2017

MedHUB

PRE-ANALYSIS REPORT

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Executive summary

MedTech Innovation (MTI) has over the past years observed a need for a more structured effort to support for Danish medtech companies and academic stakeholders to establish, connect and develop their activities in the single largest medical device market in the world; being USA.

Pilot projects[1] held in Medtech Innovation, have demonstrated great value for the participating companies. However, in the collective feedback participants have also expressed a need for more continuity in their engagement with US market access specialists. Furthermore, from our research in the medical device community in Denmark, we have found that even established companies' experiences challenges in filtering their options and pathways to the US market. In the academic sphere, access to leading US research entities is also sought after, by both companies and academia from Denmark.

Therefore MTI set out to assess the need in the medical device community for a dedicated medical device platform that on a continuous basis support commercial, regulatory and academic activities in the medical device space to the US.

There are several initiatives that support general export and startup activities to the US market across a broad span of industries. Within life science, there are even specially oriented initiatives. However, biotech, pharma and medical devices differ greatly in both R&D and commercial tasks and pathways. Biotech and pharma are typically linear processes with a long and extremely expensive development horizon whereas medical devices in contrast requires multiple professional disciplines (software, mechanics, electronics, material science, usability engineering etc.) and generally have shorter time to market.

Therefore, MTI has developed a hypothesis that:

> *A dedicated medical device focused hub in the US will greatly benefit Danish medical device stakeholders in their continuous effort to develop and expand their commercial and academic activities in the US.*

To test the hypothesis, MTI asked dedicated members and the extended medical device community in Denmark, counting more than 1,700 individuals. MTI received qualified feedback from more than 200 individuals to substantiate the findings and conclusions in this report. In conjunction with the survey, the project team also researched and mapped out the pool of Danish medical device companies and academic institutions with a focus or potential to work/cooperate in the USA.

The results clearly proved the proposed hypothesis and added several additional value drivers supporting the notion to separate biotech from medical device and provide a dedicated effort for medical device activities. Based on this, the report recommends assessing the possibilities to set up and finance a US based Medtech hub supporting Danish medical device stakeholders' commercial and academic activities.

The findings have a strong correlation with the recently published report from the Danish government's life science growth team's 17 recommendations for strengthening the life science sector in Denmark. A commentary on these are thus included in the pre-analysis report.

[1] BSR (Baltic Sea Region – internationalization projects) and ERFA meetings (special interest groups; with focus on the US market and FDA approvals in MTI).

Background

Denmark has an internationally renowned life science industry fronted by companies such as Novo Nordisk, Lundbeck, Leo Pharma, Coloplast, AMBU and Radiometer. Partly because of their respective market leadership and partly because of Denmark's long-time tradition for developing high quality user-centric products, services and solutions. Strong industry locomotives foster a strong underground of smaller companies either as followers (spins-outs or ex-employees starting their own businesses) or as sub-suppliers to the bigger companies and then of course the service providers making a living on their specialist knowledge supporting the field.

Medical Device Focus

In this report, the focus is purely on medical device companies. In most other analyses, initiatives and activities medical devices are put under the umbrella of life sciences. But medical devices differ greatly from their bigger "siblings" in terms of best practices for R&D and commercial development. It is the belief that a strong and dedicated focus on the challenges and opportunities of the Danish medical devices activities are in place now.

According to Medicoindustrien[2] there exist approximately 200 pure device companies in Denmark. However, the surrounding eco-system counts close to 1,500 companies involved as service providers, sub-suppliers or semi-device manufacturers[3]. The medtech companies reported revenues in 2015 of 60b DKK, app 1/3 of the total revenue of the Danish life science sector. In Denmark, the medtech companies employ app. 10,000 employees which is ¼ of the total FTE's in Denmark in the life science industry in total. On average, the medical device sector exports 95% of total sales. Over the past 25 years, the life science's share of total export has increased from 4% in 1989 to 17% in 2016. The Danish government has noticed the strength and financial impact of the life science industry to the Danish economy and have recently commissioned a panel of life science experts to come up with recommendations that can support a doubling of revenues in the Danish life science sector by 2025. The recommendations will be further analyzed later in this report.

The general Pareto rule can be applied that 80% of the value creation, export and employment stem from the top-20 medical device companies. However, these industry leaders depend on the surrounding eco-system when talking recruitment, knowledge-sharing, flexibility and outsourcing. The many small companies also rely on the bigger players for the same reasons as well as role models, inspiration and quasi references when approaching new clients or research partners (clinically / academically).

A Strong Industry

Danish politicians often taken pride in our strong medical device sector and reference them as a huge success story and value driver for the Danish economy (along the pharma/biotech and hearing aid industry). It is therefore important to maintain the strong medical device industry and support the many new initiatives that consolidated drive future growth and sustainability for this sector.

Part of this is also startups and academic projects both clinically and technology-wise. In a recent informal survey among DTU[4]'s departments it was established that well above 80% of their 20+ departments have research projects and activities in the medical device sector, either internally and in cooperation with

[2] The association of Danish medical device companies
[3] Where less than 100% of the revenue stem from medical devices; e.g. an engineering company
[4] Technical University of Denmark

industry partners. In parallel, over the past five years the clinical ecosystem has experienced a strong growth in innovation projects that not only improve care but also foster commercial end-points.

Drivers of growth

Growth require a strong home-turf to grow from but also a big market to expand in. In most cases, Denmark offer a great home-turf as a developed country with a strong healthcare system. However, Denmark does not offer a large market potential. Most medical device companies must look outside the borders to identify long-term and sustainable growth potential. The typical pathway is to look at the near-by markets such as Sweden, Norway, Germany and sometimes even Great Britain. It is in close proximity and thus easier to control. In terms of market potential, there is however only one market that supersedes all other market together. The US market, due to their world leading healthcare spend, represent more than 50% of all medical device turnover. But this market is far away and the legislation and healthcare system differ from what we know in Denmark and the before-mentioned near-markets.

