

# Annual Report 2022

**Trial Nation**  
Clinical Trials Denmark

## **We pave the way to a future where:**

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

Healthcare 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.

Clinical research creates a better health and wealth for  
Denmark.

# Table of contents

Table of contents .....	1
Executive summary.....	2
Activities in 2022.....	4
Center for Dementia.....	11
Center for Dermatology.....	15
Center for Hematology.....	18
Center for Infectious Disease and Immune Modulation .....	23
Center for Oncology.....	28
Center for Respiratory Medicine .....	34
DanPedMed.....	38
Trial Nation MedTech Network.....	42
Digitalisation of Clinical Trials .....	44
Appendix A .....	49

## Executive summary

In Trial Nation, the year 2022 will be remembered for a positive development in our already well-run and organized Centers. A new network in psychiatry has been formed and recently established Trial Unions have been further developing the past year. These new Networks and Unions further highlight the benefits of organizing sites nationally around clinical trials.

With more activity follows increased demands. The Feasibility Coordinators across all Centers, Networks, and Unions have been doing a tremendous job in 2022 of supporting the expanded specialties.

Clinical trials are moving in a direction towards more digitalisation – a key focus area in Trial Nation's day-to-day work. During the year we have been highly involved in the development of the National Overview of Clinical Trials and is the project lead in the upcoming national implementation. The digital platform will help healthcare professionals, patients, and citizens find relevant, updated information on clinical trials in Denmark using an easy-to-access tool.

The development towards more digitalisation can also be seen in the immense focus on decentralised clinical trials (DCTs). In 2022 Trial Nation collaborated with various stakeholders to ensure solid framework-conditions for decentralised clinical trials in Denmark. In the DCT Dialogue Forum, the Danish Medicine Agency, life-science companies involved in DCT, and Trial Nation joined forces to identify barriers and recommend adjustments in the DCT framework. Further, Trial Nation and Healthcare DENMARK published a whitepaper on decentralised clinical trials in Denmark to promote the unique environment for conducting DCTs.

2022 was also a year of new partnerships and collaborations – across borders and in Denmark. In October, Trial Nation visited USA to explore opportunities for partnerships across infectious diseases medicine. The trip also served as a good opportunity for potential collaborations in other therapeutic areas, across Trial Nation as a whole.

How Trial Nation work in public-private partnership to support clinical trials was also on the agenda when we in collaboration with the Foreign Ministry met with representatives from Canadian provinces and Ministry of Health, as well as the UK, to showcase the capabilities and possibilities in Danish clinical research.

These activities show how valuable synergies are between different organizations, networks, countries, and competencies for inspiration and potential future collaborations. We will continue the international dialogue in 2023.

Trial Nation's outreach was present also within Denmark. A two-day course for study nurses, attracting 80 attendees, was held in 2022. With education and networking for relevant groups we facilitate knowledge sharing in clinical trials. This was also apparent when our network DanPedMed held a one-day conference in collaboration with the corresponding Nordic networks in September. The conference showed that cooperation and networks are key pillars in expanding the knowledge about medicines and clinical trials for children and adolescents.

It was also the year where the spotlight was put on the vast variety of clinical trials done by researchers in Denmark. The award show "Denmark's Best Clinical Trials 2022" was arranged by nine organisations, including Trial Nation. 138 projects signed up and 21 was nominated in seven categories. It was an amazing opportunity to recognize and celebrate all the hard work and great, innovative clinical trials done in Denmark. Trial Nation was represented in the jury by our CEO, Marianne Pilgaard. We look forward to the next award show in June 2023.

In all, 2022 was a year of meaningful work towards the development of clinical trials in Denmark. We look forward to what 2023 brings.

## Activities in 2022

This chapter gives an insight into activities driven by Trial Nation solely or in collaboration with public and private stakeholders during 2022. It consists of three overall themes: Clinical Trials and Infrastructure in Trial Nation Centers, Clinical Trials - Now and in the Future, and Creating Awareness. To deep-dive into a comprehensive list of 2022-activities, please see appendix A

### Clinical trials and infrastructure in Trial Nation Centers

The Danish clinical trial ecosystem is both leading and defying a sad European trend (figure 1), where Europe see a decline in its share of clinical trials globally.

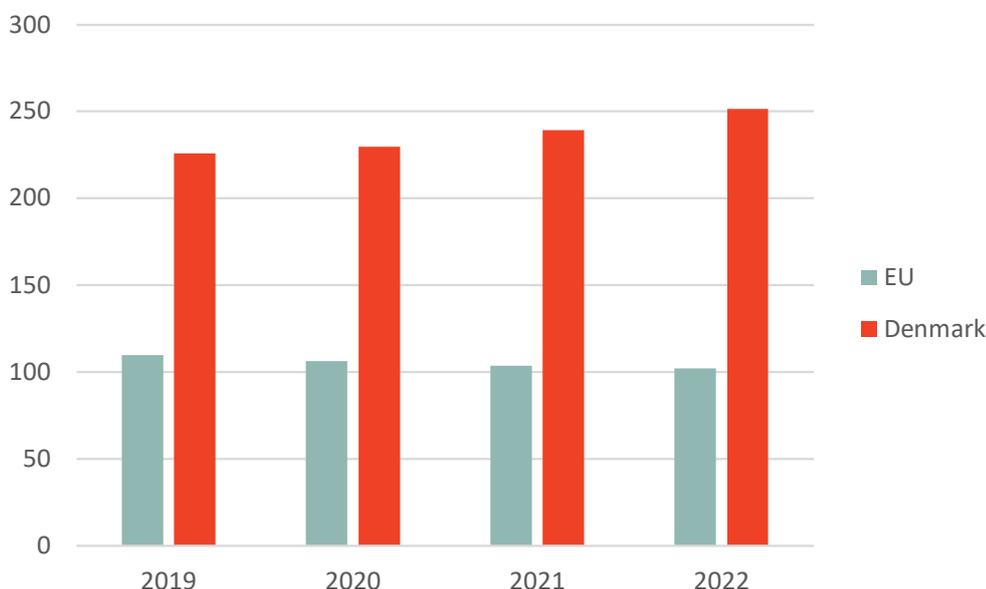


Figure 1: Denmark is #1 in trials per million inhabitants in EU. The numbers are based on all ongoing trials in the year.  
Source: GlobalData January, 2023

Trial Nation support medical specialties in forming nationally coordinated structures for collaboration around clinical trials to improve the infrastructure and attracting more clinical trials to Denmark. Even though no data is available to conclude Trial Nation's impact on each individual trial run in Denmark, establishing a strong infrastructure in combination with strong clinical trials environments has led to Denmark being number one in Europe in number of clinical trials per capita. The structures exist in three levels of coordination and collaboration, of which the first two receive financing from Trial Nation: Centers, Networks, and Unions. In 2022 a new network in Psychiatry was added. Consolidation meetings for both investigators and project nurses took place during 2022, led by a

committed group of professionals from psychiatric sites across Denmark. Trial Unions in nephrology and neurology facilitated by Trial Nation were developed further in 2022.

In the established Trial Nation Centers, the year 2022 was overall defined by continued collaborations across sites in the Centers, and a focus on best-practice and addressing challenges related to conducting clinical trials. Trial Nations secretariat facilitates a number of these processes. An example is in Center for Oncology where Aarhus University Hospital prioritized to evaluate their entire process flow for clinical trials in 2022. The evaluation was conducted with input and feedback from nine pharma companies experienced in conducting clinical trials at Danish sites and the findings led to several changes to improve the process flow.

The figures below on the next page show the status of commercially funded clinical trials in the Trial Nation Centers from 2019-2022. We saw a slight decrease in the total number of clinical trials reported from the Trial Nation Centers and networks in 2022. Numbers and status related to clinical trials is described in more detail for each Center.

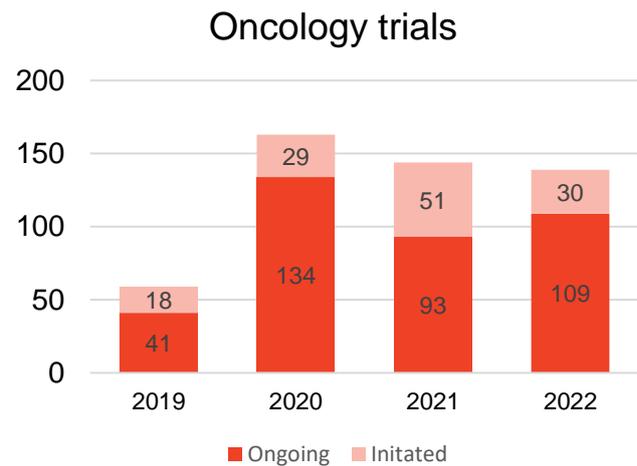
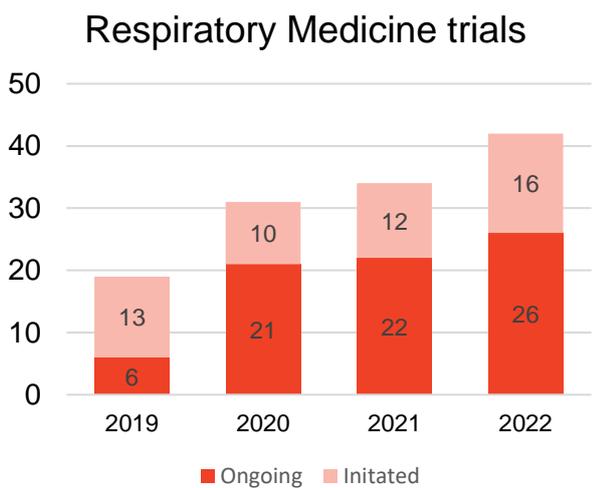
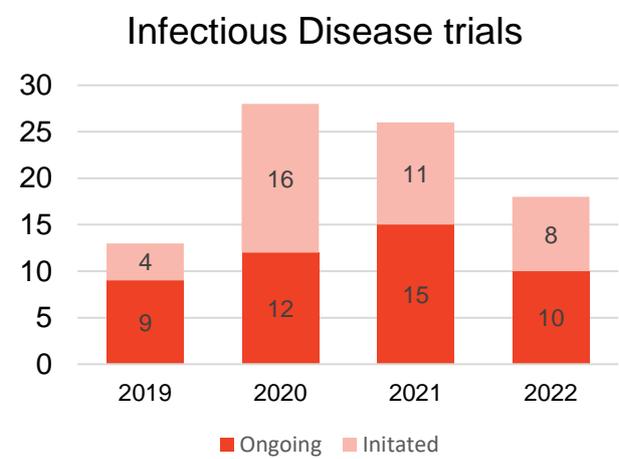
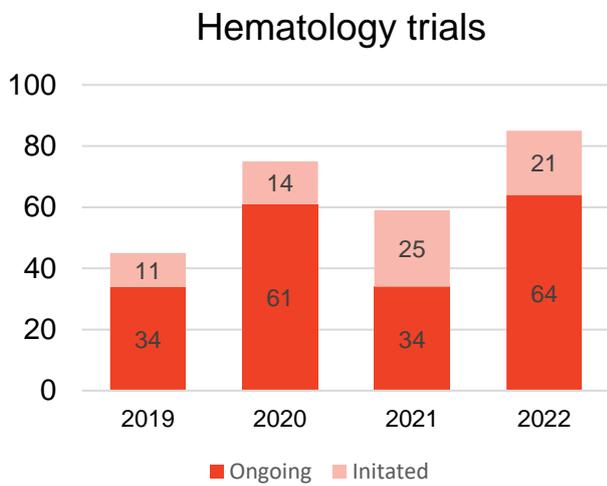
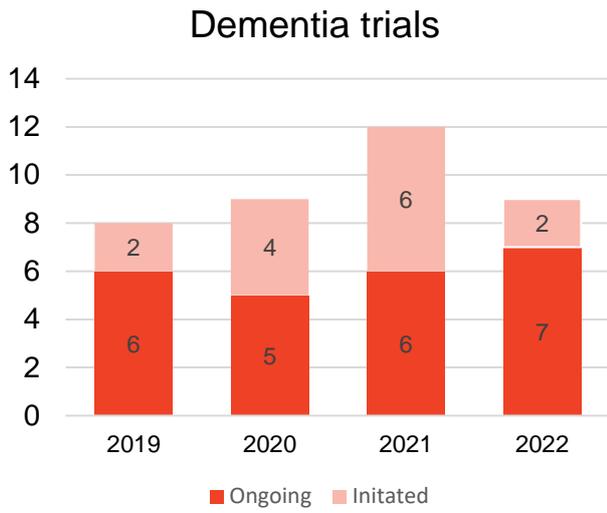


Figure 2. Number of commercial trials in Trial Nation Centers from 2019 to 2022. The numbers for 2022 are divided into ongoing and initiated trials whereas the numbers for 2019-2021 are the total number. Unique EudraCT numbers are reported.

The Trial Nation Legal network negotiates contract templates between the pharma- and medtech industry and the five Regions to accelerate the confidentiality and clinical trials agreement approval process in commercial clinical trials. A work that has shown great value for all users, as use of approved contract templates fast-tracks the legal approval process. The network has observed an increase in the complexity of the set-up in many of the contract template negotiation requests, leading to increased handling time for each negotiated contract template. During 2022 a facilitated dialogue between stakeholders has taken place to harmonize the interpretation of GDPR in relation to clinical trials, and a nationally applicable paper has been published.

A budget optimization process meeting with pharma companies, CROs and clinicians from all Centers was facilitated by Trial Nation in the fall of 2022. The purpose was to discuss and understand the budget negotiation process in connection to commercial clinical trial agreements better with viewpoints from all parties in the process. Processes, ideas, and best practices were shared, and a recommended process line was developed. This will be evaluated in the spring of 2023.

Several feasibility coordinators are, despite a persistent effort, facing challenges collecting all feasibility inquiries within their respective area. This is in part caused by the use of various channels for feasibility inquiries. Data related to feasibility in 2022 is communicated separately to the Trial Nation Board of Directors.

### **Clinical trials now – and in the future**

An important focus for Trial Nation is a strong public-private collaboration to strengthen the framework conditions for clinical trials, thereby playing a part in the development of a life science ecosystem that benefits patients, industry partners and researchers - now and in the future. This focus is reflected in our activities in 2022. Amongst others we have worked on framework conditions, supporting the growing need for augmenting traditional clinical trials data with additional health data and continuing the strong development of a collaborative research infrastructure.

Trial Nation has contributed to the work of “The Working group for Better Framework Conditions for Clinical Research” providing recommendations to the Danish Life Science Council. Trial Nation also organises a Dialogue Forum gathering The Scientific Ethics Medical Committees, the Danish Medicines Agency and industry associations. Both initiatives are examples of improving the framework conditions for clinical trials in Denmark by identifying and addressing concrete challenges and areas needing development.

In the Life Science Strategy from 2021 the importance of Decentralised Clinical Trials (DCT) is underlined, and Trial Nation contributes to the agenda by leading the PACT-project (see chapter

10 for more information about PACT). To accommodate the DCT-agenda in another setting Trial Nation facilitates the DCT-Dialogue Forum in partnership with the Danish Medicine Agency. This is an arena where public and private organisations can discuss best practice and obstacles for decentralised clinical trials in Denmark. The forum is intended as a fast-track lane to raise issues relating to DCT framework conditions and investigate and propose solutions. This constellation has played a significant role in the creation of the Danish DCT guideline, which in its turn has been an inspiration in the creation of the EMA recommendation paper on DCT.

