

abbvie

**RESEARCH  
AND  
COLLABORATION**

– THE UNIQUENESS OF DENMARK

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Research and Collaboration  
The Uniqueness of Denmark

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**RESEARCH  
AND  
COLLABORATION**

## THE UNIQUENESS OF DENMARK

Denmark is a small, knowledge-based economy with one of the strongest pharmaceutical and biotech industries in Europe. Today, the pharmaceutical industry has an export of more than **\$10 billion** (DKK 74B) of which DKK 18.6B goes to USA.

Denmark is home to world-leading companies, such as Novo Nordisk, Lundbeck, Leo Pharma and ALK, and research teams of the highest international class at the Danish universities. Danish pharmaceutical companies rank among the absolute world elite in therapeutic areas, such as diabetes, depression, skin disorders, and allergies. The ten largest Danish pharmaceutical companies employ more than 76,000 people worldwide.

The Copenhagen area houses one of the largest bio-pharma clusters (consisting of both biotech and pharmaceutical companies) internationally. According to a major study conducted by the Danish Business Authority from 2012 with international comparable data, Copenhagen employs **more than**

**26,000 people in the biopharma cluster** compared with 34,000 in Boston, 17,000 in San Francisco, 15,000 in New Jersey, and 9,000 in San Diego. The so-called Medicon Valley of Greater Copenhagen and Southern Sweden employs more than 40,000 people when combining pharmaceutical, medtech, and relevant service providers.

This strong international position is aided by a wide range of **political initiatives** by which the public authorities have established and supported an **excellent framework** for research and development in Denmark. In addition, the long Danish tradition for cooperation between the public and private sectors has helped to create a flourishing and innovative pharmaceutical industry.

Clinical research in Denmark has already led to **significant results**. However, this could not have been achieved without the pre-clinical, innovative, and groundbreaking basic research that provides fundamental knowledge for the future development



of treatments and medication for the benefit of patients.

AbbVie has, as a global biopharmaceutical company that discovers and advances innovative therapies, a vested interest in supporting the research initiatives carried out in Denmark. One way of doing so is this publication that aims at presenting and highlighting the excellent conditions and good opportunities that Denmark provides for pre-clinical research in the hope of stimulating international cooperation among researchers.

We thank Invest in Denmark, part of the Ministry of Foreign Affairs of Denmark and The Danish Regions for offering their valuable advice and contributions to this publication.

General Manager Christina Dyreborg Jeppesen  
AbbVie  
Copenhagen, October 2015

A handwritten signature in black ink, appearing to read 'Christina Jeppesen', written over a light grey background.

**Revised and updated in 2016**

The very high level of clinical research in Denmark is a position of strength in Danish research, and this remains crucial for both the public health system and as a platform for Denmark's many private-sector companies in the pharmaceutical, medical devices, and welfare technology industries. This AbbVie publication: The Uniqueness of Denmark - Research and Collaboration is a second version with an even stronger focus on clinical research. We thank all of the contributors for offering their valuable advice and contributions to this publication.

Copenhagen, March 2016



Photo: Scampix

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Pharmaceutical  
headquarters  
stimulate research

Patients  
support research

Danish universities  
of high international  
quality

Initiatives to  
strengthen Public  
Private Partnership



Numerous national  
health registries

A homogeneous  
population profile

# UNIQUENESS OF DENMARK

Comprehensive  
biobanks

The regulatory frame-  
work for research in  
Denmark

Public funding  
for research and  
development

# INTRODUCTION

## **Denmark is a modern, knowledge-based society with excellent framework conditions for research-based industry**

The excellent framework includes a flexible labor market, favorable taxation rules for research-based businesses, a well-educated population, low level of corruption, a high level of security, and stable macroeconomic conditions. In October 2015, this resulted in the World Bank ranking Denmark as the [easiest place in Europe to do business](#) for the fifth year in a row, and number three in the global ease of doing business ranking, and [Forbes Magazine's ranking Denmark as no. 1](#) in their global league table "Best Countries for Business".

## **Solid investments in research and development**

Denmark is one of the countries in the world that invests the most in research and development. In 2013, private investments in research and development in total accounted for 1.98% of Gross Domestic Product (GDP) while public investments in research

and development in total accounted for 1.11% of GDP. Compared to other OECD countries, Denmark had the [fourth highest public investment](#) in research and development and the [seventh highest private investment](#) in research and development in 2013.

Overall, Denmark has four universities teaching medical science, located in Copenhagen, Aarhus, Odense, and Aalborg, and the Technical University of Denmark teaches systems biology. Greater Copenhagen, including Zealand and Skåne, has a population of 4 million people, highly specialized universities, a world class biotech cluster, and a long tradition for innovative private public collaborations. Lund University, University of Copenhagen and the Danish Technical University are among the world elite. There is easy access in the Greater Copenhagen area thanks to the Oresund Bridge linking Copenhagen and Sweden, high-speed trains, metro and highways, and there is access to 140+ intercontinental and European destinations from Copenhagen airport, as a major Northern Europe hub.

### Scientific institutions in the forefront of science

The European Spallation Source (ESS) is one of the world's largest and most advanced research facilities, and it will be established in Lund (Southern Sweden, only 60 km from Copenhagen) in the coming years, while the ESS Data Management and Software Centre is located in Copenhagen. The ESS can be compared to a giant microscope allowing researchers to study material at an atomic level. It will be useful in the health and life science sector, where neutrons and the neutron scattering techniques and methods are becoming a **tool of choice** in the understanding of **drug delivery mechanisms** and early **drug development** and characterization.

### About the ESS

- ESS is one of the largest science and technology infrastructure projects in Europe, **30 times more powerful** than the facilities in the US and Japan with a total budget of **\$2.1 billion** (DKK 14 B)
- ESS includes a linear proton accelerator, a rotating tungsten target station, 22 public state-of-the-art neutron instruments, a suite of laboratories, and a supercomputing data management and software development center
- ESS will allow researchers to take very precise images and film sequences of structures and processes that are otherwise hidden under the surface of materials and could be compared with X-ray technology.
- ESS will produce the first neutrons in 2019 and is expected to be fully completed by 2025.
- It is expected that between 2,000 and 3,000 researchers will visit the ESS annually to carry out experiments.
- ESS will be co-located with MAX IV, which will, after opening in 2016, be the world leading synchrotron facility.

### **Efficient research and development**

The general Danish research and development framework proves efficient and delivers high quality compared to other countries in a range of various indicators.

### **High number of scientific publications and citations**

Denmark is one of the most productive countries when measured by the number of scientific publications in relation to its population size. Similarly, Danish research has a great impact in terms of citations per publication and in both cases, Denmark is placed third in a comparison of OECD countries, and ranks fourth on the list of the 10 percent most cited publications. The quality and relevance of science is often measured by the “mean normalized citation score” on which Denmark is placed in the **top three** above the USA, United Kingdom and Germany. The normalized citation score measures the average citation rate per article, taking into account the number of articles from the specific country, the type of publication, etc.

### **Longstanding tradition for international perspective and cooperation**

Denmark has a high degree of international collaboration with **60 percent of publications** co-authored with at least one researcher from another country. Due to the high quality of research, Denmark is very successful in attracting EU funds. Among EU's 27 members, Denmark ranks second when it comes to the ratio between the number of granted applications and the applications submitted to the EU, thereby emphasizing the quality of the applications.

### **Strong focus on innovation**

Denmark is consistently ranked in the **top three best countries** in the world after USA by Scientific American for the development of biotechnology. Denmark is ranked fifth on the EU Innovation Output Indicator that measures the extent to which ideas from innovative sectors (all R&D intensive sectors) are able to reach the market .

### **World class universities**

The Academic Ranking of World Universities (2015) have ranked the University of Copenhagen and the University of Aarhus in the **top 100 among universities worldwide**.

### **Efficient public authorities**

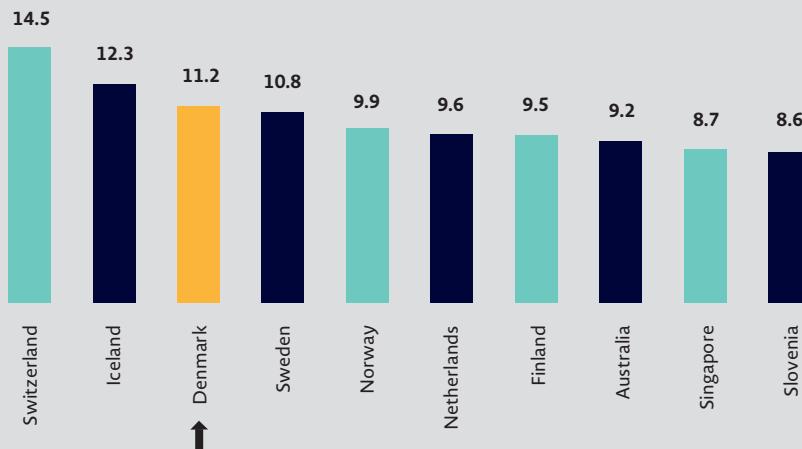
The Danish authorities are known for their quick, efficient, and service-oriented handling of inquiries from the private sector without compromising their strong focus on quality. For clinical trials in particular, the processing of applications by the authorities is highly efficient. Moreover, Danish authorities are very active on the EU level making it possible for even a small country to make an impact.



3.1%

OF DENMARK'S GDP IS  
SPEND ON RESEARCH  
AND DEVELOPMENT  
(2013)

### PUBLICATIONS PER MILLION CAPITA, 2008-2012



#### FOR FURTHER INFORMATION

The European Spallation Source  
[www.europeanspallationsource.se/](http://www.europeanspallationsource.se/)

The World Bank Group, Doing Business  
[www.doingbusiness.org/](http://www.doingbusiness.org/)

Forbes Magazines  
[www.forbes.com/magazines/](http://www.forbes.com/magazines/)

Danish Medicines Agency  
[www.lmst.dk/en](http://www.lmst.dk/en)



# A HOMOGENEOUS POPULATION PROFILE

**The Danish population is homogeneous in terms of its ethnic and socio-economic differences. This minimizes the risk for confounding factors in research and increases the validity of the research outcome.**

As of January 2015, close to 90% of the Danish population was of ethnic Danish origin. This is an advantage in clinical trials since the more homogenous the population, the less variation and hence the smaller the number of patient samples needed to prove a hypothesis. The low level of genetic variation and the uniform phenotypic expression is also an advantage in pre-clinical research and development

## **An equal society**

In addition to this, the Danish health care and educational systems are primarily funded through taxes, and the basic principle for both is free and equal access for all citizens. This results in a high educational level and a high level of health equality in Denmark compared to other countries. It minimizes the risk

of confounding factors, since everyone has the same access to healthcare. The relative equality in Denmark is confirmed by the Gini coefficient, which is the most commonly used measure of economic inequality. Most recent OECD data shows that the Gini coefficient is low in Denmark, at 25.0 compared to an average of 32 in OECD countries and 40 in the United States.

