



Start with Denmark



The Heart of Life Sciences
for Research and Business

Executive Summary

Start with Denmark - the Heart of Life Sciences for Research and Business

For many years, Denmark has constituted an international health laboratory, attracting international businesses and researchers. Some of the main reasons are stated below:

- The presence of several different types of healthcare industries makes Denmark a promising location for investments in healthcare research
- The Danish healthcare industry is strongly placed: for example, measured in drugs per inhabitant Denmark has the largest commercial drug development pipeline in Europe, and measured by market size per capita, the medical device industry is the second largest in Europe. Regarding eHealth, Denmark is a global leader in the deployment and use of Health IT systems
- Danish clinical research is a world leader: according to currently available ratings, Danish publications rank in the top in the most commonly used listings
- The Danish population is homogeneous and clinical standards are well described. There is access to comprehensive national health registries and quality databases. This offers unique conditions for clinical research
- Denmark is poised for a comprehensive modernisation of its national health service which will involve the renewal of just under one third of the existing hospital square meterage
- There is keen political focus on creating framework conditions conducive to research and business development in healthcare and welfare. Investment in research and innovation is a key criterion for securing national revenue in the future. The Danish Government will increase public-sector investment in research on an on-going basis to ensure that at least 1 per cent of GDP is spent on state-funded research. Combined with private research investments, which accounted for approximately 2 per cent of GDP in 2013, Denmark has achieved the Barcelona objective of investing 3 per cent of GDP in R&D. This is a growth driver

- Danish society is well-ordered: there is a low level of corruption and the public sector is highly effective
- With a corporate tax rate of 22 per cent, competitive business costs and some of the world's most flexible labour market conditions, Denmark is an attractive choice for foreign investors. Add to this a very simple procedure for establishing a business and the presence of a highly skilled and motivated workforce. The result: some of the best possible conditions for doing business

Clinical research

In Denmark there is a long-standing tradition for efficient public-private partnerships in areas such as development and testing of healthcare and welfare solutions. This applies both to the pharmaceutical industry and in medical technology. Regarding the medical technology industry, the hearing aid segment may be held up as a shining example, which has resulted in approximately half of the hearing aids sold in the world being manufactured by a Danish company.

In the past 5 years a number of initiatives have been implemented to improve the conditions of conducting clinical trials in Denmark. These initiatives include:

- In 2011 the Danish regions and Danish industry established a joint project to create a simple and efficient portal for concluding agreements on clinical trials for the whole of Denmark. This is achieved via Clinical Trials Office Denmark, which facilitates corporate access to preparing and planning clinical trials in Denmark and recruiting trial subjects
- In 2013 the government presented their plan for growth in Health and Care Solutions. Clinical research was a key focus, and as a practical result of the plan, the National Action Plan for strengthening Public-Private Collaboration on clinical research was presented in 2014. The action plan includes 10 concrete initiatives to improve the framework for both public and private parties involved in the cooperation in clinical research
- In 2013 the advisory group STARS* (Strategic Alliance for Registry and Health Data), consisting of stakeholders and experts representing public agencies, hospital owners, patient organisations, industry associations, universities, medical societies, researchers and other healthcare professionals, was established. Amongst others STARS* aim to advise the Danish government on the development of a new national strategy for better use of the unique Danish public health data (health care data, registries and biobanks) for research

- In 2014 the public-private partnership NEXT (National Experimental Therapeutic Partnership) was established. In NEXT, private and public players join forces and invest in the establishment of national research centers in Denmark, focusing on making Denmark the preferred place to conduct early-stage clinical studies. NEXT contains clinical research centers within oncology, dermatology, lung diseases and infectious diseases
- In 2016 the Danish government is conducting a preliminary analysis of the ethical, legal, technical and financial implications of a national program for personalized medicine (also known as precision or stratified medicine). There is currently a lot of activity within the area of personalized medicine, both in the health care sector and research sector in Denmark
- In 2016 the Danish government set up a growth team whose main task is to put forward suggestions to boost the Danish Life Science industry

This report offers a thorough introduction to why Denmark is a unique laboratory for healthcare and welfare technology, and why Denmark is an excellent place to do business.

The report contains an introduction to the Danish healthcare industry, covering the pharmaceutical industry, the biotechnological industry, the medical technology industry and the eHealth industry. Starting with a presentation of 'Top 10 Reasons' for choosing Denmark for research and business activities, the report is then divided into chapters focusing on the different aspects of the healthcare industry.

To learn more about investing in Denmark, please contact the Life Sciences team at Invest in Denmark:

<http://www.investindk.com/Contact-us>

The following chapters provide information within these areas:

- **A world-leading healthcare industry:** facts and figures on the pharmaceutical industry, the biotechnological industry, the medical technology industry and the eHealth industry in Denmark **(Chapter 2)**
- **A strong healthcare system:** information on the framework conditions of the Danish healthcare system **(Chapter 3)**
- **A strong tradition and good framework conditions for clinical trials** **(Chapter 4)**
- **World class research:** information on Danish research areas and strongholds in the field of healthcare **(Chapter 5)**
- **Denmark as a great place to do business:** information on the framework conditions for doing business in Denmark **(Chapter 6)**

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10 Reasons for choosing Denmark for R&D and Business Activities

This chapter presents the 'Top 10 Reasons' for choosing Denmark for research and business activities within the pharmaceutical industry, the medical technology industry and the eHealth industry.

1.1: Top 10 reasons for choosing Denmark as the location for pharmaceutical research activities

1. Unique framework conditions for the pharmaceutical industry

Denmark is a modern, knowledge-based society with excellent framework conditions for the research-based pharmaceutical industry – including a flexible labour market, favourable taxation rules for research-based businesses, a well-educated population, a low level of corruption, a high level of security and stable macroeconomic conditions. Pharmaceutical products constitute Denmark's largest export commodity (about 13,5% of total Danish exports). Denmark has excellent framework conditions in the shape of low corporate tax, tax breaks on research partnership expenses, and international researchers benefit from a special low tax rate (26%). Also, Denmark has fulfilled the Barcelona objective of investing at least 3 per cent of GDP in R&D.

2. Denmark ranks 2nd internationally by the number of articles in the New England Journal of Medicine (per inhabitants)

Denmark offers access to high-capability research centres devoted to the field of pharmaceuticals. The medical foundation at both universities and hospitals is very solid, as demonstrated by the high output of frequently cited scientific articles in leading international journals.

3. Tradition for close public-private partnerships

Danish universities and hospitals are open and accustomed to collaborating with private-sector businesses. In 2014 the companies MSD and Novartis entered into a Framework Agreement with the Capital Region and Copenhagen University with the aim of increasing the intensity and the visibility as well as the speed of decisions for all types of research collaboration within the pharmaceutical value chain. Also, in 2014, the public-private partnership NEXT (National Experimental Therapeutic Partnership) was established. In NEXT, private and public players join forces and invest in the establishment of national research centers in Denmark focusing on making Denmark the preferred place to conduct early-stage clinical studies (phase I and II). NEXT contains clinical research centers within oncology, dermatology, lung diseases and infectious diseases.

4. State investments in public-private research partnerships

Denmark offers excellent opportunities for public-sector funding for establishing public-private research partnerships, for example via Innovation Fund Denmark and the Industrial PhD Programme. Furthermore, the funding of Industrial Post Docs is increasing these years.

5. Highly qualified labour

In Denmark it is easy to recruit staff with the right medical expertise at the highest international level. Denmark has a large and rising number of masters' equivalent and PhD degree holders. In addition, Danish pharmaceutical and biotech companies constitute an international powerhouse conducive to recruitment of international employees. In addition, Denmark has the most flexible labour market in Europe.

6. Heavy investment in new research infrastructure creates unique frameworks for pharmaceutical research in Denmark

Denmark is currently making a large number of research infrastructure investments. Examples include: 1) European Spallation Source; 2) a National Center for Particle Therapy is under construction (Aarhus University Hospital); 3) International Science City at North Campus (University of Copenhagen); 4) Center for Protein Research, The Danish Stem Cell Center and The Novo Nordisk Foundation Center for Basic Metabolic Research, all at the University of Copenhagen; 5) New hospital buildings worth more than \$7bn will renew and modernise many Danish hospitals over the next 10-15 years; and 6) The establishment of the multidisciplinary Danish Platform for Large-scale Sequencing and Bioinformatics.

7. World-class patient registries, civil registries and biobanks

In Denmark there is access to comprehensive biobanks and to large registries containing detailed patient data, which offer unique opportunities for epidemiological research and support for both basic scientific research in pharmaceuticals and clinical pharmaceutical research.

8. The best clinical trial subjects

Danish patients (and healthy clinical trial subjects) are compliant, readily identified and monitored. They are highly educated and are positive about participating in clinical research.

9. Health service of a high international standard

In Denmark there is access to a well-organised, public-sector financed health service of a high clinical standard, with qualified, reliable and experienced doctors and nurses in clinical research environments of a high international standard.

10. Efficient public authorities

Efficient administrative procedures performed by competent public-sector authorities ensure rapid approval of clinical pharmaceutical trials by the Danish Medical Agency and the national and regional system of committees on health research ethics.

MSD Denmark

"One of the key factors why MSD places studies in Denmark is speed. We have no delays in HA/IEC approvals, fast turnaround in signing of contracts and most importantly, rapid and predictable recruitment. MSD makes a significant difference in conducting clinical research in Denmark by executing with excellence, using innovative recruitment methods such as Facebook and Danish registries, resulting in sustainable deliverables for many past years. In 2012, MSD conducted 13% of all sponsored clinical research and invested DKK 100 million in clinical research in Denmark. These differentiators are why Denmark is a preferred country within MSD to place clinical research in and on the top 10 list in total allocation of studies."

Iben Ordrup Christensen,
Clinical Research Director,
MSD Denmark & Iceland

Company Statements

Baxter Denmark

"In Denmark there is a political will to focus on quality for the patient which means an open-door policy for innovative solutions that sustain and save lives."

Jan Ulrik Stevnsborg,
General Manager,
Baxter Denmark

AbbVie

"As a global biopharmaceutical company that discovers and advances innovative therapies, AbbVie has a vested interest in conducting clinical development programs in Denmark."

The efficient, high-quality healthcare infrastructure ensures a motivated, highly accessible and well-characterized patient population. The clinical investigators are highly experienced and scientifically very productive, and the Danish regulatory and ethics approval systems are efficient."

Furthermore, Denmark offers a number of high quality databases that can provide excellent basis for private-public collaboration on registry research. This is an area of increasing focus for AbbVie."

Medical Director
Karin Madsen,
AbbVie A/S

Biogen

Denmark has a strong infrastructure in the healthcare system and is renowned worldwide for its registries. In addition, the seamless interaction with authorities, and the excellent quality of data generated by dedicated and highly competent staffs, make Denmark an important country for Biogen - reflected in the willingness to invest in R&D in Denmark."

Managing Director
Janne Harder,
Biogen Denmark

1.2: Top 10 reasons for choosing Denmark for your medical devices business

1. Strong, large and well-established medical devices industry

The Danish medical devices industry is well-reputed abroad for a number of leading global companies in consumables, hearing aids, diabetes devices and diagnostic devices. These companies are prominent in Danish business and industry and spearhead a strongly positioned Danish medical devices industry, which, measured in exports per capita, is one of the largest in the world. Furthermore, market size per capita is the second largest in Europe and employment per capita also.

2. Boom in medical devices SMEs

The core of the Danish medical devices industry is made up of a large number of small and medium-sized enterprises comprising innovative manufacturers, distributors and international sales companies, subsidiaries and consultancies. The many players in the industry make for a dynamic environment of clusters and networking opportunities.

3. Well-developed innovation environment

The medical devices industry is sustained by innovation and product R&D, and Danish enterprises benefit from an array of well-established innovative cluster organisations distributed throughout Denmark. Furthermore, many Danish venture capital companies have shifted towards solely focusing on MedTech for their portfolios.

4. Strong medical devices industry clusters with research centres and well-qualified staff

Across Denmark, regional authorities, universities and science parks are investing heavily in the development of medical devices, industry clusters and innovative research environments in an interaction between businesses, universities and hospitals – these clusters foster the development of new technologies and the emergence of new businesses.

5. Productive tradition and culture for collaboration between industry, healthcare personnel and researchers

Denmark has a very unique tradition and culture for collaboration, open-door policy and a spirit of inquiry in fostering new partnerships between industry, healthcare personnel and researchers. In each of the Danish Regions there is a single point of entry for companies conducting clinical trials which make feasibility and patient-recruiting fast and effective.

