

Experience from Denmark on nationally coordinated clinical trials collaboration

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Topics that will be covered in this session

- Trial Nation today
- Societal aspects
- Cases from our centers and networks
 - Case - Center for infectious diseases and immunomodulation
 - Case - Psychiatric network

Trial Nation Vision

We pave the way to a future where:

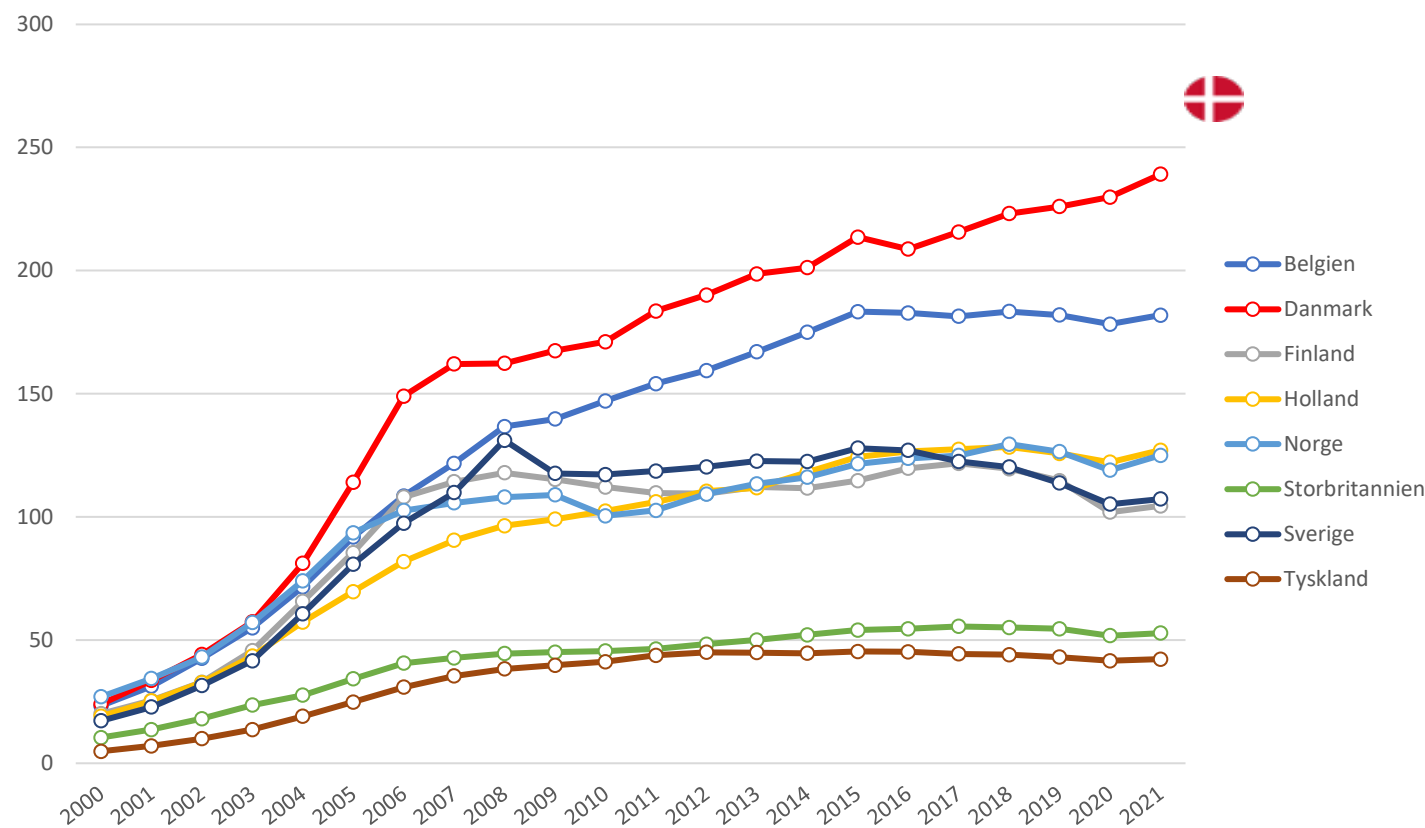
Patients enjoy stronger sustainable health
driven by fast access to cutting-edge medicine
and medical technology