## **A well-educated society**

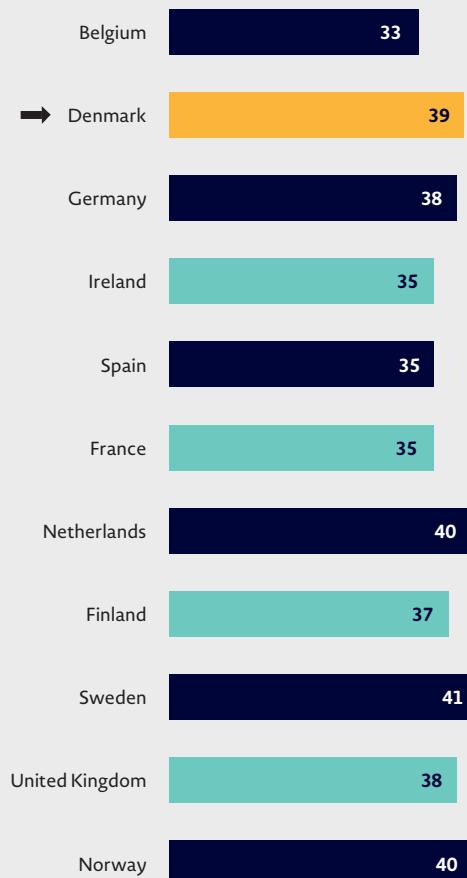
The average Dane is well-educated and literate. Thus, it is possible to expect a high level of compliance, since there is consequently great certainty that, the trial subjects will understand and behave accordingly with the oral and written information about a study.

## **Easy access to information on clinical trials**

To reduce any practical barriers and facilitate fast recruitment, the Danish Ministry of Health has launched a site on the Danish official health website sundhed.dk. The primary purpose of the site is to inform the public about clinical trials and the benefits

of conducting trials. This helps to ensure patients and their relatives that it is safe to participate in a clinical trial. This supports the recruitment of human subjects for research, which benefits the pharmaceutical companies, medical devices companies, and researchers at hospitals.

#### DURATION OF WORKING LIFE, 2013 IN YEARS



THE GINI COEFFICIENT  
IN DENMARK

25

COMPARED TO AN  
AVERAGE OF 32 IN OECD  
COUNTRIES AND 40 IN  
THE UNITED STATES

**FOR FURTHER INFORMATION**

OECD statistics on Denmark  
<https://data.oecd.org/denmark.htm>

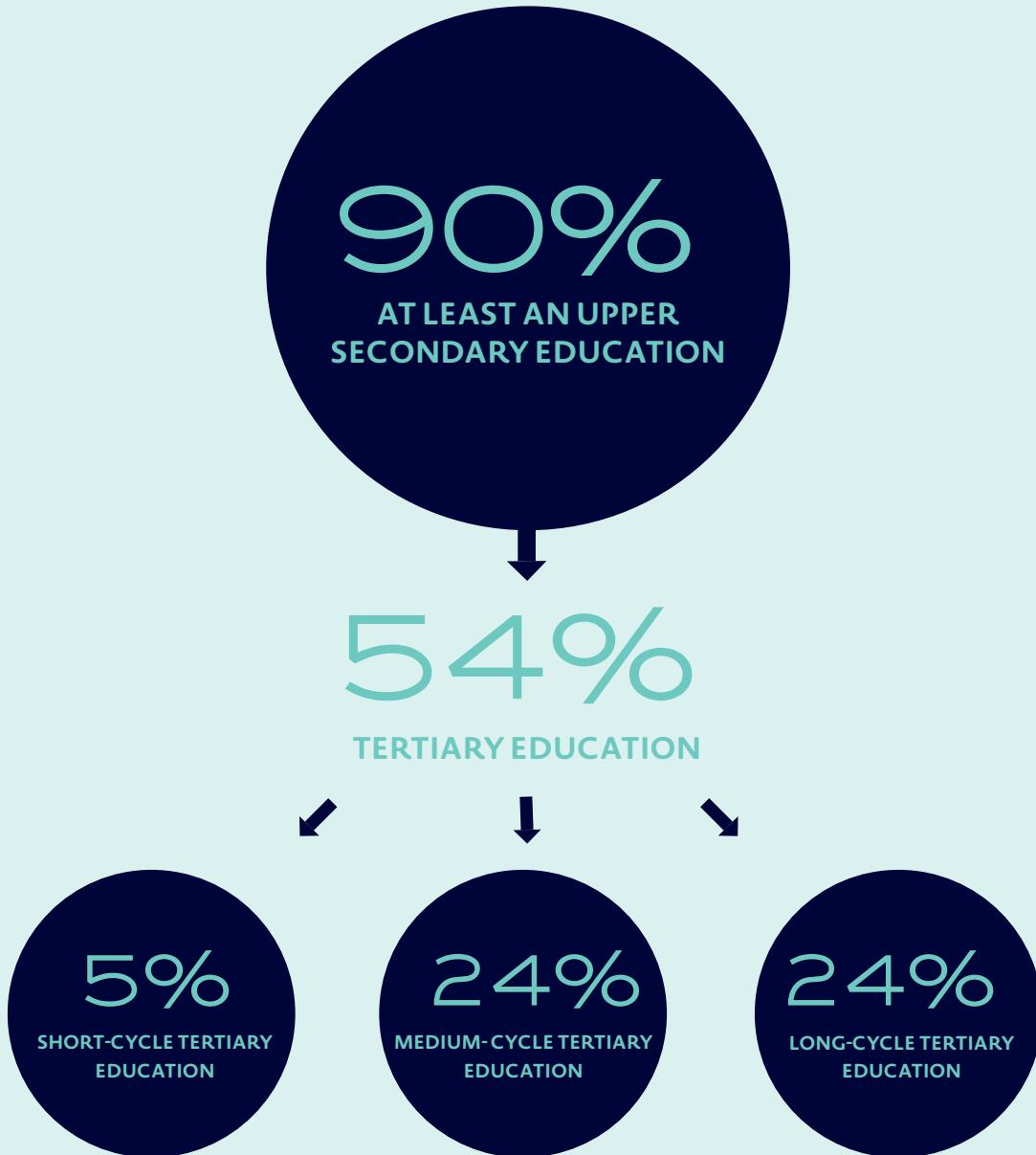
The Danish Ministry of Education  
[www.uvm.dk](http://www.uvm.dk)

Statistics Denmark  
[www.danmarksstatistik.dk](http://www.danmarksstatistik.dk)

Sundhed DK  
[www.sundhed.dk](http://www.sundhed.dk)

## THE DANISH POPULATION IS HIGHLY EDUCATED, 2010

Percentage of a youth cohort that is expected to attain at least upper secondary education and the percentage that is expected to attain a tertiary education.



# DANISH UNIVERSITIES OF HIGH INTERNATIONAL QUALITY

**Worldwide Danish Universities are recognized for their high quality. Recent university rankings from World University Ranking and Academic Ranking of World Universities have placed two Danish universities in the top 100 worldwide and five Danish universities on the overall lists. This is remarkable for a country with eight universities and a population of only 5.5 million.**

An important Danish strength is the public ownership of universities and university hospitals, which presents great possibilities for the integration of research and clinical care and it is further supported by the fact that these public resources are supplemented by substantial public and private investment in medical research in universities and industry.

New opportunities for healthcare research Today's health research is not only taking place at the Faculty of Health and Medical Sciences, and the Danish Universities are in the forefront when it comes to applying other methods and disciplines to research

in health. In recent years, an expanding number of researchers from other fields of study such as the social and humanitarian sciences have contributed to health science. Examples of this development are studies in patient safety and patient compliance using qualitative methods to analyze how adverse events in healthcare may be avoided or to understand why patients do not always comply with the treatment requirements. Many of these studies are conducted as a partnership between researchers and the industry, and they help to develop a more value based healthcare, giving the system and the industry a much better understanding of the needs, values and barriers that patients experience going through a course of disease. Another example of this new approach to health research is studies in health economics that, for example, helps decision makers understand the impact of policy decisions on healthcare issues. One reason why Denmark is in the forefront in this area comes down to the existence of high quality semi-public financed research institutions facilitating this multidisciplinary research.

### **Focus on interdisciplinarity and entrepreneurship guides Danish research**

The same development is taking place in pharmaceutical research. Today, pharmaceutical research is interdisciplinary research drawing on a complex mix of competences and technologies that requires researchers from different fields of knowledge to be able to work together. It combines various disciplines and methods from the natural, technical, and medical science areas, e.g. basal and clinical disease research, biomedicine, pathophysiology, biochemistry, biophysics, (pharmaceutical) chemistry, protein chemistry, pharmacology, biotechnology, nanotechnology, etc.

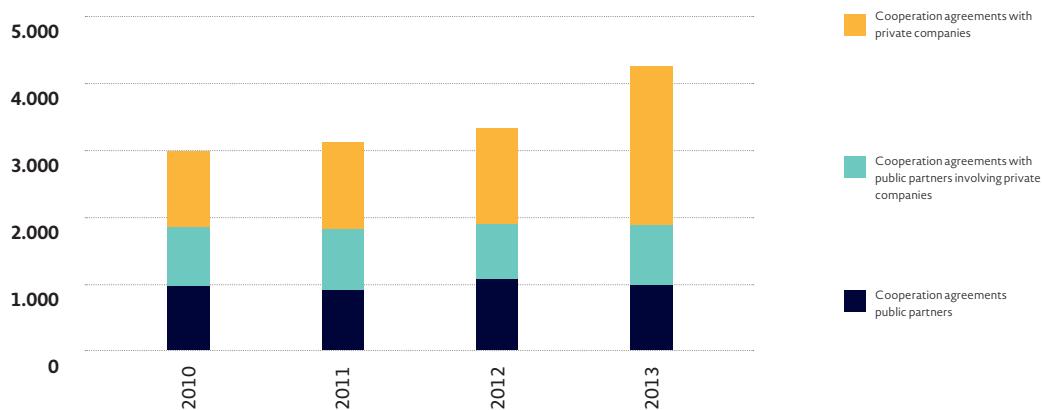
Also in this area, Denmark is in the forefront supporting the development with several initiatives such as the industrial PhD project and innovation programs (both are described in detail in other sections) and public funding for research often stresses the importance of an interdisciplinary approach. As an example the Innovation Fund Denmark state in their

strategy that they are looking for the following when they invest in projects: Innovation and technological advances, interdisciplinary alliances, thriving entrepreneurship, research excellence and a dynamic international outlook. This explicit focus influences Danish research and is making it a top priority not only to be interdisciplinary but also to be able to translate research into solutions.