The Big Unserved Need

Over the past years, MTI has held several events and lead projects in which several hundred device stakeholders (academics, clinicians and business professional) have been in dialogue. Talk of the town often centers around the US market, what is best practice, who knows who and what are the opportunities over there? Over time, the dialogue has led to the idea that a more structured approach to the US within especially "market access"[5]. Funded through Innovation Express funds available to MTI, three projects have headed visits to the US for interested companies, clinicians and academics interested in learning more about US Market Access and establishing network in the US.

The findings further established the need for a more structured and dedicated effort to help Danish medical device interests to excel in the largest medical device market, the US. Not only those companies and projects that already have the US on the radar, but also motivating companies and projects that find US market access too challenging for various reasons. If combining the strengths and knowledge embedded among Danish medical device interests can unleash additional and passive potential, then this is all worth it to strengthen the sector.

In support of this argument we would like to draw the attention to two recent reports that demonstrates the benefits of challenging your company on new export ventures. One analysis[6] showed that companies that challenge themselves with (new) export activities statistically tend to grow more than peers that try to grow within the current market places. In fact, 68% of companies trying out new markets showed stronger growth whereas only 28% of companies sticking to existing markets experienced increased revenue. The other study[7] by Aarhus University and the Export Association identified five critical success factors for exporting companies. Besides cost, HR, efficacy and quality, the more novel finding was the importance of a strong network to be successful. The report concludes that peer-based best practice networking must be further supported in the future for Danish companies to strengthen their competitive edge and growth.

[5] Market Access typically includes regulatory affairs, reimbursement, distribution set-up, pricing, healthcare economics and other activities required to go-to-market

[6] "Virksomheder, som satser, vinder" ("Companies that gambles, wins") Berlingske, 11 November 2014

[7] Virksomheder skal lære af den succesfulde eksportkerne (Companies must learn from the successful export crux) Berlingske, 21 January 2015.

The hypothesis

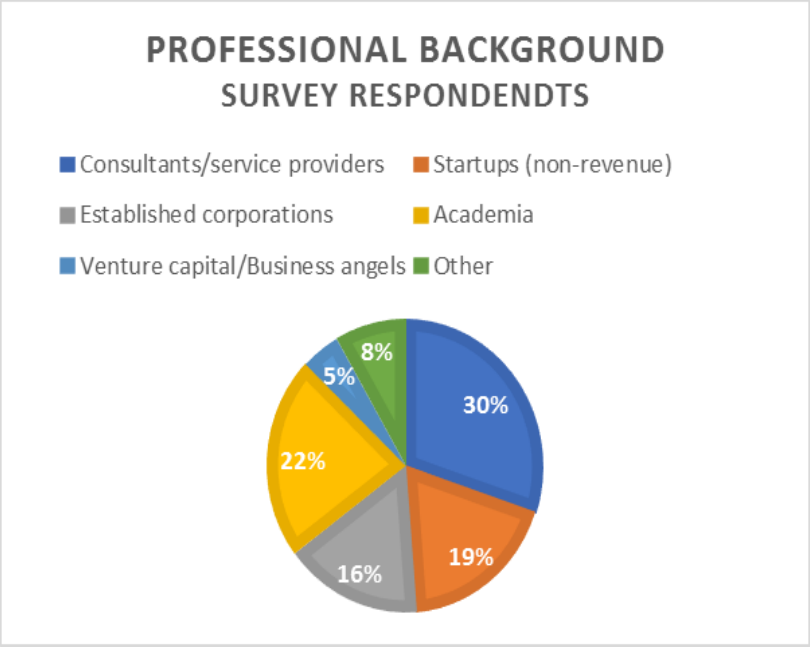
MTI set out to investigate the demand for a dedicated effort to support Danish medical device companies' and projects' activities in the single largest medical device market, USA. A hypothesis was developed and a project team was engaged to test the hypothesis:

> *A dedicated medical device focused hub in the US will greatly benefit Danish medical device stakeholders in their continuous effort to develop and expand their commercial and academic activities in the US.*

Research Methodology

To test the above hypothesis, it was decided to conduct a combined qualitative and quantitative research analyses aimed at the Danish medical device stakeholder representing commercial, academic and clinical stakeholders from all regions of Denmark.

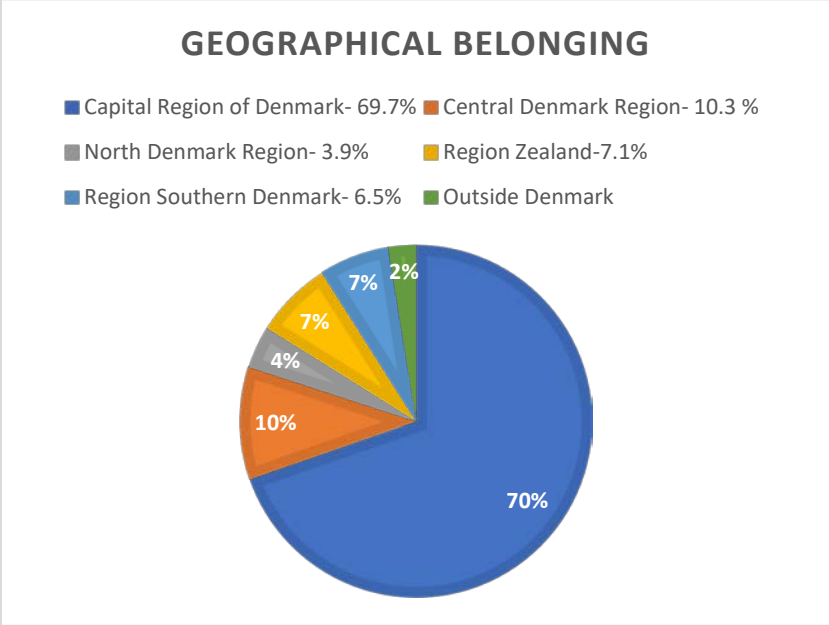
At first, seven individuals representing the target group broadly were interviewed using a semi-structured questionnaire. The feedback was used help set-up and pilot test the subsequent quantitative questionnaire that was sent out to 1,845 medical device stakeholders. 172 responses were registered (9,3% response rate) which is considered statistically representative. The respondents represented the following backgrounds and geographical belongings.



