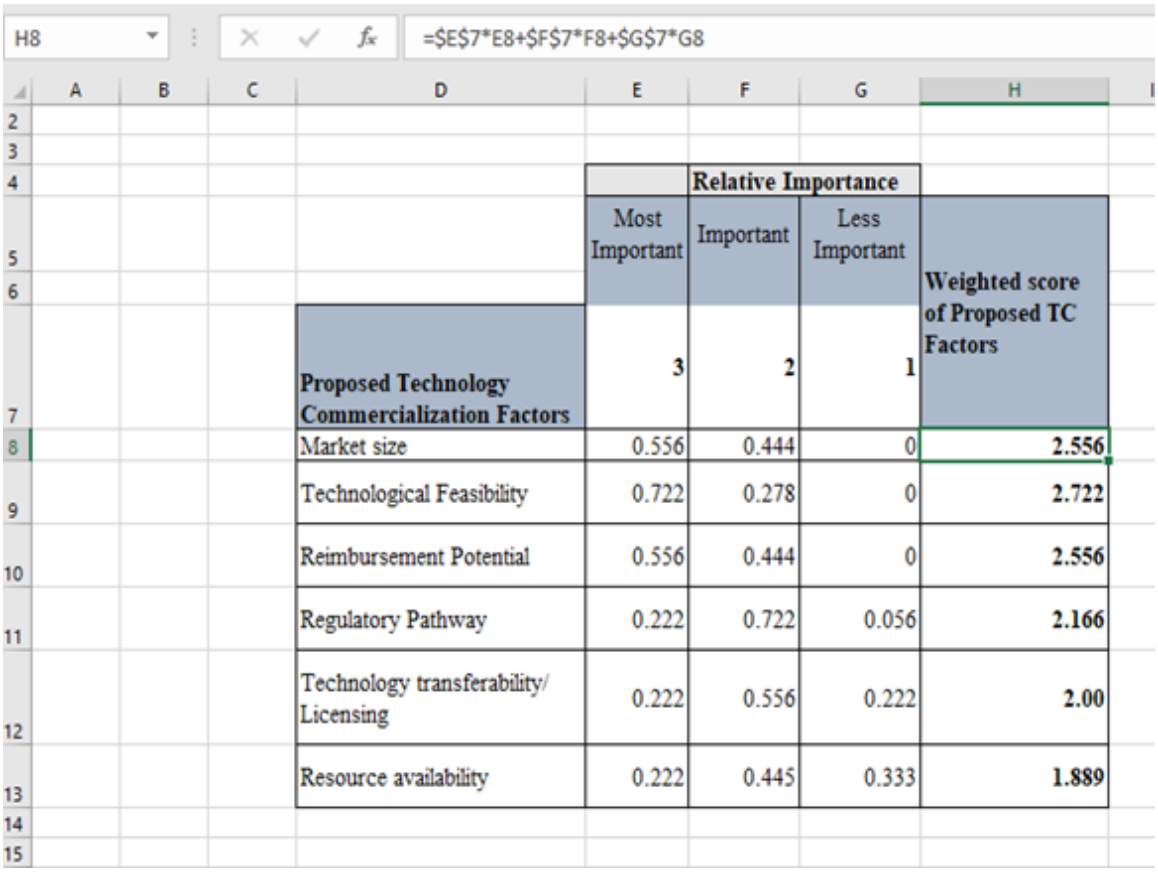
Based on the survey result, relative weighting of the proposed technology commercialization factors (TCF) is calculated. For ease of calculation, the percentage values (of Table 8) are converted into decimal values here. For example, 55.6% is converted to 0.556 (in Table 12). The calculation is shown below in Table 12:

Table 12: Relative weighting of the proposed technology commercialization factors

	Relative Importance			
Proposed Technology Commercialization Factors	Most Important	Important	Least Important	**Weighted score of Proposed TC Factors**
	3	**2**	**1**	
Market size	0.556	0.444	0	2.556
Technological Feasibility	0.722	0.278	0	2.722
Reimbursement Potential	0.556	0.444	0	2.556
Regulatory Pathway	0.222	0.722	0.056	2.166
Technology transferability/ Licensing	0.222	0.556	0.222	2.00
Resource availability	0.222	0.445	0.333	1.889

Figure 6 outlines the calculation of relative weighting of the proposed TC factors.

The statistical importance of the TC factors is discussed in the 'Statistical analysis' section to identify the statistical significance between the weightings.



	Relative Importance			
	Most Important	Important	Less Important	
Proposed Technology Commercialization Factors	**3**	**2**	**1**	**Weighted score of Proposed TC Factors**
Market size	0.556	0.444	0	**2.556**
Technological Feasibility	0.722	0.278	0	**2.722**
Reimbursement Potential	0.556	0.444	0	**2.556**
Regulatory Pathway	0.222	0.722	0.056	**2.166**
Technology transferability/ Licensing	0.222	0.556	0.222	**2.00**
Resource availability	0.222	0.445	0.333	**1.889**

Figure 6: Calculation of relative weighting of the proposed technology commercialization factors

Key formula for weighted score of an individual TC factor is SUMPRODUCT of the Percentage of response (from the survey) for that factor and Relative importance value. For example, Technological feasibility was marked as most important (=3) by 72.2% participants and important (=2) by 27.8% of the participants. So, the weighted score for Technological feasibility is (0.722*3+0.278*2+0*1) = 2.722.

Following is the depiction of distribution of relative importance of the TC factors in a bar chart:

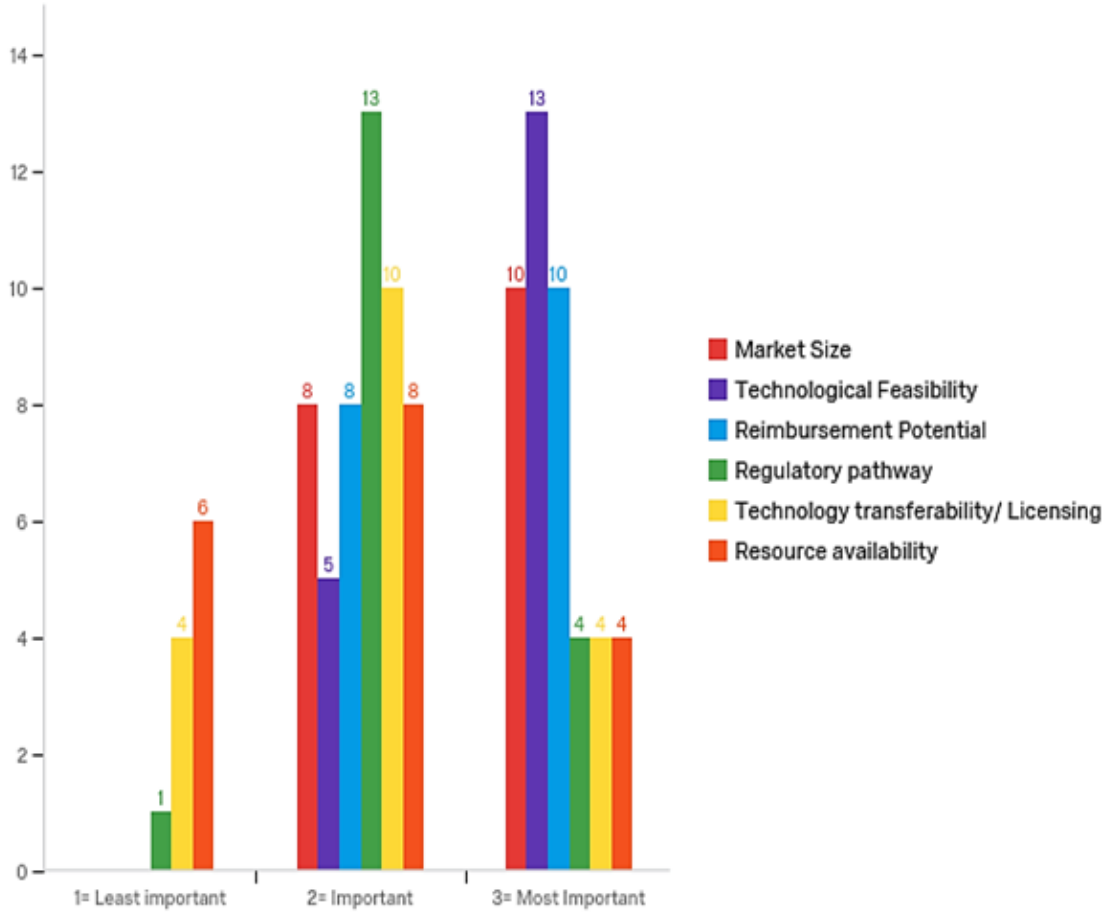


Figure 7: Distribution of relative importance of TC factors

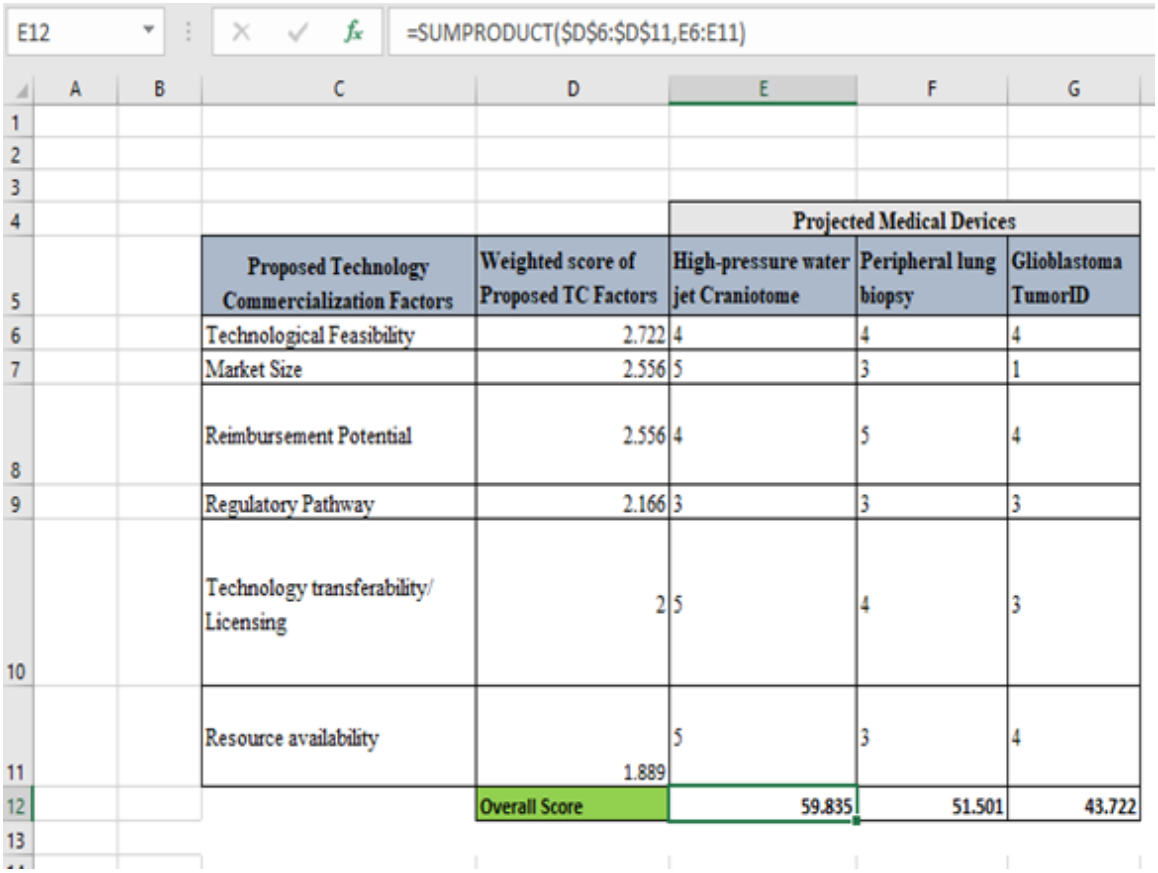
X-axis and Y-axis stand for the relative importance of the factors and the number of participants assigning that relative importance on each TC factor respectively.

Now, calculated values of the proposed TC factors weights from Table 12 are applied to the proposed medical devices of this study. Here, data from decision matrix (See Section 5.5) is used as well. Table 13 below shows the detailed results:

Table 13: Calculation of overall score of proposed technology commercialization factors of proposed medical devices

		Proposed Medical Devices		
Proposed Technology Commercialization Factors	**Weighted score of Proposed TC Factors**	**High-pressure water jet Craniotome**	**Peripheral lung biopsy**	**Glioblastoma TumorID**
Technological Feasibility	2.722	4	4	4
Market size	2.556	5	3	1
Reimbursement Potential	2.556	4	5	4
Regulatory Pathway	2.166	3	3	3
Technology transferability/ Licensing	2	5	4	3
Resource availability	1.889	5	3	4
	Overall Score	**59.835**	**51.501**	**43.722**

Figure 8 outlines the calculation for overall score of proposed technology commercialization factors of the proposed medical devices.



				Projected Medical Devices		
	Proposed Technology Commercialization Factors	Weighted score of Proposed TC Factors	High-pressure water jet Craniotome	Peripheral lung biopsy	Glioblastoma TumorID
6	Technological Feasibility	2.722	4	4	4
7	Market Size	2.556	5	3	1
8	Reimbursement Potential	2.556	4	5	4
9	Regulatory Pathway	2.166	3	3	3
10	Technology transferability/ Licensing	2	5	4	3
11	Resource availability	1.889	5	3	4
12		Overall Score	59.835	51.501	43.722

Figure 8: Calculation of overall score of proposed technology commercialization factors of proposed medical devices

Key formula for overall score of an individual medical device is SUMPRODUCT of the calculated weighted score of the proposed TC factor for that medical device and Decision Matrix Score of that device taken from Table 7. For example, overall score for High-

pressure water jet Craniotome is: (2.556*5+ 2.722*4+2.556*4+ 2.166*3+2*5+1.889*5) = 59.835. Hence, overall scores of the proposed technology commercialization factors of proposed medical devices in Table 14:

Table 14: Overall scores of the proposed TCF of proposed medical devices

Proposed medical devices	High-pressure water jet craniotome	Peripheral lung biopsy	Glioblastoma TumorID
Overall TCF score	**59.835**	**51.501**	**43.722**

The high-pressure water jet craniotome, having highest overall score among the three medical device innovations, shows most promising aspect to commercialize, considering the proposed technology commercialization (TC) factors here. The statistical significance of relative weightings of TC factors is described in the next section.

