Healthcare IT & Device Sector Mapping in Iceland

ÍSLANDSSTOFA
PROMOTE ICELAND

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Preface

In December of 2014, Promote Iceland, the Federation of Icelandic Industries, and myself began the due diligence and research of mapping the health technology sector. It began with understanding who were the players and devising a series of questions to gauge focus and needs of the companies. The first interviews began in May of 2015 and finished the first week of June. In the end, key personnel (mainly founders) from 16 companies were interviewed by myself and Björn H. Reynisson of Promote Iceland.

Innovation is alive and well in Iceland. Moreover, innovation is very alive and very well within the health technology sector in Iceland. The companies within this sector are either unique and one of a kind, or reinventing the wheel to be better than existing products on the market. Significant narrative was gained from these interviews and is unfortunately lost within the text of this report.

However, with all the findings and strengths & weaknesses within the sector, the biggest takeaway for me is that this sector will increase multifold in Iceland within the next decade.

I would like to thank Promote Iceland and the Federation of Icelandic Industries for this opportunity, with special thanks to Björn H. Reynisson, Andri Marteinsson, and Davíð Lúðvíksson. Foremost, I would like to thank all of the companies involved in the mapping. It was a phenomenal experience seeing so much innovation within a sector that devotes itself to improving patient lives, either directly or indirectly.

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Executive Summary

Promote Iceland initiated the first mapping of the healthcare technology (including health information technology) and medical device sector in Iceland. The purpose of this mapping is to understand objectives, technologies, and needs of Icelandic companies in this growing sector. Initial criteria for those participating in this mapping was an emphasis on the exportation of healthcare products and solutions to the larger United States (U.S.), European Union (E.U.), and Asian markets.

Innovative companies in this space are sprouting from market demands, the already strong information technology sector, and rich population-based data, to name a few. The results of this mapping indicate many strengths of these companies, as well as perceived roadblocks, sales strategies, target clients, opportunities for domestic and foreign partnerships and investors. Finally, the uniqueness of being a health technology company from Iceland is outlined.

State of the Industry

Globally the healthcare technology sector is booming. Today, the sector is around $41 billion and, by 2017, will reach upwards of $57 b (Markets & Markets, 2013). Moreover, $26 b will be from the mobile health software and services market (research2guidance, 2013). While the drive behind this growth varies, the most significant reasons for this growth include:

- Aging populations
- Significant increases in chronic conditions, like diabetes
- Innovation to cut healthcare costs, e.g. clinical reengineering
- Consumerism pushing more complete and integrated systems
- Investment in technologies to drive population health management and improvement
- Government initiatives

Rising incidences of chronic conditions and healthcare operational concerns are producing hundreds of new startups in the space annually, with the majority evolving from or focusing on the United States.

The changing healthcare landscape is observing a transition from treatment to prevention. This new paradigm is witnessing a large-scale investment by health systems for population health management initiatives, including engaging and communicating with patients between episodes of care, transitioning care into cheaper care settings (i.e. outpatient, home), Big Data, predictive analytics and risk segmentation, early diagnostics, etc. Health systems

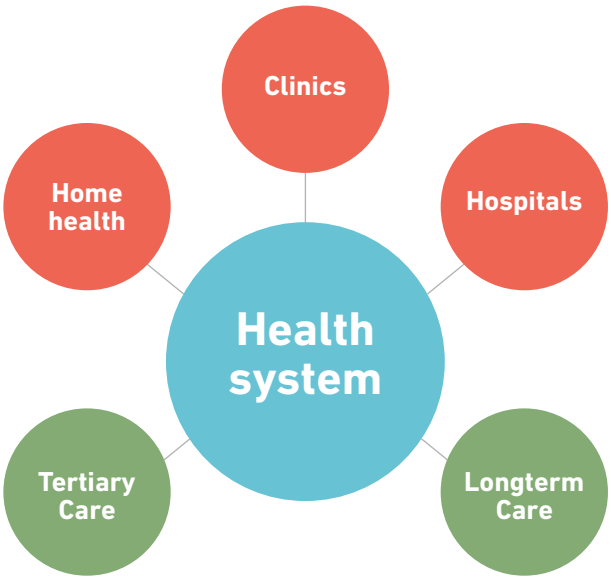


Figure 1. Health system organization (hub-and-spoke model)

are in prime positions to tackle these major issues as they follow a traditional hub-and-spoke model of care delivery. Depicted in Figure 1, the hub-and-spoke approach has health systems focusing across the continuum of care, with the health system corporate entity at the center and primary/tertiary care services as the spokes (e.g. outpatient, inpatient, rehab, long term care, etc.).