65% represents commercial entities whereas 22% stem from the academic (including clinical) ecosystem. 5% of responses came from the financial environment that support especially the new activities and the remaining 8% came from a varied group of stakeholders such as public authorities, trade council, industry associations and others.

We find this distribution represent the entire Danish ecosystem of medical device stakeholders very well.

From a geographical viewpoint, it is often said that most Danish medical device activities are headed out of Greater Copenhagen. Up to 80% have been mentioned. Responses support this, showing nearly 70% of responses from the Capital Region followed by 10% from the second largest Danish region. There are no big surprises in the distribution but it should be pointed out that 2% of respondents are based outside Denmark. We believe "external" input support the validity of the analyses, especially because those responses most likely stem from posted business professional or researchers with a Danish background.



The questionnaire was sent out to individuals who have previously either signed up to MTI's newsletter or attended MTI events around the country coupled with individuals from the LinkedIn group.

The questionnaire was open for 14 days and based upon the results follow-up qualitative interviews were conducted both with individuals and as a focus group.

In total 29 respondents[8], have been interviewed with open-ended questions for this analysis.

[8] Please refer to Appendix 1 for a list of respondents (qualitative interviews)

Survey findings

The overall survey findings can be distributed into the following four areas:

1. The importance of the US healthcare market
2. Challenges facing Danish stakeholders in the US
3. The necessity of a strict and dedicated focus on medical devices
4. The opportunities and strength of peer-to-peer knowledge sharing

In this section, we will examine the findings in more detail supported by both the quantitative survey response as well as the feedback from the qualitative interviews.

1) The Importance of the US Health Care market

From the initial qualitative interviews, we discovered that everyone recognizes the significance of the US market for companies' long-term business potential. However, many respondents expressed frustration when it came to getting their heads around the US market access, both as newcomers but also as established corporations. Therefore, it is often considered the best avenue to start out with the home market and slowly expand via near-markets before even considering the US market. We therefore set out to ask respondents in the survey whether the US market was part of their current strategy or activities.

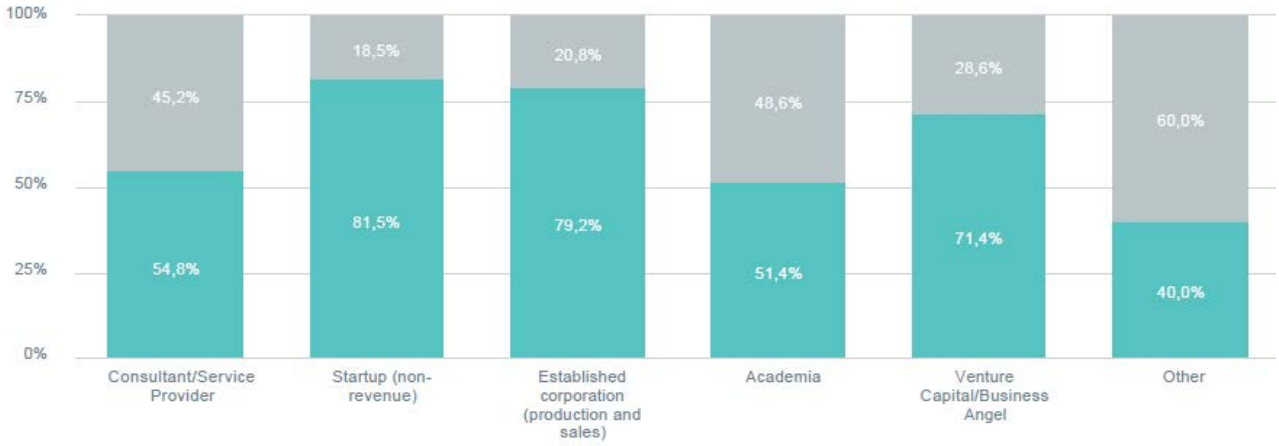
63% of total respondents answered yes to that question. Looking close at this number, we see that the "product commercial" segments "startups" and "established corporations" pushes even higher rates in respectively 82% and 80%. But even within service providers that mostly focus at the Danish market more than half (55%) answers that the US is part of their current strategy/activities.

Venture and business angels answer 71% - a number that would be expected to be closer to the startup segment.

Academic respondents do not see the same significance. Those we spoke to do see a value in US research projects but grants are easier to get from Danish and EU based funds which to a high degree dictates their geographic focus.

These high percentages indeed support the notion that startups, established and venture capital, the demographic groups that are of more interest in the Medtech hub, all agree mutually in having a focus on the US market, and they do so to the extent to have it be part of current operations and strategy.

Below illustrated the cross referencing of the two questions. The turquoise color representing the respondents answering yes.



When asked why the US is an important market for Danish companies the answer is:

- Market size/potential
- Homogeneous regulations
- Reference factor

Even though we can register a high market importance rating, we wonder why not all respondents include the US market in their strategy, at least as a market to explore at a later stage. We asked at the follow-up interviews. The main reasons were:

- It is too difficult to even plan for
- It requires way more cash than accessible
- They feel they are too small to even think about the US market

These reasons are all valid but they are at the same time of a character that can be eased by external support and more focused networking.

This means that even though we already see a significant share of respondents having US as part of their strategy, there is room to increase this number even further.

