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Go-To-Market Strategy

For New Medical Device

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<p>Purpose of this study is to define the components of a Go-To-Market (GTM) strategy for a new disruptive medical device and study how they are utilized by startups. As many companies entering the market for digital medical devices are startups the focus here is in looking at the startup specific questions of strategy formation. The globally increasing healthcare costs create the demand for new and more advanced medical devices, technologies and services. Some of the technologies utilized in medical devices are more established but there is an increasing number of more disruptive technologies and new startups entering the market resulted by the digitalization requirements of many of the products and services. Additionally many medical companies are already stating digital as their focus area.</p> <p>The data collection method of the study was semi-structured interview with interview guideline followed up by telephone and face-to-face meetings. Ten startups were interviewed.</p> <p>The results showed that there were two startup specific areas affecting the planning which customer influence and financial situation. Also customers had a strong impact on the planning and decision making.</p> <p>There are various components most companies include in their GTM plans. These were trade fairs, locating the opinion leaders and seeking customer feedback. On the other hand, very few used publications, conducted market research or used formal models in their planning. Additionally the approach for geographic sequence for new markets to enter had a variety of methods and many of the interviewees had not finalized the planning for opening offices in other countries.</p> <p>Based on the articles, books and interviews it was quite evident that there really is no easy to use formula on how to get the GTM strategy right. There are just pointers on what should be taken into consideration, which are the most common areas to cover and various examples of unsuccessful attempts as well as a few successes. Still by and large it is a question on making subjective decisions on what is important for your company, the constraints affecting it, disruptiveness of technology, competition and many other internal and external factors.</p>	
Keywords	Startup, disruptive technology, Go-To-Market, GTM, medical device

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1 Introduction of the topic and research problem

The purpose of this study is to define the Go-To-Market (GTM) strategy and its components for a new medical device my company, PulseOn, is developing. Here medical device consists of physical device and service. As we are a startup company the study is conducted from startup perspective.

There are various new medical devices which are brought into markets globally. The healthcare costs in Western world are rising steadily with US leading the way with its current annual cost increase of 6-7 % which is exceeding its GDP growth. For this reason the healthcare providers should focus on improving the utilization of current resources. They should also focus on promoting more effective means of care and collaboration between different industry stake holders towards more transparent system with lower cost delivery settings. (PWC 2018, p 2-3.)

Some of the technologies utilized in medical devices are more established but there is an increasing number of more disruptive technologies and new startups entering the market resulted by the digitalization requirements of many of the products and services. Additionally, many medical companies are already stating digital as a focus area so there is additional investment on these areas as well. (Chadha, Chilukuri, Van Kuiken 2017.)

The device PulseOn is developing is an Optical Heart Rate device. The device is based on photoplethysmography (PPG) technology. The device is a wrist wearable device for healthcare professional users for screening and monitoring of arrhythmias and sleep apnea from their customers. The device development started in late 2016 and it is currently in data collection and prototyping stage. The proof-of-concept is completed, we have concluded that arrhythmia detection is possible with the technology and a prototype device for additional studies is available.

Remote patient monitoring and treating people at their home instead of in the hospitals is becoming more widely adopted and various new mechanisms for re-imburement and less regulation are being put in place for enabling this progress. Also supply of the telehealth services may in the future be not by specialist companies but done as part of current healthcare service providers standard process. (Comstock 2018.)

When needing to plan the Go-To-Market strategy for a new disruptive medical device we have no experience for doing this inside the company as this is the first device the company is developing on medical side. There is no straightforward model to follow on how to define this plan so there is a need for obtaining more information on how this planning should be done and also for studying if other startups have utilized the same components for the plan.

1.1 Market background and target users

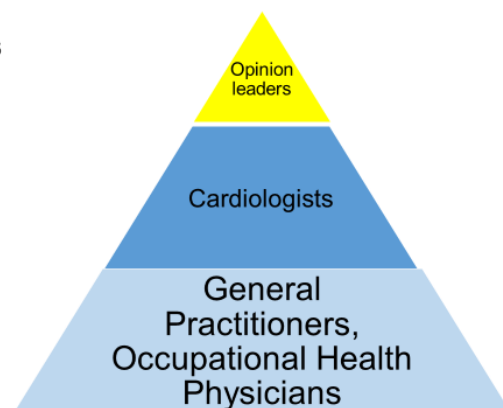
Medical and clinical-grade wearables is a high growth technology area for the future years. One estimate for the annual turnover of the industry is to exceed eight billion US dollars by 2020. The growth percentage exceeds 30 percent during the time. (Frost&Sullivan 2017, p 28.)

The growth is due to various factors, according to Frost&Sullivan these are for example aging population creating pressure for more cost efficient health care solutions. Another factor is emerging technologies which are transforming the growth of the global healthcare industry enabling an affordable collaborative care model where integration of wearables and services enable personalizing patient care and higher efficiency. (Frost&Sullivan 2017, p 16-18.)

Target users for the device and service



- Intended users: healthcare professionals
- Get opinion leaders as key promoters
- The device will be used by cardiologists as a part of their regular screening and diagnosis work
- The device can also be utilized by other medical professionals for the first level screening of symptoms which could be resulted by AF, Sleep Apnea, poor sleep quality or lack of exercise



Private and Confidential

Figure 1: Users for the device

As we are designing a regulatory medical solution for health care professionals, the above illustration highlights the target user groups. As the device can be utilized by cardiologists as well as general practitioners, doctors and other health care personnel, we are also involving these additional groups into our GTM planning for additional feedback on later studies. As within the group of cardiologists there are some who are more deemed as opinion leaders and followed up by others, it will be of importance for us to cooperate with them as part of our early research and studies

1.2 Company and technology background

PulseOn Oy develops wearable devices based on optical heart rate technology. The company is a Nokia spin off from 2012 and initially started with business-to-consumer (B2C) offer but has since then pivoted to business-to-business (B2B) offer of technology licensing to consumer brands. Due to the high accuracy of our technology we have now started development for a long term wearable medical device for atrial fibrillation and sleep apnea detection and monitoring as first features.

Optical Heart Rate monitoring is based on the photoplethysmography principle. The skin tissue is illuminated by an LED and the intensity of the propagated or reflected light is measured with a photodetector. The measured light intensity depends on the variations of the subcutaneous blood flow, which are directly related to heart pulsations. (Tarniceriu 2017.)

The PulseOn wearable wrist device accurately estimates heart rate and (in the absence of movement) beat intervals from the optical signals. In turn, the beat intervals are used for atrial fibrillation detection where periods of atrial fibrillation are isolated from the regular sinus rhythm. The atrial fibrillation periods can be detected for as short duration as 30 seconds which makes it accurate enough for medical purposes. (Tarniceriu 2017.)

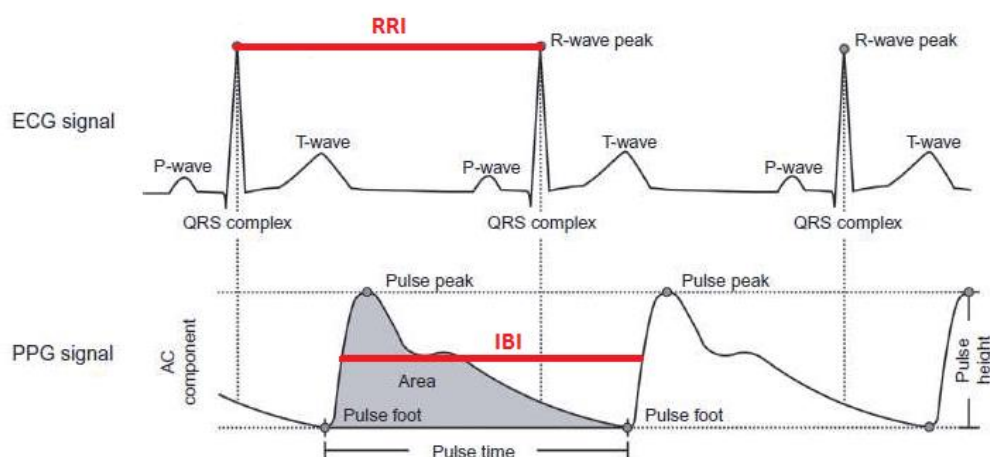


Figure 2: ECG and PPG technology comparison (Tarniceriu 2017)

PulseOn studies in hospital environments and in cooperation with cardiologists confirm that the highly accurate Inter-Beat Interval estimation can be used for medical applications. The IB intervals calculated from PPG signal are in close agreement with the ECG reference, enabling a comfortable and affordable long term screening and monitoring option. (Tarniceriu 2017.)

