



Trial Nation

Clinical Trials Denmark

ANNUAL REPORT 2023

Our Vision and Mission

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 create a better health and wealth for Denmark.

Trial Nation's mission is to contribute substantially to Denmark's position as the leading public-private ecosystem for clinical trials in Europe – to the benefit of patients, research and the economy.

- We create the foundation for expansion, and we maintain a position for Denmark among the top three countries in Europe, measured as number of clinical trials per million inhabitants.
- We strengthen frameworks and conditions to attract significantly more clinical trials at the highest international level.
- We lead in state-of-the-art methods and technologies in set-up and execution of clinical trials.

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S U M M A R Y

Letter from the CEO

I look at 2023 with pride. The global competition in the allocation of clinical trials is high, and Denmark stands its ground. In the tough international competition for attracting clinical trials, we are witnessing positive developments in Trial Nation Centers and Networks - a strong testament to the abilities of the clinical trials ecosystem and the professional capacity among clinical researchers, which is recognised by the companies. It provides benefits to Danish patients by giving them increased opportunities to participate in clinical trials as an alternative to their standard treatment. I take pride in Trial Nation's contribution to this agenda.

One of the cornerstones of Trial Nation is the clinical infrastructure. National collaboration in Trial Nation Centers, Networks and Trial Unions is combined with regional support for clinical specialties not nationally facilitated by Trial Nation. Together, these create a fabric of clinical infrastructure where a match for a clinical trial can be found regardless of indication.

During 2023, Trial Nation welcomed two new clinical specialties as national networks—nephrology and neurology—and established a Trial Union within Phase IV, further enhancing the national clinical trial infrastructure. We have also continued building our collaboration with general practice – a strategic collaboration that continues in 2024. This is important as primary care is the first point-of-care for patients.

Looking into the future of clinical trials, we see a shift towards more decentralised and patient-centric approaches. To meet the new demands from both patients and life science companies, Trial Nation is leading a public-private partnership, the PACT-project.

The project aims at developing supportive national infrastructures for decentralised clinical trials in Denmark and gathers all the Danish regions, private partners, as well as academia. We will continue building the new infrastructures during 2024 to ensure Denmark is the frontrunner in the Decentralised Clinical Trials setting.

Attracting additional clinical trials and investigations to Denmark a constant focus area in Trial Nation. Throughout 2023, we have met with international life science companies to showcase Denmark's capabilities and are pleased with the positive outcomes.

Lastly, I am very pleased to see the close collaboration with life science companies and public stakeholders that we have continued to build upon in 2023 to secure the best conditions for conducting clinical trials in Denmark.

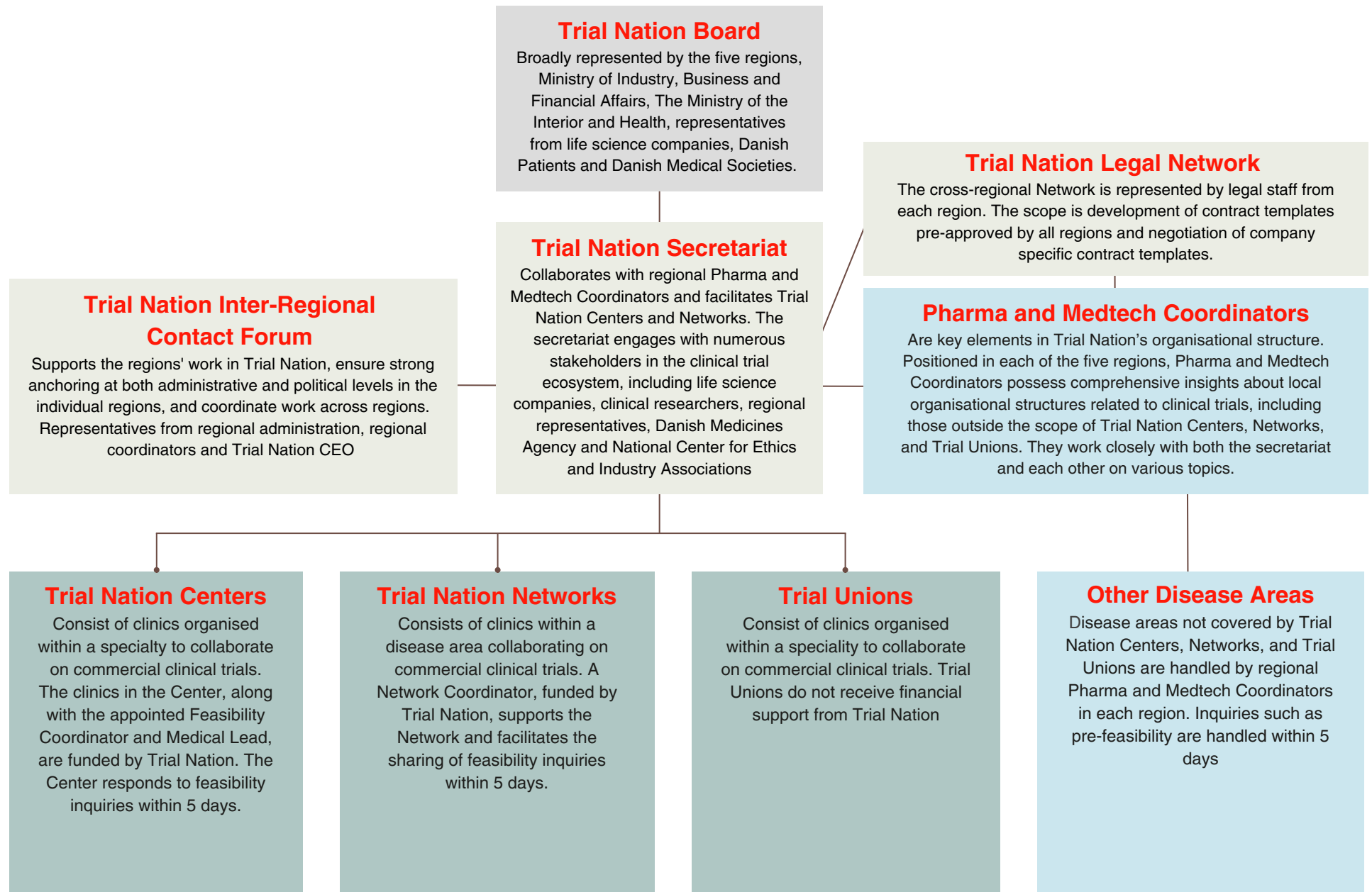
Having an organisation that makes the conduct of clinical trials easier and facilitates stakeholders to create national solutions for common operational barriers has proven of high value – and I look forward to continue the journey in 2024.



A handwritten signature in blue ink that reads "Marianne Pilgaard".

Marianne Pilgaard
CEO, Trial Nation

Trial Nation at a Glance



Introduction to the Trial Nation Model

Trial Nation is the result of strong and continuous governmental support of the Danish life science sector, regional prioritisation and life science companies acknowledgement of the importance of nationally coordinated access to clinical trial sites in Denmark. Trial Nation is supported by the Ministry of Industry, Business and Financial Affairs, the five Danish Regions and life science company members. The key incentive is to ensure the best conditions for conducting clinical trials at Danish clinics. How is this done? At Trial Nation we work on several parameters to support this agenda:

- A solid infrastructure for conducting clinical trials in Denmark
- An organisational structure that builds on close collaboration with regional Trial Nation colleagues and the Trial Nation secretariat to facilitate inquiries about clinical trials the best way possible.
- Capacity building in Trial Nation Centers, Network and Unions.
- Facilitate public-private initiatives that supports a strong infrastructure for conducting clinical trials in Denmark.
- Collaborating with life science companies on various topics relating to clinical trials.

Background and History

In 2012 the five Danish regions established Clinical Trial Office Denmark, to attract more clinical trials to Danish hospitals. In 2014 the second precursor to Trial Nation, NEXT Partnership, was established with political and industry endorsement. The purpose was to promote centers of excellence - sites that conducts clinical trials on a high level and work together naturally. Six Centers within different specialties were formed.

Trial Nation was founded in 2018 as a merge between NEXT Partnership and Clinical Trials Office Denmark. A broad representation of stakeholders are reflected in Trial Nation. The board consist of regional and national representatives, Danish Patients and Danish Medical Societies. The Trial Nation secretariat and regional colleagues have a close-knit collaboration on clinical trial related topics. Today, eight Centers, three Networks and one Trial Union are established in Trial Nation.



Clinical Trials in 2023 at a Glance

The number of commercial clinical trials in the Trial Nation Centers has increased in 2023 compared to 2022 (fig. 2). It is impressive considering the challenges with high pressures on the healthcare system and the implementation of the Clinical Trials Information System (CTIS) leading to changed processes and ways of working. In 2023, Denmark is leading in the number of clinical trials per million inhabitants (commercial/non-commercial) compared to other similar countries in Europe (fig. 1).

Clinical trials in Denmark compared to other European countries

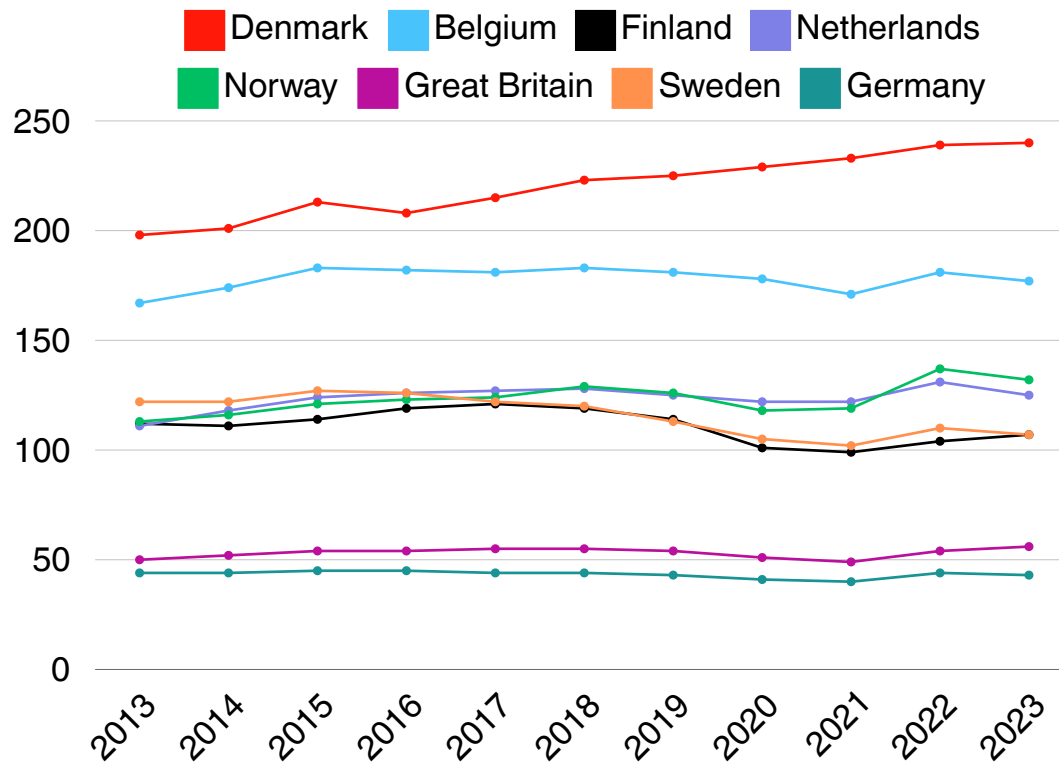


Fig. 1: Number of clinical trials per million inhabitants. The numbers are based on all ongoing trials in the year (both commercial and non-commercial clinical trials). Source: GlobalData January, 2024. Search criteria: Country ; Year

Commercial clinical trials in Trial Nation Centers 2020-2023

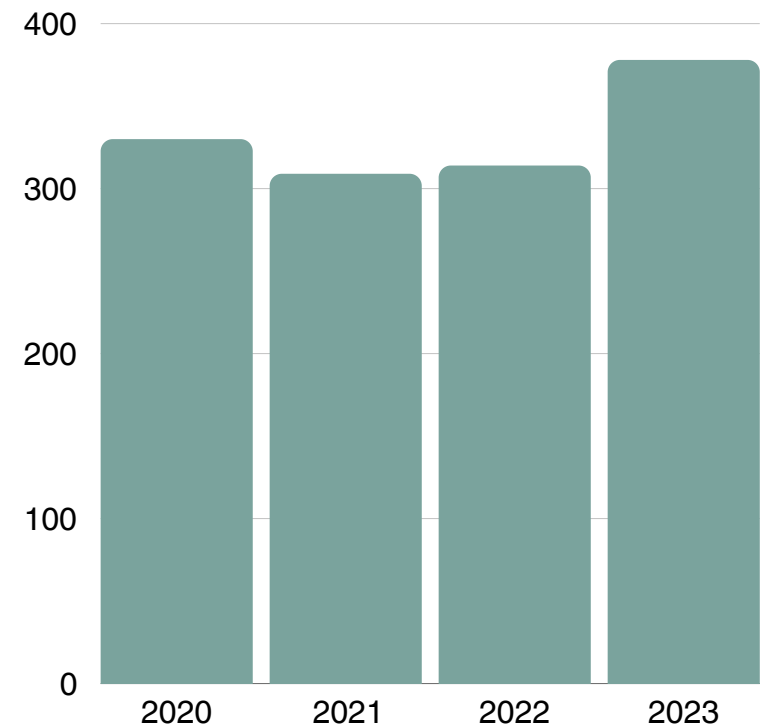


Fig 2. Ongoing and initiated commercial clinical trials in 2023: Center for Oncology, Hematology, Dermatology, Dementia, Respiratory, Infectious disease and modulation. See separate graphs for Center for Medtech and Paediatric Medicine (DanPedMed)

Trial Nation Activities in 2023

A snapshot of some of our activities in 2023 - for a more detailed list, see [Appendix A](#)

Education and Knowledge sharing

Trial Nation course for project staff
Synapse Winter School (co-organiser)
Webinars for member companies

Legal Framework

Clinical Trials Agreement
Updated standard contract templates for single and multi site use
Clinical Investigation Agreement
Updated standard contract templates for MedTech for single and multi site use

Decentralised Clinical Trials

Facilitating DCT Dialogue Forum
Formalised collaboration initiated with the Association of Danish Pharmacies
Dissemination activities across the life science ecosystem

Presentation at Conferences

Clinical Innovation Summit 2023, Copenhagen, Denmark
National Conference for Clinical Trials 2023, Göteborg, Sweden
International Clinical Trials Day 2023, Dublin, Ireland
Biological and Clinical Evaluations Conference for Medical Devices, Copenhagen Denmark

Clinical Relations

Inauguration of the Psychiatric Project Staff Network
Annual Spring meeting for the Professor Association at Aarhus University Hospital
Neurology and Nephrology Network start-up activities

Danish Capabilities

Meetings with life science companies
Meeting series for member companies
Meeting for member companies: Budget negotiation processes

Danish Clinical Research Conditions

Life Science Strategy: Working Group on Clinical Research
The Danish Data Protection Agency's Special Committee on Research
Danish reference group for Horizon Europe
Denmark's clinical trial and investigation of the year

