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8 – 12 JULY 2023 | SYDNEY, AUSTRALIA

National Trial Overview: Towards Accessible and Patient-Centered Healthcare

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AIDH IMIA

Access to clinical trials in Denmark

- DK is a frontrunner in digitalisation and clinical trials
- System-centred approach vs. patient-centered approach
  - Patients have to be at the right hospital at the right time to be recruited for clinical trials → inequity
  - There is no access to updated information concerning active clinical trials in Denmark for patients, relatives or health professionals → difficult to identify and match patients to clinical trials
    - https://clinicaltrials.gov/:
      - No up-to-date overview of clinical trials
      - Not all trials in DK are included
      - Unfamiliar platform to patients
- Hypothesis: Decentralising access to clinical trials to patients and health professionals can improve equity in access to health care

Denmark in the top ranking
of clinical trials per capita

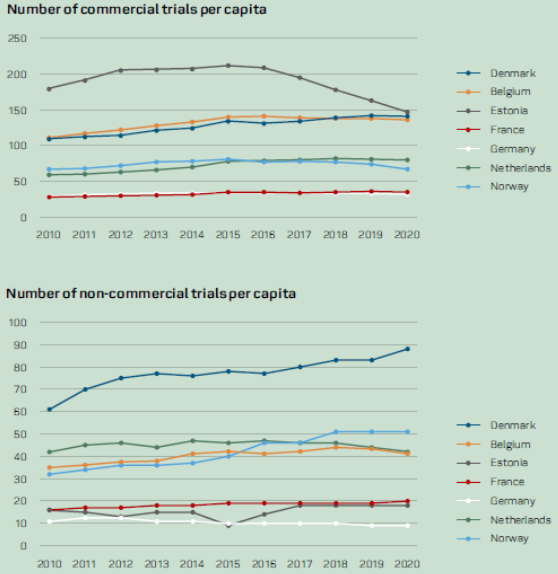

Figure 1– Number of commercial and non-commercial clinical trials per capita in selected European countries.

Innovationsfonden

National Trial Overview

- An up-to-date national, publically owned digital overview of all approved, prospective clinical trials in Denmark
- Demand from patient unions, researchers and sponsors
- Focus area in the governments Life Science Strategy 2021
- Development process:
  - Developed by Trial Nation, Danish Comprehensive Cancer Center, the Danish Regions, Ministry of Health, Ministry of Commerce, National Center for Ethics, Danish Medicines Agency
  - Involvement of patient organisations, doctors, nurses, companies
  - IT supplier: Netcompany

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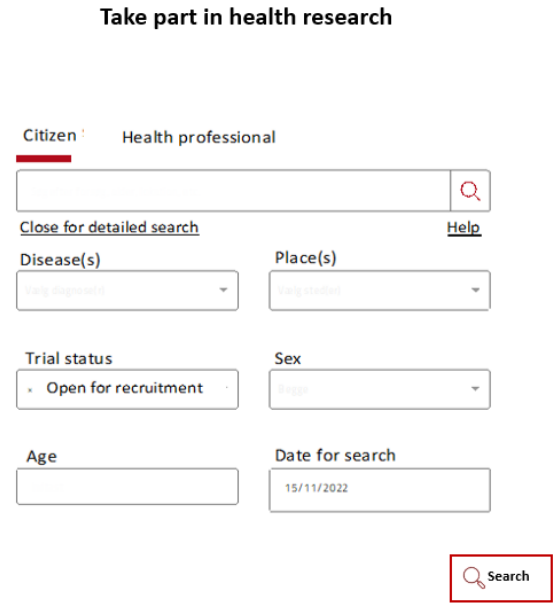
Content:

1. All clinical trials in Denmark
2. The most important in- and exclusion criteria's
3. Overview of participating sites in Denmark
4. Contact information on participating sites
5. Status of the study (open for recruitment, closed etc.)
6. Primary data: trials with medication, medical equipment, other forms of interventions