Most national health systems are engrossed in this model. Moreover, the vast majority of care in the U.S. is operated by these large health systems, many of which are equal in revenue and size to most Fortune 100 companies. As large entities, facing tumultuous pressures and obstacles, scalable innovation is not often home grown. Innovation from industry is critical to their successes.

Introduction to the Healthcare Technology Sector in Iceland

The Icelandic healthcare technology sector – focusing specifically on information technologies and medical devices – has seen a paralleled boom in recent years to fit this innovation demand. The organization of the Icelandic sector follows a similar categorization as observed in other global healthcare technology sectors, though not all categories are yet observed (figure 2):

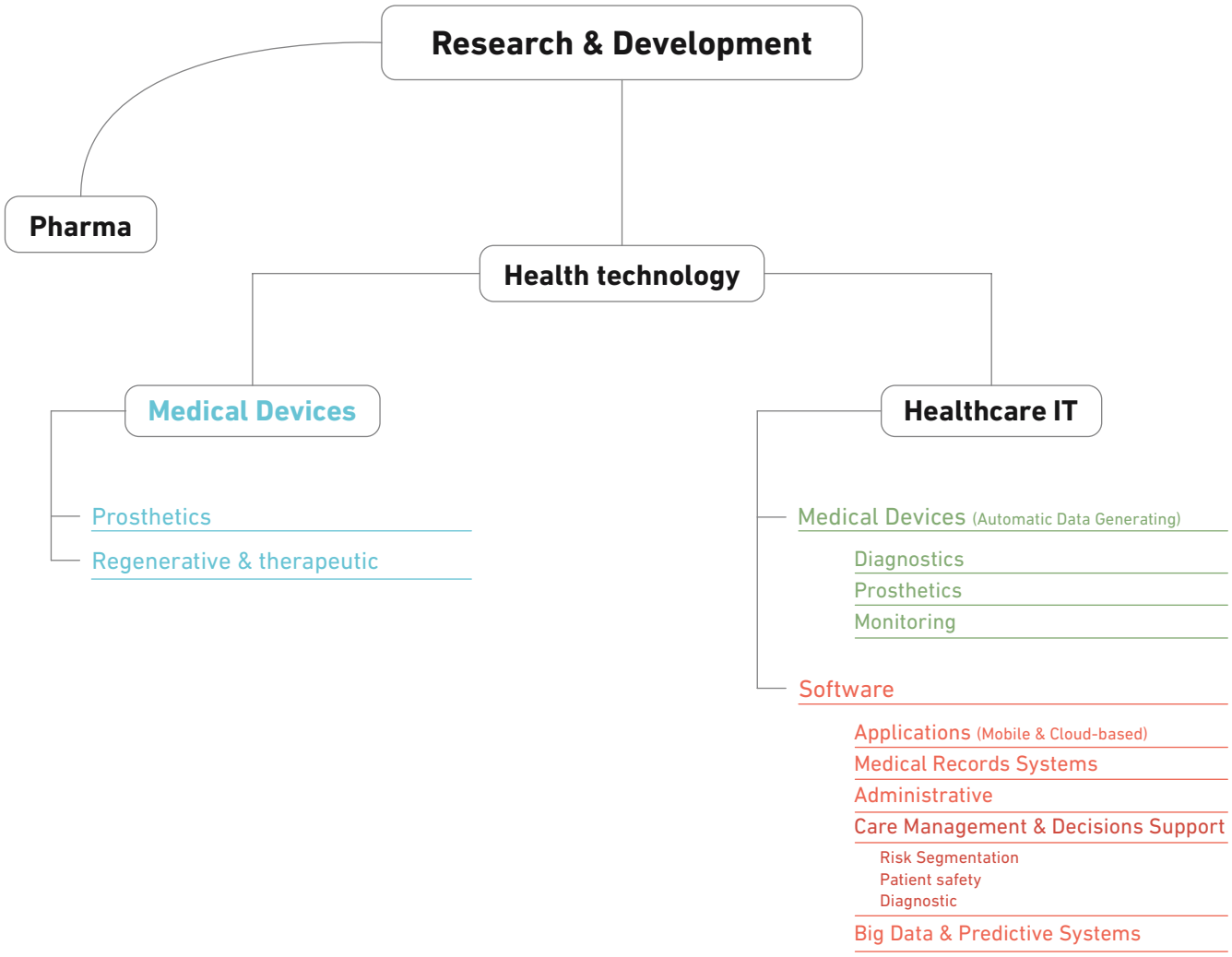
- Clinical Admin & Patient Safety
- Medical Devices
- TeleHealth
- EHR/EMR
- Population Health Management
- Online Health Communities
- Patient Engagement/Gamification
- Genomics
- Doctor Networks
- Big Data & Analytics
- Services Search
- Mobile (Health, Wellness, Fitness, Monitoring, Communication)

