

# **Trial Nation**

Clinical Trials Denmark

## **CENTER FOR INFECTIOUS DISEASES & IMMUNE MODULATION**

A network of Danish infectious diseases research  
clinics

**Your clinical research partner in  
infectious diseases and immune  
modulation**

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# Center for Infectious Diseases and Immune Modulation

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The Center for Infectious Diseases and Immune Modulation was established in 2016 as a collaboration of Danish hospital clinics specialized in the treatment of infectious diseases and primary immune disorders. In 2021, the center was expanded with five regional network clinics. The Regional Clinics are emerging research sites within the area of Infectious Diseases and Immune Modulation. The center covers all regions of Denmark and thereby allows a single point of entry to a dedicated, national network of hospital departments with a strong focus on clinical research in infectious diseases, immune modulation, and vaccine trials.

Over the past 15-30 years, the Danish infectious disease departments have built considerable knowledge and expertise in the execution of clinical trials through participation in a wide range of company sponsored trials but also through an extensive portfolio of investigator driven clinical studies. The Center for Infectious Diseases and Immune Modulation has experience in both early (phase I and II) as well as late stage (phase III and IV) clinical research. Through strong research collaboration the center has established:

- High quality clinical data based on detailed patient registries and national health registries
- A solid research infrastructure and collaboration platform across the center enabling expert handling of clinical trials in a national setting
- An internationally recognized research portfolio in infectious diseases and vaccine studies
- A successful track record for timely delivery of high-quality data, low rates of screen failures and loss to follow up
- Strong capabilities for handling the increasing complexity of clinical research in terms of clinical trials execution, technological infrastructure, scientific knowledge, and personalized medicine

The primary objective of the Trial Nation Center for Infectious Disease and Immune Modulation is to offer a single, national platform for clinical research within the therapeutic area.



1. Aalborg University Hospital
2. Aarhus University Hospital
3. Odense University Hospital
4. Zealand University Hospital
5. Hvidovre Hospital
6. Rigshospitalet
7. Gødstrup Regional Hospital
8. Kolding Regional Hospital
9. Copenhagen University Hospital, Bispebjerg
10. Copenhagen University Hospital, Herlev and Gentofte
11. Copenhagen University Hospital, Nordsjælland

Figure 1. Infectious Diseases and Immune Modulation clinics across Denmark.

● Means center clinics ● Means network clinics

### Center clinics

Clinic	Clinical trial phases	Industry sponsored	Investigator initiated	Population base	Study population experience
Dept. of Infectious Diseases, Copenhagen University Hospital, Rigshospitalet	I-IV	App 5-10	App 5-10	N/A*	Rigshospitalet is a referral hospital for patients needing highly specialized treatment. Healthy adults and elderly. Patients with acute or chronic infections. Cystic fibrosis. Primary cilia dyskinesia
Dept. of Infectious Diseases, Copenhagen University Hospital, Hvidovre Hospital	I-IV	5	4	570,000	Healthy children, adolescents, adults and elderly. Pregnant women. Patients with acute or chronic infections.
Dept. of Infectious Diseases, Zealand University Hospital, Roskilde	Ib, II, III, IV	App. 5-10	App. 5-10	200.000	Healthy adults and elderly. Pregnant women. Patients with acute or chronic infections.
Dept. of Infectious Diseases, Odense University Hospital	II, III, IV	App. 10	5	490.000	Healthy children, adults and elderly, patients with acute or chronic infections
Dept. of Infectious Diseases, Aalborg University Hospital	II, III, IV	5	5	490.000	Healthy adults and elderly. Patients with acute or chronic infections.
Dept. of Infectious Diseases, Aarhus University Hospital	Ib, II, III, IV	5-10	5-10	366.000	Healthy children, adolescents, adults and elderly. Pregnant women. Patients with acute or chronic infections. Cystic fibrosis.

\*Rigshospitalet is a referral hospital for patients needing highly specialized treatment.