On an EU level Trial Nation is an associated partner in the Innovative Medicines Initiative (IMI) project Health Outcomes Observatory (H2O), which amongst others has an objective to create standardized patient-centric outcomes measures. Furthermore, Trial Nation is a member of the Danish reference group to Horizon Europe Health Cluster. This is a structure to bring together knowledge of amongst others Danish strengths, potential and interests to be channelled to the program committee.

### **Creating awareness through collaboration and outreach**

Trial Nation brings awareness to life-science companies and other relevant stakeholders about the unique Danish Healthcare system and the advantages of conducting clinical trials in a highly digitalised, progressive environment. By reaching out, engaging, and collaborating with national and international stakeholders from e.g., life-science companies, patient organisations and authorities, we strive to inform about the opportunities in Denmark. In 2022, Trial Nation hosted, co-hosted or contributed to several events with stakeholders in the life-science industry.

Trial Nation participated, represented by our CEO, in a Bilateral Symposium on Regulatory Science for Clinical Trials in London arranged by the Embassy of Denmark in the UK, Danish Medicines Agency, Invest in Denmark, Healthcare DENMARK and Trial Nation. Bringing together UK-DK sector peers and life-science companies, the symposium aimed to identify ways and means to improve patient care and deliver long-term economic growth through cooperation within clinical research. Decentralised clinical trials, regulatory environment and clinical infrastructure were central topics of this meeting, which has led to post-meeting best practise sharing on selected topics.

Furthermore, representatives from Trial Nation Center for Infectious Diseases and Immunomodulation visited New York and San Francisco together with Invest in Denmark. The delegation displayed Danish capabilities within clinical trials in general, with a special focus on infectious diseases and vaccines development to US-based companies.

Cooperation invites to collaboration. Trial Nation contributed to an international study tour to Denmark arranged by the Ministry of Foreign Affairs of Denmark and Healthcare DENMARK, presenting on clinical trials in Denmark to the Canadian delegation. We had the opportunity to continue the conversation in more depth when we met with Nova Scotia Health Innovation Hub in August.

Moving East, Trial Nation was invited to present at the 3rd China-Denmark Clinical Research & Health Development International Cooperation Conference arranged by the Embassy of Denmark in Beijing and to showcase what investing in a strong public – private collaboration can deliver. A specific interest was shown for decentralised clinical trials.

Throughout 2022 Trial Nation arranged meetings with our member companies. These meetings provide important feedback on topics of relevance, information exchange and opportunities to discuss general topics related to clinical trials in Denmark, to formulate possible solutions and next steps. Member companies were also invited to seven joint company meetings to share knowledge with peers and get informed on specific topics by invited speakers. We look forward to continued collaboration in 2023.

The importance of external communication to reach, inform and engage people is evident. In 2022, we have increased our communication, especially in social media. We have reached more followers and readers and increased our engagement, making us more visible. A goal in 2022 was to launch our new website, and with this goal being achieved, we can keep developing on this better platform and improve the experience for our visitors.

### **Outlook in 2023**

We expect that the outcomes from the governmental working group on better framework conditions for clinical trials will be concluded during 2023. Trial Nation will take an active role in the implementation of the recommendations from the working group, as attractive framework conditions are key to placing clinical trials in Denmark.

We continue our work on infrastructure for national implementation of decentralised clinical trials together with partners around the life-science ecosystem. A national implementation is an important framework condition to make it easier to run trials in Denmark. Another important aspect is to provide better opportunities for equal access and make it easier for patients to participate in clinical trials irrespective of geography and diagnosis. Engaging with research environments within primary care is key to providing these opportunities, as the first line of contact to the healthcare

system is through primary care. In 2023, we will continue to support the existing infrastructure in primary care research to allow increased engagement in clinical trials.

Having study personnel with the right clinical trial competencies and a good network amongst peers across Denmark is of essence for good clinical trial performance. Trial Nation has for several years invested in a very popular 2-day course for project personnel, and in 2023 we are very happy to be able to offer this course in two iterations. The course provides both hands-on knowledge as well as opportunities for an informal, national network.

We will also continue to support medical specialties interested in working together on industry-initiated clinical trials in national networks. We will identify and work with new Trial Unions, which is a non-financed collaboration structure either within a medical specialty or around a specific area of clinical trials. In 2023 we are welcoming nephrology and neurology, already established as Trial Unions, to join as Trial Nation Networks. This is part of our intent to provide possibilities for nationally coordinated public-private clinical trials collaboration for more medical specialties. This also plays to our core purpose – to attract clinical trials in pharma and medtech to Denmark, which is engrained in our day-to-day activities.

Medtech clinical trials is an area in development and in 2023 we will continue to develop Denmark as the destination for medtech trials by working with partners to increase visibility and through building on established strategic partnerships.

Celebrating and showcasing all the excellent work done in relation to clinical trials is important and is an opportunity to bring energy to the clinical trials community. In 2022 the initiative “Denmark’s Best Clinical Trials 2022” was launched, and we are proud partners also in this year’s event.

We will continue our work as associated partners in the Health Outcomes Observatory (H2O) project, which amongst others will allow patients to measure outcomes in a standardised way.

Trial Nation created its current strategy in late 2019. Since then, a lot has happened in clinical trials, both internationally and nationally. Therefore, we will update our strategy to ensure that we are in sync and capture opportunities based on our strengths in order for Trial Nation best to contribute to Denmark as an attractive destination for clinical trials –as these create a better health and wealth for Denmark.

## Center for Dementia

The Center for Dementia covers all five Danish regions and is a collaboration of Danish memory clinics. The clinics have experience with clinical research in Alzheimer's disease, Huntington's disease, and other neurodegenerative disorders.

85-90,000 people are living with dementia in Denmark. Of these, 50,000 has Alzheimer's disease. 9.000-12.000 patients with cognitive symptoms or dementia are referred annually to Danish memory clinics and about 50% of them are referred to the five memory clinics in Trial Nation Center for Dementia.

Diagnosing and treating dementia often involves several specialties such as neurology, psychiatry, and geriatrics. These medical specialties are therefore also contributing to conducting clinical trials in dementia. The Center for Dementia supports the organisation across memory clinics. Gunhild Waldemar, Professor at Rigshospitalet notes:

*" Trial Nation adds high value to the collaboration across memory clinics, including harmonisation of guidelines and methods and equity in access to high quality diagnostic evaluation and treatment. Regarding participation in clinical trials, the collaboration in Trial Nation provides safety in numbers, as you have a network. Offering clinical trials with new treatment in the field of dementia helps to profile Denmark positively, and it also has a positive impact on the opportunity to participate in and lead other international research projects."*

### **Clinical Trials**

In 2022, the Center for Dementia initiated two new commercial clinical trials – a small decrease compared to 2021. Two trials are not included in this year's overview although initiated at a site in 2022. This is as the trials were opened at other sites in the Center in 2021. Overall, nine clinical trials were ongoing and initiated in 2022 (see Figure 3) with seven trials initiated before 2022 and still open in 2022. Please refer to the distribution across trial phases in Figure 4.

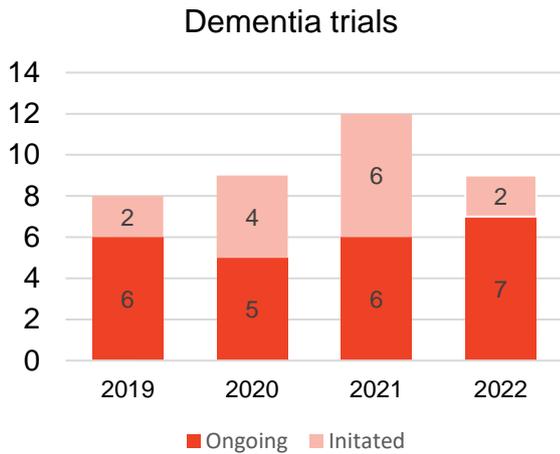


Figure 3. Number of commercial clinical trials in Center for Dementia from 2019 to 2022. The numbers for 2022 are divided into ongoing and initiated trials whereas the numbers for 2019-2021 are the total number. Unique EudraCT numbers are reported.

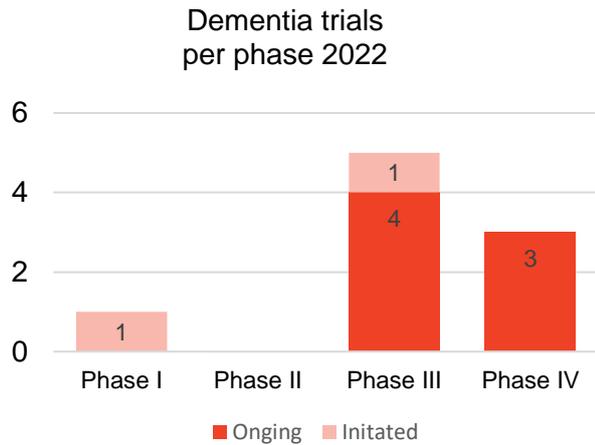


Figure 4. Number of open commercial clinical trials at the Trial Nation Center for Dementia in 2022 distributed into phases. Unique EudraCT numbers are reported.

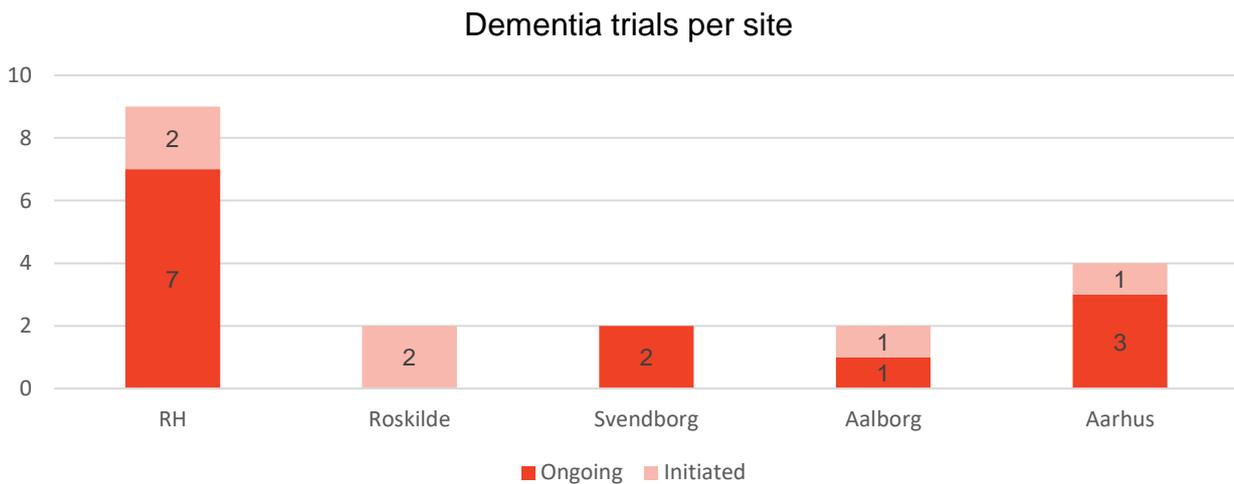


Figure 5. Number of Dementia commercial clinical trials distributed per site in 2022. All clinical trials running at each site during 2022 are listed, to reflect the actual clinical activities at the sites.

The Center has established a solid framework for collecting feasibility inquiries by referring companies and CRO, to use the Trial Nation feasibility service. All relevant feasibilities have been shared in the Center.

### Trial participation

The Center has access to well-characterized patient cohorts with a wide range of neurodegenerative disorders from which participants for clinical trials can be recruited, and 2022 shows an increase in the number of patients participating in clinical trials. Studies on patients suffering from Alzheimer's and Huntington's disease are very complex with regards to both

inclusion and exclusion criteria (specific biomarkers and cognitive scales) and operational aspects, as the number of visits, tests, and interventions are often high. Therefore, the number of participants in these trials are not very high compared to other disease areas. Currently, the waiting lists to memory clinics for diagnostic evaluation are long as there is a lack of specialists. This also has an impact on the capacity to run clinical trials:

*"Where there are long waiting times for dementia assessment and diagnosis - and a pressured healthcare system, it can be difficult to allocate time to solve trial tasks as there is an underlying lack of access to specifically qualified medical specialists and nurses. Hence, it is not possible to just hire staff, and this limits the number of trials which can be carried out, especially in relatively small clinics."*

*Gundhild Waldemar, Professor, Rigshospitalet*

## **Center activities 2022**

In Center for Dementia the following activities took place:

- Annual meeting in Trial Nation Center for Dementia with participation of the steering committee and research personnel from all sites in Denmark. Focus was on collaboration and ensuring alignment and quality of diagnosis.
- Four steering committee meetings.
- Activities related to feasibilities, company meetings, grant administration, requests, and other organisational matters on an ad hoc basis.
- The coordinating sites supported other sites in relation to certification of raters, advice on administration and budget negotiation.
- Three meetings between study coordinators from all sites has been conducted, focusing on developing relevant SOPs for the research sites to support sharing worksheets, collaboration between the sites and new research staff.
- The Trial Nation Center for Dementia has been promoted to relevant companies by the Medical Lead and the Feasibility coordinator at Alzheimer's Association International Conference, San Diego CA and at 8th Congress of the European Academy of Neurology, Vienna.

## **Focus in 2023**

In 2023, the Center will focus on:

- Continue to attract trials in Alzheimer's disease and Huntington's disease and other indications within the area of dementia by:

- Ensuring efficient feasibility handling with one-point-of-contact for sponsors.
- Focusing on a close collaboration with the sponsors and CROs to facilitate entry into, and understanding of, the trial environment in Denmark within the dementia disease area.
- Increasing visibility of the competencies in the Center for Dementia towards the industry by arranging one-to-one meetings with selected companies.
- Continue to strengthen the collaboration between sites and the Trial Nation secretariat.
- Continue the focus to further build on the high specialist competencies in research and strengthening the capacity to conduct clinical trials, both from a departmental and management level.
- Ensuring the right competencies and capacity are in place in each of the sites to be able to conduct the relevant trials, by articulate the need for prioritizing specially trained doctors and nurses.
- Continue to support the positive collaboration between the study coordinators to maintain the good work environment and the high quality of clinical trial data.