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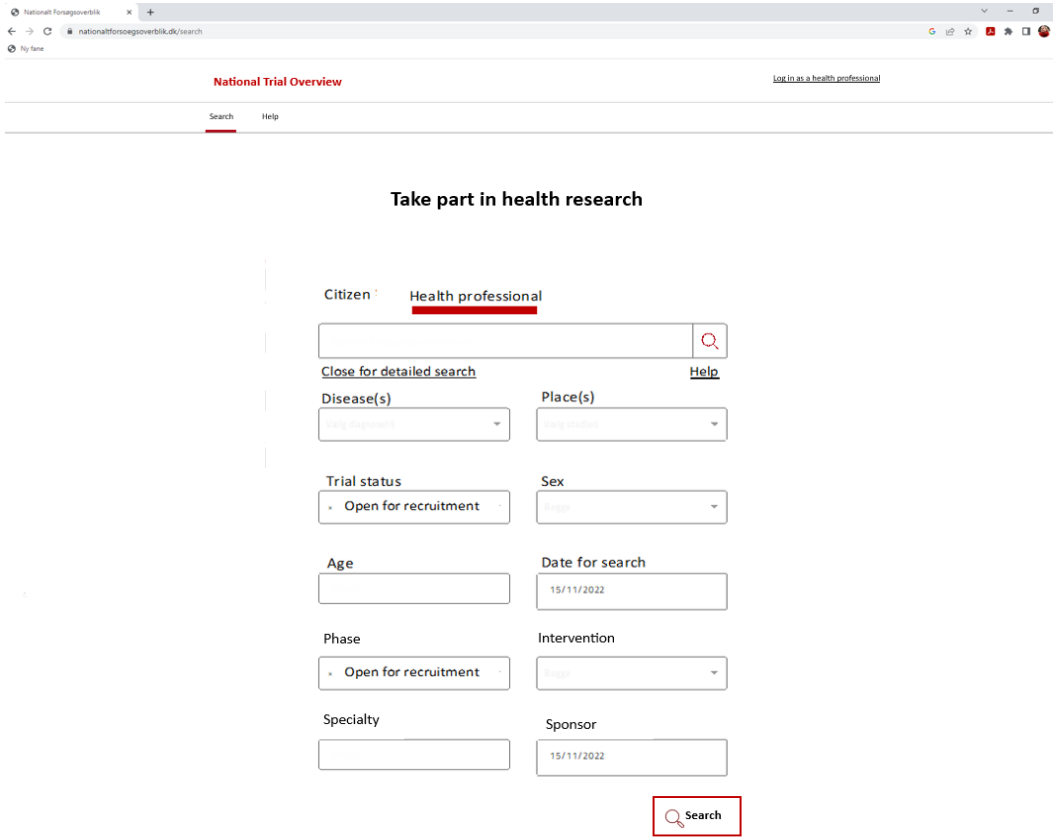
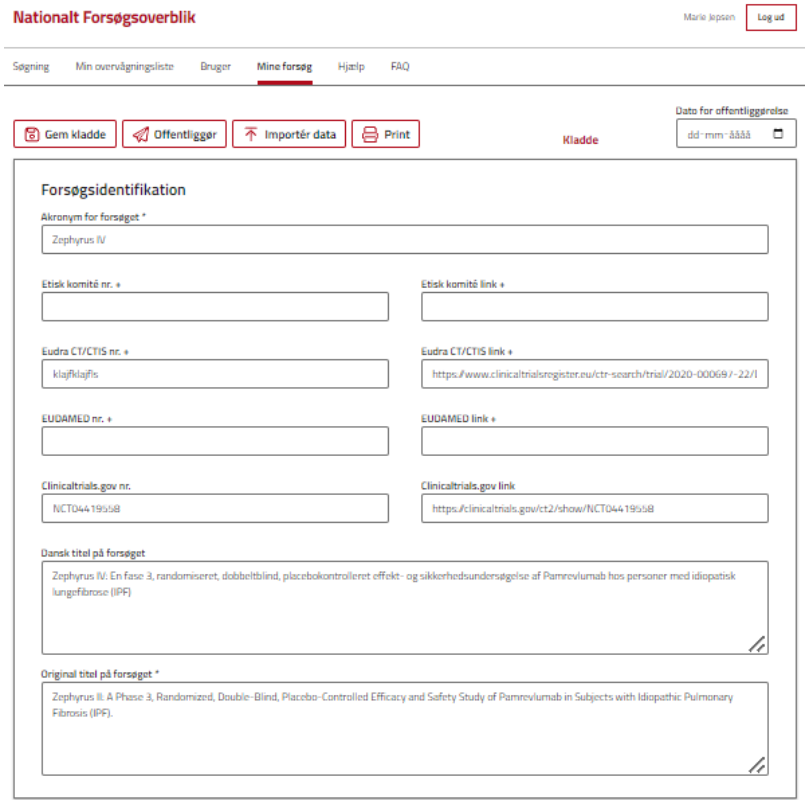