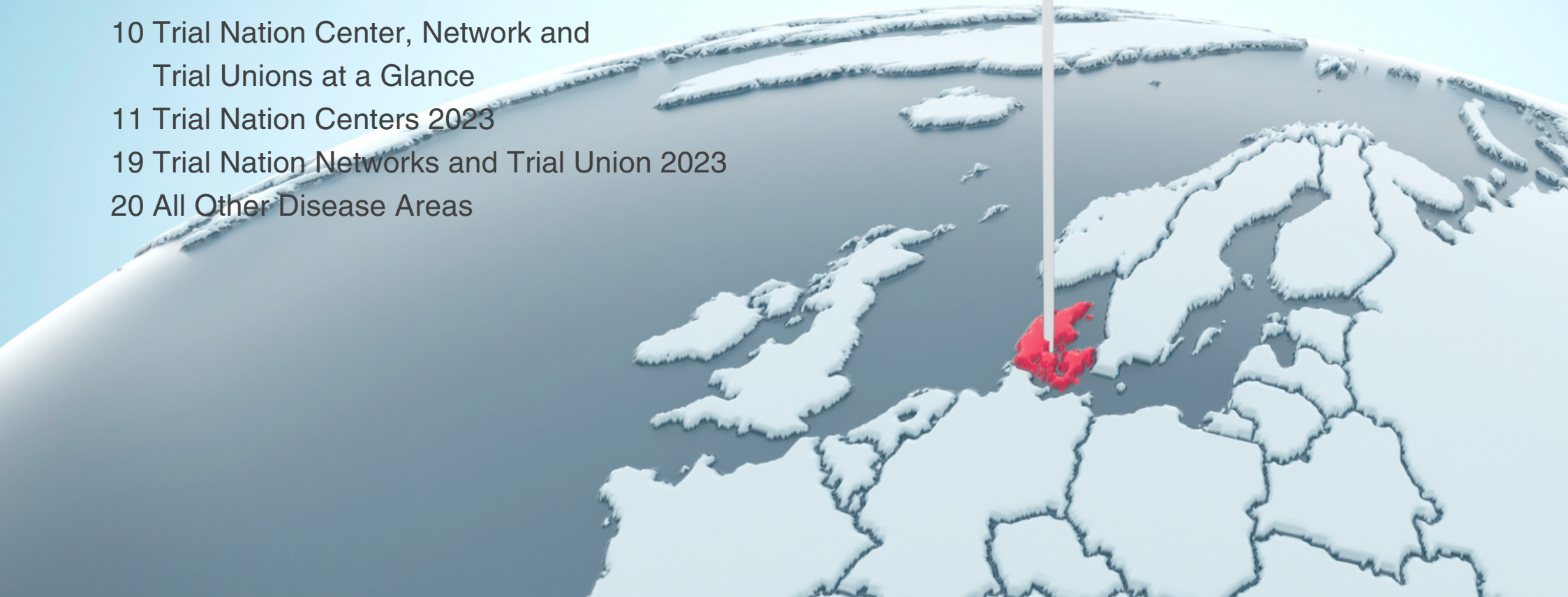
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Trial Nation Centers, Networks and Trial Unions at a Glance

Trial Nation consists of 8 Centers, 3 Networks and 1 Trial Union within a broad range of medical specialties and specific competencies. In 2023 we welcomed two new networks within Neurology and Nephrology. The Center and Network structure supports the focus on sharing feasibility inquiries and conducting commercial clinical trials within a specialty. The national organisation of specialties promotes collaboration on clinical trials between clinics across Denmark. Centers and Networks receive funding through Trial Nation. Trial Unions are national collaboration structures on either a specific theme or a clinical specialty, and are not funded. Read more about the structures [here](#).

Trial Nation Centers

- Center for Dementia
- Center for Dermatology
- Center for Hematology
- Center of Infectious Disease and Immune Modulation
- Center for MedTech
- Center for Oncology
- Center for Paediatric DanPedMed
- Center for Respiratory Medicine

Trial Nation Network

- Network for Nephrology
Established in 2023
- Network for Neurology
Established in 2023
- Network for Psychiatry

Trial Unions

- Phase IV Trial Union
Established in 2023

Center for Dementia

The Center for Dementia represents a collaborative effort involving five Danish memory clinics spanning all five regions of Denmark. These clinics have extensive experience in clinical research, encompassing Alzheimer's disease, Huntington's disease, and other neurodegenerative disorders, covering clinical trials from phase I to phase IV.

In 2023, the memory clinic at Southern Denmark University Hospital, Esbjerg, joined the Center as a network clinic*, enhancing the collaborative landscape. The study coordinators in the Center have established a forum, with the focus in 2023 being on collaboration between the sites and the CROs, as well as a better understanding of the budget proposal.

Throughout 2023, there has been a notable uptake in initiated commercial clinical trials, with a total of six trials started, primarily in Alzheimer's Disease and Huntington Disease. The total number of clinical trials in 2023 reached 13, as illustrated in Figure 1, including the seven trials initiated before 2023.

Despite persistent challenges such as prolonged waiting lists for diagnostic evaluations and a shortage of specialists impacting the clinics' capacity for conducting commercial clinical trials, all clinics have succeeded in initiation and conduct of relevant studies. It is prioritised to address the substantial unmet needs of their patient population. The clinics have purposefully streamlined and optimized diagnostic evaluation and treatment processes.

To learn more about the Centers capabilities, clinics involved and contact information: [center information](#)

*Network clinics definition: Affiliated to the Center without funding. Requirements related Center clinics does not apply.

Commercial Clinical Trials in the Center for Dementia

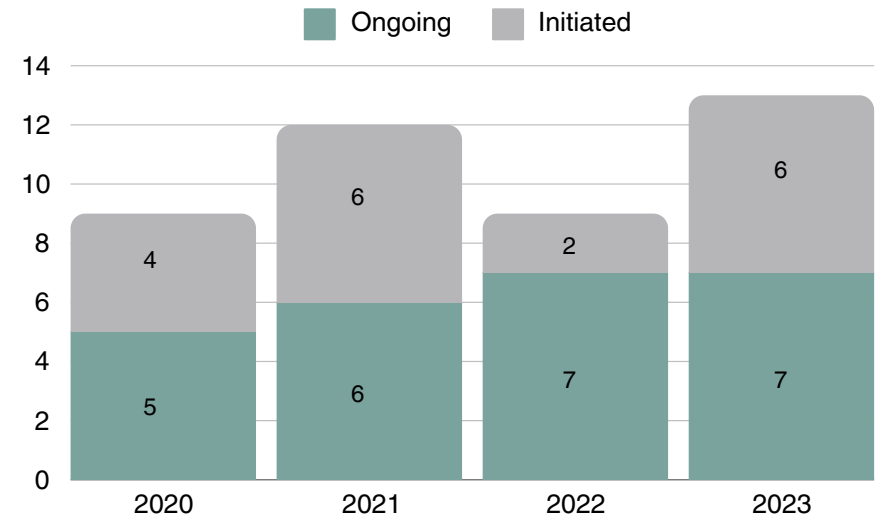


Figure 3: Ongoing and initiated commercial clinical trials in Center for Dementia from 2020 - 2023

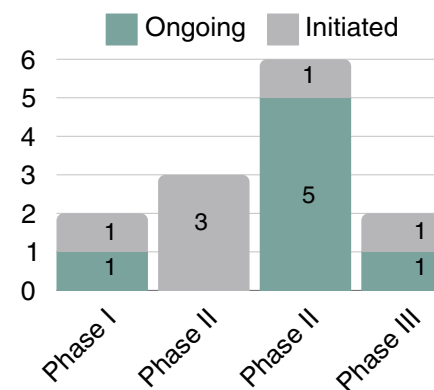


Figure 4: Ongoing/initiated commercial clinical trials per phase in 2023

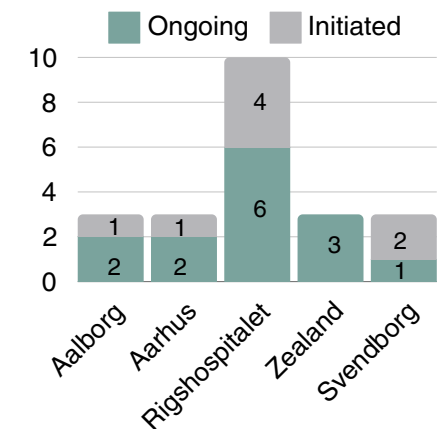


Figure 5: Ongoing/initiated commercial clinical trials per clinic in 2023

Center for Dermatology

The Center consist of five dermatology clinics in Denmark. 2023 saw a continued and stable activity with regards to feasibilities, as of which 22 were shared in the Center – mostly concerning phase II and III studies. Like in previous years, many feasibilities are sent to individual investigators outside of the Trial Nation procedure as Danish dermatologists are acknowledged worldwide for their research capabilities. During 2023, the Center for Dermatology has had a positive uptake of patients in decentralised clinical trials (DCT), a prioritised area within the clinical trial setting. DCT creates more flexibility for patients and the clinic/site.

"An acne study, in particular, represented a significant achievement, where we swiftly recruited 100 patients through online methods and subsequently randomized them."

Simon Francis, Professor, MD in Dermatology at Bispebjerg Hospital

An interesting trend has been that the number of investigator-initiated trials in collaboration with the industry has increased. This type of collaboration is an add-on to the many purely investigator-driven trials in the Center. The Center notes that the industry partner practice to use multiple vendors in each trial drives project staff workload. This means there is need for a minimum number of patients in a trial to ensure coverage of baseline cost.

At the annual face-to-face meeting in 2023 it was decided that an investigator and a project nurse from each site will attend future Center meetings. This is to make for a robust basis for decisions, collaboration and networking across functions and is expected to have a positive impact on trial operations and on the study teams.

To learn more about the Centers capabilities, clinics involved and contact information: [center information](#)

Commercial Clinical Trials in the Center for Dermatology

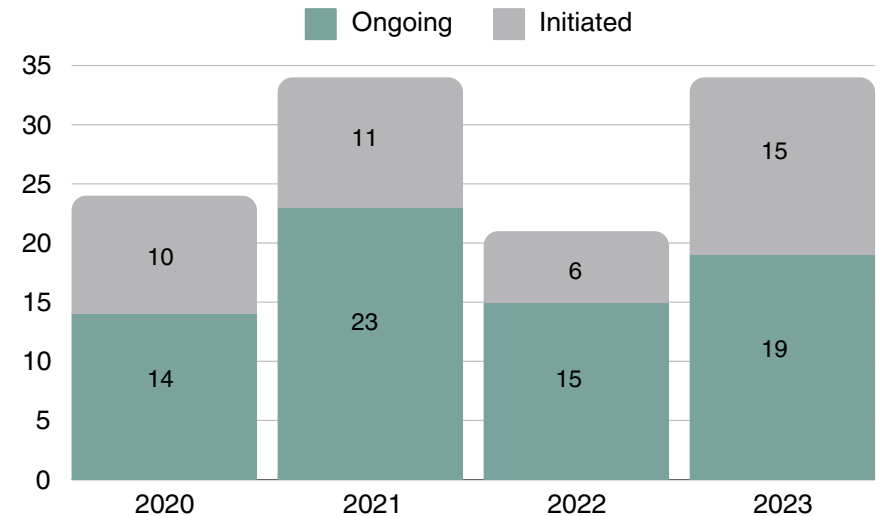


Figure 6: Ongoing and initiated commercial clinical trials in Center for Dermatology from 2020 - 2023

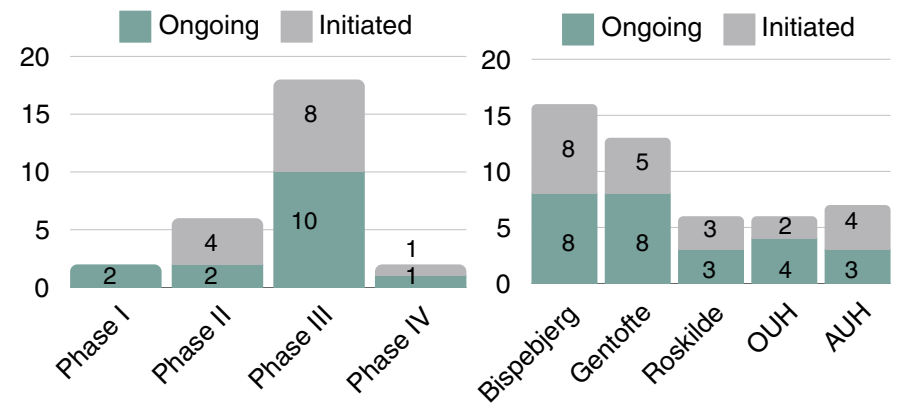


Figure 7: Ongoing/initiated commercial clinical trials per phase in 2023

Figure 8: Ongoing/initiated commercial clinical trials per clinic in 2023

Center for Hematology

The Center for Hematology encompasses 8 Danish hematology outpatient clinics, addressing the growing need for specialised sites for clinical trials. Both commercial and non-commercial clinical trials across all diagnoses are performed within the Center.

To enhance expertise in clinical trials, many clinics in the Center have phase I capabilities. By the end of 2023, 7 out of 8 clinics possessed phase I capabilities, with First in Human capabilities available in 3 clinics. Additionally, preparations were made for trials involving Advanced Therapeutic Medicinal Products, leading to the creation of the Danish CAR-T cell network. Each clinic in the Center now hosts its own local tumor board.

Simultaneously, the Center's Budget Group streamlined processes for clinical trial budget negotiations, and the Trial Nation folder detailing the Center's capabilities was updated. Chair Professor Francesco D'Amore, Department of Hematology, Aarhus University Hospital is satisfied with the collaborative efforts, stating, "Great teamwork across the Center and a strong support for new ideas."

A notable portion of feasibility inquiries in Denmark are directly sent to potential hematological investigators. However, the Center observed a slight decrease in the number of documented commercial feasibility inquiries despite the Center's rapid (5 working day) guidance and guided national feasibility process.

There has been documented 121 commercial and 92 non-commercial clinical trials in the Center and they are often conducted at several Danish sites. Both commercial and non-commercial clinical trials across all diagnoses are performed with the Center for Hematology.

To learn more about the Centers capabilities, clinics involved and contact information: [center information](#)

Commercial Clinical Trials in the Center for Hematology

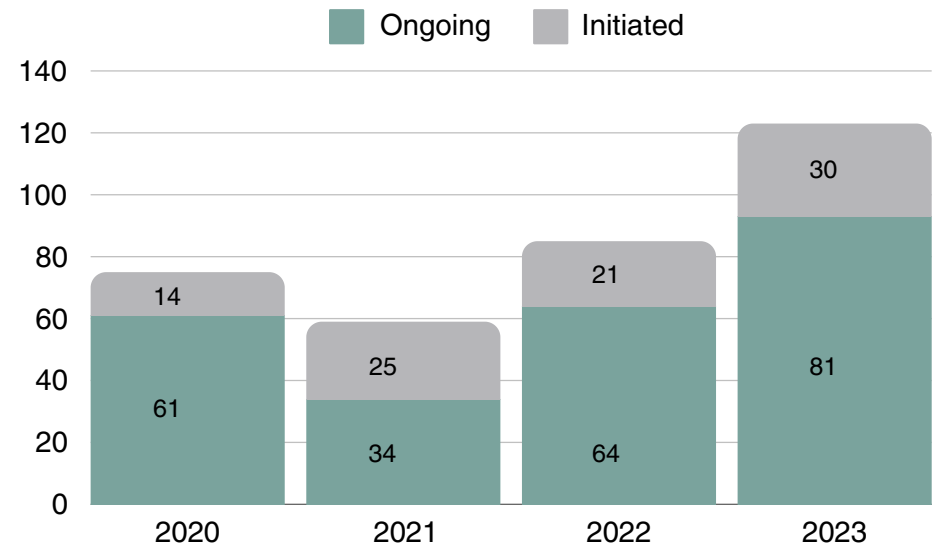


Fig. 9: Ongoing and initiated commercial clinical trials, Center for Hematology, 2020-2023

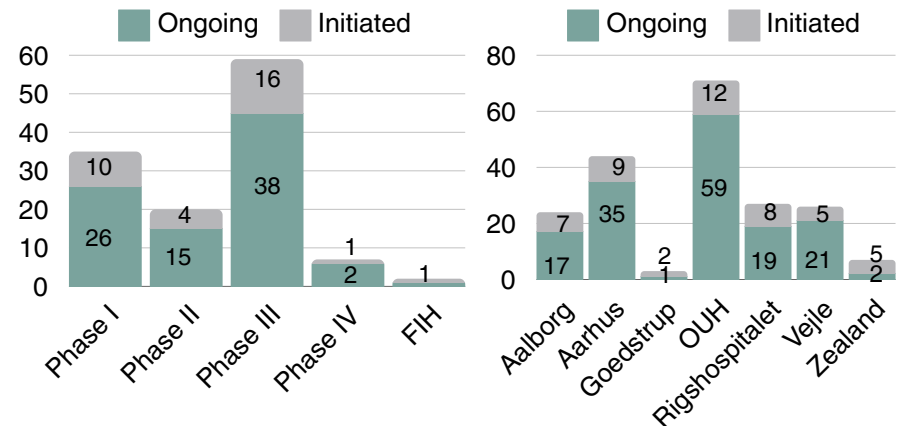


Fig. 10: Ongoing and initiated commercial clinical trials divided per phase

Fig. 11: Ongoing and initiated commercial clinical trials divided per site/clinic

Center for Infectious Disease and Immune Modulation

The Center comprises six clinics that span all five Danish regions. These clinics specialise in treating patients and conducting clinical trials in infectious diseases, including vaccine trials involving healthy participants. Their expertise covers trials from phase I to phase IV. Additionally, the Center is associated with a network of six regional clinics, fostering a close collaboration. Relevant feasibilities are shared, and annual joint meetings are held between the Center and Network clinics.