7.2 **Statistical analysis**

Table 12 and Figure 6 showed the calculation of the weights for the proposed TC Factors. Now, to determine if there is a statistical difference between the weightings, a statistical analysis is represented here.

Following is the table of the outline of the statistical analysis:

Table 15: Outline of the statistical analysis

Statistical analysis tool	Minitab
Sample size	18
Analysis method	one-way ANOVA analysis (Welch's method)
Obtained p-value	<0.001 (robust evidence against the null hypothesis when $p \leq 0.05$) (See Figure 9)
Summary of result	There is a statistical difference between the mean ranking of the TCF values

The participants of the survey assigned relative importance to each proposed TC factor. There were 18 participants who responded to the survey questions related to weighting the TC factors. Table 16 below shows the survey data used for the identification of statistical significance of the TC factors. The screenshot this data utilized in Minitab is included in the 'Appendix' section as well. For a graphical portrayal of break-down of the assigned relative importance to each factor, see Figure 7.

Table 16: Survey data for statistical analysis

	Importance of the individual TC factor assigned by the participants					
Participants	**Market size**	**Technological Feasibility**	**Reimbursement Potential**	**Regulatory Pathway**	**Technology transferability/ Licensing**	**Resource availability**
1	3	3	2	2	2	2
2	3	3	2	2	3	2
3	3	3	3	3	2	3
4	3	2	2	2	1	2
5	2	3	3	3	2	3
6	2	3	3	2	2	1
7	3	3	2	3	2	2
8	3	3	2	2	2	1
9	2	3	2	2	2	3
10	2	3	2	3	1	1
11	2	2	3	2	2	1
12	2	3	2	2	3	3
13	2	2	3	2	3	1
14	2	2	3	2	1	1
15	3	2	3	1	1	2
16	3	3	3	2	2	2
17	3	3	3	2	2	2
18	3	3	3	2	3	2

Figures 9, 10, 11 and 12 show one-way ANOVA (Analysis of Variance) analysis Summary Report, Diagnostic report, Power report and Report card respectively.

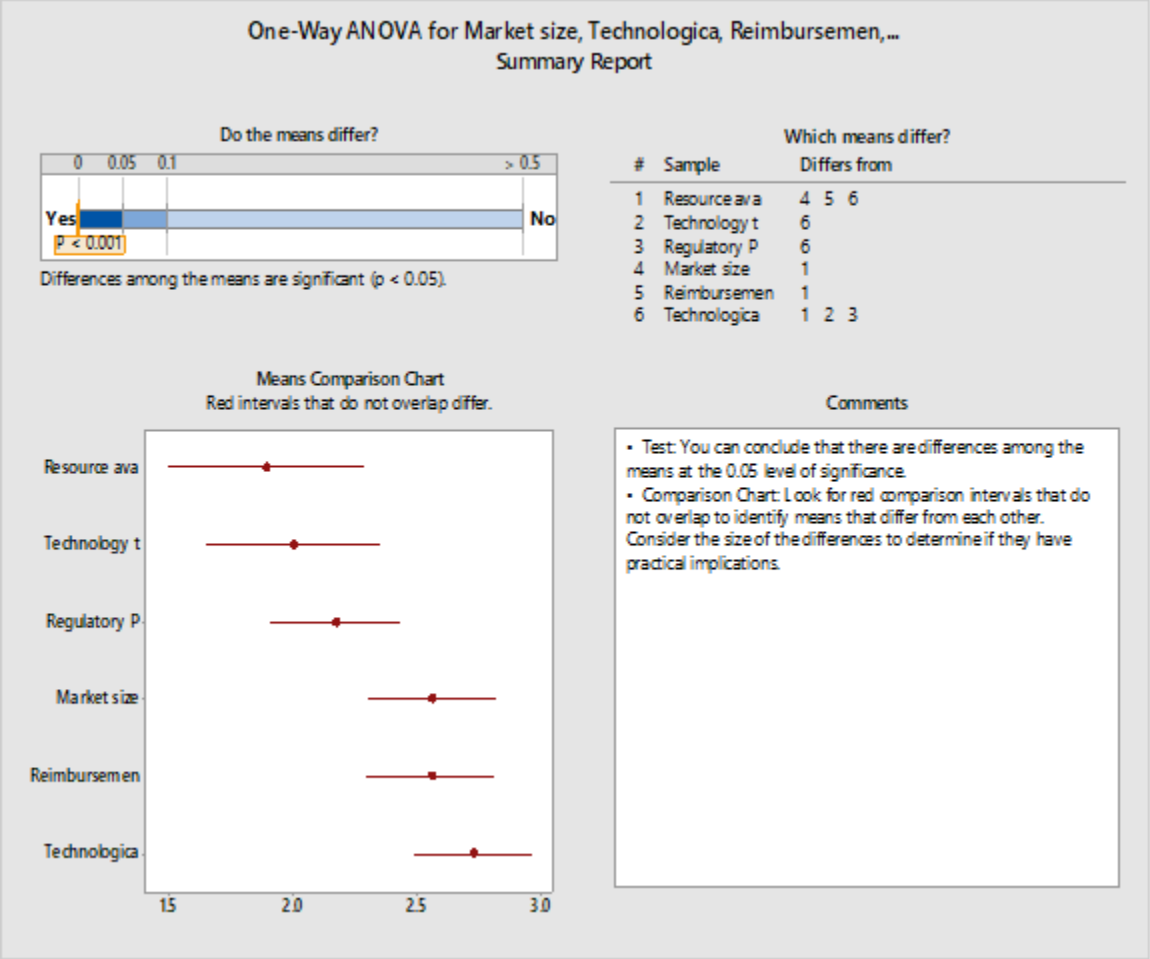


Figure 9: One-way ANOVA analysis Summary Report

A Summary Report of one-way ANOVA analysis of the survey response, which was carried out in Minitab, is shown on Figure 9. A null hypothesis is a hypothesis that intends to prove that there is no statistical significance between the variables in the given hypothesis. The researcher tries to invalidate the null hypothesis [64].

The alternative hypothesis is the one the researcher would believe if the null hypothesis is concluded to be untrue. All hypothesis tests ultimately use a p-value to weigh the strength

of the evidence. A p-value helps determine the significance of the results. A p-value of ≤ 0.01 indicates very strong indication against null hypothesis. A p-value of ≤ 0.05 indicates convincing evidence against the null hypothesis, so the null hypothesis is rejected. A large p-value (> 0.05) indicates weak evidence against the null hypothesis, then it fails to reject the null hypothesis [65]. The relationship between p-value and conclusive result of null hypothesis is summarized in Table 17:

Table 17: Relationship between p-value and conclusive result of null hypothesis

p-value	Decision on Null hypothesis
p≤ 0.01	very strong evidence against null hypothesis: Reject null hypothesis
p≤ 0.05	strong presumption against null hypothesis: Reject null hypothesis
p> 0.05	weak evidence against the null hypothesis: Failure to reject null hypothesis

Here in this study, the null hypothesis was to prove that that there is no statistical significance between the TC factors. The p-value is then calculated as <0.001 from Minitab one-way ANOVA analysis, which is less than 0.05. Therefore, the null hypothesis is rejected since differences among the means are significant, and so, there is a statistical difference between the mean raking of the TC factor values. In other words, there are differences among the means at the 0.05 level of significance.