"There is no doubt that the US present by far the largest market opportunity but we are just way too small yet to approach the US market, we do not have all the specialists needed nor enough cash to invest. But once we have, we will start making plans [for the US]"

Co-founder,
Danish medical device company having recently launched their first product in selected near-markets

The US market in comparison to other markets

Respondents were asked to score the following markets from 1-5 according to their perceived importance. The Nordics, the rest of EU, USA, Asia, and South America.

When comparing the responses for each market within each demographic background, and only taking the scorings; 5 (very important) and 4 (important) into account, the landscapes looks as follows:

Percentage of respondents whom answered 5 or 4 in scoring the markets importance

	Startups	Established	Academia	Venture Capital	Consultants & Svc Providers	Other
Nordics	62.9%	66.7%	81.2%	66.7%	65%	80%
Rest of EU	85.1%	75%	75%	100%	69.2%	60%
USA	88.9%	75%	59.4%	66.7%	56.4%	70%
Asia	37%	37.5%	21.8%	0%	28.2%	20%
South America	14.8%	16.6%	0%	0%	12.7%	0%

From the table above, it is evident that startups weigh the US market very high and even higher than the rest of EU. Reason could very well be the sheer market size that one gains access to once the regulatory approval has been reached. In comparison, the EU market is still quite fragmented to approach with each region/country still having their own systems of reimbursement, cultures and barriers to adopt etc.

For established companies the EU and US weigh in at the same level. Followed by the Nordics. The picture looks quite different with regards to academia. Here the Nordics and the rest of EU take front seat to a third place for the US. This is not surprising however, as research grants and partnerships are more incentivized by the Horizon 2020 program within the European borders.

For the venture capital respondents, the numbers are a bit different, with the Nordics and US sharing a second place whereas the rest of EU takes a clear first place. It is still very much in the VC's optics to gain a market foothold within EU.

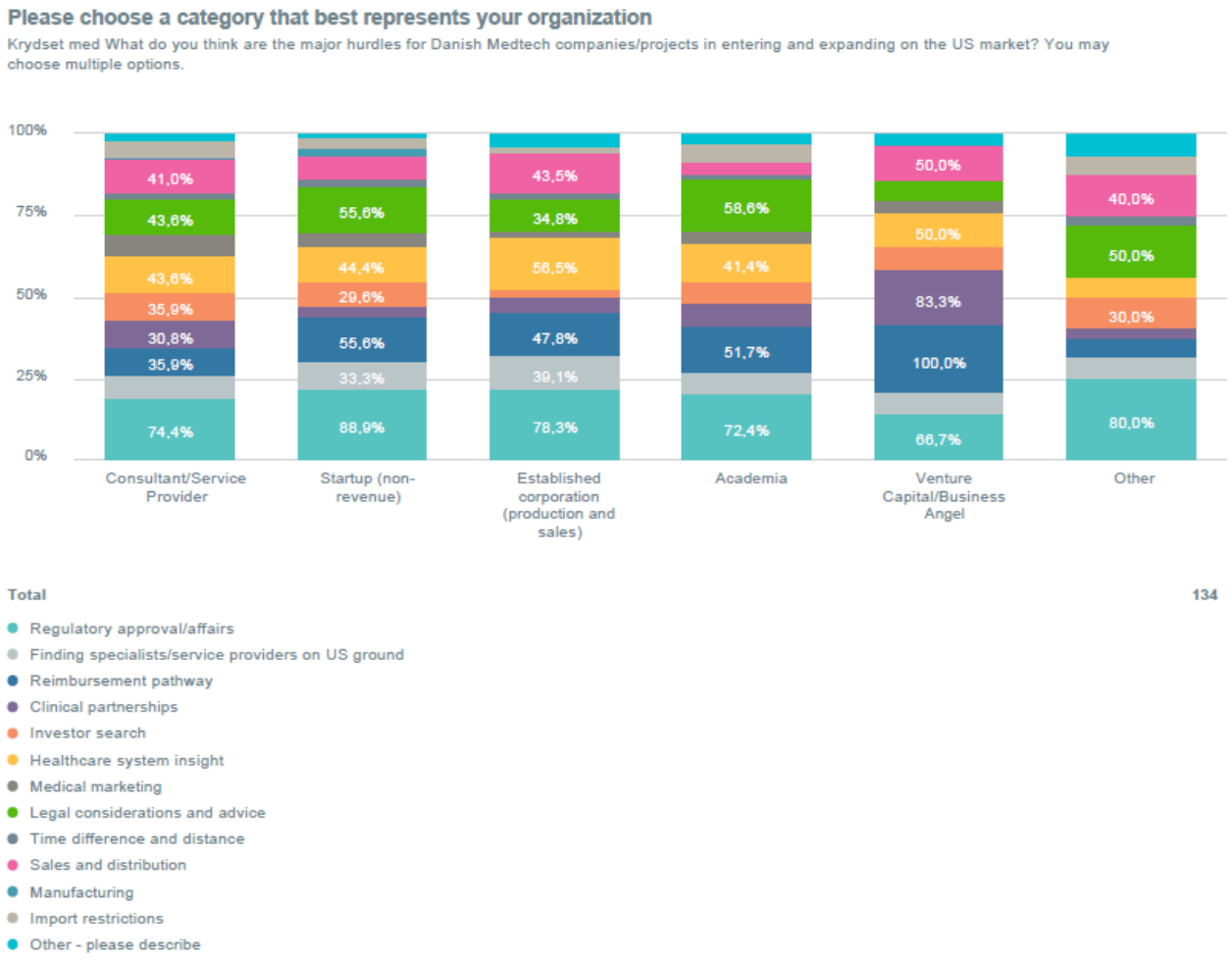
We asked respondents in follow-up interviews about the cultural and language barriers when it comes to rating "perceived importance". It stood out that the higher the barriers, the less perceived importance. In the dialogue, we also learned that the less exposure to the respective markets, the higher the anticipated barriers – and thus lower importance. This may well explain the significantly lower numbers for Asia and especially South America. On the other hand, this also indirectly mean that the more continuous exposure to a (new) market, the lower barriers and the higher importance. We do not have statistical evidence supporting this hypothesis, but from the qualitative interviews we sure felt that the comfort-zone factor has a saying too.