6. Unique capability in developing and incorporating design in product development

The strong Danish design tradition extends to R&D in medical devices and is a unique competitive parameter in this sector. User-friendly and intuitive design is an increasingly crucial element in medical devices R&D, and in this field Denmark has a unique position of strength.

7. Large-scale redevelopment of Danish hospitals up to 2024

During the next 10 years, Denmark will be investing \$7 billion in renewing its hospital infrastructure. Out of the total budget for new hospitals, an amount of \$1 billion has been earmarked for the procurement of medical equipment and information technology.

8. Cooperative and modern health service

The Danish public health service gives high priority to partnerships with business and industry. In the light of the hospital construction works, immediate opportunities exist for increased cooperation on developing new technologies and solutions for future efficiency-improvements in the hospitals sector. This applies both to core functions and non-patient-centric functions.

9. A well-qualified workforce

Denmark has a very well-qualified workforce within the life sciences area as a whole, with recruitment opportunities from medical device specific educations at the major Danish universities as well as specialists and experts from the nation's large life sciences sector.

10. Efficient and service-oriented authorities

The Danish authorities, among which the Danish Medical Agency is a key partner for new medical devices businesses, are known for their rapid, efficient and service-oriented administrative procedures, extensive digitisation and self-service. This helps to ensure the best possible framework for establishing and running a business in the country.

Company Statements

Philips Healthcare

"Philips is delighted to be partnering with Danish Regions to help realize their aim of developing innovative solutions for the Danish healthcare system. Collaboration is an important step for Philips and we see Denmark as a key partner country in relation to developing leading-edge innovative solutions for future healthcare systems."

Karen Lykke Sørensen,
Nordic CEO of Philips
Healthcare

Attention

"One significant area is our ability in productive innovation environments to jointly come up with highly patentable solutions that give the companies value for money in the long term."

Henrik Jeppesen,
Managing Director,
Attention

Siemens Healthcare

"Located in the middle of Scandinavia and closely linked to Europe you get access to a flexible workforce and Denmark is among the best when it comes to scientific output."

Bjarne Roed, Head of
Siemens Healthcare
Sector Denmark,
Siemens A/S Healthcare

1.3: Top 10 reasons for investing in Denmark and the Danish eHealth industry

1. Test on a small scale among the best

Use Denmark as a testing ground! The business risks are manageable in a country with only 5.5 million citizens. Denmark is representative of the leading markets in the world, with fierce competition between the best eHealth companies. Solutions selling well in Denmark can be expected to do well everywhere.

2. Public-sector funding

Public-sector funding is available for eHealth solutions that test new grounds for delivering health services faster and cheaper. The Danish Government is investing more than \$7 billion in an ambitious plan to establish new and digitised hospitals.

3. The infrastructure of tomorrow

With almost universal penetration of broadband, the Danish digital infrastructure is among the best in the world. Denmark offers a unique opportunity for testing demanding solutions in a national setting with the infrastructure of tomorrow.

4. Empowered patients and e-ready staff

Danish citizens are among the most e-ready in the world. In all public and private sector domains digitisation has been widely adopted, including within eHealth services at hospitals, at GP surgeries, in municipalities and in people's own homes. Highly skilled staff across the health sector facilitates the testing of innovative solutions.

5. Patients first

Danish solutions are designed and tested for their ability to put patients first whilst cutting across sectoral barriers to deliver continuity of care.

6. Standards-driven integration means ready for export

Denmark is committed to adhering to international standards for data-processing and sharing. This makes it easier to both import and export solutions worldwide. In Denmark we test and deploy in settings with challenging demands for integration. Solutions capable of delivering results in Denmark are known worldwide for their ability to integrate with solutions used abroad.

7. National references readily attainable

Regarding eHealth solutions, the public sector is aware of the value of strong national reference cases. In combination with a coordinated public effort for nationwide usage of solutions demonstrating positive outcomes, national references are readily attainable for companies.

8. Companies willing to partner up

Given the relatively small size of the majority of the Danish eHealth companies, international partners ready to invest in partnerships stand to benefit from shortcuts to Danish solutions and markets.

9. "Danish inside" means assured data protection

Denmark has a long tradition for secure handling of large data volumes. Companies can use the Danish skilled developers as a springboard for readying their solutions to meet the stringent international requirements for personal data protection. If it's secured in Denmark, it's done right.

10. Stable business environment

Denmark is characterised by political, economic and regulatory stability.

Company Statements

IBM Healthcare Denmark

"Denmark is a leading country within eHealth. The infrastructure for IT within this industry is well-established and the clients are ambitious. The local access to innovation and talent is a great advantage for IBM.

Denmark is, in many ways, at the forefront of new developments. So, supplying IT to the Danish healthcare sector ensures us a leading position in the global marketplace. The vibrant and innovative business environment is attractive for us due to the highly dedicated and flexible workforce.

This creates and attracts talent, also from abroad, and provides the basis for real innovation - also for IBM."

Associate Partner,
IBM Healthcare Denmark,
Henrik Wieland

Cetrea A/S

"With the global trend of empowering patients to take more control of their own healthcare, our eHealth solutions are moving into the patients' homes. To gain acceptance of these solutions from the patients, it is helpful that the infrastructure is universally available and that it is as robust and reliable as is the case in Denmark."

Freddy Lykke,
CEO Cetrea A/S

Hitachi Ltd

"It is a great honour to be involved in developing even better healthcare solutions in Copenhagen.

We look forward to combining the Danish experience in areas such as medical and hospital care with the Hitachi Group's expertise and technology in the field."

Executive Vice President and
Executive Officer,
Yutaka Saito,
Hitachi Ltd.

Chapter

2

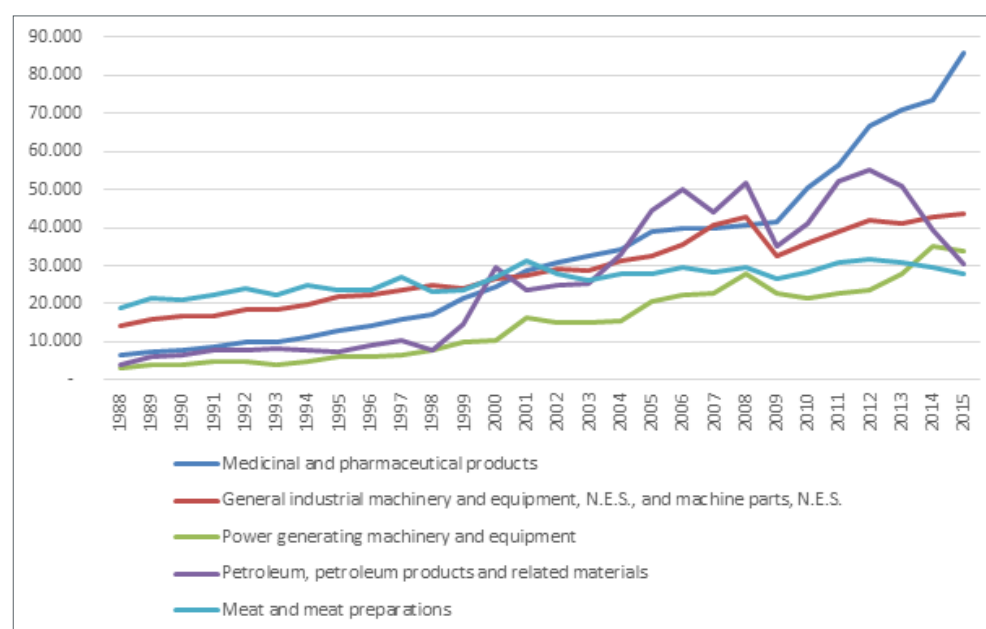
A world-leading healthcare industry

In this chapter, you can read more about the healthcare industry in Denmark, covering the pharmaceutical industry, the biotechnological industry, the medical technology industry and the eHealth industry.

2.1: The pharmaceutical industry

Research, development and manufacture of pharmaceutical products represent one of Denmark's commercial strengths. Danish pharmaceutical companies rank among the absolute world elite in therapeutic areas, such as diabetes, depression, skin disorders and allergies, while subsidiaries of all the major international pharmaceutical firms are also present in Denmark where many of them have substantial clinical research activities.

This means that from a global perspective, Denmark is at the forefront in pharmaceuticals R&D and pharmaceutical exports. Measured per capita, Denmark has the largest drug development pipeline in Europe¹ and Danish exports of pharmaceutical products have been increasing sharply over many years. In 2015 exports amounted to DKK 85,7bn - about 13.5 percent of the total export - making pharmaceuticals Denmark's largest export area and contributing to 95 percent of the total profit of the Danish trade balance.



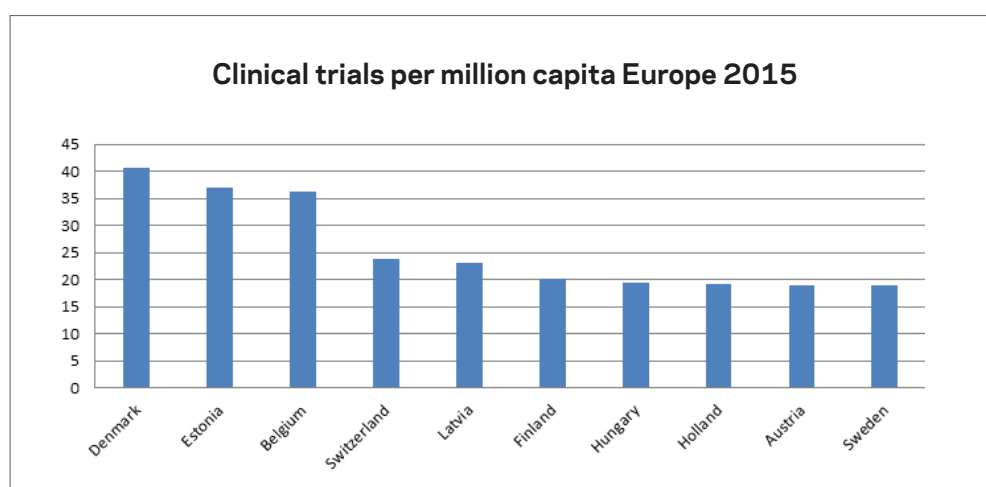
Source: Statistics Denmark 2016

1. Ernst & Young, Beyond borders, Biotechnology Industry Report 2015.

Denmark is one of six countries in the world, which invests more than three per cent of Gross Domestic Product on research and development. The ambition is to be among the leading countries in research and innovation².

Medical and health sciences is by far the most prioritized research area in Denmark, with more than 1/3 of all public investments going to this scientific field. Furthermore, Denmark is the country with the largest share of R&D investments in the medical and health sciences. The quality of Danish pharmaceutical research is also at the top internationally. Based on the number of articles published in 2013 in the New England Journal of Medicine, Denmark is second globally when it comes to scientific articles published per million capita. For publication in Lancet in 2013, Denmark is fifth³.

Measured per capita, Denmark is the country in the world that conducts the most clinical trials.



Source: Danish Association of the Pharmaceutical Industry (Lif), July 2015, measured by www.clinicaltrials.gov.

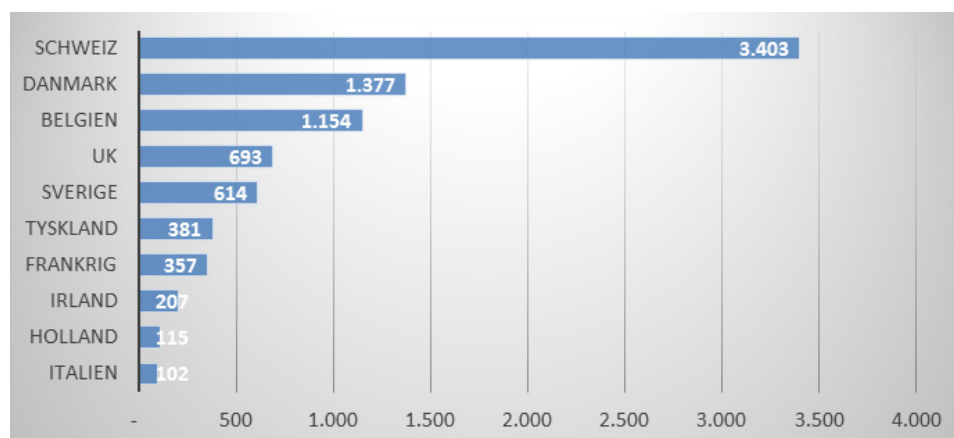
The Danish pharmaceutical companies are involved in a range of research activities in close collaboration with Danish universities and the public health service. Private-sector pharmaceutical research as a whole accounts for approximately 30 per cent of all private-sector research in Denmark (and 51% of the industrial research); in absolute figures the pharmaceutical industry in Denmark invested approximately DKK 10,8bn in research in 2013.