Health care professionals save more lives
and promote stronger health
by always having state-of-the-art medical research
and the latest discoveries right at their hand

Through clinical research we create a better health
and wealth for Denmark

Continued growth of clinical trials in Denmark

Strong tradition for both industry initiated and academic clinical trials



Number of ongoing industry- and investigator initiated clinical trials per million inhabitants

Source: GlobalData and Eurostat

Burning Platform

Conventional clinical trials

- ↓ In-hospital patients
- ↓ Recruitment of patients (hospitals)
- ↓ Research staff
- ⌚ Decentralized patients / local & community based patients

The health care system

- ↑ Patients
- ↑ Patients with comorbidities
- ↓ Care-takers
- ↓ Hospital beds & consultations

Organisation of Healthcare in Denmark



- Tax funded **Universal Healthcare**
- The **State** - overall regulatory and supervisory functions in health and elderly care.
- The five **Regions**:
 - hospital care, including emergency care
 - psychiatry
 - healthcare services provided by general practitioners (GPs) and specialists in private practice.
- The **Municipalities** are responsible for a number of primary health and social services, such as elderly care

Ansvar for Danmark

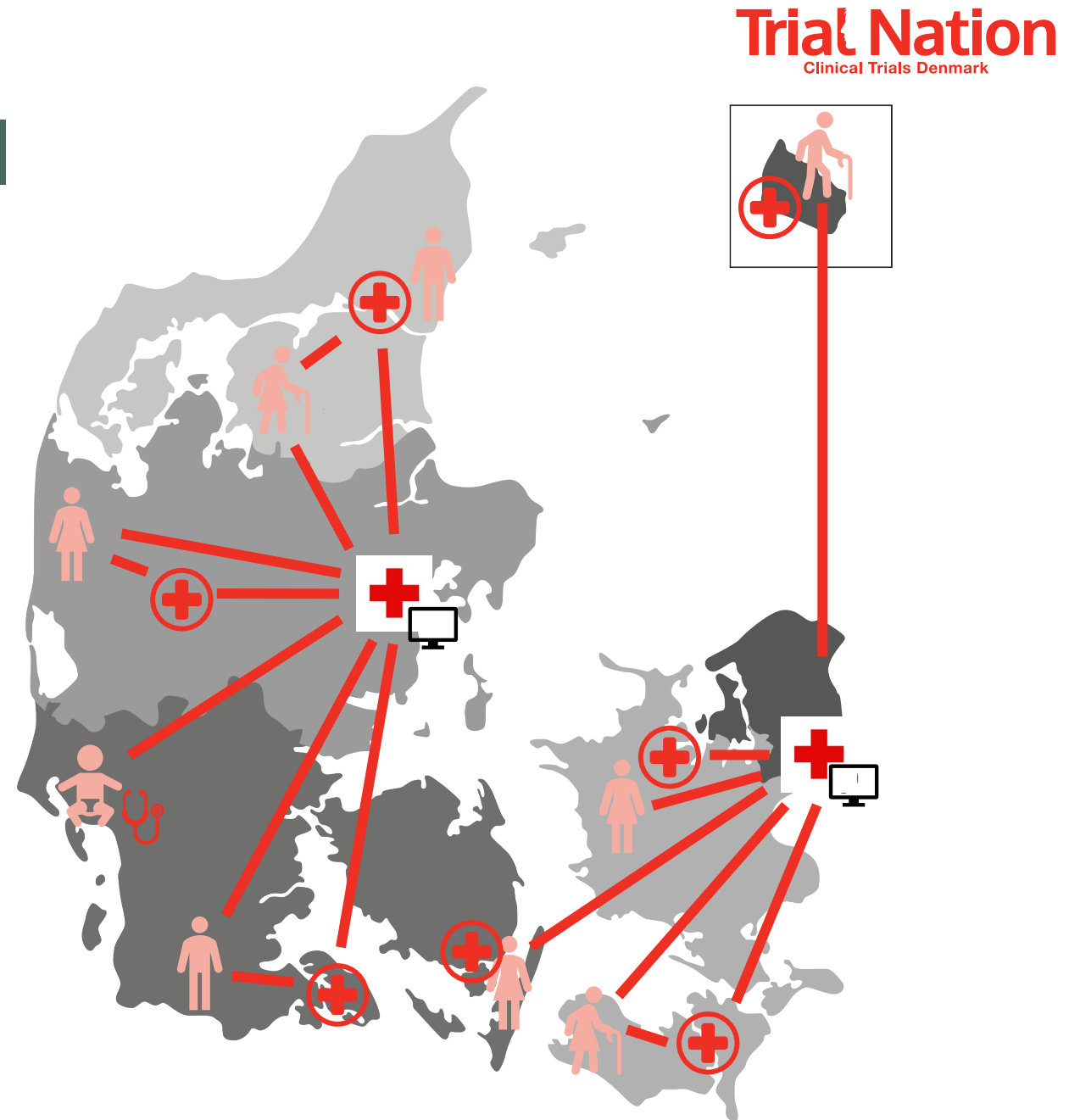
Det politiske grundlag for Danmarks regering