1.3 Core Concepts

The core concepts for this study are:

Startup: company starting a new business and bringing a new device to the market

Disruptive technology: technology which is new and different from the other technologies already existing on the market

Go-to-Market (GTM) strategy: the plan for bringing a new solution to the market

Medical Device: regulated device used for medical and clinical purposes, the medical device PulseOn is developing is called “Aino” so the medical device and Aino may be used interchangeably in this report

2 Theoretical background

For the theoretical background I have mainly focused on publications on startups and disruptive technologies to reflect the situation where the Go-To-Market strategy is being created.

2.1 Planning for Startup Company

As PulseOn is a startup company and also developing a new technology device, I will look into Eric Ries's insight in startups in more detail here. According to Ries the first problem why startups fail is that they rely too strongly on planning, solid strategy and market research as indicators of likely success. This may be misleading in a case of a startup. As startups operate with very high uncertainty and the world is also becoming much less easy to forecast the planning and forecasting based on historical data can be very misleading. However, neglecting any management and adopting trial and error based "Just Do IT" principle on its own does not work very well either. (Ries 2011 p 18-19.)

2.1.1 Startup Vision and Business Model

There are various questions which should be asked and included in a successful business plan and model for the GTM strategy. These include defining the unmet clinical need, product and technology differentiation, regulatory process, budget required and commercialization strategy. Also the time span, investment and required skills from management should be considered in detail. (Zadno 2015.)

Ries divides the startup planning and management into three phases; Vision, Steer and Accelerate. I am focusing here on the vision which I believe also works for the task of planning the Go-To-Market Strategy (Ries 2011 p 20.) As we are in the early stage of the GTM strategy creation the main focus here is presenting the vision part of the strategy and tying it together with the planned actions.

The business model is the real product, not the solution so the focus should be placed on fine tuning the business model. This is especially important when raising capital. An easy tool for evaluating the different business models is a lean business model canvas. It is also important to make sure that the Key Performance Indicators (KPIs) are used correctly, reflect the business, and that there are not too many of them. You should also define your minimum success criteria which should not be for longer time than maximum of three years. (Maurya 2016 p 58-60.)

The vision includes the theory that an early stage venture should address from the beginning vision and concept, product development, organizational structure, scaling up, marketing, sales and partnerships. Neglecting doing this, and avoiding any forms of management, process and discipline, instead, easily results a chaos. As the goal of the startup is building the right products that people want and are willing to pay for in the fastest possible ways, special emphasis should also be placed on how the people and teams are organized and how they cooperate. Emphasis should be in fast iteration and customer insight, vision and ambition at the same time. (Ries 2011 p 24-30.)

We are also building these components into our GTM-strategy in awareness creation stage where we also collect actively feedback from prospective customers and end users. We also utilize the research and development studies for preparation of sales start and additional testing of the concept. As the device will be a regulated medical device, we cannot start sales and promotion until we have the regulatory approval, so we need to be careful on the venues, extent of actions and methods we use until then.

2.1.2 Startup entrepreneurship and Learning

According to Ries the definition of an entrepreneurship is seeing the future of the industry and ability to take risks to seek new and innovative solutions to problems. For a startup innovation is the heart of company's success. Also in this sense as the startup operates in environment of extreme uncertainty and unpredictability it should not be managed by standard forecasts, product milestones and detailed business plans. Instead the teams need to be flexible, reacting fast and experimenting and the management role is to create the environment for this to happen. Also in many cases having a higher number of ideas to try out can be better than fixing on one only which can be possible especially in cases where the startup operates inside a bigger and more financially strong institution. (Ries 2011 p 35-44.)

Extremely important factor in the startups success is the ability to learn fast. And especially learning fast what customers who are willing to pay for their solutions really want, not what they say they want or what we think they want. For this Ries suggests validated learning process for demonstrating empirically that team has made valuable discoveries on present and future business prospects. The learning should always focus on how potential or intended customers find the product. If they are included in the development

from the earliest stages the learning is faster and can aid in preventing the situation where product is ready but the company then finds that there are no customers willing to pay for the device. According to Ries in general any effort which is not absolutely necessary for learning what customers want should be eliminated as it is waste. All validated learning should be backed up by empirical data collected from real customers. (Ries 2011 p 46-56.)

2.2 Planning for Disruptive Technology

According to Christensen's definition a disruptive technology is something that brings to market a different value proposition than previously available. In general they underperform established products available, but they have other features valued by customers like being more cost effective, simpler to operate and smaller in size. (Christensen 1997 p 11.)

As the device PulseOn is bringing to the market can be defined as a disruptive technology we are here looking into specifics of planning for a disruptive technology.

Unless the company is able to understand the disruptive forces affecting the industry it can very easily go out of business or in the case of startup not to even manage to go into business. The disruptive technology could be coming from another industry altogether so being aware on the progress outside your own are is very important as well as being able recognize these changes. Following up what competition is doing as well as keeping up good understanding on the problems your customer or potential customer is facing as well as their thinking is also vital. When the changes are expected to happen it is most likely better to be fast to accommodate them or becoming the disrupter. (Myler 2013.)

2.2.1 Planning market research for disruptive technologies

As the PulseOn device is intended for faster and more cost efficient screening of atrial fibrillation and sleep apnea instead of using the more uncomfortable, shorter term usable and Holter ECG devices for atrial fibrillation and the sleep laboratories for sleep apnea detection we can say that we are working with a disruptive technology which increases the uncertainty and lack of historical data for decision making.

Based on Christensen's findings the historical method of market research backed planning and execution are invaluable when applied to sustaining technological innovation. However, with disruptive technologies they may in many instances lead to failures rather than successes. In situations where there is least knowledge on market there are strong fastest mover advantages which is called the innovator's dilemma. Craving for market data when it does not exist or using planning and marketing techniques created for sustainable technologies can lead to highly unsuccessful outcomes. (Christensen 1997 p 15.)

2.2.2 Learning, Discovery and Surveys

The strategies and plans for disruptive technological change should be for learning and discovery and not fixed execution. This is as in a situation where the decision makers do not understand the complexity and uncertainties of the developing market which cannot be analysed are very different in their behaviour. Instead in the planning phase there should be flexibility and the approach for customers and supplier to discover the new markets together. As many sustainable innovations are developed by established companies by known markets and is a very different situation from managing the disruptive innovation technology the management techniques applied in wrong type situations can cause paralyzing effect. Inappropriately applied marketing, investment and management processes can render companies incapable of creating the markets for disruptive technologies. (Christensen 1997 p 117.)

According to Maurya, one has to be careful with market research when doing customer surveys. Focus groups can easily lead to group thinking which would not bring the genuine points of view from all participants. Also surveys are not good for the early stage learning but can be used for hypothesis validation from customer interviews. For this reason, starting with qualitative approach and then continuing with quantitative survey can be the most efficient tool. The qualitative validation can help in uncovering strong signals in behalf or against the hypothesis even when using a moderate number of participants. After this qualitative validation the results can be used for drafting a larger quantitative study. Also in general using every opportunity to talk to potential customers and testing your views is strongly recommended and very useful in speeding up the testing your hypothesis and changes in it. It is also strongly recommended to involve potential customers already during the concept development prior to any tangible product or

solution is available as it could be wasted time spent on doing even an early prototype prior to getting the first feedback. (Maurya 2016 p 80-81.)

What we have done is involving our potential customers and opinion leaders early on into the development process. As we are doing the tests in hospital environments we naturally need to have involvement from health care personnel, doctors and nurses and well as the patients. For the initial studies we were able to utilize our previous generation device for some early testing and comments which were then used for the design of the proof of concept device. Already prior to the actual studies taking place we started with informal interviews amongst our contacts and advisory board to get the feedback from as early point as possible. Of course in our case the technology was also giving a high level of guidance on what kind of solutions we would be able to provide based on what the technology is suitable for but this is only a small fraction of the total plan.