### **The Copenhagen Centre for Regulatory Science (CORS)**

A recent example of this broad understanding and innovative approach to health and pharmaceutical research at the universities in Denmark is the establishment of the Copenhagen Centre for Regulatory Science in 2015. The Centre is established in cooperation with both authorities and industry and it aims to influence and conduct regulatory research and education in an international perspective to the benefit of stakeholders, such as patients, authorities, payers, and industry.

### NUMBER OF COOPERATION AGREEMENTS WITH PUBLIC AND PRIVATE PARTNERS AT THE DANISH UNIVERSITIES, 2010-2013



Research at CORS will be focusing on developing new tools, standards, and approaches to evaluate the efficacy, safety, quality, and performance of medical products in order to assess benefit-risk and facilitate sound and transparent regulatory decision making. Preferably, the research involves multiple CORS partners, and the use of a diversity of academic

approaches. CORS also focuses on the importance of having patients more involved in the entire process of medicines research and development as demonstrated with a workshop on “Patient Involvement in Medicines Development and Approvals: A Paradigm Shift Toward True Patient Impact in Medicines Development and Regulatory Science”.

 Universities without medical faculties

 Universities with medical faculties

 Airports

  Aalborg University

  Aarhus University



 Roskilde University

 University of Southern Denmark

 Technical University of Denmark

 University of Copenhagen

 Copenhagen Business School  
IT University of Copenhagen

  Lund University

 Swedish University of Agricultural Sciences

  Malmö University

  Kristianstad University

50 mi  
50 km



115

IS THE NUMBER OF  
RESEARCH AGREEMENTS  
PER 1000 RESEARCHERS IN  
DENMARK, COMPARED TO AN  
EU AVERAGE OF 83  
(2011)

#### FOR FURTHER INFORMATION

University of Copenhagen  
[www.ku.dk](http://www.ku.dk)

Aarhus University  
[www.au.dk](http://www.au.dk)

University of Southern Denmark  
[www.sdu.dk](http://www.sdu.dk)

Roskilde University  
[www.ruc.dk](http://www.ruc.dk)

Aalborg University  
[www.aau.dk](http://www.aau.dk)

Technical University of Denmark  
[www.dtu.dk](http://www.dtu.dk)

Copenhagen Business School  
[www.cbs.dk](http://www.cbs.dk)

IT University of Copenhagen  
[www.itu.dk](http://www.itu.dk)

Copenhagen Centre for Regulatory Science  
[www.pharmacy.ku.dk/research/cors/](http://www.pharmacy.ku.dk/research/cors/)

Universities Denmark  
[www.dkuni.dk](http://www.dkuni.dk)



# NUMEROUS NATIONAL HEALTH REGISTRIES

## Numerous national registries

The Danish population is and has for decades been registered. Owing to the personal identity number system (CPR), it is possible to combine and compare a large number of data from different registries. This offers unique opportunities for epidemiological and clinical research as well as other types of research such as health economic research, and it offers a solid starting point for basic scientific research.

## A wide range of health registries

Denmark has a wide range of health registries comprising data on the nation's health, morbidity, and mortality, together with data on healthcare sector organization and economics. Examples of the nationwide Danish health registries include the National Patient Register, the National Prescription Register, the Danish Cancer Register, the Medical Birth Register, and the Cause of Death Register.

Other nationwide registers on economic and social issues, such as the Education Register, the Em-

ployment Classification Module, and the Income Statistics Register, are accessible through Statistics Denmark. The CPR number system makes it possible to [link data from](#) different sources and perform analyses across different registers and databases to discover new connections and explanations, which improves the opportunities to conduct, for example, health economic and outcomes research. Finally registerbased analyses are a lot cheaper and faster to conduct than clinical trials. There is a strong [focus on quality and usability of registries](#), which is further improved by the PROCRIIN - Program for Clinical Research Infrastructure, as described in the section: Public funding for research and development.

## Quality databases

Supplementing the nationwide registries, Denmark has around 70 Clinical Quality Databases concerning specific diseases or treatments /surgery procedures. The databases are managed by the organization Danish Clinical Registries (RKKP). RKKP is founded on a national initiative. It is mandated by law and regulated

by national government, but financed and owned by regional governments. Each registry has to pass appraisal in the National Health Authority every three years, where it is assessed whether it fulfills national criteria for functionality, data safety, and methodology. RKKP designs new databases, and facilitates the reuse of available data in hospitals to lighten the data collection burden, and optimize the use of the available data sources.

The databases contain information about all of the individual patients and are used for the improvement of quality, research, and surveillance purposes. Internationally, the databases are unique since they contain information on all of the patients that have been or are currently being treated in the Danish hospital system and since it is public and free of charge it includes all Danes, which means there is **no selection bias**. This extends to data on prescribed medicine since the public covers all the costs when it exceeds a certain amount. Again, this provides a unique resource of data with no selection bias since all Danes can afford

their prescribed medicine.

The formation of a database can be initiated either top-down – RKKP asking clinicians to collect data on a given topic – or bottom-up with clinicians asking RKKP to manage a database on a topic of its interest. The relevance of conducting a database on a given topic is decided on by weighing; disease severity, incidence/prevalence, quality problems/ possibility for improvement, resources and appropriateness, political and patient preferences.

### **Using registries for new purposes**

The opportunity of combining data from different registries has led to new approaches to the analyses of large amounts of data using **data mining**. This type of research will improve the understanding of, for example, comorbidity and thereby point to **new possibilities in prevention, diagnostics, treatment, and rehabilitation**.

An example of this is the Novo Nordisk Foundation Center for Protein Research at the Faculty of Health

and Medical Sciences, University of Copenhagen, which aims to promote basic and applied discovery research on human proteins of medical relevance. The Center develops integrated protein technology platforms and large heterogeneous data management systems to further the understanding of complex protein networks in fundamental biology and disease. Although the Center is founded by Novo Nordisk it also cooperates with other companies.

Especially in the Disease Systems Biology group, [data mining](#) plays an important role. The group analyzes a wide range of data related to biology and medicine. If properly mined, this data can reveal knowledge on human health, disease mechanisms, and novel pharmaceutical targets and in the case of basic biology, systems level information. This data mining has produced [new patient stratification methods](#) and by analyzing the disease terminology data from patient records across millions of patients, the group has defined cohorts, which may be subjected to screening. In particular, the group creates data integration techniques that in terms of scope go beyond conventional combinations of data and connect more levels of disparate data types. For example, the group performs the integrative text mining analysis of large

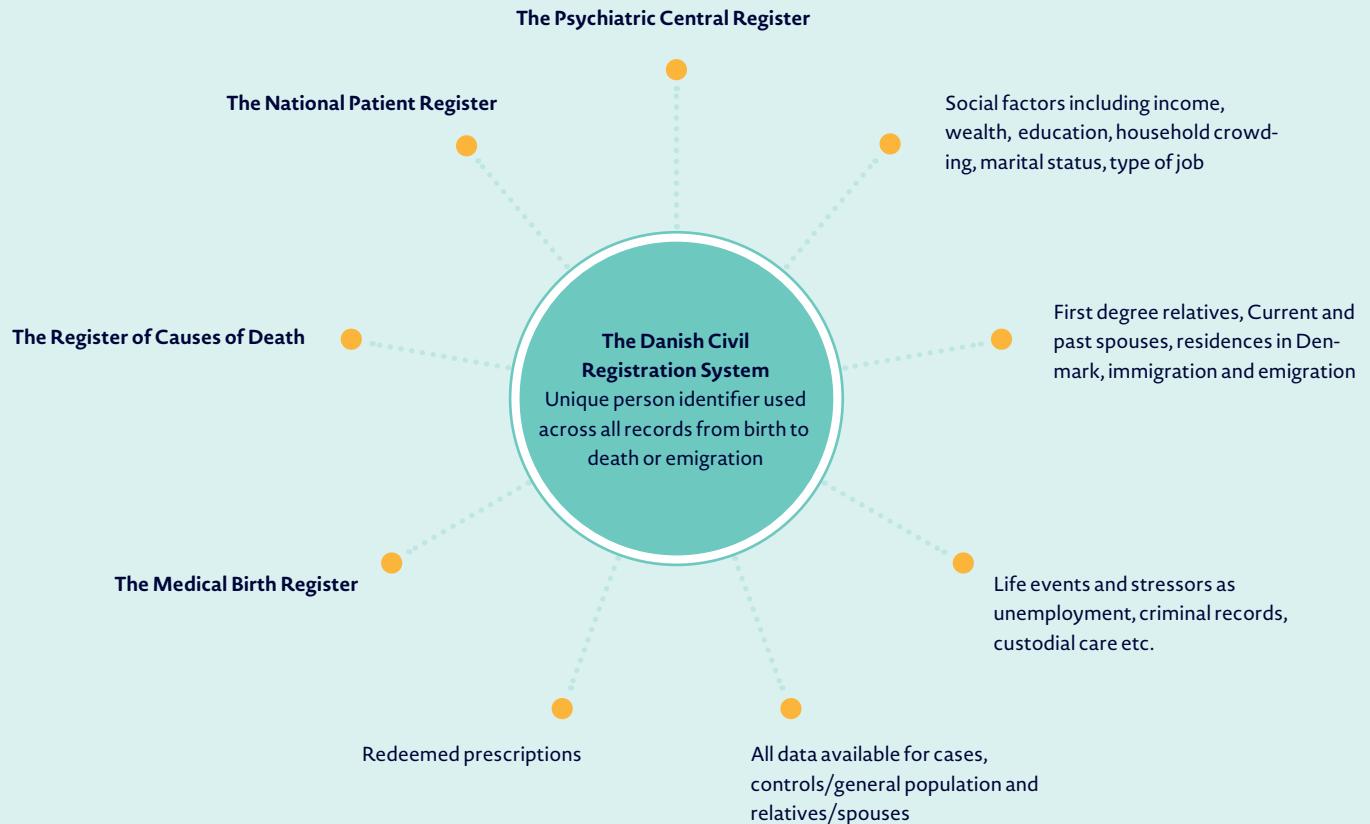
corpora of Danish electronic patient records from exactly the same individuals as they have molecular level information for – and in this manner, they approach the problem of patient stratification from widely different angles.

Another example comes from oncology. Previously, researchers hypothesized that cancer in general is due to a weakened immune system. However, by linking data from the Danish Cancer Registry with information from, among others, the Danish Transplant Registry and the National Patient Registry, Danish researchers have succeeded in showing that cancer does not occur more frequently among those with poor immune systems, but only in connection with certain immune disorders. This means that cancer is not caused by a generally weakened immune system, and research into the causes of cancer can now focus on other areas. As a final example, the Danish register research has also made a significant contribution to the understanding of the link between oral contraceptives and blood clots, which have helped to qualify the discussion on the subject.