A relational diagram is illustrated in Figure 3 and includes an oversimplified categorization of the Icelandic sector, focusing on the core businesses of the companies. While it is not a direct mirror of comparative markets, similar patterns do emerge. The sector of health technology stems into two subsectors (i.e. medical devices & healthcare IT). Medical devices are then segmented into (1) prosthetics and (2) regenerative/therapeutic. Healthcare IT (HIT) are segmented into (1) medical devices, which automatically generate data, and (2) software services and solutions. HIT medical devices include (a) diagnostic, (b) prosthetic, and (c) monitoring; HIT software include (a) applications, (b) medical records systems, (c) administrative, (d) care management and decision support, and (e) Big Data and predictive analytics.

Health IT	**Medical Device**
Expeda	Kerecis
GoodLifeMe	Medilync
Kvikna	Nox Medical
Mentis Cura	Ossur
Mint Solutions	Oxymap
Raforninn	Zymetech
Risk Medical Solutions	
Somnify	
Stiki	
Thula	

Figure 2. Companies within the sector by core product offering

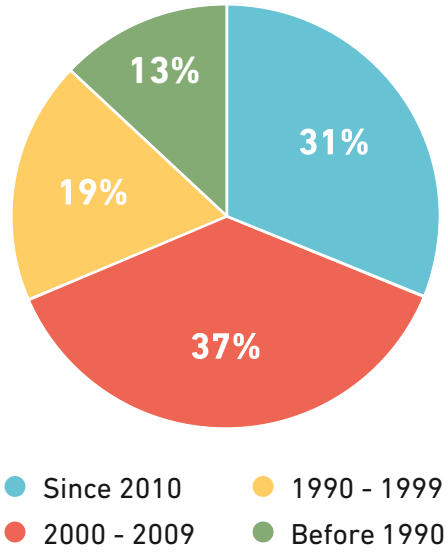
Figure 3. Map of the Icelandic Healthcare Technology Sector



Background of Companies

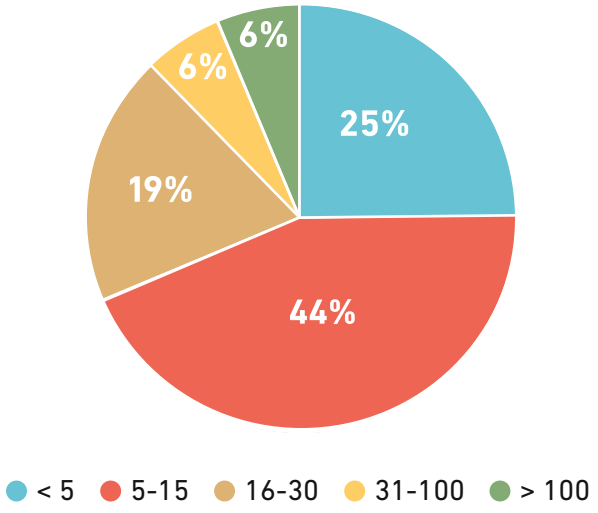
The mapping initiative focused on those companies in the healthcare technology sector, primarily HIT and medical devices. Companies with core sales relying on research & development services or pharmaceuticals were not part of this mapping. Among the 16 companies interviewed, the interviewees were CEOs (8), Managing Directors (3), COOs (2), CTO (1), or Heads of Research, Development, and/or Strategy (2); eight (8) of which were original founders or cofounders. All of the companies were headquartered in Iceland, and primarily Reykjavik. Moreover, a majority of the companies (11) were founded post-2000, with the remained founded between 1990-1999 (3) and two (2) before 1990 (Figure 4).