We also did some two staged market research in a form of qualitative followed by quantitative studies. In order to bring in additional insight on European level they were taking place in Germany which is the largest European market in numbers of people suffering from atrial fibrillation and also as Germany in general is considered as a rather traditional market which could be a difficult situation for disruptive technology.

2.3 Go-To-Market Planning

2.3.1 Technology user groups and learning

The High-Tech Marketing Model is based on the idea that the users of technology can be divided into different groups: innovators, early adopters, early majority, late majority and laggards. According to the model the development of a high-tech market starts from innovators and working towards the later groups while growing the market. In this approach each captured group is used as a reference base for going on to the market of the next group. Winning over the innovators and being able to use them as a reference when creating the pitch to early adopters, early adopters to early majority and then on. This process should be designed to run smoothly and not to lose the momentum on when to move on to the next group. (Moore 2001 p 10-13.)

The other reason for keeping the momentum is also to stay ahead of other new technologies being developed. If the momentum is lost it creates the opportunity for the competitor to take over. Losing the technology leadership position also often means losing the higher profits of the middle to late stage customers which is the main component of high-tech fortunes. The High-Tech Marketing Model is a vision of smooth path through the different stages of the Technology Adoption Life Cycle. There can be opportunity for virtual monopoly if you manage to enter the market before your competitors and be the first to enter the curve and stay in front of your competition. If you have long enough to establish your solution as the de facto market standard you may be able to own a highly profitable market for a long time. However, one has to bear in mind that the offering to each different group has to be customized for them and missing the customization or doing it wrong way can cause the loss of momentum the same way as being too slow. (Moore 2001 p 10-13.)

At PulseOn we are now starting the path with our awareness creation amongst the industry opinion leaders in order to use them as our advocates for the early adopters and this way moving towards the early and late majority for the largest portion of the market. However, the idea of virtual monopoly may not be reachable as there are already competitors who are developing similar technology with much higher resources than ours. Therefore we have chosen that instead of competing on the consumer devices market with the technology, we will be focusing on the B2B, a more niche area of professional users.

Christensen calls the approach of disruptive technologies market discovery agnostic marketing where the underlying assumption is that nobody, not the company, not their customers or potential future customers is able to know if, how or in which volume a disruptive product could or would be used until they have experienced it. In some occasions it is easier to decide to wait until other players have started defining the market but this would give away the advantages of being the first mover. Instead with using focus groups and going on a discovery driven exhibition to the market would be a better way to proceed. (Christensen 1997 p 127.)

This is also to great extent the starting point of PulseOn GTM-planning, we are starting with ongoing high intensity data collection from various sources and also looking into the changing healthcare market enabling our disruptive technology. We are utilizing the medical experts and the patients in the studies as well as other care personnel as our first

hand sources of information and also planning to include the end users wearing the devices. Also, we are not making highly fixed, high cost plans for the initial GTM part until we have more information and have tested our hypotheses on our potential new customers and users as well as the authorities in medical world.

If disruptive technologies are kept within in house development with the target to improve them to suit the mainstream markets the result is often not as successful as it is for companies who seek markets which embrace the initial product attributes and then develop them further. In this way the marketing takes the lead from the laboratory in making the product successful. In many cases the disruptive technology satisfied the markets functionality requirement and because it is simpler, cheaper and more reliable than what is already available on the market. As the established companies often tend to push for more advanced features and complex devices they may overlook the requirement for simplicity by the market. (Christensen 1997 p 150-151.)

One of the major pitfalls after the stage of securing further investment and proving the commercial viability of the solution is the actual scaling of the revenue after the first pilots and small scale trials. At this stage the actual GTM and sales plan becomes extremely important in order to guarantee further commercial success. It may easily be that the solution still lacks deeper understanding on the actual problem the customer is facing. If this is not clearly understood and addressed with the solution, it is very easy to fail with the GTM. Also, the clear understanding on the customer problem should be investigated prior to the planning to make sure the actions are correct. Prior to making the actual decisions on how for example the sales channel is designed, the problem and the process should be looked into from the customer perspective. Also in depth study on the customer business challenges should be part of the planning. This what can be also called “consultative sales approach” should be started prior to the actual GTM planning. This can be done by identifying a specific group or specific customers and getting to know their problems and perspective more closely. It is then advisable to start discussing with a higher number of other potential target customers as well to verify the hypothesis prior to the actual drafting of the plan. (Askhenas, Finn 2016.)

Even though according to Moore the process of entering a larger and more lucrative market should be started from securing the niche, which is the opinion leader section of that market, there are strong forces guiding towards faster attempts of market entry. One of these is the hockey stick growth expectation of many investors. Their expectations for

growth happen very quickly after the initial proof of concept device availability and can easily push the planning to too fast execution of a high growth revenue and failure. Also, as the earlier stages of the growth the company quite easily falls into making expensive and difficult to maintain customer promises and agreements this may cause problems as they need to be honoured even though they take on a large portion of the resources. (Moore 2001, p 139-144.)

We are preparing for this with choosing our target niche to be the Finnish cardiologists who are seen as the opinion leaders amongst their colleagues. As they are often interested in new technology and development and follow it up closely in order to maintain their position as opinion leaders and experts it is also possible to involve them in the study and development phases. There will be some degree of global visibility through this niche group but we also need to have the same approach for the other markets we enter in different countries after Finland. We also investigate possibility to do some of the clinical studies outside Finland in another European country in order to extend the niche to cover some additional experts in other areas.

2.3.2 Intended GTM sequence and local presence

As the medical device the actual launch date in GTM is dependent on the regulatory approval the development and approval schedules often define the final time lines. As the actual timing often depends on the regulatory officials and cannot be decided or influenced by the company themselves the plan should be seen as a process where the sequences are planned and actual timing triggered by the approvals. For disruptive technology the actual planning should be started well in advance of the anticipated product launch for familiarizing the potential customers with the new approach. The planning should also closely involve all company functions working on the delivery of the device, not only sales and marketing. (Steelman 2014.)

There are various reasons why companies expand their operation outside their home country even if staying in their home country would be the most simple and easiest option. However, if the domestic market is not big enough or there are better profit opportunities outside this may be reasons for geographical expansion. Also, larger customer based for economies of scale, less dependability on local economy and individual market or customers relocating or expanding overseas may be amongst the reasons for this.

There are also various considerations if the decision is to go including differing preferences, different business culture and regulations and various currency and policy related questions. (Kotler & Keller, 2016, p 241.)

At first stage at PulseOn we defined the countries and the sequence for the market entry. This is based on following main criteria:

- Geographical location
- Size of the country
- Timing of the regulatory approval

Below Figure presents the timeline, estimated revenue impact and sequence of selected countries.

