



### Denmark - Building Tomorrow's Clinical Trials Ecosystem Today through a Strong Public-Private Collaboration

Marianne Pilgaard CEO Trial Nation



# Topics that will be covered in this session

- 1. Denmark: Healthcare and health data
- 2. Life Science is a Danish political priority
- 3. Trial Nation and its role



# Topics that will be covered in this session

1. Denmark: Healthcare and health data



#### Denmark

- 5,9 million people
- Outstanding clinical competencies
- Extensive, saturated, longitudinal (health) data
- "Central Person Register" Unique 10 digit identifier linked to each individual since 1968
- CPR linked EMR system from cradle to grave
- 160 additional CPR linked health registries
- National biobank w/ 30.6 mio CPR linked samples and growing



# Organisation of Healthcare in Denmark



- Tax funded Universal Healthcare Coverage
- 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

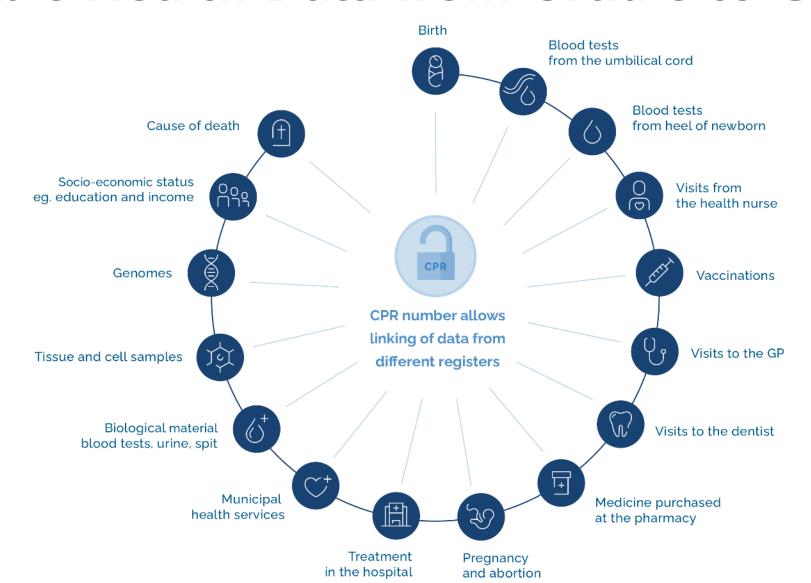
#### IMAGINE A COUNTRY THAT HAS....



Source: The Danish Health Data Authority



#### Linkable Health Data from Cradle to Grave





## Topics that will be covered in this session

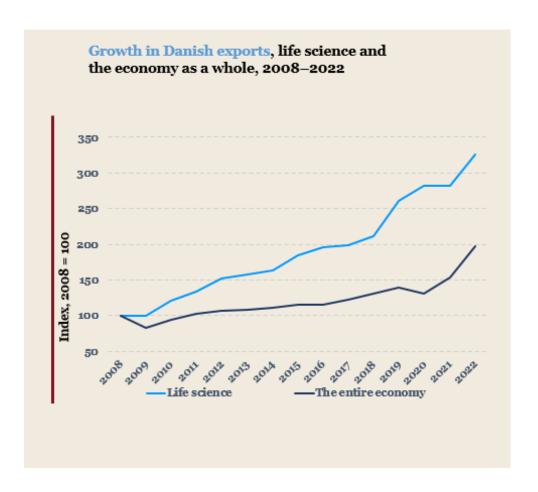
2. Life Science is a Danish political priority



#### Share of Exports from 5.5% to 19.7% in 14 years

In 2008, life science exports accounted for 5.5 per cent of total Danish merchandise exports. This number has increased to 19.7 percent in 2022.

Exports from life science alone have more than tripled, in comparison to total exports just under 100 percent.





## Strong Policy Prioritization of Life Science







Growth Plan for Life Science from 2018 and

Agreement on a strategy for life science from 2021



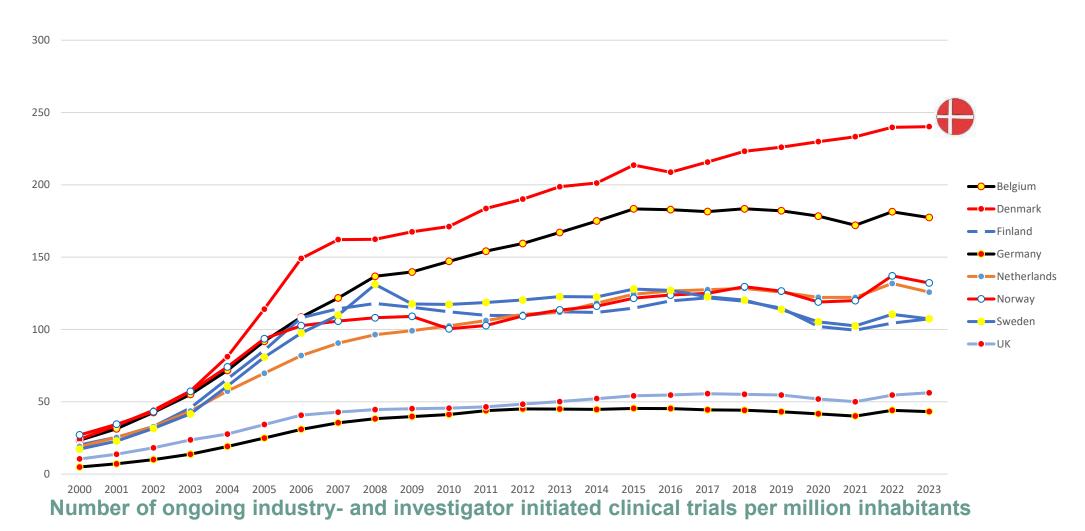
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3. Trial Nation and its role