## Overview of Center for Dementia

The five sites forming Center for Dementia, key responsible personnel and all neurologists are listed below:

- *Rigshospitalet (Copenhagen University Hospital), Danish Dementia Research Centre, Dept. of Neurology: **Trial Nation Medical Lead, Professor Gunhild Waldemar; Trial Nation Feasibility Coordinator Senior Consultant and Clinical Trial Unit Director Kristian Steen Frederiksen** and Senior Consultant Lene Hjermind.*
- *Aarhus University Hospital, Dementia Clinic, Dept. of Neurology. Senior Consultant Hanne Gottrup and Staff Physician Jan Lykke Scheel Thomsen.*
- *Aalborg University Hospital, Dementia Clinic, Dept. of Neurology: Senior Consultant Karsten Vestergaard.*
- *Zealand University Hospital, Regional Dementia Research Centre, Dept. of Neurology: Senior Consultant Peter Høegh.*
- *Odense University Hospital, Svendborg Dementia Clinic, Dept. of Neurology, Senior Consultant Michael Oettinger and Professor Morten Blaabjerg.*

**Facilitator** for the Center is **Kirsten Bødker, Trial Nation**.

Detailed information about Center for Dementia and their capabilities can be found [here](#)

## Center for Dermatology

Trial Nation Center for Dermatology is a network of Danish dermatology departments involved in clinical research within the areas of Dermatology, Allergy, Venereology, Auto-immunity and Wound healing. The five departments in the Center cover the entire Danish population and treat all types of dermatologic, allergic and venereologic diseases and have more than 250.000 consultations yearly. The Center's doctors, nurses, laboratory technicians and pharmacists are all trained in clinical research and ensure the highest possible quality in the execution of clinical trial.

### Clinical trials

A total of 21 studies were ongoing in the Center for Dermatology; of these six studies were initiated during 2022.

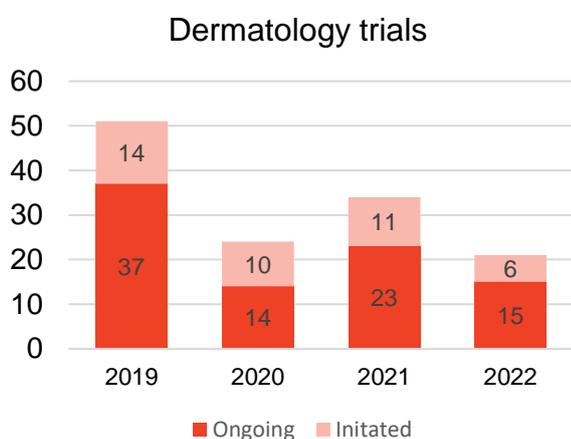


Figure 6. Number of commercial clinical trials in Center for Dermatology from 2019 to 2022. The numbers for 2022 are divided into ongoing and initiated trials whereas the numbers for 2019-2021 are the total number. Unique EudraCT numbers are reported.

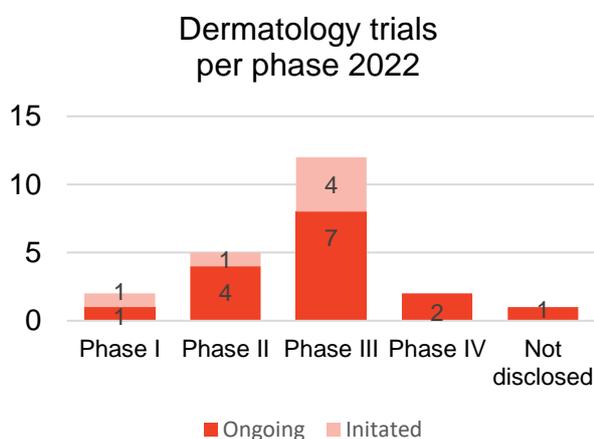


Figure 7. Number of open commercial clinical trials at the Trial Nation Center for Dermatology in 2022 distributed into phases. Unique EudraCT numbers are reported.

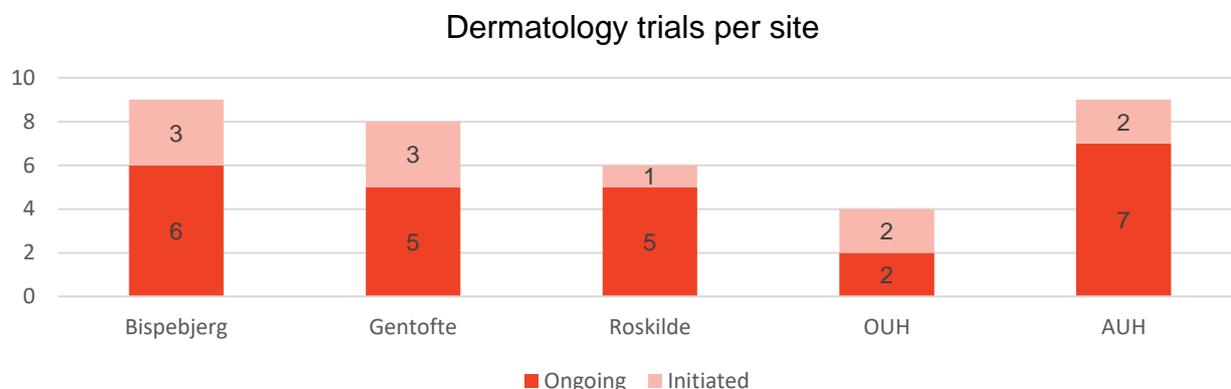


Figure 8. Number of Dermatology commercial clinical trials distributed per site in 2022. All clinical trials running at each site during 2022 are listed, to reflect the actual clinical activities at the sites.

During 2022 the number of feasibilities for clinical trials increased dramatically over multiple dermatological indications in Center for Dermatology. Correspondingly, both the number and the complexity of clinical trials have increased, compared to previous years:

*“The collaboration with Trial Nation has had tremendous impact not only financially, but also in terms of drug development. Denmark is now the preferred country for dermatological studies and has become one of the most influential countries in the world within dermatology (relative to country size). The number of published scientific papers by Bispebjerg Hospital researchers alone amounts to a staggering 260 in 2022, which is an increase of more than 100% compared to five years ago.”*

*Simon Francis Thomsen, Professor, Bispebjerg Hospital*

Several sites have had to decline participation in clinical trials as they are fully booked with clinical trials. This seen as a very positive change after two years where departments have been heavily involved in the management of COVID19, thereby impacting clinical trials capacity.

### **Trial participation**

A very fruitful collaboration with the private-practice dermatologists regarding recruitment to clinical trials were continued in 2022. At Aarhus University Hospital, the PI issues a monthly newsletter to the privately owned local dermatology clinics, informing about studies open for recruitment and the relevant inclusion and exclusion criteria. This has resulted in quite a few referrals of patients to clinical studies. Other initiatives to increase patient recruitment have included a good collaboration with the patient organisations, which may have contributed to a slight increase in patient participation compared to 2021.

### **Center Activities 2022**

The first fully Decentralised Clinical Trial (DCT) in Denmark was planned to be initiated at Copenhagen University Hospital Bispebjerg in collaboration with two life-science companies. This study, which included patients with actinic keratosis, exposed some challenges related to safety, technical, and legal aspects, and the initiation of the study is now planned for 2023. Finding a solution to technical issues related to DCT will continue to be a focus point in 2023.

Following up on the targets for 2022, an Innovation Fund project, phase V, was initiated late 2022, and a patient “school” for patients with Hidrosadenitis Suppurativa was started in collaboration with the relevant patient organization. Training of new staff (PIs, sub-investigators, and project nurses) has had priority at most sites.

The sites in the Center for Dermatology improved their internal collaboration on budget and contract negotiation.

Other activities at Center sites include systematic reviews of legal agreements, GDPR requirements and cost estimation relevant for initiating clinical research projects, as well as risk assessment of the databases and software used.

### **Focus in 2023**

In 2023, the focus in Center for Dermatology will include the following activities to strengthen collaboration, patient recruitment and site development:

- Initiate the first RCT-VCT in Denmark.
- Highlight specific advantages at the clinical sites.
- Cooperate with patient organizations on clinical trials.
- Co-design clinical trials with industry, for stronger influence on protocol development.
- Continue collaboration internally in the Center for Dermatology by meeting regularly in physical and virtual meetings.
- Support the development of the research unit at Aalborg University Hospital as a clinical trial site.

### **Overview of the Center for Dermatology**

- *Copenhagen University Hospital Bispebjerg, Department of Dermato-Venereology: Trial Nation **Medical Lead, Professor Simon Francis Thomsen, and Feasibility Coordinator/Project Nurse Stine Ørts Pedersen***
- *Copenhagen University Hospital Herlev-Gentofte, Department of Dermatology, Venereology and Allergy: Professor Lone Skov*
- *Zealand University Hospital, Department of Dermatology: Professor Gregor Jemec*
- *Odense University Hospital, Department of Dermatology and Allergy Centre: Professor Carsten Bindslev-Jensen*
- *Aarhus University Hospital, Department of Dermatology and Venereology: Professor Mette Deleuran & Lead Project Nurse Mette Thorup*

**Center facilitator is Annette Buusman, Trial Nation.**

All departments and our general Center presentation can be found [here](#)

## Center for Hematology

Trial Nation Center for Hematology is a network of Danish haematology departments involved in clinical research. The eight departments in the Center covers, the Danish population and treats all kinds of haematological cancers including the paediatric and adolescent setting. Approximately 2350 patients are diagnosed yearly with haematological cancers in Denmark. This is divided into lymph node cancer (1100), multiple myeloma (300), acute leukaemia (380), chronic leukaemia, myeloproliferative syndromes, and myelodysplastic syndromes (570). The Center has extensive experience with all phases of clinical trials from First in Human to phase IV.

### Clinical Trials

In 2022, 85 commercial clinical trials involving clinical departments in the Center were reported ongoing (64) or initiated (21). This is a substantial increase in the number of ongoing clinical trials compared to prior years (25). Still the figures represent an element of underreporting as some sites have only included trials initiated during the year. Best practice for reporting of clinical activity will continue to be an area of interest in 2023. Given challenges with retention and recruitment of qualified study staff, the increased number of clinical trials is impressive. A significant number of clinical trials are reported to be active at only one haematological site, which will be investigated and discussed with the sites during 2023. Eight trials included only or partly a paediatric and adolescent population compared to six trials in 2021. As expected, there are variation in the number of commercial clinical trials conducted by the sites. Figures 10 and 11 provide a visual representation of the commercial clinical trials divided by phase and by site.

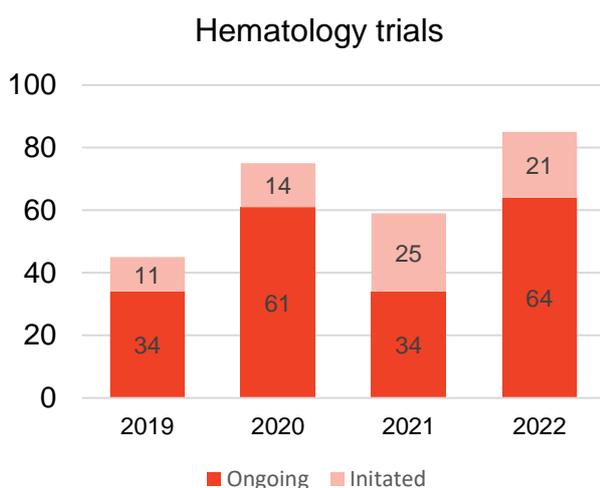


Figure 9. Number of commercial clinical trials in Center for Hematology from 2019 to 2022. The numbers for 2022 are divided into ongoing and initiated trials whereas the numbers for 2019-2021 are the total number. Unique EudraCT numbers are reported.

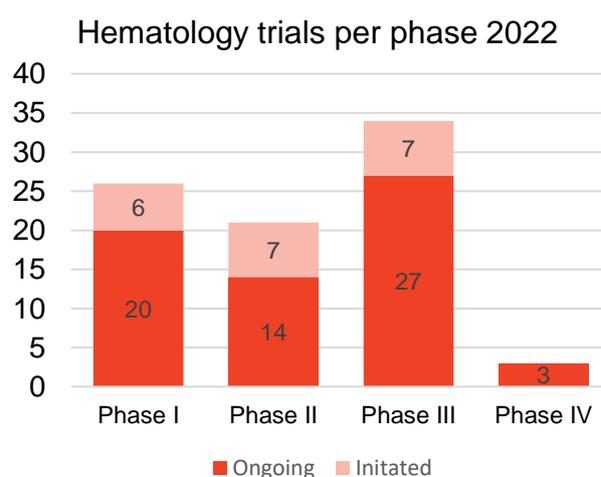


Figure 10. Number of open commercial clinical trials at the Trial Nation Center for Hematology in 2022 distributed into phases. Unique EudraCT numbers are reported.

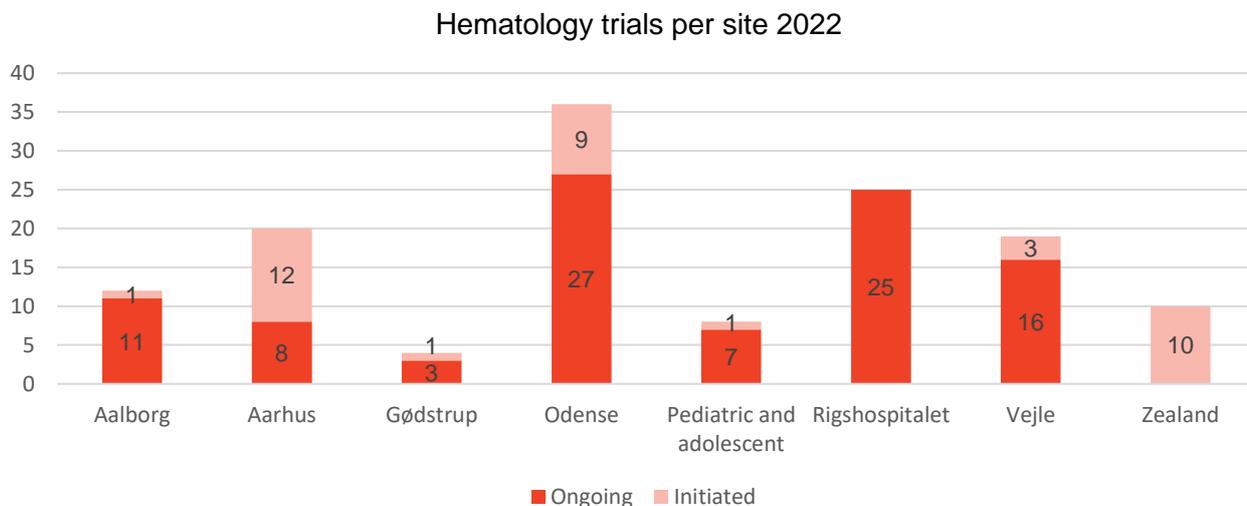


Figure 11. Number of Hematology commercial clinical trials distributed per site in 2022. All clinical trials running at each site during 2022 are listed, to reflect the actual clinical activities at the sites.

The organisation and collaboration between the clinical departments in the Center and Trial Nation, is a contributing factor to the positive development in the number of clinical trials within hematology. This is highlighted by Medical Lead, Professor Niels Abildgaard, Odense University Hospital:

*“Protocolized treatment is often an opportunity for patients to get a newer and better treatment than standard treatment. Trial Nation has contributed significantly to attract more inquiries about new studies to Denmark and the Danish departments. An increased number of protocols have been initiated in Denmark. Accordingly, more Danish patients have been offered participation in clinical studies.”*

It is also important to address challenging issues, that could be beneficial to solve in near future. Feasibility inquiries received by the Feasibility Coordinator or Trial Nation were shared within the Center as relevant according to the specialty guideline for Denmark, competences and sponsor wishes. Sponsors who expressed a need for specific contacts were informed whom to address. Phase III feasibility inquiries were further shared with Southwestern Hospital Denmark, Esbjerg. Still there is a substantial amount of feasibility inquiries that are not shared with *all* relevant sites in Denmark. Improving the ratio of shared feasibilities inquiries in 2023 is a focus area for the Center.