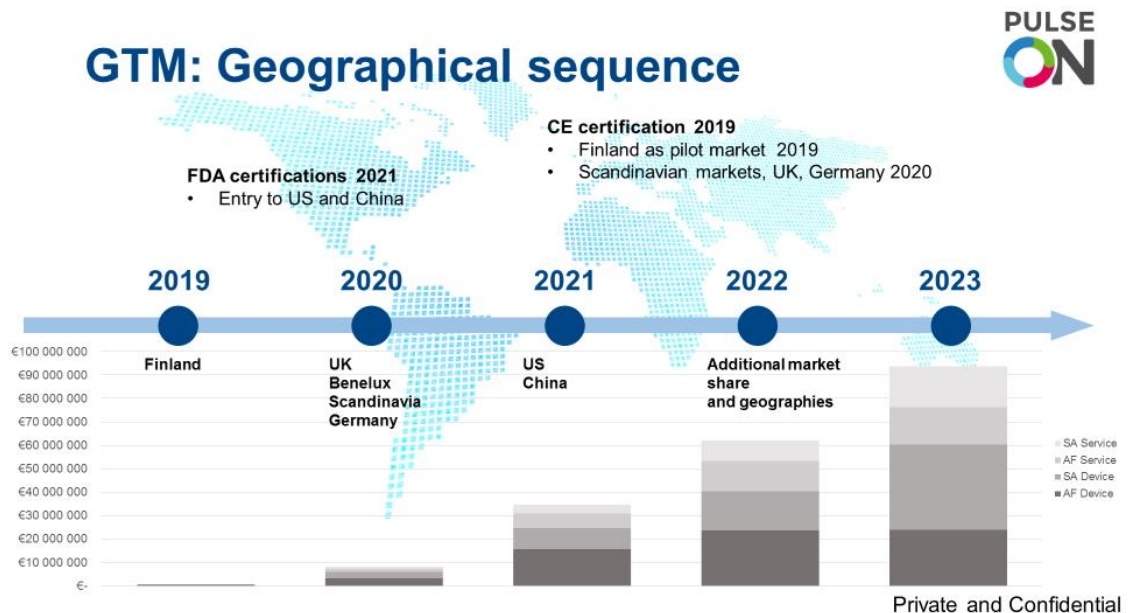


Figure 3: Geographical GTM sequence

Europe is our home market and we will start the regulatory approval process with CE MDD regulatory certification which we expect to obtain first during 2019. Finland is the natural first European country to enter as many of our ongoing studies where the development is based are conducted in Finnish hospitals which creates us a contact network amongst Finnish medical professionals.

Due to the close proximity and similarity in health care system in the Nordics countries Scandinavia is part of second stage of the expansion. Germany and UK represent the largest European countries for population and we expect Benelux to complement them. All selected European countries are facing the same issues with aging population where the prevalence of arrhythmias, especially atrial fibrillation, and sleep apnea is increasing causing increasing health care costs. (Berisso & Lercali & Carazza 2014.)

US and later China both require their own country specific regulatory medical approvals which will require some longer time to achieve so they are placed on a later stage. Also both countries due to the size, time difference and especially in China the language barriers will require local sales force.

For local presence outside Finland we need to consider opening our own sales offices to the most important target countries prior to the market entry. This would be initially Germany and at a later stage UK, US and China. The other option for the later stage could be starting to work through distribution. In most countries being able to sell our device we would need a local representative with legal entity which could be our own company or a distributor.

2.3.3 Market research and awareness creation

We decided to conduct market research in order to test the hypothesis that we have a solution which is of interest to our potential customers, commercially viable in pricing and with a sustainable business model. This was done for our internal development and business case development purposes as well as for convincing the main investor that we have a high potential value generating solution and proven interest also outside Finland.

We used an external market research company called Amalfi Business Consultants. The reason for outsourcing was their experience in conducting medical device market research and existing contact network amongst medical professionals from main European countries. We got a referral from one of my colleagues who had used them in her previous company and was happy with their service.

For creating awareness and promoting ourselves as a medical company we need to re-brand ourselves from a high quality sports and fitness company to a high quality medical

company. This will require new type of awareness creation amongst new types of potential customers so we need to have even more focus on the scientific accuracy of our solutions. However, as all our previous research is already academic and scientific this will not result a major change in the way how we operate in our research and development. Also the awareness creation works as the simplest starting point for future sales creation as this way our potential customers will familiarize themselves on our devices and offer.

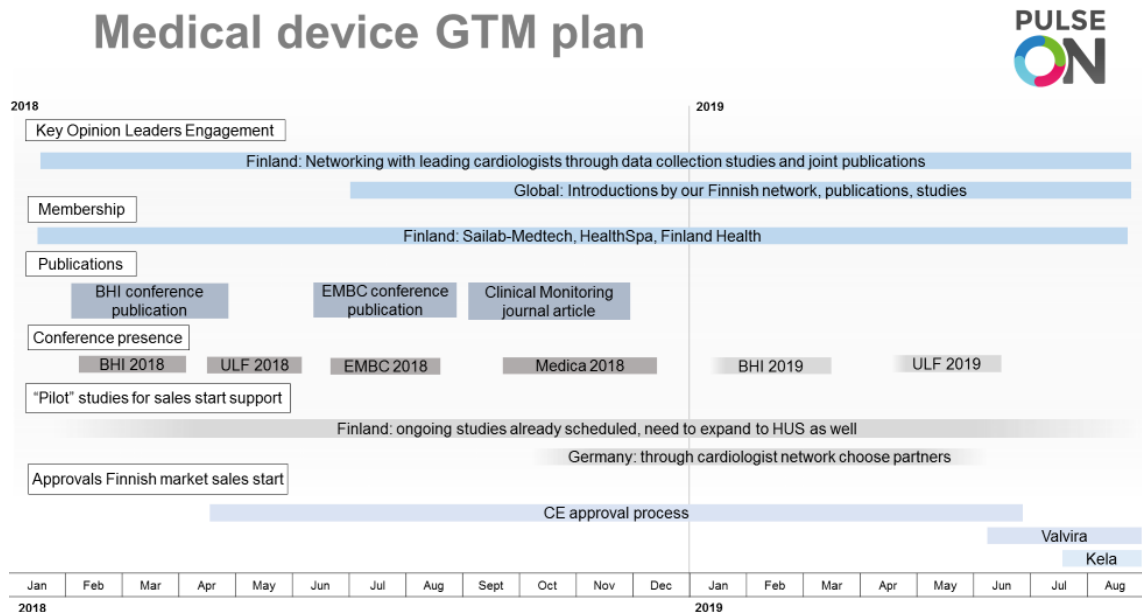


Figure 4: Medical device GTM plan

Above is the high level GTM activity plan as of November 29th 2017. The implementation has already started on the applicable sections.

PulseOn scientists will publish articles in medical journals and medical exhibitions based on the results from the ongoing studies with hospitals. The cardiologists and other health care personnel are also participating in the publications as co-writers and will further present them in additional venues.

We will seek for suitable speaker slots in the main European and Global medical venues and seminars. If there is an exhibition which coincides with the speaking opportunity we will also have stand presence.

We have selected two leading global medical venues for 2018 and these will in the continuation also be our main international exhibitions to attend with stand presence. The two selected ones are Medica in Dusseldorf Germany in November and Health Information Management Systems Society (HIMSS) in Las Vegas, US, in March. They both have global attendance as well as many delegates from the country they are located in which is also in line with our geographical reach of countries where we plan to launch. With HIMSS coincides another medical technology Biomedical and Health Informatics (BHI) conference where our algorithm development team will present the first public results on the PulseOn ongoing studies on Atrial Fibrillation.

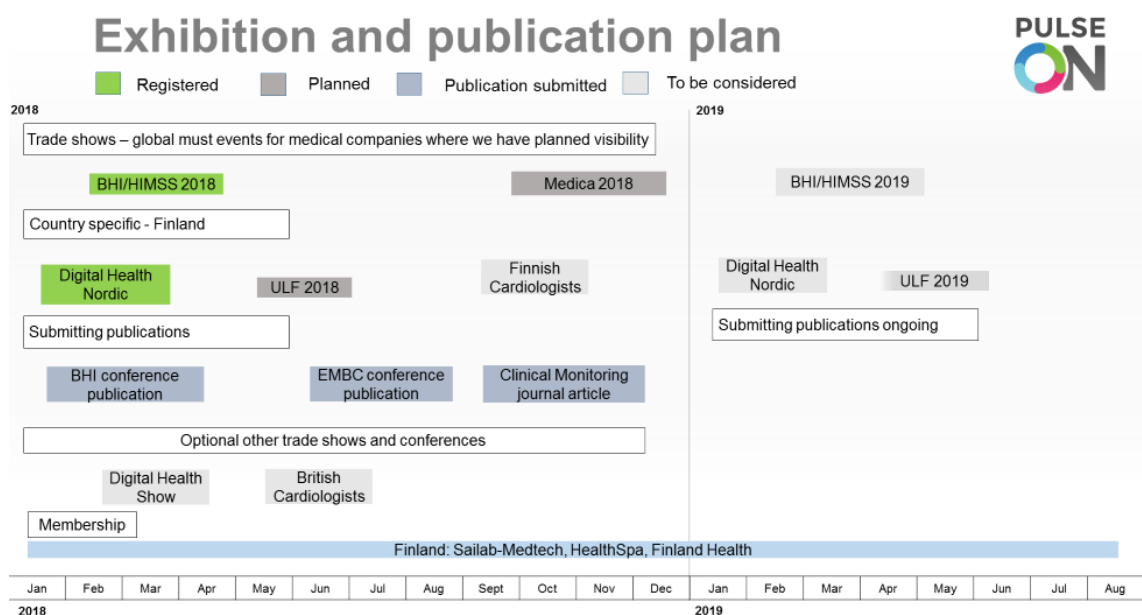


Figure 5: Exhibition and publication plan

As Finland will be our first country to launch in 2019 we are also attending some country specific venues for Finland; Digital Health Nordic, Upgraded Life Festival (ULF) and Finnish Cardiac Society autumn summit.