#### Continued Growth of Clinical Trials in Denmark Trial Nation



Strong tradition for both industry initiated and academic clinical trials

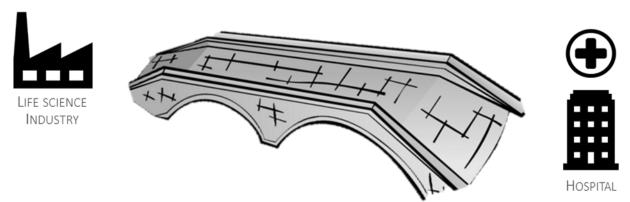


Source: GlobalData and Eurostat



#### This is Trial Nation

- Trial Nation is a single entry to commercial clinical trials in Denmark
   – clinical infrastructure
  - Primarily publicly funded.
  - Alle Trial Nation's services are free of charge
- Trial Nation is a prioritised stakeholder in the Danish life science strategy focussing on:
  - A public-private partnership in clinical trials
  - Framework conditions for clinical trials in Denmark
- Established to make Denmark the preferred destination for commercial clinical trials





#### 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



# **Strategic Position**

Trial Nation promote clinical trials in Denmark and is the leading publicprivate ecosystem for clinical trials in Europe

Trial Nation's remit is to expand and maintain the foundation to secure Denmark's position among top three in Europe (number of clinical trials relative to population)

Trial Nation strengthen framework conditions to attract more clinical trials at the highest international level by efficient collaboration and coordination across regions, authorities, clinical researchers and stakeholders

Trial Nation lead *state-of-the-art* methods and technologies in the planning and execution of clinical trials