Figure 4.
Year Established



The majority (10) of companies were classified as software providers, while a minority (6) were medical device. Figure 5 illustrates the size of the companies in terms of full-time employees (FTEs), with 12 companies having less than 15 FTEs. The background and roles of FTEs varied greatly, but were consistent across both software and medical device oriented companies, which included computer scientists, physicians, engineers, researchers/scientists, and business/operational. However, only five (5) firms had an FTE focused entirely marketing and/or sales.

Figure 5.
Number of FTEs



Sales and Export Strategies

An overwhelming majority (14) of companies have less than 500 million ISK in annual sales, with 56.3% (9) of all companies observing more than 90% of their sales from healthcare exports. Most importantly, a large proportion of these companies are classified as being in a start-up phase, recently completed development of initial products, or recently received investment funding to begin dedicated marketing. Main countries/regions of export are the U.S., Scandinavia, Germany, and Asia (centrally China). All companies are focusing on increasing their exports and view the U.S., China, and central Europe as key targets, which requires most of them to be FDA approved (U.S.) or CE marked (E.U.). Figure 6 shows the breakdown of current sales & marketing strategies and the percentage of companies practicing each respective strategy. In line with figure 5, 81.3% (13) of companies established customers traditionally through their partners or networks.

Figure 6.
Sales Strategies

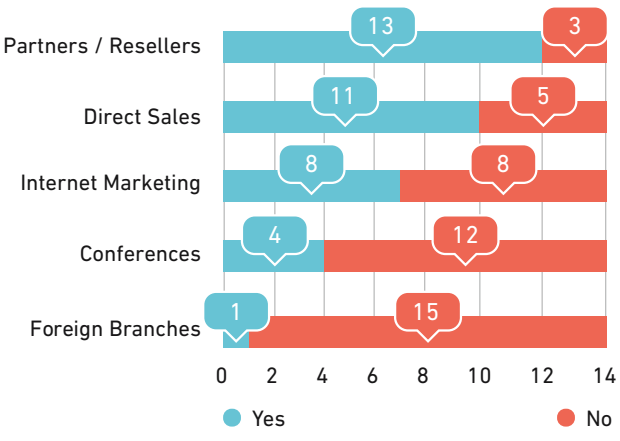


Figure 7.
Target Clients

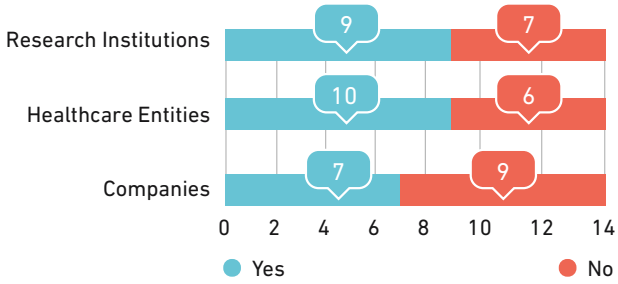


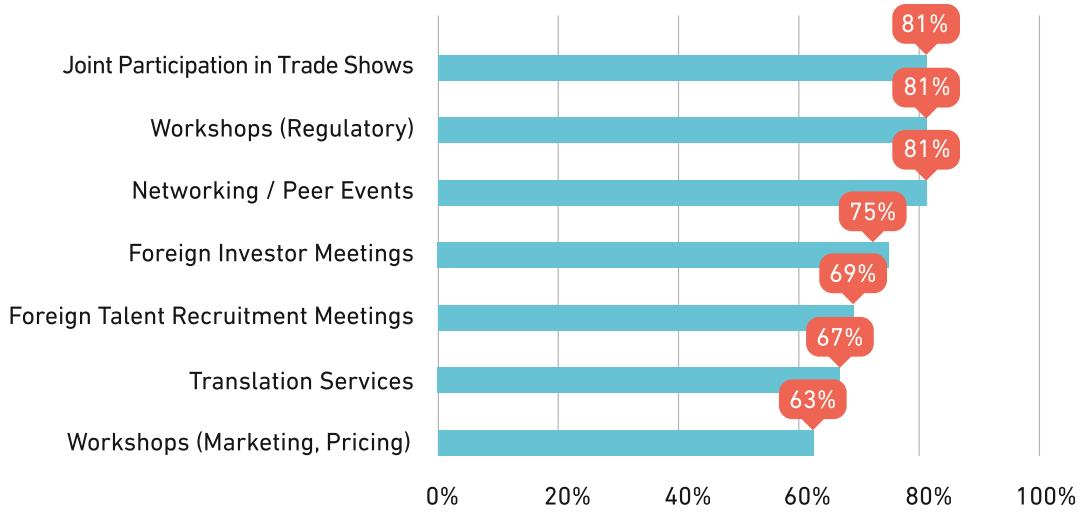
Figure 7 shows the central target clients, with a majority focusing on research institutions and health entities (e.g. health systems, hospitals, ambulatory care, etc.). While more are focusing on research institutions than health entities, this is largely explained by those stressing the initial testing of their products and services prior to obtaining licenses and going to market. This categorization, however, can be impervious as most health entities can and are testing innovations without certification and regulatory approval, as data is typically needed to prove validity, reliability, and safety. Moreover, 43.8% (7) of companies are selling their solutions to other companies, which include employers.

Sales and Export Strategies

Collaborative Efforts

As a means of knowledge-sharing, peer support, marketing/sales, increasing economies of scale, etc., most companies are expanding their collaborative efforts domestically (60.0%, 9) and abroad (80.0%, 12) with other companies in the same sector. Deeming it important, with varying reasons, the vast majority (80.0%, 12) would like to see an increase in possible collaboration within the domestic sector. Exploring potential opportunities for collaborative efforts, Promote Iceland fielded the company's interest in different projects and initiatives. Figure 8 shows the proportion of projects and opportunities which were indicated as being interesting to bring domestic companies together in this sector. A majority (62.5%, 10) of companies indicated that workshops focusing on bringing in marketing, pricing/contracting would be interesting. Moreover, almost all (81.3%, 13) companies indicated having workshops focusing on experts from other markets, including regulatory, would be of highest interest.