Nationalt Forsøgsoverblik
nationaltforsoegsoverblik.dk/search
Ny fane
National Trial Overview
Log in as a health professional
Search
Help
Take part in health research
Citizen
Health professional
Close for detailed search
Help
Disease(s)
Place(s)
Trial status
Open for recruitment
Sex
Age
Date for search
15/11/2022
Phase
Open for recruitment
Intervention
Specialty
Sponsor
15/11/2022
Search


Nationalt Forsøgsoverblik
Marie Jepsen
Log ud
Søgning
Min overvågningsliste
Bruger
Mine forsøg
Hjælp
FAQ
Gem kladde
Offentliggør
Importér data
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Kladde
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Forsøgsidentifikation
Akronym for forsøget *
Zephyrus IV
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Eudra CT/CTIS link +
https://www.clinicaltrialsregister.eu/ctr-search/trial/2020-000697-22/I
EUDAMED nr. +
EUDAMED link +
Clinicaltrials.gov nr.
NCT04419558
Clinicaltrials.gov link
https://clinicaltrials.gov/ct2/show/NCT04419558
Dansk titel på forsøget
Zephyrus IV: En fase 3, randomiseret, dobbeltblind, placebokontrolleret effekt- og sikkerhedsundersøgelse af Pamrevlumab hos personer med idiopatisk lungefibrose (IPF)
Original titel på forsøget *
Zephyrus II: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Efficacy and Safety Study of Pamrevlumab in Subjects with Idiopathic Pulmonary Fibrosis (IPF).

NTO implementation

User evaluation

1) Healthcare professionals
   - Observation of handover (training, dialogue) from regional coordinators to health professionals (one-to-one observations in clinic) in all regions in the pilot and test phase.
   - User evaluation with regional coordinators (workshop)
   - User evaluation with health professionals across regions and specialties (workshops)
     - Identify interpersonal, informative and technical challenges to the system
     - Allow adjustments to the system

2) Patients/citizens
   - Individual user sessions (show-me-how, think aloud)
   - Focus group interviews
     - Target group: 'DDDs' (Disempowered, Disengaged and Disconnected) and 'People Like Us' (Super-users)
     - Testing user interface

Challenges to NTO implementation

- Placing data responsibility
  - Solution: no direct personal data storage in the platform - overview of data (clinical trials)
- Stakeholder management
  - Multiple stakeholders complicates communication and task delegation
- Integration of NTO into other IT systems and platforms
- Burn-out risk among health professionals
  - Project nurses are likely the ones responsible for entering trial data into the system
    - They are paid ('bought out') but we need to identify their other tasks and whether burn-out is a risk through open dialog.

THANK YOU FOR LISTENING

- Questions?