From Statistics Denmark, we have furthermore learned that 30% (=32b DKK) of Danish life science export goes to North America and shows an annual growth rate of 13% thus standing out to Europe's life science export growth rate of only 3% (however total export share is larger; 40%).

2. Challenges Facing Danish Medical Device Stakeholders in the US

Although everyone agrees that the US market is by default the most important medical device market in the world we also registered red flags withholding companies from starting out in this important market. We therefore set out to investigate the challenges in US market access in more detail.

After scoring the markets in their importance, survey respondents were asked to check from a list the major hurdles they envision for Danish Medtech companies/projects in entering and expanding on the US market.



The top-3 general challenges

1) Regulatory affairs
2) Reimbursement pathway
3) Healthcare system insight

The first two presents great business case risks whereas the third topic; health care system insight caters to the lack of comfort entering unknown territory.

These are again very significant numbers proving that even though there is a great market potential, there are also very valid reasons to withstand the temptation of approaching “the wonderland of medical devices”. But again, the perceived challenges can all be alleviated by systematic and dedicated support in the area.

88.9% of the startup respondents chose “Regulatory approval” as the top and main hurdle for them to overcome. On a shared second place was reimbursement pathway and legal considerations and advice. Coming in on a third place was Healthcare system insight, and on a fourth was finding specialist/service providers on US ground.

Interestingly the respondents from established industries had a slightly different prioritization of major hurdles. With a clear first place, was again regulatory approvals, second place reimbursement, but on a close third place healthcare systems insight. Fourth place were sales and distributions – which of course is more relevant to an established company than to a startup.

In comparing the two demographic groups against each other on their prioritizations, Interestingly the established corporations may have some experienced insight on the longer perspective with regards to experienced hurdles. Naturally, having fine-tuned processes over the years with multiple product launches on the US market they may have adopted the perspective that sales and distributions require much more investment than many startups may think initially.

The venture capitalists and business angel prioritizes the reimbursement pathway. This is for a good reason. A company may develop a great product that achieves regulatory approval. However, outside the US only little emphasis is paid upon reimbursement. If the reimbursement does not cover the cost of using the device you do not have a market, except maybe for a few researchers.

From qualitative interviews, we have learned that the VC's are generally more broadly exposed to several business cases that have approached the US market, also the failures that have cost them a lot of money. It is a learning that should be disseminated to all other device companies in their approach to the US because it can have fatal consequences if the product design dictates an existing reimbursement class that does not support the business case.

> *"I have seen several European companies that have successfully launched in Europe and even made sure that regulatory demands from the FDA are in compliance, but when approaching US market launch they find out that they have designed a product which reimbursement does not support their US business case and thus needs to either redesign a US version from scratch or give up on the US market… "*
>
> **Kermit Nash**,
> US based corporate counsel specialized in medical devices

Interestingly, academia also acknowledges the need for thorough understanding of the regulatory system. This is because even research projects must comply with certain FDA or local authority regulated requirements.

Distance and time difference

Although the survey did not report significant challenges in the major time difference and long travel distance between Denmark and the US, the interviews painted a different picture.

In this it was noted that it was almost impossible to work with California/West Coast due to the 9 hours' difference. However, 6-7 hours (East Coast and Midwest) are considered more manageable. Distance is also a challenge. You do not want to spend a day each way for a single meeting. However, one respondent mention that Danes tend to worry too much about travelling time. In the US, it is not abnormal to go from New York to San Diego for a single meeting even though this also takes two days of travel. And if you want to do business in the US, you better learn to live with lots of transport time.

It is not a surprise to learn that established companies that have a subsidiary or a distribution partner in the US did not worry as much about the travel time nor distance. However, when asked for ideal logistical locations, East coast and Midwest were preferred alternatives.

3. The necessity of strict and dedicated focus on medical devices

Based on the survey results on challenges we saw a clear picture of matters related to medical device specific challenges. We therefore set out to discuss this in follow-up interviews.

It very quickly became evident that all people interviewed feels that medical devices tends to be forgotten in the big "life science" category. And this even to a point that annoys the stakeholders because they feel the attention is always put on the biotech/pharma activities. As examples the following were mentioned; Medical Valley Alliance, DI (Confederation of Danish Industries), Trade Council/Innovation Center Denmark.

"You cannot serve both device companies and biotech/pharma companies with the same support offerings. The processes and pathways differ too much and the time horizon and the budgets are very different too"

CEO,
Serial Entrepreneur in medical devices

The argument is that medical device encompasses multiple disciplines such as electronics, mechanics, material science, software, IT, IoT, UX experts etc. The validation process also differs although the overall legislation may be the same.

From a R&D perspective, there is also a huge difference. Biotech/pharma tends to follow a (long) linear step-by-step approach whereas the device pathway is much more iterative and shorter. Therefore, the is a strong wish for more dedicated support within the medical device field.

During the focus group interview, it was argued that all medical devices contain some form of IT/software and that within long most devices will have their own IP address. This just adds to the difference between drugs and devices. When thinking of the US, the focus groups related this matter to a specific challenge. Medtech SME's from Denmark will have a hard time getting in touch with the right people in the telecom industry in the US. A focused effort combining the strength of several SME's would surely increase the likelihood of being heard.

Even on the funding side, there is a huge difference between medical device and pharma/biotech. The clinical trials for drugs are much more expensive and lasts longer. Patient investors willing to risk the big bets play the pharma game whereas the investors with shorter investment horizons focus on the device ventures. Therefore, helping Danish companies raise funds for US activities require a dedication to medical device to establish and maintain the specific network for medical devices.