## Network clinics

Clinic	Clinical trial phases	Industry sponsored	Investigator initiated	Population base	Study population experience
Dept. of Infectious Diseases, Gødstrup Regional Hospital	II, III	4	<3	288,000	Adults and elderly. Patients with acute or chronic infections.
Dept. of Infectious Diseases, Kolding Regional Hospital	II, III, IV	2-3	1-2	300,000	Adults and elderly. Patients with acute or chronic infections, Immunodeficiency, No HIV.
Dept. of Infectious Diseases, Copenhagen University Hospital, Herlev-Gentofte	III, IV	3	3	425,000	Adults and elderly. Patients with acute, chronic, bacterial and viral infections
Dept. of Infectious Diseases, Copenhagen University Hospital, Bispebjerg	II, III, IV	3	2-3	483,000	Adults and elderly with acute or chronic infections, in particular respiratory tract infections (viral, bacterial and fungal)
Dept. of Infectious Diseases, Copenhagen University Hospital, Nordsjælland	II, III, IV	>3	>3	350,000	Adults and elderly. Patients with acute or chronic infections, in particular respiratory tract infections (viral, bacterial and fungal) and sepsis.

## Vaccines and immune modulation

Knowledge and understanding of the immune system and the interplay between host and microorganism is an integrated part of the infectious diseases specialty, and hence clinical studies investigating novel vaccines or immune therapy are a natural part of our research portfolio.

The Trial Nation Center for Infectious Diseases and Immune Modulation sites have successfully performed several vaccine studies with diverse indication and with different target populations, such as children, adolescents, the elderly, participants with a specific medical history, or pregnant women. Vaccine studies have ranged from dose finding and lot-to-lot comparative studies, to large-scale efficacy studies with active case-finding during follow-up. As an example of a large-scale vaccine study, the center sites collaborated to perform an investigator-initiated phase IV study following more than 8000 participants with serology measurements for two years starting from just before their first covid-19 vaccination.

The use of immune therapy for the prevention or treatment of both acute and chronic infectious diseases have gained more and more ground within recent years. Center sites have participated in several studies investigating the use of immune therapy in the treatment of diverse disease categories such as HIV, hepatitis B, covid-19 and influenza, both initiated by academic groups within the Center and by life sciences companies.

## Chronic diseases

There is a strong tradition for collaborative research on a national level within HIV and viral hepatitis in Denmark. The Danish HIV database (DANHIV) is a prospective cohort that include all Danish HIV patients diagnosed since 1995, based at Rigshospitalet in Copenhagen. Also, within viral hepatitis a national cohort study (DANHEP) is in place, collecting data on all patients with hepatitis B or C treated or followed in the Danish health system since 2002. DANHEP is based at Hvidovre Hospital. These national databases and biobanks enable both the performance of long-term observational studies on e.g. treatment outcomes, concomitant diseases and side effects, as well as the identification of study candidates for interventional studies.

The department at Aarhus University Hospital has a large research group devoted to HIV cure

research at the highest international level. This group has initiated several interventional studies, applying immune stimulatory strategies in an effort to reach functional cure of HIV, which all of the center sites have contributed to.

Adult patients with cystic fibrosis are followed and treated by infectious diseases specialists in Denmark, and therefore sites from the center have taken part in studies investigating the new CFTR modulatory treatments, which have completely revolutionized the treatment and life expectancy of cystic fibrosis patients.

## Acute infections

Patients with all types of acute infections may be admitted and treated at the departments of infectious diseases in Denmark and for many disease entities national research initiatives have been established.

In 2014 a prospective national cohort study on patients experiencing central nervous system infections (Danish Study Group of Infections of the Brain, DASGIB) was initiated by researchers from the site at Aalborg University Hospital. This study is continuously collecting data and biobank material from patients admitted with CNS infections in Denmark, and recently an interventional study on patients with brain abscesses have also been initiated.