The legal text companies apply to electronic platforms for feasibility creates issues at sites pertaining to legal review of the text as feasibility inquiries often cannot forwarded for approval.

## **Trial participation**

Figures reported by the sites on the number of trial participants includes both commercial and non-commercial clinical trials with variation of the granularity of reporting. Hence, the numbers are not further specified into categories.

## **Center activities 2022**

In 2022 the Center for Hematology has:

- Successfully attracted several new commercial clinical trials due to:
  - The Medical Lead's active and engaged meetings with companies during international congresses.
  - Medical Lead, Trial Nation-responsible Investigators and Therapeutic Area Lead actively engaged in meetings with sponsor companies individually and in collaboration with the Trial Nation secretariat and Invest in Denmark.
- Collaborated on national sharing and handling of feasibility inquiries.
- Discussed and coordinated site participation in commercial clinical trials in small populations.
- Supported national referral of patients to phase I clinical trials at Rigshospitalet.
- Held a Center meeting where representatives from the clinical departments in the Center participated. Topics discussed were best practice for sharing feasibilities and preparedness for commercial clinical trials, herein human resources. The meeting paved the way for the establishment of a budget group. See next bullet point.
- Continued to implement initiatives to improved capabilities for commercial clinical trials e.g.
  - Development of phase Ib-capabilities for commercial clinical trials at several departments e.g., Aalborg University Hospital.
  - Odense University Hospital established facilities for First-In-Human clinical trials, adding to the extensive experience with First-in-Human commercial clinical trials at Rigshospitalet and Vejle Hospital.
  - Establish a group in the Center to ensure coordination of the budget items in connection with new clinical trials and to address joint challenges, e.g., to streamline the budgeting process for sponsors and departments.
- Identified barriers for the conduct of clinical trials -legal review by far being the biggest issue.

## Focus in 2023

- Attract more commercial clinical trials to the Center for Hematology; an effort for all partners in the Center, including the Medical Lead and the Trial Nation secretariat.
- Improved process for sharing feasibility inquiries: Investigate ways to improve the ratio of feasibility inquiries shared with alle relevant sites.
- Revisit the organisation of the Center for Hematology at the Center meeting in May. The positions as Medical Lead and Feasibility Coordinator are up for re-election.
- Focus on how to streamline the budget process to improve the timing and quality.
- Activity data: Smoother and more to the point reporting of clinical trial activity.
- Clinical Trial Overview: Implementation of the web-based National Overview of Clinical Trial in hematology, to make information about clinical trials more accessible to health care personnel and patients across the country. Hematology sites are set to form part of a pilot test, and this will further support referral of patients between departments.
- Investigate and map legal challenges relating to contracts to find long-term solutions to reduce these challenges in clinical trials.

## Overview of Center for Hematology

The eight sites in Center for Hematology and key responsible personnel is listed below:

- *Aalborg University Hospital, Department of Hematology:* Senior Consultant Henrik Gregersen, and Leading Study Coordinator Mette Gulbæk. Consultant Søren Rammen Bro takes substitutes Henrik Gregersen January 1, 2023.
- *Aarhus University Hospital, Department of Hematology:* Chair Professor Francesco Annibale d'Amore, Leading Study Coordinator Tia Vetterli and Contract Negotiator Jens Kanstrup Kjær.
- *Odense University Hospital, Department of Hematology:* **Trial Nation Medical Lead, Professor Niels Abildgaard**, Leading Study Coordinator Pia K Pedersen and **Feasibility Coordinator Sally Grant**.
- *Regional Hospital Gødstrup, Department of Hematology:* Senior Consultant Robert Skov Pedersen, Study Coordinator Mette Kynde Jakobsen & Karen Marie Nielsen.
- *Rigshospitalet (Copenhagen University Hospital), Department of Hematology:* Senior Consultant Peter Brown and Leading Study Coordinator Jytte Kock.
- *Rigshospitalet (Copenhagen University Hospital), Department of Pediatrics and Adolescent Medicine:* Senior Consultant Karsten Nysom & Study Coordinator Sune Høirup Petersen.

Data from the department is reported under Center for Oncology as the department treats both hematology and oncology patients.

- *Vejle Hospital, Department of Hematology:* Professor Torben Plesner, Consultant Sarah Leeth Hansen Farmer and Study Coordinator Anne Tørsleff.
- *Zealand University Hospital, Department of Hematology:* Senior Consultant Christian Bjørn Poulsen and Leading Study Coordinator Merete R. Storm Larsen.
- The Center further collaborates with Southwestern Hospital Denmark, Esbjerg

**Center facilitator is Ask Aabenhus, Trial Nation.**

All departments and our general Center presentation can be found [here](#)

## Center for Infectious Disease and Immune Modulation

The Center for Infectious Disease and Immune Modulation consist of six sites covering all five Danish regions. The sites treat patients and conduct clinical trials within the infectious diseases' specialty as well as vaccine trials with healthy participants. The Center has experience with trials from phase Ib to IV.

In 2021 a network connecting to the Center for Infectious Disease and Immune Modulation was established. The Network encompasses six regional sites and there is a close collaboration between the Center and the Network. The advantage of a strong collaboration is highlighted by Professor Lars Østergaard, Aarhus University Hospital. He states:

*“Participating in the Trial Nation collaboration has a great value for the departments, regardless of whether it is a large university department with a lot of experience in clinical research or a smaller department with a newly started clinical research unit. The quality of the work carried out in the studies is heightened through the close cooperation with the other departments, which ensures that we also will be considered for participation in future studies.*”

This perspective is shared amongst peers from other sites in Denmark. Senior Consultant Lothar Wiese from Zealand University Hospital notes:

*“Several clinical studies in the department promote professional discussions and thus contribute to raising our professional level. The close collaboration in the Center and Network also makes collaboration around patient treatment and clinical issues easier.”*

### Clinical trials

In 2022, the Center for Infectious Diseases and Immune Modulation initiated a total of eight commercial clinical trials. Overall, 18 clinical trials were ongoing in 2022, as seen in Figure 11. Ten trials with trial initiation before 2022 were still open in 2022. There has been a small decrease in number of initiated trials in 2022. This is expected, as the number of clinical trials was exceptional high in 2020 and 2021 due to COVID-19. Figure 11 showcases the commercial clinical trials and adding to these numbers, five investigator-initiated trials were ongoing in 2022, trials of high important clinical relevance where almost all sites participated. These huge investigator-initiated trials are not included in figure 11, 12 or 13 as they only report sponsor-initiated trials. They were included in 2020 and 2021 due to the high importance to the society, which together with the decrease of COVID trials accounts for the decrease in the number of trials.

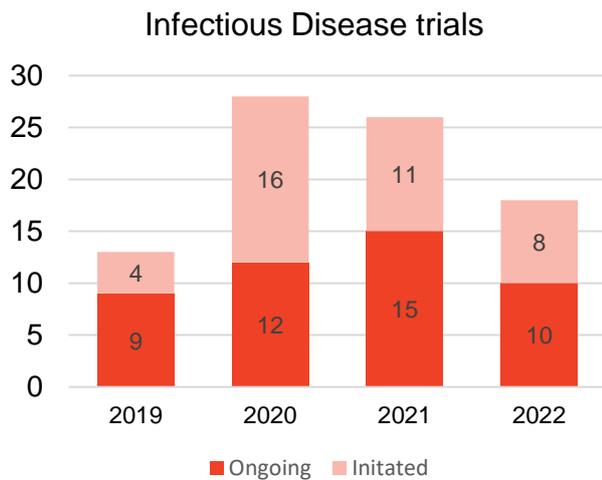


Figure 11. Number of commercial clinical trials in Center for Infectious Disease from 2019 to 2022. The numbers for 2022 are divided into ongoing and initiated trials whereas the numbers for 2019-2021 are the total number. Unique EudraCT numbers are reported.

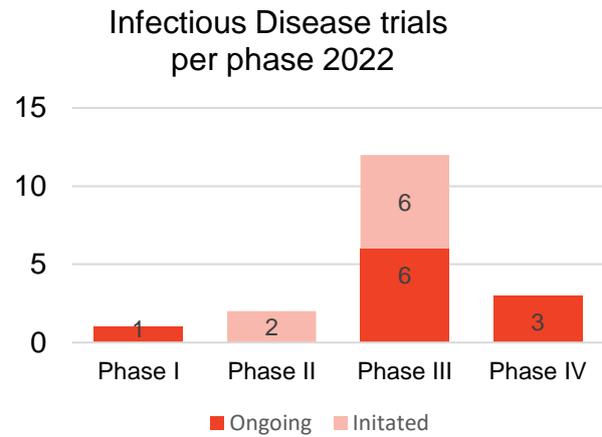


Figure 12. Number of open commercial clinical trials at the Trial Nation Center for Infectious Disease and Immune Modulation in 2022 distributed into phases. Unique EudraCT numbers are reported.

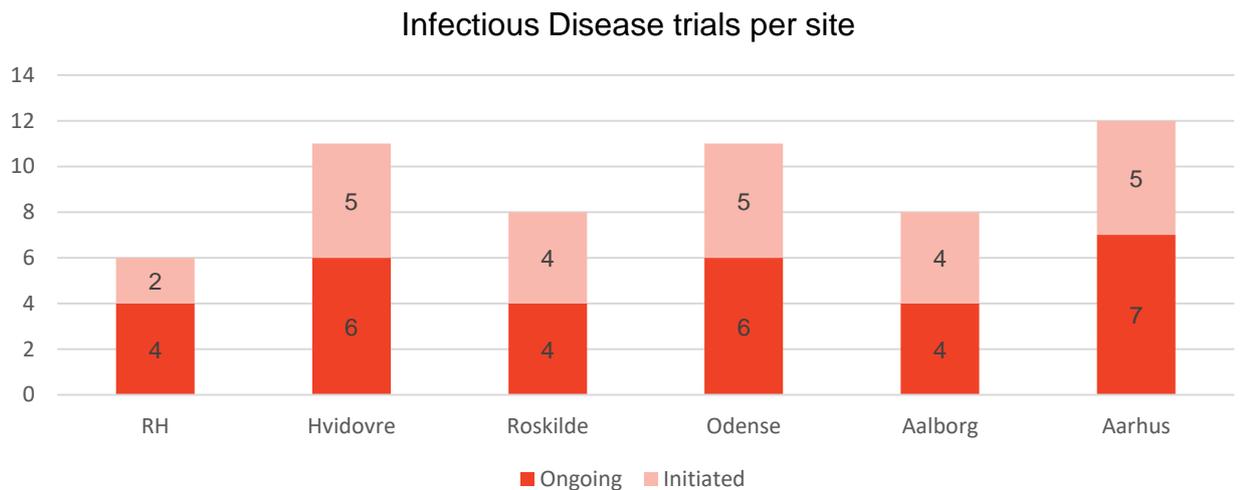


Figure 13. Number of Infectious Disease commercial clinical trials distributed per site in 2022. All clinical trials running at each site during 2022 are listed, to reflect the actual clinical activities at the sites.

The Center has established a solid framework for collecting feasibility inquiries, referring companies and CRO to use the Trial Nation feasibility service. The feasibility request increased in 2022 and all relevant feasibilities have been shared in the Center and Network and positive interest has been shown for trials relevant in Denmark and where site capacity is available. Nina Breinholt Stærke, Consultant, Ph.D., Aarhus University Hospital comments on the one-point-of-contact approach noting:

*“Small research sites have received feasibility inquiries and selected to be part of studies they may not have been considered for before entering the Trial Nation*

*collaboration. The collaboration has resulted in several clinical studies for the departments - both complex studies, which can only be carried out at the University Hospitals, and less complex studies, such as vaccine studies.”*

## **Trial Participation**

In 2022 the Center for Infectious Diseases and Immune Modulation enrolled a high number of participants, especially in vaccine trials. The process of finding and enrolling participants quickly in a healthy population without previous contact to the sites has been a great opportunity to learn for several of the sites:

*” We have succeeded in initiating the studies in a shorter time and we continue to work on recruitment methods. This year we managed to include significantly more participants in a shorter time. Our research unit has often been among the 3 most recruiting sites in international trials.”*

*Isik Somuncu Johansen, Professor, Odense University Hospital*

## **Center activities in 2022**

- Two meetings were held in the steering group of Trial Nation Center for Infectious Disease and Immune Modulation as well as in the Center and Network for Infectious Diseases. The budget process for clinical trials was discussed and a CRO-company gave their perspective of the process and specific complicated trials were discussed at one of the meetings.
- Formalized meetings took place every second week between study coordinators and facilitator from Trial Nation to discuss and coordinate ongoing and forthcoming trials. The outcome is better qualified study coordinators and improved collaboration between sites, ultimately helping to provide higher quality of data in clinical trials.
- In October, a US roundtrip took place, planned by Medical Lead, Feasibility Coordinator, Invest in Denmark and Trial Nation. The group had meetings in New York and San Francisco with 11 companies (small- and big pharma companies, CROs and biotech companies), where Danish research- and clinical trial competencies in particular infectious disease and immune modulation were presented. These meetings have already resulted in one vaccine trial, several one-to-one meetings and feasibilities, and more are expected in near future.
- The feasibility coordinator participated on behalf of the Center and Network in the budget optimization process meeting with the industry, CROs and clinicians facilitated by Trial Nation.

- The feasibility coordinator was invited to speak at Center for Dementia's annual meeting. The topic was best practice and collaboration in establishing a Center and a Network, sharing information across specialties to strengthen the collaboration.

*“The collaboration between the sites in the Center and with the secretariat are impeccable. All involved are very helpful. In particular, the collaboration between the project coordinators at the sites in the Center and Network deserves great praise.”*

*Thomas Benfield, Professor, Hvidovre Hospital*

### **Focus in 2023**

Continue to attract clinical trials within the area of infectious disease and immune modulation by:

- Proactively seek collaborations with new industry partners to expand the site’s capability to conduct clinical trials in new areas in the field of infectious disease and immune modulation.
  - Attracting vaccine trials, as it is gaged that these will be an important part of the Center’s future activities.
  - Bringing attention to experiences gained through the logistically highly complex and high- patient-number vaccine trial to boost Denmark’s readiness for future large-scale vaccine trials.
  - The Center will continue to follow up on contacts established on the US roundtrip in October 2022.
- Ensuring efficient feasibility handling with one-point-of-contact for sponsors and focusing on close collaboration with sponsors or CROs to facilitate entry into, and understanding of, the clinical trial environment in Denmark within the infectious and immune modulation area.
- Increasing visibility of the competencies in the Center and Network towards the life-science industry.
- Arranging meetings with selected companies based on their pipeline to discuss opportunities for clinical trials in Denmark.
- Strengthen the collaboration with the Infectious Diseases community.
- Further expanding collaboration with other specialties, e.g., paediatrics, respiratory, and hematology as the Center sees a trend in trials which require a broader collaboration across disease areas.