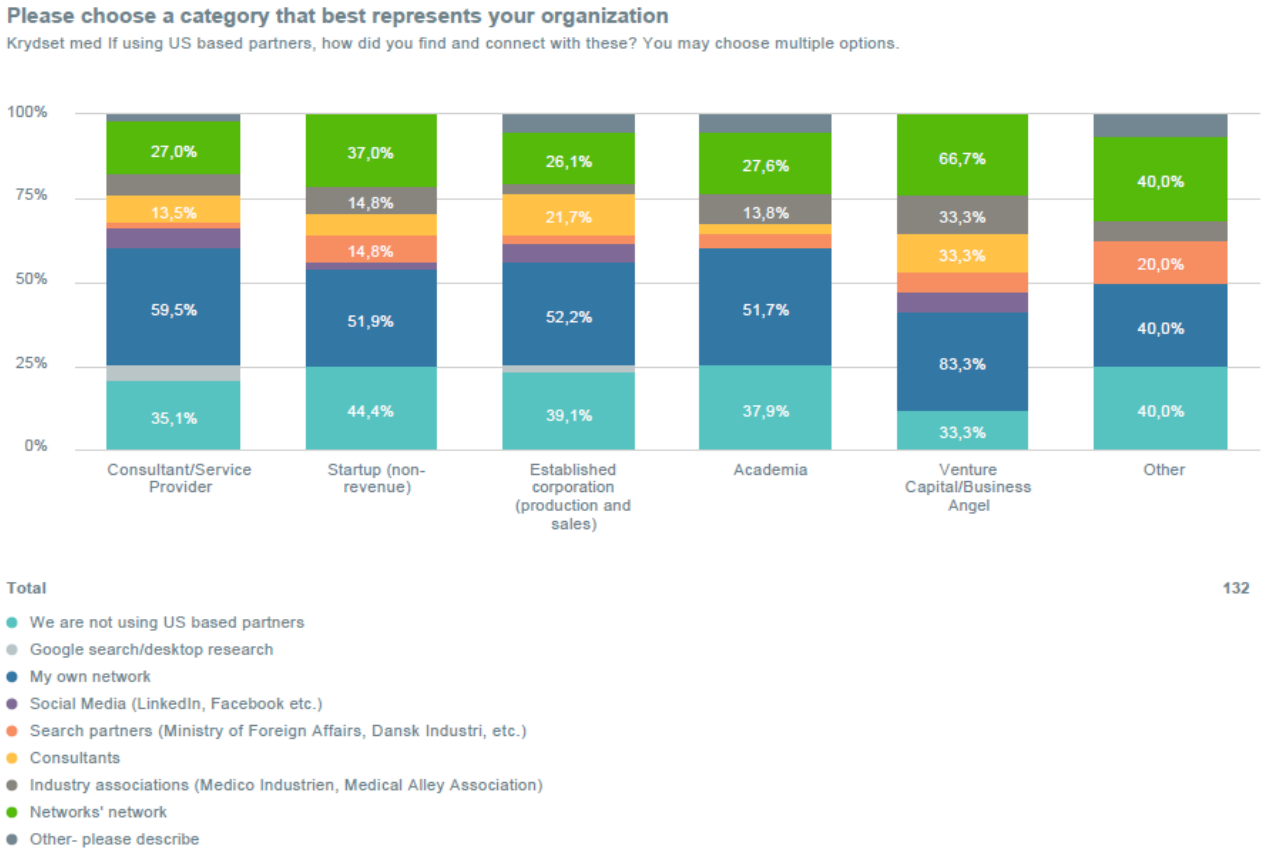
Going to market is the last element mentioned that differs from biotech/pharma. Drugs get a new drug approval that automatically provides exclusivity whereas a device needs to fight for each customer after approval. The entire mindset behind going-to-market is different and for devices tend to be more "box-mover" oriented (especially when it comes to technical support) than pharma

During the interview, we did however learn that a few initiatives do in fact cater for the dedicated focus on medical devices, where especially Medicoindustrien (Danish Medical Device Association) was mentioned several times.

Case
A large Danish pharma company decided years ago to launch a medical device product to support their core business. The project team assembled for this purpose all came from the existing (pharma) organization. They applied best practice pathways and processes from pharma development resulting in over-engineering both QA and RA processes. External specialists gave up on the project due to extreme documentation requirements. Project was delivered way above cost and with a huge delay. Subsequent versions of the device have since been completely outsourced to external development partners.

4. The opportunities and strength of peer-to-peer knowledge sharing

From the previous cited analyses[9] we learned that networking is a determinant for successful export. This was indirectly proven in our analyses when we asked the respondents in the survey and in the interviews about how they find and connect with US based partners.



55% answered that their own network led them to their new partner. Closely followed by 32% saying that it was their 2nd circle of network (network's network). In contrast, the internet offers apparently only little help; 3% turn to online searches and 6% to social media. 1 out of 8 turn to an industry association to seek help, which can be added to the category network. The reason here fore is that during the qualitative interviews we learned that the reason why people find their long-distance based advisors, partners etc. is that they need some proof of trust before engaging with a person or company they have otherwise little chance to validate before-hand.

"…if someone in my close network, whom I trust, have had a successful partnership with a give consultant, then there is a good chance that I will not be disappointed. This is instant validation. The other way around, I would never hesitate telling the truth if I have had a bad experience…not in order to "get back" but rather to ensure others do not risk a similar experience"

CEO, established company with several US based commercial partnerships

[9] Virksomheder skal lære af den succesfulde eksportkerne (Companies must learn from the successful export crux) Berlingske, 21 January 2015.

"I trust peers more than advisors and consultants"

The second learning from the interviews about the value of networking is that the medical device stakeholders regard recommendations from peers of higher value than introductions from advisors of the simple reason that the latter is biased towards making more money.