Since the beginning of the covid-19 epidemic many studies investigating the treatment of lower respiratory tract infections caused by SARS-CoV-2 have been performed at the Danish departments of infectious diseases, some initiated by investigators and some by medical companies. The national collaboration within the Center of Infectious Diseases and Immune Modulation was highly strengthened during the pandemic at strategic, administrative, and practical levels.

In the backdrop of the covid-19 pandemic researchers and medical companies have increased their focus on respiratory infections with viral pathogens, which have given rise to a number of clinical studies including patients with e.g. influenza or RS-virus at the center sites.

In recent years a growing interest for the management of complicated bacterial infections, such as blood stream, bone- or graft related infections, have surged in Denmark, with a focus on antibiotic sparing strategies. This interest has given rise to e.g. a national prospective cohort of spondylodiscitis patients, and several clinical studies investigating shorter duration of antibiotic therapy for different types of bacterial infections.

## Recruitment strategies

The Center for Infectious Diseases and Immune Modulation have developed diverse recruitment strategies fitting to the need of the different types of studies each with their unique target population.

In Denmark all hospital diagnoses are registered centrally, enabling sites to make data extractions on specific diagnoses and thereby send out invitations for study participation directly to all relevant patients in a specific geographical area. When searching for healthy volunteer's similar approaches or a wider community outreach utilizing online and physical channels may be used.

The populations of patients with chronic infections in Denmark may be relatively small, however they are followed at few clinics all connected to the Trial Nation Center for Infectious Diseases and Immune Modulation, and hence they are easily approached for study participation opportunities.

The Center has a good collaboration network with other medical specialties such as pediatrics, obstetrics, rheumatology, hematology, pulmonary medicine, transplant specialists etc. enabling the recruitment of participants from other specialties for clinical studies.

## Center services

The Trial Nation Center for Infectious Disease and Immune Modulation handles all requests and trial coordination as one national center. The center has a strong focus on maintaining rapid response times (e.g. time from industry contact to feedback on patient availability). This is supported by access to the established infrastructure and national databases for major disease

areas such as HIV, sepsis, pneumonia, encephalitis, meningitis, and hepatitis. In addition, the clinical partners have access to a broad range of international databases providing companies with a more in depth evaluation of patient availability from both a national and international perspective. Further patient specific treatments, based on genotyping, have been an integrated part of the clinical research in hepatitis C and HIV at all participating clinics. The combined setup allows an increased focus on personalized therapy supported by centralized laboratory facilities for genome analyses at Aalborg University Hospital and through the availability of patient material at the Odense University Hospital biobank.

Among the services offered by The Trial Nation Center for Infectious Disease are the following:

- One point of entry for all trial queries.
- Rapid turn-around of requests – information on patient availability is based on existing databases.
- Uniform regulatory and ethics approval.
- Uniform contract negotiation for all clinical sites.
- Uniform set of standard operating procedures (SOPs) for all sites.
- A precision medicine approach that includes biobanking and genotyping.
- A full range of complementary services are available aimed specifically at Small and Medium-sized Enterprises (SMEs), e.g.: assistance with protocol development/scientific content, trial conduct, sample collection, data collection, report writing, and scientific publication.

<b>Infectious diseases, Prevalence and Incidence in Denmark.</b>		
The current population of Denmark is app. 5,961,000		
Indication	Prevalence (#)	Incidence (#/year)
HIV infection, adults	5.800	185
Chronic Hepatitis C	15.000	180
Chronic Hepatitis B	5.000	250
CNS infections (purulent meningitis)	n.a.	130
Primary Immune Deficiencies (CVID)	300	50
Severe sepsis	n.a.	1.000
Multiresistant infections (obs/isolation)	500	5.000
Cystic fibrosis	400	30
Tuberculosis	275	275
Infectious spondylodiscitis	300	350
Viral respiratory infections	n.a.	50,000
Bacterial pneumonia	n.a.	48,000

## Contacts

### Center clinics

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