This means that within an international context, private-sector pharmaceutical research in Denmark is distinctive in that it accounts for a very large share of total business and industry R&D investments. Denmark ranks 2nd in the world when it comes to private investments in pharmaceutical research per inhabitant.

2. In 2013 the public invested 1.11 per cent of GDP in research, while private research investments accounted for 1.98 per cent, placing Denmark sixth among the 34 OECD countries <http://www.danmarksstatistik.dk/da/Statistik/NytHtml.aspx?cid=19303>

3. Source: Ministry of Higher Education and Science – Research and Innovation Indicators 2014: http://ufm.dk/publikationer/2014/filer-2014/research-and-innovation-indicators-2014_web.pdf

Industry investments in pharmaceutical research per capita



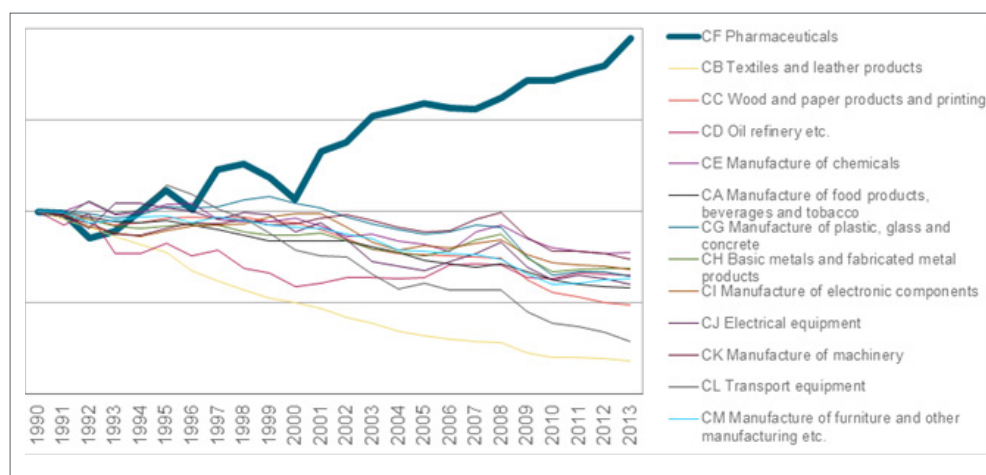
Source: OECD, STAN Database for Structural Analysis R&D expenditures in industry (ISIC Rev. 4). 2012 numbers except for Belgium and Ireland where 2011 numbers has been used.

Looking at clinical research in isolation, pharmaceutical companies in Denmark with research activities invest approximately 34 million dollar per annum⁴ (external clinical R&D cost).

The long-standing tradition and solid foundation for pharmaceutical research in Denmark have also facilitated the establishment of a number of biotech companies, for example, in the Danish-Swedish Medicon Valley cross-border cluster, which in turn has helped to place Denmark firmly on the world map.

Human Resources

Within the pharmaceutical industry, the employees of Danish pharmaceutical firms are characterised by their high level of educational attainment. Around 33 per cent of the some 26,500 employees have a long-cycle tertiary education or holds a PhD degree. Almost 1200 hold a PhD degree.



4. Source: Danish Association of the Pharmaceutical Industry (Lif) and Danish Biotek (2015)

According to the most recent Research and Innovation Indicators, in Denmark the largest share of R&D employees is found in the medical and health sciences. Denmark is also the country with the largest share of R&D personnel employed in this area. In relation to the financial and human resources used for R&D, Denmark gives the highest priority to medical and health sciences. Health science is also the field with the highest number of PhDs awarded in Denmark, which again underlines Denmark's specialization in this area.

The image of an ever-more significant pharmaceutical industry is also reflected in the fact that the Danish universities offer master's or master's-equivalent programmes geared specifically to employment in the pharmaceutical industry. The latest pharmaceutical-oriented degree programmes include: Molecular Biomedicine, Nanobioscience, Biomedicine, Biotechnology, Bioinformatics, Pharmaceutical Chemistry and Pharmaceutical Science.

Looking at clinical research in isolation, in 2014, almost 2,000 individuals had jobs in clinical research at pharmaceutical firms, of whom 200 were engaged in clinical research sites in Denmark.

Facts about the Danish Pharmaceutical Industry:

- **Number of companies:**
170 marketing authorisation holders. The 20 largest accounts for two-thirds of the market.
- **Number of employees:**
Approx. 26,500 employees (creates a total of approx. 90,000 jobs, including employees in sub-industries). In the period 2000-2013 the number of employees increased by 83%. All other Danish industries have shown a huge decline in the number of employees. Measured by the number of employees relative to the size of the Danish population, Denmark has the third-largest pharmaceutical industry in the world.
- **Exports:**
Pharmaceutical exports currently represent Denmark's largest export sector with about 13,5% of total Danish exports. Since 1997, pharmaceutical exports have more than tripled. Approx. 90% of Danish pharmaceutical production is exported.
- **Sales 2013:**
Danish companies achieved global sales of \$17bn equating to 2.7% of global sales for top 100 companies.
- **The Danish market 2015:**
Sales in Denmark were \$2.6bn measured in pharmacy purchase prices where the market shares for Danish companies were 4.6%.

2.2: The biotech industry

The long-standing tradition and solid foundation for pharmaceutical research in Denmark have facilitated the establishment of a number of biotech companies. More than 150 years ago, Danish agriculture sowed the seeds for a national research industry and since then, research methods have been evolving continually in Denmark.

The Medicon Valley hub, spanning Eastern Denmark and South-Western Sweden, is one of Europe's strongest life science clusters, with its large number of life science companies and research institutions concentrated within a very small geographical area. The cluster is connected by the Øresund Bridge which makes for an easy daily commute between Denmark and Sweden.

Medicon Valley represents the entire (bio)pharmaceutical value chain from target identification through preclinical and clinical development to manufacturing. The presence of large pharmaceutical companies in the cluster has a positive effect on SMEs when it comes to research initiatives and research talents. More than 40,000 people are employed in the life science sector in Medicon Valley and there is a strong tradition and culture for networking and collaborating in the region. This also facilitates informal networking and meetings between the cluster's stakeholders.

2.3: The medical technology industry

The medical device industry consist of companies that develop, manufacture and sell instruments, apparatuses, implants, and reagents for the diagnosis, treatment and prevention of disease. The industry is innovation-led and characterised by a short route from concept to finished product and a rapid product lifecycle. Measured by market size per capita, Denmark is the second largest medical device market in Europe and by employment per capita the second largest in Europe. Denmark also has one of the largest medical devices industries in Europe in terms of exports and as an industry has a long and proud Danish industrial heritage.

The Danish medical device industry is known for its large global manufacturers of disposable devices, and apparatus and hearing aid manufacturers. In addition, the industry consists of a large number of small and medium-sized manufacturers, including several innovation companies as well as distributors and sub-distributors. At the same time, all the major international medical device companies maintain a presence in Denmark via sales companies and subsidiaries.

The Danish medical device industry upholds a long-standing tradition for close and systematic collaboration with healthcare professional environments at hospitals and with university research environments, and is at the leading edge of the latest developments in medical technologies, including e-health, robot technology, point-of-care and sensor technologies. The medical device industry also links in with the diagnostics, rehab and assistive technology industries, and there is widespread overlap between multiple companies and collaboration across different industries.

The medical device industry is characterised by a high concentration of small and medium-sized enterprises, and two-thirds of companies in the industry have fewer than 50 employees. More than 95 per cent of Danish medical devices are exported, and there is a substantial export surplus. A large share of Danish medical devices imports is

incorporated into domestic production and subsequently re-exported as finished products.

Development of medical devices is characterised by a high level of cooperation between companies and the clinical setting. Many different tests are carried out during development such as different forms of usability tests and clinical studies. In Denmark, companies need to have tests and studies within medical devices approved by the Danish Medicines Agency and/or The Regional Committee on Health Research Ethics. The Danish Medicines Agency under the Danish Ministry of Health is the national regulatory body for medical devices. The Authority's principal function in this domain is to implement regulatory systems for the safety and performance of medical devices on the market. **Information about rules and guidance on medical devices is available at <http://medicaldevices.dk/>**

Facts about the Danish medical device industry:

- **Sales:**
Approximately \$8bn in 2014 (medical device companies in Denmark and Danish companies abroad)
- **Number of companies:**
250 companies solely working with medical devices (total of 1,000 companies with medtech related activities)
- **Number of employees:**
33,000+ in Denmark (measured per capita, this gives Denmark one of the largest medical device industries in the world)

In order to safeguard and facilitate easy access for medical device companies to relevant hospitals and clinical department, the Capital Region of Denmark has launched a "Single-Point-of-Entry- initiative". Launched in 2015 the initiative is targeted directly at medical device companies and offers access to sparring, initial counselling and the possibility of match-making with relevant clinical hospital departments. The initiative has been designed on the basis of industry recommendations, which pinpoint challenges when it comes to cooperation with the public hospitals. Identical "Single-Point-of-Entry- initiatives are currently being prepared in the remaining four other Danish regions.

Further information on the initiative, please consult: www.clinicaltrialsdenmark.com

2.4: The eHealth industry

Danish eHealth companies grow, show profit and are regarded internationally as holding huge potential for both further national growth and international exports. Out of 92,000 persons employed in Danish private-sector ICT-companies, approximately 2,000 work for companies devoted mainly to eHealth, with annual turnover of an estimated \$680m. A majority of these companies are organised under the Danish IT-Industry Association.

For more information see <http://www.itb.dk/>

A Strong Healthcare System

In this chapter you can read about the framework conditions of the Danish healthcare system. The healthcare industry in Denmark is supported effectively by:

- Five regions with responsibility for the public health service
- New hospitals within a robust hospitals structure
- Extensive digitisation

The health service in Denmark is mainly operated by the country's five regions, which have primary responsibility for the healthcare sector, including clinical psychiatry, doctors in private practice and specialists etc. In addition, the regions, jointly with four faculties of health sciences, have executive responsibility for optimising the frameworks and conditions that govern national healthcare research.

The 98 municipalities under the five regions provide a number of health services, such as out-patient rehabilitation and preventive and health-promoting initiatives.

3.1: New hospitals and robust hospital services structure

Over the next 5-10 years, Denmark will invest \$7 billion in 16 new hospital projects, \$4.2 of which comes from a governmental Quality Fund. These projects include new Greenfield projects as well as extensions to and modernisations of existing hospitals. The goal is to ensure national access to modern health services and to raise quality levels in the entire healthcare sector. Designing the new hospitals involves broad-based collaboration with research institutions and private businesses in the health area.

The process of modernising Denmark's future hospital capacity is focused on sustained specialisation and flexibility. The goal is to ensure flexible functions and capacity which can be changed, expanded, or reduced depending on future demand for treatment and care.

Out of the total budget for new hospitals, an amount of \$1 billion has been earmarked for the procurement of medical equipment and information technology. These investments will enlarge the basis for scientific research at Danish hospitals. Concentrating specialist medical care and enhanced research facilities at the new hospitals will hold obvious opportunities for more wide-ranging collaboration with business and industry, including in research. Furthermore, the investments will strengthen the collection of health data which already represents a significant competitive parameter for attracting investments to Denmark and for the quality of R&D and the documentation of new products.

