INNOVATIVE HEALTH INITIATIVE – COPENHAGEN EXPERT ROUNDTABLE

Held at DTU, the Technical University of Denmark
21 April 2022

Contents

1. INTRODUCTION

At the end of 2021, the European Commission and five European Health Industry Associations launched the new Innovative Health Initiative (IHI) – a public-private partnership on health research and innovation in Europe. IHI is expected to invest €2.4 bn. in large-scale cross-sectoral health research and innovation between 2022 and 2027. IHI funds pre-competitive research to foster the creation of new products and services that prevent, intercept, diagnose, treat, and manage diseases.

On 21 April 2022, The Technical University of Denmark, Greater Copenhagen EU Office and the Danish Ministry of Education & Science organized an expert roundtable for Danish stakeholders representing academia, health care, industry and regulatory affairs. The experts discussed strengths and challenges relating to IHI-specific objectives and Danish front-runners in translational research and innovation. The aim was to provide insights and inspire future IHI investments.

2. CONCLUSIONS & RECOMMENDATIONS

The roundtable concluded that Danish research interests, competencies and advantages correlate with IHI's vision and aims in several ways. This includes:

- Improved health data sharing and data-sharing infrastructure,
- Development, implementation and legislation concerning personalized medicine,
- Development and implementation of quantum computing and the use of AI and machine learning for drug development.

The roundtable participants agreed that improved opportunities for data sharing and -reuse could be a fast track to more, better, and more cost-effective health research. The rapid development in the fields of Artificial Intelligence, quantum computing and their applications, e.g., towards development of personalized medicine, or in drug development and diagnostic modalities, will allow for the use and analyses of vastly larger amounts of data than in the past, which makes the need for fewer obstacles against data sharing even more pressing.

Denmark's relatively modest population and tradition for open and interdisciplinary communication allows for a rich cross-pollination between industry, academia, and the clinic, which is a huge advantage in terms of testing out new approaches and correcting the inevitable failures.

Two key obstacles against the full use of the opportunities provided by the IHI programme is the complexity of the funding model, and IPR issues in public-private collaboration.

The experts therefore submitted the following recommendations to IHI:

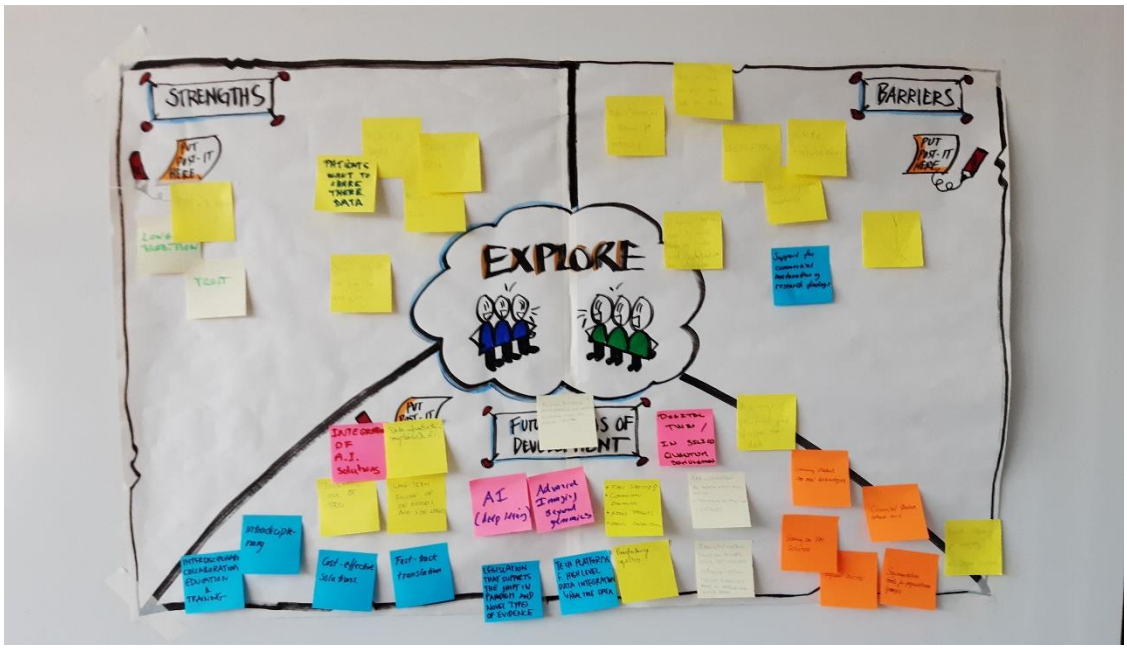
1. Data sharing was highlighted as a major obstacle for public-private health research and innovation across borders. **It is recommended that IHI continues to play a strong role in pushing data-driven cross-border and cross-sectoral research collaboration.** IHI should support research projects that require data-sharing and seek to identify legal and technical obstacles as well as develop and validate data-sharing models and best practices.
2. AI & quantum computing hold a major potential to push the development of personalized medicine and improved drug development. **IHI should support projects that maintain and develop European strengths and competitiveness in AI and quantum computing applied in biomedical research, personalized medicine and drug development.**
3. IHI is perceived as a highly complex programme with high entry barriers for researchers, companies and stakeholders. **It is recommended that IHI, in parallel with research and innovation activities, systematically register reported challenges and obstacles related to proposals, to the financial and project model of IHI, and to the implementation of projects.** The aim is to understand challenges and further improve framework conditions for IHI stakeholders in the long term. Additionally, **it is recommended that IHI partners continue to provide support to applicants on legal, IPR, financial and implementation issues** to make the programme as open and accessible as possible to the entire pool of European talent in academia, industry and public health care sector.