### **Access to health registries**

The national registries publish statistics on a regular basis and offer access to data extraction for activities

## THE UNIQUENESS OF THE DANISH REGISTRATION SYSTEM



such as analysis, research, and planning provided by its “Research service” at the Danish Health Data Institute or at the Statistics Denmark. “Research Service” is a one stop access, which aims to provide efficient and professional service to scientists combined with a high level of data security. Data from all the clinical quality databases are accessible by following the same appli-

cation procedure described on the RKKP website. The Act on Processing of Personal Data lays down the rules regulating the processing of personal data in electronic and manual registers. The rules ensure that the patients’ confidentiality is protected, and this contributes to maintain the patients’ confidence in the system.



21

NATIONAL HEALTH  
REGISTRIES ARE  
EASILY ACCESSIBLE  
FROM A ONE-STOP-SHOP  
SERVICE AT THE DANISH  
STATE SERUM INSTITUTE

#### FOR FURTHER INFORMATION

The Health Data Institute  
[www.sundhedsdatastyrelsen.dk/](http://www.sundhedsdatastyrelsen.dk/)

Statistics Denmark  
[www.danmarksstatistik.dk](http://www.danmarksstatistik.dk)

Clinical Quality Databases  
[www.rkkp.dk](http://www.rkkp.dk)

Novo Nordisk Foundation Center for Protein Research  
[www.cpr.ku.dk/](http://www.cpr.ku.dk/)

The Danish Data Protection Agency  
[www.datatilsynet.dk](http://www.datatilsynet.dk)

National Centre for register-based research  
[ncrr.au.dk](http://ncrr.au.dk)

## COMPREHENSIVE BIOBANKS

### **Denmark is a pioneer in establishing population-based biobanks.**

In Denmark, there is access to comprehensive biobanks containing samples of various tissues and blood that offer unique opportunities for epidemiological research and support for both basic scientific research in pharmaceuticals and clinical pharmaceutical research. Biobank collections of tissue, blood, and other biological samples from humans provide unique opportunities for genetic epidemiology studies, and can give researchers precise information on the pharmacological, environmental, or nutritional exposures of the population. The biological information will be key to identifying biomarkers and instrumental in identifying the causes of some of the major diseases, thereby developing new therapies and personalized/tailored medication.

Biological information is the stepping stone to a more optimal treatment of each patient, personalized medicine, since it provides scientists with knowledge on how each person will respond to a specific type

of medicine, thereby making it possible to tailor the treatment. This will help patients experience a better, more efficient treatment with fewer side effects and save both money and valuable time.

Taken together, the personal identity number, access to comprehensive biobanks together with access to various registries containing detailed patient data provide unique opportunities for epidemiological research and for advancing basic health science research.

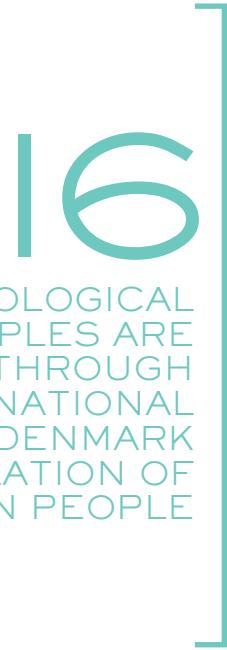
Denmark has many unique biobanks, e.g. The Danish National Biobank, The Danish Cancer Biobank, and the Danish Reuma Biobank.

### **The Danish Biobanks – a goldmine of knowledge**

The main purpose of the Danish National Biobank is to give scientists from Denmark and abroad an overview of more than **16 million biological specimens** collected in the Danish health care system in both existing and future collections, and will become

one of the world's largest biobanks. Specimens from seven different biobanks are collected in the Danish National Biobank. These are the Danish National Birth Cohort, Danish Neonatal Screening Biobank (NSB), Danish Pathology Biobank, Greenland Biobank, Copenhagen Hospital Biobank, Danish Cancer Society (Diet, Cancer and Health Cohort), and Genetic Biobank of the Faroes.

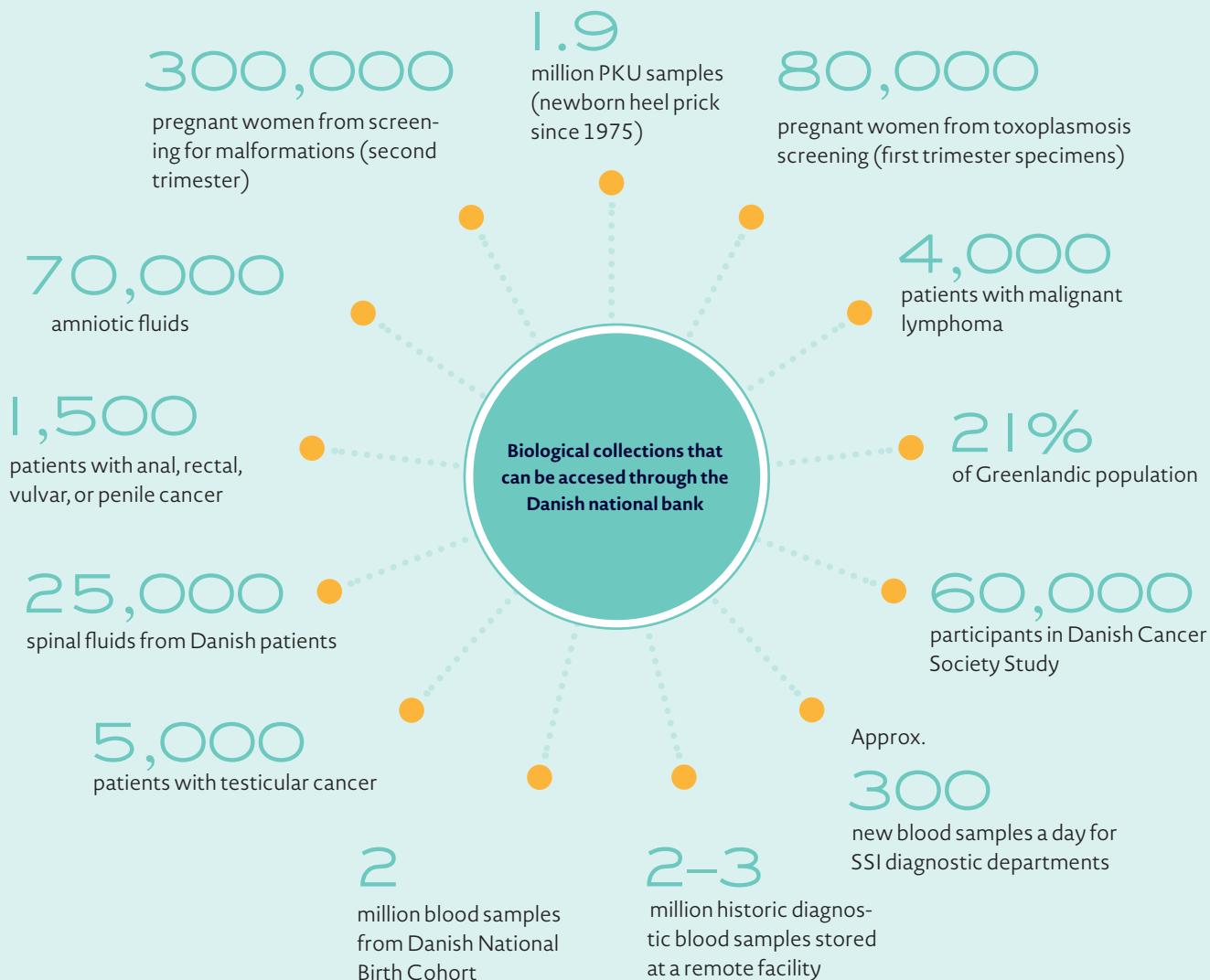
The Danish National Biobank, inaugurated in 2012, boasts of having state-of-the-art freezers, robotic systems, and laboratory facilities. In addition to the physical biobank, the Danish National Biobank also includes an online biobank registry, which links information about available biological specimens with disease codes and demographic information from national registries. In the register, it will be possible to look up the number of biological specimens available for patients with a certain diagnosis.



# 16

MILLION BIOLOGICAL  
SAMPLES ARE  
ACCESSIBLE THROUGH  
THE DANISH NATIONAL  
BIOBANK, AND DENMARK  
HAS A POPULATION OF  
5.5 MILLION PEOPLE

**EXAMPLES OF THE BIOLOGICAL COLLECTIONS THAT CAN BE ACCESSED THROUGH THE DANISH NATIONAL BIOBANK**



In addition to the National Biobank, The Danish Cancer Biobank was established in 2009, and the Danish Regions established The Danish Rheuma Biobank in 2014. The regions have the main responsibility for the provision of hospital services. Tissue, blood, and other biological samples are systematically collected at all hospitals in Denmark and stored according to the standard procedures in local centers.

All data are registered in a nationwide online register and services are provided by the Regional Biobank Office. These services give scientists the possibility to link information about biological samples from individuals with the large amount of information that is contained in the Danish health and clinical registries.

#### FOR FURTHER INFORMATION

Danish National Biobank  
[www.nationalbiobank.dk](http://www.nationalbiobank.dk)

Danish Cancerbiobank,  
[www.cancerbiobank.dk/](http://www.cancerbiobank.dk/)

The Danish Rheuma Biobank  
[www.regioner.dk/sundhed/forskning/biobanker](http://www.regioner.dk/sundhed/forskning/biobanker)

# INITIATIVES TO STRENGTHEN PUBLIC PRIVATE PARTNERSHIP

**It is a longstanding priority for the Danish government to strengthen Public Private Partnerships in research and innovation. The current Danish government states in its recent political program that it will ease the framework and procedures for clinical research to support the pharmaceutical and medical device industry, and emphasize the need to further improve authorization procedures and assessment time.**

Identifying the common need for innovative solutions  
One of the most recent initiatives, Inno+, describes specific and significant societal challenges, in which there is a potential for Denmark to create innovative solutions in the short or medium term. The Danish Ministry of Science, Innovation, and Higher Education led the process by inviting a wide range of parties to contribute, such as industry, interest organizations, knowledge institutions, foundations, etc. Thus Inno+ served as basis for [strategic investments in innovation](#).

## **STARS**

In 2013, a working group named STARS, consisting of stakeholders and experts representing public agencies, hospital owners, patient organizations, industry associations, universities, medical societies, researchers, and other healthcare professionals, was established. Among others, the aim of STARS is to advise the Danish government on the development of a new national strategy for [the better use of health-care data](#) (Big Data). Industry potential and the use of unique Danish public health data (registries and biobanks) is also addressed in this ongoing work.