In 2023, the Center for Infectious Diseases and Immune Modulation initiated 10 commercial clinical trials, contributing to the total of 21 trials (as shown in Figure 15). 11 trials were initiated before 2023. The Center has been conducting international clinical trials funded by NIH and the EU besides their own investigator-initiated trials for many years. In 2023, there were 11 ongoing non-commercial trials, three of which were initiated that year. Lars Østergaard, Professor and Medical Lead in Trial Nation Center for Infectious Disease and Immune Modulation, notes:

"The successful vaccines developed during Covid have left a mark and led to a significant increase in international clinical vaccine trials, to which Trial Nation has contributed significantly in attracting them to Denmark"

Collaboration has been a headline for many activities in the Center during 2023. In September, the Pediatric Network was invited to a Center and Network meeting to discuss collaboration and share experiences in conducting clinical trials in children involving both specialties. Also a strong collaboration has been established at the study coordinator level, with bi-weekly meetings in the Center for Infectious Disease and Immune Modulation. In 2023, a two-day study coordinator meeting took place, focused on collaboration with the industry, CROs, and understanding GCP rules in this context.

To learn more about the Centers capabilities, clinics involved and contact information: [center information](#)

Commercial Clinical Trials in the Center for Infectious Disease and Immune Modulation

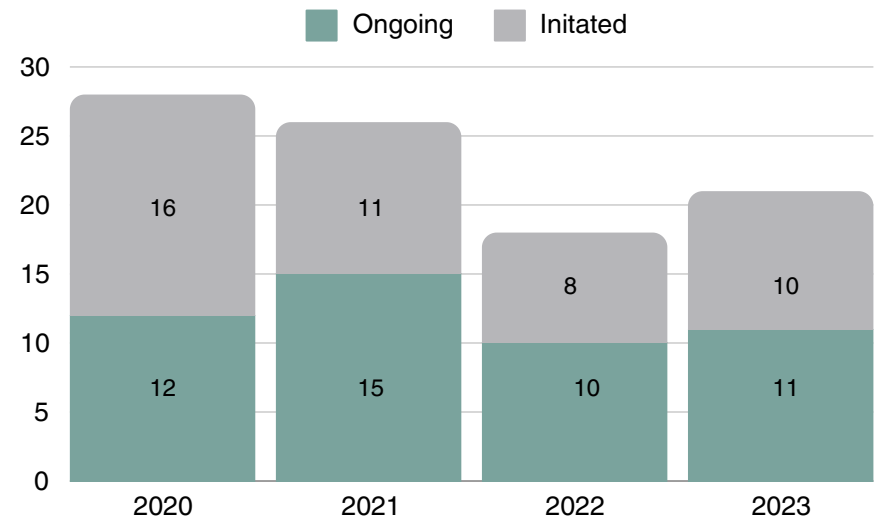


Figure 12: Ongoing and initiated commercial clinical trials

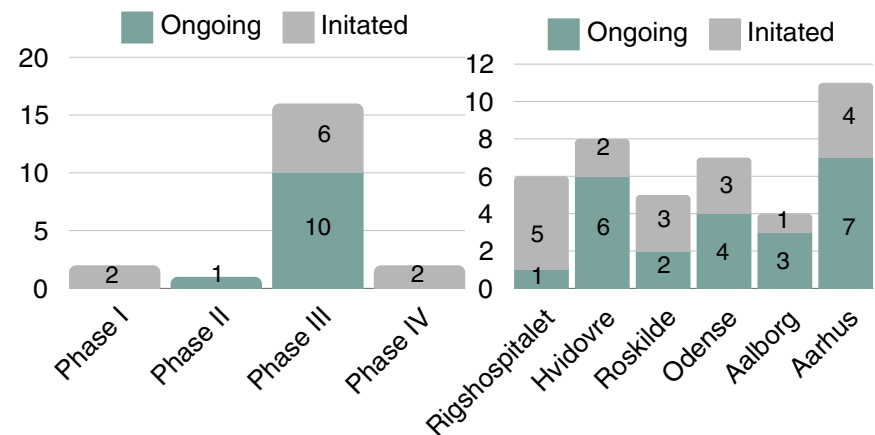


Figure 13: Ongoing/initiated commercial clinical trials per phase in 2023

Figure 14: Ongoing/initiated commercial clinical trials per clinic in 2023

Center for Medtech

Trial Nation Center for Medtech diverge from standard setups of Centers by covering all specialties. Medical device trials span across various specialties and all hospitals, facilitated by regional MedTech coordinators rather than specialists within each field.

Clinical trials for medical devices are as diverse as those for pharmaceuticals, and the implementation of the EU Medical Device Regulation has added further complexity to the field. Providing the best guidance requires staying abreast of new developments. Consequently, we are in frequent dialogue with relevant authorities and interest organisation e.g., MedTech Denmark.

Supporting and guiding Medtech companies from the early stages of product development is a crucial aspect of Trial Nation's dialogue. Our goal is to facilitate the best and most suitable connections between companies and clinical departments.

Throughout 2023, Trial Nation engaged in discussions with companies about 20 different clinical investigations, resulting in nine enquiries establishing contact with clinical departments. The remaining inquiries provided guidance to companies on prerequisites before clinical investigation becomes relevant or on how to approach procurement departments, depending on their development stage. Additionally, we connected with numerous companies when Trial Nation was asked to present at the conference “Biological and Clinical Evaluations Conference for Medical Devices” hosted by Key2Compliance in October.

A significant focus of this year's activities was expanding our strategic partnerships, which now include Invest in Denmark,

The Danish Health Technology Council, Nova Scotia Health (Canada), NordicProof (Norway), and UCC (Ireland).

In 2024, together with Invest In Denmark, we will continue to focus on identifying barriers and business opportunities for attracting more studies to Denmark.

Clinical Investigations* in Center for Medtech

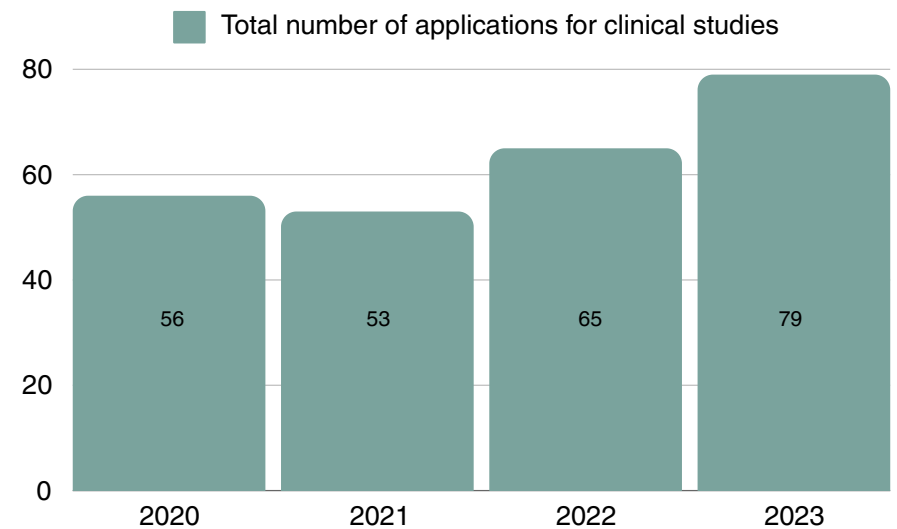


Fig. 15: Clinical investigations* in Center for Medtech. Data source: 2020 and 2021 data points are derived from Global Data January 2022. Data from 2022 and 2023 is provided by Danish National Center for Ethics. *Definition: Clinical Investigations covered by article 62, 74 and 82 in Medical Device Regulation are included in these.

Center for Oncology

Center for Oncology consist of 9 clinics and 2 network clinics* connected to the Center. In 2023 several clinics created phase I capacity and improved their capabilities and a total of eighth clinics now have phase I capacity including 3 clinics with First in Human capabilities. Competencies expand to encompass preparedness for clinical trials involving Advanced Therapeutic Medicinal Products, such as T-cell engaging immunotherapy and cellular therapies.

Per Pfeiffer, Professor in Oncology at Odense University Hospital appreciate the collaboration in the Center and notes:

“The collaboration internally in the Oncology Center and the clinical research unit network works well. The exchange and sparring across the country help to strengthen the clinical research at each site.”

There is a decline in the number of documented commercial feasibility inquiries making use of the centers quick guidance and guided, national feasibility process. The Center reports that many feasibility inquiries performed in Denmark go directly to potential investigators. The number of documented commercial clinical trials is stable compared to previous years and include at least 20 First-In-Human studies. Worth noticing is that Aarhus University Hospital has seen 6 new commercial clinical trials being initiated in 2023 after improving their start-up process.

In 2023 the out-patient clinics at Southern Denmark Hospital, Soenderborg and Southern Denmark University Hospital, Esbjerg joined the Center as network clinics.

*Network clinics definition: Affiliated to the Center without funding. Requirements related Center clinics does not apply.

To learn more about the Centers capabilities, clinics involved and contact information: [center information](#)

Commercial Clinical Trials in Center for Oncology

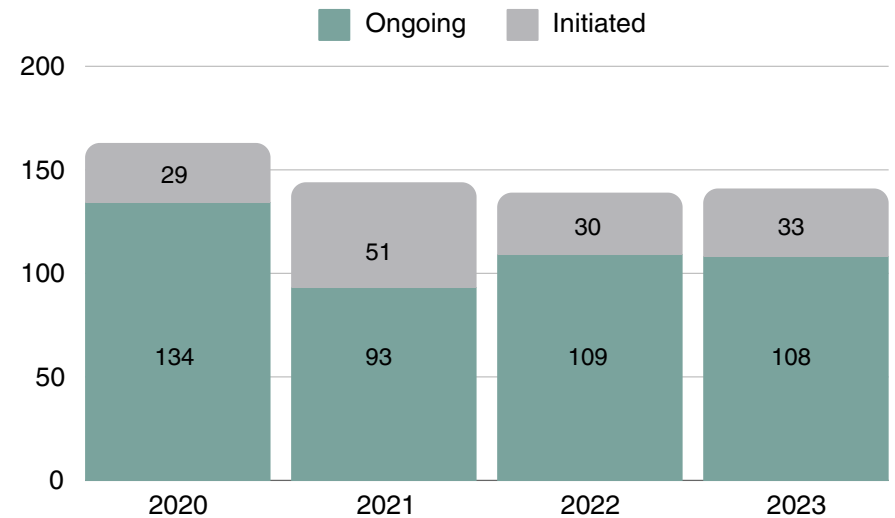


Figure 16: Ongoing and initiated commercial clinical trials in Center for Oncology from 2020 - 2023

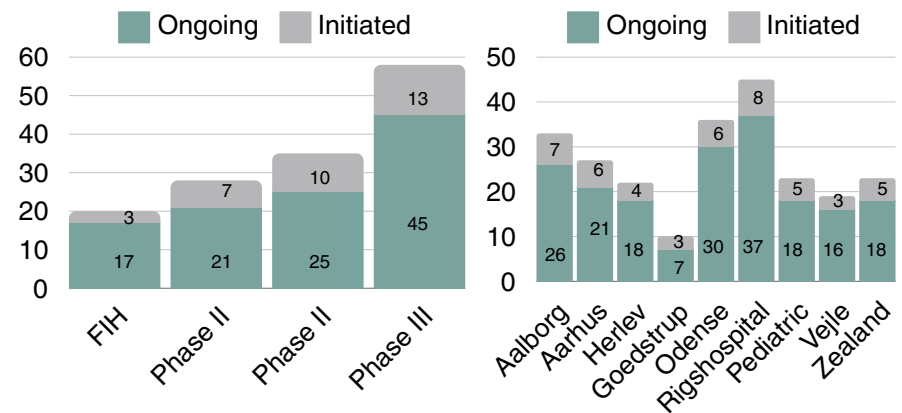


Figure 17: Ongoing/initiated commercial clinical trials per phase in 2023

Figure 18: Ongoing/initiated commercial clinical trials per clinic in 2023

Center for Paediatric Medicine - DanPedMed

DanPedMed represents a collaborative initiative among all 18 pediatric departments in Denmark, encompassing around 160 clinicians specialising in various pediatric sub-specialties in children and adolescents, including psychiatry. Established in 2016 by the Danish Pediatric Society and the Danish Society of Clinical Pharmacology, DanPedMed aims to advance the use of better medicine for children and adolescents.

On a broader scale, DanPedMed is linked at the Nordic level as part of Nordic PedMed and at the EU level as a full member of the Pan-European network conect4children (c4c) as of 2024.

DanPedMed has employed three part-time research nurses who play a pivotal role in enhancing the site's preparedness for conducting clinical trials. This is achieved through close collaboration with the DanPedMed Steering Committee and the National Coordinator.

In 2023, DanPedMed witnessed a shift in the nature of inquiries it handled, resulting in an upsurge of initiated pediatric clinical trials in Denmark. Additionally, there is a seamless workflow with c4c, and a heightened focus on pediatric clinical trial units across Denmark is evident, reflecting a strengthened commitment to advancing pediatric healthcare.