Figure 8.
Interesting Projects to Bring Domestic Companies in the Sector Together (% indicating 'Yes')



Views of the Healthcare Technology Sector in Iceland

Advantages of being a health technology company from Iceland

A majority of companies interviewed view it as a uniqueness and advantage being a healthcare technology company from Iceland, which include:

1. **Access to rich, complete health data**
   For many companies, this has led directly to an innovative and unique product offering, including early detection of chronic conditions & rare disease to clinical support systems.
2. **Positive, strong start-up environment**
   Though with a small population, Iceland is immersed in startups across sectors and, specifically, IT. This evolution of innovation within IT has led to emerging developments in HIT. Some indicated that founders and innovators within this sector have been afforded opportunities to explore their innovations as a result of governmental social safety nets (e.g. unemployment, healthcare benefits, child care subsidies, etc.). Moreover, start-ups and small companies receive tremendous social and operational support with the presence of associations, accelerators, and think-tanks supporting startups in their initiatives (e.g. Startup Reykjavik, Startup Iceland, etc.), as well as low cost, open space to collaborate with other companies of similar focus or age (e.g. Innovation House, Iceland Ocean Cluster, Innovation Center of Iceland, etc.).
3. **Pilot testing**
   Being an affluent, small nation with a vastly high proportion of its population connected to the internet and social media, as well as observing tremendous interest in early adoption of new technologies, health technology companies indicate a significant opportunity to pilot their solutions on the small population. This is especially true of those with solutions going straight to consumers, for example, apps for wellness, personal health, or patient engagement.
   However, those with a business to business model (e.g. focusing on hospitals and health systems) have also found an inviting pilot testing market in Iceland. Though not all, most indicate early opportunities to pilot their solutions in a healthcare or research setting, which result from a close-knit society and an expanded domestic network.
4. **Innovation & talent pool in IT**
   As observed in Promote Iceland's previous reports, the IT sector is rich in innovation and talent. The expertise of those within the sector have expanded over time and into other industries, lending to tremendous development within HIT. Interviewees in this report indicated that the talent pool is now expansive, deep, and more than sufficient to supply the technical needs of companies developing and growing.
5. **Location between U.S. and European markets**
   Physical location to many companies is critical. Being centrally located between two large markets – the U.S. and European – has its advantages, especially in terms of travel.