2.3.4 Clinical studies and pilots utilized in GTM

As part of the development and clinical approval process a number of clinical studies is required. These studies are also used for data collection for development purposes and for collecting feedback on functionality required from the health care professionals participating in the studies.

As part of the clinical evaluation required for the MDR project (medical device regulation) we will need to complete external efficiency evaluation by a third party. This third party represents the potential customer for the solution with their end users who represent the real types of end users for the device. (Ruuskanen 2017.)

Ongoing studies in Finland are planned and agreed with university hospital personnel and undergo the ethical committee approvals. The studies will also familiarize us with the key opinion leaders in the medical field and who in many cases can also aid us with preparing the requirement towards the procurement organization.

Hospital Study Summary



Collection campaign	Goal	Status	Start-end (expected)	Comments
Post Anesthesia Care Unit (PACU, Tampere)	<ul style="list-style-type: none"> - Confirm the IB detection algorithm on elderly subjects with arrhythmias - Evaluate the AF detection algorithm on subjects with continuous AF 	Completed	May – Aug 2017	Results submitted to BHI 2018. Two more submissions in progress
Cardiac Hospital Study (Tampere)	<ul style="list-style-type: none"> - Long-term recordings of data with irregular AF episodes - Evaluating the amount of usable data during daily/rest activities - Evaluate the AF detection algorithm on subjects with irregular AF episodes 	On-going	Nov 2017 – Feb 2018	<ul style="list-style-type: none"> - 3 recordings out of 30 completed - Initial starting date (May) delayed due to measurement technology issues – high RF disturbance on BT - Completion date depends on the availability of suitable patients
Ambulatory AF Study (Tampere)	- Same as for the Cardiac Hospital Study, but at the subject's home	Study plan submitted. Decision on 12 Dec	Jan 2018 – Apr 2018	- One month delay caused by the hospital
Sleep Lab Study (Helsinki)	- Record data with reference to be used for sleep and respiration analysis, and for sleep apnea detection	Planning ongoing		Slow response time from the doctors.
AF study (Oulu)	<ul style="list-style-type: none"> - Record data for the validation of AF algorithms - Patients recorded in Hospital 	Study plan submitted. Decision end-Nov	Dec 2017 – Mar 2018	
Sleep Lab Study (Tampere)	- Record data with reference to be used for sleep and respiration analysis, and for sleep apnea detection	Study plan submitted. Decision on 12 Dec	Jan 2018 – Mar 2018	

Figure 6: Ongoing hospital studies 29.11.2017 schedule

The ongoing studies number will increase over the time as more research and especially data collection is required for finalizing the development. Also as we move towards additional features we will be required to conduct additional studies.

2.4 Medical Device

As Finland is our first go to market country and complying with European directives we are looking into the specific requirements for the market entry in more detail from Finnish perspective. Aino is designed in order to fulfil the regulatory medical requirements so this

is essential to take into account in general planning, product development and GTM planning.

2.4.1 Healthcare device regulatory guidelines and QMS

Medical device manufacturers operating in Finland have to get their devices regulatory approved by Valvira, National Supervisory Authority for Welfare and Health. Definition of the healthcare device in this case is an instrument, device, accessory, program, material or any alone or in combination used device and any program required for its proper use which the manufacturer has meant to be used in diagnosis, prevention, monitoring, surveillance or treatment of illness. (Valvira 2017.)

When bringing a healthcare device on the market and taking it into use it has to fulfil the regulatory requirements. The manufacturer has to give assurance on the compliance to regulations and attach the CE marking to the device to show this. For bringing the device into the market the manufacturer has to prove that the device usage is according to the regulations for health and medical devices. (Sailab-Medtech 2017.)

Regulatory requirements for medical devices are associated to

- safety & effectiveness of the devices (device quality)
- medical device manufacturers' capabilities to ensure device quality

Medical device safety/effectiveness shall be evidenced by preparation of technical documentation for each device, preparation of a declaration of conformity for each device, CE marking of each device and post-market monitoring of actual performance of each device. Trustworthiness of the documented evidence shall be demonstrated by quality & comprehensiveness of the technical documentation and compliance of the QMS of the device manufacturer. (Finlex 2010.)

The EC directives in general are meant for guidance to member states in defining their respective laws. The directives are not legally binding but the national laws based on them are. In many cases however if there is discrepancy between national law and the directive the national law needs to be amended accordingly as EC member countries have jointly agreed on unifying their laws on this area.

The Finnish law on medical and health care devices aims to guide and insure the safety and the safety of operation of medical devices. It implements European Community directive on conformity of member states legislation 90/385/ETY, known as AIMD directive, medical devices directive 93/42/ETY, known as MD-directive (MDD) and in vitro diagnostics medical devices European Parliament and Community directive 98/79/EY, known as IVD-directive and any later changes to them. (Finlex 2010.)

The European (European Community) device safety/effectiveness requirements are based at the moment on MDD, Medical Device Directive, (93/42/EC) & after a transition period on MDR, Medical Device Regulation (745/2017/EC). Finland complies with these. (Finlex 2010.)

Medical device manufacturer's Quality Management System, QMS, is the foundation for

- achieving confidence for device compliance
- driving continuous improvement

It is mandatory for a medical device manufacturer to have QMS, however, how it is deployed can be decided by themselves. The most straightforward and commonly used way to guarantee the required compliance is basing the QMS system on ISO9001 standards. However, as having a QMS system is mandatory and legally binding requirement, if the manufacturer uses a different system it is their responsibility to convince the authorities on the compliance with the law requirements. (Ruuskanen 2018.)

If using the ISO9001 standards the applicable ones QMS would be based on are:

- ISO 13485 = model for QMS scope
- ISO 14971 = model for risk management subsystem

Additionally, approximately 15-20 harmonized EU standards apply to a medical device manufacturer determining device-related requirements which fulfilment requires incorporation of associated control methods in the company QMS. Implementing the QMS system requires cooperation between all company functions and often takes considerable amount of time in the initial requirements planning, documentation rules preparation, change processes determination, risk management process determination, contact persons naming, required employee skills determination, job description preparation based on them and various document templates preparation even before the actual documentation work even begins. The product development process has to be documented

according to the system and the system has to be actively used for all change management and product development process documentation. (Ruuskanen 2018.)

2.4.2 Promotion and re-imburement requirements

Promotion of regulatory devices is defined in CE law articles 2 and 4 which are applicable for promotion in Finland as well, there are no additional country specific guidelines. The guidelines are strict on how the devices can be promoted until they have received the CE regulatory marking.

Only CE marked medical devices may be promoted and placed on the market (Article 2) Non-CE marked medical devices may be exhibited at trade fairs and exhibitions (Article 4(3)). However, they must be clearly marked to be for Demo purposes only and that they are not to be “available to the public” (e.g. – “Any supply of a product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge”)

Re-imburements on medical expenses are listed and provided to public by Kela, the Social Insurance Institution (SII), which is a Finnish government agency in charge of settling benefits under national social security programs. The National Institute for Health and Welfare in Finland (THL), has a process for adding a new treatment code into the official listing. (THL 2017.)

The Kela (SII) re-imburement is relatively low and mostly in Finland used for medicines and in treatment purposes used for logging into the patient record data base the treatment the person has received. Therefore it would not have impact on the procurement of the device. (Härkönen 2017.)