To learn more about the Centers capabilities, clinics involved and contact information: [center information](#)

Types of Inquiries Recieved in 2023

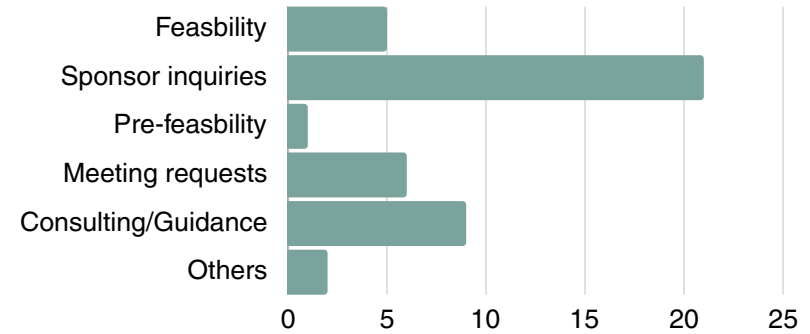


Fig 19: Inquiries recieved by DanPedMed Coordinator during 2023 relating to pediatric clinical trial

Number of commercial and academic clinical trials in DanPedMed 2023

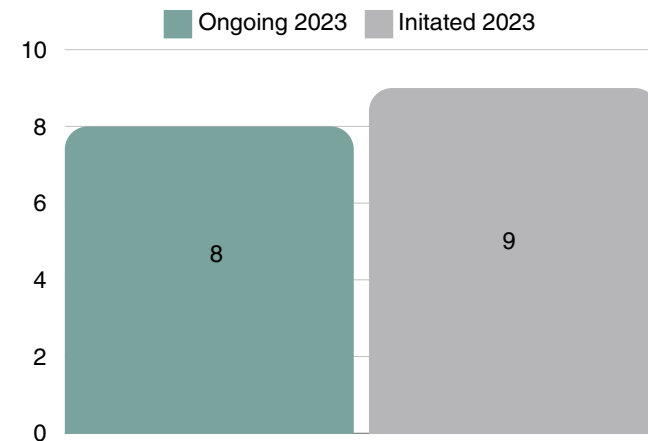


Fig. 20: Ongoing and initiated commercial and academic clinical trials in DanPedMed, 2023

Center for Respiratory Medicine

The Center consists of six Danish respiratory clinics specialising in sponsor-initiated clinical research with medicinal products across all respiratory diseases.

2023 was a positive and busy year for Danish respiratory clinics. The timelines for many clinical trials were extended due to decreasing recruitment in other Scandinavian countries, resulting in more patients being allocated to Denmark. In general, recruitment has been easier in 2023 because inclusion/exclusion criteria are more in accordance with the standard of care treatment in Denmark. That being said, all sites would welcome a more mature collaboration with the general practitioners, who are seeing many potential study participants. A robust model needs to be established.

The focus on reducing timelines from Site Initiation Visit to First Patient First Visit has been successful across most studies initiated in 2023.

In October 2023, Medical Lead Charlotte Suppli Ulrik had the opportunity to present the Center for Respiratory Medicine at meetings with leading international life science companies in New York facilitated by Invest in Denmark. Raising awareness of Denmark's capabilities in clinical trial settings is crucial for initiating and sustaining collaborations with life science companies. For Trial Nation, prioritising international outreach is paramount. The collaboration with Invest in Denmark and the Center for Respiratory Medicine demonstrates Danish clinical trial capabilities to a global audience.

To learn more about the Centers capabilities, clinics involved and contact information: [center information](#)

Commercial Clinical Trials in the Center for Respiratory Medicine

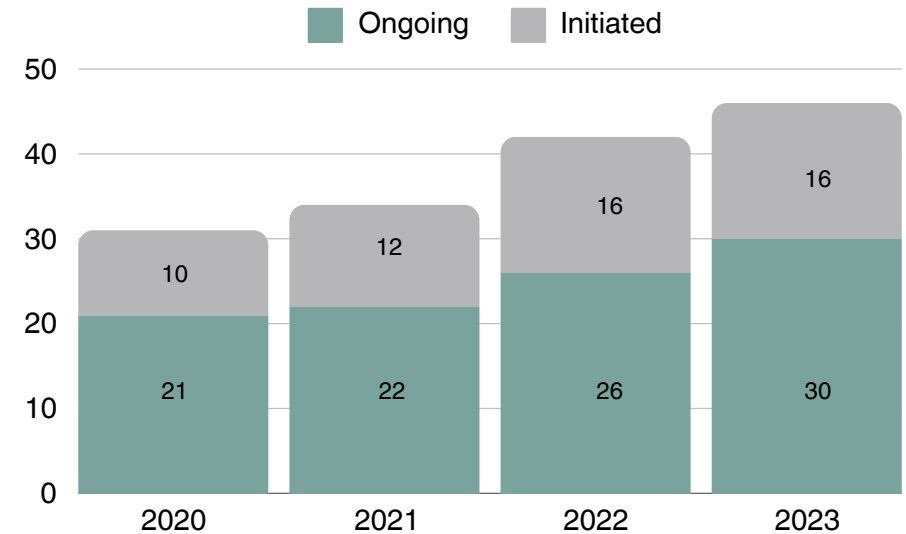


Fig. 21: Ongoing and initiated commercial clinical trials, Center for Respiratory medicine

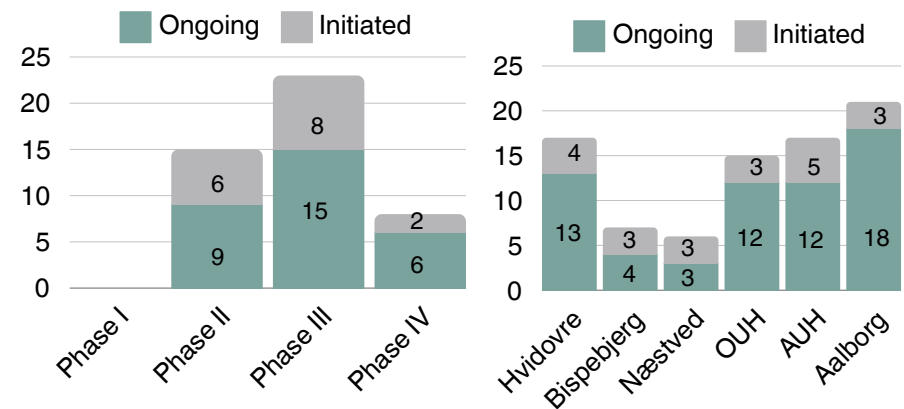


Fig. 22 Ongoing and initiated commercial clinical trials divided per phase

Fig. 23 Ongoing and initiated commercial clinical trials divided per site/clinic

Trial Nation Networks and Trial Union

In 2023 two Trial Nation Networks have been established: Nephrology and Neurology. The Networks provide a possibility to coordinate inquiries about commercial clinical trials on a national level, including nationally coordinated response to feasibilities within five days. Trial Nation funds a Network Coordinator. A Trial Union focusing on Phase IV trials was founded as well. For more detailed information on Trial Nation Networks and Trial Unions: [Trialnation.dk](https://trialnation.dk).

Network for Neurology

Evolving from a Trial Union to a Network in 2023 Network of Neurology were established with a Network Coordinator situated at Aarhus University Hospital. The network covers all (15) neurological outpatient and hospital clinics in Denmark.

The first meeting in the Network was held in beginning of the year. The Network Coordinator visited most of the clinics during 2023 to support the collaboration in the Network. This has resulted in 1) Establishment of a neurology project staff network, 2) Updating of the Trial Nation Neurology Network folder to reflect the current status and capabilities of the Network and 3) a strong wish to participate in Trial Nation's 2-day course for project staff.

17 commercial feasibility inquiries were shared within the network in 2023. This is in addition to the feasibilities sent directly to individual investigators.

Find more information about the Network [here](#).

Trial Union: Phase IV

Phase IV Trial Union is a network of Danish phase IV units specialised in research and execution of studies on marketed drugs with a real-world evidence perspective. The Phase IV Trial Union covers all regions of Denmark and offers a single point of contact to a dedicated, national network of units with a strong focus on collecting data that meets the requirements from authorities and health economic bodies to pharmacoepidemiological registry studies and clinical research. The Phase IV Trial Union have a unique access to 250+ general practitioners in Denmark. Find more information about the union [here](#).

Network for Nephrology

In 2023, the Trial Unions for Nephrology developed into a Network, overseen by a national Network Coordinator based at Zealand University Hospital in Roskilde. The Network now includes 15 nephrology outpatient and hospital clinics across Denmark, all actively engaged in conducting clinical trials. Their competences include investigation, diagnosis, and treatment of a broad spectrum of kidney diseases, as well as severe hypertension. Furthermore, the Network is specialised in the secondary effects of kidney insufficiencies.

All clinics in the network provide high-tech methods, and selected clinics in every region provide advanced immunosuppression, plasmapheresis and kidney transplantation.

During 2023, the Network of Nephrology has been very active in showcasing their abilities at relevant events.

Find more information about the Network [here](#)

Network for Psychiatry

In 2022, a new network was established in Psychiatry, with the national Network Coordinator stationed at Aalborg University Hospital, Psychiatry. This collaborative effort now includes 14 out-patient psychiatry clinics and hospital clinics across Denmark, all with the ambition to contribute to conducting more clinical trials. Project staff have established monthly meetings to benefit from the differential experience levels between clinics. The national Network Coordinator, Prof. René Nielsen from Aalborg University Hospital, Psychiatry noted:

“The Trial Nation collaboration has provided us with a greater collaborative inclusion catchment area and will help sites with a deeper understanding of clinical trial conduct and processes. It has facilitated stronger connections and collaboration among Danish sites, fostering peer-to-peer interaction.”

With the capacity to accommodate more relevant clinical trials, the Network Coordinator is available to discuss with potential sponsors and evaluate study feasibility within the network.

Find more information about the Network [here](#)

Other Disease Areas

- Pharma/ Medtech Coordinators

The Network of Pharma and Medtech Coordinators comprises representatives appointed in each region. It serves as a fundamental part of Trial Nation's ambition to create optimal conditions for clinical trials and investigations in Denmark, as well as to attract additional clinical trials to the country

In Trial Nation's eight Centers, three Networks, and one Union infrastructures have been established to support clinics' collaboration on commercial clinical trials within disease-specific areas. Trial Nation's Pharma and Medtech Coordinators offer the same service for all other disease areas. The Pharma and Medtech Coordinators possess in-depth knowledge of clinical trial infrastructures in their respective regions, enabling them to identify operational barriers and opportunities in hospitals and clinical research units. This, combined with close inter-regional collaboration in the network, makes it possible to identify potential investigators in their region and respond to inquiries from life science companies quickly, efficiently, and competently, within five days.

Another important element is the close cooperation with the local representatives in the Trial Nation Legal Network and the Trial Nation Secretariat. The Trial Nation Legal Network is for instance, responsible for creating nationally pre-approved contract templates (CDA, CTA, and Clinical Investigation). A seamless initiation of clinical trials often depends on the swift and uncomplicated signing of contracts. Issues related to contracts and contract templates identified by Pharma and Medtech coordinators and the Trial Nation Secretariat are addressed in this forum, providing a platform for information sharing and resolution.

Together, the constructive and close collaboration between the Trial Nation secretariat and regional functions, united in a well-aligned matrix organisation, makes a solid foundation for supporting clinical trials in Denmark and building the necessary capacity in the Danish research environments.



Investigator identification



Responding to inquires from life science companies



Cross-regional coordination and knowledge sharing

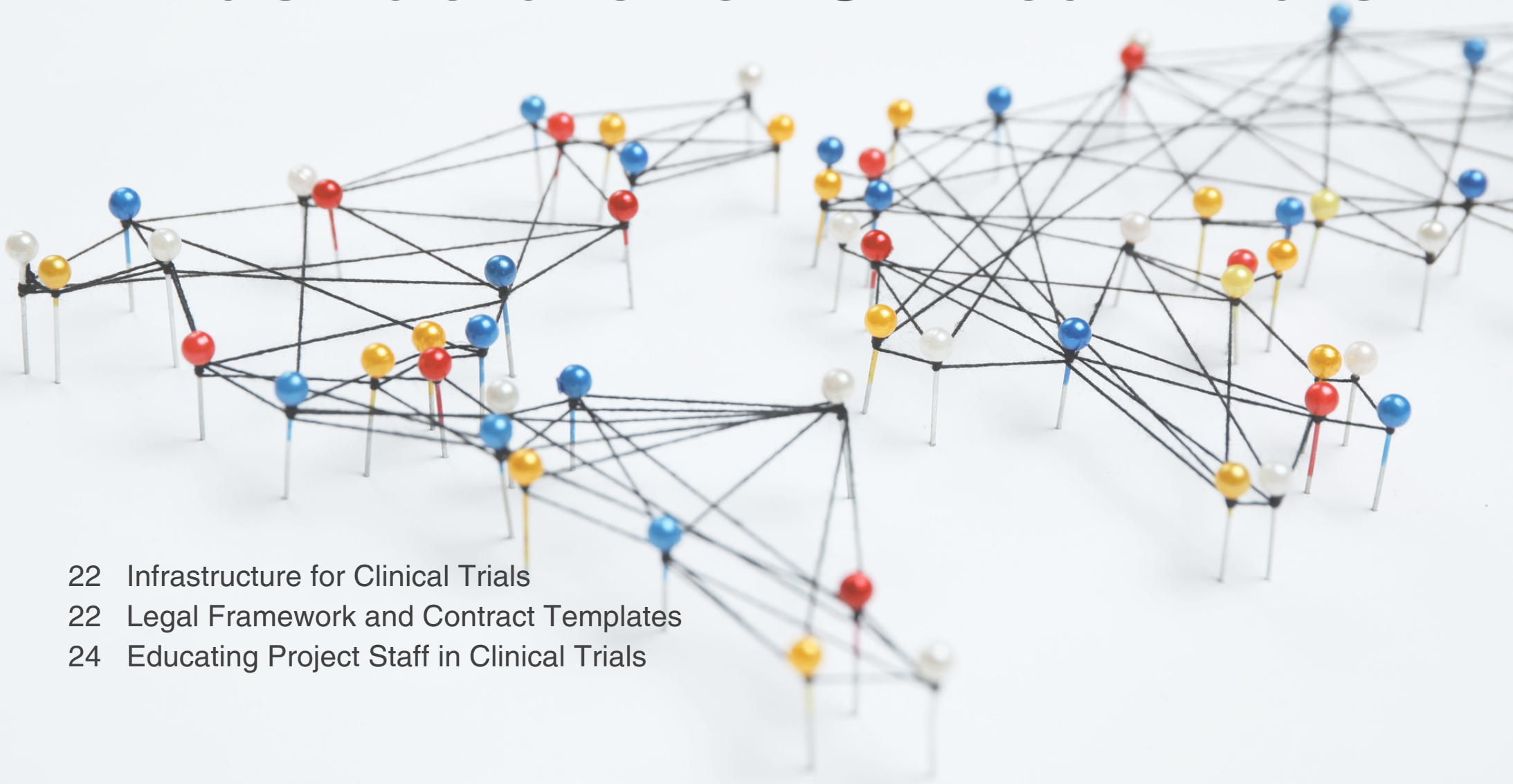


Collaborating with Trial Nation Legal Network



Advising clinical researchers about commercial clinical trials

Infrastructure for Clinical Trials



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Infrastructure for Clinical Trials

At Trial Nation, our focus is on enhancing infrastructure and framework conditions for clinical trials, along with fostering robust public-private collaboration. This involves nurturing effective collaboration between public and private entities and capacity building at clinics - critical elements for successful trial conduct.

To support the strong infrastructure for clinical trials, Trial Nation runs training for project staff with to provide up-to-date training as well as creating valuable contacts between different research units all over Denmark.

Another aspect is to support a short timeline for trial initiation, where the possibility for quick legal review of clinical trial and investigations agreements is important. Trial Nation facilitates the availability of pre-approved contract templates for this purpose. The chapter provides examples of Trial Nation's initiatives to support clinical infrastructures during 2023.

Legal framework and contract templates

Having approved contracts in place is a key element on the path to starting a clinical trial. Sponsors are therefore dependent on pre-approved templates that are easily implemented by the regions. Traditionally, contracting is a process that may take some time to get in place. The Trial Nation Legal Network creates and maintains Trial Nation confidentiality and clinical trials/investigation agreement templates which are approved nationally, i.e., in all Danish regions. Using the Trial Nation templates is the fastest way to have a contract in place for a clinical trial or clinical investigation in Denmark.

