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Decentralised Clinical Trials in Denmark

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"Medicine development teams planning global studies are struggling to understand the country-by-country differences in how to introduce decentralised methods that meet the needs of patients for access, as well as regulators for decision-making. The thoughtful positions coming from Denmark send a clear signal of being open for collaboration, positioning the country to become a **key destination** for the next generation of clinical trials."

— **Craig Lipset**
Co-Chair, Decentralized Trials & Research Alliance

Foreword

Clinical studies are essential for responding to patients' needs for the best future treatment options. Clinical trials are therefore a central political priority in the Danish Government's life science strategy. To increase equity in healthcare, it should be possible for patients to participate in clinical trials regardless of mobility and geography. The development of decentralised clinical trials can ensure a broader representation of patients and the inclusion and retention of more patients.

The decentralisation of clinical trials goes hand in hand with the general digitalisation of healthcare in Denmark. The digital technologies that power the performance of decentralised clinical trials in Denmark rest on the highly advanced digital infrastructure that we have been building over the years. Today, the Danish healthcare system is perhaps the most digitalised in the world. By keeping up the ongoing political focus and development of favourable structures and systems, we will continue to position Denmark as an attractive place to perform decentralised clinical trials.

Magnus Heunicke
Minister for Health

The Danish Medicines Agency is committed to driving regulatory innovation that will create value for patients and improve health. Clinical studies are undergoing rapid development towards digitalisation and decentralisation, and the Danish Medicines Agency has initiated an ambitious project to secure a modern and robust regulatory framework for digitalisation and the decentralisation of clinical trials.

Denmark is a unique sandbox for decentralised clinical trials, and we have gained a lot of early insights on a national level. However, regulatory innovation will have the broadest impact if developed and agreed to across national borders. Hence, we also put a lot of effort into sharing our experiences and driving the agenda in the EU.

Lars Bo Nielsen
Director General,
the Danish Medicines Agency

Contents

A decentralised clinical trial uses digital tools and innovative processes to bring the clinical trial to the patient, for example direct-to-patient delivery of medicine.

Introduction

Decentralised clinical trials (DCTs) introduce a revolution in the clinical trial industry by enabling faster trial execution, delivering more representative and diverse datasets, and providing clinical trials that are easily accessible and convenient for participants to take part in.

Denmark is moving full speed ahead to become a global DCT frontrunner. The close collaboration between all parties involved; authorities, clinicians, companies, and patients, is a huge advantage and has manifested in the establishment of the Danish DCT Dialogue Forum (see page 12). Key to this journey is the proactive role of the Danish Medicines Agency (DKMA), which launched a DCT guideline in 2021[1]; a document which has received broad recognition from foreign stakeholders and paves the way for significant collaboration across regulatory and clinical areas. Denmark's strong position within DCTs is also enabled by focused political prioritisation and continuous investment.

The development of DCTs in Denmark builds on already existing favourable structures and systems, which have contributed to placing Denmark at the top of the list of countries with most clinical trials per capita (229 trials per million citizens[2]). The Danish person registry system (CPR system) enables a lifelong record of all citizens' health entries and ties together all personal data, including disease-specific registries and biobanks. This data is available for authorised research. Denmark's highly digitalised and centralised healthcare system enables the roll-out of new systems to all parts of the country. Furthermore, the population has a high willingness to participate in DCTs, due to a digital mindset and a high degree of trust in the healthcare system.

We hope this high-level description of decentralised clinical trials in Denmark will be of inspiration and fuel the dialogue about how to perform clinical trials in the future.

The **Danish Approach** to **Decentralised Clinical Trials**

In Denmark, the clinical trial ecosystem has demonstrated a readiness for decentralising clinical trials. According to authorities, companies, and healthcare professionals, DCTs will lead the way towards a simplified, faster, and less expensive trial process. This will mean a wider representation of the population, both in and out of Denmark, will be able to participate in DCTs, leading to increased diversity and deeper knowledge about the effect of treatments.

Digitalised clinical landscape

A fundamental factor making Denmark a desired place to perform decentralised clinical trials is its highly digitalised clinical landscape. In 2021, the European Commission concluded that Denmark has the EU's most advanced digitalised infrastructure[3]. A well-functioning digital landscape is essential when performing DCTs as the processes are highly dependent on the use of digital tools. Danish hospitals are technologically agile, which was illustrated by their capability to rapidly implement digital tools in the onset of the COVID-19 pandemic.