Regeringen vil derfor nedsætte en strukturkommission, der skal udarbejde et beslutningsgrundlag, der opstiller og belyser modeller for den fremtidige organisering af sundhedsvæsenet, herunder hvordan vi får:

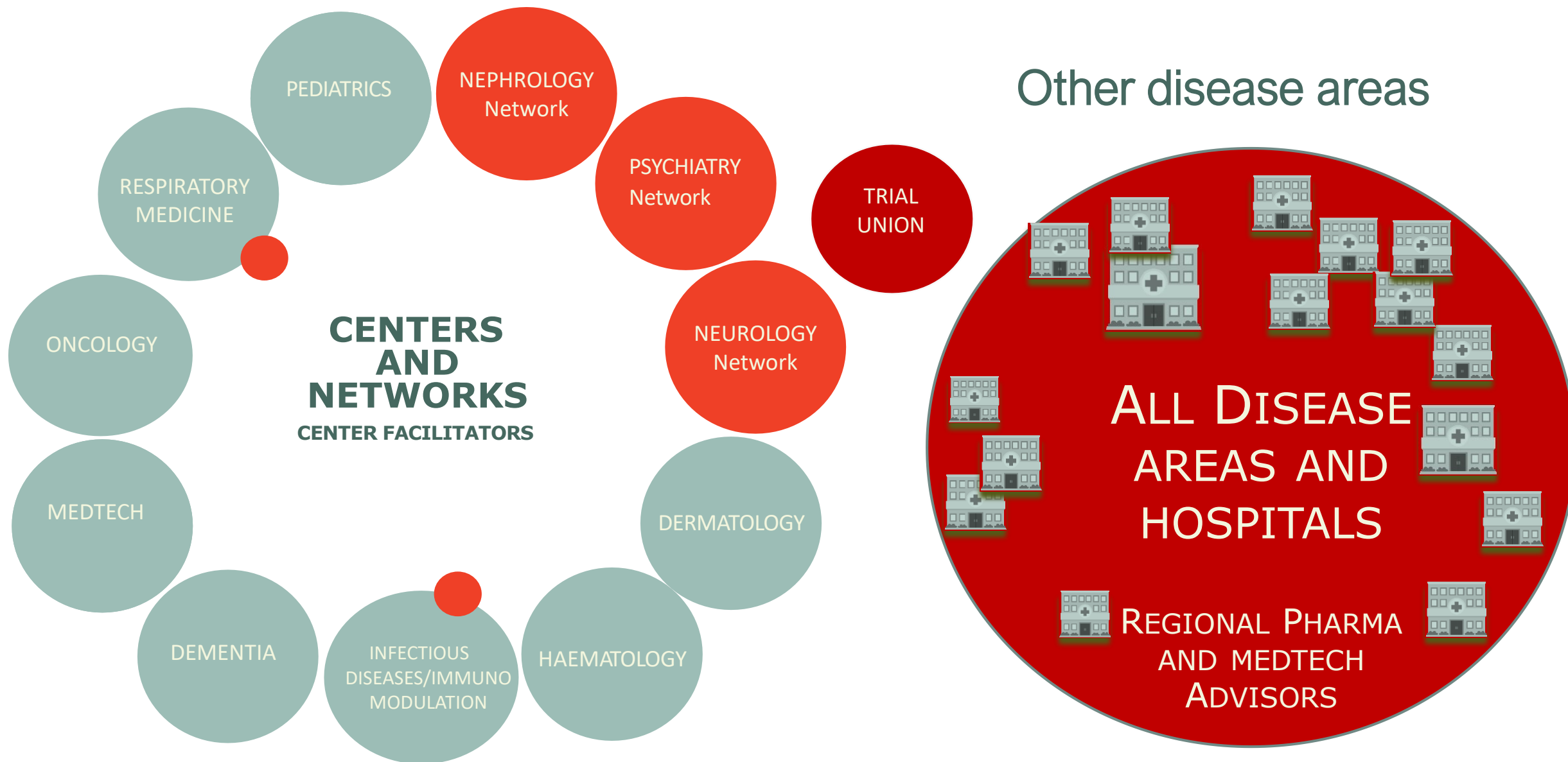
- Et sundhedsvæsen, der er sammenhængende og samarbejder på tværs af fagligheder og geografi.
- En opgavefordeling i sundhedsvæsenet mellem sygehuse og det nære sundhedsvæsen, der sikrer, at patienten kommer i centrum og får en sammenhængende plan for behandling.
- Nedbragt uligheden i sundhedsvæsenet – både geografisk og socialt.

Decentralized Clinical Trials

- Create a permanent public-private framework that supports patient-centered implementation of decentralized clinical trials in Denmark
- Meets the patients where they are



Centers, Networks and Unions



CASE:

CENTER FOR INFECTIOUS DISEASES AND IMMUNOMODULATION



COVID19-MITC Trial Nation - COVID-19 Multiplying Infectious Disease Trial Capacity

Ved at øge kapaciteten til kliniske forsøg i seks meget erfarne kliniske forsøgssenheder, der danner centrum for infektionssygdom og immunmodulation, er det projektets mål at multiplicere antallet af kliniske forsøg, som de kliniske forsøgssenheder kan udføre. Via investeringen fra Innovationsfonden vil projektet øge kapacitet, infrastruktur og national koordinering for kliniske forsøg, hvilket giver agilitet og kan øge antallet af forsøg, som de kliniske forsøgssenheder vil kunne iværksætte - og samtidig bibeholde kvaliteten.

Projektpartnere: Trial Nation, Region Hovedstaden, Region Sjælland, Region Syd, Region Midtjylland, Region Nord.

“We have experienced significant positive spillover effects from the Trial Nation collaboration. The close collaboration between departments in large clinical trials has also contributed to a closer collaboration in many other aspects such as investigator initiated clinical trials. Project staff have, through courses and close collaboration, increased their competences and lead to a quicker onboarding of new staff. The Trial Nation collaboration has also made it possible for smaller departments to engage in clinical trials.”.