Furthermore, the Trial Nation Legal Network negotiates nationally approved company specific templates upon request. By using a pre-approved template, the legal approval process in the regions is handled within days instead of a lengthier negotiation period.

About the Trial Nation Legal Network

The cross-regional Network is represented by legal staff from each region. The scope is the development contract templates pre-approved by all regions and negotiation of company specific contract templates.*

The Regions have increased their focus on a timely first-review of clinical trial contracts and two regions has had a specific focus -and succeeded - to reduce backlog of individual contracts and set the scene for a continued efficient process. Neither the Trial Nation Legal Network, nor the legal functions at each region solicit general legal advice related to clinical research.

*Contracts for individual trials is the responsibility of the relevant legal unit(-s) in the regions and is out of scope for the network.

Updating templates for clinical trials in 2023

It has been a productive and busy year in the Trial Nation Legal Network. During 2023, the Network has update Trial Nation clinical trial agreement templates to make them applicable for both single-site and multi-center trials and investigations. The contracts reflect the nationally agreed interpretation of GDPR in clinical trials and investigations in accordance with the guideline on Data Roles in Research, issued in Danish by the Danish Data Protection Agency in July 2023. All templates are also updated to accommodate the EU-US Data Privacy Framework which came into effect during the summer of 2023. The Network tells:

“We have a very good collaboration in the Trial Nation Legal Network, and it is a meaningful collaboration as we can see that it makes a difference for clinical research in Denmark. During the year we have noted an increased used of the Trial Nation standard templates. This makes us happy and proud as it is a signal that the templates are seen as useful – and for us it is an important step to make it faster to set-up clinical trials in Denmark. We believe that the legal network is an important steppingstone to harmonize legal interpretations across regions.”

The template for Clinical Investigations has also been revamped during 2023 to reflect the medical devices regulation that has come into effect in recent years. Having a ready-to-use, all-regions approved template available is helpful, especially for smaller medtech companies who may have limited legal resources.

The update has been made in close collaboration with industry partners and Medtech Denmark. The collaboration brings value to Trial Nation and Medtech Denmark members alike.

Medtech Denmark and our member companies have been pleased with the responsiveness in connection with the update of the contract template, as demonstrated by Trial Nation's MedTech Coordinator and the Trial Nation Legal Network. Bearing in mind that medtech is different from pharma and therefore needed a dedicated contract template. Moreover, our members are very happy with the smooth handling of various inquiries provided by the Trial Nation MedTech coordinator.

Lene Laursen, Deputy Director General, Medtech Denmark

As the EU guidance and decisions on interpretation, on e.g., GDPR is an area under development, efficient and up-to-date contract templates continues to be a focus area in 2024.

Furthermore, the network has, together with the Trial Nation members and stakeholders, identified the need for a CRO three-party template and a non-interventional template. These will be developed during 2024 in collaboration with Trial Nation members.

Educating Project Staff in Clinical Trials

Project staff with updated capabilities and competencies is a key factor to both attract and drive clinical trials in the clinics, and Trial Nation's biannual two-day courses for project staff support and maintain the high standards in the Danish clinics. During the years clinicians and project staff have expressed a wish for project staff to receive updated and comprehensive education in the field of conducting clinical trials. However, existing courses in this domain tend to be expensive and may not always cater to the specific needs of operational staff.

To address the lack of courses for project staff, Trial Nation has taken the initiative to organise biannual courses aimed at enhancing the qualifications of project staff across clinical trial units in various fields including investigator initiated trials. This strategic effort started in 2018 and aims to better equip Danish clinics to actively participate in commercially funded clinical trials, potentially extending their participation to MedTech studies as well.

The courses are designed and planned by a team in Trial Nation with members from the secretariat and pharma/Medtech Coordinators, and feature experienced presenters who delve into crucial aspects of running a clinical trial, including:

- Good Clinical Practice (GCP)
- Legal frameworks
- Contract management
- Budget processes
- Decentralised Clinical Trials

The content is tailored to tackle real-world challenges encountered at clinical trial sites and the learning environment is based on concrete tuition and dialogue between presenters and participants. Charlotte Calov, Pharma/Medtech Coordinator and speaker at the courses notes the following:

"We observe a significant workload in the healthcare system, simultaneously with an increasing complexity in clinical trials, where, for example, new types of drugs and digitalization are rapidly advancing. It can be challenging for project staff to stay updated on all relevant rules and guidelines. In a course for project staff, I have the opportunity, based on many years of working with clinical trials, to share relevant knowledge with the participants. Hopefully, they can take this knowledge home and apply it in practice to enhance the quality of research. Additionally, the course provides a great opportunity for project staff to share experiences with others 'in the same boat.'"

*Charlotte Calov,
Head of the GCP-unit at Odense University Hospital, OPEN
and Pharma/Medtech Coordinator at Trial Nation*



In March and October 2023, Trial Nation hosted the course with great success. The demand is high and the courses have been fully booked within a matter of hours. Furthermore, the project staff praised the course in both the evaluations and to their colleagues, which further emphasises the continued need for these courses. One participant notes:

“As a project nurse, there is a lot to keep track of in connection with research projects, and at Trial Nation, there is good assistance available. A free course that I can certainly recommend other healthcare professionals to participate in. There is ample opportunity to clarify and discuss questions on the day amidst the many excellent presentations.”

Camilla Hostrup, Study Nurse, Psychiatry at Aalborg University Hospital

In 2023, we included a session on decentralised clinical trials to touch upon trends in the clinical trial settings. We will continue to keep the topics relevant for project staff working with standard clinical trials as well as to introduce new trends. Given the high demand for these courses, Trial Nation is proactively planning additional webinars that will cover emerging and relevant issues, ensuring that our educational offerings stay in sync with the evolving landscape of clinical research. Two courses are planned for 2024 to cater to the need in the project staff community.

Supporting Life science companies

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Supporting Life Science companies

A cornerstone in Trial Nation's operations is to support life science companies on clinical trials related topics. This encompasses both our member companies and those seeking guidance on various aspects in the clinical trial setting.

There is a great value in public-private partnerships in the Danish life science ecosystem, fostering open dialogue and knowledge sharing. We aim to unite with individuals from public and private organisation to tackle issues raised by any party and find sustainable solutions. This commitment is exemplified through some of our 2023 initiatives:

- Conducting workshops with member companies and clinicians to enhance collaboration amongst contract research organisations (CROs), clinical researchers, and life science companies on selected clinical trials processes.
- Organising workshops aimed at identifying best practices and overcoming barriers in e.g., contract negotiations and startup timelines.
- Hosting a series of webinars for member companies, serving as platforms for knowledge sharing and discussions. Pertinent topics like personalised medicine and health data with experts Danish Genome Center, sessions on patient referrals across borders, featuring paediatric researchers, and discussions on use of AI in clinical trials has been featured.

This chapter touches upon some of these initiatives and explore a case study illustrating how a proactive approach to public-private collaboration can positively impact departmental clinical trial processes

New Member Companies in 2023

In 2023, Trial Nation welcomed three new member companies: Daichii-Sankyo Nordics, NMD Pharma and Evnia, each bringing expertise in diverse areas of life science to Trial Nation. As member companies, they receive invitations to events about e.g., clinical trials and fostering public-private collaboration. They hold voting rights at our general assembly, and benefits from personalised guidance from Trial Nation to support them in navigating the landscape of clinical research in Denmark. See all members of Trial Nation [here](#).



Daiichi Sankyo Nordics is part of Daiichi Sankyo, a global pharmaceutical company with a presence in more than 20 countries and employing over 16,000 individuals.

In 2018, Daiichi Sankyo Nordics was established in Copenhagen. The Nordic organisation primarily focuses on medicines within oncology and hematology. Daiichi Sankyo has a strong tradition in clinical research. The value of clinical trials is also the reason why the Nordic organisation chose to become a member of Trial Nation:

“Daiichi Sankyo Nordics’ ambition is to increase the number of clinical trials in Denmark within oncology and hematology. To achieve this goal, Daiichi Sankyo Nordics sees membership in Trial Nation as an important strategic partnership to attract clinical trials to Denmark.”

Martin Ahlgren, Nordic Medical Director,
Daiichi Sankyo Nordics



NMD Pharma is a clinical-stage biotech company founded in 2015, headquartered in Aarhus, Denmark. NMD Pharma focus on improving outcomes for patients suffering from neuromuscular disease and develops novel treatments to improve muscle function and quality of life for patients with neuromuscular diseases. Currently, NMD Pharma is performing several clinical trials with CIC-1 inhibitors in early clinical trials, which includes sites in Denmark. Membership of Trial Nation is a natural part of NMD Pharma’s engagement in the ecosystem of clinical research in Denmark.

“The membership of Trial Nation aligns perfectly with our strategy. It provides us with a valuable network and insights into the clinical research ecosystem we operate within, allowing us to share our experiences and perspectives on the challenges and advantages of conducting clinical research in Denmark.”

Thomas Kongstad Petersen, Chief Operating
Officer NMD Pharma



Evnia proudly joined Trial Nation in 2023. Evnia is a regulatory and clinical affairs specialist organisation, founded in 2016. It has a unique positioning in Real World Evidence creation for Medical Devices and IVDs since it also operates its own clinics and clinical network. Through the last decade Evnia has consistently enabled manufacturers in Europe, USA, and Asia to remain in compliance with EU/MDR and FDA requirements in clinical, regulatory and technical documentation areas.

“Evnia’s key expertise lies within the field of medical device & IVDs and specifically regulatory and clinical activities affairs. Given our long-term commitment to Real World Evidence generation, joining Trial Nation was a natural development in order to contribute towards a healthy eco-system of knowledge exchange and Clinical – Regulatory excellence in Denmark.”

Efstathios Vassiliadis, CEO, Evnia

A Triangle of Collaboration: CRO Companies, Sponsors, and Investigators

Sponsor companies often engage CRO companies (clinical research organisations) as full-service or partial-service partners for conducting clinical trials. The level of contractual engagement affects the degree of collaboration and the roles of the CRO company and the sponsor company. Effective partnerships between CRO companies and sponsors are key, as well as a well-functioning collaboration with investigators.

All three parties share a common goal of producing high-quality and relevant clinical data. It is for the benefit of present and future patients, as well as promoting Danish sites as frontrunners in conducting clinical trials.

Several companies within the Trial Nation CRO-Network, have highlighted the need for exploring the triangle of collaboration in commercial clinical research among CRO companies, sponsors, and investigators/clinical research units.

In September 2023, a Trial Nation CRO-Network meeting was convened, inviting sponsor companies and investigators from clinical research units. Each party was asked to deliver a brief presentation and address some questions regarding this triangular collaboration, focusing on challenges, successes, and ideas for enhancing collaboration.

There was a constructive dialogue and a willingness to share experiences and ideas, as well as willingness and understanding of each other's work processes. By the end of the meeting a joint list of focus areas for a better triangular cooperation was ready:

- Ensure effective communication throughout the "triangle," maintaining cooperation with equality and mutual respect, striving to enhance each other's performance.
- Emphasise the significance of the site initiation visit, focusing on mutual alignment of expectations and collaboration.
- Recognise that a one-size-fits-all approach may not be suitable and remain open to making minor adjustments where possible.
- Revisit sub-processes to identify opportunities for mutual assistance in streamlining processes

The collaboration is beneficial for all parties involved, and additional meetings will be arranged as necessary in the future. Focus areas have been developed for each of the three parties involved in the collaboration and shared among them.

Optimising Budget Negotiation and Start-up Timeline

Budget Negotiations

A robust clinical trials budget negotiation process is important, especially considering the increased complexity of clinical trials protocols, which can lead to misunderstandings and negatively impact collaboration and efficiency. Therefore, it's essential to enhance processes and demonstrate a transparent best-practice approach for all parties involved. At Trial Nation, we have collaborated closely with CROs, sponsors, and clinicians to optimise the process flow for budget negotiations.

Following a meeting on negotiation processes in 2022, Trial Nation reached out to clinicians, sponsors, and CROs in early 2023 to share key findings. They emphasized the need for improved communication,

transparency, and understanding of each other's processes to enhance negotiations. As a result, a joint proposal for a "good clinical negotiation process" was developed (see Figure 24). The process is available at [Trialnation.dk](https://www.trialnation.dk) along with a summary of findings. Several parties urged the Trial Nation secretariat to continue this initiative, and in November 2023 Trial Nation member companies were invited to a new meeting focusing on improving references for budget negotiations and start-up timelines.

Companies stressed the importance of transparent pricing and advocated for transparent cost breakdowns. They also wished for a consistent pricing across regions. The rates provided by the Medicinal Council (Medicinerådet) and links for rates in various diagnostic areas were suggested as starting points. In 2024, we will further investigate possibilities for optimising budget negotiation.

Overview of Approval Process and Contract Negotiation Process

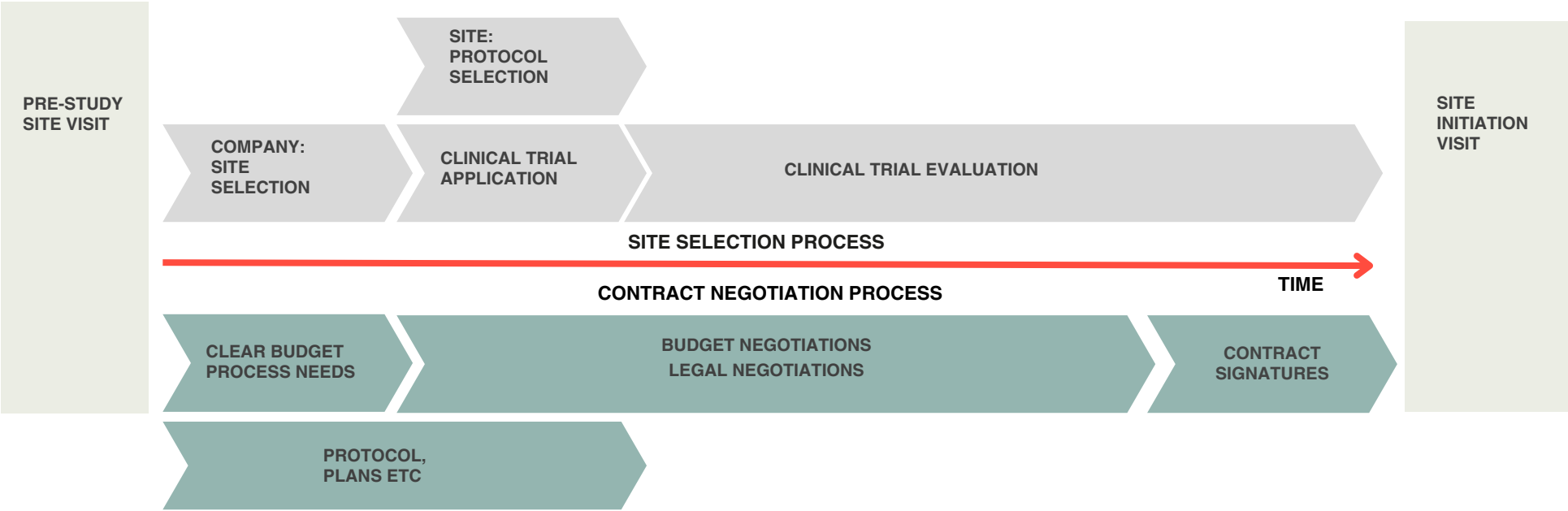


Fig. 25: Overview of Approval Process and Contract Negotiation process from pre-study visit to site initiation visit

Start-up Timelines for Clinical Trials

Clinical trial start-up timelines is a significant area of interest, as they serve as an important competitive factor for countries and clinics. Shorter start-up timelines enable sponsors and clinics to conclude clinical trials early or use the recruitment period in full, thereby enhancing the likelihood of meeting agreed-upon recruitment targets. Short study start-up timelines in Danish clinics are thus preferred. However, there are currently no publicly available references for start-up timelines in Denmark or in the countries we typically compare with. Addressing this knowledge gap on start-up timelines is vital to position Denmark in a highly competitive environment.