## Overview of Center for Infectious Disease and Immune Modulation

The six sites forming The Center for Infectious Disease and Immune Modulation and key responsible persons are listed below:

- *Aarhus University Hospital, Department of Infectious Diseases*: **Trial Nation Medical Lead, Professor Lars Østergaard** and **Trial Nation Feasibility Coordinator MD PhD Nina Breinholt Stærke**
- *Hvidovre Hospital (Copenhagen University Hospital), Department of Infectious Diseases*: Professor Thomas Benfield
- *Rigshospitalet (Copenhagen University Hospital), Department of Infectious Diseases*: Professor Jan Gerstoft
- *Odense University Hospital, Department of Infectious Diseases*: Professor Isik Johansen
- *Aalborg University Hospital, Department of Infectious Diseases*: Professor Henrik Nielsen
- *Zealand University Hospital, Department of Infectious Diseases*: Senior Consultant Lothar Wiese.

The six sites forming The Network for Infectious Diseases and key responsible persons are listed below:

- *Regional Hospital Silkeborg, Department of Infectious Diseases*: Senior Consultant Britta Tarp
- *Regional Hospital Gødstrup, Department of Infectious Diseases*: Consultant Steffen Leth
- *Regional Hospital Kolding, Department of Infectious Diseases*: Senior Consultant Birgit Thorup Røge
- *Herlev (University of Copenhagen), Department of Infectious Diseases*: Senior Consultant Pernille Ravn
- *North Sealand Hospital, Hillerød, Department of Infectious Diseases*: Senior Consultant Birgitte Lindegaard
- *Bispebjerg (University of Copenhagen), Department of Respiratory- and Infectious Diseases*: Senior Consultant Daria Podlekavera

**Facilitator for the Center and Network is Kirsten Bødker, Trial Nation.**

Detailed information about the Center presentation can be found [here](#)

## Center for Oncology

Trial Nation Center for Oncology is a network of nine Danish oncology sites involved in clinical research. It covers all five Danish regions and has extensive experience with all phases of clinical trials i.e., First-in-Human to phase IV. The sites in Center of Oncology treat all variations of oncology cancers including paediatric and adolescent malignant solid tumours. In 2020 approximately 360.000 persons have a cancer diagnosis, and 45.000 persons were diagnosed with cancer. Every year 16.000 patients die from cancer.<sup>1</sup>

### Clinical Trials

All feasibility inquiries received by the Feasibility Coordinator and Trial Nation were shared in the Center. Phase III feasibility inquiries were further shared with North Zealand Hospital, Hillerød, as relevant, and will from start 2023, be shared with Sønderborg Hospital as well.

*“We think it's great that Laurine [ Feasibility Coordinator] keeps the thread and keeps track of inquiries. The information she lists in inquiries is useful and she is good at following up on messages from other sites. It is important that we stand together as a country. We believe we have a good network across the country.”*

*Per Pfeiffer, Professor, Odense University Hospital*

However, most of the feasibilities received at the sites come directly from the companies or are shared via the Danish Multidisciplinary Cancer Groups (DMCG's). Feasibility inquiries received by the Feasibility Coordinator or Trial Nation were shared within the Center as relevant according to the specialty guideline for Denmark, competences and sponsor wishes. Sponsors who expressed a need for specific contacts were informed whom to address. Phase III feasibility inquiries were further shared with Northern Zealand Hospital. Feasibility inquiries are also shared by the disease specific treatment groups (DMCGs). Still there is a substantial amount of feasibility inquiries that are not shared with *all* relevant sites in Denmark. Improving the ratio of shared feasibilities inquiries in 2023 is a focus area for the enter.

The legal text companies apply to electronic platforms for feasibility creates issues at sites pertaining to legal review of the text as feasibility inquiries often cannot forwarded for approval by relevant legal department.

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<sup>1</sup> Kræft I Danmark 2022, Kræftens Bekæmpelse; The numbers refers to solid tumor cancer.

The efforts to harmonize the approval process for clinical trials has been a priority in the Center of Oncology and is emphasized by Kristoffer Rohrberg, Medical Lead and Chief Consultant at Rigshospitalet:

*“During the past year Trial Nation continued to promote Denmark as a country that prioritize and excels in running clinical trials. Ongoing efforts are made within the Danish legal network to harmonize legal issues across the Danish Regions which will be beneficial for continued progress and increment in the number of clinical trials in Denmark. Furthermore, great efforts have been made to move the implementation of decentralised clinical trials forward.”*

In 2022, the Center performed about 139 commercial clinical trials involving one or more of the sites. 109 of the clinical trials were reported as ongoing (initiated before 2022) and 30 as initiated in 2022. The total number of commercial clinical trials fell compared to the 2020 and 2021, though a slight increase was seen in the number of ongoing clinical trials compared to the 93 in 2021. However, the number of initiated clinical trials was halved compared to the 51 in 2021. 13 clinical trials focused on the paediatric and adolescent population alone or in part as the year before.

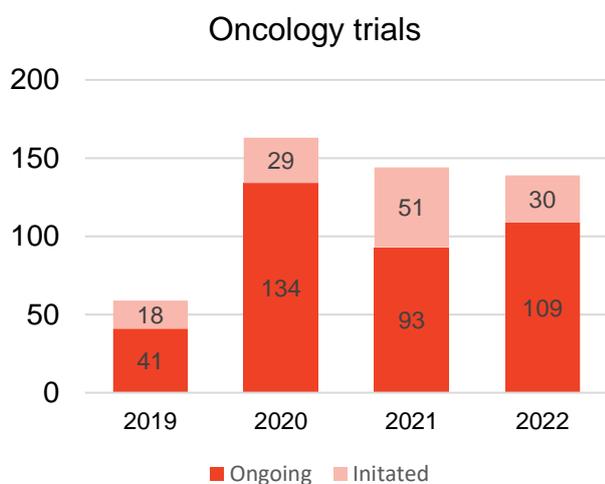


Figure 14. Number of commercial clinical trials in Center for Infectious Disease from 2019 to 2022. The numbers for 2022 are divided into ongoing and initiated trials whereas the numbers for 2019-2021 are the total number. Unique EudraCT numbers are reported.

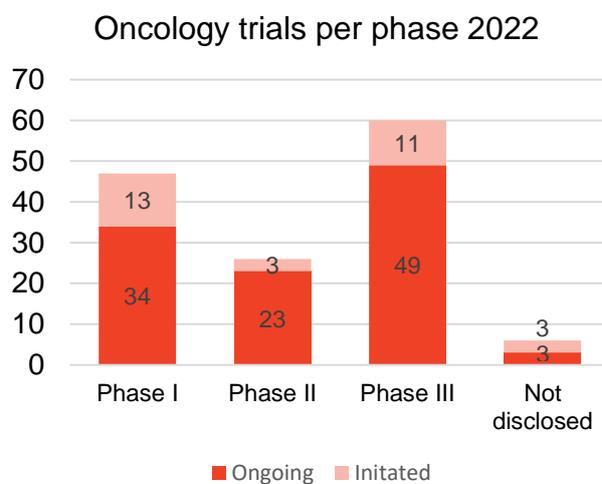


Figure 15. Number of open commercial clinical trials at the Trial Nation Center for Oncology in 2022 distributed into phases. Unique EudraCT numbers are reported.

## Oncology per site 2022

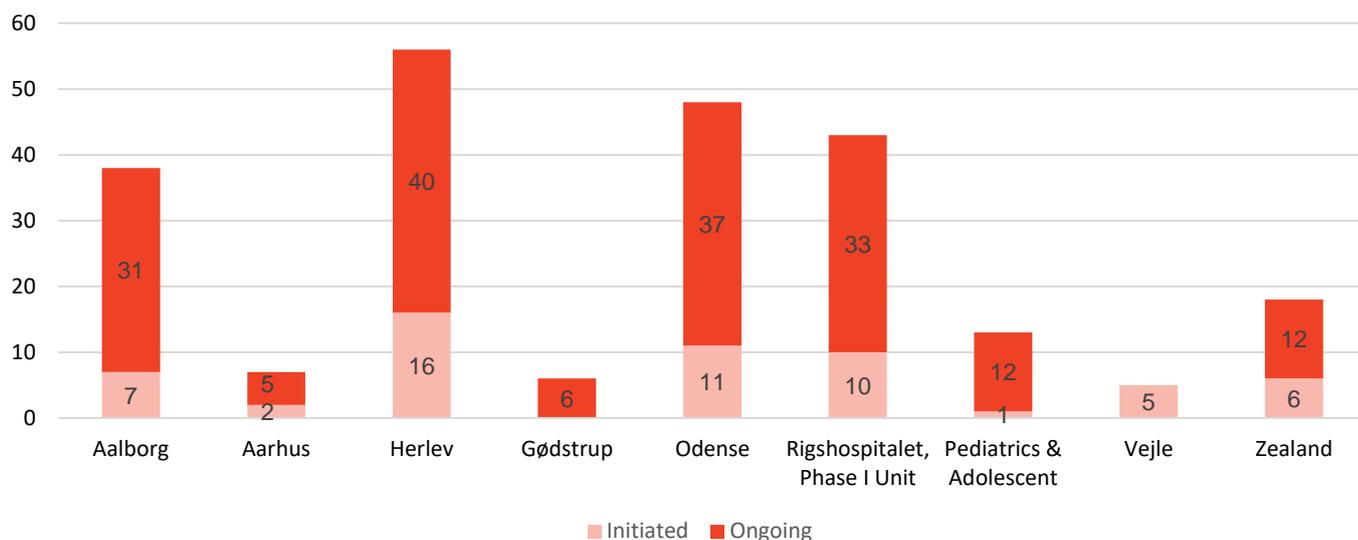


Figure 16. Number of Oncology commercial clinical trials distributed per site in 2022. All clinical trials running at each site during 2022 are listed, to reflect the actual clinical activities at the sites.

A limitation to the reported figures is that there has been a lack of common understanding of what was to be reported and how. Also, Rigshospitalet's Phase I Unit, forming part of the Department of Oncology, only reported phase I and I/II trials. Best practice for reporting of clinical trial activity will continue to be focus area in 2023.

Resources in the healthcare system is an overall challenge, and it is also the case for the highly skilled and specialized study staff. The effect of this bottleneck will be part of the review of why there has been a decrease in the number of initiated clinical trials from 2021 to 2022. Based on the size of the sites there is variations between the hospitals in the number of clinical trials performed. Figure 15 and figure 16 provide a visual representation of the commercial clinical trials performed divided by phase and by site.

### Trial Participants

The Phase I Unit at Rigshospitalet, the Oncology departments at Herlev Hospital, Odense University Hospital and Aarhus University Hospital and Rigshospitalet's Department of Pediatric and Adolescent included 144, 94, 33, 1 and 12 patients respectively in commercial clinical trials. Reporting trial participation figures are not a requirement and were either not reported by the other hospitals or reported including both commercial and non-commercial clinical trials.

## Center activities 2022

In 2022 the Center

- Has successfully attracted several new commercial clinical trials due to Medical Lead's, Trial Nation-responsible Investigators and Therapeutic Area Lead's active and engaged meetings with sponsor companies, individually and in collaboration with the Trial Nation secretariat. These activities were further supported by Invest in Denmark (US tour) and Copenhagen Capacity (e.g., Nordic Life Science Days).
- Collaborated on national sharing and handling of feasibility inquiries.
- Supported national referral of patients to phase I clinical trials at Rigshospitalet.
- Identified barriers for conducting clinical trial - legal review of contracts being the biggest issue by far. A permanent working group with members representing regions, universities and ministries is working to eliminate this issue.
- Improved capabilities for commercial clinical trials through e.g.
  - Developing capabilities at sites making it possible for Odense University Hospital to perform phase Ia, and for Vejle Hospital and Aalborg University Hospital to perform phase Ib commercial clinical trial in addition to Rigshospitalet and Herlev Hospital - both hospitals having extensive experience with First-In-Human commercial trials.
  - Establish a group to ensure coordination of budget items in connection with current clinical trials and streamline the budgeting process for sponsors and sites.
  - Investigator motivation report: Qualitative interview with investigators at the oncology department, Aarhus University identifying barriers (in the process) for conducting commercial clinical trials. The final report was done in close collaboration with the management at the Oncology department, Aarhus University hospital, Roche a/s and Aarhus University. The outcome will be communicated to sites and companies in 2023.

## Focus in 2023

In 2023 the Center will focus on

- Attracting commercial clinical trials to the Center.
- Sharing feasibilities: Investigate ways to secure that feasibilities inquiries are shared with all relevant sites.
- Recruitment and retention of study personnel: Can the human resource constraints experienced by the clinical research units be alleviated?

- Investigator motivation: Communicate findings from the Investigation of Investigator Motivation at Aarhus University Hospital to sites and companies as relevant.
- Dialogues with the medical societies and sites: How to consolidate the number of sites participating in clinical trials that target few patients ( $\leq 1$  patient/site/year)?
- Budgets: Coordinating budget items and streamlining of the budget process.
- Clinical trial activity: Smoother and more to the point reporting.
- Patient involvement: How can patient involvement in clinical trials improve?
- Extending collaboration between sites to cover all hospitals treating oncology patients in Denmark.
- Bureaucracy: Review and minimize the administrative processes related to the collaboration between the clinical sites and Trial Nation.

The good collaboration in the Center is a key driver for the clinical sites continuing to be part of a Trial Nation Center and is reflected in open dialogues about areas of improvement as well as best practice:

*“We greatly appreciate a smooth cooperation with our contact person, and we are especially happy that Trial Nation is trying to put focus on the challenges that prevent a quick and flexible start-up - this applies particularly to the approval process and financial challenges. Our wish going forward is that the requirements for being able to document activity are reduced, as it, like everything else, requires a lot of time and the results may not be as valid as you would like.”*

*Anja Rahbek, Leading Study Coordinator, Herlev Hospital*

## **Overview of Center for Oncology**

The nine departments forming part of Center for Oncology and key responsible personnel is listed below:

- *Aalborg University Hospital, Department of Oncology: Chair Professor Ursula Falkmer, Consultant Laurids Østergaard Poulsen and Leading Study Coordinator Lone Rosborg.*
- *Aarhus University Hospital, Department of Oncology: Chair Professor Signe Borgquist, Senior Consultant Mads Agerbæk.*
- *Herlev Hospital, Department of Oncology: Professor Dorte Nielsen, Consultant Rikke Løvendahl Eefsen and Leading Study Coordinator Anja Rahbek.*
- *Odense University Hospital, Department of Oncology: Professor Per Pfeiffer, Senior Consultant Karin Holmskov-Hansen and Leading Study Coordinator Anitha Pedersen.*

- *Regional Hospital Gødstrup, Department of Oncology:* Chief Physician Hanne Linnet, Senior Consultant Gabor Liposits & Study Coordinator Trine Donsgaard.
- *Rigshospitalet (Copenhagen University Hospital), Department of Oncology:* **Medical Lead, Senior Consultant Kristoffer Rohrberg** and **Feasibility Coordinator Laurine Harsløff**.
- *Rigshospitalet (Copenhagen University Hospital), Department of Pediatric and Adolescent Medicine:* Professor Karsten Nysom & Study Coordinator Sune Høirup Petersen.
- *Vejle Hospital, Department of Oncology:* Senior consultant Torben Frøstrup Hansen and Study Coordinator Monica Søgaard Trondhjem.
- *Zealand University Hospital, Department of Oncology:* Professor Jørn Herrstedt, MD Anne-Cathrine Bareid, and Leading Study Coordinator Tina WB Hansen.