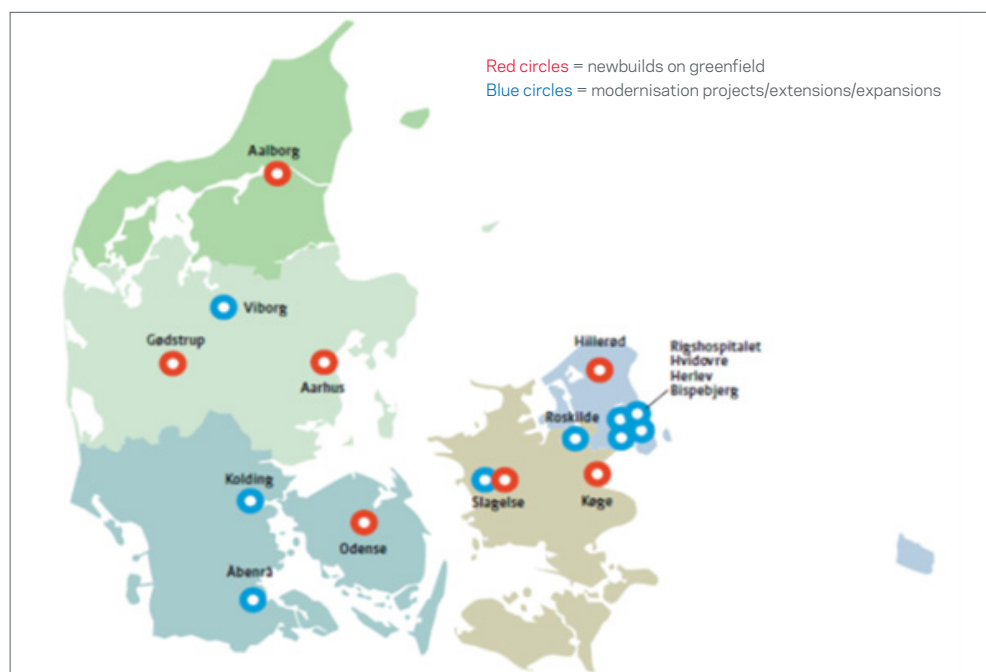
The ongoing investments in a modernised hospital infrastructure are expected to make a significant contribution to fulfilling the government's vision that Denmark should be among the most attractive countries in the world for developing, testing and manufacturing health and care solutions based on strong research, fast implementation of innovative new technology, good conditions for public-private collaboration and a well-functioning, development-oriented home market.

Building tomorrow's hospitals

The new hospitals will be built to provide better and more cohesive patient flow, improved patient safety, efficiency, and quality. The number of beds at the new hospitals is expected to be reduced by 20%, and outpatient treatment to be expanded by 50% from 2007 to 2020.

The construction of the new hospitals requires new technologies and more intelligent solutions to ensure cost-effective health solutions and even shorter average admission times. At the same time, the hospital layout will enhance communication between patients and their families, and the ICT infrastructure will play an important part in developing communication.

The new hospital landscape



Releasing resources for treatment and care

The modernisation of Denmark's hospital capacity will spur dissemination of the latest knowledge, technology, and best practices throughout the country. Increasing digitalisation ensures efficient operation of core services in hospitals, with new work methodologies, technologies, and organisation. This provides additional resources for treatment and care, while also providing better health and safety conditions for personnel.

The government and the regions have agreed to implement GS1 as a common standard for supply chain visibility on all Danish hospitals. This opens up a wide range of possibilities, including storage facilities for linen, utensils, medicines which are monitored electronically, enabling a real-time overview of what the hospital has in stock and where relevant devices are located. Inventory control systems can be integrated with procurement systems, allowing utensils to be ordered and received in due time.

Once the hospital investments have been made, they will be a significant boost to what is already a modern and flexible hospital system in Denmark, which, compared with systems abroad, will consist of a relatively small number of high-capability units. This will mean high patient volume per unit, consolidation of expertise and improved capacity for the continuity of medical care.

3.2: Extensive digitisation – electronic communication between health service partners

ICT and digital workflows are fully integrated in the Danish health care system, and general practice and the hospital sector in Denmark are characterised by extensive digitisation. The prevalence of common IT standards means that a lot of the communication between health service partners – hospitals, GPs, specialists, laboratories, local authority domiciliary care services etc. – is electronic:

- All GPs keep electronic health records (EHRs)
- General practitioners receive all laboratory test results from the hospitals electronically
- 99 per cent of all prescriptions are sent to the pharmacies electronically
- All referrals to medical specialists and psychologists are made electronically
- The practice sector receives 100 per cent of all hospital discharge summaries electronically
- 100 per cent of all lab test orders and reports from/to GPs are electronically
- 98 per cent of all general practitioners can exchange entire health records electronically

Denmark has a long tradition for thorough monitoring and registration of patients who are in contact with the health service. Extensive digitisation means that there are excellent opportunities for monitoring patients within the practice sector as well as the course of their disease over time.

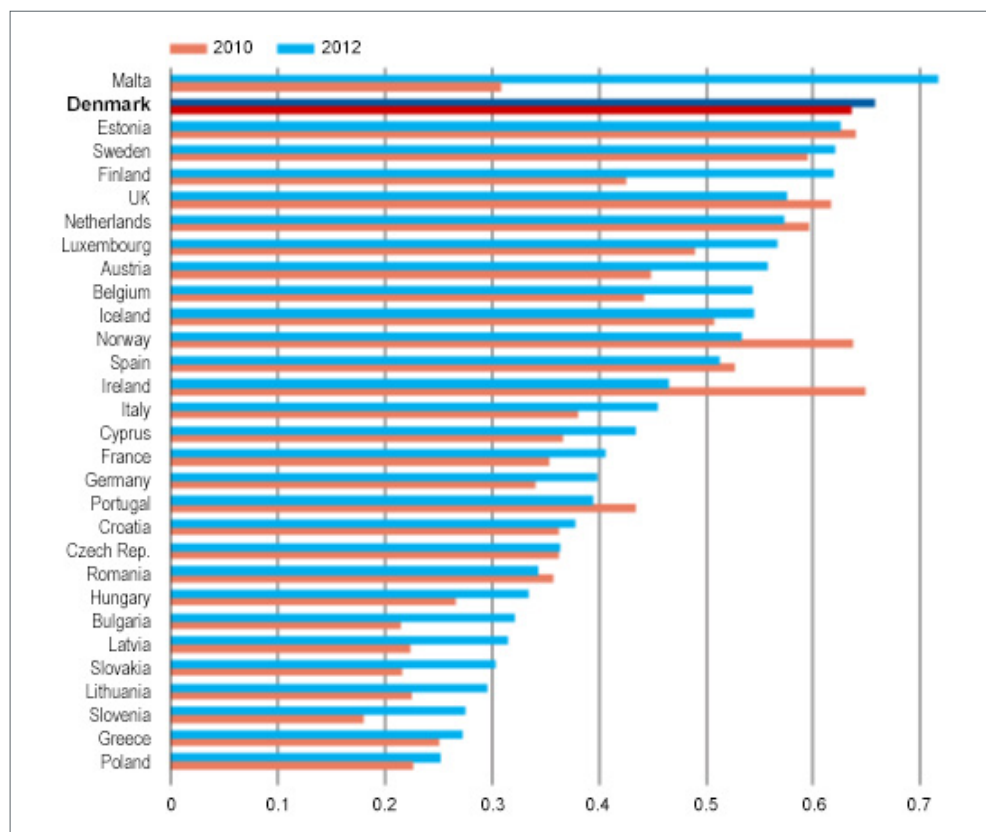
Across the different sectors in the Danish health service, work is currently in progress to link the various IT solutions even more seamlessly so that existing patient data can be accessed by different healthcare professionals and care staff, irrespective of where in the health service the data were originally entered. The vision is to achieve a single, cohesive health service in which IT and digital processes support continuity of care across hospitals, GPs, local authority domiciliary care services and so forth.

Denmark has notably won international acclaim for:

- Prevalence of the so-called Medcom standards that have digitised much of the communication within the health service. Prescriptions, referrals and discharge summaries are now on the whole transmitted electronically
- Establishment of the health data network for secure electronic communication between all health service partners
- The web portal sundhed.dk, where citizens have access to their own medical data from national health registers, hospital EHR systems, medication data and so forth. These data can also be accessed by the patient's GP
- Establishing the Shared Medication Record, which gives citizens and healthcare professionals access to a complete electronic record of each citizen's current prescription medications. The Shared Medical Card system simplifies communication concerning medication between health service partners and helps to reduce the risk of mismedication. The Shared Medication Record is nearly fully implemented at hospitals and general practitioner and local health authorities (eg. municipal home nurses).

According to the EU's e-health deployment indicator, Denmark is one of the front-runners in the deployment of e-health. The figure below shows the deployment rates across Europe and the general trend towards the increased use of e-health solutions. Note that the results for Malta are based on a single hospital.

Dissemination of e-health in hospitals in the EU (+3)



Source: European Commission and OECD: Benchmarking information and communication technologies in health systems.

3.2.1: Electronic health records and electronic communication at Danish hospitals

Since 2011, the regions have been consolidating their EHR systems to a single EHR system covering each individual region. In order to make data sharing between the EHR systems possible, the regions have undertaken the “Sundhedsjournalen” project (i.e. “The Health Record”), which gives health professionals and citizens access to health records from hospitals and general practitioners as well as information on a patient’s current medication.

Clinicians at hospitals and general practitioners have access to Sundhedsjournalen directly through the hospital’s EHR system. Furthermore, patients can also gain access to their own data via sundhed.dk.

Sundhedsjournalen benefits Danish healthcare in several ways:

- Increased patient safety and improved patient treatment by providing a more solid basis for decision making, as doctors have better access to existing patient data.
- Linking of various EHR systems used at the Danish public hospitals in a cost-effective and pragmatic way.
- Support the exchange of patient data between hospital departments more cost-effectively. Prior to the Sundhedsjournalen system, information was often delivered by ordinary mail or fax.

Furthermore, Sundhedsjournalen has contributed to transparency in the health sector by providing patients with easy access to their personal health data. This has created a stronger basis for involving and activating the patient in relation to his or her treatment as well as increased patient empowerment.

3.2.2: Telehealth

Over the past years, Denmark has seen a shift away from many small telemedicine pilot projects towards more coordinated efforts to establish large-scale studies reflecting telemedicine in actual operation.

Following the “National Telemedicine Action Plan” (launched in 2013) and the launch of cross-sectoral large-scale telemedicine study Telecare Nord (see the below box), it has been decided to secure national implementation before the end of 2019 of clinically integrated home monitoring aimed at citizens suffering from chronic obstructive pulmonary disease (COPD).

Telemedical initiatives

Telecare Nord

For most chronic obstructive pulmonary disease (COPD) patients, it is vital that their lung capacity is monitored regularly and COPD patients are often hospitalised for long periods of time. This is both time-consuming and resource-intensive for the patient and the GP's and hospitals. COPD is therefore an area in which telehealth solutions can add value. The objective of the TeleCare Nord project is to monitor patients closely, adjust their medication and treatment and thereby avoid hospital admissions.

When patients agree to take part in the project, they are given a set of devices which enable them to measure their oxygen saturation, pulse, blood pressure, and weight a couple of times per week. The measurements are transmitted via a small tablet computer to healthcare personnel in the patient's municipality or at the local hospital. Here, the personnel monitor these data and may, if necessary, provide further counselling to the patient. By measuring their health, the patients become aware of what they can do personally to ease life with COPD, for example the effects of exercise and the right diet on oxygen saturation and pulse.

TeleCare Nord is a cross-sector partnership in the North Denmark Region between municipalities, the region and general practitioners. This large-scale project, in which all stakeholders in the regional healthcare system collaborate across sectors, is unprecedented in Europe, making the project unique. The results from the project together with the large-scale project Clinically Integrated Home Monitoring have led to an agreement to roll out telehealth to COPD patients in all municipalities and regions of Denmark by 2019.

The TeleCare Nord project continues until 2018 targeted a new group of patients with chronic heart failure, heart insufficiency. With a research project in cooperation with Aalborg University the objective is to evaluate both quantitative and qualitative effects of telemedicine.

Telemedical wound assessment

This national roll-out project is designed to diffuse telemedical wound assessment to all regions and municipalities. The solution involves a municipal nurse attending to patients' wounds in their own homes or at the local health clinic, taking photographs of the wounds and sending them to a specialised doctor or nurse at the hospital as an online health record that can be accessed by doctors and nurses (and the patient).

The aim is, e.g. to reduce the number of hospital admissions, to minimise the patients' transport time and to reduce doctor and nurse time at the hospitals. The project is also expected to help improve the skills of the municipal nurses administering wound care and increase patient satisfaction.

The initiative is intended to roll out the solution to all the municipalities and regions of Denmark, and the aim is for almost 70 per cent of all relevant patients to be included in the telemedical wound assessment by 2017.

As a part of the "National Telemedicine Action Plan", a national infrastructure for telemedicine has been established as part of the large-scale roll-out of telemedicine in operation. This includes standards and relevant reference architectures spanning the entire healthcare service, covering, e.g. measuring data, video, questionnaires and images. Consequently, within the foreseeable future, digital infrastructure and IT architecture will be in place so that all kinds of information can be exchanged across sectors of the healthcare service and welfare areas.

Innovative digital solutions designed on the basis of internationally recognized standards and architecture adopted at national level will drive standardized data exchange and use of reference architectures and create a raft of new opportunities for private-sector enterprises. This will reinforce provider confidence while the market grows to become a more secure environment for innovation.