This was a topic on meetings with life science companies during 2023. At Trial Nation we continue to have this top of mind, and find a way to agree upon a common definition on start-up timeline as well as obtain robust data to close the knowledge gap since it is a key factor for sponsors choosing countries and sites.

Trial Nation now awaits input from stakeholders on the best way to move forward to address this important topic, given that data is not readily available in the public domain.



Meeting with members of Trial Nation on contract negotiation processes and start-up timelines for clinical trials in Denmark, November 2023

Case: Improving Process Flows for Commercial Clinical Trials: Department of Oncology, Aarhus University Hospital

The cooperation between clinics and life science companies is an integral part of maintaining a high level of public-private collaboration. In the Department of Oncology at Aarhus University Hospital, they saw a decrease in commercial clinical trials over time and identified lacks in the process flow relating to clinical trials as a possible cause. As a response, the department management set out to further investigate the root causes. The investigation ended in late 2022 and new processes has been implemented during 2023 already leading to positive changes.

To investigate the gap between the department's intentions to attract commercial clinical trials and the reality three focus areas were identified:

How did life science companies perceive the clinical trial performance at the Department of Oncology at Aarhus University Hospital? In dialogue with Trial Nation, ten life science companies were invited to share their thoughts on the clinical trial process flow at the Department of Oncology at Aarhus University Hospital as well as suggestions for improvements.

How did project staff view the internal process flow at Aarhus University Hospital? Project staff were invited to share their thoughts on the process flow and suggest improvements in smaller workshops. Follow-up workshops were held with department management to discuss the findings, leading to initiatives such as a smoother prioritisation process for clinical trials being implemented during 2023.

What motivates clinical researchers to conduct clinical trials at the Department of Oncology? Chair Professor Signe Borgquist launched an investigation into the motivations of clinical researchers to conduct both commercial and non-commercial clinical trials. Several qualitative interviews with clinical researchers were conducted in collaboration with Aarhus University, Roche, and Trial Nation

The key findings revealed that the primary motivation for all clinicians was to improve patient care. Demotivating factors included complex protocols poorly aligned with clinical practice, cumbersome processes, low expected patient recruitment per site, and a lack of influence on trial design. Overall, the investigation and its findings have contributed to improvements in clinical trial processes and provided a deeper understanding of the motivational factors driving clinicians to conduct trials. Chair Professor, Signe Borgquist notes:

"Public-private collaboration has moved up management's agenda. The change of flow in processes has resulted in smoother and faster processes for the initiation of clinical trials and a renewed interest from the industry, initiating 6 commercial clinical trials in 2023 in the department versus 1 the year before. My impression is that the changes has resulted in an increased interest in performing clinical trials at the department."

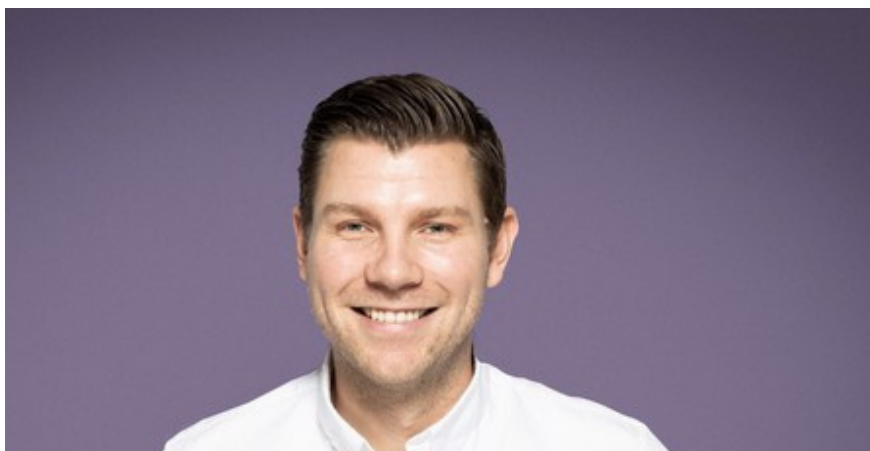
Signe Borgquist, Chair Professor, Department of Oncology
Aarhus University Hospital



For Christian Juul-Nielsen, Senior Innovation Partner at Roche, the collaboration with the Department of Oncology at Aarhus University Hospital provides insights into the conditions necessary to maintain or establish a strong public-private collaboration.

"The collaboration has uncovered the investigators key motivation for performing clinical trials at Aarhus University Hospital. We hope both Aarhus and other Danish hospitals will build on this knowledge and repeat the investigation to ensure high investigator motivation for clinical trials. It is a key factor - also for the industry."

Christian Juul-Nielsen, Senior Innovation Partner, Roche,



At Trial Nation, we are pleased to contribute to minimising gaps in public-private collaboration and applaud the initiative by the Department of Oncology at Aarhus University Hospital to reach for an inclusive and collaborative approach to investigate a problem affecting the department as well as life science companies.

International Outlook



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International Outlook

Awareness from international life science companies and public organisations about Danish clinical trial capabilities is a priority.

Trial Nation, including several Trial Nation Centers participate in international collaborations during 2023, such as EU projects on clinical research and infrastructures for clinical trial. Center for Paediatric Medicine (DanPedMed) is a good example taking part in a large EU project – the IMI-project Conect4Children.

Another aspect of international outlook is our close collaboration with organisations such as Invest in Denmark, Copenhagen Capacity, Innovation Center Boston, Healthcare Denmark and the Health Diplomacy on a shared agenda: Positioning Denmark on the international stage as a leading country in life sciences. Companies considering Denmark to place their clinical trials often require guidance on framework conditions and infrastructure in Denmark, as well as specific knowledge about Danish capacity within a disease area. Trial Nation's ability to draw on our extensive professional network of clinicians, regional colleagues, and other organisations, is a fast lane to addressing the often very specific questions life science companies have.

In this chapter we will touch upon international collaboration in conducting of clinical trials in children and adolescents as well as Trial Nation's international engagements to attract clinical trials to Denmark.

Clinical Trials in Children and Adolescents - Collaboration is Key

Clinical trials in children and adolescents rely on collaboration across borders. In pediatric and adolescent disease areas where the number of patients often are small, international facilitation of clinical trials is important to secure successful recruitment. Hence, fostering collaboration with other Nordic and European countries becomes indispensable for Danish clinics, and DanPedMed's international approach is pivotal. DanPedMed is an active member of several organisations that addresses topics relating to clinical trials within children and adolescents at an international level, e.g., NordicPedMed and c4c. It leads to opportunities to take part in projects and working groups aiming at improving processes for clinical trials for the benefit of patients and sites.

Nordic countries joins forces in NordicPedMed

DanPedMed is a driving force in NordicPedMed, with Dr René Mathiasen as Chair and National Coordinator of DanPedMed Pernille Skovby as secretariat. It is a Nordic network of investigators, centers, and national networks with recognized expertise in performing pediatric clinical trials. The aim is to increase cooperation on a Nordic and European level and position Denmark, Finland, Iceland, Norway and Sweden as a uniform, transparent option for companies placing clinical trials in the pediatric setting.

Conect4Children (c4c)

DanPedMed is actively involved in c4c, a pan-European project dedicated to enhancing the infrastructure and procedures for pediatric clinical trials across Europe. Through c4c, clinical trials are coordinated effectively and distributed to suitable sites across the EU.

The membership of c4c ensures that Danish sites are considered when pediatric and adolescent-targeted clinical trials, coordinated by c4c, are placed. By coordinating with other clinics in Europe it ultimately increases the chances of a robust patient population. DanPedMed offers swift and proficient responses to feasibility inquiries from c4c, because the Center has the expertise and insight required. In 2023, Danish sites, through their engagement with c4c, actively participated in three international pediatric studies.

ENPR-EMA

Parallel to the engagement with NordicPedMed and c4c, DanPedMed also contributes to ENPR-EMA (European Network of Paediatric Research at the European Medicines Agency). Its purpose is to enhance the development of medicines for children by promoting high-quality research and collaboration among stakeholders involved in pediatric healthcare. In 2023, DanPedMed has been appointed to participate in two working groups under ENPR-EMA:

1. *'Paediatric research nurses': A survey of employment, qualifications and Training of Research Nurses working on Paediatric Studies in European Countries.* It aims at determining the similarities and differences in the employment conditions, qualifications and training of nurses employed in pediatric research. The working group investigates and maps qualifications of research nurses across the EU. There are synergies between ENPR-EMA and c4c in this project because both organisations strive for better infrastructure for clinical trials for children and adolescents. c4c is investigating how they can facilitate e.g. educational webinars designed to close gaps that the survey may identify. This work will continue in 2024.

2. 'Identifying and mapping existing quality criteria and standards for paediatric sites.' Denmark chairs this working group. It aims to provide a comprehensive overview of existing quality criteria and standards applicable to paediatric clinical trial sites. Having this comprehensive overview of quality criteria and standards for pediatric sites in the EU enables sites to work systematically to achieve all relevant requirements.

Denmark has contributed to a third working group, delivering data to "Cross-border clinical trials" that analyses the obstacles children and families face when a child participates in cross-border clinical trials. The Danish perspective on this subject is based on years of experience with cross-border referrals of pediatric patients in clinical trials, thereby providing first-hand insights into barriers and best practices. Karsten Nysom, MD, Ph.D., from the Department of Pediatrics and Adolescent Medicine, University Hospital Rigshospitalet, comments:

"The Department of Paediatrics and Adolescent Medicine at Copenhagen University Hospital – Rigshospitalet has a decade-long experience in having paediatric patients referred across borders for clinical trial participation, in particular patients with inborn errors of metabolism or with cancers. We draw on that experience in our guidance of other colleagues on how to facilitate this, e.g. by close coordination of visits with the patient and family, and by continuously updating the local referring paediatricians about the patient's situation, making it a true shared care experience."



Karsten Nysom, MD, Ph.D at the Department of Paediatrics and Adolescent Medicine, University Hospital Rigshospitalet

Overview: Center for Pediatric Medicine, DanPedMed's International Public-Private Engagements

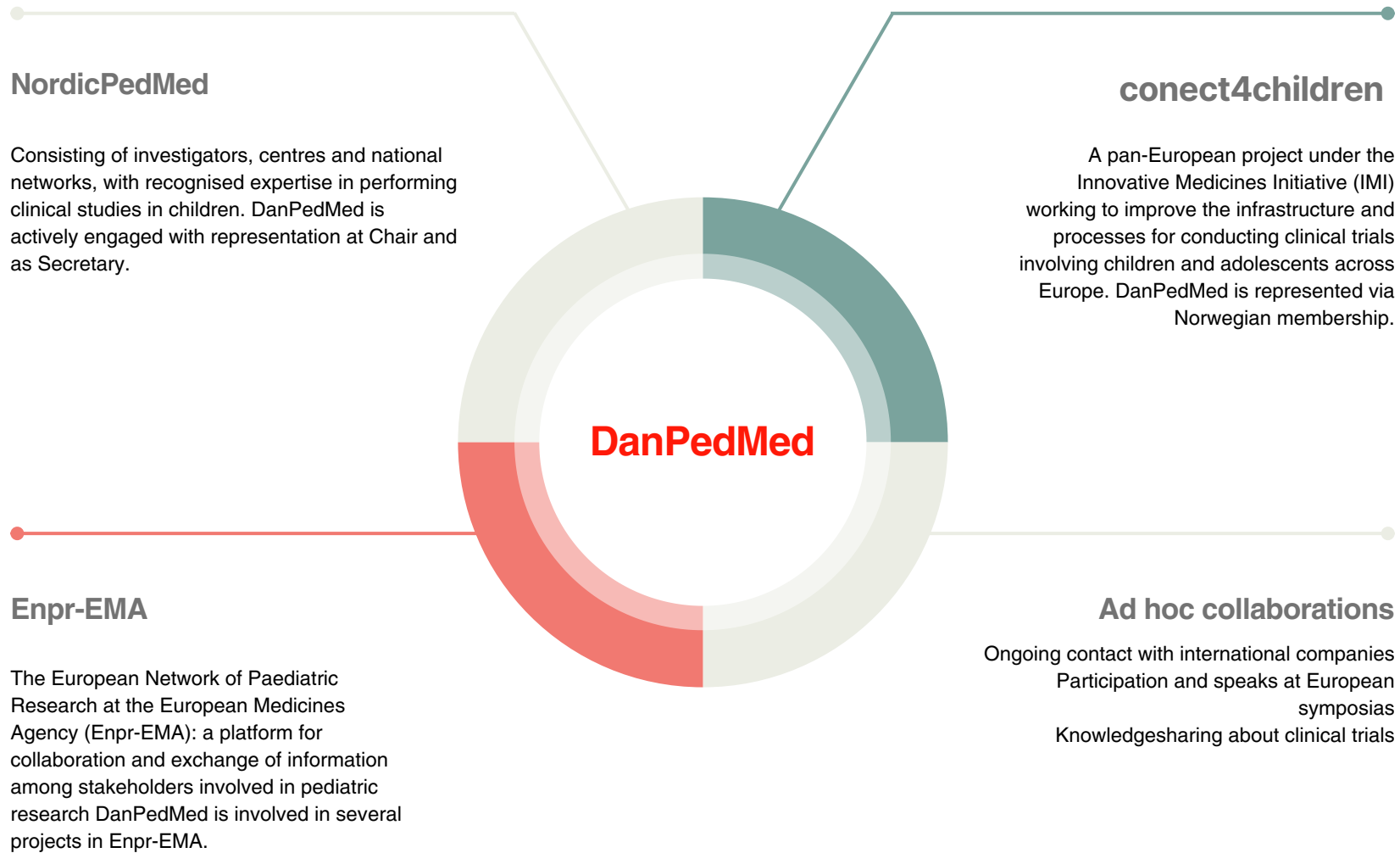


Fig. 26: Center for Pediatric Medicine, DanPedMed's International public-private engagements

Collaborating with other Organisations

Trial Nation collaborate with several other organisations on attracting clinical trials to Denmark. Invest in Denmark, Copenhagen Capacity, Healthcare Denmark and the Innovation Centers such as Innovation Center Denmark in Boston are important partners. The specialised knowledge of each organisation has a great synergy effect when we meet with companies, organisations and international delegations to promote the Danish life science ecosystem.

Invest in Denmark

Since its inception Trial Nation has continuously developed and expanded the collaboration with Invest in Denmark to join forces in attracting clinical trials to Denmark. Invest in Denmark's Life Science team and Trial Nation are in close contact about potential opportunities to present Danish clinical trial capabilities within medical devices or pharmaceuticals. The collaboration is primarily centered around roundtables and individual meetings with companies' R&D departments, who are looking for possible clinical trial sites in Europe. We work both with large and medium sized life science companies who are interested in the opportunities in the Danish life science.

Trial Nation's capabilities lie in its ability to address disease and site-specific inquiries from companies. Leveraging the extensive expertise within Trial Nation's Centers, Networks, Trial Unions, as well as regional Pharma and Medtech Coordinators, we provide qualified responses to meet the diverse needs of our partners. The Trial Nation structure allows for the possibility to interact directly with potential sites and investigators. Clinicians from Trial Nation Centers and Networks are often invited to these meetings to provide detailed insights and in-depth discussions related to the relevant disease area(-s), which is highly appreciated by the companies.