From the 'Means comparison chart' of the summary report, the red intervals do not overlap, which identifies that the means differ from each other.

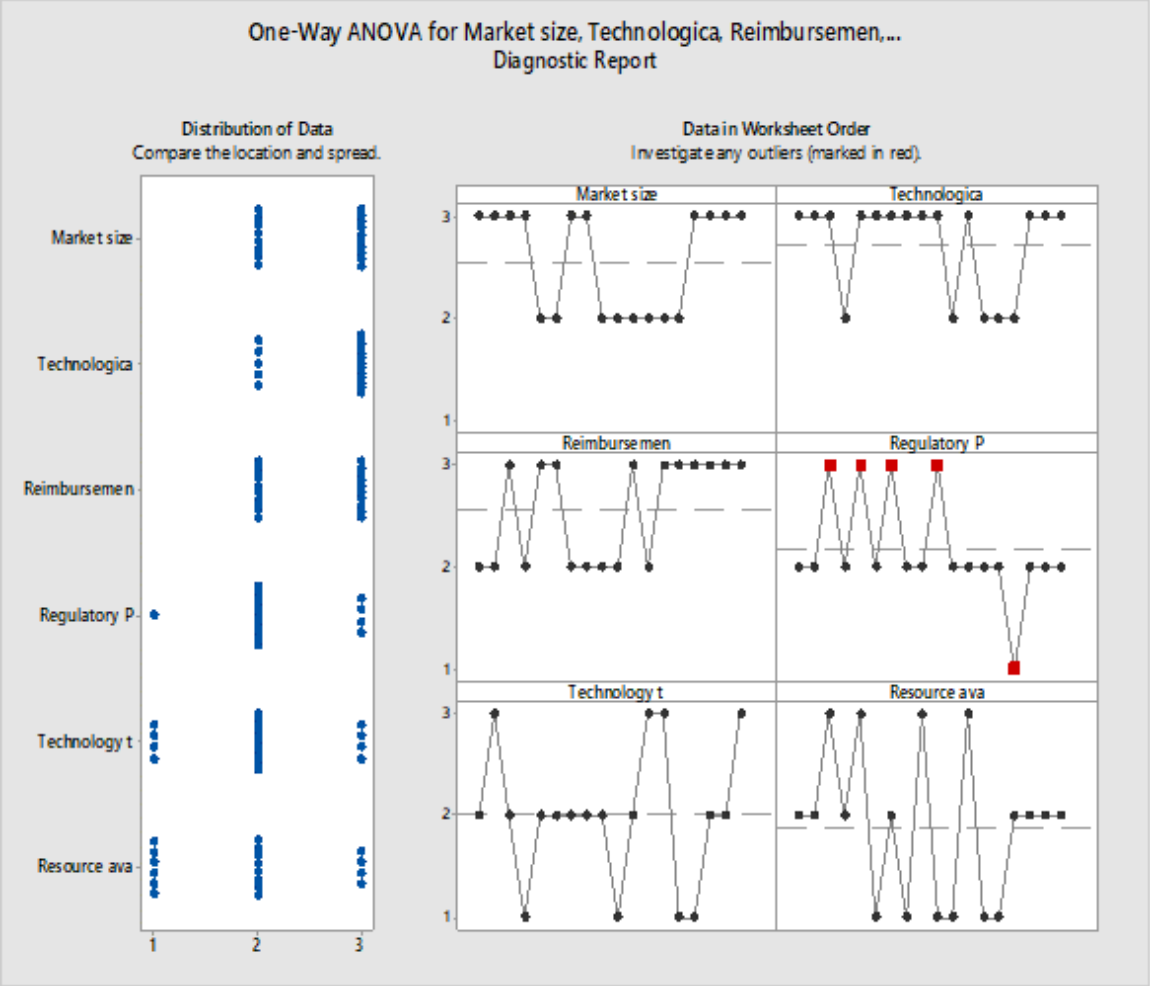


Figure 10: One-way ANOVA analysis Diagnostic Report

Diagnostic Report helps to explore the chance of detecting a significant difference. The power report of one-way ANOVA analysis shows this result in detail. Here, distribution of data for TC factors is shown in the diagnostic report.