Prof. Lars Østergaard, Aarhus University Hospital

ENFORCE – a clinical trial building on outcomes from the COVID19-MITC project

- The DKMA and the Ministry of Health commissioned an investigation of the effectiveness and safety of SARS-CoV-2/Covid-19 vaccines (Nov 2020) in conjunction with the roll-out of the vaccination programme.
- Phase 4 trial, 2 – year follow up period, with a budget of 102 mDKK
- Rolled out in the Trial Nation Center for Infectious Diseases and Immunomodulation in collaboration with CHIP, Center of Excellence for Health, Immunity and Infections.
- From idea to recruitment in 2 months in a close collaboration between authorities, universities and hospitals.

National Cohort Study of Effectiveness and Safety of SARS-CoV-2/Covid-19 vaccines (ENFORCE)

Trial Nation
Clinical Trials Denmark

7 study sites
2 laboratories
~ 7000 participants
Recruitment: feb-july 2021



Study visit



Vaccine dose

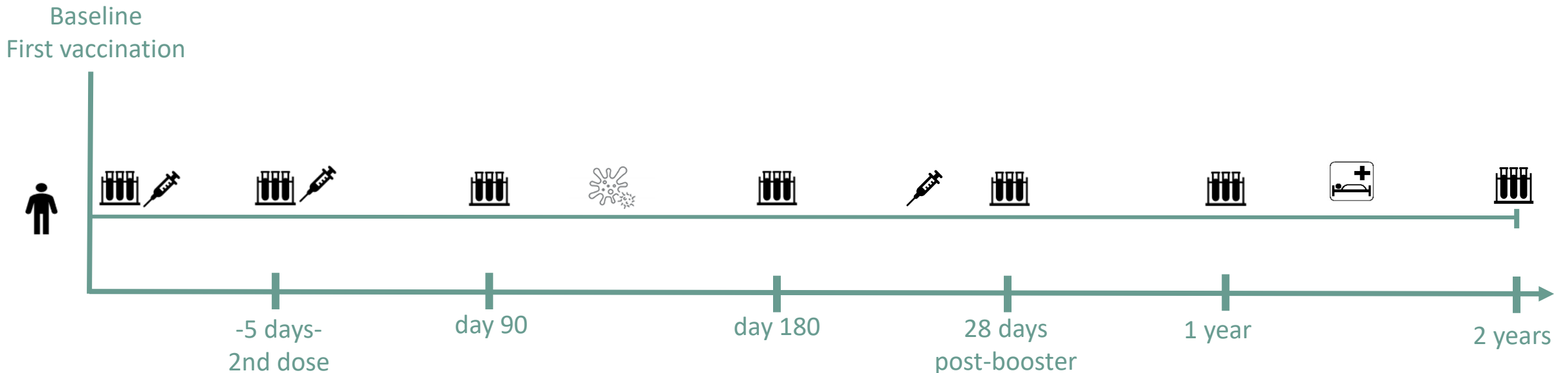


Breakthrough infection



Hospitalization

Data from
registries



Academic Output from ENFORCE

Trial Nation
Clinical Trials Denmark



CMI CLINICAL
MICROBIOLOGY
AND INFECTION

ESCMID

EUROPEAN SOCIETY
OF CLINICAL MICROBIOLOGY
AND INFECTIOUS DISEASES

ORIGINAL ARTICLE | VOLUME 28, ISSUE 8, P1126-1133, AUGUST 01, 2022

Characteristics associated with serological COVID-19 vaccine response and durability in an older population with significant comorbidity: the Danish Nationwide ENFORCE Study

Ole Schmeltz Søgaard   • Joanne Reekie • Isik Somuncu Johansen • ... Lars Østergaard • Jens Lundgren • on behalf of the ENFORCE Writing Group • [Show all authors](#)

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 **frontiers**
in Immunology