When asked which type of networking events provided the highest value most responded the ones where most attendees are not there to sell but to learn and share. It must be emphasized that our analysis does not report a general distrust in the quality delivered by service providers but rather ranks the value of peer-to-peer networking extremely high. This can be illustrated by other feedbacks to the same questions as above, where several people responded that the most valuable networking event they have ever participated in were those where a specialist either inspired them or improved their knowledge on certain topics.

Case

A Danish company have been selling their products to the US for more than 25 years without the need for a 510(k) approval. In the lack of a regulatory function, they very late discovered that the FDA planned to include their product type under new legislation giving companies one year to obtain retrospective approvals. The company discovered this with only 6 months left. They hired a Danish based FDA advisor based on a google search. They were able to submit their 510(k) application but were turned down by the FDA resulting in a market exclusion lasting more than one year. Via network they identified a US based FDA specialist to help them get their 510(k)-approval allowing them back on the market.

Together we are stronger!

As a third learning from the interviews were the fact that the stakeholders highly recommended delegation visits, not only to learn but also to increase exposure to Danish projects and companies. When travelling as a group, companies and hospitals tend to be more open towards visits and meetings they would otherwise not offer. Especially small companies enjoy the feeling of "together, we are stronger" in the sense that they are taken more seriously when being part of a bigger group. Larger, established companies also enjoy the delegation visits but for a different reason. They normally do not have problem setting up the visits to the stakeholders they want to meet but being part of a delegation visit offer them anonymity where the can ask more "free" questions and at the same time view the same situation through the lenses of other peers instead of the lenses of other colleagues.

As described in a previous section, one of the major red flags are regulatory affairs when thinking about US market access.

We assessed how many companies have achieved a 510(k) over the past three years. The result is that 50 approvals have been granted to 27 companies since 2014[10].

This is very useful information to fuel networking activities of high value which can be easily facilitated. Imagine motivating just five people from these companies to step up and tell their story as free advice to the hundreds of Danish medical device projects that have the US on the

[10] Please refer to Appendix 2 for a full list of 510(k) approvals granted to Danish companies since 2014.

radar. Furthermore, what if all these companies were called upon to collect a best practice / knowledge sharing guide on good tips when approaching the FDA?

Danish Government's Life Science Growth Team Report (2017)

The three main categories of recommendations of the Life Science Growth Team:

1. *Grow, improve and more focus on innovation*
2. *Internationalization*
3. *More funding to life science startups.*

The Danish government assembled in end of 2016 a group of senior life science experts from industry, academia and clinic to develop a set of recommendations to strengthen the life science industry in Denmark. In March, the team published the report which is available online[11].

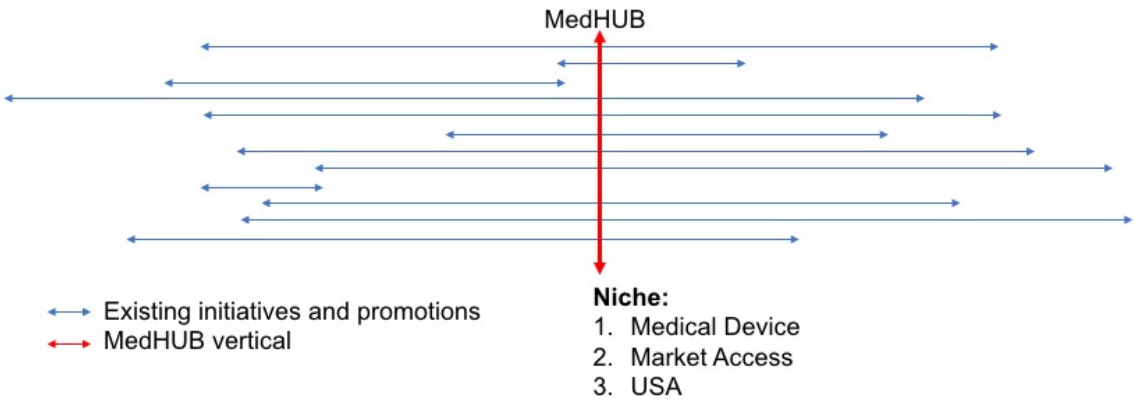
The report contains 17 recommendations[12] and many of these support the concept of a MedHUB. We have therefore reviewed the relevant recommendations and put forward a distillery of these in this section.

The Life Science Growth Team's report focus on life sciences broadly but the content of the report very often split the data and recommendations in biotech and devices. This further support our findings on a dedicated focus on medical devices.

Under the section of Internationalization, the Growth Team recommends "Denmark shall prioritize and target export promotion efforts to ensure increased exports of Danish life science solutions and products. This implies strengthening the government dialogue on key markets for Danish life science and increasing focus on international framework conditions". The MedHUB concept will rely on many partners to extend its reach and offerings. The Government initiatives are one of them and we have already interviewed several life science advisors from the Danish Trade Council in the US with positive feedback on the concept.

The MedHUB concept is all about growth, for established Danish medical device companies as well as well as startups and academia/clinicians. This triple-helix focus support all three main categories of recommendations (Innovation, Internationalization and Funding). The MedHUB concept will have its own very narrow niche (or vertical as Americans tend to describe it). Therefore, MedHUB will complement and strengthen current and future initiatives and promotions rather than competing with them.

[11] Link to the Lifesciene Growth Team Report "Life science i verdensklasse" (in Danish): HERE
[12] See Appendix 3 for a list (in Danish)



Recommendations

At the very end of the survey, we introduced the concept of a physical hub based in the US providing:

- Peer-to-peer knowledge sharing
- Partner introductions
- Best practice hub for market access and expansion
- Soft landing in the US

We then asked the respondents whether they were interested in hearing more about this concept. 81% answered yes and provided their email address for this purpose.