The Center further collaborates with Northern Zealand Hospital, Hillerød, and from 2023 with Sønderborg Hospital.

**Facilitator** for the Center is **Ask Aabenhus, Trial Nation**.

The Center presentation can be found [here](#).

## Center for Respiratory Medicine

The Center was established in 2016 and has six sites at its core – their capabilities regarding clinical trials are summarized below. The sites are committed to develop and maintain Denmark as a preferred country for respiratory clinical research. The six sites in the Center collaborates with the Respiratory Network, which is a broader structure of all the remaining 12 research sites in Denmark.

### Clinical trials

A total of 42 studies were ongoing in 2022 in the Center for Respiratory Medicine; of these, 16 were initiated in 2022.

Following the COVID19 pandemic the clinical activities in respiratory research are again steadily growing. Clinical trials which had to be put on hold during the pandemic have been initiated or continued in 2022, and because of extensive vaccine programs the patients feel safer visiting the hospitals and participating in clinical studies.

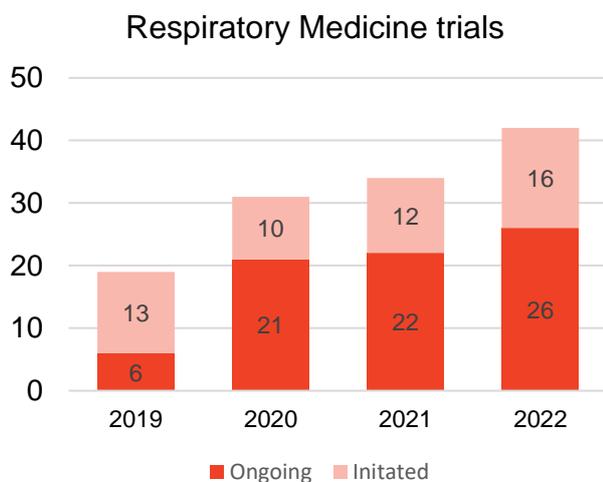


Figure 17. Number of commercial clinical trials in Center for Respiratory Medicine from 2019 to 2022. The numbers for 2022 are divided into ongoing and initiated trials whereas the numbers for 2019-2021 are the total number. Unique EudraCT numbers are reported.

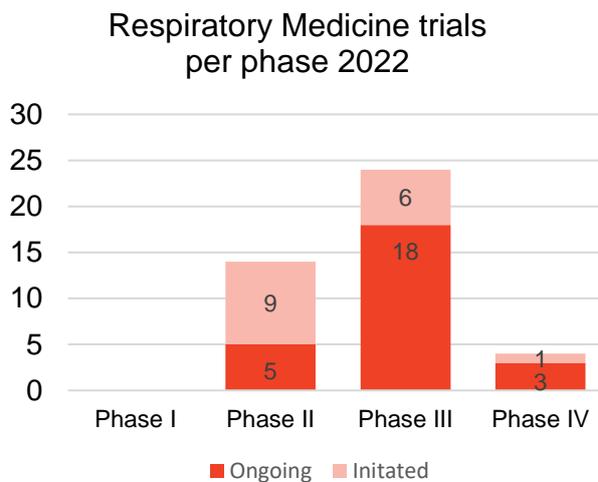


Figure 18. Number of open commercial clinical trials at the Trial Nation Center for Respiratory Medicine in 2022 distributed into phases Unique EudraCT numbers are reported.

## Respiratory medicine trials per site 2022

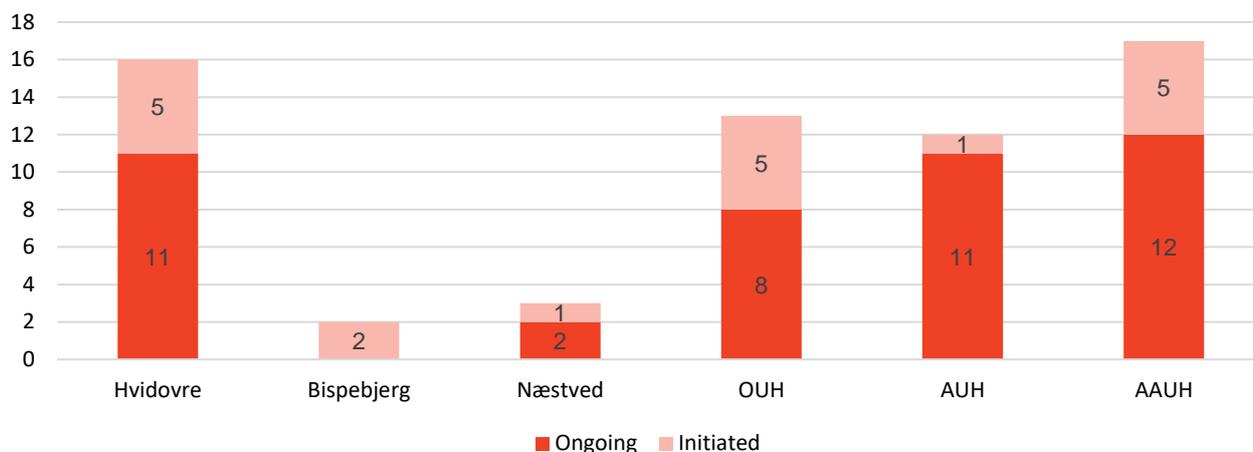


Figure 19. Number of Respiratory Medicine commercial clinical trials distributed per site in 2022. All clinical trials running at each site during 2022 are listed, to reflect the actual clinical activities at the sites.

Feasibilities are shared with all research sites in the Center and in the Network. It has been the impression at some sites that sponsors and CROs are not always willing to distribute feasibilities to all respiratory sites. Also, the increase of clinical trials involving biological investigational products narrows the selection of patients in certain diagnoses.

Finally, long approval times for legal documents continue to be a challenge and has resulted in several cancellations of clinical trial initiations in Denmark in 2022. During 2022 significant work has been made to improve the timelines for contract review in all regions, and it continues to be an area of focus for all involved in 2023.

### Trial participation

An observation point with significant impact on the potential for patient recruitment is that study eligibility criteria are not always in perfect concordance with Danish and European current treatment guidelines. This leads to fewer study protocols matching the patients seen in clinical practice in Denmark. It is a topic to be raised in the clinician - company dialogue during 2023.

Despite this, 2022 saw an impressive development in recruitment within some diagnoses, e.g. bronchiechtasis. Systematic training of personnel at outpatients' and ward sections connected to the CRU has been implemented to provide an opportunity for more patients to participate in clinical trials. In general, it has been easier to recruit patients in 2022 compared to the two previous years.

Medical Lead, Professor Charlotte Ulrik highlights the positive development and collaborative spirit in the Centre, saying:

*'We work very well together across sites, help each other solve issues, ensure timely feedback to sponsors and are genuinely pleased when colleagues at other sites manage to over-recruit'.*

## **Center activities**

A major challenge in Center for Respiratory Medicine has been to reduce the time from Site Initiation Visit to First Patient First Visit, which was a general focus area. Study related tasks are now more frequently outsourced by sponsors to a variety of CROs, subcontractors, and other specialists. The increased number of roles and people involved have had an impact on response times. Collaborating to optimize this process will continue to be a focus point in 2023.

2022 saw the following main activities:

- A successful annual meeting, gaining insights and sharing better practice regarding administrative challenges, including budgeting and contracts.
- Training of new staff, harmonizing competencies across staff roles to make CRU more robust It has been a priority to allow time for the most experienced project nurse to lead this task.
- New collaboration partners from other clinical fields introduced (maxillofacial surgery), and improved workflow with existing clinical collaborators (ENT).
- Upgrading and extending the lab facilities and IT equipment at the CRUs.

## **Focus in 2023**

In the coming year, activities in the Center for Respiratory Medicine will build on the existing high level of collaboration and research, targeting the following areas:

- Work to attract studies in less common respiratory diseases with an unmet need for treatment, as well as studies for patients with multiple diseases (e.g., respiratory + skin diseases and respiratory + cardiac diseases).
- Collaboration across specialties and disease areas, including infections and vaccines.
- Increase the collaboration with the pharmaceutical companies in the early stages of a study (pre-feasibility and feasibility) to increase the likelihood of a sufficient pool of patients eligible for the planned studies.
- Continue the work on optimization of the collaboration processes around outsourced study related tasks.

- Continued communication with sponsors and regulatory authorities around study eligibility criteria in line with treatment guidelines, to increase the likelihood of including patients seen in clinical practice.
- Furthermore, the Medical Lead and the Steering Committee of the Center will update the description of the terms of reference for Center and Network for Respiratory Medicine to ensure input and engagement from all corners of the Network.

### **Overview of clinical trials**

- *Copenhagen University Hospital Hvidovre, Department of Respiratory Medicine: **Trial Nation Medical Lead, Professor Charlotte Suppli Ulrik***
- *Copenhagen University Hospital Bispebjerg, Department of Respiratory Medicine: Professor Celeste Porsbjerg*
- *Aarhus University Hospital, Department of Respiratory Diseases and Allergy: Professor Elisabeth Bendstrup*
- *Aalborg University Hospital, Department of Respiratory Medicine: Senior Consultant Ulla Møller Weinreich*
- *Zealand University Hospital Næstved, Department of Respiratory Medicine: Professor Uffe Bødtger*
- *Odense University Hospital, Department of Respiratory Medicine: Senior Consultant Ingrid Louise Titlestad*

**Facilitator** for the Center is **Annette Buusman, Trial Nation**.

All sites and our general Center presentation can be found [here](#).

## DanPedMed

DanPedMed is a partnership including all 18 paediatric departments in Denmark and approximately 160 clinicians in various paediatric sub-specialties and departments of child and adolescent psychiatry.

The Network was established in 2016 through a collaboration between the Danish Paediatric Society and the Danish Society of Clinical Pharmacology working for better medicine used in children and adolescents. DanPedMed disseminated knowledge about clinical trials and research collaborations by managing inquiries and arranging meetings for doctors, project nurses, project staff and stakeholders working for better medicine for children and adolescents.

DanPedMed is part of NordicPedMed including all Nordic countries and is a full member of the Pan-European network Conect4Children (c4c) from 2024 -currently represented through a collaboration with the Norwegian - NorPedMed. Conect4Children aim to facilitate better medicines and other therapies for the entire paediatric population. Today, DanPedMed is funded by Trial Nation.

Following a grant from Trial Nation DanPedMed has been able to employ three research nurses part-time. They support activities that strengthen the site's readiness to conduct clinical trials in close cooperation with the Steering Committee and the National Coordinator.

In 2022 there has been an increase in the inquiries that are handled by DanPedMed, which has led to an increase in initiated paediatric clinical trials in Denmark. In addition, there is a good workflow with c4c and a strengthened attention towards paediatric clinical trial units around the country.

All feasibilities were circulated to relevant sites and in 2022 the number of feasibilities and clinical trials increased compared to 2021. 55 inquiries were received and distributed in the Network.

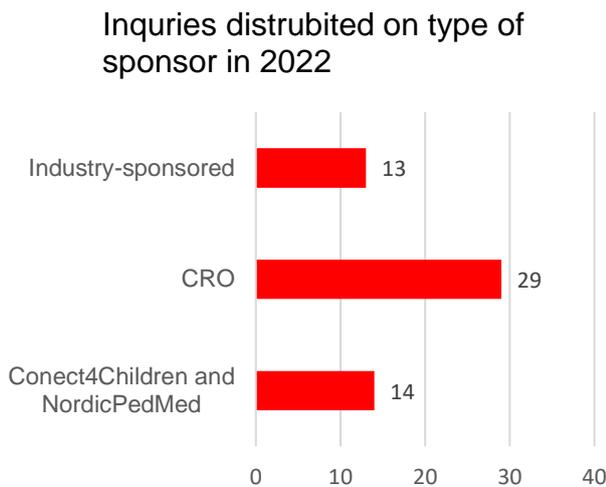


Figure 20. Number of inquiries per type of sponsor in 2022.

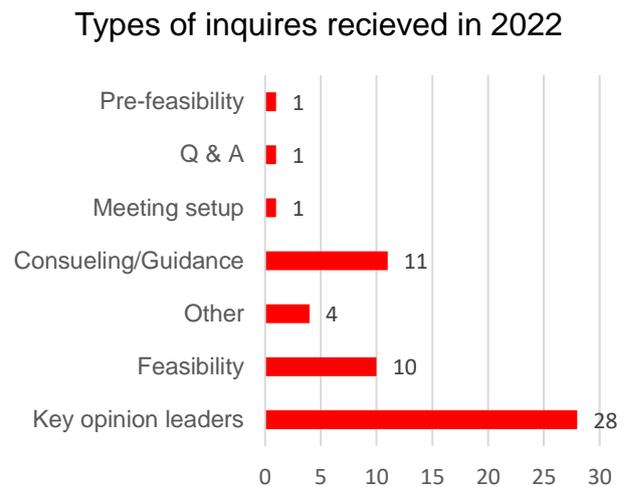


Figure 21. Types of inquiries received in 2022.

## Activities in 2022

In DanPedMed one of the aims is to expand collaborations with other clinicians both nationally and across borders to ensure more opportunities for children and young people to enrol in clinical trials. This is reflected in the activities where DanPedMed is involved, including but not exclusive:

- On March 4<sup>th</sup> DanPedMed hosted a conference with topics on medicine for children and adolescents with 100 participants and both national and international speakers. The theme for the conference was *“Medicine for children and young people – from bench to bedside”*.
- In September, DanPedMed had an oral presentation at the 4<sup>th</sup> Nordic Conference on Paediatric Medicines in Finland.
- On September 23<sup>rd</sup> DanPedMed, in collaboration with NordicPedMed, hosted a 1-day conference with the title: *“Establishment of Network for Nordic Pediatric Clinical Trial Units”*. The aim was to establish a network for all paediatric clinical trial units in NorPedMed to increase the collaboration and coordination of activities between clinical trial units. There were 55 participants representing all the Nordic countries.

In 2022 Denmark was regarded as a relevant and eligible partner in the large, pan-European Innovative Medicines Initiative (IMI) project Conect4Children (c4c) and will be considered as an independent hub after the project ends mid-2024. Being a part of a European collaboration will deliver high quality clinical trials in children and young people across all conditions and phases of the drug development process. DanPedMed contributes to several tasks in the c4c project description.

In 2022 The Department of Neonatology, Rigshospitalet, Denmark included patients in an investigator-initiated clinical trial running under c4c. The site is one of the best performing sites in Europe and was asked to renegotiate a new contract to include more patients. Denmark is also participating in two industry proof of viability studies in the c4c project. DanPedMed is also a driving force in NordicPedMed, with René Mathiasen as Chair and Pernille Skovby as secretary.

DanPedMed as a Network has increased its activities, including raising awareness of the benefits of performing sponsor-initiated clinical trials. Today DanPedMed can offer advice and support to Departments of Paediatric and Adolescent Medicine as well as to departments of Child and Adolescent psychiatry interested in initiating clinical trials.