What makes Denmark a frontrunner in decentralised clinical trials?

- **Highly digitalised healthcare system:** Danes are #1 in the EU in societal digitalisation.
- **Support by regulatory authorities:** DCTs in Denmark have received a high level of political prioritisation.
- **Strong collaboration** across the ecosystem's central stakeholders: DCT Dialogue Forum was established to ensure a robust regulatory framework.
- **A centralised public universal healthcare system**: Decisions, priorities, and technologies are rolled out centrally.

An entirely public healthcare system is an entirely coordinated healthcare system

Treatment in Denmark meets the same standards from east to west and north to south, making it easier to perform DCTs across trial sites in all regions of the country. Five public health regions operate almost all hospitals in Denmark, where 99% of hospital beds are found in public hospitals. This enables the five regions to run a highly uniform and cohesive healthcare system, coordinated and regulated by the central government. The Danish Health Authority is responsible for defining and allocating specialised hospital services for all publicly funded hospitals and the 36 medical specialities they house.

Regulatory framework by Danish Medicines Agency (DKMA)

Decentralised clinical trials in Denmark have received considerable political attention. In 2021, the DKMA proposed a regulatory framework for how decentralised elements should be implemented in clinical trials[1]. The guidelines have strengthened the ecosystem's public-private collaboration; an important factor for successful DCT implementation. By setting the clinical ecosystem's standards, the regulatory authorities have advanced Denmark's strong position in clinical research and Danish stakeholders are speeding towards a decentralised future for clinical trials.

Ethical approach in Denmark

The Danish National Centre for Ethics (DNCE) has a strong focus on DCTs and acknowledges the many ethical aspects of enabling decentralised trial activities.

Members of the Medical Research Ethics Committees (MREC) are educated in the general aspects of DCTs and actively engage in discussions on how to evaluate such studies. This ensures that DCTs meet the high ethical standards of traditional trials, thereby underscoring that the inclusion of decentralised activities is not to be regarded as a decrement to participant safety and comfort.

The DNCE has published specialised DCT guidance[5] for sponsors, investigators, and participants, which aims to improve ethical considerations and decision making when designing DCT protocols or choosing to participate in a DCT. Moreover, the DNCE runs a time-limited experimental programme[6] that seeks to obtain knowledge on fully decentralised informed consent processes by removing unnecessary regulations that would normally restrict such DCTs.

By focusing this much attention on the ethical aspects of DCTs, the general public's trust is maintained in the transformation from traditional trials to hybrid and fully decentralised clinical trials.

"It's fantastic that Denmark is **spearheading** the development and implementation of decentralised clinical trials, and there is no doubt that the high level of digitalisation in Denmark is essential to promoting this agenda. LEO Pharma is conducting clinical trials on a global scale, so, to promote the DCT agenda, it's important to also have a **global outlook** about how to promote this in the EMA and FDA."

— **Stephen Lutsch**
Director – Revolutionize Clinical Trials, LEO Pharma

The Danish DCT Dialogue Forum

With the aim of ensuring a robust, up-to-date regulatory framework for clinical trial decentralisation, the DKMA has created the Danish DCT Dialogue Forum in collaboration with Trial Nation.

The forum includes stakeholders from academic research units, Good Clinical Practice units, the Danish National Committee on Health Research Ethics, Danish Patients, the five health regions, contract research organisations (CROs), the life science industry, and interest organisations.

The forum assembles twice every quarter, giving it the best conditions to proactively navigate unforeseen challenges and opportunities in this rapidly developing field. It enables broad interaction between authorities, patients, researchers, and industry, and the exchange of viewpoints on both strengths and barriers from perspectives across the entire clinical trial ecosystem.

"The DCT Dialogue Forum provides a space for the companies to **share experiences** from an industry perspective, which is highly valuable. The dialogue forum enables the industry to discuss DCTs with decision makers in an informal setting, with other companies to leverage learnings, and with clinicians and patient representatives. In that sense, the DCT Dialogue Forum is **quite unique**."

