



**MINISTRY OF FOREIGN AFFAIRS
OF DENMARK**
Invest in Denmark

2018

DENMARK THE PLACE IN EUROPE FOR CLINICAL TRIALS

www.investindk.com



WHY DENMARK?

Where do you go to conduct the clinical trials that your business depends on? For a growing number of the world's major life science companies, the answer is Denmark – a global player in life sciences, the home of a world-leading healthcare industry and a country with a strong national health system, reliable and effective public authorities and a dynamic business environment. Today, Denmark conducts the most clinical trials per capita in Europe.

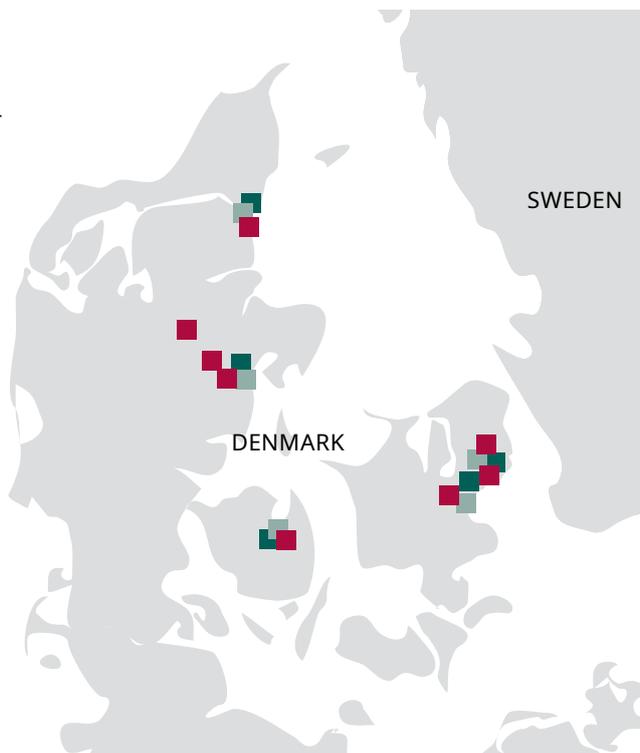
Take a look around, and you will also find:

- One national point of contact for facilitating clinical trials in Danish hospitals
- World-class research conducted by high-qualified scientists and technicians
- A tradition for public-private partnerships
- Excellent framework conditions for medical research and clinical trials
- World-class patient registries, civil registries and biobanks
- The best clinical trial subjects

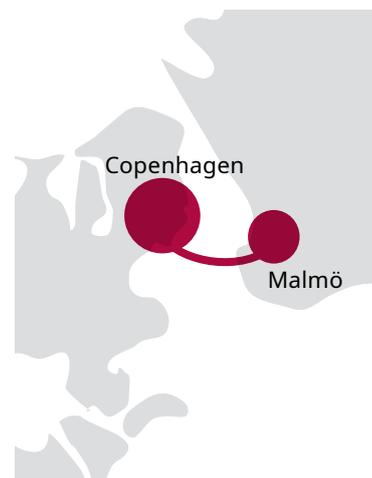
This publication is a short introduction to the reasons why Denmark is a great location for your clinical trials.

UNIVERSITY HOSPITALS IN DENMARK

- Science Park
- Innovation Incubator
- University Hospital



MEDICON VALLEY



ALL THE RIGHT CONDITIONS

STRONG POLITICAL FOCUS IN A STABLE ECONOMIC ENVIRONMENT

- Keen political commitment to the life sciences industry
- One of the strongest economies in Europe, ranked no. 1 for ease of doing business

Denmark is an increasingly attractive location for businesses that depend on clinical trials. In recent years, the Danish government has taken active steps to boost the life sciences industry by building further on the strong national health care system and world-class environment for business and science. Based on the recommendations of an expert growth team, in 2018 the government presented its new 'Growth Plan for Life Science'. The aim is to make Denmark a leader in life sciences in Europe.

Improving the framework conditions for clinical trials is a vital part of the growth plan. Initiatives include establishing a national organisation to help businesses find the right investigators for clinical trials within all fields and to support all phases of trials to document the effect of medicine and medical devices. The plan also promises to reduce the authorisation fee for clinical trials that are initiated by business.

Furthermore, Denmark offers a low corporate tax rate, competitive business costs, flexible labour market conditions and simple procedures for establishing a business.