3.2.3: Unique registers, patient traceability and a culture of collaboration

Denmark has a number of unique framework conditions tailored to facilitating high-quality research. The country maintains a number of unique registers and facilities for linking data across registers and databases. In addition, Denmark has a tradition of openness and collaboration between the healthcare sector and academia.

3.2.4: Easy to conduct research based on healthcare data

In Denmark there is access to comprehensive biobanks and to large registries containing detailed patient data, which offer unique opportunities for comparing and updating personal data across a large number of both public-sector and private-sector IT systems and registers.

Public hospitals and general practitioners collect systematic data, and their contact with the patient is sustained, which allows follow-up to an unique extent world-wide, while records in the national patient register and medication databases permit an outstanding degree of, for example, patient-compliance monitoring. By linking the different registers, unique knowledge may be acquired on delivery of medical care across health service sectors. In addition, Danish research is strongly placed in bioinformatics and basic pathobiology.

Safe and secure modalities for conducting research based on health care data within the Danish legal framework are being maintained and improved.

3.2.5: National registries

As of July 1th 2015, national data on the state of public health and data concerning health service activity, economics and quality has been consolidated, analysed and published by The Danish Health Data Authority.

The data are utilised for national and local authority tasks and made available for research and analysis purposes in the field of health.

The registries comprise data on the nation's health, morbidity and mortality, along with data on healthcare sector organisation and economics etc.

The national registries publish statistics on a regular basis, and offer access to data extraction. In addition, extracts from the registries are provided for activities such as research and statistics.

As of 2016, The Danish Health Data Authority has stepped up its commitment to providing enhanced, effective and secure services to researchers who conduct research on healthcare data.

National Registries State Serum Institute

- National Patient Registry
- Cause of Death Registry
- Danish Cancer Registry
- Healthcare workforce mobility registry
- Child health database
- Danish National Diabetes Registry
- Register of Legally Induced Abortions
- Medical Licences Registry
- Central Office of Civil Registration
- DUSAS (Danish patients treated at foreign hospitals and activities in specialist practice)
- Danish Medical Birth Registry
- Rehabilitation
- IVF registry
- Municipal health schemes
- Registry of Congenital Malformations
- National alcoholism rehabilitation registry
- National pathology registry
- National military service registry
- Registry of substance abusers undergoing rehabilitation
- National health insurance registry
- Compulsory psychiatric admission
- Human tissue utilisation registry
- Registry of healthcare providers
- Pharmaceutical statistics registry

Source: The Danish Health Data Authority

3.2.6: The Danish clinical quality databases

The Danish clinical quality databases contain systematically collected data related to clinical observations, diagnostic procedures, treatments and outcomes in the Danish health sector.

A clinical quality database is a registry containing selected measurable indicators, based on individual courses of treatment and serves to shed light on performance standards and treatment outcomes within the health sector. A clinical quality database is restricted to a specific group of patients defined by diagnose and/or treatment.

As an example, this means that separate clinical quality databases are maintained for patients with conditions such as COPD, breast cancer, cardiac insufficiency etc.

Data from clinical quality databases are used for monitoring the quality of treatment in order to assess any underperformance and potentials for improving quality of care.

There are currently more than 60 national clinical quality databases.

The data completeness in the clinical quality databases is generally very high. With a requirement for completeness of at least 90 per cent, the databases are attractive both nationally and internationally. In addition, the clinical quality databases are closely integrated with the scientific societies and are highly reputed within professional environments.

3.2.7: Biobanks

Denmark is a pioneer in establishing population-based biobanks. Several large biobank cohorts provide standardised information on enrolment and repeated follow-up of morbidity and mortality through linkage to the population-based health data registry systems. Amongst the biobanks are the Danish National Biobank, the Danish Cancer Biobank, the Neonatal Screening Biobank, the National Birth Cohort Biobank and the Dementia Biobank.

Specific Danish resources such as our civil registration number, national healthcare system, registries defining genetically informative populations (such as the Twin Registry and the Multiple Generation Registry) and health outcomes (Inpatient registry, Cancer Registry and Cause of Death registry) make Denmark uniquely suited to a successful biobanking infrastructure. Several Danish biobanking initiatives have achieved international visibility and respect for their focus, vision and scientific as well as organisational quality.

Biobank collections of human tissue, blood and other biological samples pose a goldmine of information for research and healthcare. Comparison of genetic factors with lifestyle information and environmental impacts affecting a population will be instrumental in identifying the causes of some of the major diseases. This knowledge may be key to developing new therapies and tailored medication.

Taken together, the civil registration number, access to comprehensive biobanks together with access to various registries containing detailed patient data provide unique opportunities for epidemiological research and for advancing both basic health science research and clinical drug research. The fact that Denmark is a world leader in epidemiological research is to a great extent attributable to the nation's many biobanks and the unique Danish registries which provide detailed information on the entire population.

Access to healthcare data for research purposes

Healthcare data can be made available for specific scientific purposes in accordance with Danish laws and regulations, and Denmark has a strong tradition for epidemiological and clinical research based on these data. In 2013, a National Strategy for Access to Health Care Data has been initiated which aims broadly to improve the use of data for research purposes.

For more information and guidance on the use of healthcare data for research please contact: Regionernes Kliniske Kvalitetsudviklingsprogram (RKKP): <http://www.rkkp.dk/kontakt>

3.2.8: Culture of openness and collaboration between universities, healthcare professionals and industry

Ideas for new therapies and new products often come from doctors, nurses and other users of medical devices and technologies. Hence, close, productive collaboration between healthcare professionals and the companies and universities that help to translate the ideas into new products is crucial.

Denmark has a long-standing tradition for close and fruitful collaboration between these parties based on a culture of open-door policy, a spirit of inquiry and mutual interest in turning new ideas into real products. Many characterise this as a uniquely Danish culture, founded on trust and informal relations, which makes for flexible, dialogue-based and equitable collaboration on the development and testing of new products.

This unique collaborative culture is a precondition for effective collaboration between society, research and industry, which forms the basis for an effective healthcare industry. The research institutions develop collaborative projects and research platforms, while industry contributes market expertise and actual participation in development programmes. This collaborative culture co-exists in Denmark alongside the more formal frameworks for strategic partnerships between researchers and industry. Within the pharmaceutical area, one example is the NEXT Partnership. For further information on NEXT Partnership go to chapter 4.

Within the medical technology area, Denmark also distinguishes itself in offering a range of university degree programmes combining medicine with engineering studies in close partnership with industry. These programmes are offered at the University of Copenhagen/Technical University of Denmark, Aarhus University and Aalborg University.

Another good example is the unique Danish Industrial PhD Programme run by the Ministry of Higher Education and Science, and a sound formal system for research-industry collaboration contracts within the National Network for Technology Transfer – techtrans.dk.

Collaboration examples from the regions

There is close collaboration between hospitals and universities on research, training and research appointments. This collaboration largely concerns combination appointments, research infrastructure and translational research. If a company contacts a clinical researcher with a view to conducting a trial at a hospital, it has the certainty that the researcher is qualified, has access to state-of-the-art equipment, methodologies and expertise and has a network within the associated university. In this way, industry gains access to a network within the university setting. The regional structure of the Danish hospital sector ensures that, on making contact with the regions, industry not only has access to a hospital, but, in principle, access to all of the region's hospitals, researchers and patients.

Clinical Trials Office Denmark: Section 4.1.2 describes Clinical Trials Office Denmark, a joint service which works to attract clinical trials to Denmark in alliances with industry (pharmaceutical and medical technology industry).

Region of Southern Denmark: With its policy on regional health research, the Region of Southern Denmark has taken a firm stance on its mission to improve its capacity to form research partnerships with industry. One initiative is called "South Denmark Health Innovation" (Syddansk Sundhedsinnovation). By concentrating regional initiatives within healthcare innovation, the Region is committed to achieving the best possible coherence and synergy between research, training, innovation and uptake of welfare solutions at the Region's hospitals and institutions. At operational level, the Region of Southern Denmark's OPI work is anchored in the Health Innovation Centre of Southern Denmark, an interdisciplinary staff function under the Board of Directors. The Health Innovation Centre of Southern Denmark was established in 2012.

Overall, the Health Innovation Centre of Southern Denmark is a single-point-of-entry for the region's hospitals (including the new hospital buildings) and other institutions in relation to innovation and public-private partnerships. The Health Innovation Centre of Southern Denmark is also the gateway for companies wishing to join forces with the region to develop new products. In this respect, the Health Innovation Centre of Southern Denmark develops products with a focus on needs as well as optimising work procedures and services.

In terms of structure, the Health Innovation Centre of Southern Denmark has three professional units; innovation partnerships and media, health innovation and cross-sectoral ICT and Telemedicine.

The Health Innovation Centre of Southern Denmark is located in Odense Science Park near key partners such as Odense University Hospital, the University of Southern Denmark, MedCom, Welfare Tech and Healthcare Denmark.

In October 2013, the Region of Southern Denmark opened a 1,100-square-metre innovation hall adjoining the Health Innovation Centre of Southern Denmark in the Science Park. The hall is used for testing, e.g. equipment, work procedures, advanced technologies and robots in realistic surroundings. Both hospitals and companies can use these facilities.

The Capital Region of Denmark: At operational level, in early 2012, the Capital Region of Denmark established a Centre for Innovation and Research (VIF), which acts as a single-point-of-entry for staff and companies in relation to research and innovation in the Capital Region of Denmark. VIF helps with a wide range of tasks within law, commercialization and clinical studies in co-operation with the industry as well as innovation and business collaboration.

Chapter
4

A strong tradition and sound framework conditions for clinical trials

In this chapter you can read about the strong tradition and good framework conditions for conducting clinical trials in Denmark. By siting clinical research activities in Denmark, companies gain access to:

- Highly qualified, reliable and experienced doctors and nurses in research environments of a high international standard
- Interested and suitable trial subjects – combined with sound registries and representative population statistics that make it possible to identify and trace the trial subjects
- A well-organised hospital sector conforming to a high clinical standard
 - with administrative procedures aimed at collaboration with private-sector firms
 - and geared to international studies
 - with excellent research infrastructure geared to clinical research
- Effective administrative processing by competent public authorities
- High-quality Danish patient data

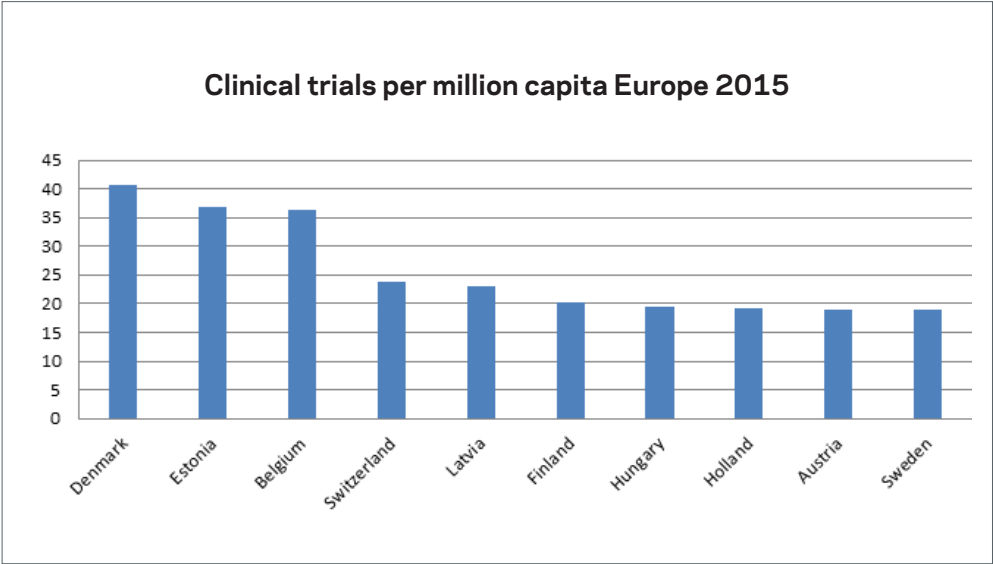
4.1: Clinical trials

The strengths outlined above have been a contributory factor in Denmark's ability to attract a great deal of clinical research – beyond what is otherwise merited by our population size. In 2015 Denmark was in 10th place internationally (Europe) in terms of the total number of clinical drug trials per country. If the number of clinical drug trials is measured in relation to population size, in 2015 Denmark was in first place.