Kela can give re-imburement recommendation or interpretation to treatment if it is already included in the code listing but does not have confirmed costing available. If the treatment does not have an existing code the manufacturer can request it to be added into list by THL, Department of Health and Wellbeing. It can be proposed to THL to be added into the examination code chart. (Kela 2017.)

3 Purpose, aim and objectives of the study

Purpose of this study is to define the components of a Go-To-Market (GTM) strategy for a new disruptive medical device and study how they are utilized by startups. I am responsible for drafting this strategy and implementing it at my employer PulseOn as well as planning the actions on how we start the implementation.

The aim is to create a GTM strategy for a new medical device. The other aim is to take into account in the planning that the technology is new and disruptive.

The research questions are:

- Which are the components of a Go-To-Market strategy for a new disruptive medical device?
- What should be taken into account in the strategy planning?
- How are other startups utilizing the GTM components in their planning?

As I am responsible for the actual planning it is also to an extent based on my own knowledge and decisions on what is relevant and what should be included, what should be the sequence and how under our budget and investment related constraints we can progress with the implementation.

4 Materials and methods

4.1 Description of the context, subjects, sample size and sampling

This study is conducted amongst medical technology startups in Finland. There are various new medical devices which are brought into markets in Finland and globally. Some of the technologies utilized in these devices are more established but there is an increasing number of more disruptive technologies caused by the digitalization of many of the products and services. Also there is a higher requirement for digital products and services caused by the increasing health care costs and higher requirements this is causing for home based care and more cost effective solutions for both, chronic and preventive, disease management and many of these solutions are developed by startup companies.

For the study I interviewed health and wellness startup companies who are bringing or have recently brought new solutions to the market. The companies were from my network of business partners who I have worked with over the last three years. They were selected as they were either in the process of bringing to market new disruptive health and wellness solutions or had recently done so. I included 10 interviews from relevant parties to cover the applicable areas of the GTM strategy formation. I chose the interviewees who were the decision makers actively working on GTM-planning, sales, marketing and business development and this way were able to provide me the full information on their process.

4.2 Data collection, analysis methods and timetable

The data collection method of the study was semi-structured interview with interview guideline. The interviews were conducted by telephone or Skype where during the call I went through the list of ten questions. Due to timing and convenience for the interviewees Skype and phone was the best method and therefore chosen. The data analysis method is deduction where I have first studied the theory and then studied how companies have formulated their strategy in practice. This is because it is seen as an efficient way to conduct qualitative research. (Gilgun 2014.)

The reason for choosing the interview guideline for method is that asking the questions and writing the answers down myself was the best way for full understanding what the respondents meant as it gave the opportunity to discuss and explain question further if needed. I then analysed the answers I wrote down.

The interview guideline questions were:

1. Did you conduct market research for the GTM plan?
If yes, did you do it in house or outsource?
2. Did you seek customer feedback any other way?
3. Did you define who are the opinion leaders and early adopters for your solution?
If yes, did you include how to approach them in your GTM plan?
4. How did you decide on geographical order of markets to enter?
5. Did you include publications in your GTM plan?
If yes, where did you publish?

6. Did you include trade fairs in your GTM plan?
If yes, which ones?
7. Did you conduct clinical studies for your solution?
If yes, were you able to utilize these in your GTM plan?
8. Is opening new offices part of your GTM plan?
9. Did you use business model canvas, SWOT or other formal models for the GTM Plan?
If yes, which one?
10. Was there something you would consider startup-specific in planning the GTM?

4.3 Ethical questions, validity and reliability issues

As the Head of Sales and Marketing at PulseOn, it is my main responsibility to create the GTM strategy. As I would like to create the optimal plan I will take into account all advice I get from theory as well as the interviews. I do not myself foresee any major problems in staying objective as the starting point for the plan is the theory and learning from the theoretical part as well as learning on how the other companies with similar targets implement the theory in their planning.

I studied the TENK, Finnish National Board on Research Integrity, instructions on Responsible conduct of research and procedures for handling allegations of misconduct in Finland. I am conducting the study using scientifically accepted methods and have obtained the required permissions for the research (TENK 2012).

I asked the suitable contact persons from other medical area startup companies to participate in the study and explain the purpose why I am conducting the study. I will also give them the guarantee that their replies will be presented without any company or personal details in the final results. Also, I will guarantee them that I am the only person who will have access to this information and that it will be stored on my personal laptop until the study is finalized and submitted and then deleted.

As I am responsible for the GTM plan I will of course have the responsibility on the finishing of the plan, what should be included and how it should be timed. My colleagues and our management team will also assist and support in defining the time lines which will also depend on the device development and investment schedules. In the end the

validity of the strategy will be determined by the success of the device in the market which can be judged during the years after the market entry in late 2019.

5 Results

5.1 Background information of interviewees

The ten companies interviewed are health care and wellness area startup companies who are bringing or have recently brought new healthcare solutions to the market. The duration of interviews was 30-40 minutes. The person interviewed was either CEO, founder or heading sales, marketing or business development. All the companies were European startups. The interviews were conducted in English in order to keep the results compatible.

5.2 Startup specific areas affecting the planning

There were two areas which were mentioned by many of the respondents, customer influence and financial situation. Especially the respondents who had prior experience on non-startup companies mentioned them.

Many companies, four, replied that their GTM planning was strongly affected by customers as they were co-developing the product with them. They all mentioned that this affected mainly the timing as this was guided by customer schedules. One of them stated that their KPIs, Key Performance Indicators, were different from a more standard development project as they were guided by individual customer. For this reason they were mainly focused on outcome of the development project and if the end solution would be suitable to be brought to market for additional customers or if it needed additional adjustment. In this case the end solution of the co-development was not necessary the solution offered to other customers.

Also four of the respondents concluded that the lack of money had a huge impact in the planning, like one respondent concluded:

“Where does money come from and is there enough?” (interview 9)

It was also mentioned that when it was founders own money they had to be very careful in spending whereas a bigger company can start with larger operation immediately. One respondent stated that it also takes long time to apply for both public and private funding and if the funding is then granted especially public side there may be very short space to actually do the spending which also has an impact in the planning.

“Perhaps a bit more careful in thinking, money is scarce and also own money at stage, bigger company can “start bigger” so startup has to be more selective” (interview 8)

One respondent pointed out that it took them a fair bit of time to try out the most cost effective ways to do marketing and promotion and that personnel has to be correct in order to be able to work with little support from other functions as they do not always exist. They also described a situation where hiring an inexperienced sales person who would have required further support caused them considerable delay in executing the GTM plan as they had to replace him.

“A lot of trialling on how to do marketing in a cost effective way, cost control, doing things first time, we hired a sales guy, green, not prepared to be on their own, we could not give him support from marketing. But there is a lot you can do on low cost if you have right people, fit in the market but not if everybody else has already got there, connections and understanding the market is very important” (interview 4)

As one respondent concluded when asked if they found something in their planning startup specific:

“Everything, we need to have personal relationship with customers and partners, cannot use external services due to cost issues, have to be very agile in development and do bug fixing etc in half day, test in the morning and afternoon fix it, resources allocated really quickly and not time for long approval processes” (interview 5)

All the respondents did agree that there were areas which they would consider startup specific in their GTM planning. One interviewee also did state that in their company they did do a lot of trialling also resulting errors it was still what they found the best way of learning for planning. For this reason they encourage people within the organization to make mistakes.

5.3 Market research and customer feedback

The relationship between market research and customer feedback was seen very close by many of the interviewees and some of them did not separate them.

The interviewees were asked if they conducted market research for their Go-To-Market plan and if so, was it done in house by own employees or outsourced. All the respondents had conducted market research and 80% of them had conducted it in house.

“In house, some doctors we know well who know the use area, sparring with 3-5 Finnish experts used already in product development and idea generation phase” (interview 6)

“Go to schools and do in depth interviews with potential users” (interview 9)

One of the companies who had used external sources used students from Haaga-Helia School of Applied Sciences and got the research done as student project free of charge.

The other company used Finpro, nowadays Business Finland, consultants for doing the market research against a fee. For most of the others the market research was done in house by using internet searches, locating experts and seeking feedback from them and also from potential customers.