BUSINESS LANDSCAPE IN DENMARK

| | |
|---|--|
| NO. 1 IN EUROPE for ease of doing business World Bank 2012-2019 | NO. 2 IN THE WORLD on corporate values IMD 2018 |
| 2ND LEAST CORRUPT COUNTRY Transparency International Cor- ruption Perceptions Index 2018 | NO. 2 IN THE WORLD on ethical practices in companies IMD 2018 |
| ONE OF THE MOST flexible labour markets in the world IMD 2018 | NO. 4. IN EUROPE on human capital World Economic Forum 2017 |

A HEALTHCARE INDUSTRY BUILT ON WORLD-CLASS RESEARCH

- Priority area for public and private research investments
- Highly qualified and motivated workforce with many Master's degrees and PhD graduates
- Research widely published in international scientific journals

State-of-the-art companies, visionary universities and an effective public health sector are the backbone of Denmark's innovative healthcare industry – which spans pharmaceuticals, biotechnology, medical technology and eHealth. A strong research community is the foundation. Medical and health science is the highest priority area by far in Denmark, accounting for more than one third of all public research investments.

The solid medical expertise of Danish universities and hospitals draws frequent attention from abroad. Within pharmaceuticals alone, leading international journals regularly publish and quote from their many scientific articles.

In recent years, the pharmaceutical industry has invested increasingly in the development of new drugs. Today, Denmark is a world leader for private investments in drug research and development. Altogether, that makes the pharmaceutical industry the most research-intensive industry in Denmark.

A STRONG TRADITION FOR PUBLIC-PRIVATE PARTNERSHIPS

- National clinical research centres for key health areas
- Continuous optimisation of clinical trial processes and procedures
- Support service for patient recruitment

Within Denmark's well-organised and publicly financed healthcare sector, there is a long tradition for collaboration between the public sector, academia and industry. This explains why clinical research has become one of Denmark's absolute strengths.

Established in 2014, the public-private partnership National Experimental Therapeutic Partnership (NEXT) focuses on making Denmark the pharmaceutical industry's country of choice for early clinical trials.

NEXT has brought industry, leading clinicians, regulatory agencies, ministries and patient organisations together to establish a series of national clinical research centres. At present, NEXT centres are in operation for oncology & haematology, dermatology, respiratory diseases, infectious diseases and dementia. Additional research centres are in the pipeline.

The NEXT centres offer a national feasibility service and support patient awareness and recruitment for clinical trials. NEXT also optimises processes and procedures to ensure clinical trials run smoothly.

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COMPLEMENTARY SUPPORT SERVICES FOR CLINICAL TRIALS

A key element in the Danish government's 'Growth Plan for Life Science' was quickly put into action in 2018: the establishment of a national organisation for clinical trials. Following several years of successful performance, it was only natural to appoint NEXT to the role.

As the national organisation for all phases of clinical trials, NEXT will have the lead responsibility for consolidating Denmark's position as a European leader for clinical trial collaborations to document the effectivity of medicines and medical devices.

Once fully established, services will include identifying the right investigators for clinical trials in all fields of health and disease, evaluating potential patients for recruitment and supporting organisations in conducting the trials. All NEXT services are free of charge.

FAST PROCESSING OF TRIAL APPLICATIONS

Danish authorities are known for their fast and service-oriented handling of inquiries from the private sector. For clinical trials in particular, their processing of applications is highly efficient.

The official processing time for new trial applications is maximum 60 days. However, the Danish Medicines Agency has set a goal to process all applications within a maximum of 30 working days, corresponding to 42 calendar days. On average, more than 90% of all applicants receive a first reply within 42 days – around 95% of applications are accepted.

EASY ACCESS TO DATA, BIOBANKS AND TRIAL RECRUITS

- Ranked first in Europe for number of clinical trials per capita (2017)
- Access to biobanks and registries of patient data
- High willingness in the population to participate in research