## **NEXT Partnership**

National Experimental Therapy partnership (NEXT) is a public-private partnership within clinical research that comprises six public institutions and five pharmaceutical companies. The partnership was established in 2014. The goal of NEXT is to establish [Denmark as a country of choice](#) for the pharmaceutical industry for carrying out [early clinical trials](#) of new drugs on patients. NEXT is working to optimize all of

the processes relating to the start-up and implementation of clinical trials, where optimizing legal and statutory processes has a high priority. A high degree of predictability in the clinical trials is also a key element of NEXT. The trials are being started as planned, and the agreed number of patients is being recruited. In 2015, NEXT launched clinical research centers within dermatology and oncology and established a center for bioinformatics. In the following years, NEXT will expand within other diseases for which Danish clinical researchers have internationally competitive medical expertise.

### **Clinical Trials Office Denmark**

Denmark is working actively to attract more clinical trials and the five Danish regions have established the “Clinical Trials Office Denmark”, a service and website for companies seeking a less complicated and more direct path to conduct clinical trials in Denmark. Instead of approaching each individual hospital, companies can now use the services offered on the website. Clinical Trials Office Denmark offers free of

charge services, which meet feasibility requests, facilitate fast access to relevant groups of patients, and help the conduct of clinical trials. Altogether, these services help pharmaceutical companies and CRO’s 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 and a high knowledge of the Danish healthcare registries. Companies that use the services offered by Clinical Trials Office Denmark, automatically gain access to the legal, medical, and research expertise, and are able to:

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

As an example, the Clinical Trials Office will be able to provide information on the exact number of patients with a specific disease currently being treated in each hospital ward by using information from the Danish Patient Registry. This is extremely valuable and unique information when you are planning to conduct a clinical research.

### **Industrial PhD project**

An Industrial PhD project is a three-year industrially focused PhD project where the student is employed in the private sector company and enrolled at a university at the same time. This means that the research of the student is academically supported by the university while the data collection is performed at the private employer. The company gets a candidate who is able to carry out a high quality research project and create results that can lead to commercial gain, and at the same time this **strengthens the relations** between the company and the public sector research institutions, creating a foundation for new research. Moreover, the company receives wage **compensation from the public** authorities, so that the expense of employing the PhD is lowered. The Industrial

PhD program is a unique Danish program that has received a number of favorable evaluations.

### **Leading the way from ideas to solutions**

Bright ideas are not always fostered in places where they are easy to realize and within healthcare, they often come from employees at the hospitals, patients, and relatives. So how can these ideas be turned into workable solutions? Two public organizations in Denmark are leading the way in how to overcome this barrier, and invite the industry to participate in the process.

### **“Idéklinikken”**

In the North Denmark Region, the public authorities have established the innovation department “Idéklinikken” (The Ideas Clinic) that is located at Aalborg University Hospital. The main aim of Ideklinikken is to ensure that good ideas within healthcare are collected, concretized, tested, and eventually realized. Idéklinikken receives all kinds of ideas and inventions – from both clinical and executive employees as well as patients and relatives. Idéklinikken’s competencies consist of handling and processing good ideas and the



team is composed of specialists in different fields – from industrial design, idea and project development to commercial law and commercialization. Idéklinikken involves external partners early on in the process to take advantage of the emerging potential between public and private actors in the transformation of innovative ideas into new solutions.

An example from Idéklinikken is a software based solution that enables an easier and more secure process for the calculation of patients' kidney function - also known as the glomerular filtration rate (GFR). This will enhance patient safety and improve the working conditions of health professionals through the automated process of data collection. As another example, a nurse from the Anesthesia department at Aalborg Hospital got the idea to use a soother to deliver oxygen to children - a challenge not solved effectively by available products. In collaboration with Idéklinikken, a patent pending solution has been developed.

### **“IdéRiget”**

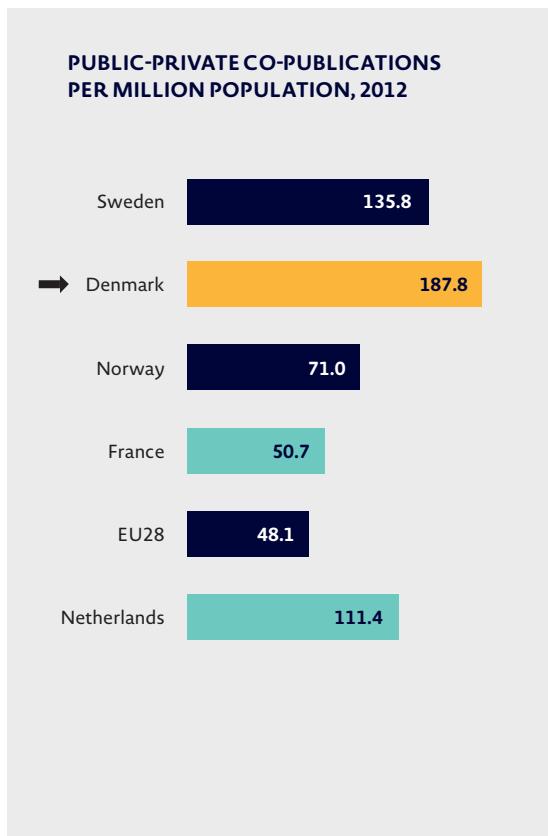
With the innovation program “IdéRiget” (“A Wealth of Ideas”), Rigshospitalet (Copenhagen University Hospital) set out on a new course, i.e. to make the obvious move to boost public sector innovation by inviting frontline staff to come forward with their innovative ideas. On the basis of a prequalification process 10 frontline employees were given a timeframe of 6 months to take the steps needed to develop their individual ideas into solutions having the potential to be implemented. Rigshospitalet's Innovation Board selected the two very best concepts for a large scale implementation.

One of these makes it possible for patients with leukemia to receive chemotherapy in the comfort of their homes due the use of a portable digital pump originally intended for other clinical purposes now combined with a complete redesign of the patient-flow. A key component in this has been an ongoing dialogue with the company producing the pump on staff/patient issues such as usability, safety, programming, simple restart tweaks, and standardized production/ delivery process from Rigshospitalet's

pharmacy facility. Furthermore, pharmaceutical companies have been helpful in providing products to the Danish market that are suitable to the operation of this concept. The concept enables patients to spend more time with their families, stay on their own favorite menus, keep up with physical training, go shopping, enjoy usual pastime routines and avoid risks of acquiring infections at the hospital (due to the disease and its treatment). The patients will come to the clinic every second or third day to exchange the pump and to have a feedback session with doctors and nurses before going back for another stint at home. The solution also has the potential to reduce ward capacity and to sharpen focus on the in-clinic patients most in need of 24/7 attention. The concept is also extended to treatment with antibiotics to patients with serious infections that cause hospitalization for up to 4-6 weeks. This is applied not only to leukemia patients but also to other patient segments.

EMPLOYMENT AMONG  
THE INDUSTRIAL PhDs  
IS HIGH. IT VARIES  
DURING THE PERIOD OF  
2004-2010 BETWEEN

95-99%



#### FOR FURTHER INFORMATION

Inno+ and Industrial PhD Program  
[www.ufm.dk](http://www.ufm.dk)

NEXT Partnership  
[www.nextpartnership.dk/](http://www.nextpartnership.dk/)

STARS  
[www.sum.dk](http://www.sum.dk)

Clinical Trials Office Denmark  
[www.clinicaltrialsdenmark.com](http://www.clinicaltrialsdenmark.com)

Danish Association of the Pharmaceutical Industry  
[www.lif.dk](http://www.lif.dk)

Dansk Biotek  
[www.danskiotek.dk/](http://www.danskiotek.dk/)

Idéklinikken  
[www.ideklinikken.rn.dk/](http://www.ideklinikken.rn.dk/)

IdéRiget  
[www.rigshospitalet.dk](http://www.rigshospitalet.dk)



# PUBLIC FUNDING FOR RESEARCH AND DEVELOPMENT

**Medical and health sciences is by far the most prioritized area in Denmark, with more than 1/3 of all public investments in research and development going to this scientific field.**

National public funding for research and development is agreed upon by the Danish parliament and administered by the Danish Ministry of Higher Education and Science through a research council and three foundations at the national level:

- The Danish Council for Research and Innovation Policy advises the Minister and the Danish Parliament on research, technology, and innovation with the objective to further the development of Danish research, technology, and innovation to the benefit of society.
- The Danish Innovation Foundation Funds strategic research, technology, and innovation, which are currently based on the recommendations published in Inno+ and the catalogue RESEARCH2020.
- The Danish Council for Independent Research funds specific research activities within all scientific areas that are based on the researchers' own initiatives.
- The Danish National Research Foundation is an independent organization that aims to promote and stimulate basic research at the highest international level at the frontiers of all scientific fields.

Recent numbers show that the public sector in Denmark spent \$3.14 billion (DKK 20.9 BN) in 2013 on Research and Development, corresponding to 1.11 percent of GDP. There was an increase from 2012 to 2013 equivalent to \$0.18 billion (DDK 1.2 BN) reflecting a [strong political focus on increasing public funding](#) on R&D. In comparison with other OECD countries, Denmark comes in third on public R&D investments in relation to GDP, and Denmark is ranked fifth in OECD on public health-related R&D investments in relation to GDP.

At the same time, Denmark uses the largest share of public research and development investments in the medical and health sciences compared to other OECD countries corresponding to nearly \$1.2 billion (DKK 8 BN) in 2013. In 2013, 17.9 percent of the Danish R&D work years were allocated to health care research. The quality of Danish pharmaceutical research is 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 fifth. Furthermore, Denmark has for a number of years had the largest commercial drug development pipeline in Europe measured per capita. Within biotechnology, Denmark has the largest percentage of patents in the world, and Denmark is the best country in Europe, and second best in the world after the USA, for development of biotechnology.

### **Public and private funding in research infrastructure**

Besides the direct funding for research and development, the Danish government and private foundations makes a large number of other research infrastructure investments. Examples include:

- A National Centre for Particle Therapy (Aarhus University Hospital)
- International Science City at North Campus (University of Copenhagen)
- Center for Protein Research, The Danish Stem Cell Center and The Novo Nordisk Foundation Center for Basic Metabolic Research (University of Copenhagen)
- A multidisciplinary Danish Platform for Largescale Sequencing and Bioinformatics coordinated from COBIS in Copenhagen.

A number of initiatives in Denmark aim to bridge research and clinical practice and advance innovative biology research.

### **PROCRIN**

#### **- Program for Clinical Research Infrastructure**

Denmark's well-developed electronic databases and registries offer many advantages for conducting clinical and epidemiological research, and 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. Still, the private and public interests are working together to improve the opportunities and the data quality even further.