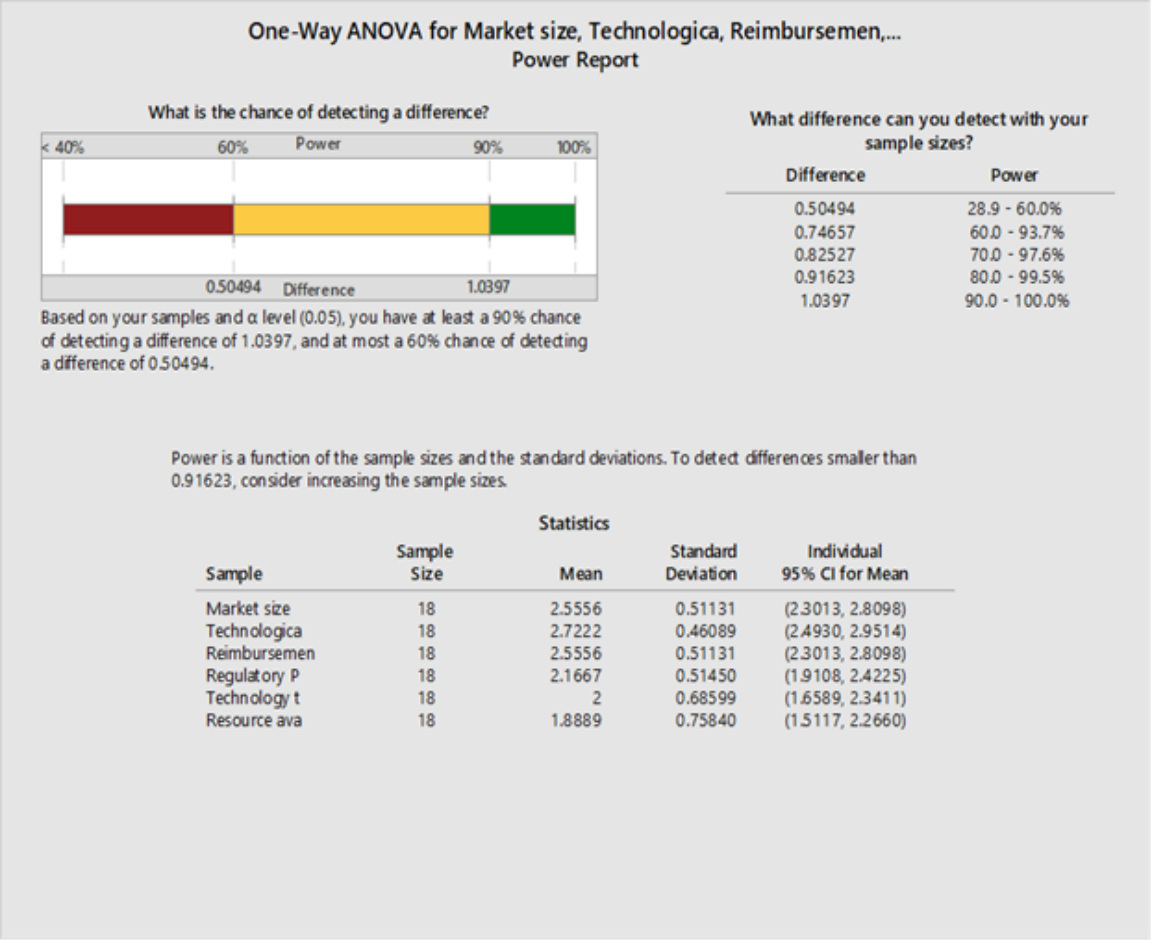


Figure 11: One-way ANOVA analysis Power Report

Power is a function of sample sizes and standard deviations. Based on the Power report and Report card, it is proven that that the sample size was sufficient to detect the difference among the means with high confidence.

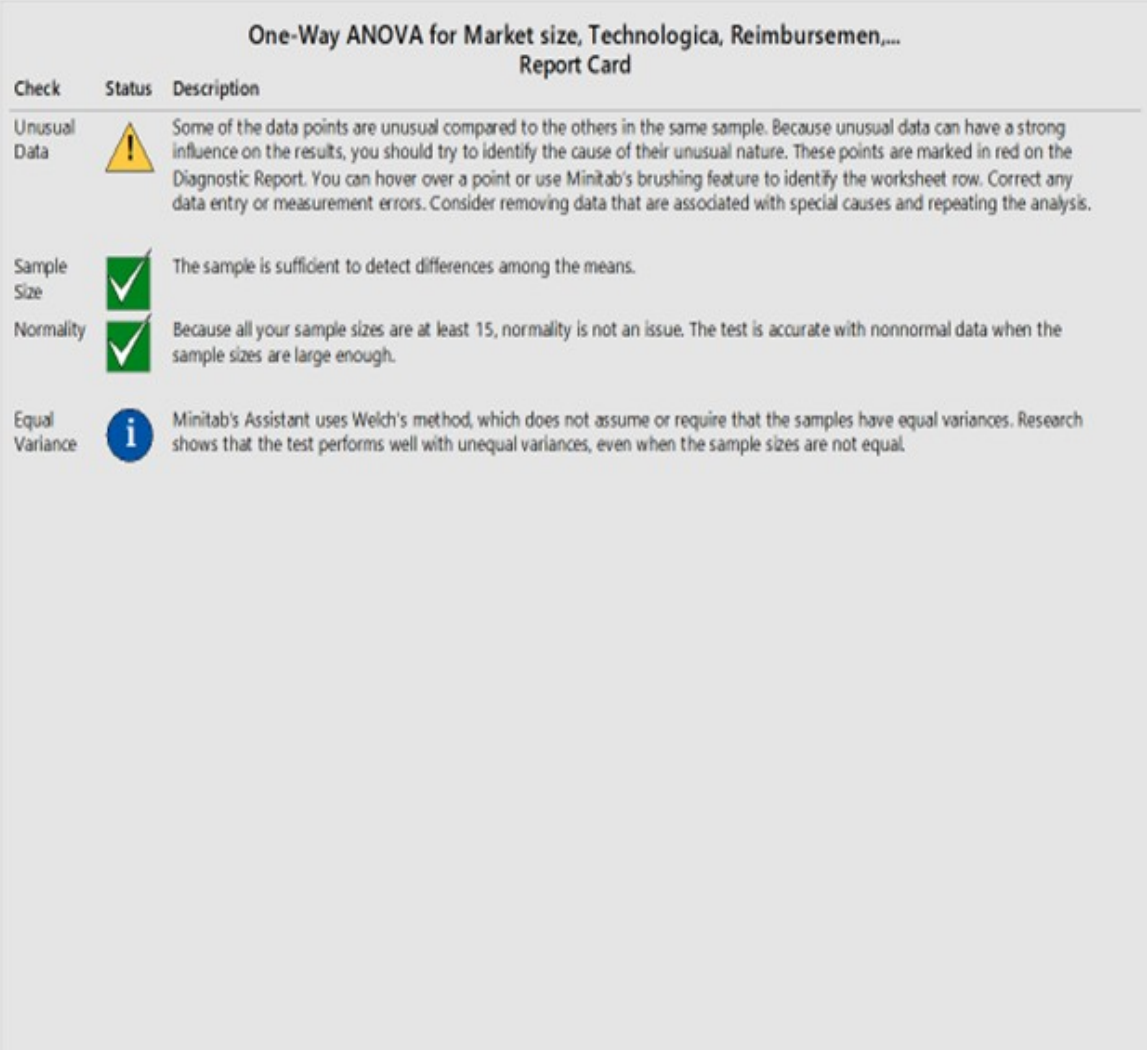


Figure 12: One-way ANOVA analysis Report card

7.3 **Discussion**

The list of recommendation of additional Technology Commercialization Factors enlightens few new TCFs to be considered. For example, team composition could be a possible commercialization factor to add, since there were recommendations as ‘Strong and Diverse Team’, ‘Team composition’, ‘Appropriate technical and business staff’.

The factor ‘Team Composition’ relates to the size and the background of the teams working on projects which ultimately impacts technology commercialization process. Here, the background refers to previous experience, whether it might be entrepreneurial skill or industrial exposure. Technology focus and proper marketing skills also play significant role in building the background of the teams.

The composition of startup founding teams has been studied in different business environments. Eesley et al. [66] suggested that the founding teams should be diverse in competitive commercialization spheres. When followed by an innovation strategy in a cooperative environment, technically focused teams perform better [66].

Per Roure and Keeley [67], the success of an innovative commercialization depends on a complete founding team. Cross-functional collaborations of the team helps improving TC performance. In addition, Eisenhardt and Schoonhoven [68] proposed that the success of a new company may contingent on prior experience of the appropriate technical and business staff. Team members with diverse industry experience positively affect growth rates of the startup companies [67] [68].

Diversity in team members introduces a knowledge-creating entity, which would benefit the build-up process of new companies. To commercialize a new product or service, starting from university-based research, the involvement of the university researchers is crucial. Per Jensen and Thursby [69] the academic staff, who developed the new technology, needs to be involved in the further development of the new technologies

towards a successful commercialization. According to O'Shea et al and Powers and McDougall [70] [71], higher rates of spin-off success are accompanied with faculty leads with integrity and technical aspects. Ambos et al. [72] suggested that a higher involvement in TC activities has also led to more spin-offs.

O'Shea et al. [68] also emphasized the quality of the academic staff over the quantity for the spinning-off of companies. Rasmussen and Borch [73] recommended that university spin-offs be highly associated with students and academics, who have good industrial exposure and entrepreneurial interest. Especially appropriate are academic staff who would substantially support the technology commercialization with their market-insights and target market forecasts based on the customers' point of views [73]. Therefore, proper team composition with well-organized and diverse team-members can lead to successful spin-offs and commercialization.