Eight companies had also sought additional customer feedback directly from their customers during the GTM planning. For this they had mainly used existing customers apart from one exception who had additionally contacted a wider potential audience through personal contacts, LinkedIn and conferences.

“We sought customer feedback as an ongoing part of our development and GTM process and when introducing new features to solution” (interview 5)

One of the companies who did not seek direct customer feedback instead looked into competitor performance with their target customer groups and additionally used information collected by their application. The other one started only contacting potential new customers for feedback after they launched device so this was not included in the GTM plan.

5.4 Locating opinion leaders

Vast majority, eight, of the respondents located the opinion leaders for their type of solution and used them in the GTM plan as well. Of the two who did not both instead focused on locating the early sales opportunities and using them as references in the GTM plan.

“Not relevant as we choose our customers, part of the market study is customer finding” (interview 2)

One respondent decided to do custom development with the opinion leader and then use this as part of GTM when promoting to additional customers. One of them located a partner who was already doing studies in new disruptive technologies and therefore the setup for this type of cooperation. One of them stated that they first defined who their target customers are but that it was not easy to locate who were the opinion leaders for those potential customers. Two additional companies stated that especially trying to locate the opinion leaders outside their own country was very hard and sometimes impossible. One of them pointed out that this was also in some occasions due to luck of meeting up with correct people on exhibition stand by chance.

“Yes, most companies within the industry are looking into our type solutions so we sought the one with most visibility as opinion leader and worked with them on custom development” (interview 10)

One respondent had used outside consultant in aiding with locating the correct opinion leaders. All the others who located them did the research in house and through existing networks.

There was also one model of a hybrid type of approach, the company first located any customer who was willing to enter into a pilot with them. When the pilot was ready they then used the results for additional proof when contacting the opinion leader for the area. This was tightly integrated into their GTM plan.

5.5 Publications and trade fairs

We discussed also the usage of publications and attending trade fairs and if these were included in the actual GTM plan or separate items.

When asked if they used publications in their GTM a majority, eight, of respondents did not use them.

“Not yet, there is a plan to do publications after we have results from studies” (interview 8)

One of them pointed out that even though they had conducted scientific research and some of this had been included in university studies they decided not to use them for the GTM plan in order to not release too much information to the market which competitors could benefit from.

“We did scientific and university publications and white papers but decided not to publish in order to not release too much information” (interview 5)

Of the two who did use publications for their GTM plan they both used magazine articles for industry publications and press releases on industry conferences. One of them had also managed to get interviews on local TV and the other one also published white papers on their web site.

Only one company did not include trade fairs and exhibitions into their GTM plan. The remaining nine were present at industry specific trade fairs. From them three companies mentioned Medica in Dusseldorf as their main annual focus fair.

“Yes, selective ones, 2-3 per year for finding partnerships and new customers” (interview 2)

The others participated range of smaller regional ones and there were no other common ones mentioned.

5.6 Clinical studies

For the five who did conduct clinical studies they all utilized them in their GTM plan. Two of them mentioned that they also conducted clinical studies in cooperation with their customers, one of them had been approached by customer with a new application idea and agreed to joint development based on positive results from clinical study.

“Yes, for CE Class IIb we used external organization for the research” (interview 6)

“Absolutely! 1st level clinical as part of RD, 2nd level pilots with potential customers” (interview 7)

Half the respondents stated they did not utilize clinical studies in their GTM plan. For them the reason was that their offering was not regulatory medical and for this reason they did not undertake any clinical studies.

5.7 Geographical market entry order and opening additional offices

There was a range of different ways to define the market entry sequence including purely geographical location, cultural similarities, where the market is and existing contacts.

Four respondents stated that geographical location was most important criteria, first they started in their own home country and then expanded to close by countries. One of them also utilized external consultant for confirming their GTM sequence. One of them pointed out cultural similarities within the close by areas as one of the reasons for their choice.

“Practical, stayed in Benelux as we are located there, then to France and Germany for close proximity” (interview 5)

“First after Finland to Germany due to close cultural similarity, due to volume to Asia where potential client’s daily rhythm is warped, market size is important but US legislation is scary so we leave it off” (interview 9)

Two respondents decided the countries to include in GTM plan based on language. For them both the criteria was English speaking countries. One of them still further decided on language and proximity in order to avoid issues with time zones.

“Finland is good for entry but then looked at languages and chose English speaking countries” (interview 8)

“English speaking market makes SW side easier, you can flip between different countries but English is spoken widely and UK because proximity and little time difference” (interview 4)

One of the other companies looked into where the global players for their industry were located and pilots established and based the results and experience from pilots on the regional importance for key players the final sequence was decided.

“Not geographical area but reach out to global players within the industries for piloting and this way gaining understanding which area is most important for global player and go according to that” (interview 7)

There was only one company who based the geographical sequence on where they had the existing contacts and past experience on.

“Based on likelihood and past knowledge of different markets to be able to utilize the advantages of the new product” (interview 3)

Two other companies first defined where majority of their potential customer would be located and chose these countries as their sequence. One of them did point out that they still excluded from this sequence the biggest ones as they deemed it would be very expensive to start the operation in them and for this reason selected some smaller markets.

For the plan of opening new offices outside home country there was equal split, half the companies had this planned into their GTM and half of them did not.

The ones who were not planning to open offices in additional countries were either leaving it to possible further expansion in the distant future or had made a GTM plan for expansion through partnerships and distribution channel. Three companies were relying heavily on using the distribution channel for all their sales outside the home country but two of them mentioned that they did leave open the option that in a few years' time in the future they might re-consider opening their own operations in the largest countries with highest revenues.

“Not yet, not in first five years, we will now work through distribution, find partners, finalize basic standard product version and modules suitable for offer for different businesses” (interview 9)

One of the companies who had included new offices into their GTM plan was going to start with local service partners for their cloud based service and managing them centrally for the first piloting phase and if successful then establishing the local office.

“We start in Europe with local cloud service in new countries as our solution is based on localized cloud service with easy integration, the machine room will be located in the country of operation due to information security laws, we can handle pilots remotely until we start the local office” (interview 6)

“Yes, after we find business” (interview 7)

“We will work through partners” (interview 1)

Also one of the other companies with the plan was tying this together with success from initial pilots. Reason for one to open an overseas office was for obtaining easier funding in another country but they were not actively using it for GTM.

5.8 Using formal planning models

The participants were asked if they utilized any formal planning models for their GTM strategy. Majority, seven, of participants had used some model and two none. One respondent had tried some canvases but concluded that due to the disruptive nature of their business area it was not possible to find a model that would work but instead they opted for trying out different approaches in practice rather than formal modelling.

“Tried to use canvas but most of the time it was not relevant, disruptive technology and market makes it hard to compare so just trying out tends to work best” (interview 2)

The most popular formal model used was business canvas which was specified by three companies. Two of them used the canvas as their only model. SWOT was utilized by two companies, one of them combined this with lean and canvas.

“We did SWOT, some canvassing, SWOT is standardized and easy to understand, we also applied LEAN for very quick short cycles of development” (interview 5)

One company focused solely on lean service creation model.

6 Discussion

There were two key factors influencing the Go-To-Market planning for the startups interviewed which were co-development with customers and potential customers and financial constraints. Often a good business idea may start as part of a more established business and then of course there is a customer involved originally. Also, it is becoming increasingly more important that a proper level of customer engagement is formed very early on in the company's life span also due to the purposes of attracting further finance as the investors requirements are for early proof. For these reasons it is quite easy to see why these two factors were brought up by many of the respondents. This is also what Maurya highlights that customers should be brought into the development process at the very early stages (Maurya 2016 p 80-81).

It is also seen increasingly important that the customer is brought into the product creation process and service design process for making sure that the solution is attractive to potential customers and the testing of the concept ongoing part of the processes. As one of the pitfalls in “staying in the lab” for too long time and finalizing the concept and solution is that critical time to market can be lost if the solution is not when finished attractive enough for the potential customers. This again is exactly what Maurya recommends so quite in line with what is happening (Maurya 2016 p 80-81).