The fact that the quality of Danish patient data is high is illustrated by the fact that repeated FDA and EMA inspections of Danish trials have revealed no problems. The standard of quality is underpinned by the fact that Denmark has been one of the pioneer countries in the introduction of the principles of Good Clinical Practice, and the fact that the country currently has an effective network of competent GCP units attached to its university hospitals. Danish investigators and other clinical research staff consequently find it a given to abide by the GCP principles.

However, the quality of clinical research in Denmark has also been documented as being of a high standard. The volume of Danish scientific publications based on clinical trials is high (measured by per million capita) – and internationally Denmark is surpassed only by Sweden on this measure⁵.

5. Dansk Sundhedsforskning – status og perspektiver (Danish Healthcare Research – Status and Perspectives), a report by the Ministry of Health and Prevention, as represented by the executive forum for medical health research and the Danish Agency for Science, Technology and Innovation, June 2008.



Source: Danish Association of the Pharmaceutical Industry (Lif), July 2015, measured by www.clinicaltrials.gov.

Throughout the 1990s, a very large number of clinical trials were conducted in Denmark in, e.g. the cardiovascular area. Denmark has also subsequently demonstrated its strengths in connection with the performance of complex studies requiring extensive coordination and access to high-technology equipment such as scanners. This is one of the reasons why clinical cancer research has risen to prominence in Denmark.

The below list presents the therapy areas with the most applications for clinical trials in 2015⁶

Reported Trials for Therapy Area	
MedDR ³ Code for Therapy Area	Total trials
Neoplasms benign, malignant and unspecified (incl. cysts and polyps)	101
Nervous system disorders	24
Respiratory, thoracic and mediastinal disorders	22
Infections and infestations	21
Surgical and medical procedures	21

6. Sundhedsstyrelsen: Årsrapport 2015, Kliniske forsøg med Lægemidler, juli 2016 (<http://laegemiddelstyrelsen.dk/da/nyheder/2016/-/media/C82ACD764E5B401CBBE73850CC70C807.ashx>)

The new hospital structure

With the prospect of significant improvement of the physical settings for the hospital service in Denmark over the next decade, during which \$7 bn will be invested in new, specialised hospitals, the settings for clinical research in Denmark will also be greatly enhanced and align the national research infrastructure to meet future demands.

A significant strength for clinical research in Denmark is that approximately one third of each year of new graduates of medicine goes on to complete a PhD degree. A large number of such doctors conduct clinical research and, in so doing, gain qualifications which in the international context are outstanding. This means that within the Danish health service there are a great many professionals who are capable of organising and conducting clinical research at the highest international level.

4.1.1: Openness towards participation in clinical trials

More than 100,000 Danes participate annually in clinical trials and medical research. Approximately 13 per cent of the adult Danish population has participated at least once in medical research or a clinical trial⁷.

Looking in isolation at clinical drug trials sponsored by private-sector pharmaceutical firms, figures from the Danish Association of the Pharmaceutical Industry (Lif) and Dansk Biotek⁸ indicate that almost 15,000 Danish citizens participate in such trials every year. The majority participate in clinical phase III trials⁹.

The Danes are generally satisfied with the outcome of their participation in clinical trials and the majority would like to participate in trials/research if they were invited to do so again. Also, a study by A&B Analyse has shown, that the Danes are very open towards participating in clinical trials, with 40 percent answering that they are positive, while only 20 percent are against the thought of participating in a clinical trial¹⁰.

One significant determinant of positive perceptions of trial participation among subjects is a confidence-inspiring setting for participation. The standard of ethics of the researchers and the companies involved must be high, and in Denmark this is achieved by factors such as the tradition for explicit collaboration agreements on Clinical Drug Trials between the Danish Association of the Pharmaceutical Industry, the Danish Medical Association and the Organization of Danish Medical Societies.

Moreover, Danish legislation ensures assessment of such trials by an effective system of committees on health research ethics, and readily available insurance cover. The existence of a public-sector patient insurance system covering participation in clinical trials ensures that Danish trial subjects have easy and flexible access to insurance cover, if, contrary to expectations, they come to any harm as a result of trial participation.

In addition, Danish patients exhibit a high degree of trial compliance. In international terms, Danes have a high level of educational attainment – illiteracy being rare – and there is consequently great certainty that both oral and written information about the

7. Source: http://www.si-folkesundhed.dk/upload/medicinske_forsoeg_fkj.pdf

8. Industry association of Danish companies within biotechnology applied to drug development and industrial biotechnology.

9. Results from the Danish Association of the Pharmaceutical Industry's (Lif) and Dansk Biotek's study of clinical research activities in Denmark in 2014, Lif and Dansk Biotek.

10. http://medwatch.dk/secure/Sygdom__Sundhed/article7095796.ece?utm_source=Feed&utm_medium=top&utm_campaign=Morgen&utm_content=2014-10-13+08%3A13%3A00

study will be understood as intended. An effective infrastructure and readily available health service to which patients are accustomed to seek medical care without demands for direct payments is also conducive to good dialogue between the trial subject and doctor/investigator. Finally, flexible arrangements in the labour market appear to reduce the practical barriers that may otherwise hinder participation in a clinical trial.

To reduce the practical barriers and facilitate fast recruitment the Danish Ministry of Health has launched a site on the Danish health portal sundhed.dk. One of the purposes of the site is to be able to recruit human subjects for research fast, which benefits the pharmaceutical companies, the medical devices companies and the researchers at the hospitals. The site, "Become a human subject", can be found here: (<https://www.sundhed.dk/borger/sundhed-og-livsstil/bliv-forsoegsperson/>).

When a company applies to the Danish authorities for approval of a clinical trial it is possible to indicate whether the company wishes to recruit patients using the site "Become a human subject" when the Danish authorities have approved the clinical trial.

4.1.2. Clinical Trials Office Denmark

Denmark already ranks among the leading countries when it comes to recruiting subjects for clinical trials. Equally Denmark is among the countries with the highest number – measured per capita – of clinical trials. Denmark is strongly committed to retaining and developing that position. To that end, in 2012, the Danish regions and Danish industry established a joint project to create a simple and efficient portal aimed at attracting more clinical trials to Denmark. Therefore, Clinical Trials Office Denmark has been established facilitating corporate access to preparing and planning clinical trials in Denmark, including recruiting trial subjects.

Clinical Trials Office Denmark works to ensure that industry can make contact with a unified health service, processes and contracts are standardised and recruitment is streamlined. The model ensures joint allocation of roles and responsibilities between regions and industry and consistent information. Companies can use Clinical Trials Office Denmark to:

- Obtain a comprehensive overview of relevant partners to clinical trials in Denmark, including contact information, within just 4 working days
- Obtain access to national negotiation of contracts
- Get an estimated number of patients for the specific disease you are interested in

Clinical Trials Office Denmark is collaborating closely on concluding agreements with industry for access to clinical trials with relevant patient groups. Companies that apply via the Clinical Trials Office Denmark system in one region thereby automatically gain access to legal, medical and research expertise.

Consistency is also safeguarded through a formalised alliance of legal staff, who in each of Denmark's five regions deal with contracts for clinical trials. The legal staff dealing with clinical trials are organised in a way that ensures a rapid and coherent response from all five regions. Whenever a company seeking subjects for clinical trials contacts one region,

it is automatically forwarded to colleagues working in the other four regions. Subsequently, and within only four days, legal staff from all five regions delivers a coherent answer to the inquiry.

Clinical Trials Office Denmark is preparing a number of disease-specific networks and seeks to develop improved registries for rare diseases. One network, for example, will be dedicated to respiratory medicine, and will provide nationwide-coverage. Another network is dedicated to paediatrics.

For more information, please see: <http://www.clinicaltrialsdenmark.com/>

What is Clinical Trials Office Denmark?

Clinical Trials Office Denmark works to attract more clinical trials to Denmark. Clinical Trials Office Denmark offers services that meet the feasibility requests, facilitate fast access to relevant groups of patients, and conducting clinical trials. Altogether, these services help pharmaceutical companies and CROs to gain fast access to the Danish healthcare system. Thus, the entire Danish healthcare system can be reached through a single point of contact with local knowledge of hospital departments in Denmark. Clinical Trials Office Denmark is a collaboration between the five Danish regions that have operational responsibility for the healthcare system. Hence, use Clinical Trials Office Denmark to:

- Obtain a comprehensive overview of relevant partners for clinical trials in Denmark, including contact information, within just 4 working days
- Obtain access to national negotiation of contracts
- Address challenges linked to the conditions for clinical trials in Denmark
- Get an estimated number of patients for the specific disease you are interested in

4.1.3. Quick processing of drug trial applications

The Danish authorities assigned to approve clinical trials work swiftly and efficiently. Applications for approval of new trials must be processed within 60 days, but the Danish Medicines Agency is aiming for processing to be completed within a maximum of 30 working days, corresponding to 42 calendar days.

In 2014, 91% of all applications were reviewed within 42 calendar days. 9% were reviewed within 60 calendar days, which is the time limit laid down in Directive 2001/20 EC on review of clinical trial applications. The remaining <1% were replied to after more than 60 calendar days¹¹.

Just less than half of the applications have their trial approved at first response by day 42. The remaining applications were turned down with a letter of justification, whereupon the final, and in most cases positive, decision was announced within 60 days. On a yearly basis, some 2 per cent of applications are rejected by the Danish Medicines Agency.

11. Årsrapport 2014 Kliniske Forsøg med lægemidler:
<http://laegemiddelstyrelsen.dk/da/udgivelser/2015/-/media/D8E52FA276FC4E6CAE7C04AE8C986639.ashx>

Fast Track

Since April 2012, the Danish Medicines Agency has offered shorter assessment times for trials suitable for risk-adapted assessment. A 14-day assessment time is offered for trials which satisfy the following criteria:

- The investigational medicinal products to be tested are authorised in an EU or EEA country. Investigational medicinal products are tested in the patient population they are licensed for.
- The investigational medicinal products are tested under the licensed indication, dose and route of administration.
- The investigational medicinal product is used alone or in well-described (dose, route of administration, duration) and known combinations with other medicinal products
- The risk involved for the trial participants is on the same level as the risk of standard treatment.

Since 2009, it has been possible to obtain a coordinated assessment of an application for a clinical trial that is to take place in several European countries through the Voluntary Harmonisation Procedure (VHP). Denmark participates voluntarily in all requests for a VHP and contributes actively to improve the procedure. In 2014, Denmark participated in 45 clinical trials that have been coordinated with the European authorities concerned.

Applications to the Danish Medicines Agency may be submitted electronically. The trials are registered in EudraCT, the European Community database of all clinical trials commencing in Europe from 2004 onwards, trial approval status vis-à-vis the national medicine regulatory authorities and research ethics assessment bodies together with information on which countries and hospitals are participating. EudraCT is used for information exchange between the European medicine regulatory authorities. In addition, much of the content is publicly available via www.clinicaltrialsregister.eu

In 2014 a one-shop-stop for electronic submission of clinical drug trials applications and submission of subsequent amendments, notifications and safety related material was launched for users from companies. The extranet portal of Danish Medicines Agency DKMANet is a shared platform for submission to the research ethics committee system and the Danish Medicines Agency. Applicants from companies can use a digital company certificate to send the application electronically. The platform makes use of information indicated in the European application form EudraCT and requires that the information is available therein before using the DKMANet platform. The portal automatically makes a selection of relevant documents for the two bodies, i.e. the research ethics committee system and The Danish Medicines Agency. An improved version will be launched in 2016 and researchers will be able to apply by using a digitalised signature.

At the national level, the Danish Medicines Agency liaises with the national and regional system of committees on health research ethics, regional GCP bodies, the Danish Association of the Pharmaceutical Industry, the Danish Medical Association and the Organization of Danish Medical Societies (representing 117 societies) on clinical trials. The Danish Medicines Agency holds regular briefings and dialogue sessions for companies and researchers, and its staff teaches courses and hold seminars etc. in this area.

A new EU-regulation on clinical trials in humans was adopted in April 2014 but will apply no earlier than 2018 due to development of an EU data portal. The new regulation on clinical trials will replace the existing directive from 2001 and aims to further harmonise the requirements of clinical trials across the EU while ensuring the safety of patients and robustness of data generated. The main purpose of the regulation is to set-up an improved framework for clinical trials in the EU thereby encouraging more research in new and improved medicines for European patients.

The Ministry of Health is currently working towards adaptations needed in preparation of the new regulations on clinical trials. With this purpose, the ministry has set up working groups with members from both the Medicines Agency and The National Committee on Health Research Ethics to adapt the current national law on clinical trials and establish the new IT-system. The Parliament is currently debating a new legislation that together with the new EU-regulation will provide the legal basis in Denmark for clinical medical trials.