Views of the Healthcare Technology Sector in Iceland

Disadvantages of being a health technology company from Iceland

Counter to the advantages, all companies indicated disadvantages to being from Iceland, which revolved primarily around:

1. **Proximity to target markets and experts**
   While the physical location is often indicated as a strength between large healthcare markets, it also present a tremendous limitation. Expert knowledge on markets of interest (e.g. U.S., E.U., Asia, etc.) is typically not found domestically and must be sought after. As a result of this situation, it because difficult to secure needed knowledge to penetrate a market, including regulatory guidelines, reimbursement models, organization and governance of delivery systems, etc. This issue becomes increasingly difficult, as most companies must receive approval from the FDA (U.S.) or the European Commission (CE mark) before going to market. Within Iceland, there is a significant lack in diverse expertise from those who have gone through those processes. Through this mapping we found this to be especially true of the FDA approval process.
2. **Difficulties scaling: no domestic market within healthcare delivery**
   The ability to rapidly pilot and test is a positive of being in the Icelandic environment. However, with the goal of scaling up through increased sales or partnerships, companies encounter marginal to no opportunities within the domestic delivery system. Because no domestic market exists to grow, it is then exacerbated by the costs of going to market abroad, e.g. travel costs, hiring knowledge experts, etc.
3. **Talent pool scarcities**
   In addition to the scarcities of marketing experts, most participants indicated difficulty in finding talented employees with market experience in sales, product managers (specifically with regards to regulatory standards), and legal counsel.
4. **Investor market is very weak**
   The sector as a whole is not lacking in innovation or plans to innovate further. One of the most significant obstacles for these companies in their ability to scale up, grow, and sell abroad is the bleakness of the domestic investor market, which was intensified during the economic downturn of 2008. In the past year or so, the investment landscape has shown new life with more available funds and investors. The velocity at which these sources are being made available is too low to keep up with the demand from all sectors, not just health technology. Moreover, if a company would receive funds domestically they most likely find themselves going through the exercise of securing foreign investment funds.

Views of the Healthcare Technology Sector in Iceland

5. **Financial incentives to research and develop in Iceland**

   A portion of those involved indicated a pressing issue stemming from a lack of financial incentives to research, develop, and keep quarters in Iceland. Many governments around the world give significant tax incentives to those R&D-minded firms willing to stay domestically, hiring local talent, etc. As companies grow, setting-up branches and locations in other countries which offer more financial incentives to research and develop domestically, they find it difficult to justify keeping their R&D initiatives in Iceland.

Conclusions

Iceland is witnessing a relative boom in the health technology sector. As a vast majority of the companies are small or start-ups, there are many eminent needs, including market and sales knowledge and capital, including financial and human. For all smaller companies, their sales and scaling strategies are to leverage partners and networks. Successes may be had by many within this sector utilizing these strategies as result, but not for all. Though the environment represents many barriers, including physical location and investor opportunities, it can be assumed that it simultaneously laid the foundation for this boom in innovation. Going forward, Icelandic health technology companies may continue to find a unique role in the changing global healthcare landscape, if these barriers are incrementally overcome.

Promote Iceland, in collaboration with other governmental agencies, has a tremendous opportunity to assist these generally young, growing, and vibrant companies. In addition to recruiting market and regulatory experts, facilitating involvement in international trade shows, and organizing peer networking events, there is an opportunity to be the first place that companies, stakeholders, and interested parties turn to with questions and concerns that affect their livelihood. Whether it is seeking experts on market penetration to logistics of establishing a branch location abroad, there is a need for centralized governance and information.

Participating Companies (alphabetized)

Expeda
Expeda produces quality medical bioinformatics diagnostic tools that allow the best practices to be captured, distributed and automated. Expeda's goal is to help our clients become leaders in providing quality healthcare at minimal cost using our highly efficient expert solutions. Delivering quality medical products for the treatment and prevention of Osteoporosis and Rheumatic diseases, the company builds its professional health care service on trust and integrity.