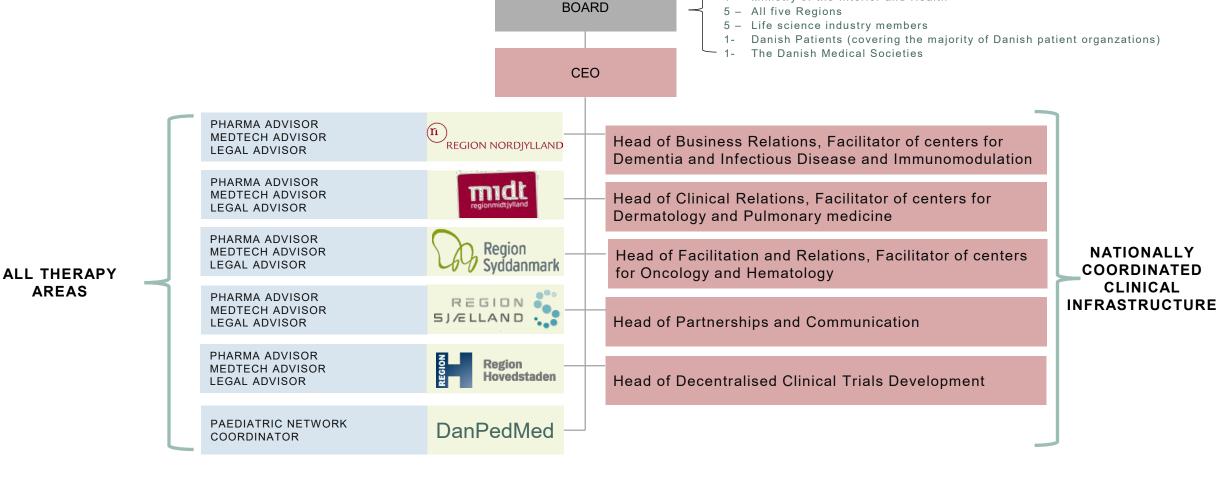


1 - Ministry of Industry, Business and Financial Affairs

1 - Ministry of the Interior and Health

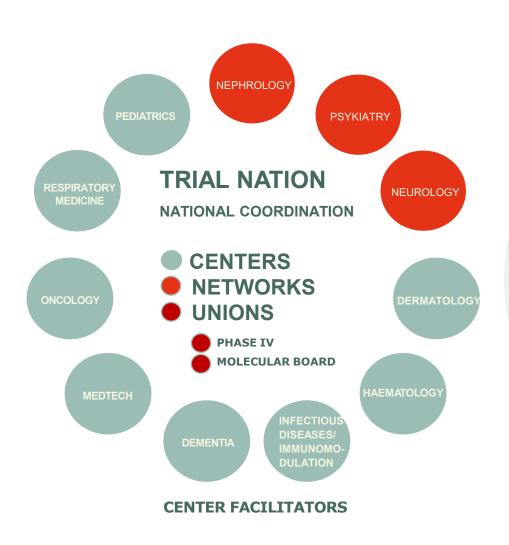
**Trial Nation Organisation** 

**AREAS** 





# **Easy Access to Clinical Infrastructure**



#### **OTHER DISEASE AREAS**

TRIAL NATION REGIONAL PHARMA
AND MEDTECH COORDINATORS
FACILITATES CONTACT TO SITES IN
ALL OTHER DISEASE AREAS IN ALL
PARTS OF DENMARK



WHO WE ARE

COLLABORATIONS

**CONTRACT TEMPLATES** 

CONFIDENTIALITY UNDERTAKING FOR A CLINICAL TRIAL

STANDARD CLINICAL TRIAL AGREEMENT

STANDARD CLINICAL INVESTIGATION AGREEMENT - MEDICAL DEVICES

STUDY START-UP AGREEMENT

**CRO - STANDARD CLINICAL TRIAL AGREEMENT** 

#### **READY TO USE TEMPLATES**

The healthcare regions in Denmark have formed a legal network within Trial Nation to ensure that the regions act as a united negotiation party for contract templates in relation to the industry.

The network provides efficient negotiation of contract templates (for CDAs, CTAs and Clinical Investigations) relating to clinical trials and investigations in Denmark. Contract templates can be used as they are or be tailored to your company. Consider using the standard templates below for the fastest possible processing time as they are pre-approved in all regions and no negotiation time is need. Please note that the Trial Nation network only negotiate contract templates, individual contracts are handled in each region. Please also note that the Trial Nation network does not provide general legal advice.

You can contact us regarding a company specific contract template (CDA/CTA/Clinical Investigation) negotiation request at <a href="mailto:legal@trialnation.dk">legal@trialnation.dk</a>

#### **Examples of Trial Nation Clinical Trials Interfaces**







# Frontrunner in Digitalization

Borger

Fagperson

sundhed, dk



Laboratoriesvar

Journal fra sygehus

Dine sundhedsdata







#### Din digitale indgang til sundhedsvæsnet

Vi samler dine sundhedsdata og gør det nemt for dig at få overblik over din sundhed og sygdom. Du kan også bruge sundhed.dk til at søge efter en behandler, finde information om sundhed og sygdom, læse om patientrettigheder og meget mere. Log på og se dine egne sundhedsdata.

Se dine sundhedsdata

#### nnovationsfonden



#### Supporting Decentralized Clinical Trials Implementation

Trial Nation is leading a powerful public-private partnership of Danish life science stakeholders.

PACT (Decentralised Patient Centered Clinical Trials) project: A € 5 M project (4 years, 2022-2026)

The overall aim is to make the clinical research more available for Danish patients and citizens



























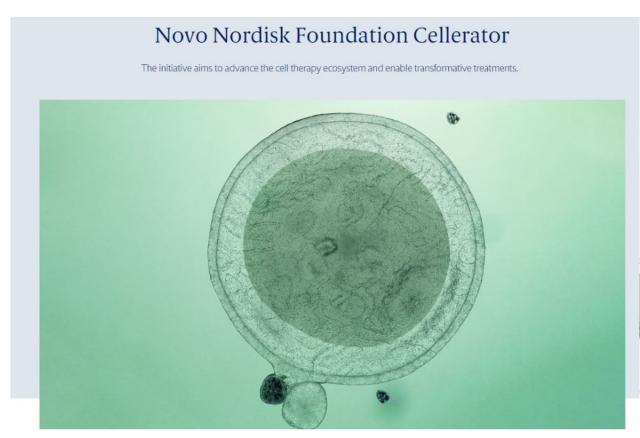








# **Advanced Therapy Medicinal Products**



The Cellerator will serve public and private, national and international clients from academia, biotech and the pharmaceutical industry. Approval will be sought from the Danish Medicines Agency to produce cell therapies for clinical use and the facility is expected to be operational in 2027.



Illustration of the facility building on Lyngby Campus developed during the conceptual design phase. Credit: Tegnestuen Kontekst ApS.



# **Key Messages**

- 1. Continous political support to Life Science in Denmark
- 2. Excellent public-private collaboration creates health, wealth and knowledge
- 3. Having an organisation gathering clinical trials stakeholders around a shared, national agenda is impactful.



# Trial Nation

Get in touch: contact@trialnation.dk www.trialnation.dk

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