3. SUMMARY OF ROUNDTABLE

The roundtable discussions focused on strengths in Danish health research, innovation and industrial communities that relate to the translation of basic science into health products, services, processes, applications, and solutions. Public-private collaboration on translational research is at the core of IHI. Therefore, the discussion revolved around the Danish stakeholders' potential contributions to IHI's objectives. The discussion also touched on some challenges and areas for development that may inspire the implementation of IHI. The views and inputs expressed during the roundtable are the informal views of the participating experts, and not formal positions of the organizers or the institutions that the experts represent.

3.1.1 Recommended areas for development

IHI is open for ideas concerning research areas or challenges that require public-private collaboration with strong industrial involvement and commitments. Such ideas may be submitted to inspire future calls under IHI. Therefore, the roundtables explored a wide range of topics and ideas that may feed into IHI. The description of ideas were based on the expected outcomes of the proposed research.



Areas highlighted by the roundtable experts included the following:

Sharing and use of data across countries: Several experts pointed to an urgent need for better conditions for data sharing between countries, and for better integration of data from various sources, e.g., health data and demographic data. Data could and should be made available to physicians and patients in real-time platforms. Legislation is needed to support new types of big data research. Rare diseases, in particular, would benefit from better data sharing. Researchers typically only have easy access to national data, which is a huge problem for research into rare diseases and conditions. For some of these diseases, international sharing of data can be the only opportunity to achieve a 'critical mass' of data.

Personalized medicine: The need to scale up personalized medicines, technologies, segmentation tools and solutions is more urgent than ever. Additional development on the understanding of health determinants is necessary if we are to realize the ambitions and potentials of personalized medicine. One aspect of personalized medicine that is expected to become more important in the near future is the holistic approach, where data and research is shared between separate clinical areas to ensure that therapies align and benefit from each other.

Artificial intelligence (AI): AI-based platforms hold the potential to centralize and analyze medical observations into a comprehensive diagnosis. It requires the development of a few national pipelines combined with stratification and validation at scale to allow for the implementation across regions or health care institutions. Quantum computing and further integration of AI solutions will advance the simulation field in the next 10 years. Increasing complexity in drug development processes implies that future drug development will rely on *in silico* - developed drugs based on AI and quantum computing.

Manufacturing challenges: 3D-printing enables procurements of APIs for drug development industry.

Improved biological understanding: There is a strong need for an improved understanding of human biology to reduce or eliminate the use of animals in drug development. Currently, animal models are required for toxicity testing. Improved understanding of the human biology can lead to better and more effective drug development that can be tested in computers and humans rather than animals.

Companion diagnostics: Development of cheaper, safer and more efficient therapies will require companion diagnostics to help identify novel targets and approaches to drug delivery.

Novel approaches to clinical studies: The cost and duration of large-scale clinical trials can be prohibitive. New models and approaches are urgently needed to support better, faster and less costly quality control of new therapies, drugs and technological solutions.

3.1.2 Strengths & frontrunners in Danish translational research

Denmark and its life science and health research and innovation communities possess strengths, traditions and experiences that align nicely with IHI's objectives. It includes paving the way for safer and more effective health care products and solutions that both meet unmet public health needs, and can be taken up by health care systems. It means that Danish stakeholders are in good positions to contribute to improving health outcomes for patients in line with scientific progress and industrial competitiveness in life science and medical technologies across Europe. Denmark has a small population with strong networks and relations across the innovation ecosystem. Therefore, Denmark has a strong tradition for interdisciplinary and public-private cooperation, including patient involvement.

Denmark is among the leading European countries in data-driven health research and innovations due to collection, sharing and use of electronic health records. It has driven innovation in technology development and biotech both in academia, public health care institutions and industry including spin-outs and start-ups.