Another recommended TCF, which can be mentioned here, was Intellectual Property/ Patent landscape. Respondents used the terms as 'IP position', 'Freedom to operate', 'Patent landscape', 'Strong Intellectual Property', 'IP protectability'. But, the proposed TCF list enlisted the factor of 'Technology transferability/ Licensing' which encompasses intellectual property/ patentability and freedom to operate. It is possible that the initial information presented in the survey questions provided a very brief information about what the factors really stood for. However, from the feedback of the participants of the survey, patent landscape is noted to be an important factor for technology commercialization.

7.4 Limitation of the study and future work

The survey results might have been different if the number of the participants would be even larger as the variation in the result could have been smaller or larger in that case. It is recommended that the addition of other technology commercialization factors to the proposed factors in this paper could result in new weighted scoring for those additional factors. The future work includes performing the survey in longer timeframe to get responses from more participants.

The future work also includes the implementation of the research methodology of this study in case of deciding a new technology to commercialize. The methodology of this study shows quantified result which proves that the decision-making approach, for choosing one technology over another, works. Therefore, a pilot project is recommended to show the application of the research methodology of this study. The result of the pilot project will bolster the validity of the decision made by the proposed approach to achieve successful commercialization.

8 Conclusion

This study provided a comprehensive picture of decision criteria for technology commercialization factors (TCF) of three heterogeneous medical devices: high pressure water jet craniotome, peripheral lung biopsy, and glioblastoma TumorID. After analyzing the SWOT analysis and literature review, initial scores were assigned to the proposed

technology commercialization factors from a decision matrix. A survey was held to weight the decision criteria for technology commercialization. It was recorded that participants assigned the most importance on Technological Feasibility (weighted score of 2.722). The second most important factors were found as Market Size and Reimbursement Potential (weighted score of 2.556). Statistical analysis of the TC factors proved that the there is a significant statistical difference between the mean raking of the TC factor values.

Additional TCF, recommended as Team Composition and Patent Landscape, were reflected from the feedback. Therefore, further research with these additional TCFs is highly recommended for future study. Since, the weighted scores were only recorded from the current proposed TCF list, the overall score for decision criteria for the technology commercialization factors (TCF) of the three medical devices have been calculated accordingly. Finally, high pressure water jet craniotome shows most promising aspect for technology commercialization based on this study. The overall score for the technology commercialization of the peripheral lung biopsy tool was recorded as 51.501, whereas high pressure water jet craniotome scored 59.835 and glioblastoma TumorID scored 43.722. Therefore, weighting of TC factors helps decision-making for the innovator/startup firm, or in this case, university technology transfer efforts.

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Appendix: Survey Questionnaire

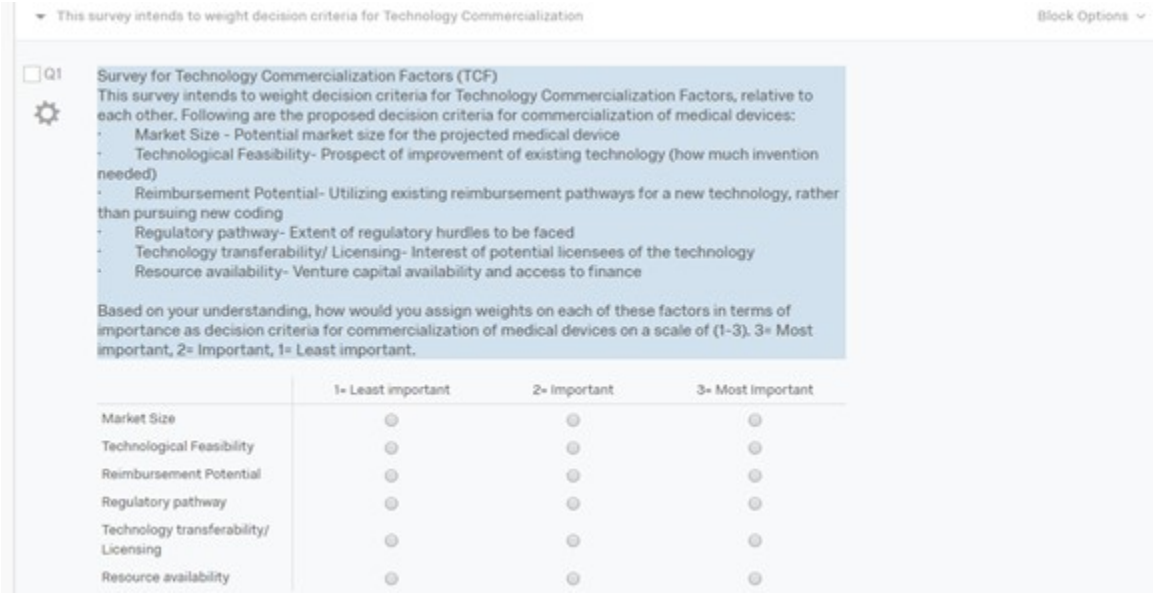


Figure 1: Survey Questionnaire, page 1

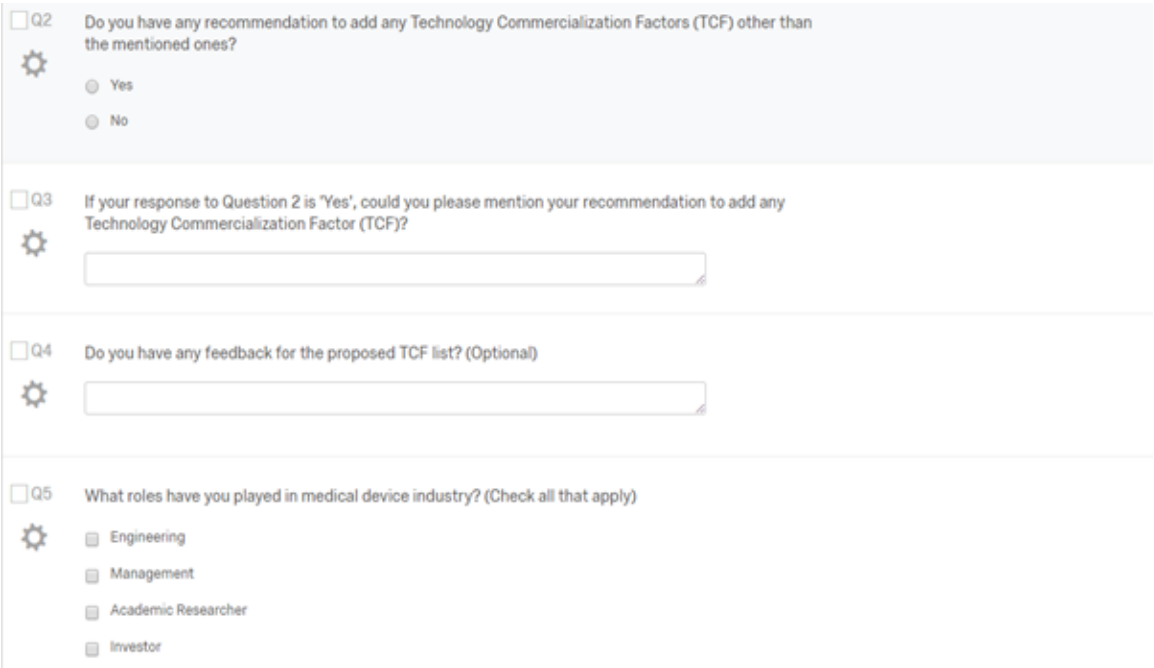
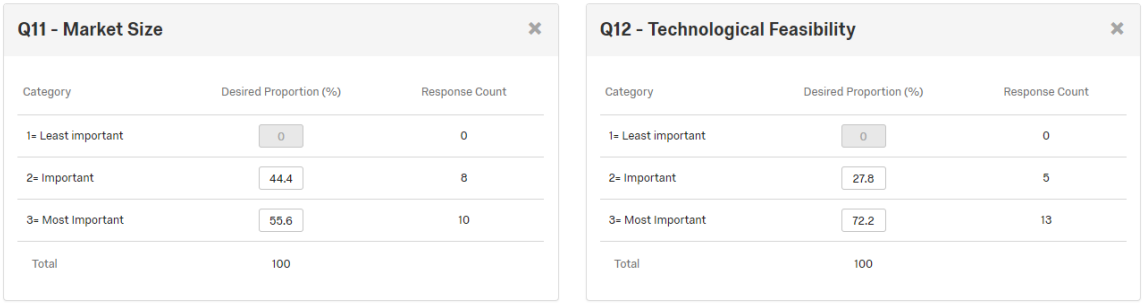