One focus area identified by leading clinical researchers and hospital managers is the need for improved medical databases and registries, especially in regards to issues of data quality and content. Therefore, PROCRIN has been established to improve the overall Danish health data infrastructure already put into practice in the public sector.

The goal of PROCRIN is to improve medical database research by developing effective national structures and procedures and to support the long-term efforts to ensure that all the data related to a person and the healthcare system is systematically collected.

By standardizing and optimizing the health data that can be analyzed, clinical researchers will be better able to identify disease factors and treatment effects that will ultimately benefit the quality of patient treatment and safety. Moreover, standardized data classification will further improve the already unique possibilities of combining and linking health data. A major objective is to integrate research findings into daily clinical work, building bridges between research and clinical practice. Danish public authorities are in charge of the program which is supported by public funds and grants from several private foundations.

#### **BGI Europe research center**

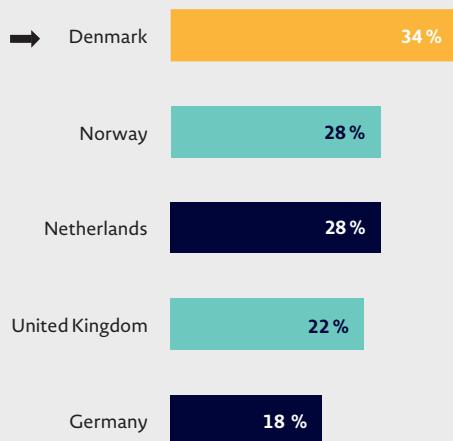
BGI was founded in Beijing, China. The goal is to make leading edge genomic science highly accessible. BGI Europe has since 2010 had its headquarter in Copen-

hagen, Denmark. The mission is to partnering with researchers and contributing to the advancement of innovative biology research. In 2012, BGI European Genome Research Center opened in Copenhagen. The center strengthen global genomics research and development in various areas including human health.

PUBLIC SECTOR IN  
DENMARK PERFORMED  
RESEARCH AND  
DEVELOPMENT IN 2012  
EQUIVALENT TO \$

2.9 BILLION

### AMOUNT OF PUBLIC R&D INVESTMENTS SPENT ON MEDICAL AND HEALTH SCIENCE



### FOR FURTHER INFORMATION

Ministry of Higher Education and Science  
The Danish Council for Research and Innovation Policy  
The Danish Council for Independent Research  
[www.ufm.dk](http://www.ufm.dk)

The Danish Innovation Foundation  
[www.innovationsfonden.dk](http://www.innovationsfonden.dk)

Invest in Denmark  
[www.investindk.com](http://www.investindk.com)

The Danish National Research Foundation  
[www.dg.dk](http://www.dg.dk)

PROCRIN  
[www.regioner.dk/sundhed/forskning/procrin](http://www.regioner.dk/sundhed/forskning/procrin)

BGI Europe research center  
[www.cobis.dk](http://www.cobis.dk)



# THE REGULATORY FRAMEWORK FOR RESEARCH IN DENMARK

**The Danish Medicines Agency handles applications regarding medicinal products and pharmaceutical companies. The authorities are known to be quick, efficient, and service-oriented handling of inquiries from the private sector. In particular, they are highly efficient in processing the application for clinical trials.**

As one example of this, the Danish Medicines Agency in 2014 established a joined platform for the electronic submission of clinical drug trials applications and submission of subsequent amendments, notifications, and safety related material. This means that applicants from companies can use a digital company certificate or digitalized signature to access the platform and send the application electronically. The platform is shared between the submission to the research ethics committee system and the Danish Medicines Agency, and it makes use of the information indicated in the European application form, from which it automatically makes a selection of the relevant documents for the two bodies. The platform

is intended to harmonize and simplify the submission process. As another example, the Danish Medicines Agency has offered shorter assessment times for trials suitable for risk-adapted assessment, when the trials meet certain criteria.

Both examples show that the Danish authorities are adopting new methods to accommodate the needs from the applicant's perspectives without compromising quality or patient safety.

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 primarily servicing clinical trials not sponsored by the pharmaceutical industry. Danish investigators and other clinical research staff consequently find it a given to abide by the GCP principles.

### **Efficient handling of trial applications**

All new trial applications to the Danish Medicines Agency must be approved within 60 days, and in 2014 83% were replied to within 42 days. The efficiency also applies to the licensing of medicinal products, and recent numbers from 2015 show that:

- 86% of the cases were finished within the performance requirement's maximum of 240 days (129 days on average).
- 81% of the cases finished within the performance requirement's maximum of 210 days in the assessment and closing phases (106 days on average).

These efficient procedures may be one of the reasons that Denmark, according to the numbers from 2013, hosts more clinical trials per capita than any other country in the world.

### **Important dialog between the authorities, industry, and clinical practitioners**

At the national level, there is a strong tradition for dialog and cooperation between the Danish Medicines Agency and 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 dialog sessions for companies and researchers, and its staff teaches courses and holds seminars etc. in this area.

### **Danish authorities participate in an EU coordinated application process**

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 Harmonization Procedure (VHP). Denmark participates voluntarily in all requests for a VHP and contributes actively in improving the procedure.

This means that when the application is submitted to the countries where the trials are taking place, the assessment is conducted and coordinated between the national competent authorities (medicines agencies) of the countries. It is an offer through which sponsors can obtain a harmonized assessment of an application. The actual trial must still be authorized at the national level, and it is, therefore, not a centralized authorization. In 2012, 9 clinical trials in Denmark were coordinated with the European authorities in this procedure.

### **The system of health research ethics committees**

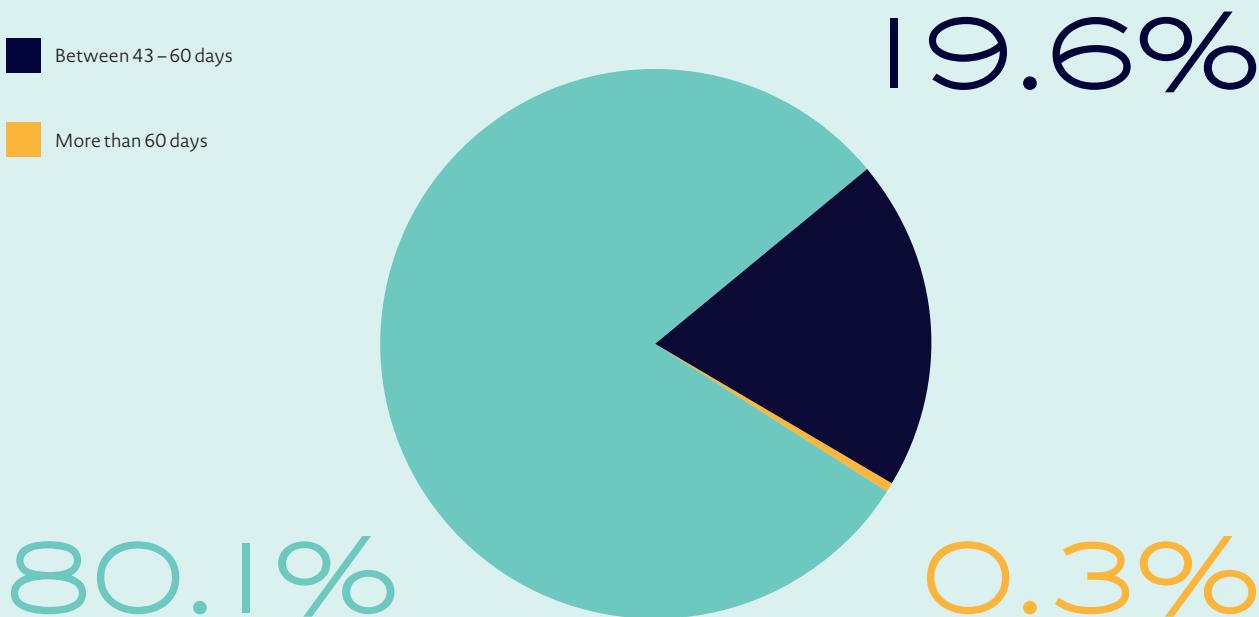
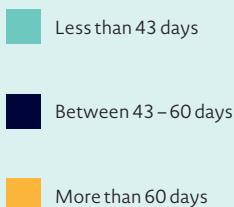
To ensure the assessment of clinical trials, Denmark was the first country in the world to establish a system of nationwide, independent committees on health research ethics in 1980. The Danish system of committees on health research ethics is known even today for the principle of having a lay majority serve among the committee members, based on the viewpoint that when it comes to ethics, lay people are just as much experts as researchers and, moreover, they are independent of research ambitions and interests.

Today, according to Danish law, all research projects in Denmark involving human beings or any kind of human tissue, cells etc. need permission from a regional ethics committee before the project can be initiated, and in the case of medicinal and medicinal devices trial projects, permission from the Danish Medicines Agency is also required. It is the responsibility of the committee system on health research ethics to ensure that from a research ethical point of view, health research projects are carried out in a responsible manner. Making sure that the rights, safety, and well-being of the trial subjects participating in such biomedical research projects are protected, while at the same time possibilities are being created for the development of new, valuable knowledge.

New legislation, which is currently on the way, aims to introduce an even more efficient process for the approval of medicinal trials in the ethical committees without compromising patient safety or quality. This will be done through the introduction of a number of ethics committees specialized in the assessment of medicinal trials.



## ASSESSMENT TIME FOR TRIAL APPLICATIONS TO THE DANISH MEDICINES AGENCY IN 2015



### Danish Data Protection Agency

The Danish Data Protection Agency works to protect individuals with regard to the processing of personal data in order to respect and preserve the patient's confidentiality. This duty is performed in part by providing guidance to and advising authorities, companies, and citizens, but the Danish Data Protection Agency can also take up cases of its own initiative if, due to a citizen inquiry or newspaper article, for ex-

ample, the agency suspects a violation of the regulations of the Act on Processing of Personal Data. Apart from attaining explicit permission from the authorities mentioned previously, a clinical trial must be compliant with relevant provisions in the Act on Processing of Personal Data. The Danish Data Protection Agency supervises compliance of the Act on Processing of Personal Data.

40.4

CLINICAL TRIALS PER MIL-  
LION CAPITA WAS CON-  
DUCTED IN DENMARK  
IN 2013, AND THIS PUT  
DENMARK IN FIRST PLACE  
WORLDWIDE.

**FOR FURTHER INFORMATION**

Danish Medicines Agency  
[www.sundhedsstyrelsen.dk/](http://www.sundhedsstyrelsen.dk/)

The National Committee on Health Research Ethics  
[www.dnvk.dk](http://www.dnvk.dk)

Danish Data Protection Agency  
[www.datatilsynet.dk](http://www.datatilsynet.dk)

# PHARMACEUTICAL HEADQUARTERS STIMULATE RESEARCH

## **The presence of pharmaceutical headquarters and affiliates provide optimum conditions to sustain a vibrant research environment.**

The headquarters of main pharmaceutical companies such as Novo Nordisk, Lundbeck, and Leo Pharma, and ALK are located within the Capital Region together with the subsidiaries of many of the major international pharmaceutical companies. In total, there were more than 450 companies within the life science sector in Denmark in 2013, with the main part of the companies in medtech and pharma. Nearly 300 of these companies have their headquarters based in Denmark and more than 250 conduct research in Denmark.