Additionally, Danish research communities enjoy the privilege of easy access to private foundations that make significant contributions to funding in life science and health. The Novo Nordisk Foundation is of course a gigantic driver of medical research in Denmark in particular, but many other foundations make significant and important contributions to medical research in Denmark, such as Innovation Fund Denmark, The Lundbeck Foundation, The Independent Research Council Denmark et al. This means that Denmark is in a good position to attract and retain national and international talent.

3.1.3 Preconditions and challenges for successful translational research collaboration

The experts mentioned both systemic and cultural barriers in the discussions. The competition for national and international research funding is fierce. Therefore, researchers spend a lot of time and administrative resources

on writing applications for various funding sources and under a variety of rules and conditions. IHI is seen as among the most complex funding opportunities. There may be room for further reducing the complexity.

In Denmark there seems to be a lack of professionalization of proposal writing compared to some other countries where e.g. universities have dedicated resources to write applications on behalf of researchers. In addition, research communities often struggle with legal issues. Protection of intellectual property rights (IPR) is also among the obstacles in collaborations because pre-commercial cooperation between industries and in public-private partnerships challenges the legal policies that traditionally apply for industrial stakeholders.

While access to data is perceived as a major Danish advantage, data management also incurs significant challenges. The interpretation and implementation of the General Data Protection Regulation (GDPR), in particular, has proven to be a challenge. Denmark has applied a rather restrictive interpretation of GDPR that significantly challenges data-driven collaborative health research and innovation. Specifically, the lack of acceptance of pseudo-anonymization as a solution to make personal data accessible and connectable across different measures, without revealing personal identity or allowing the individual donating the data to be traced, is a serious obstacle for data sharing and health-data driven research.

Currently, personal data is owned by individuals, who have to grant access to the data and agree to the use of their personal data for research purposes. It was suggested that ownership of pseudo-anonymized data could be transferred to public health care institutions instead. The participants agreed that patients often agree to share their data and are eager to see their data used for health care research and subsequent societal benefit, but that the rigid consent mechanism frequently prohibits re-use of data.

The participants found that an open dialogue and increased knowledge in the general population about the advantages of data-sharing would be useful to overcome these hurdles. At present, the GDPR regulations are a major obstacle for international collaborations and for sharing of research data – even for published datasets. Therefore, it is essential to increase public awareness and improve the public's trust in data-sharing, and to develop flexible solutions, to further develop data-driven health innovation.

Translation barriers between universities and companies: A number of issues hinder collaboration between universities and private companies, including IPR issues that indirectly force universities to hand over data to companies. Companies can use data generated by public institutions to build new solutions and therapies that are afterwards commercialized and sold to public health-care institutions. Furthermore, despite a vast number of support schemes, programmes, initiatives and collaboration platforms, there is still no unified and systematic innovation infrastructure to support the flow of ideas between sectors.

Knowledge does jump the fence between sectors in Europe, but it is often the exception rather than the rule. One reason for this is that some universities and researchers for various reasons prefer to not become involved with spinout/startups. Thus, many Danish universities suffer from a fragmented and inefficient innovation infrastructure. The Novo Nordisk Foundation recognized this issue and set up the BioInnovation Institute, but that is exclusively for the top 5% of researchers. A lot of valuable research and development takes place outside of this small group of researchers. Other countries have addressed these issues with a certain amount of success, e.g., Israel. However, the cultural differences between Denmark and Israel means that Israel's solutions may not be directly applicable in a Danish context.

In conclusion, the experts find that there is an unmet need for a (university-based?) innovation infrastructure to facilitate public-private translational research.

ANNEX: LIST OF EXPERTS

Anja Boisen	**Professor**	**DTU**
Annika Eberstein	Interim Secretary General	COCIR
Bo Andreassen Rix	Head of Quality & Development	Danish Cancer Society
Christian Clausen	CSO	Bioneer
Claus Stie Kallesøe	CEO	Grit42
Elisabetta Vaudano	Scientific Officer	IHI Secretariat
Emil Bjerrum	Senior associate	Bech-Bruun
Gitte Kjeldsen	Facilitator	Danish Life Science Cluster
Jakob Bardram	Professor	DTU
Jesper Kjær	Director	Danish Medicines Agency
Jørgen Dirach	Senior Vice President	Novo Nordisk
Kasper Hallenborg	Professor	University of Southern Denmark
Kirsten M. Danielsen	Facilitator	Danish Life Science Cluster
Martin Roelsgaard Jakobsen	Professor	Aarhus University
Nicolas Creff	Senior Manager Research Partnerships	EFPIA
Ole Kesler Andersen	Professor	Aalborg University
Ove Andersen	Professor	Copenhagen University Hospital
Peter Karl Jakobsen	Head of Heart Tech Team	Copenhagen University Hospital
Sine Reker Hadrup	Professor	DTU
Sisse Ostrowski	Professor	Copenhagen University Hospital
Tanja Thybo	CSO	Danish Diabetes Association
Trine Winterø	Vice-Dean	University of Copenhagen