Figure 2: Survey Questionnaire, page 2



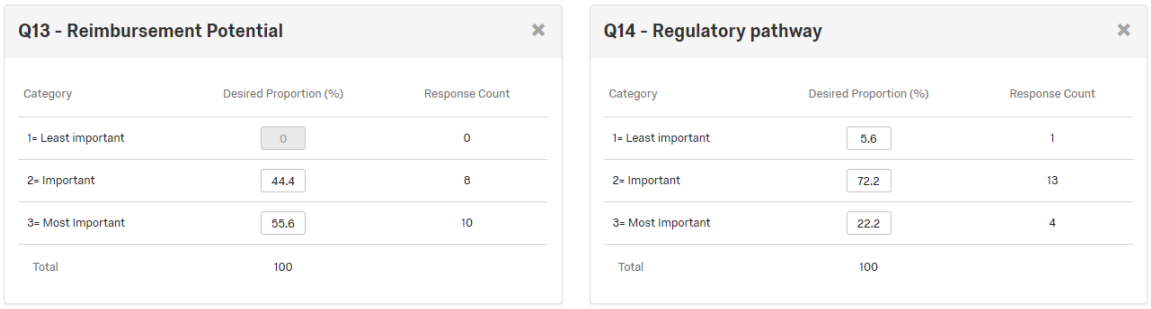
Q11 - Market Size

Category	Desired Proportion (%)	Response Count
1= Least important	0	0
2= Important	44.4	8
3= Most Important	55.6	10
Total	100	

Q12 - Technological Feasibility

Category	Desired Proportion (%)	Response Count
1= Least important	0	0
2= Important	27.8	5
3= Most Important	72.2	13
Total	100	

Figure 3: Survey Question 01- Choices 1 and 2



Q13 - Reimbursement Potential

Category	Desired Proportion (%)	Response Count
1= Least important	0	0
2= Important	44.4	8
3= Most Important	55.6	10
Total	100	

Q14 - Regulatory pathway

Category	Desired Proportion (%)	Response Count
1= Least important	5.6	1
2= Important	72.2	13
3= Most Important	22.2	4
Total	100	

Figure 4: Survey Question 01- Choices 3 and 4

Q15 - Technology transferability Licensing

Category	Desired Proportion (%)	Response Count
1= Least important	22.2	4
2= Important	55.6	10
3= Most Important	22.2	4
Total	100	

Q16 - Resource availability

Category	Desired Proportion (%)	Response Count
1= Least important	33.3	6
2= Important	44.5	8
3= Most Important	22.2	4
Total	100	

Figure 5: Survey Question 01- Choices 5 and 6

Q2 - Do you have any recommendation to add any Technology Commercialization Factors TCF other tha...

Category	Desired Proportion (%)	Response Count
Yes	55.6	10
No	44.4	8
Total	100	

Figure 6: Survey Question 02- Response count

If your response to Question 2 is 'Yes', could you please mention your recommendation to add any Technology Commercialization Factor (TCF)?	Q3 - Topics
clinical unmet need (current solution is poor or with poor outcomes), competitive activity in the space, IP position, knowledge or know how of the people introducing the new technology.	
Clear path to profitability. Even if you have all the other factors, if it doesn't make business sense it won't be successful. Include clinical utility with technological feasibility. Just because you can build it doesn't mean anyone will want to use it.	
Patient impact (of the disease/condition on quality of life as well as the ability of the technology to remedy) Potential for cost savings to payors and providers Patent landscape (available whitespace and freedom to operate)	
Patent landscape & competitors in the market.	
Strong Intellectual Property Strong and Diverse Team	
Competitive position (is there one or more competing products)	
Amount of capital required to get to the market? Have other technology startups been acquired? If yes, for how many dollars and at what stage i.e. post FIM, FDA approval or after demonstration of reimbursement?	
Team composition and expertise Freedom to operate and IP protectability	
Appropriate technical and business staff	
Evidence exists to supports a claim that the device delivers better outcomes at a lower cost than existing solutions.	

Figure 7: Survey Question 03- Responses

Do you have any feedback for the proposed TCF list? (Optional)	Q4 - Topics
I see you wanted to rank the top technology commercialization factors, however this is probably not how people would look at it, rather they would look at each factor on a pass/fail basis. i.e. you need to have all these factors as considerations and they all need to be feasible or "green lights". You can have "yellow lights" that you still need to develop or work out the strategy, but any one factor that is "red" would likely kill the project if it is truly a "red light". For example if the market is too small, or the reimbursement is lower than cost of technology to solve it, or reg pathway is $$$ in clinical studies and years to marketability with a small market potential etc... none of the factors outweigh the others, as you need them all to at least be reasonable.	+
More just a comment, that how I think about these issues is less of a weighted factor and more of a threshold. E.g. is the market 100 million or more? Can it be built? Can you get paid for it? Can it be FDA approved? If yes to all then proceed. If not then find a new project. The trick is that you won't get all the needed information to say Yes to each one at the same time, so you will need to iterate and investigate each one. Usually, I look to see what the market potential is first because that is fairly easy. If it is more than $100 million it might be worth it. Then do a quick assessment if the technology is feasible. Then check the regulatory and reimbursement pathways because those depend on the technology. Finally, how much will it take to get it to market. Usually, along the way the idea will change e.g. an idea for a different tech that is actually a different market, so the process will start again.	+
In my opinion, technology transferability (potential ability to license as I'm understanding it) is the combined result of the other factors.	+
The level of importance is difficult to ascribe to each of these factors, since any one could potentially lead to failure of commercialization efforts.	+
Completed survey a second time	+