In addition, DanPedMed has achieved a very strong connection to c4c by actively taking part in meetings and working groups.

### **Focus in 2023**

- DanPedMed will further strengthen the national collaboration on medicines for children and continue to be an attractive member of the c4c network, participating in international meetings related to c4c and contributing to their activities.
- Continue to focus on improving the national collaboration across departments of paediatrics and adolescent medicine and departments of child and adolescent psychiatry.
- Increase awareness about DanPedMed on a national level: Connecting with the right stakeholders, Social Media engagement, and oral presentations in relevant meetings.
- In March 2023 DanPedMed is co-hosting a one-day workshop on children, adolescents, and medicine. The aim of the workshop is to bring together active stakeholders who work for better medicine for children and young people in Denmark to ensure coordination, inspiration, and the further work. Therefore, the participants invited are stakeholders that can impact how to work on better medicine to children and adolescents: Danish Medicines Agency, Danish Patient Safety Authority, Danish Health Authority, Trial Nation, Danish Society for Clinical Pharmacology, representatives from the Society of Child and Adolescent Psychiatry, the Chair of Danish Pediatric Society.
- Continuing the work for an independent national membership in c4c, to ensure Danish participation in new c4c-projects.
- Further develop cooperation in the Nordic countries with the aim of creating a network between the paediatric clinical trial units across the Nordic countries.

## **Overview of DanPedMed: Governance**

The steering committee meet once a month, and in NordicPedMed meetings are held every second month. The National Coordinator ensures contact to relevant clinicians at the paediatric departments to facilitate participation in relevant research collaborations, including clinical trials.

**Chair:** Pernille Mathiesen, Consultant, member of the Danish Society of Paediatrics. Consultant at the Department for Paediatric and Adolescent Medicine, Herlev Hospital.

**National Coordinator:** Pernille Skovby, Nurse at research Unit for Paediatric and Adolescent Medicine, Rigshospitalet University Hospital Copenhagen.

NordicPedMed representative: René Mathiasen, Associated Professor, Consultant at the Department for Paediatric and Adolescent Medicine, Rigshospitalet University Hospital Copenhagen.

Member of the Danish Society for Clinical Pharmacology and NordicPedMed representative: Torben Laursen, Assistant Professor, Consultant at the Department for Pharmacology, Aarhus University Hospital.

Member of the Danish Society of Paediatrics: Søren Hagstrøm, Professor, Consultant at Department for Paediatric and Adolescent Medicine; and Department of Clinical Medicine, Aalborg University Hospital

Member of the Danish Society of Paediatrics: Anne-Cathrine F. Viuff, Senior staff specialist, Associated Professor at Department for Paediatric and Adolescent Medicine, Aalborg University hospital.

## Trial Nation MedTech Network

Clinical trials on medical devices are as diverse as pharmaceuticals, and with the implementation of the Medical Device Regulation from EU, the field has become even more complex. Medical device trials are performed within most specialties and across all hospitals and are therefore supported by regional MedTech coordinators instead of facilitators within a specialty.

### Activities

In 2022, 17 contacts were made to Trial Nation from MedTech companies seeking assistance. The number of applications to conduct clinical trials on medical devices is still relatively low but is expected to increase until the implementation of the new MDR in 2027 and 2028.

When the national clinical trials overview is launched in Denmark, it will be possible to access real-time data also for medical devices and across specialties.

Historic (2010-2019)		2020	2021	2022
Cumulative: 598	Average pr. year: 60	56	53	65

Figure 22. Ongoing and completed clinical trials on medical devices. Data source: Historic, 2020 and 2021 data points are derived from Global Data January 2022. From 2022 data is provided from National Center for Ethics.

### Strategic activities

Supporting and guiding MedTech companies from the early stages of product development is an essential part of Trial Nations dialogue. The aim is to ensure the best and most appropriate contact between companies and clinical departments.

Throughout 2021, Trial Nation sponsored a project on identifying the most appropriate way through development and implementation for a medical device based on artificial intelligence. In April 2022, this AI project was finalized after three workshops and a conference. The conference can be streamed [here](#). Six recommendations, from procurement to health data and legal clarifications, were identified along with current potentials and pitfalls in the eco-system. The recommendations have afterwards been communicated to relevant organizations, that support or regulate this area.

Establishing and maintaining strategic partnerships have been a priority in 2022, where amongst others Medicoindustrien (Medtech Denmark) is an important collaborator. In September 2022, Trial Nations MedTech coordinator participated in a workshop on clinical investigations aimed at industry expert arranged by Medicoindustrien. Furthermore, the collaboration with Invest in Denmark was attracted many international companies to consider Denmark for future clinical trials. Lastly, we have continued the dialogue with national initiatives similar to Trial Nation from Sweden, Norway, and Canada. For instance, MedTech coordinator has monthly meetings with Nova Scotia Health to share best practices across institutions.

In October 2022, MedTech and Pharma jointly facilitated and financed a two-day training for project personnel with 80 participants from most specialties and most hospitals in Denmark. Two life-science companies kindly shared their expertise on contracts and conduction of clinical trials from a company perspective.

### **Focus for 2023**

The regional MedTech coordinators will continue to collaborate closely on increasing the awareness of Trial Nation services to life-science companies in collaboration with our strategic partners. Continued education on performing commercial clinical trials on medical devices will enable departments to participate to accommodate the expected number of trials following the introduction of MDR.

## Digitalisation of Clinical Trials

Denmark is spearheading when it comes to digitalisation in Europe. Every year since 2014 the European Commission publish the DESI-report that tracks the progress of EU-countries in their digital competitiveness - Denmark is displayed as a digital front-runner in the EU and continues to be in the top-three year by year.<sup>2, 3</sup>

Clinical trials are accelerating when it comes to digitalisation and decentralisation. Digital technologies that power the performance of decentralised clinical trials rest on the highly advanced digital infrastructure that we have been building over the years in Denmark. Thus, it is essential to keep up the political prioritisation and investments, as well as developing favourable structures and systems to support the current transition, if we will continue to position Denmark as an attractive place to perform clinical trials moving forward.

Trial Nation is committed to drive and support the transition towards a more patient-centric approach - utilising digital as well as decentralised tools and processes in clinical trials. It is demonstrated in the Trial Nation strategy as well as through the activity portfolio for 2022, where Trial Nation is project leading a €5M project on *Decentralised Patient-centred Clinical Trials* (PACT-project)<sup>4</sup> funded by Innovation Fund Denmark.

Together with a powerful public-private consortium of Danish life science stakeholders<sup>5</sup> Trial Nation will facilitate the development and implementation of public digital tools that make clinical trials more accessible for patients and empower patients to participate in clinical trials.

The PACT-project facilitates the implementation of a “National Overview of Clinical Trials” and a “Digital Recruitment Platform” as well as create a public-private framework that supports implementation of patient-centred decentralised clinical trials in Denmark. The project will reduce the experienced and perceived barriers for patients, healthcare personnel and companies to participate in clinical trials in Denmark. To read more about the individual activities, please visit the sections “National Overview of Clinical Trial” “Digital Recruitment Platform” and “Decentralised Clinical Trials” below.

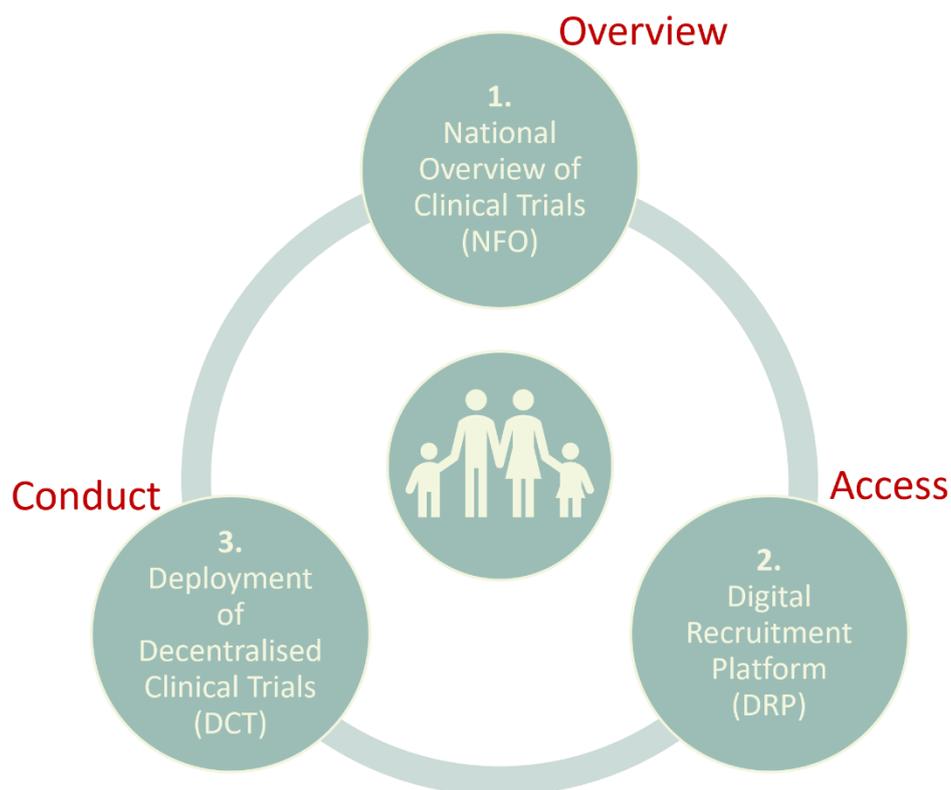
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<sup>2</sup> <https://digital-strategy.ec.europa.eu/en/library/digital-economy-and-society-index-desi-2022>

<sup>3</sup> “Digital Economy and Society Index (DESI)” the European Commission publish the report that monitors Europe’s overall digital performance and tracks the progress of EU countries in their digital competitiveness.

<sup>4</sup> The PACT-project runs from 2022-2026.

<sup>5</sup> PACT project partners: Trial Nation, the five Danish regions, one knowledge institution (Aalborg University), and six private partners (IQVIA Solutions Denmark A/S, Merck A/S, Novartis Healthcare A/S, Oticon A/S and Oticon Denmark A/S, Roche A/S, World Courier).



## National Overview of Clinical Trials in Denmark

Together with committed partners<sup>6</sup> Trial Nation developed a unique National Overview of Clinical Trials that provide patients and healthcare personnel with up-to-date information on all clinical trials (medical device and pharmaceutical) performed in Denmark, including their status and location. This was made possible by, amongst others, the support through funding by the life-science strategy.

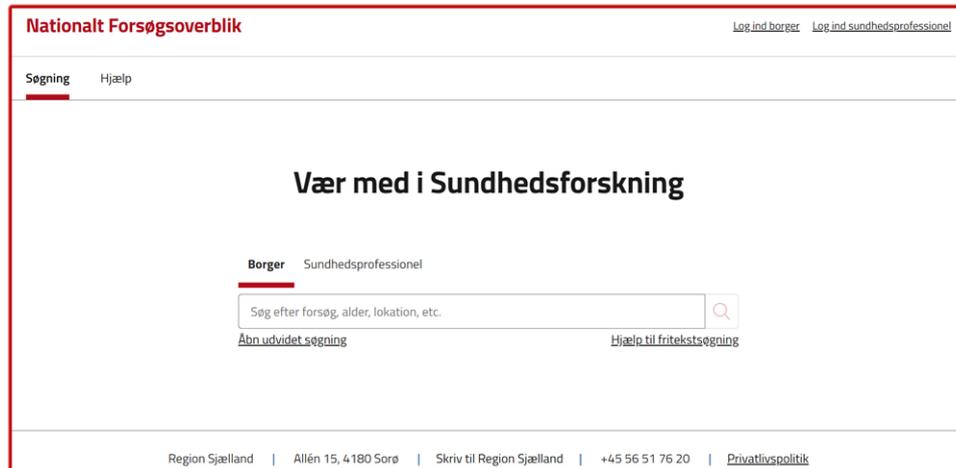
*Professor Niels Abildgaard, Odense University Hospital* emphasizes the value of the overview noting that:

*“The established National Clinical Trial Overview will contribute significantly by creating an overview of active studies in Denmark. A very big benefit is that it will also be possible for the patients themselves to obtain information and seek out departments with active studies.”*

Through the year of 2022 we have worked dedicated on developing the platform. However, due to a need for clarification about the data roles it was not possible to implement the platform in 2022 as

<sup>6</sup> NFO project partners: Trial Nation, The Danish Ministry of Health, The Danish Ministry for Industry, Business and Financial Affairs, The regions, The Danish Health Data Authority, The Danish Medicines Agency, and Danish Comprehensive Cancer Care

targeted. We expect to initiate the implementation of the National Overview of Clinical Trials in 2023.



## Digital Recruitment Platform (DRP)

The Digital Recruitment Platform project is set to investigate ways to create a digital platform that can improve patient participation in clinical trials in Denmark by use of health data. As project leader Trial Nation has involved patient associations, researchers and company representatives and other stakeholders in uncovering the need for a digital recruitment platform, and a clear need was identified. Possible scenarios have been discussed with the above parties and the Steering Committee including representatives from the ministries, agencies, and regions in Denmark, but no viable path is seen for the outlined scenarios. Therefore, a memorandum has been prepared for the National Board for Data in the Health and Elderly Area regarding the solution scenarios for a Digital Recruitment Platform recommending that, given the current legal and ethics considerations of possibilities, the development of a Digital Recruitment Platform should not be initiated at this time.

In 2023, it will be investigated how existing tools may help recruitment of patients via other routes in a meaningful way, e.g., the Danish Health Data Agency's Research Service. The impact on the PACT project of the changed approach, from implementing a newly developed platform, to the use of existing tools will be assessed in 2023. The original plan was to support the implementation of the Digital Recruitment Platform in late 2023/2024, and the needs for such a service remains high in all stakeholder groups.

## Decentralised Clinical Trials (DCTs)

Denmark is moving full speed ahead to become a global DCT frontrunner. Flexible trial designs, incorporating digital technology, processes and services that support remote interaction for patients, are being developed to accommodate patient needs. This means that patient can engage in clinical trials in the comfort of their homes. Through the PACT-project, Trial Nation, and partners<sup>5</sup> will create a public-private framework that supports implementation of decentralised clinical trials in Denmark by develop and implement logistics for general use of decentralised elements in clinical trials.

In 2022, Trial Nation and partners initiated a mapping of DCT barriers and potentials as part of the PACT-project. The mapping is built on already existing knowledge and learnings and will once it is completed comprise the foundation of new infrastructures to better support the conduct of decentralised clinical trials. Trial Nation and partners will continue the mapping in 2023.

Alongside, Trial Nation has in 2022, actively engaged in the dialogue with essential stakeholders, such as the research units for general practices as well as the Danish pharmacy association, to investigate opportunities for a stronger collaboration on the futures needs in clinical research.

Twice a year, Trial Nation facilitates, together with the Danish Medicines Agency (DKMA), the Danish DCT Dialogue Forum. The forum, gathers authorities, patient representatives, researchers, clinicians, the life science industry, DKMA and Trial Nation to discuss views, barriers, and experiences with DCT.