ORIGINAL RESEARCH
published: 23 November 2021
doi: 10.3389/fimmu.2021.779453



Inflammation and Platelet Activation After COVID-19 Vaccines - Possible Mechanisms Behind Vaccine-Induced Immune Thrombocytopenia and Thrombosis

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nature communications



Article


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Levels of SARS-CoV-2 antibodies among fully vaccinated individuals with Delta or Omicron variant breakthrough infections

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 Check for updates

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CASE: PSYCHIATRY



One of our newer Trial Nation networks - Psychiatry

- Unmet medical needs
- Need for increased research, especially clinical evidence in the form of clinical trials
- Societal need
- High political focus
- Possibilities for synergies (digitalization / decentralized clinical trials) with the healthcare system as a whole



Aftale om en **10-årsplan for psykiatrien og mental sundhed**

Dette indebærer:

1. Opbygning af et lettilgængeligt tilbud i kommunerne til børn og unge i psykisk mistrivsel og med symptomer på psykisk lidelse
2. Styrkede indsatser for mennesker med svære psykiske lidelser og her-og-nu kapacitetspakke til den regionale psykiatri
3. Oplysnings- og afstigmatiseringsindsatser
4. Styrkede tværfaglige og evidensbaserede miljøer
5. Bedre rammer for forskning i forebyggelse og behandling af psykiske lidelser

8	Forskning i psykiatrien er prioriteret.	Ikke tilgængelig data.	Der arbejdes videre med udvikling af indikator.

Psychiatric network was formed in 2022

Nation 1. udg. i november 2022
7mo • 0

Trial Nations velbesøgte kick-off møde i det psykiatriske netværk er netop overstået.

De to dage bød på masser af udsigt - både over Aalborg og til et styrket samarbejde om psykiatrisk forskning til gavn for patienterne. Der var stor spørgelyst, og deltagerne fremhævede bagefter især de mange relevante oplæg og muligheden for at reflektere over egen praksis i mindre grupper.

I kommentarfeltet kan du se mere input til de to dage; opfølgingsarbejdet er allerede i gang.

[#clinicaltrials](#) [#medicine](#) [#network](#)

[See translation](#)



Projektpersonale fra alle regioner mødtes i går i Aalborg til "stiftende generalforsamling" i netværket for projektpersonale på life science studier i psykiatrien i [Trial Nation](#) regi. Det var på mange måder en produktiv dag, hvor der var mulighed for at drøfte både generelle, men også specifikke opgaver og udfordringer i kliniske studier både fra life science industrien, men også eget initierede studier. Der var stort engagement, og der blev sparret og rådgivet på tværs af regioner, enheder og studier om udfordringer.

Gruppen blev enige om et uforpligtende online møde hver uge samt at mødes én gang årlig til et 2-dages seminar. Er du projektpersonale i Psykiatrien eller skal du snart være det og interesseret i at høre mere, komme på mailinglisten eller mødeindkaldelserne så send gerne en besked til [Mette Marcus Munk](#) og [Simon Johnsen](#) [#psykiatriskforskning](#) [#lifescience](#) [Psykiatrien i Region Midtjylland](#) [Psykiatrien i Region Syddanmark](#) [Psykiatrien Region Sjælland](#) [Region Hovedstadens Psykiatri](#) [Psykiatrien, Region Nordjylland](#)

[See translation](#)



“The Trial Nation collaboration has given us a closer understanding of clinical trial conduct and clinical trial processes. It has given us an opportunity to deepen the contacts and collaboration between Danish sites and peer-to-peer interaction. We already knew each other, and already had a good collaboration between investigators, however now there is also a formalized collaboration between project staff across the sites.”

Prof. René Nielsen, Aalborg University Hospital

Key messages

1. Clinical trials is a prioritized focus area in Denmark – now and in the future
2. Trial Nation Centers, Networks and Unions supports physicians in organising strong collaborations across sites.
3. This strong collaboration is used to leverage an agenda wider than industry-initiated clinical trials