Figure 8: Survey Question 04- Responses

Q5 - What roles have you played in medical device industry? Check all that apply

Category	Desired Proportion (%)	Response Count
Engineering	36.8	14
Management	29	11
Academic Researcher	26.3	10
Investor	7.9	3
Total	100	

Figure 9: Survey Question 05- Response count

Q1.
Survey for Technology Commercialization Factors (TCF)
This survey intends to weight decision criteria for Technology Commercialization Factors, relative to each other. Following are the proposed decision criteria for commercialization of medical devices:

- Market Size - Potential market size for the projected medical device
- Technological Feasibility- Prospect of improvement of existing technology (how much invention needed)
- Reimbursement Potential- Utilizing existing reimbursement pathways for a new technology, rather than pursuing new coding
- Regulatory pathway- Extent of regulatory hurdles to be faced
- Technology transferability/ Licensing- Interest of potential licensees of the technology
- Resource availability- Venture capital availability and access to finance

Based on your understanding, how would you assign weights on each of these factors in terms of importance as decision criteria for commercialization of medical devices on a scale of (1-3). 3= Most important, 2= Important, 1= Least important.

	1= Least important	2= Important	3= Most Important
Market Size	○	○	◉
Technological Feasibility	○	○	◉
Reimbursement Potential	○	○	◉
Regulatory pathway	○	○	◉
Technology transferability/ Licensing	○	◉	○
Resource availability	○	○	◉

Q2. Do you have any recommendation to add any Technology Commercialization Factors (TCF) other than the mentioned ones?

◉ Yes
○ No

Q3. If your response to Question 2 is 'Yes', could you please mention your recommendation to add any Technology Commercialization Factor (TCF)?

clinical unmet need (current solution is poor or with poor outcomes), competitive activity in the space, IP position, knowledge or know how of the people introducing the new technology.

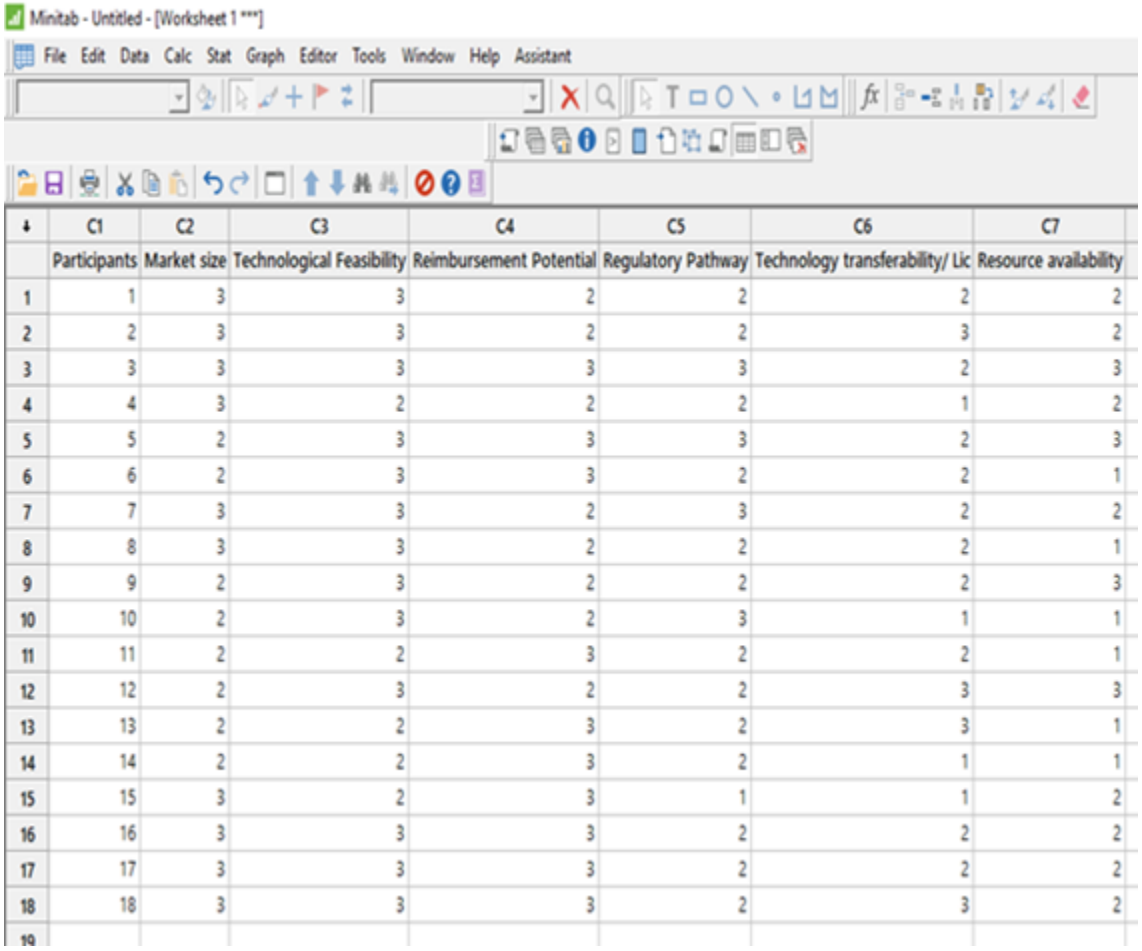
Q4.
Do you have any feedback for the proposed TCF list? (Optional)

I see you wanted to rank the top technology commercialization factors, however this is probably not how people would look at it, rather they would look at each factor on a pass/fail basis. i.e. you need to have all these factors as considerations and they all need to be feasible or "green lights". You can have "yellow lights" that you still need to develop or work out the strategy, but any one factor that is "red" would likely kill the project if it is truly a "red light". For example if the market is too small, or the reimbursement is lower than cost of technology to solve it, or reg pathway is $$$ in clinical studies and years to marketability with a small market potential etc... none of the factors outweigh the others, as you need them all to at least be reasonable.

Q5.
What roles have you played in medical device industry? (Check all that apply)

☑ Engineering
☑ Management
☑ Academic Researcher
☐ Investor

Figure 10: Sample response of the Survey



	C1	C2	C3	C4	C5	C6	C7
	Participants	Market size	Technological Feasibility	Reimbursement Potential	Regulatory Pathway	Technology transferability/ Lic	Resource availability
1	1	3	3	2	2	2	2
2	2	3	3	2	2	3	2
3	3	3	3	3	3	2	3
4	4	3	2	2	2	1	2
5	5	2	3	3	3	2	3
6	6	2	3	3	2	2	1
7	7	3	3	2	3	2	2
8	8	3	3	2	2	2	1
9	9	2	3	2	2	2	3
10	10	2	3	2	3	1	1
11	11	2	2	3	2	2	1
12	12	2	3	2	2	3	3
13	13	2	2	3	2	3	1
14	14	2	2	3	2	1	1
15	15	3	2	3	1	1	2
16	16	3	3	3	2	2	2
17	17	3	3	3	2	2	2
18	18	3	3	3	2	3	2
19							

Figure 11: Minitab screenshot of the statistical data for ANOVA one-way analysis