

# Trial Nation

Clinical Trials Denmark

# **Trial Nation Center for Hematology**

## Introduction and overview

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# Clinical Key Features – infrastructure 1

- Fully publicly funded health care with a high level of standard of care
- The national Specialty Plan defines who can treat what
- New EMA approved treatments are adopted at an early stage in the Danish Health Care system
- High data quality
  - Unique possibilities for characterization of patients and follow-up of patients in data registries based on the unique national personal identification number (CPR no.) -> superior RWE data collection possibilities
  - National biobanks
    - Danish Cancer Biobank
    - Danish National Genome Center

# Clinical Key Features – infrastructure 2

- Established National multidisciplinary study groups within all hematological diagnoses (leukemia, lymphoma, multiple myeloma, myeloid neoplasia, benign diseases)
- Close collaboration between patient associations, companies, clinics, and multidisciplinary study groups
- High willingness in the population to participate in clinical trials
- Focus on implementation of PRO measurements
  - QOL measurements implemented in all clinical trials
- National collaboration on clinical trials
  - National feasibility process
  - Referral of patients for clinical trials on regional, national, and international level
    - National referral center for phase I clinical trials (Copenhagen University Hospital)
  - Attraction of clinical trials

# Trial Nation Center for Hematology



| Dept. of Hematology  | Trial Nation Responsible MD                     |
|--|---|
| Copenhagen University Hospital (1) <ul style="list-style-type: none"> <li>• Dept. of Hematology</li> <li>• Dept. of Paediatrics and Adolescent Medicine</li> </ul> | Peter Brown / Martin Hutchings<br>Karsten Nysom |
| Zealand University Hospital (2)  | Christian Poulsen                               |
| Odense University Hospital (3)   | Niels Abildgaard                                |
| Vejle Hospital (4)   | Torben Plesner                                  |
| Aarhus University Hospital (5)   | Francesco D'Amore                               |
| Hospitalsunit West, Holstebro (6)  | Robert Schou Pedersen                           |
| Aalborg University Hospital (7)  | Henrik Gregersen                                |

Center Facilitator: Ask Aabenhus, Trial Nation

# Clinical Key Features - experiences

- Comprehensive experience with commercial and academic studies
  - Phase I (incl. FIH), II, III & IV and pediatric & adolescent hematology clinical trials
- Gene profiling and sequencing translated into clinical use at hospital and regional tumor board meetings
- Front-line functional imaging established at most centers (PET/MRI, DW-MRI, PET/CT)
- Immunotherapy implemented at all clinics
- Academic centers for cancer immune therapy and CAR-T cell therapy

# Dept. of Hematology, Odense University Hospital

- Secretariate for Trial Nation Hematology
- Elite Research Center for Geriatric Cancer (AgeCare)
- Elite Research Center for Cellular Immunotherapy in Hematological Cancer (CITCO)
- Multidisciplinary Amyloidosis Center of Clinical Excellence (AmyC OUH)
- Multidisciplinary Research Centers for Mastocytosis and Eosinophilia
- Center for Quality of Life Research (QOL Research OUH)
- Center for Precision Medicine at OUH (PreMedico)

# What can we offer? – short Start-Up Timelines

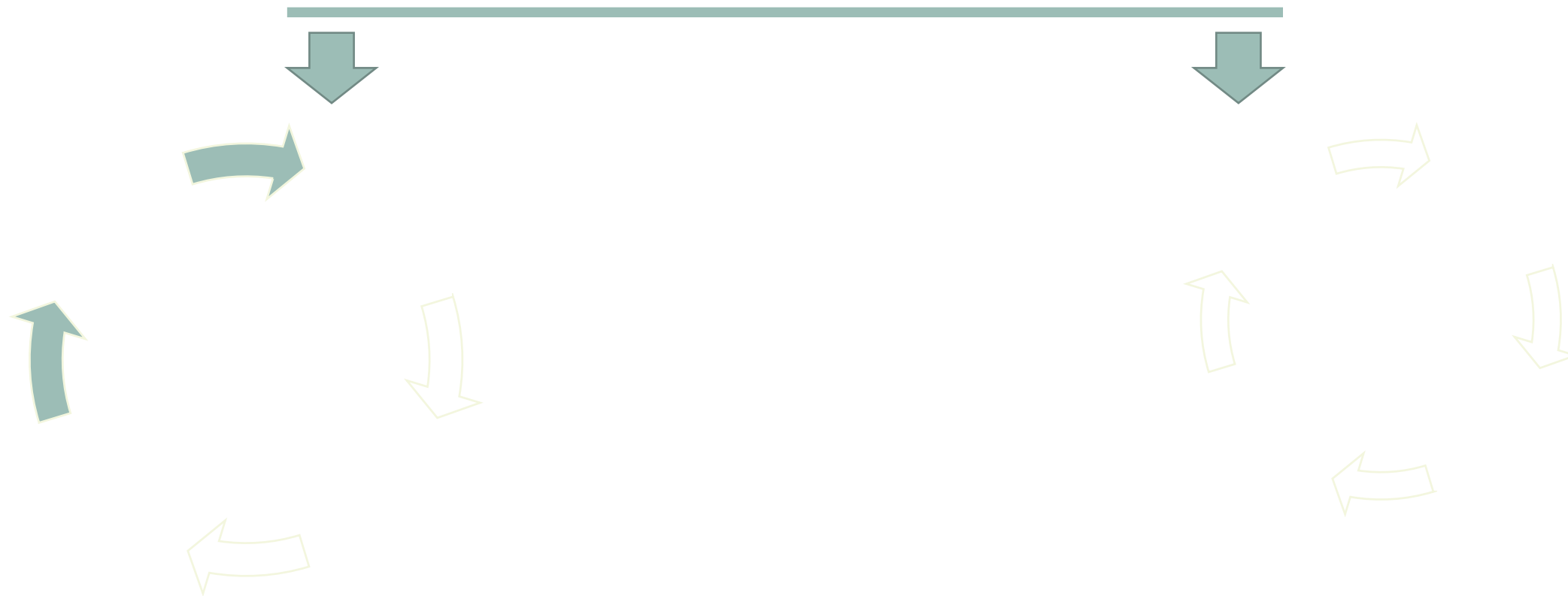
- Competent authority:  $\leq 35$  days from check-in to first response ( $\geq 95\%$ ) and  $\leq 14$  days for FIH trials
- Ethics committees:  $\leq 60$  days from check-in to approval
- Clinical trial agreements: 45-90 days from submission to approval.
  - National clinical trial agreement templates available.
  - Negotiation of a company specific national clinical trial agreement template possible
- Parallel submission and approval of applications and agreements