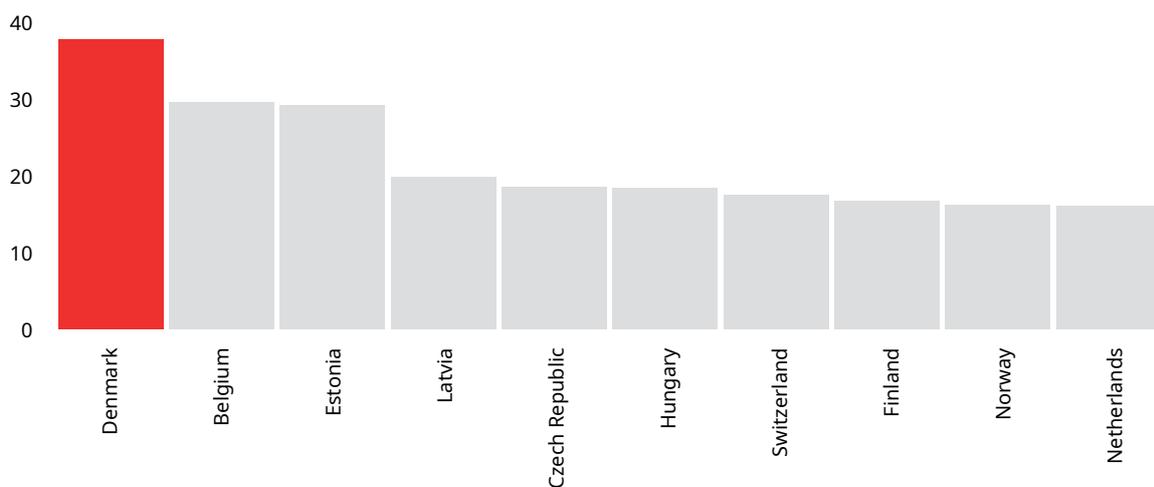
An efficient civil registration system, a tradition for patient registration and access to comprehensive biobanks make Denmark an ideal location for medical and clinical research.

Drawing on the biobanks and registries containing detailed patient data, businesses have outstanding opportunities to conduct epidemiological and pharmaceutical research.

Danish patients and healthy subjects for clinical trials are readily identified and easy to monitor. A high level of education in Denmark contributes to the population's generally positive attitude towards participating in clinical research. A single point of entry facilitates both the identification of relevant subjects and contact with leading clinical centres of excellence at hospitals nationwide.

A high level of education in Denmark contributes to the population's generally positive attitude towards participating in clinical research.

NUMBER OF CLINICAL TRIALS PER MIO. INHABITANTS 2017



Source: Danish Association of the Pharmaceutical Industry (Lif). Measured according to www.clinicaltrials.gov.

TOP TEN REASONS FOR CHOOSING DENMARK

1. Political commitment at national level

The Danish government takes active steps to boost the life sciences industry, including the initiation of a national growth plan.

2. A strong healthcare industry

Denmark has a strong, innovative and productive healthcare industry, covering pharmaceuticals, biotechnology, medical technology and eHealth.

3. World-class research standards

Medical and health science is the most prioritised research area in Denmark, accounting for more than a third of all public investments. Denmark is also a world leader for private investments in drug research and development.

4. Highly qualified labour

In Denmark, it is easy to recruit staff with the right medical expertise at the highest international level. The number of Master's degree and PhD graduates within the healthcare area is growing.

5. Tradition for public-private partnerships

Industry, academia and authorities often join forces. The National Experimental Therapeutic Partnership (NEXT) has enabled the establishment of a series of national clinical research centres.

6. Excellent framework conditions for medical research and clinical trials

Denmark offers world-class patient registries, civil registries and biobanks. This provides access to detailed patient data, facilitating epidemiological and pharmaceutical research.

7. Efficient public authorities

The Danish authorities provide fast and service-oriented handling of inquiries from the private sector. Processing of applications for clinical trials is highly efficient.

8. The best clinical trial subjects

Danish patients and healthy subjects for clinical trials are readily identified and monitored. They are highly educated and generally positive about participating in research.

9. Number of clinical trials

Denmark ranks no. 1 in Europe for conducting most clinical trials per capita.

10. Attractive to foreign investors

Denmark is characterised by political, economic and regulatory stability and offers a low corporate tax rate, flexible labour market conditions and simple procedures for establishing a business.

WHAT THE COMPANIES SAY

DAIICHI SANKYO

”The Nordic countries are a key market for oncology. To be present in these markets is a milestone in the development of our oncology business. But it is especially good news for the patients in this region who will get access to novel treatment options, addressing the high unmet need in breast cancer and AML therapies. Especially Denmark’s strong position within oncology research and treatment as well as the close collaboration between universities, hospitals, authorities and the industry were central for our decision to establish our new affiliate in Copenhagen. The new growth plan for the Danish life sciences will boost this already successful industry even more, launching 36 specific initiatives targeting barriers and opportunities for the industry across the entire value chain.”