GoodLifeMe
We are applying novel motivational methods grounded in social network theory and behavioral economics, a field that combines psychology and economics to study and influence incentives for health behavior. The applications being developed by GoodLifeMe are user-friendly, fun and personalized. They will motivate and assist users to improve diet and physical activity, fight addictions and improve mental health – providing a health-promoting platform for individuals, schools and companies. With the option of connecting to encrypted clinical portals, GoodLifeMe will also offer tailored solutions for science-based follow up and treatment of chronic diseases such as obesity, diabetes and heart disease – supporting treatment and increasing patient-provider interaction in an economical manner.

Kerecis
Kerecis develops the Kerecis™ Omega3 acellular dermal matrix technology for use in products to treat chronic wounds, for dura mater repair, breast reconstruction and abdominal wall reconstruction. Our patent pending acellular fish skin derived material improves upon current human and porcine technologies through improved economics and clinical performance, reduced disease transfer risk and absence of cultural constraints on usage. Kerecis develops the mOmega3™ fatty acid technology for use in several dermatological indications, including; psoriasis, eczema, dermatitis, keratosis pilaris and pseudofolliculitis.

Kvikna
Kvikna is an international software development firm providing technical solutions for the medical, financial, educational, environmental and scientific industries. We excel in implementing complex algorithms, designing and storing information in an optimal and accessible way, and presenting the resulting software package in an elegant, user-centered interface – all to meet your specifications. We specialize in medical and technical software solutions, and have the technical expertise and regulatory processes in place to deliver.

Medilync
Medilync was founded with the goal of revolutionizing the way diabetes is managed and treated in a value-based care landscape. Medilync designs and develops with three key concepts in mind: (1) alleviating the burden of diabetes with simplicity, (2) activating and engaging patients, as well as their families, friends and providers, and (3) answering the simple question of "would we want our friends and family using it?" Medilync links healthcare data from all sources in our predictive analytics, Big Data platform – Cloudlync.

Participating Companies (alphabetized)

Mentis Cura Diagnostics
MentisCura, based in Reykjavik, Iceland, is a privately held diagnostic company serving clinicians and pharmaceutical clients with state-of-the-art services and technology to improve and accelerate the differential diagnosis of CNS disorders. The company currently operates the world's first fully automated EEG-based biomarker service for clinicians through its own clinic and remotely via electronically transmitted EEG recordings.

Mint Solutions
Mint Solutions builds tools to help nurses and doctors provide exceptional care for patients. Our first product is MedEye which ensures patients get the right medication at the right time, improving safety, saving lives, and reducing the costs of medication errors world-wide. Backed by long term investors and an outstanding development team, Mint is expanding across Europe.

Nox Medical
Nox Medical was founded in 2006 by engineers, investors and medical professionals with extensive experience in providing industry standard solutions for sleep monitoring and diagnostics. It's our main goal to bring to the market a new generation of products to support the growth of sleep medicine with easy to use solutions, embraced by established practitioners.

Össur Corporate
At Össur, we pride ourselves on continuously pushing the boundaries to create some of the most effective, non-invasive mobility solutions on the market today. True advocates of "Life Without Limitations", our focus is on Prosthetic, Osteoarthritis and Injury Solutions. For many years Össur has served an extensive range of medical professionals, and worked closely with leading research and educational bodies in our field. We maintain a powerful service ethic, listening and responding to the diverse needs of our customers across the continent.

Oxymap
Oxymap is an Icelandic company whose flagship product is the Oxymap T1 – a solution for non-invasive ocular measurements. The company produces novel imaging products and services targeted towards eye-care professionals and clinical researchers to further the understanding of common eye diseases. A team of researchers established Oxymap in Reykjavik in 2002. Their efforts lead to the creation of the Oxymap T1 add-on for a fundus camera, which allows for non-invasive retinal oxygen saturation and vessel-width measurements. The device and accompanying software provide user-friendly access to metabolic and structural information with a single image. Customers at many international institutions are currently relying on the Oxymap T1 for their investigations.

Raförninn
The company, Raforninn, was founded in 1984. The mission is to provide consultation and modern technological service to the medical imaging community. Including f. ex. site planning, software design, acceptance and status testing, PACS services and implementation of QA programs.

Participating Companies (alphabetized)

Risk Medical Solutions
Risk Medical Solutions (RMS) uses individualized risk analysis to control the use of health-care resources in chronic diseases such as diabetes and hypertension. Our software functions as a restructuring device that aligns current available health care resources with current needs of patients. Our company uses information technology and epidemiological data to create solutions that give a precise risk and severity profile of individuals and improve quality of care and reduce cost.