This concentration of innovative companies promotes an active environment of researchers both in academia and in the private sector.

The research, development, and manufacture of pharmaceutical products represent one of Den-

mark'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.

## **Contributing to an innovative research environment**

In many aspects these companies are contributing to a large, innovative, and productive research environment in Denmark: By attracting and contributing to the education of highly skilled researchers, by investing in universities, research facilities and centers of excellence, by partaking in the important dialogue with public authorities and public institutions and patients.

As an example, the largest share of R&D employees in Denmark is found in the medical and health sciences, and this is the field with the highest number

of PhDs awarded in Denmark. In addition, the private-sector pharmaceutical research as a whole accounts for approximately 28% of all private-sector research, with the pharmaceutical industry in Denmark investing approximately \$300 million (DKK 2B) in research in 2012.

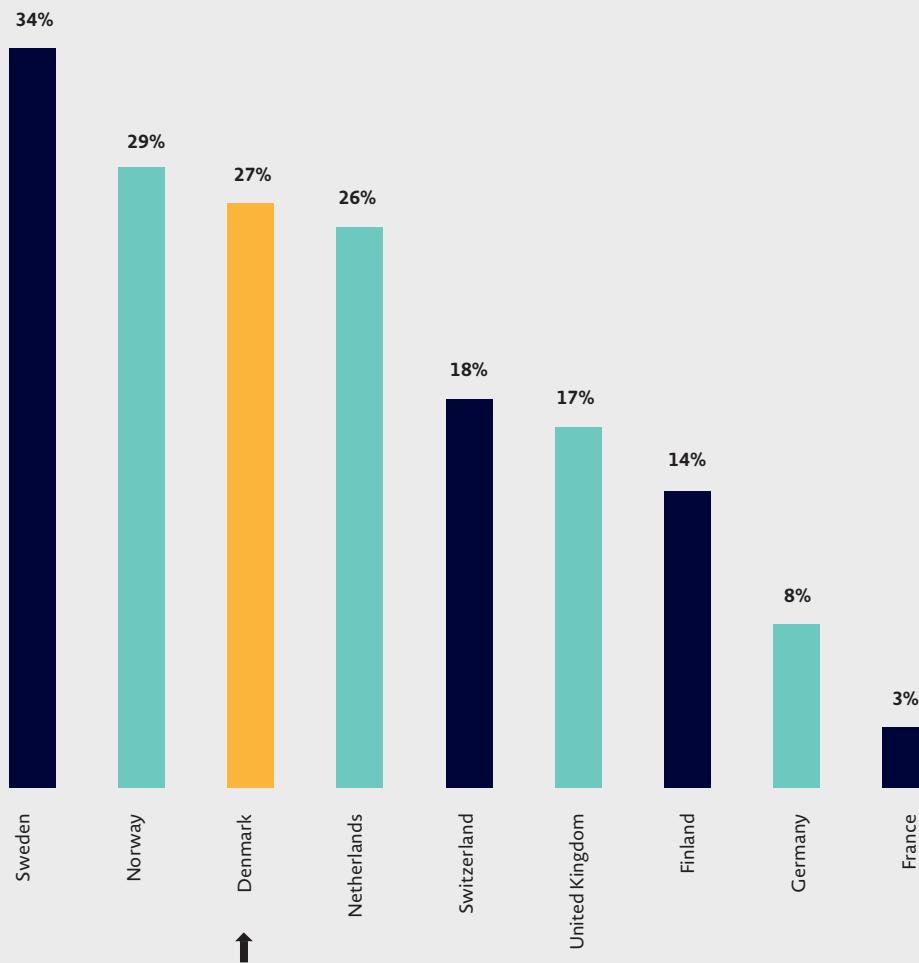
Acknowledging the importance of a vital and innovative science environment of high quality several companies have established foundations, such as the Novo Foundation and the Lundbeck foundation. These foundations support, promote, and stimulate basic research at the highest international level, investing in facilities, research, and educational resources to support scientists and provide sustainable conditions for the research. In addition to this, several of the companies have inaugurated prestigious awards, such as the Novo Nordisk prize awarded to recognize unique medical research or other research contributions that benefit medical science. An example of public-private partnership is the establishment of a major new diabetes Centre in Copenhagen as announced in September 2015, by the Capital Region

of Denmark and the Novo Nordisk Foundation. The latter has granted \$418 million (DKK 2.8B) from now until 2029.

### **Medicon Valley**

The Medicon Valley covers the region of eastern Denmark and southwestern Sweden and is branded the 'Medicon Valley' to reflect the region's life science strongholds that is one of the strongest in Europe. In Medicon Valley there are more than 100 biotech companies with own research and development and major pharmaceutical companies. There are more than 200 medtech companies, more than 50 relevant service providers, contract research organizations, and contract manufacturing organizations (CMOs) that produce both sterile and non-sterile products, monoclonal antibodies, and large molecules such as enzymes and proteins, the latter being a particular stronghold of Medicon Valley. In addition, the Medicon Valley covers 12 Universities, 7 Science Parks/ Innovation environments, and several dedicated Research Centers like the Center for metabolic research or the Steno Diabetes center.

### SHARE OF PHD STUDENTS IN HEALTH AND WELFARE SERVICES, 2012



THE PHARMACEUTICAL INDUSTRY IN  
DENMARK INVESTED APPROXIMATELY \$  
**2 BILLION**  
IN RESEARCH IN 2012

**FOR FURTHER INFORMATION**

Medicon Valley  
[www.mediconvalley.com/](http://www.mediconvalley.com/)

Steno Diabetes Center  
[www.steno.dk](http://www.steno.dk)

The Novo Nordisk Foundation Center for Basic Meta-  
bolic Research  
[www.metabol.ku.dk/](http://www.metabol.ku.dk/)

Foin, The Science Park Association in Denmark  
[www.foin.dk](http://www.foin.dk)

## PATIENTS SUPPORT RESEARCH

**The aim of all medical science is to improve the treatment and well-being of patients. Therefore, the patients' part of research and development must be recognized, and the trust of patients must be kept since all participation involves a risk.**

The level of trust is high in the Danish society, and this is reflected in a positive attitude toward research as demonstrated by a willingness to participate in clinical trials. More than 100,000 Danes participate in clinical trials and medical research annually, and approximately 13 percent of the adult Danish population have participated at least once in medical research or a clinical trial. This places Denmark in 20th place internationally in 2013 in terms of the total number of clinical drug trials per country, and in first place when the number of clinical drug trials is measured in relation to the population size. The number of applications for clinical tests has increased by 14 percent from 2012 to 2013.

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. Furthermore, a recent study from (Oct 2014) has shown that Danes are very open to 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 trial.

One significant determinant of the positive perceptions of trial participation among subjects is a confidence-inspiring setting for participation. The standard of ethics of the researchers, participating health professionals, and the companies involved is high. Denmark was among the first countries to establish a system of Ethics Committees where lay people are represented and that serves to reassure the population that the conducted research is ethically sound. A contributing factor is the public insurance coverage of patients.

### Support through the patient organizations

Some of the Danish patient organizations have their own research centers, such as the Danish Cancer Society that generates internationally recognized results and contributes to a strong research climate in Denmark. The Danish Cancer Society spends \$45.1 million (DKK 300 million) on research every year. Other organizations, such as the Danish Heart Foundation, the Danish Diabetes Association and the Danish Rheumatism Association support research that aims to cure and improve conditions for their patients. In addition to supporting research, some of the patient organizations also run some of the more specialized treatment facilities, such as the rheumatology hospital.

The opportunity of establishing a good relation and dialogue with the patient organizations in Denmark is relatively high and improved by the fact that the patient organizations in Denmark are well organized. Danish Patients, which is an umbrella organization for 79 patient associations in Denmark, representing

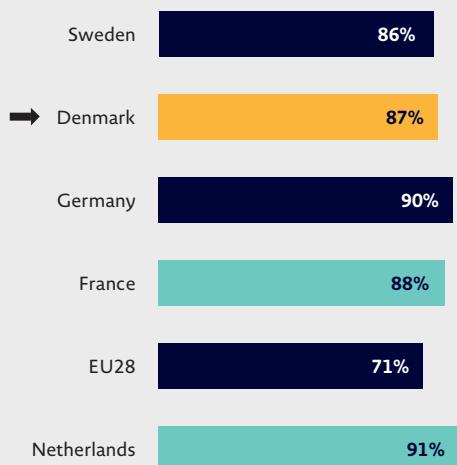
DANES ARE VERY OPEN  
TO PARTICIPATING IN  
CLINICAL TRIALS, WITH

40%

ANSWERING THAT  
THEY ARE POSITIVE  
TOWARDS THE THOUGHT  
OF PARTICIPATING  
IN A CLINICAL TRIAL

870,000 members co-operates with health authorities, research institutions, and other healthcare organizations. The patient organizations not only provide researchers with good opportunities for gaining access to a large number patients and establishing a dialogue with patients, they also provide substantial funding for research initiatives.