In the follow-up interviews we had a better opportunity to explain further about the vision of a dedicated medical device hub supporting medical device projects and companies in the US. Everyone interviewed found this idea great and intuitively offered their help and assistance in getting it up and running. Even stakeholders of various backgrounds from the survey has reached out to offer their support to the project.

Based on the four overall findings described in the previous section and the overwhelming interest and support in the "MedHUB" concept, we safely conclude that the pre-analysis has proven the hypothesis that:

> ***A dedicated medical device focused hub in the US will greatly benefit Danish medical device stakeholders in their continuous effort to develop and expand their commercial and academic activities in the US.***

Next steps

Not only is there a significant documented need for and interest in the MedHUB concept, but the concept itself is closely aligned with the recommendations of recent report from the Danish government's growth team for life science.

In investor terms, we have identified a huge unmet need that has an enormous potential to strengthen the Danish medical device sector.

Our recommendation is to commission a project team to

- Define the MedHUB concept in further details
- Investigate the opportunities to finance it short-term and long-term
- Describe a potential business model
- List potential partners and position the concept against these
- Describe its place in the ecosystem of life science initiatives and programs
- Recommend one or several location(s) for the physical hub
- Evaluate the viability of launching a MedHUB project

Appendix 1: List of Respondents in Qualitative Interviews

**** Details not for external distribution ****

Name	Company	Org Type
		Startup
		Venture Capital
		SME
		Startup
		Startup
		Startup
		SME
		SME
		Startup
		Venture Capital
		SME
		Enterprise
		SME
		Other
		Other
		Enterprise
		Academia
		SME
		Other
		Service-Provider
		Enterprise
		Other
		Other
		SME
		Academia
		Enterprise
		Other
		SME
		SME

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Appendix 2: List of Danish companies having received FDA 510(k) approvals in 2014-2017

2014	2015	2016	2017 (YTD)
BK Medical	BK Medical	Origio	Origio
BK Medical	Brainreader	3Shape Ortho	Immudex
Oticon	Heka Dental	R82	Origio
Origio	GN Resound	Tonika Elektronik	Interacoustics
Rhinix	Radiometer	Origio	Tonika Elektronik
Ellipse	Radiometer	Ambu	
3Shape	Tonika Elektronik	UnoMedical	
Lina Medical	Ellipse	Ambu	
Lina Medical	Interacoustics	Mermaid Medical	
Alpine Biomed	BK Medical	3Shape	
Lina Medical	GN Otometrics	Firma Ingemarsson	
	BK Medical	Ellipse	
	GN Otometrics	Ambu	
	Vitrolife	GN Otometrics	
	3Shape	DDD- Diagnostics	
	Interacoustics	BK medical	
		Radiometer	
		Reapplix	
		18 devices in total	

Comment: There are no public available reports on how many companies have been denied a 510(k)

Appendix 3: The Life Science Growth-Team's 17 Recommendations (in Danish)

1. Danmark skal afsætte flere ressourcer og målrette den offentlige forskning samt øge den private forskning, som er grundlaget for innovation i dansk life science. Samtidig skal uddannelse af højtkvalificerede forskere til den private og offentlige sektor styrkes.
2. Koordination af klinisk forskning i Danmark samles ét sted under det nuværende NEXT samarbejde, der udvides til en landsdækkende organisation omfattende alle kliniske områder. Det nye NEXT 2.0 forankres mellem stat, regioner og virksomheder, og mulighederne for klinisk forskning på hospitalerne styrkes.
3. Der skal arbejdes for at skabe rammerne for et transparent og tillidsfuldt offentligt-privat samarbejde mellem sundhedsvæsen og virksomheder.
4. It og sundhedsdata skal kunne anvendes sikkert til at udvikle og forske i nye og innovative behandlingsformer og medvirke til et bedre, sikrere og mere sammenhængende sundhed- væsen.
5. Lægemiddelstyrelsen styrkes, så den kommer i den absolutte europæiske top.
6. Der skal være flere notified bodies (organer som certificerer medicinsk udstyr) i Danmark med relevant kompetence af høj kvalitet for at imødekomme efterspørgslen.
7. Danmark skal være forgangsland inden for personlig sundhedsteknologi (PST).
8. Det danske uddannelsessystem skal organiseres, så det i højere grad er i stand til at levere medarbejdere i verdensklasse med de rette kompetencer til hele værdikæden i den danske life science industri.
9. Dansk life science er global – og vilkårene for tiltrækning og fastholdelse af internationale talenter og kvalificeret arbejdskraft skal være i den europæiske top.
10. Der skal sættes øget fokus på entreprenørskab og innovation i life science forsknings- og uddannelsesmiljøerne, og vilkårene herfor skal forbedres.
11. Der skal banes vej for flere life science virksomheder gennem bedre adgang til tidlig finansiering.
12. Danske life science virksomheders muligheder for at tiltrække kapital skal styrkes.
13. Skatteincitamenterne for forskningstunge virksomheder og for investorer skal forbedres.
14. Life science virksomheder skal have gode rammer for produktion i Danmark med forskning og udvikling som fundament.
15. Der skal fortsat arbejdes for at understøtte et smidigt, stabilt, rationelt og innovationsfremmende hjemmemarked, der kan fungere som et internationalt udstillingsvindue.
16. Der skal udarbejdes en national eksportstrategi for life science, og denne skal understøttes med ny finansiering øremærket til eksportfremmeaktiviteter med den målsætning, at eksporten af danske life science løsninger fordobles frem mod 2025. Herudover skal der udarbejdes en handlingsplan, som skal danne grundlag for en øget indsats for målrettet tiltrækning af udenlandske investeringer til den danske life science klynge.
17. Der skal på baggrund af vækstteamets anbefalinger udarbejdes en vækstplan for life science samt etableres et permanent life science kontor med reference til erhvervsministeren.