

# The Infrastructure of Clinical Research in Denmark

Please note that all links are in Danish unless otherwise specified.

The healthcare system operates across three political and administrative levels: the state, the regions, and the municipalities (national, regional and local levels). A short introduction to the Danish healthcare system and relevant organisations will be covered below.

## Public authorities

The national level of healthcare in Denmark is governed by the [Ministry of Health](#) (English). They establish principles and provide guidelines that set the overall political agenda and they hold the overall regulatory and supervisory functions in healthcare and elderly care. The Ministry of Health is responsible for the agendas regarding health and medical care, including hospitals, healthcare system and hospital pharmacies. Clinical trials are controlled by the [Danish Health Authority](#) and the [Danish Medicines Agency](#) (English), both of which are inferior agencies of the Ministry of Health. Furthermore, research projects shall be approved by the [National Committee on Health Research Ethics](#).

The Danish Health Authority primarily works to promote health through prevention programs, structure the healthcare system, establish a framework for health education, responsible for health contingency plans, and establish coherence between health and social service efforts. The Danish Health Authority has published [national clinical guidelines](#), which contribute to ensuring uniform treatment services of high professional quality across Denmark. Additionally, they are responsible for establishing the framework for specialized hospital services in Danish hospitals, whereas the regions are responsible for planning standard hospital services. Information on the planning of hospital services of the 35 different specialities can be found [here](#). Hence, it is possible to identify which hospitals have which functions and where a specific disease or illness is treated in Denmark.

The Danish Medicines Agency manages the legislations on medication, medical devices, pharmacies and similar areas. Their main tasks are to approve and monitor pharmaceutical companies and medications on the Danish market, supervision of side effects and adverse events (medical devices and pharmaceuticals) and approval of clinical trials, deciding which medications get a subsidy, and supervise pharmacies. This means that any clinical trial – sponsor as well as investigator-initiated – must be approved by the Danish Medicines Agency before the trial can start.

If you want to learn more about the Danish healthcare system, the Ministry of Health has an in-depth [overview of the Danish healthcare system](#).

## The Danish regions

There are five regions in Denmark: Capital Region of Denmark, Central Denmark Region, North Denmark Region, Region of Southern Denmark, and Region Zealand (figure 1). Each region is responsible for maintaining the healthcare system, regional development and manage a variety of social institutions. All regions are governed by a regional council and the members of these councils are elected by the Danish population every four years. Furthermore, the five Danish regions are legal entities and can decide their health agenda.

For more information about legal issues concerning clinical trials, please contact Trial Nations [legal network](#).

The universities in Denmark have a close collaboration with the hospitals, both when it comes to education and research. The faculties of health and the university hospitals are intertwined as many doctors also are employed as professors at the universities. Furthermore, the universities and the regions have a joint special responsibility for the framework and conditions regarding medical health research in Denmark and established the Clinical Research Management Forum to ensure high-quality research that has a great effect and that influences the development in the Danish healthcare system and the business community.

Lastly, the Danish hospitals collaborate with most engineering and technical faculties on technological developments.



## The structure of the Danish healthcare system

The Danish healthcare system aims to improve health for the Danish population and to prevent and treat disease, illness, and disabilities for individuals. In respect for the individual, their integrity and autonomy, the Health Care Act strive to ensure easy and equal access to healthcare, treatment of high quality, coherence between services,

freedom of choice, easy access to information, transparency, and short waiting time for treatments.

To accomplish this, the Danish healthcare system is divided into primary, secondary and tertiary healthcare.

- The primary healthcare system includes several health services. Furthermore, the local/municipal level offers disease prevention and health promotion measures. The majority of primary healthcare services are provided by general practitioners and other private practising healthcare professionals such as dentists, physiotherapists, and psychologists. Furthermore, the municipalities provide home nursing, prevention measures and rehabilitation.
- The secondary healthcare system includes the vast majority of hospital services and is provided by the region of residence free of charge. Additionally, private hospitals also deliver some services.
- The tertiary healthcare system includes specialized hospital treatment, which accounts for about 10 per cent of all hospital services. This includes highly specialized services and regional functions and is based on an assessment of the size of the patient group as well as the complexity and cost of the service.

Collectively, these prevent and treat all patients in all stages of disease, illness or disability. If one provider is not able to offer services within a reasonable amount of time, patients can be referred to other providers as there is a close collaboration between regional and private providers.

The Danish regions own and run all public hospitals. Healthcare professionals at the hospitals are therefore also regional employees. The number of hospitals within each region varies, nevertheless, each region has at least one university hospital. The regions are individually responsible for planning the location of standard hospital services, whereas the Danish Health Authority is responsible for planning the overall distribution of specialised hospital services. The specialised regional functions are, depending on the speciality, distributed among one to three hospitals per region, while highly specialised services are located in one to three hospitals in the country.

These specialized functions are tasks at the hospitals that are considered exceedingly difficult, highly complex patient care or very expensive treatments.

The Danish hospitals, both somatic and psychiatric, can be divided into two main categories with appertaining functions:

- University hospitals combine hospital services with education and research and are therefore often allocated highly specialized functions. Education and research

are carried out in close collaboration with the regional university and university colleges.

- Regional hospitals perform standard hospital functions and some specialized regional functions.

All hospitals have access to laboratory and imagery departments, and all research departments have well-established collaborations for clinical trials. Furthermore, all hospitals have a well-established collaboration with a hospital pharmacy, which also includes collaborations for clinical trials.

Both general research strategies at regional level and local hospital research strategies exist and these are executed by the research-active personnel and the clinical research units. Links to research units and research strategies can be found in a separate document at [www.trialnation.dk](http://www.trialnation.dk)

Furthermore, private clinical trial management companies also conduct clinical trials in Denmark on behalf of sponsors and contract research organizations.

## **Trial Nation – Clinical Trials Denmark**

Trial Nation is an independent organization, founded in 2018 by the Ministry of Industry, Business and Financial Affairs, the Ministry of Health, several Danish life science companies and the five Danish Regions. The goal was to establish a national organization that could promote clinical research in Denmark to increase the number of clinical trials, as this has a positive influence on the economy. Trial Nation offers a single, national entry point for global companies, patient organizations and clinical researchers wishing to conduct clinical trials within public hospitals in Denmark. Trial Nation operates at the regional level, as this is where the majority of pharmaceutical and MedTech clinical trials are carried out. Hence, this will be the focus below.

If you have any questions regarding the above, please contact the [Trial Nation regional advisors or the Trial Nation secretariat](#) for further information.