The Danish Medicines Agency is actively engaged in the European network of regulatory bodies to contribute to the implementation of the EU clinical trials regulation and the development of the EU portal and database. This is done in close dialogue with the National Committee on Health research and stakeholders.

4.1.4: Committees on health research ethics

The Danish health research ethics committee system, consist of regional committees on health research ethics, and a national committee that is appointed with a number of special powers to ensure consistency within the committee system. The Act on Research Ethics Review of Health Research Projects entails electronic reporting and the possibility of ultimately coordinating the committee system's reporting procedures with the Danish Medical Agency. In addition, English-language trial protocols no longer need to be translated into Danish.

Research solely involving anonymous human biological material doesn't require the approval of the system of research ethics committees provided that the material has been collected in accordance with applicable rules.

Generally in the case of multi-centre trials, the application is only required to be submitted to one regional committee, i.e. the regional committee in the area where the principle investigator will carry out the research project. The approval then covers all Danish sites.

4.1.5: Public private research partnership on clinical trials

In recent years several research partnerships on clinical trials between the public and private has been formed. In 2014 the companies MSD and Novartis entered into a Framework Agreement with the Capital Region and the University of Copenhagen. The aim of the collaboration is to increase the intensity and the visibility as well as the speed of decisions for all types of research collaboration within the pharmaceutical value chain.

National Experimental Therapy partnership (NEXT) was formed by an investment of the Innovation Fund Denmark. NEXT is public-private partnership within clinical research which originally comprised the Danish regions, universities, Bioneer and five pharmaceutical companies. The partnership was formed to make Denmark the preferred country of choice for the pharmaceutical industry for carrying out early clinical trials of new drugs in patients. In particular, the partnership focuses on proof of concept trials and is also working to optimize all processes relating to the start-up and implementation of clinical trials, where optimizing legal and statutory processes has a high priority as well as national recruitment of patients.

A high degree of predictability of trial success in the clinical trials is also a key element of NEXT. The trials start as planned, and the agreed number of patients is recruited. The founding partners of NEXT were: the Capital Region of Denmark, Region Zealand, Central Denmark Region, Region of Southern Denmark, The North Denmark Region, University of Copenhagen, Aarhus University, Aalborg University, University of Southern Denmark, Bioneer, LEO Pharma, Novo Nordisk, MSD, Novartis and Roche.

In 2016, The Innovation Fund Denmark invested further in NEXT enabling the establishment of two new clinical research centers and NEXT now contains clinical research centers within oncology & hematology, dermatology, respiratory medicine and infectious diseases. 7 new pharmaceutical or biotech companies joined as partners: AstraZeneca, Boehringer Ingelheim, Pcover, RSPR Pharma, Serendex Pharma, Statens Serum Institut and Symphogen. NEXT will expand further in the future with new clinical research centers, associated partners and associated hospital departments too.

For more information, please check: <https://nextpartnership.dk/en/>

4.1.6: Denmark as a pioneer/world champion of personalized medicine

In Denmark, there is access to comprehensive biobanks containing samples of tissues and blood that offers unique opportunities for epidemiological research and support for both basic scientific research in pharmaceuticals and clinical pharmaceutical research (as already noted in 3.2.7 concerning biobanks). With access to biological material and information, scientists are able to tailor a more precise medical treatment of each patient, personalized medicine. In Denmark has the ambition to become a leading country when it comes to personalized medicine, paving the way for future generations. In close collaboration with the Ministry of Health and other central stakeholders Danish Regions is currently establishing a framework enabling pharmaceutical companies to take advantage of the unique collection of biological specimens in the Danish health care system ensuring better and more efficient treatments of patients.

World-class research

In the healthcare area there is access to a strong research environment in Denmark. For example within pharmaceuticals, the medical foundation at both universities and hospitals is very solid. In this chapter you can read about healthcare research at the Danish universities. This is followed by a description of a number of Danish research strengths and finally some of the new research initiatives in Denmark.

5.1: Healthcare research at the Danish Universities

5.1.1: University of Copenhagen (KU) – Faculty of Health and Medical Sciences

At KU, healthcare research is undertaken across the biomedical, natural and social sciences. Human and veterinary health and disease are addressed as one, from a 'single-health' perspective. Key areas include metabolic, neurological and mental health, healthy ageing, lifestyle diseases, cancer and communicable diseases including zoonoses. Basic and clinical disciplines within human and veterinary medicine are combined in translational and innovative research approaches, supported by a strong Danish platform based on stringent legal requirements and ethical standards in databases, biobanks and animal models combined with world-class laboratories and human test facilities. The close relationship with public-sector and private-sector stakeholders completes the innovation cycle towards the implementation of early diagnostics, prevention and treatment of human and veterinary diseases including personalised treatment and drug development.

For more information about the research and facilities at KU, see:

<http://healthsciences.ku.dk/>

5.1.2: Technical University of Denmark (DTU)

DTU has a wide range of research activities within life sciences, covering medical devices and services as well as biotechnology, food and veterinary related research. The research has a strong focus on technical disciplines and technological development and spans disciplines such as electromechanics, imaging, robotics, nanotechnology and informatics through drug delivery, bioinformatics, nutrition and health to organisational planning of healthcare services, construction and facility management and ambient assistive living technologies. DTU has a strong tradition for industry collaboration and access to state-of-the-art labs and facilities, e.g. a centre for micro- and nanofabrication with clean room facilities and a centre for electron microscopy.

For more information about research and facilities at DTU, see: www.dtu.dk

5.1.3: University of Southern Denmark (SDU) - Faculty of Health Sciences

The strength of SDU lies in research in public health and diseases that adversely affect the population, individual citizens, and society, in order to advance understanding of:

- The biomedical basis,
- The incidence and trends within the population,
- The influence on quality of life and functioning,
- And diagnostics and treatment.

This is done by combining advanced biomedical and epidemiological research with research in health promotion, disease prevention, rehabilitation, and methods of examination and treatment. The Faculty of Health Sciences offers a wide range of health-oriented and research-based study programmes at Bachelor, Master, postgraduate, and PhD levels respectively.

For more information about the research and facilities at SDU, see:
<http://www.sdu.dk/health>

5.1.4: Aarhus University (AU) - Faculty of Health

The Faculty of Health at AU consists of five strong departments. It houses research activities from basic science to applied clinical research and even epidemiological research within a wide range of areas. A hallmark of Health is its close cooperation with the Central Denmark Region, Aarhus University Hospital and other Regional Hospitals where medical research on a large scale is taking place literally among the patients for the benefit of both patients and the academic disciplines. Knowledge exchange is a core activity at Health and comprises knowledge sharing and cooperation with private companies, within areas such as: Genes, cells and molecules; Infection and immune system; The body's organs and functions; Cancer; Nervous system; Mental disorders; Health and society; and Register-Based Research.

For more information about research and facilities at AU, see: <http://health.au.dk/>

5.1.5: Aalborg University (AAU) – Faculty of Medicine

The Faculty of Medicine at Aalborg University is working to create better health, welfare, and growth in close cooperation with the surrounding society, e.g. industry and the health sector. The Department of Health Science and Technology combines basic research and innovation in the fields of health science and technology. The research areas range from cell to system, e.g. biomedical technology, medicine, sensory systems, pain, translational research, drug testing (clinical trials), neural prostheses, rehabilitation, telehomecare, sports science, biomedicine, and medical informatics. Key areas of the Department of Clinical Science, which is located at Aalborg University Hospital, covers research within almost 40 medical specialties ranging from cardiology, cancer diseases, orthopedics and hypothermia to research on nutrition and exercise, clinical nursing and sexology. The Faculty is practicing interdisciplinary research and knowledge sharing. Aalborg University has a long and strong tradition for collaborating with industry partners.

For more information about the research and facilities at AAU, see:
<http://www.hst.aau.dk/> and <http://www.medicine.aau.dk/>

5.2: Positions of strength in Danish research

5.2.1: Lifestyle

Danish registries are well suited to investigating epidemiological correlations in obesity research and to formulating hypotheses on the development and treatment of obesity. Several European alliances have been established within this field, and several groups hold strong positions within metabolic integrative research, while other groups are engaged in the interaction between food and drugs. The UNIK consortium at the University of Copenhagen within Food, Fitness and Pharma is an example of a multidisciplinary approach involving more than 200 researchers. Denmark has some of the best-characterised population studies internationally with biological material and genetic research focusing on disease aetiology and biological markers.

5.2.2: Diabetes mellitus

Diabetes is a chronic disease that presents a major and growing health problem globally. Denmark has a strong tradition in both type 1 and type 2 diabetes research, from epidemiology, pathogenesis and genetics to treatment of diabetes and its complications. Danish registries and data from the Scandinavian homogeneous populations have been important tools in translating diabetes research into treatment options covering all phases of diabetes. Also, Denmark has a tradition for public-private partnerships and via Novo Nordisk has contributed considerably to diabetes research and advances in diabetes therapy worldwide.

In 2015 the Capital Region of Denmark and the Novo Nordisk Foundation announced their plans to establish a major new diabetes centre in Copenhagen. The centre will be a driving force for treatment and clinical research within diabetes. The new centre will collaborate with other hospitals, universities and participants in the public and private sectors both in Denmark and abroad to create one of the leading global environments for the treatment of diabetes and clinical research in the Capital Region.

5.2.3: Neuropsychiatry

Neuropsychiatric disorders constitute a major disease and financial burden worldwide and improved treatments based on the latest insights into disease mechanisms will be of pivotal importance. The universities and university hospitals in Aarhus and Copenhagen have strong research environments within psychiatric genetics and preclinical as well as clinical neuropsychiatry. Furthermore, these centres collaborate closely with the Danish pharmaceutical company Lundbeck A/S on basic preclinical research as well as drug development targeting the neuropsychiatric area.

The outcome of translational research in neuropsychiatry in Denmark is promising, for example:

- Danish research in psychiatric genetics has identified early chromosomal changes in schizophrenia, which may provide the basis for development of new medical treatment.

- Brain imaging studies and psychopathological measurements have provided new insight into and identified biomarkers of diseases such as depression, obsessive-compulsive disorders and schizophrenia, while preclinical studies have elucidated some of the brain mechanisms involved in drug addiction.

5.2.4: Cancer research

Cancer is the fastest growing major disease in Europe due to the increasing age of the European population. Denmark has strong expertise as well as clinical infrastructures in this important area. As far as prevention is concerned, Denmark has a very strong cancer registry (actually the oldest in the world) existing for more than 50 years. With cancer treatment taking place almost exclusively within the public hospital system it is possible to track both the general population and individual patients to study their exposure to environmental factors, and most importantly the relationship between genotype and environment – termed molecular epidemiology. Denmark also has several strong groups in biomarker discovery together with comprehensive biobanks (from 2008 a national cancer biobank programme for all branches of oncology) that are essential for biomarker validation. Denmark has a solid tradition for clinical cancer research with established research units at all university hospital oncology departments. The research is conducted across medical specialties and has strong international impact.

In response to the increasing technical demands of early clinical trials, the Department of Oncology at Rigshospitalet in Copenhagen has opened a dedicated unit for Phase I and early Phase II trials. At the Phase I unit they offer complete project management and clinical trial management systems.

For more information, see: <http://www.rigshospitalet.dk/RHenglish/Menu/Departments+and+Clinics/Finsen+Centre/Department+of+Oncology/Phase+1+Unit/>

5.2.5: Dermatological research

Chronic and acute skin diseases constitute a major health burden worldwide. Denmark has a longstanding strong position within dermatological research and plays a leading role in several therapeutic areas including chronic inflammatory skin diseases such as psoriasis, eczema and collagen-vascular disorders, as well as skin cancer, chronic wounds and venereal diseases. Clinical research and innovation have high priority at the dermatological hospital university departments, which hold special laboratory facilities for the diagnosis of allergies and infections as well as special imaging techniques, histopathology and molecular diagnostics.

Denmark is also one among only a few countries in Europe that have expertise in confocal microscopy. The dermatological hospital university departments maintain large nationwide clinical patient databases covering several major diseases such as psoriasis, contact dermatitis, atopic eczema, urticaria, hidradenitis suppurativa, skin cancer and venereal diseases to support academic research and faster recruitment into industry sponsored clinical trials. The dermatological hospital university departments collaborate closely with pharmaceutical companies and are part of the private-public National Experimental Therapy Partnership (NEXT) dedicated for fast track execution of phase I and II clinical trials.

5.2.6: Respiratory medicine

Respiratory diseases represent one of the major socio-economic challenging health areas, as chronic patients with asthma, COPD or fibrosis are the major constituents of this disease burden. These patients experience life-long illness with required treatment and does also have significant impairment of their working capabilities.