Somnify
Somnify started initially in Iceland and was founded by Erla Björnsdottir, a clinical psychologist, and two medical doctors, Gunnar Jóhannsson and Steindór Ellertsson. They received great results for their Icelandic patients. Somnify develops interactive insomnia treatment solutions, taking clinical results to the public and making it accessible and easy to use.

Stiki – Information Security
Stiki – Information Security offers expertise in information security and quality management consulting with services ranging from information security risk management to development of secure telecommunications networks. Serving multiple industry sectors, our services include information security, risk management, quality management, network design, IT audit services, and intrusion testing.

Thula
Thula is a dynamic consulting firm with special expertise and broad experience in the field of healthcare solutions and integrations. Over the past 10-15 years, Thula's consultants have had continuous focus on the design, implementation, maintenance and support of mission critical solutions within the healthcare sector in Holland, Denmark, Iceland and Norway. Medication management, drug logistics and electronic exchange of healthcare information are the primary focus areas. For the past 7 years Thula has gained unique expertise through practical project work in the Norwegian healthcare market.

Zymetech
We are the global leader in the therapeutic application of marine-derived enzymes. Our technology of developing and manufacturing formulations containing marine-derived enzymes is called the Penzyme® technology and is at the core of our intellectual property. Our use of cod enzymes (that we call Penzyme®) for therapeutic application is protected by a global patent. Our core and clinical research has demonstrated effectiveness of Penzyme® against a variety of skin conditions, wound healing and viral and bacterial infections.

Survey Questions

Basic Questions:

1. Company Name
2. Location (HQ)
3. Interviewee (Name/Position)
4. Year Established
5. Number of Employees - today, 2 years ago, 5 years ago
6. Demographic of Employees (Background, Education, Skills, Titles)
7. What sector within health is the company working in?
8. Annual Sales
    - **a.** <500 m
    - **b.** 500-1000 m
    - **c.** 1000-1500 m
    - **d.** 1500-2000 m
    - **e.** >2000 m

Export

9. What percentage of income is associated with exports? Today, 2 years ago, 5 years ago
10. Are there any plans to increase healthcare exports?
11. What is the main market/country of exportation?
12. Are there plans to sell to other markets/countries?
13. Sales Strategies - How are healthcare products marketed/sold?
    - **a.** Direct Sales
    - **b.** Branch
    - **c.** Partners/Reseller
    - **d.** Internet
    - **e.** Conferences/Exhibitions
    - **f.** Other:
14. Target Groups – Who are the central clients of the company?
    - **a.** Retailer
    - **b.** Distributor
    - **c.** Wholesaler

Survey Questions

d. Health systems

e. Hospitals

f. Ambulatory/Outpatient Clinics

g. Physician Organizations

h. Other Health

i. Companies

j. Research Institutions

k. Other:

15. How have you traditionally become in contract with these customers?

Partnerships/Collaborations

16. Are you in collaboration with other Icelandic companies in health technology?

a. Foreign companies?

17. Do you think it is possible to increase the cooperation of companies in the sector domestically?

a. If yes, how? Ideas for joint ventures?

18. Below is a list of projects that could bring domestic partners together. Please rate (on a scale of 1-10, with 1 – not very likely; 10 – very likely) the degree to which you believe they could be of success to your company.

a. Workshops on:

i. Internet marketing

ii. Direct marketing

iii. Pricing

iv. Contracting

v. Other:

b. Joint participation in trade missions

c. Joint participation in trade fairs

d. Companies meet, share experiences and relationships/networks

e. Translation services

f. Foreign investor meetings

g. Foreign talent recruitment

Survey Questions

Certification

19. Is your company or products certified?

- **a.** If yes, how/what?
- **b.** If no, do you need a certification?
- **c.** Is a certification crucial in order to sell the product?
- **d.** In your opinion, how crucial do you think certification is for Icelandic health technology companies?

Iceland

20. Do you think that Icelandic health technology companies are unique in some areas?

21. Do you think it is an advantage or disadvantage coming from Iceland?

22. What do you think Íslandsstofa can do for Icelandic health technology companies?

23. Other suggestions or ideas?