

## Danish hospitals and authorities are prepared for COVID-19 related clinical trials

Trial Nation offers a single point of contact to identify potential sites

In Denmark, the COVID-19 epidemic is still in its early stages and restrictions to prevent further spread of the virus have been in place since March 12, 2020. Our government and authorities monitor the situation and have implemented proactive measures to prevent health care system overload.

Our society acknowledges the need for fast action, and new measures are being implemented every day:

- Fast track authorization of COVID-19 related clinical trials at Danish Medicines Agency and the Ethics Committees.
- Fast track negotiation of contracts on COVID-19 related clinical trials by our regions.
- The government allocates app. €7M for research projects with the aim of diagnosing and treating COVID-19 related disease.
- The private funds Novo Nordisk Foundation, Lundbeck Foundation and Carlsberg Foundation allocate app. €19M for emergency response to the coronavirus epidemic in Denmark.

Danish researchers have strong international networks and on March 22, 2020, the first clinical trial application for testing an antiviral drug in patients suffering from COVID-19 was authorized with Rigshospitalet as the European coordinator of the trial. On the same day, the protocol for the first Danish nationwide controlled trial of anti-inflammatory /anti-microbial therapy for COVID-19 was submitted for ethical approval. Several other COVID-19 trials are currently finding their way to Danish clinical research units.

### **Trial Nation**

Trial Nation is a governmentally funded association facilitating public-private collaboration on clinical trials. We offer a single national point of contact for clinical trials in all therapeutic areas in Denmark.

Currently, we are especially interested in COVID-19 related trials and two of our centers, Center for Infectious Disease and Immunomodulation and Center for Respiratory Disease, have specific areas of interest that we would like to draw attention to:

### **Areas of special interest to the centers:**

- Clinical trials of investigational SARS-CoV-2 vaccines
- Clinical trials of antiviral drugs for prevention and treatment of COVID-19 disease
- Clinical trials of immunomodulatory and anti-inflammatory drugs for treatment of COVID-19
- Clinical trials of measures to reduce risk of transmission of SARS-CoV-2 while still providing optimal care

## **Trial Nation Center for Infectious Disease and Immunomodulation:**

The center is a network of dedicated clinical trial units at university hospitals covering all regions of Denmark. The clinics have a strong focus on clinical research in infectious diseases, immune modulation, and vaccine clinical research.

Over the past 10-15 years, the infectious disease departments in Denmark 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.

In 2019, the clinics had 13 open trials of which 9 were initiated during the year. Four trials are industry sponsored and five trials are investigator initiated. The clinics included 674 trial participants of which 534 were included in large industry-sponsored vaccine trials.

## **Trial Nation Center for Respiratory Disease:**

The center is a network of Danish lung clinics that specializes in sponsor-initiated clinical research with medicinal products across all respiratory diseases. The center facilitates clinical trials requiring participants diagnosed in a specialized clinical setting with trained staff, harmonized clinical assessments, and specialized diagnostic methods. All departments have continuously and increasingly committed to the demanding activity of running multiple clinical trials. The center was established in 2016 and has since been involved, with one or more departments, in all relevant commercial respiratory clinical trials in Denmark.

In 2019, a total of 19 commercial clinical trials were open of which 13 were initiated during the year. 124 patients were included in clinical trials in 2019. Of these, 34 patients participated in early phase (I and II) studies.

### **The centers are available for dialogue on industry-sponsored or investigator-initiated trials.**

We will do our utmost to ensure expedited response.

If you are interested in further dialogue, please contact:

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