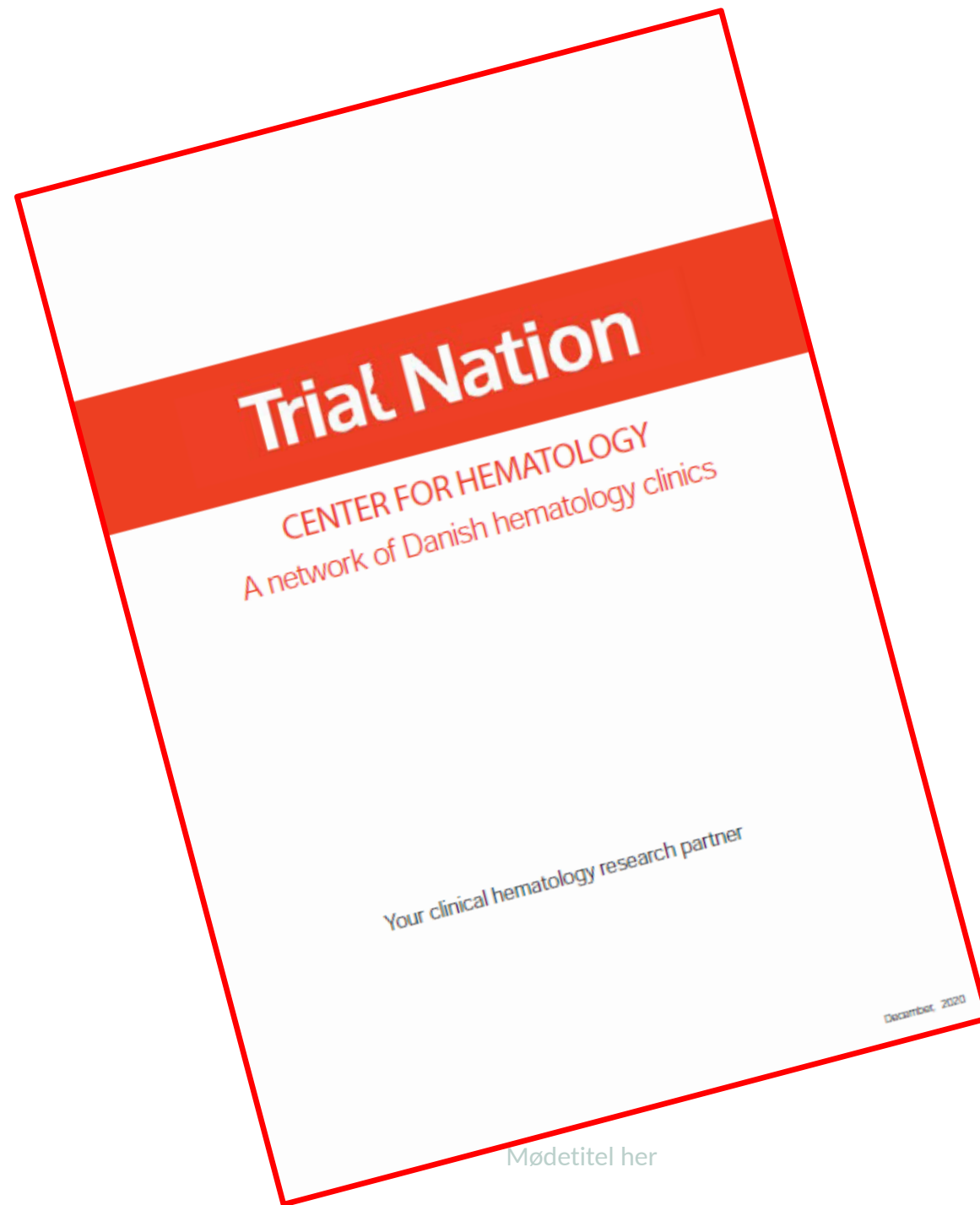


# Feasibility Process

Advice on who to contact regarding a given feasibility

Full feasibility process handling





Mødetitel her

# Trial Nation

Get in touch:

[contact@trialnation.dk](mailto:contact@trialnation.dk)

[www.trialnation.dk](http://www.trialnation.dk)

[Niels.Abildgaard@rsyd.dk](mailto:Niels.Abildgaard@rsyd.dk)