In 2023, Trial Nation and Invest in Denmark organised several meetings with companies who had no prior knowledge of the opportunities in Denmark. Here, we introduced Denmark and the competences in various disease areas. In other meetings the disease area had been defined beforehand - often based on specific request from the company or the research clinicians. Clinicians show a strong interest in participating in roundtable as well as individual meetings, providing their extremely useful perspectives.

“The collaboration between Invest in Denmark and Trial Nation is highly valued. We complement each other: Invest in Denmark has access to decision makers at large foreign-based life science companies through our presence at official Danish representations around the world, while Trial Nation brings the knowledge of the clinical research environment and has the direct connection and collaboration with the researchers in Denmark. Together, we make it easier for foreign life science companies to discover opportunities for doing research in Denmark.”

Vanessa Vega Saenz, Director, Invest in Denmark, Ministry of Foreign Affairs of Denmark

Case: Long Term Effort Leads to new Opportunities - Moderna

A close-knit collaboration between Innovation Center Denmark in Boston, Invest in Denmark, and Trial Nation, along with a virtual meeting during the pandemic, served as the starting point for a partnership with Moderna. The meeting, held in March 2022, brought together representatives from Moderna's headquarters, the Center for Infectious Disease and Immune Modulation, Trial Nation, and Invest in Denmark, laying the groundwork for Danish participation in Moderna's Covid-19 vaccine trials.

In 2023, a new opportunity to collaborate arose when representatives from Moderna's HQ team in Virology reached out to Trial Nation and Invest in Denmark to discuss further potentials for conducting vaccine trials in Denmark. Trial Nation's Centers, Networks, and Trial Unions form a robust infrastructure of knowledge across various disease areas. Therefore, it was possible to organise a meeting on short notice in Copenhagen, with six representatives of Moderna's Infectious Disease Development Leadership Team, two clinicians from the Center for Infectious Disease and Immune Modulation, Trial Nation, and Invest in Denmark.

At the meeting, Moderna's representatives engaged in discussions with investigators from Danish clinics regarding topics crucial to their clinical trials. They received prompt and concise information on subjects such as population demographics, access to participants, standard of care, utilisation of healthcare data in clinical trials, and possibilities for long-term follow-up.

These topics were briefly discussed and aligned during the meeting, which created a good basis for faster decision making.

"It has been very positive experience meeting with Trial Nation. In April 2023, we had the opportunity to meet in person with highly competent clinicians with expertise in virology and clinical trials. Having the right people sitting together enable us to align on the opportunities and potential barriers to conducting clinical trials in Denmark. It provided us with rapid clarity on the possibilities, and the end-result was extremely positive and of great benefit to the Moderna team."

SVP Jacqueline Miller and VP Robert Paris,
Infectious Disease Development Leadership Team, Moderna

Moderna starts new clinical trials in Denmark in 2024. The positive outcome is a result of the shared focus on attracting clinical trials to Denmark and we are excited to continue the collaboration in 2024 and forward. Medical Lead in Trial Nation Center for Infectious Disease and Immune Modulation is also pleased and notes:

"Trial Nation has once again been an invaluable initiative this year in putting Denmark on the map when it comes to attracting sponsored drug trials. In our center for 'Infections and Immunomodulation,' particular attention has been drawn to immunomodulation in the form of new vaccines."

Lars Østergaard, Professor, MD and Medical Lead in Trial
Nation Center for Infectious Disease and Immune Modulation

Clinical Trials In the Future

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FUTURE

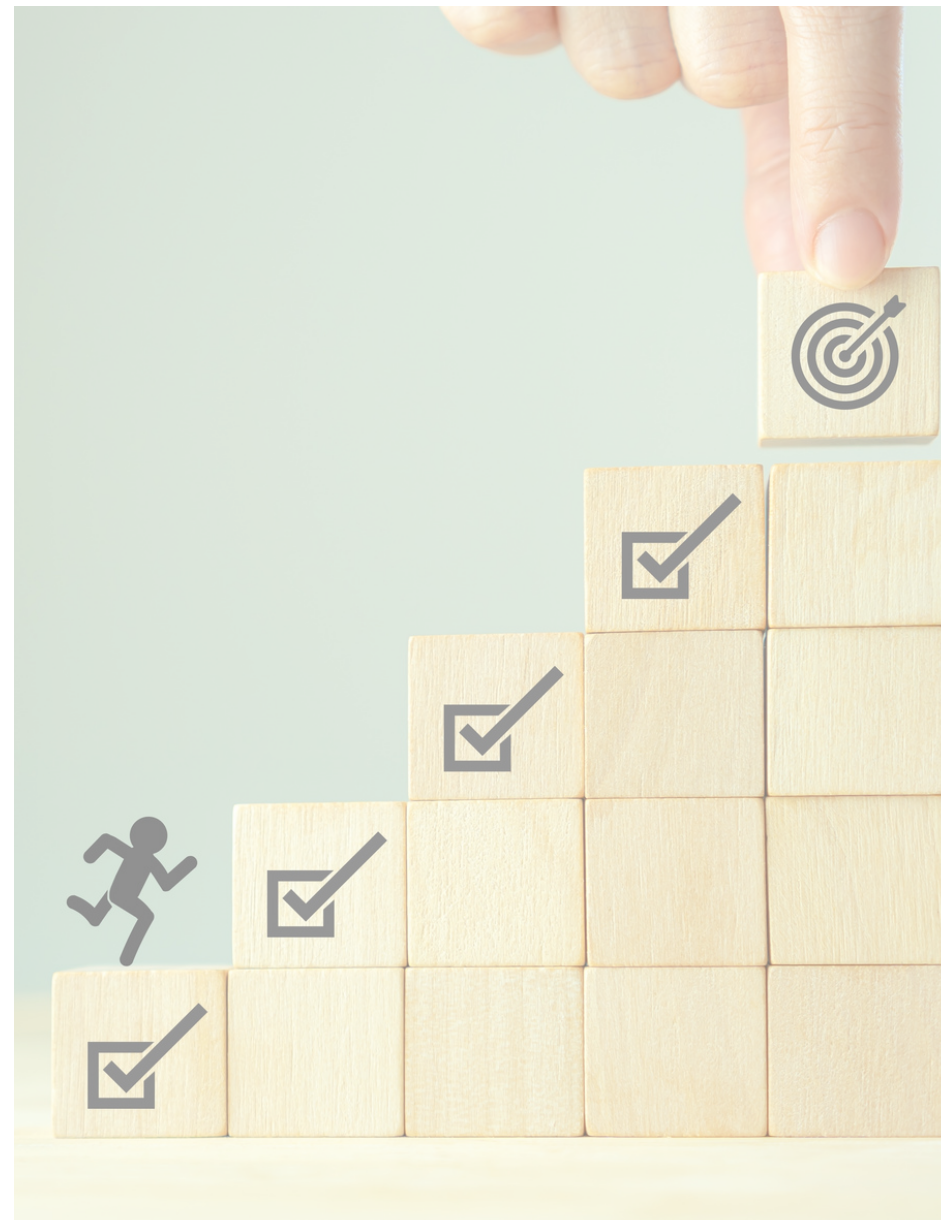
Clinical Trials in the Future

What does the future of clinical trials look like? How do we ensure that Denmark remains an attractive place to perform clinical trials in? And finally, how do we make sure that Danish patients have access to the clinical trials that provides the treatment of tomorrow today? Looking into the future, we expect that several global trends will impact the clinical trial landscape and the way we conduct clinical research – thus continuous development of the Danish infrastructure to support clinical trial conduct is a requirement.

Trends in fast development such as the use of big data, artificial intelligence and machine learning coupled with the adoption of new technologies will impact the way we conduct clinical trials. An overlying trend is the topic of personalisation – personalisation in development of new therapeutics, in the use of trial designs favouring patient-centric approaches and personalisation as a mean to build infrastructures for clinical trials that have the patient in focus.

It is top of mind for us at Trial Nation to be at the very forefront, securing optimal framework condition for conducting clinical trials in Denmark – including future clinical trials. During 2023, Trial Nation have focused on ways to drive and support the transition towards a more personalised and patient-centred approach in clinical trials. This includes building infrastructures in Denmark that supports ways of conducting clinical trials in the near future as well finding solutions for better and easier patient access and information about clinical trials. It entails better overview, access to and conduct of clinical trials in Denmark moving forward.

Trial Nation is leading the PACT-project (Decentralised Patient-centred Clinical Trials), as well as taking part of an working group about Advanced Therapeutic Medicinal Products (ATMP) and committed to the development of a national overview of clinical trials for the benefit of Danish patients. Together, the initiatives aims at building sustainable, national infrastructures for conducting clinical trials in Denmark.



Decentralised Clinical Trials (DCT)

Denmark is moving full speed ahead to become the global DCT frontrunner. In Denmark, the clinical trial ecosystem has demonstrated a readiness for decentralising clinical trials, which is depicted in the latest version of the EMA DCT recommendation paper.¹

Trial Nation is leading a powerful public-private partnership of Danish life science stakeholders to innovate and develop Denmark as the leading DCT nation. The PACT-project (Decentralised Patient-centred Clinical Trials), supported by the Innovation Fund Denmark, will create a public-private framework that supports implementation of patient-centred decentralised clinical trials in Denmark.

About the PACT-project (Decentralised Patient-centred Clinical Trials)

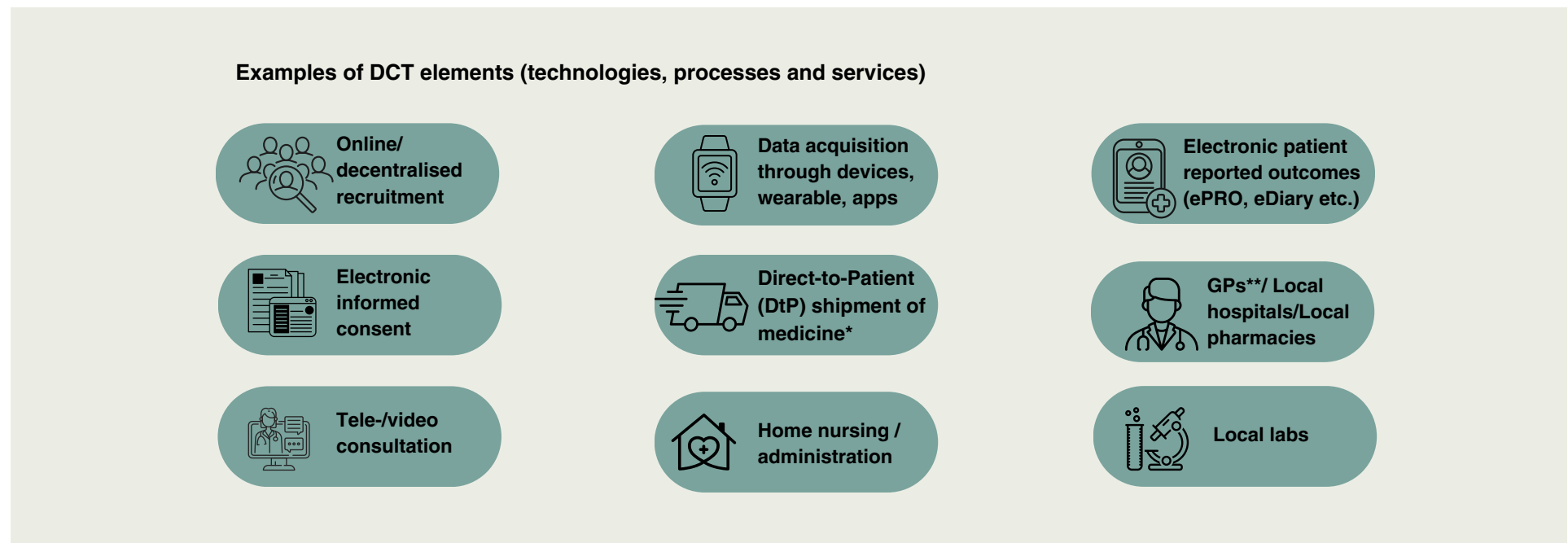
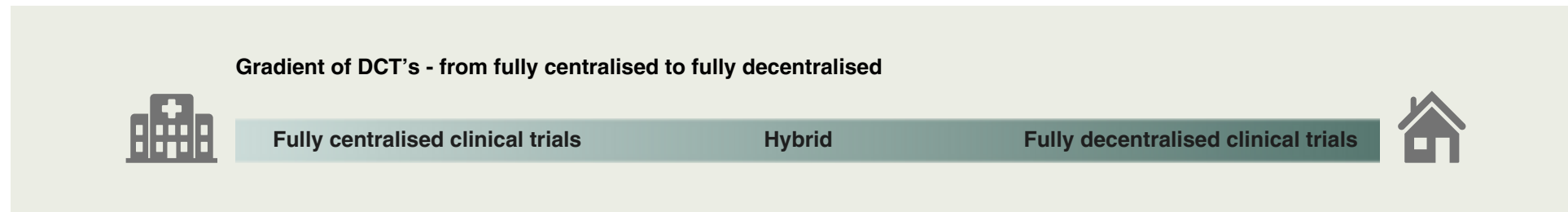
- A public-private partnership of Danish life science stakeholders to innovate and develop Denmark as the leading DCT nation.
- A €5M project, supported by the Innovation Fund Denmark and lead by Trial Nation
- The overall aim is to make the clinical research more available for Danish patients and citizens.
- The project focus on:
 - Implementing a national overview of all clinical trials in Denmark
 - Identifying and mapping public and private patient recruitment initiatives and opportunities.
 - Creating a public-private framework that supports implementation of decentralised clinical trials in Denmark

PACT-Partners



Definition of Decentralised Clinical Trials

There exist various definitions of DCTs. In the PACT project we align with the definition by Decentralized Trial Research Alliance: *A clinical trial utilizing technology, processes, and/or services that create the opportunity to reduce or eliminate the need for participants to physically visit a traditional research site.*² The definition depicts that decentralised clinical trials are not “all or nothing”. DCTs exist in a spectrum and does not only entail fully decentralised clinical trials, but also include clinical trials using few decentralized elements.



² dtra.org/priorities-and-initiatives

*Investigational medicinal products ** General practitioners

Development of supportive (DCT)-infrastructures in Denmark

Clinical trials are expected to become gradually more digitalised and decentralised enabling increased patient empowerment, patient diversity, patient retention, as well as data that is more representative of the real-world. Thus, a core element in the PACT-project is to create a public-private framework that supports implementation of decentralised clinical trials in Denmark. This will be done by creating and implementing operational setups and logistics for general use of decentralised elements in clinical trials.

In 2023, we have been working dedicated on unfolding potentials and barriers, related to operational aspects of DCTs, within selected focus areas:

- Considerations for DCT implementations
- Recruitment strategies and possibilities
- Direct-to/from-Patient (DtP/DfP) shipment of investigational medicinal products (IMPs)

This work will continue in 2024 including new initiatives such as surveillance of trial participants safety in a DCT-setup, focusing on investigator oversight and barriers related to delegation of tasks to multiple third parties.

Formalised partnerships supporting the DCT agenda

In 2023, Trial Nation further engaged in multiple collaborative initiatives to develop solid framework-conditions for decentralised clinical trials in Denmark. We have formalised several collaborations, including:

The Research Unit for General Practise

To accommodate future needs, where more patients are expected to be seen outside of the hospitals (e.g. by general practitioners), Trial Nation engage in regular meeting biannually, with the Danish research units for general practices to investigate opportunities for a stronger collaboration on e.g. DCT. Exploring potentials for a stronger collaboration is of high interest to secure the establishment of essential infrastructures to support the conduct of clinical trials closer to the patients.