The difficulties and uncertainties in the financing side are familiar to majority of entrepreneurs in startups. Mostly they use their own capital and work as the initial inputs but in most cases additional investment is required relatively early on in the company's life time. Also as mostly in the early phases there is no incoming revenue for additional finance of the operation the main source is finding external financing in the form of loans or investment.

Finding the external investor or lender is not simple either. There are many startups seeking the funding from same sources so there is extensive competition. Also, for receiving most additional funding the startup is expected to have their business plan and earnings model well thought out, evidence on their solution working and evidence on customer potential or pilot customers so the requirements can be quite extensive.

As pointed out by many this creates constraints on the GTM planning also from the point of view that the implementation of the plan requires resources and money. The lack of these will of course easily have an impact on the time schedules, possible activities and whether it is possible to actually implement what is required for the success of the enterprise.

6.1 Market research and opinion leaders

Many respondents regarded market research the same as seeking other customer feedback. Perhaps this is the case today and especially in startup world where many companies do not have the resources for traditional market research studies which are either conducted by company marketing departments or external market research companies. This is quite in line with what Christensen writes on disruptive technology needing

learning and discovery and not fixed execution (Christensen 1997 p 117). So instead of the traditional market research many of the companies studied aim to involve either a co-development customer or directly contact other potential customers for ongoing discussion. Whether these activities are more market research or actual sales or pre-sales is probably another question and in most cases they cannot be separated. As Ries claims that relying too heavily on market research is one of the main reason for startups to fail seeking customer feedback instead could be a good way to more reliable results (Ries 2011 p 18-19). It is however hard to say if this is the reason for not conducting market research or if it is just the lack of money.

Out of the respondents only two had used external resources for conducting any studies and in both cases they were free-of-charge cooperations with education and government backed up partners. Of course it is quite clear also that with limited funds spending money on external market research company or consultants would not be the most efficient expenditure but instead going for direct early customer engagement and possible pilot customers making it closer towards the actual sales start is for many preferred way.

Due to the lack of marketing budget it is also quite understandable that most respondents aimed at locating and approaching the individuals who were seen as opinion leaders with influence on their solution area. This is also what Moore advises that the opinion leaders, innovators, should be recognized and used as reference for attracting additional customers (Moore 2001 p 10-13). Locating the opinion leaders can be done with limited resources and also the opinion leaders in high tech also need to possess some interest towards new solutions and disruptive technologies if they wish to be seen as opinion leaders. This works well towards the benefit of startup with new ideas and approach but of course the solution has to be genuinely convincing in order to attract the attention of these individuals but once successful it can then be utilized as further reference.

It was however quite clear that locating the opinion leaders is not always an easy task and especially when trying to do this outside their own country for further geographical expansion it was often challenging. For new technologies it can also be demanding because in many areas due to digitalization and disruptive technologies emerging it may also be difficult to find persons who have been the opinion leaders at the era prior to the disruption and can still be deemed as opinion leaders with the changing business area. Perhaps in many cases the future opinion leaders will be different from the past ones.

6.2 Publications and presence

What was quite surprising was the lack of publications as part of the GTM. As all the companies were health and wellness area companies it could be expected that many of them would use publications in their promotion and part of the GTM. Although many reported that they were planning to use the studies at a later stage in their GTM plan it was surprising that there were not even any early stage results they would have included.

Around half the respondents did however use results from clinical studies in their GTM. Perhaps using the studies as such and not using them in publications is also a resource question or perhaps the research and development personnel do not have the academic connections or motivation for this.

Almost everybody included trade fairs into their GTM so there were no surprises here. Only three respondents participated in Medica which is the largest European fair but as it is also quite expensive to attend this is quite understandable. Physical presence at trade fairs however seems to be still very important for finding further partners and customers. Perhaps for health and wellness area companies it is also essential to be in local as well as global exhibitions as the operating area in different countries is also quite different and decision making is often done on wide area of locations instead of in a centralized way so having the advocates across different organizations is required.

6.3 Geographical market entry sequence and additional offices

For the market entry sequence there was a spread of replies ranging from where the respondents had contacts to where the biggest markets were. This could be still as simple as for four who based on physical vicinity decided on expansion to their neighbouring countries and additional two based the expansion on language. Of course especially with software based solution the language barriers can be higher, depending on the complexity of the solution and the amount of data to be translated for this. Also for cost reasons expansions close by may be seen more tempting rather than expansion to further areas. One of the claims stating cultural similarities does apply between some countries but there can also be quite large differences depending on the geographical location so as such the claim is not widely applicable. The considerations on preferences, business

culture, regulations and currency stated by Kotler and Keller were not brought up by any of the respondents (Kotler & Keller, 2016, p 241).

There was only one respondent who looked into where most of the global players were located which of course shows where market is more mature and hence has more money already available. For disruptive technology of course it may be a hindrance if there is lack of industry and market needs to be cultivated which may be expensive and take long time. However, entering a market with established players can also be risky because the competition is more extensive and it may be difficult to enter the market as a startup with limited resources. Perhaps partnering with the existing companies on the market could be an option? And also, there are always some startups which manage to start with the high enough funding for challenging the competition already on the market.

Only half the respondents had included the opening of additional offices as part of their GTM plan. This may be explained by the factors as earlier; limited funding, too early stage as still in development and perhaps trying to find the first few customer cases first. As the opening of new operations and locating personnel in more than one site adds both strain on financing and complexity of operation it may require higher visibility on the future revenue. Also as the current communications methods make the correspondence simpler and people in general speak English well in many countries it is perhaps too easy to push out the plan for market entry. This may cause losing revenue which of course is transparent as it never existed in the first place and for this reason is not realized but due to late entry in worst case it might give somebody else the advantage of early market entry and even a chance to copy the solution and making it a success.

Many of the respondents planned to utilize a distribution network instead of local presence which depending on the solution could be an option. In the longer run though on the major markets it might not be the optimal solution.

6.4 Using formal models for GTM

In the study seven respondents stated that they used formal planning models like canvases, SWOT or lean or combination for the GTM plan. According to Maurya using a business model canvas can be a very efficient way for evaluating different business models (Maurya 2016 p 58-60). It is however quite hard to say if utilizing models happened

in reality to quite this many respondents. Based on the pause before the reply for some of them it may be that even if they were aware of some models they might not have been actively used. Based on this it could be that lower percentage than claimed had actually utilized the models in reality. Some claimed that they had tried to use the models but that found them not applicable. Those few who had participated in startup incubators and programs seemed quite familiar with the models and when describing the combinations they utilized seemed quite genuine in their claims.

As we did not use other formal models for planning our GTM than SWOT I would now definitely think that a simple lean canvas would have been a good choice for us as well. In many cases formal models can be very helpful and perhaps should benefit many other companies than startups in disruptive technologies as well.

7 Conclusions

There are various components most companies include in their GTM plans. These were trade fairs, locating the opinion leaders and seeking customer feedback. On the other hand, very few used publications, conducted market research or used formal models in their planning. Additionally the approach for geographic sequence for new markets to enter had a variety of methods and many of the interviewees had not finalized the planning for opening offices in other countries.

The major startup specific factors in planning stated by most of the respondents were requirement for co-development with first customer and lack and uncertainty of finance. Not quite surprising perhaps and I myself definitely agree as money is always scarce, you have to take it into account while planning the GTM activities and schedules. Also, it is very important to try and engage the first customers on as early stage as possible for both obtaining additional funding and for making sure the solution when entering the market has a genuine requirement as well as is suitable for larger scale usage by potential customers.

Based on the articles, books and interviews it was quite evident that there really is no easy to use formula on how to get the GTM strategy right. There are just pointers on what should be taken into consideration, which are the most common areas to cover and various examples of unsuccessful attempts as well as a few successes. Still by and large it is a question on making subjective decisions on what is important for your company,

the constraints affecting it, disruptiveness of technology, competition and many other internal and external factors. I do not believe that much more theoretical input should be included into drafting our plan but that we need to be able to keep the timing as flexible as possible and also making sure we keep very close eye on what competition is working on in the meanwhile. Still in the end I personally believe that for really making it a success you do need some luck.

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