The Danish clinical research in respiratory medicine is represented by major expertise within the large indications mentioned above and Denmark has acclaimed global recognition on the clinical investigations of asthma, COPD and fibrosis.

The clinical society within respiratory medicine has a long tradition for collaboration with the medical industry and involvement in clinical studies. With the existence of the nationwide Danish Respiratory Research Network (DRRN) and the participation in the public private partnership NEXT with the Center for Respiratory Medicine, an easy and swift national feasibility process is available for the companies and the collaborations secures a top level performance, with a uniform high quality across the different departments, when conducting the clinical trials in Denmark.

5.2.7: Infectious diseases

Globally, infectious diseases represent the disease area with the largest economic burden on society as well as on humans. No other single cause kills more people worldwide than infectious diseases. Although many of the serious infectious diseases have been eradicated in the western world, infections are still the most frequent reason for people to seek medical care. This calls for continuous research in the many aspects of infections in order to translate the scientific findings into more effective treatments.

The establishment of the Center for Infectious Diseases and Immunomodulation with the public private partnership NEXT, has provided a national optimized entrance for companies to utilize the excellent clinical and translational research environments. The center eases the access to Danish university hospitals whose infectious diseases research, along with e.g. HIV and hepatitis research include a strong focus on the emerging concept of immunomodulation for infectious diseases. Overall, the Center for Infectious Diseases and Immunomodulation will create a package of key incentives for global companies to locate their early phase trials in Denmark.

5.3: Recent major investments in the research infrastructure

Denmark is currently investing heavily in a new research infrastructure that will provide unique settings for conducting research at the highest international level.

5.3.1: DanStem

With the overall goal of developing new stem cell-based therapeutic approaches for diabetes and cancer, the Danish Center for Stem Cell Research (DanStem) addresses basic questions in stem cell and developmental biology and seeks to identify the factors that govern the development of different cell types in the body. The Center opened in 2011 and comprises two sections: The Novo Nordisk Foundation Section for Basic Stem Cell Biology (BasicStem) and The Section for Strategic Translational Stem Cell Research and Therapy (TransStem).

DanStem has been established as a result of a series of international recruitments coupled with internationally recognised research groups focused on insulin producing beta cells and cancer, already located at the University of Copenhagen. These investigators and their teams are highly regarded throughout the world for their contributions to science. They all have well-established, international collaborations and actively participate in several international scientific consortia. DanStem plays an active role in training undergraduates, PhD students and postdocs. The Center's unique infrastructure, high level mentoring, and international networks makes it an international key contributor to the creation of a new generation of developmental and stem cell biologists and clinicians.

For more information, see: <http://danstem.ku.dk/>

5.3.2: The Danish National Biobank

Over the years, Danish society has invested huge sums in building up a range of national registers containing information about all residents in Denmark. In the same way, the Danish health system has routinely collected biological specimens from a large number of individuals. The main purpose of the Danish National Biobank is to give scientists from Denmark and abroad overview and access to more than 15 million biological samples in both existing and future collections.

Scientists will have the possibility to link information about biological samples from individuals with the large amount of information contained in Danish administrative registries. The Danish National Biobank will become one of the world's largest biobanks and a unique resource that will take Danish biomedical research another step forward.

The Danish National Biobank initiative has 3 pillars:

- A biobank registry with detailed information about the samples available in the Danish health system and in the large, participating research biobanks.
- A large, national biobank
- A coordinating centre for the biobank initiative

For more information, see: <http://www.biobankdenmark.dk/>

5.3.3: European Spallation Source (ESS)

The European Spallation Source (ESS) is a multi-disciplinary research centre based on the world's most powerful neutron source. The new facility will be around 30 times brighter than today's leading facilities, enabling new opportunities for researchers in the fields of life sciences, energy, environmental technology, cultural heritage and fundamental physics.

The ESS is one of the largest science and technology infrastructure projects being built today. The facility design and construction includes a linear proton accelerator, a heavy-metal target station, a large array of state-of-the-art neutron instruments, a suite of laboratories, and a supercomputing data management and software development center.

The ESS facility is being built in Lund, while the ESS Data Management and Software Centre will be located in Copenhagen. Around two to three thousand guest researchers will carry out experiments at ESS each year.

The construction of the facility began in the summer of 2014, and the planning for the ESS research programme is ongoing. Scientists and engineers from more than 60 partner laboratories are working on updating and optimising the advanced technical design of the ESS facility, and at the same time are exploring and imagining how it will be used. These partner laboratories, universities and research institutes also take part in the construction phase, contributing human resources, knowledge, equipment, and financial support.

For more information, see: <http://ufm.dk/en/research-and-innovation/international-cooperation/ess?searchterm=ESS> or <http://europeanspallationsource.se/>

5.3.4: Other investments in research infrastructure

In addition, Denmark is making a large number of other research infrastructure investments. Examples include:

- 1) A National Centre for Particle Therapy at Aarhus University Hospital.
- 2) International Science City at North Campus.
- 3) Center for Protein Research, The Danish Stem Cell Center and The Novo Nordisk Foundation Center for Basic Metabolic Research, all at the University of Copenhagen.
- 4) New hospital buildings worth more than \$7bn will renew and modernise many Danish hospitals.
- 5) And finally, the establishment of the multidisciplinary Danish Platform for Large-scale Sequencing and Bioinformatics coordinated from COBIS in Copenhagen is another example of a unique research initiative that is currently attracting international research investments.

Denmark - a great place to do business

In this chapter, you can read more about doing business in Denmark.

With a corporate tax rate of 22 per cent, competitive business costs and some of the world's most flexible labour market conditions, Denmark is an attractive choice for foreign investors.

Add to this a very simple procedure for establishing a business and the presence of a highly skilled and motivated workforce. The result: some of the best possible conditions for doing business.

Top 5 reasons for locating your business in Denmark:

- In Denmark you benefit from one of Europe's most flexible labour market
- In Denmark you have access to a highly skilled and educated workforce
- In Denmark it is easy to establish a business
- In Denmark there is no red tape and a very low level of corruption
- In Denmark there is easy access to researchers

6.1: Denmark – a country for business

The World Bank's Doing Business Report 2016 ranks Denmark's business climate as the best in Europe because doing business in Denmark has proven to be fast, efficient and profitable. The country also offers highly skilled employees, a famously flexible labour market and a stable business environment.

6.2: An easy and low-risk choice

According to the World Bank, Denmark is one of the easiest places in the world to do business. A company can be established online in just 24 hours – and some of the world's most flexible hiring and firing rules allow for a reduction in the costs related to scaling business operations up or down. So, by choosing Denmark, companies are able to minimise both long-term and short-term risks.

6.3: Quality and transparency

A recent study by leadership advisory firm Heidrick & Struggles rated Denmark first in the world in terms of the quality of its labour force. The Danish public sector has long been respected for its quality, service-mindedness and positive approach to doing

business. Corruption and bribery in the public sector are virtually unknown, which has continually secured Denmark a top ranking on the International Transparency Index.

6.4: Financially and politically stable

Due to its generally stable political and legal system, combined with its strong public finances, Denmark is among the nations best prepared to handle international economic crises. In fact, Denmark remains one of the most stable economies in the EU, as proven by its "AAA" ratings from the global credit-analysis agencies Moody's and Standard & Poor's.

6.5: Flexible labour market

Studies have repeatedly shown that Denmark has some of the most flexible hiring and firing regulations in Europe. These regulations, combined with the government-sponsored social safety-net, constitute the core of Danish 'flexicurity'. In practice, companies have the right to dismiss an employee without incurring indemnification or other costs; the period of notice is typically three months and, if requested by the employer, the employee must continue to work during this time. Between 70% and 80% of Danish employees are enrolled in an unemployment-insurance scheme.

6.6: Innovative, highly competent and motivated workforce

The Danish workforce is among the most motivated in the world, with the second highest employees motivation according to IMD. Danish employees distinguish themselves by being highly educated, efficient and responsible. Thus, 'self-managing teams' are very common within Danish business and industry: a typical team does all its own planning to achieve targets, with minimal intervention from management.

Danish employees are also known for being healthily self-critical, with a willingness to learn and a commitment to making improvements – in both production and performance. Denmark also has a strong tradition of collaboration between universities and private-sector companies, which co-operate on research that often culminates in innovative, prize-winning products.

6.7: Flexicurity is cost-efficiency

The Danish flexicurity provides new investors with significantly fewer irreversible costs and much more on-going flexibility to plan and adjust their production – especially compared with neighbouring countries like Germany and Sweden. A significant benefit is also that, other than a negligible annual expenditure of approx. EUR 1,350 per employee, employers in Denmark are not required to make a social-security contribution, whereas employers in Germany and Sweden must pay in excess of 30% of an employee's salary towards social security.

6.8: No double taxation

The Danish corporate tax has been reduced to 22%. Denmark also has a unique tax rule by which Danish companies are generally not taxed on income from foreign branches, which prevents double taxation. In most other countries, relief from such double taxation may result in adverse tax consequences or financial penalties. This makes Denmark the perfect platform from which to base a Nordic or European headquarters.

6.9: Easy access to researchers

One big advantage of a small country like Denmark is that networking is easier, with less separation between the scientist or scientific entrepreneur and the decision makers, such as government ministers, policy-makers, and industry leaders. This is conducive to productive relations between academia and industry.

Universities, university hospitals, research centres and private companies of various sizes, all work together. This is a productive form of interaction that is not seen in many other countries. This culture is also fostered by the educational institutions, where the aim is to teach students to work together in an interdisciplinary context, resulting in efficient teamwork and innovative research and products

7.0: Other interesting facts about doing business in Denmark

- 42.2% of adult Danes complete a higher-education programme; 77.1% complete an upper-secondary education; and 96% complete a secondary education
- With 86% of Danes speaking English, Denmark ranks third in the world with regard to proficiency in English as a foreign language
- The percentage of women with a professional career is amongst the highest in Europe and is only 3-4 lower than for the male population in Denmark
- Denmark is ranked among the top three countries in the EU for gender equality
- Denmark is the second most peaceful country in the entire world

For more information on establishing a business in Denmark contact Invest in Denmark
<http://www.investindk.com/>

The Authors

This report is based on input and data from the below partners:

Ministry of Health

The Ministry of Health administers functions related to the organisation and financing of the healthcare system, psychiatry and health insurance as well as the approval of pharmaceuticals and the pharmacy sector.

Ministry of Foreign Affairs of Denmark - Invest in Denmark

As part of the Ministry of Foreign Affairs of Denmark, Invest in Denmark is a tailored one-stop service for foreign companies looking to set up business or research activities in Denmark.

Ministry of Business and Growth

The Ministry of Business and Growth seeks to improve the conditions for growth in Denmark. The Ministry conducts thorough economic analyses and suggests policy initiatives in areas imperative to economic growth.

Danish Regions

Danish Regions is the interest organisation for the five regions in Denmark. Being responsible for hospital and psychiatric treatment, the five regions are the main service providers in the Danish healthcare system. Danish Regions' overall mission is to safeguard the interests of the regions nationally as well as internationally.

Danish Association of the Pharmaceutical Industry (Lif)

Lif's mission is to work to ensure that the pharmaceutical industry has the best possible conditions to research, develop market, distribute and provide information on medicinal products so as to ensure that patients have extensive and rapid access to the best medical treatment.

Medicoindustrien

Medicoindustrien is the industry association for companies in Denmark which develop, manufacture, sell or otherwise take an interest in medical devices.

Medicon Valley Alliance

Medicon Valley Alliance is a network organisation working for the life science organisations in Medicon Valley. As a non-profit member organisation the Alliance implements initiatives on behalf of the life science community with the goal of creating new research and business opportunities within the region.

The Danish IT Industry Association (ITB)

With approximately 400 IT-member companies, the Danish IT Industry Association (ITB) is the largest and leading independent representative for the IT-business community in Denmark.



Start with Denmark

Invest in Denmark provides your company with a tailor-made solution for locating your business in Denmark. We measure our success by how well we contribute to yours. So, if you are considering setting up business or expanding your activities in Denmark, make us your first stop.

Our specialized staff across the globe has the corporate background, industry insight and well-connected networks to advise you on every aspect of locating in Denmark. Not only when you set up, but also as your business grows. Our tailor-made solutions include connecting companies with key local contacts, arranging fact-finding tours and providing comprehensive benchmark analyses. We make sense of local legislation and advantages of locating in Denmark – all free of charge and in guaranteed full confidentiality.

We Look Forward to Hearing from You

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