Patrik Grandits, General Manager, Daiichi Sankyo
Oncology Nordics ApS

NOVARTIS

”The innovative and government supported NEXT network provides good access to high quality professionals conducting early phase clinical trials. Possibility for national recruitment, good data quality, fast start up times and reliable approval processes creates a very attractive environment for clinical trials which have supported our clinical trial operations strategy significantly.”

Lise Warming, Country Medical Head Denmark, Novartis

ABBVIE

”As a global biopharmaceutical company that discovers and advances innovative therapies, AbbVie has a vested interest in conducting clinical development programs in Denmark. Roundtable meetings arranged by Invest in Denmark facilitate contacts between our headquarters and top scientists, and NEXT provides access to a nationwide network of experienced investigators. Both initiatives contribute to making Denmark one of the preferred countries for conducting clinical trials of high quality and reliability.”

Thomas Ibsen, Medical Director, AbbVie A/S

MSD DENMARK

”In 2017, MSD invested almost 100 million DKK in clinical research in Denmark. Some of the key factors why MSD places studies in Denmark are speed and data quality. We have no delays in HA/IEC approvals, fast turnaround with signing of contracts and, most importantly, rapid and predictable recruitment. At the same time, the quality of data is world-class. The use of innovative recruitment methods such as Facebook and Danish registries make sustainable deliverables possible.”

Bethina Lohse Hansen, Director, Clinical Operations,
MSD Denmark

ROCHE

”There are many reasons why Denmark is one of Roche’s preferred places for phase I studies. In Denmark, there is a relatively smooth approval process. The authorities understand the need for speed, they are accommodating and easily accessible for discussions of complex study design and genetic sampling. Furthermore, as a consequence of being a small country with a limited patient pool at each hospital, Denmark has established ‘centres of excellence’ – functioning as ‘one site’ – for example within oncology / haematology phase I studies - covering the whole country, which is very attractive due to knowledge and patient pools being concentrated. Seeing Denmark as “one site” has led to the country being one of Roche’s preferred countries in Europe for first-in-human phase I studies within oncology and haematology. Conducting early clinical research in Denmark provides patients with access to novel medicines otherwise not available to them. It furthermore makes the next phase of drug development possible plus provides opportunities for more sites in Denmark to be involved in the next phases of the development of the drug.”

Dorte Klokke, Country Head, Country Clinical Operations, Roche A/S

GREENLIGHT CLINICAL

”Access to world class researchers and manufacturers, a pragmatic clinical trial approval pathway, and a host of attractive investment incentives drove GreenLight Clinical’s decision to base our European operations in Denmark. As an Australian company, the support and advice we received from both Invest in Denmark and NEXT was incredibly helpful in the startup phase, and the ongoing support from the Danish government keeps us in constant contact with cutting edge biotech and pharmaceutical companies in the region. Since the establishment of our Danish office in early 2017, Denmark has become a focus country for GreenLight, in terms of conducting clinical trials in-country, and working with various companies from the Nordic region to execute studies in Australia, the Asia-Pacific and across the globe.”

Dr. Sasi Suda, President and CEO, GreenLight Clinical

NATIONAL EXPERIMENTAL THERAPY PARTNERSHIP (NEXT)

NEXT is the government-funded, public-private partnership responsible for attracting clinical trials to Denmark. When you choose Denmark as the location for your clinical trials, the NEXT network of disease-specific research centres is well-placed at Danish university hospitals to conduct early phase trials. The centres currently in operation specialise in oncology & haematology, dermatology, respiratory diseases, infectious diseases and dementia.

The free-of-charge services that NEXT provides include:

- A coordinated feasibility process, providing one point of entry to nationwide recruitment commitment
- Support with conducting clinical trials, including patient recruitment and optimisation of processes and procedures to ensure trials run smoothly
- Liaising with patient organisations, trial units, industry and government
- Creating patient awareness of clinical trials
- Proposing potential investigators for all phases of clinical trials with medicine and medical devices and within all disease areas



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INVEST IN 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 your company is considering setting up a business or expanding your activities in Denmark, make us your first stop.

Our specialised global staff have the corporate background, industry insight and well-connected networks to advise you on every aspect of locating your business in Denmark. Not just 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 the advantages of locating in Denmark - all free of charge and with full confidentiality guaranteed.



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**START WITH
INVEST IN
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WE LOOK FORWARD TO WELCOMING YOU TO DENMARK. THE BEST PLACE IN EUROPE FOR YOUR CLINICAL TRIALS

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