The collaborative approach and joint effort of this forum have fed into a regulatory guideline on decentralised clinical trials (*“Guidance on the implementation of decentralised elements in clinical trials with medicinal products ”*) published by DKMA in 2021 – first of its kind in the world.<sup>7</sup>

The Danish DCT guideline has paved the way for a joint European recommendation paper on decentralised elements in clinical trials in the European Union/European Economic Area, which was published, December 2022, by The European Commission (EC), the Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA).<sup>8</sup> The purpose is to inform on an EU-harmonised perspective about the use of decentralised elements in clinical trials and thereby facilitate the implementation of these elements.

Trial Nation will continue to support and facilitate the Danish Dialogue Forum moving forward. The overall goal is to continue the advancement of the DCT agenda in Denmark.

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<sup>7</sup> <https://laegemiddelstyrelsen.dk/en/news/2021/guidance-on-the-implementation-of-decentralised-elements-in-clinical-trials-with-medicinal-products-is-now-available/>

<sup>8</sup> <https://www.ema.europa.eu/en/news/facilitating-decentralised-clinical-trials-eu>

Trial Nation published together with Healthcare DENMARK, May 2022, a triple-I whitepaper on “*Decentralised Clinical Trials in Denmark*” to inform, inspire and invite relevant international stakeholders to further dialogue about opportunities for DCT in Denmark.

Please visit the homepage of Healthcare DENMARK to access the publication. The publication is available in six different languages (English, German, Portuguese, French, Japanese and Korean).<sup>9</sup>

Trial Nation will continue to participate in dissemination activities what promotes and further advance DCT opportunities in Denmark.

### **Focus for 2023**

- Trial Nation will continue working on the development and implementation of the National Overview of Clinical Trials in Denmark.
- In 2023, it will be investigated how existing tools, e.g., the Danish Health Data Agency's Research Service, may help national recruitment of patients for clinical trials.
- Trial Nation will facilitate the continued mapping of DCT barriers and potentials in Denmark. This will be done by conducting interviews, meetings, and workshops with relevant stakeholders as well as through the Danish DCT Dialogue Forum.
- Trial Nation will further engage in the dialogue with the Danish Pharmacy Association and the Danish Research Units for General Practices to investigate opportunities for a stronger collaboration on the futures needs in clinical research.
- Trial Nation will continue to facilitate the Danish DCT Dialogue Forum together with Danish **Magnus** Medicine Agency.
- Trial Nation will continue to participate in dissemination activities what promotes and further advance DCT opportunities in Denmark.

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<sup>9</sup> <https://www.healthcaredenmark.dk/healthcare-in-denmark/population-health-management/decentralised-clinical-trials/>

## Appendix A

### Activities in Trial Nation 2022

#### Organisational activities

- Establishment of a Psychiatry Network in Trial Nation.
- Trial Unions in nephrology and neurology were developed and matured further.
- Strategy for Trial Nation Centers, Networks and Unions reviewed and updated.
- 1<sup>st</sup> Conference: Establishment of NordicPedMed - a Network within the Nordic Pediatric Clinical Trial Units, September.
- Contribution to Clinical Winter School.
- The Trial Nation Legal network negotiating contract templates between the pharma industry and the five Regions to accelerate the approval process in commercially funded clinical trials.
- Budget optimization process meeting with the industry, CROs and clinicians from all Centers.
- Meetings with the Trial Nation membership companies; one to one meetings and joint meetings to discuss relevant topics within the Danish clinical environment and share best practices.
- Meetings with the Trial Nation CRO-Network to discuss relevant topics with in the Danish clinical trial environment.
- **Framework conditions**
- Member of “Working group for better framework conditions in clinical trials” giving recommendations to the Life Science council.
- Facilitating DCT dialogue forum to support a public-private collaboration on establishing the best framework conditions in Denmark for decentralised clinical trials.
- Member of Danish Data Protection Agency specialist committee for research.
- Member of Health Cluster reference group in Horizon Europe.
- Member of Dialogue Forum together with National Scientific Ethics Committee and the Danish Medicine Agency. The purpose is to identify and manage obstacles as well as sharing best practice in the framework in Denmark for clinical trials.
- The Power of Data conference focusing on ethical use of health data in Denmark, June.

## **National Projects (part of PACT)**

- National Overview of Clinical Trials: Participated in developing the platform and planning the testing and implementation phase. Lead on patient- and healthcare personnel involvement and testing activities in the defining the target for a solution as well as throughout the development and implementation phase.
- Digital Recruitment Platform: National patient recruitment initiatives to support better access to Clinical Trials in Denmark. Project lead and steering committee member. Involved patients, healthcare personnel and Sponsors in developing a user requirement specification.
- Project on building framework and logistics for Decentralised Clinical Trials: initiated a mapping of DCT barriers and potentials.
  
- **Media**
- LIF Brief: Article; *Best Clinical Trial in Denmark* award show, June.
- Medwatch: Article; *Trial Nation: New EU plan is positive for the possibilities of more Clinical Trials in Denmark*, September.
  
- **Trial Nation point of view**
- Panel debate at “Innovationsutmaningen” at Folkhälsodalen arranged by LIF Nordic, March.
- Panelist on “Developing policies for neglected populations” arrange by DePNeP – a collaboration between Copenhagen University and the Danish Medicine Agency that aims at giving input to secure equality in clinical trials, May.
- Panel debate at MultiHelix Think Tank -” Clinical research and trials in the future”, June.
  
- **Promoting Danish clinical research and Trial Nation**
- Triple-I whitepaper on “*Decentralised Clinical Trials in Denmark*” published together with Healthcare DENMARK.
- Tour de Health, arranged by Health Care Denmark, Presenting Trial Nation to Canadian delegation, June.
- Meetings with life-science companies.
- Collaborating with LIF on promoting Danish clinical trial capabilities to a European management team in a life-science company, September.
- Promoting Trial Nation to a Chinese delegation in collaboration with Invest in Denmark, September.

- Promoting of Trial Nation and Danish clinical trial capabilities within infectious disease to American stakeholders within Life Science. A collaboration with Invest in Denmark health diplomacy, New York and San Francisco, USA, October.
- Promoting Trial Nation in UK and sharing knowledge about clinical trials in the primary sector. The event was arranged in collaboration with the health diplomacy, UK, November.
- Award show “Denmark’s Best Clinical Trials 2022”: Co-organizer and represented in the panel of judges, June.
- **Knowledge liaison**
- AI Conference, including a project funded by Trial Nation, March.
- Decentralised Clinical Trial event including presentation of the DCT Outlook report, March.
- Meeting between Nova Scotia's Health Innovation Hub CTU and Trial Nation, August.
- Two-day course on Clinical Trials for project personnel, October.
- Report: *Examination of Motivation for Conducting Clinical Trials* in collaboration with the Oncology Department, Aarhus University Hospital, Roche and Aarhus University, December.
- **Conference appearance**
- Nordic Congress of Dermatology and Venereology, April.
- Future Clinical Trials, speaker;” Trial Nation - A Part Of the Danish Clinical Research Ecosystem”, June.
- **Center for Dementia**
- Annual meeting in Trial Nation Center for Dementia with participation of the steering committee and research personnel from all sites in Denmark. Focus was on collaboration and ensuring alignment and quality of diagnosis.
- Four steering committee meetings.
- Activities related to feasibilities, company meetings, grant administration, requests, and other organizational matters on an ad hoc basis.
- The coordinating site supported other sites in relation to certification of raters, advice on administration and budget negotiation.
- Three meetings between study coordinators from all sites have been conducted, focusing on developing relevant SOPs for the research sites; sharing worksheets; collaboration between the sites and to support new research staff.
- The Trial Nation Center for Dementia has been promoted to relevant companies by the Medical Lead and the Feasibility coordinator at Alzheimer's Association International

Conference, San Diego CA and at 8th Congress of the European Academy of Neurology, Vienna.

- **Center for Dermatology**

- phase V project, funded by Innovation Fund Denmark initiated late 2022.
- Patient “school” for patients with Hidrosadenitis Suppurativa was started in collaboration with the relevant patient organization.
- Training of new staff (PIs, sub-investigators, and project nurses) has had priority at most sites.
- The sites in the Center for Dermatology improved their internal collaboration on budget and contract negotiation.
- Systematic reviews of legal agreements.
- GDPR requirements and cost estimation relevant for initiating clinical research projects.
- Risk assessment of the databases and software used.

### **Center for Hematology**

- Successfully attracted several new commercially funded clinical trials due to:
  - The Medical Lead’s active and engaged meetings with companies during international congresses.
  - Medical Lead, Trial Nation-responsible Investigators and Therapeutic Area Lead actively engaged in meetings with sponsor companies individually in collaboration with the Trial Nation secretariat and Invest in Denmark.
- Collaborated on national sharing and handling of feasibility inquiries.
- Discussed and coordinated site participation in commercial clinical trials in small populations.
- Supported national referral of patients to phase I clinical trials at Rigshospitalet.
- Held a Center meeting where representatives from the clinical departments in the Center participated. Topics discussed were best practice for sharing feasibilities and preparedness for commercial clinical trials, herein human resources. The meeting paved the way for the establishment of a budget group. See next bullet point.
- Continued to implement initiatives to improved capabilities for commercial clinical trials e.g.
  - Development of phase Ib-capabilities for commercial clinical trials at several departments e.g., Aalborg University Hospital
  - Odense University Hospital established facilities for First-In-Human clinical trials, adding to the extensive experience with First-in-Human commercial clinical trials at Rigshospitalet and Vejle Hospital.

- Establish a group in the Center to ensure coordination of the budget items in connection with new clinical trials and to address joint challenges, e.g., to streamline the budgeting process for sponsors and departments.
- Identified barriers for the conduct of clinical trials -legal review by far being the biggest issue.

### **Center for Infectious Disease and Immune Modulation**

- The steering group of Trial Nation Center for Infectious Disease and Immune Modulation met twice. And the Center- and Network for Infectious Diseases had two meetings. The budget process for clinical trials was discussed and a CRO-company gave their perspective of the process and specific complicated trials were discussed at one of the meetings.
- Formalized meetings every second week between study coordinators and facilitator from Trial Nation to discuss and coordinate ongoing and forthcoming trials. The outcome is better qualified study coordinators and improved collaboration between sites, ultimately helping to provide higher quality of data in clinical trials.
- In October, a US roundtrip took place, planned by Medical Lead, Feasibility Coordinator, Invest in Denmark and Trial Nation. The group had meetings in New York and San Francisco with 11 companies (small- and big pharma companies, CROs and biotech companies), where Danish research- and clinical trial competencies in particular infectious disease and immune modulation were presented. These meetings have already resulted in one vaccine trial, several one-to-one meetings and feasibilities, and more are expected in near future.
- The feasibility coordinator participated on behalf of the Center and Network in the budget optimization process meeting with the industry, CROs and clinicians facilitated by Trial Nation.
- The feasibility coordinator was invited to speak at Center for Dementia's annual meeting. The topic was best practice and collaboration in building up a Center and Network, sharing information across specialties to strengthen the collaboration.

### **Center for Oncology**

- Has successfully attracted several new commercial clinical trials due to:
  - Medical Lead, Trial Nation-responsible Investigators and Therapeutic Area Leads active and engaged meetings with sponsor companies, individually and in collaboration with the Trial Nation secretariat. These activities were further

supported by Invest in Denmark (US tour) and Copenhagen Capacity (e.g., Nordic Life Science Days).

- Collaborated on national sharing and handling of feasibility inquiries.
- Supported national referral of patients to phase I clinical trials at Rigshospitalet.
- Identified barriers for conducting clinical trial - legal review of contracts being the biggest issue by far. A permanent working group with members representing regions, universities and ministries is working to eliminate the issue.
- Improved capabilities for commercial clinical trials through e.g.
- Developing capabilities at sites making it possible for Odense University Hospital to perform phase Ia, and for Vejle Hospital and Aalborg University Hospital to perform phase Ib commercial clinical trial in addition to Rigshospitalet and Herlev Hospital - both hospitals having extensive experience with First-In-Human commercial trials.
  - Establish a group to ensure coordination of budget items in connection with current clinical trials and streamline the budgeting process for sponsors and sites.
  - Qualitative interview with investigators at the oncology department, Aarhus University identifying barriers (in the process) for conducting commercial clinical trials. The report was done in close collaboration with management at the Oncology department, Aarhus University hospital, Roche a/s and Aarhus University. Implementation is planned to take place in 2023. The outcome will be communicated to sites and companies in 2023.

### **Center for Respiratory Medicine**

- A successful annual meeting, gaining insights and sharing better practice regarding administrative challenges, including budgeting and contracts.
- Training of new staff, harmonizing competencies across staff roles to make CRU more robust. It has been a priority to allow time for the most experienced project nurse to lead this task.
- New collaboration partners from other clinical fields introduced (maxillofacial surgery), and improved workflow with existing clinical collaborators (ENT).
- Upgrading and extending the lab facilities and IT equipment at the CRUs.

## **DanPedMed**

- On March 4<sup>th</sup> DanPedMed hosted a conference with topics on medicine for children and adolescents with 100 participants and both national and international speakers. The theme for the conference was *“Medicine for children and young people – from bench to bedside”*.
- In September, DanPedMed had an oral presentation at the 4<sup>th</sup> Nordic Conference on Pediatric Medicines in Finland.
- On September 23<sup>rd</sup> DanPedMed, in collaboration with NordicPedMed, hosted a 1-day conference with the title: *“Establishment of Network for Nordic Pediatric Clinical Trial Units”*. The aim was to establish a network for all paediatric clinical trial units in NorPedMed to increase the collaboration and coordination of activities between clinical trial units. There were 55 participants representing all the Nordic countries.
- In 2022 Denmark was regarded as a relevant and eligible partner in the large, pan-European Innovative Medicines Initiative (IMI) project Conect4Children (c4c). and will be considered as an independent hub after the project ends mid-2024. Being a part of a European collaboration will deliver high quality clinical trials in children and young people across all conditions and phases of the drug development process. DanPedMed contributes to several tasks in the c4c project description.
- In 2022 The Department of Neonatology, Rigshospitalet, Denmark included patients in an investigator-initiated clinical trial running under c4c. The site is one of the best performing sites in Europe and was asked to renegotiate a new contract to include more patients. Denmark is also participating in two Industry proof of viability studies in the c4c project. DanPedMed is also a driving force in NordicPedMed, with René Mathiasen as Chair and Pernille Skovby as secretary.
- DanPedMed as a Network has increased its activities, including raising awareness of the benefits of performing sponsor-initiated clinical trials. Today DanPedMed can offer advice and support to Departments of Pediatric and Adolescent Medicine as well as to departments of Child and Adolescent psychiatry interested in initiating clinical trials.
- In addition, DanPedMed has achieved a very strong connection to c4c by actively taking part in meetings and working groups.

## **Trial Nation MedTech Network**

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- AI-project identifying appropriate way through development and implementation for a medical device based on artificial intelligence, finalized.
- Workshop on clinical investigations aimed at industry expert arranged by Medicoindustrien.

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- MedTech and Pharma jointly facilitated and financed a two-day training for project personnel with 80 participants from most specialties and most hospitals in Denmark.

# Trial Nation

Clinical Trials Denmark