**AMOUNT OF PEOPLE WHO EVALUATE  
THE QUALITY OF HEALTHCARE IN  
THEIR COUNTRY "GOOD", 2013**



**FOR FURTHER INFORMATION**

Danish Patients  
[www.danskepatienter.dk](http://www.danskepatienter.dk)

The Danish Cancer Society  
[www.cancer.dk](http://www.cancer.dk)

Danish Diabetes Association  
[www.diabetes.dk](http://www.diabetes.dk)

Danish Heart Foundation  
[www.hjerteforeningen.dk](http://www.hjerteforeningen.dk)

Danish Rheumatism Association  
[www.gigtforeningen.dk](http://www.gigtforeningen.dk)



## LIST OF CONTACTS

Aalborg University  
[www.aau.dk](http://www.aau.dk)

Aarhus University  
[www.au.dk](http://www.au.dk)

BGI Europe research center  
[www.cobis.dk](http://www.cobis.dk)

Clinical Quality Databases  
[www.rkkp.dk](http://www.rkkp.dk)

Clinical Trials Office Denmark  
[www.clinicaltrialsdenmark.com](http://www.clinicaltrialsdenmark.com)

Copenhagen Business School  
[www.cbs.dk](http://www.cbs.dk)

Copenhagen Centre for Regulatory Science  
[www.pharmacy.ku.dk/research/cors/](http://www.pharmacy.ku.dk/research/cors/)

Danish Association of the Pharmaceutical Industry  
[www.lif.dk](http://www.lif.dk)

Danish Biotech  
[www.danskbiotek.dk/](http://www.danskbiotek.dk/)

Danish Cancerbiobank  
[www.cancerbiobank.dk/](http://www.cancerbiobank.dk/)

The Danish Council for Independent Research  
[www.ufm.dk/en/research-and-innovation/councils-and-commissions/the-danish-council-for-independent-research](http://www.ufm.dk/en/research-and-innovation/councils-and-commissions/the-danish-council-for-independent-research)

The Danish Council for Research and Innovation Policy  
[www.ufm.dk/en/research-and-innovation/councils-and-commissions/the-danish-council-for-research-and-innovation-policy](http://www.ufm.dk/en/research-and-innovation/councils-and-commissions/the-danish-council-for-research-and-innovation-policy)

Danish Data Protection Agency  
[www.datatilsynet.dk](http://www.datatilsynet.dk)

Danish Diabetes Association  
[www.diabetes.dk](http://www.diabetes.dk)

Danish Heart Foundation  
[www.hjerteforeningen.dk](http://www.hjerteforeningen.dk)

The Danish Innovation Foundation  
[www.innovationsfonden.dk/en](http://www.innovationsfonden.dk/en)

Danish Patients  
[www.danskepatienter.dk](http://www.danskepatienter.dk)

Danish Medicines Agency  
[www.lmst.dk/en](http://www.lmst.dk/en)

Danish National Biobank  
[www.nationalbiobank.dk](http://www.nationalbiobank.dk)

Danish Rheumatism Association  
[www.gigtforeningen.dk](http://www.gigtforeningen.dk)

Foin, The Science Park Association in Denmark  
[www.foin.dk](http://www.foin.dk)

Forbes Magazines  
[www.forbes.com/magazines/](http://www.forbes.com/magazines/)

Idéklinikken  
<http://ideklinikken.rn.dk/>

IdéRiget  
[www.rigshospitalet.dk](http://www.rigshospitalet.dk)

Inno+ and Industrial PhD Program  
[www.ufm.dk](http://www.ufm.dk)

Invest in Denmark  
[www.investindk.com](http://www.investindk.com)

IT University of Copenhagen  
[www.itu.dk](http://www.itu.dk)

Medicon Valley  
[www.mediconvalley.com/](http://www.mediconvalley.com/)

Ministry of Higher Education and Science  
[www.ufm.dk](http://www.ufm.dk)

National Centre for register-based research  
[www.ncrr.au.dk](http://www.ncrr.au.dk)

NEXT Partnership  
[www.nextpartnership.dk/](http://www.nextpartnership.dk/)

Novo Nordisk Foundation Center for Protein Research  
[www.cpr.ku.dk/](http://www.cpr.ku.dk/)

PROCRIN  
[www.regioner.dk/sundhed/forskning/procrin](http://www.regioner.dk/sundhed/forskning/procrin)

Roskilde University  
[www.ruc.dk](http://www.ruc.dk)

STARS  
[www.sum.dk](http://www.sum.dk)

Statistics Denmark  
[www.danmarksstatistik.dk](http://www.danmarksstatistik.dk)

Steno Diabetes Center

[www.steno.dk](http://www.steno.dk)

Sundhed DK

[www.sundhed.dk](http://www.sundhed.dk)

Technical University of Denmark

[www.dtu.dk](http://www.dtu.dk)

The Danish Cancer Society

[www.cancer.dk](http://www.cancer.dk)

The Danish Data Protection Agency

[www.datatilsynet.dk](http://www.datatilsynet.dk)

The Danish Ministry of Education

[www.uvm.dk](http://www.uvm.dk)

The Danish National Research Foundation

[www.dg.dk](http://www.dg.dk)

The Danish Rheuma Biobank

[www.regioner.dk/sundhed/forskning/biobanker](http://www.regioner.dk/sundhed/forskning/biobanker)

The European Spallation Source

[www.europeanspallationsource.se/](http://www.europeanspallationsource.se/)

The Health Data Institute

[www.sundhedsdatastyrelsen.dk/](http://www.sundhedsdatastyrelsen.dk/)

The National Committee on Health Research Ethics

[www.dnvk.dk](http://www.dnvk.dk)

The Novo Nordisk Foundation Center for Basic Metabolic Research

[www.metabol.ku.dk/](http://www.metabol.ku.dk/)

The World Bank Group, Doing Business

[www.doingbusiness.org/](http://www.doingbusiness.org/)

University of Copenhagen

[www.ku.dk](http://www.ku.dk)

University of Southern Denmark

[www.sdu.dk](http://www.sdu.dk)

Universities Denmark

[www.dkuni.dk](http://www.dkuni.dk)



## LIST OF REFERENCES

Copenhagen Capacity: Clinical Trials in Denmark  
Available at: [file:///C:/Users/kra/Downloads/Fact%20Sheet%20Clinical%20Trials%20\(1\).pdf](file:///C:/Users/kra/Downloads/Fact%20Sheet%20Clinical%20Trials%20(1).pdf)

Danish Agency for Science, Technology and Innovation: Research and Innovation Indicators 2014.  
Available at: [http://ufm.dk/publikationer/2014/filer-2014/research-and-innovation-indicators-2014\\_web.pdf](http://ufm.dk/publikationer/2014/filer-2014/research-and-innovation-indicators-2014_web.pdf)

Danish Business Authority, 2012: The Danish Biotech Ecosystem.  
Available at: [http://w2l.dk/file/409979/det\\_danske\\_biotek\\_oekosystem.pdf](http://w2l.dk/file/409979/det_danske_biotek_oekosystem.pdf)

Danish Medicines Agency: Assessment times for authorisation of medicinal products.  
Available at: <http://laegemiddelstyrelsen.dk/en/licensing/licensing-of-medicines/case-statistics-and-order-books/assessment-times>

Danish Medicines Agency: Voluntary Harmonisation Procedure (VHP) for the assessment of multinational clinical trial applications.  
Available at: <http://laegemiddelstyrelsen.dk/en/news/2013/voluntary-harmonisation-procedure-vhp-for-the-assessment-of-multinational-clinical-trial-applications>

Data on the Danish Pharmaceutical Industry.  
Available at: [https://www.pharmadanmark.dk/aktuelt/pharma/Documents/2014-april/Pharma04-2014\\_samlet.pdf](https://www.pharmadanmark.dk/aktuelt/pharma/Documents/2014-april/Pharma04-2014_samlet.pdf) and <http://www.lif.dk/english/thepharmaceuticalindustry/Sider/default.aspx>

Disease Systems Biology, Research Group at The Novo Nordisk Foundation Center for Protein Research.  
Available at: <http://www.cpr.ku.dk/research/disease-systems-biology/>

European Commission: Special Eurobarometer, 411. Patient Safety and Quality of Care  
[http://ec.europa.eu/health/patient\\_safety/docs/ebs\\_411\\_en.pdf](http://ec.europa.eu/health/patient_safety/docs/ebs_411_en.pdf)

Forbes Magazine: Best Countries for Business  
Available at: [www.forbes.com/best-countries-for-business/list/](http://www.forbes.com/best-countries-for-business/list/)

Medicon Valley Alliance: Danish Life Science Industries Contribution to the Economy  
Available at: <http://mva.org/wp-content/uploads/2015/06/Danish-Life-Science-Industries-Contribution-to-the-Economy.pdf>

Ministry of Children and Education: Education and Training in Denmark – Facts and Key Figures.  
Available at: <https://www.uvm.dk/~media/UVM/Filer/English/PDF/120312%20Education%20and%20training%20in%20DK.pdf>

Ministry of Foreign Affairs, Invest in Denmark: Start with Denmark. The Heart of Life Sciences for Research and Business.  
Available at: [http://www.investindk.com/~media/Files/Sheets/Life%20Sciences/Start%20With%20Denmark%202015\\_Full%20Report.ashx](http://www.investindk.com/~media/Files/Sheets/Life%20Sciences/Start%20With%20Denmark%202015_Full%20Report.ashx)

Ministry of Foreign Affairs, Invest in Denmark: The Danish BioTech Cluster  
Available at: [http://www.investindk.com/~media/Files/Sheets/Life%20Sciences/The%20Danish%20Biotech%20Cluster\\_highres.ashx](http://www.investindk.com/~media/Files/Sheets/Life%20Sciences/The%20Danish%20Biotech%20Cluster_highres.ashx)

Ministry of Health and Prevention, 2014: Handlingsplan for styrkede rammer for offentligt-privat samarbejde om klinisk forskning. (In Danish).  
Available at: <http://www.sum.dk/Aktuelt/Publikationer/~media/Filer%20-%20Publi->

[kationer\\_i\\_pdf/2014/Klinisk-forskning-2014/HP-for-styrkede-rammer-for-offentligt-privat-samarbejde-om-klinisk-forsk-maj-2014.ashx](#)

Ministry of Higher Education and Science:  
Kommercialisering af forskningsresultater 2014 - og kortlægning af vidensamspil i bredere perspektiv (only available in Danish).  
Available at: <http://ufm.dk/publikationer/2015/kommercialisering-af-forskningsresultater-2014>

Ministry of Higher Education and Science:  
Strategic plan for how Denmark can make the most of the ESS.(In Danish).  
Available at: <http://ufm.dk/en/newsroom/press-releases/2015/giant-microscope-will-create-unique-opportunities-for-danish-research-and-business>

Statistics Denmark: Public and private investments in research and development.  
Available at: <http://www.dst.dk/da/Statistik/NytHtml.aspx?cid=19303>

The Danish Association of the Pharmaceutical Industry (Lif): The pharmaceutical industry – a Danish position of strength.  
Available at: [http://lif.dk/SiteCollectionDocuments/Publikationer/Factsheet\\_streths\\_conditions\\_20.20marts%202014.pdf](http://lif.dk/SiteCollectionDocuments/Publikationer/Factsheet_streths_conditions_20.20marts%202014.pdf)

The Danish Clinical Registries (RKKP)  
Available at: <http://www.rkkp.dk/in-english/>

The National Committee on Health Research Ethics  
Available at: <http://www.cvk.sum.dk/CVK/Home/English.aspx>

The World Bank: Doing Business 2016. Measuring Regulatory Quality and Efficiency  
Available at: [www.doingbusiness.org/](http://www.doingbusiness.org/)

Universities Denmark: Numbers on Danish Universities, 2014. (In Danish)  
Available at: <http://www.dkuni.dk/~media/Files/Publikationer/Tal%20om%20de%20danske%20universiteter%202014.ashx>

World University Ranking and Academic Ranking of World Universities  
Available at: <http://www.mastersportal.eu/ranking-country/6/denmark.html>

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