The Association of Danish Pharmacies

The collaboration aims to develop a concept/framework for the involvement of local pharmacies in the conduct of clinical trials, mapping opportunities and barriers and planning next step.

The PhaseV Project

A Grand Solution Project, supported by the Innovation Fund Denmark, aiming to e.g. develop and validate a scalable, digital platform for efficient, decentralised recruitment. The collaboration will focus on knowledge sharing and exchange of experiences around DCT's at an operational level, and include each other in relevant contexts (such as meetings, workshops, working groups, etc.). We look forward to continued dialouge in 2024

Facilitation of the Danish DCT-Dialogue Forum

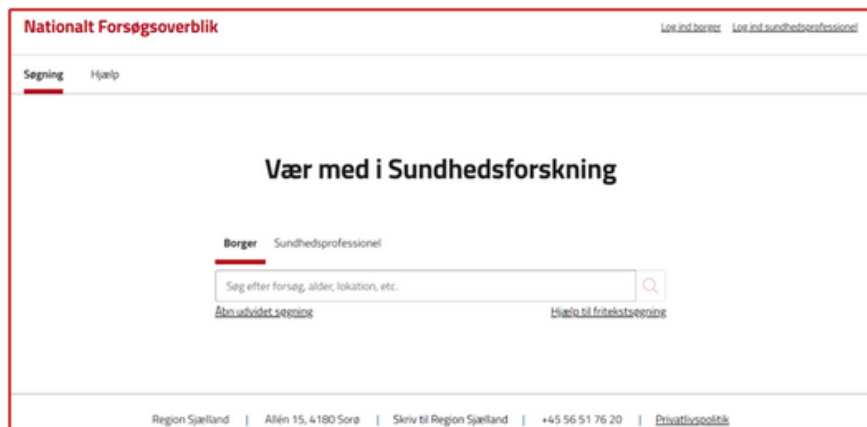
To further accommodate the DCT-agenda, Trial Nation facilitates the DCT-Dialogue Forum in partnership with the Danish Medicine Agency. The forum gathers authorities, patient representatives, clinicians, researchers, GCP units, local and hospital pharmacies, and life science industry, and meets biannually to discuss best practice and obstacles for DCTs in Denmark. The forum is a fast-track lane to raise issues relating to DCT framework conditions and investigate and propose solutions. This unique 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.¹ In 2024, Trial Nation will continue to drive the transition towards a more personalized and patient-centred approach in clinical trials – utilizing decentralised elements in clinical trials.

³ health.ec.europa.eu/system/files/2023-03/mp_decentralised-elements_clinical-trials_rec_en.pdf

National Overview of Clinical Trials

To meet the future requirements of a more patient-centric approach to clinical trials, Trial Nation, together with committed partners* are developing a National Overview of Clinical Trials that provide patients and healthcare personnel with up-to-date information on clinical trials (medical device and pharmaceuticals) performed in Denmark, including their status and location.

Through the year of 2023 we have worked dedicated on developing the platform. During the year the data landscape for automated data input has changed, which has led to delays in the implementation of the overview. We expect to initiate test and implementation of the National Overview of Clinical Trials in 2024, temporarily based on a manual approach.



*National Overview of Clinical Trials project partners: Trial Nation, The Danish Ministry of the Interior and 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 Center

Advanced Therapeutic Medicine Products

The use of advanced therapy medicinal products (ATMPs) such as gene, cell, and tissue-based therapies offer groundbreaking new opportunities for treatment of disease and injury. However, the use of ATMPs as treatment possess great infrastructural demands on the healthcare system, and public decision-makers are often faced with challenging issues related to less comprehensive clinical data, high expenses, sustainable payment models and organisational conditions to enable the uptake of these treatments. These challenges put pressure on pharmaceutical companies, public authorities, healthcare payers and other stakeholders to develop joint solutions.⁴

In Denmark, a working group was established in Spring 2023 to develop a national setup of clinical trial infrastructure for ATMPs and secure a smooth implementation in Denmark. The working group include key public stakeholders and Trial Nation e.g. Amgros, Danish Regions, hospital pharmacies, the Danish Medicines Agency, the Ministry for the Interior and Health, the Danish Medicines Council, Danish Comprehensive Cancer Center etc.

The working group has during 2023 identified barriers and discussed possible solutions to improve the implementation of ATMPs and advocated for an ATMP initiative as part of the government's upcoming Life Science Strategy.

⁴Vive: "Avancerede terapier (ATMP) En kortlægning af potentialer og udfordringer ved introduktion af nye behandlingsmuligheder i Danmark"

Appendix A

Highlights of external activities in Trial Nation 2023

Organisational activities:

Trial Nation general assembly, April
Patients across borders meeting,
Meeting with Danish Medicines Agency - 1 year of CTIS, January
Neurological network start

Framework conditions:

The Trial Nation standard templates for Clinical Trials Agreement and Clinical Investigation Agreement have been updated to accommodate the EU-US Data Privacy Framework,
ATMP working group, August
OSCAR advisory board
One year of CTIS - Meeting with Danish Medicines Agency, January
Working group in clinical trials, March
Referencegroup: Health Cluster. May
Danish Data Protection Agency: Special committee for research, March and October
The Danish Association of the Pharmaceutical Industry - Clinical committee, September
CRO-network meeting, May-June-September

National Projects (part of PACT):

DCT - Dialouge Forum, March
Cooperation in general practice, All year
PACT Workshop
PACT and Phase V

Media:

Invest in Denmark publishes report which shows that Trial Nation is reason nr. 1 to place medtech clinical trials in DK, July

Promoting Danish Clinical Research:

Cooperation between Center for Dementia and IQVIA
Denmarks best clinical trials, May
Company meeting: Presentation of Network for Psychiatry, September
Key note speak at International Clinical Trials Day Conference in Dublin, May
Co-organiser of Synapse Winter School, March
Cooperating with Copenhagen Capacity, introducing companies to the life-science eco-system in Denmark

Knowledge Liaison:

Network meeting for project nurses in psychiatry, February
Kick-off meeting for psychiatry nurses in Aalborg, February
Half-yearly meeting in Aalborg for Dementia and Infectious Medicine, August
DNMTB New union, September
Meeting between Infectious Medicine and DanPedMed, September
Trial Nations two-day course for project nurses, March and October
Yearly meetings for all center and networks in Trial Nation

Meetings and Conference:

Clinical Innovation Summit 2023
The Professors Association, Aarhus University Hospital
Moderating the symposium: Enabling regulatory science for clinical trials, September
Danish Medicines Agency - CTR, January
Danish Cancer Research Days, August
National Conference for Clinical Studies in Sweden, May

Appendix B

Trial Nation Centers, Networks and Trial Unions divided at Regional level

The North Denmark Region:

- **Center for Dementia:** Aalborg University Hospital participates (Rigshospitalet has the lead role)
- **Center for Dermatology:** Aalborg University Hospital expected to participate in 2024 (Bispebjerg has the lead role)
- **Center for Hematology:** Aalborg University Hospital participates (Odense University Hospital has the lead role)
- **Center for Infectious Diseases and Immune Modulation:** Aalborg University Hospital participates (Aarhus University Hospital has the lead role)
- **Center for Respiratory Diseases:** Aalborg University Hospital participates (Hvidovre has the lead role) North Denmark Regional Hospital, Hjoerring participate in the Network
- **Center for Oncology:** Aalborg University Hospital participates (Rigshospitalet has the lead role)
- **DanPedMed Network:** Aalborg University Hospital and North Denmark Regional Hospital, Hjoerring (coordinated by DanPedMed)
- **Psychiatry Network:** Aalborg University Hospital participates (Aalborg University Hospital has the lead role)
- **MedTech-initiative:** The entire region participates. The work is anchored by Trial Nation's MedTech Coordinator in The North Denmark Region
- **Neurology Network:** Aalborg University Hospital participates (Aarhus University Hospital has the lead role)
- **Nephrology Network:** Aalborg University Hospital participates (Zealand University Hospital, Roskilde has the lead role)
- **Fase IV Trial Union:** For The North Denmark Region anchored at the Danish Center for Health Services Research (facilitated by the Trial Nations Pharma Coordinator in Region Zealand)

Central Denmark Region:

- **Center for Dementia:** Aarhus University Hospital participates (Rigshospitalet has the lead role)
- **Center for Dermatology:** Aarhus University Hospital participates (Copenhagen University Hospital - Bispebjerg has the lead role)
- **Center for Hematology:** Odense University Hospital and Regional Hospital Vejle participates (Odense University Hospital has the lead role)
- **Center for Infectious Diseases and Immune Modulation:** Aarhus University Hospital participates and has the lead role. Regional Hospital Gødstrup participate in the Network
- **Center for Respiratory Diseases:** Aarhus University Hospital participates (Hvidovre has the lead role) Regional Hospital Vejle, Regional Hospital Hammel, Regional Hospital Randers and Regional Hospital Gødstrup participates in the Network
- **Center for Oncology:** Aarhus University Hospital and Regional Hospital Gødstrup participates (Rigshospitalet has the lead role)
- **DanPedMed Network:** Aarhus University Hospital, Regional Hospital Gødstrup, Regional Hospital Vejle and Regional Hospital Randers participates (coordinated by DanPedMed)
- **Psychiatry Network:** Aarhus University Hospital participates (Aalborg University Hospital has the lead role)
- **MedTech-initiative:** The entire region participates. The work is anchored by Trial Nation's medtech coordinator in The North Denmark Region
- **Neurology Network:** Aarhus University Hospital, Regional Hospital Gødstrup, Regional Hospital Vejle and Regional Hospital Hammel Neuro Center participates (Aarhus University Hospital has the lead role)
- **Nephrology Network:** Aarhus University Hospital, Regional Hospital Gødstrup and Regional Hospital Vejle participates (Zealand University Hospital Roskilde has the lead role)
- **Fase IV Trial Union:** Aarhus University Hospital participates (facilitated by the Trial Nations Pharma Coordinator in Region Zealand)

Appendix B

Trial Nation Centers, Networks and Trial Unions divided at Regional level

Region of Southern Denmark:

- **Center for Dementia:** Odense University Hospital/Odense University Hospital Svenborg participates (Rigshospitalet has the lead role)
- **Center for Dermatology:** Odense University Hospital participates (Bispebjerg has the lead role)
- **Center for Hematology:** Odense University Hospital and Regional Hospital Vejle participates (Odense University Hospital has the lead role)
- **Center for Infectious Diseases and Immune Modulation:** Odense University Hospital participates (Aarhus University Hospital has the lead role) Kolding participates in the Network
- **Center for Respiratory Diseases:** Odense University Hospital participates (Copenhagen University Hospital Hvidovre has the lead role) Regional Hospital Vejle and Regional Hospital Sønderborg participates in the Network
- **Center for Oncology:** Odense University Hospital and Regional Hospital Vejle participates (Rigshospitalet has the lead role) Regional Hospital Esbjerg and Regional Hospital Sønderborg participates in the Network
- **DanPedMed Network:** Odense University Hospital, Regional Hospital Esbjerg, Regional Hospital Sønderborg, Regional Hospital Kolding and Regional Hospital Aabenraa participates (coordinated by DanPedMed)
- **Psychiatry Network:** Odense University Hospital and Regional Hospital Aabenraa participates (Aalborg University Hospital has the lead role)
- **MedTech-initiative:** The entire region participates. The work is anchored by Trial Nation's medtech coordinator in The North Denmark Region
- **Neurology Network:** Odense University Hospital, Regional Hospital Kolding, Regional Hospital Esbjerg and Regional Hospital Sønderborg participates (Aarhus University Hospital has the lead role)
- **Nephrology Network:** Odense University Hospital, Regional Hospital Kolding and Regional Hospital Sønderborg participates (Zealand University Hospital Roskilde has the lead role)
- **Fase IV Trial Union:** Odense University Hospital participates (facilitated by Trial Nations Pharma Coordinator in Region Zealand)

Region Zealand:

- **Center for Dementia:** Zealand University Hospital Roskilde participates (Rigshospitalet has the lead role)
- **Center for Dermatology:** Zealand University Hospital Roskilde participates (Copenhagen University Hospital Bispebjerg has the lead role)
- **Center for Hematology:** Zealand University Hospital Roskilde participates (Odense University Hospital has the lead role)
- **Center for Infectious Diseases and Immune Modulation:** Zealand University Hospital Roskilde participates (Aarhus University Hospital has the lead role)
- **Center for Respiratory Diseases:** Zealand University Hospital Næstved participates (Hvidovre has the lead role) Nykøbing F and Zealand University Hospital Roskilde participates in the Network
- **Center for Oncology:** Zealand University Hospital Roskilde participates (Rigshospitalet has the lead role)
- **DanPedMed Network:** Regional Hospital Slagelse, Regional Hospital Nykøbing F and Regional Hospital Holbæk participates (coordinated by DanPedMed)
- **Psychiatry Network:** Psychiatry Hospital Slagelse participates (Aalborg University Hospital has the lead role)
- **MedTech-initiative:** The entire region participates. The work is anchored by Trial Nation's medtech coordinator in The North Denmark Region
- **Neurology Network:** Zealand University Hospital Roskilde and Epilepsy Hospital Filadelfia participates (Aarhus University Hospital has the lead role)
- **Nephrology Network:** Regional Hospital Holbæk and Zealand University Hospital Roskilde participates (Zealand University Hospital Roskilde has the lead role)
- **Fase IV Trial Union:** Region Zealand is covered by the other Regions (facilitated by the Trial Nations Pharma Coordinator in Region Zealand)

Appendix B

Trial Nation Centers, Networks and Trial Unions divided at Regional level

Capital Region of Denmark:

- **Center for Dementia:** Rigshospitalet participates (Rigshospitalet has the lead role)
- **Center for Dermatology:** Copenhagen University Hospital Gentofte and Copenhagen University Hospital Bispebjerg participates (Copenhagen University Hospital Bispebjerg has the lead role)
- **Center for Hematology:** Rigshospitalet participates (Odense University Hospital has the lead role)
- **Center for Infectious Diseases and Immune Modulation:** Hvidovre and Rigshospitalet participates (Aarhus University Hospital has the lead role) Copenhagen University Hospital Herlev, Copenhagen University Hospital Bispebjerg and Copenhagen University Hospital Hillerød participates in the Network
- **Center for Respiratory Diseases:** Hvidovre and Copenhagen University Hospital Bispebjerg participates (Hvidovre has the lead role) Copenhagen University Hospital Gentofte, Rigshospitalet and Copenhagen University Hospital Hillerød participate in the Network
- **Center for Oncology:** Rigshospitalet and Copenhagen University Hospital Herlev participates (Rigshospitalet has the lead role)
- **DanPedMed Network:** Rigshospitalet, Hvidovre, Copenhagen University Hospital Hillerød and Copenhagen University Hospital Herlev/Gentofte participates (coordinated by DanPedMed)
- **Psychiatry Network:** Copenhagen University Hospital Glostrup, Copenhagen University Hospital Herlev/Gentofte and Rigshospitalet participates (Aalborg University Hospital has the lead role)
- **MedTech-initiative:** The entire region participates. The work is anchored by Trial Nation's medtech coordinator in The North Denmark Region
- **Neurology Network:** Rigshospitalet, Copenhagen University Hospital Bispebjerg and Copenhagen University Hospital Herlev participates (Aarhus University Hospital has the lead role)
- **Nephrology Network:** Rigshospitalet, Copenhagen University Hospital Herlev/Gentofte og Copenhagen University Hospital Hillerød participates (Zealand University Hospital Roskilde has the lead role)
- **Fase IV Trial Union:** Rigshospitalet participates (facilitated by the Trial Nations Pharma Coordinator in Region Zealand)