— **Maria Bengtsen**
Clinical Research Medical Advisor,
Novartis Denmark

Trial Nation

Trial Nation is a non-profit, public-private partnership organisation which offers a single, national entry point for life science companies, patient organisations and clinical researchers wishing to sponsor, participate in, and conduct clinical trials in Denmark.

Read more on **trialnation.dk**

The Danish Medicines Agency

The Danish Medicines Agency (DKMA) continuously develops innovative and robust regulatory frameworks for clinical trials. This is done in dialogue with both patients and all other important stakeholders within the clinical trial ecosystem.

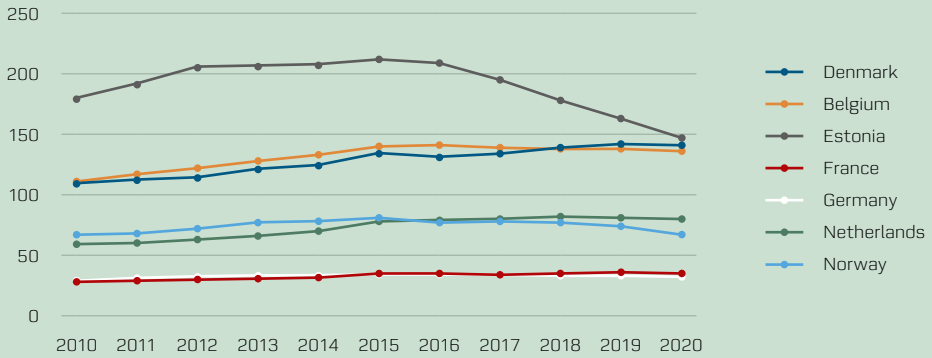
Central to these efforts was an ambitious project initiated by the DKMA in 2020 with the goal of safely implementing decentralised clinical trials, which included numerous innovative methodologies. This culminated in 2021 with the release of the first official guidance for decentralisation. As the methodologies of the decentralised approach matures, the guidance will be updated accordingly.

The know-how and robust processes developed nationally are actively integrated into EU initiatives. The DKMA works to strengthen harmonisation and pragmatic solutions for decentralisation across all EU member states.

Read more on **dkma.dk**

Denmark in the top ranking of clinical trials per capita

Number of commercial trials per capita



Number of non-commercial trials per capita

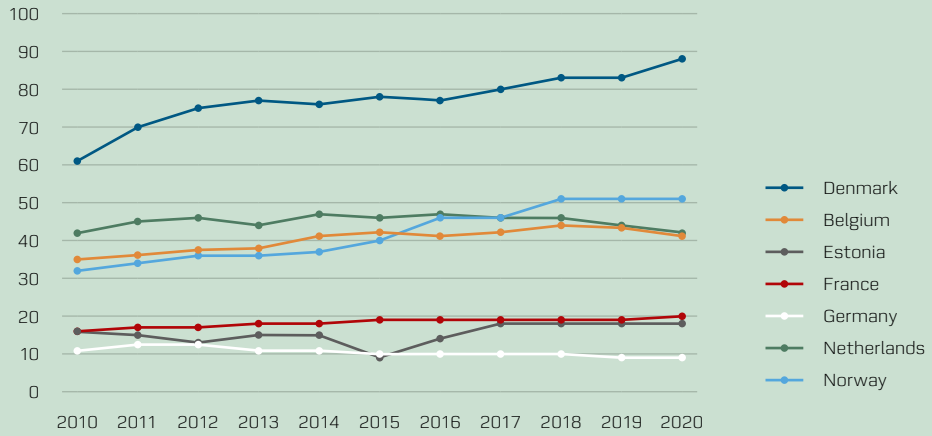


Figure 1– Number of commercial and non-commercial clinical trials per capita in selected European countries.

The Danish Life Science Strategy

In 2021, the Danish Government presented an ambitious life science strategy[4]. The first section, "Better framework for research and development", provides direction and guidance to the development of the Danish life science sector. Clinical trials take a central position in this section, and decentralised trials are specifically emphasised.

The recent establishment of a national Life Science Council was a step towards executing the strategy. With involvement and leadership from relevant ministries, and high-level participation from life science companies, foundations, patient associations, universities and health service representatives, the council will ensure that collaboration and transparency will continue to place Denmark at the pinnacle of global life science.

Scan to learn more about the Danish Life Science Strategy

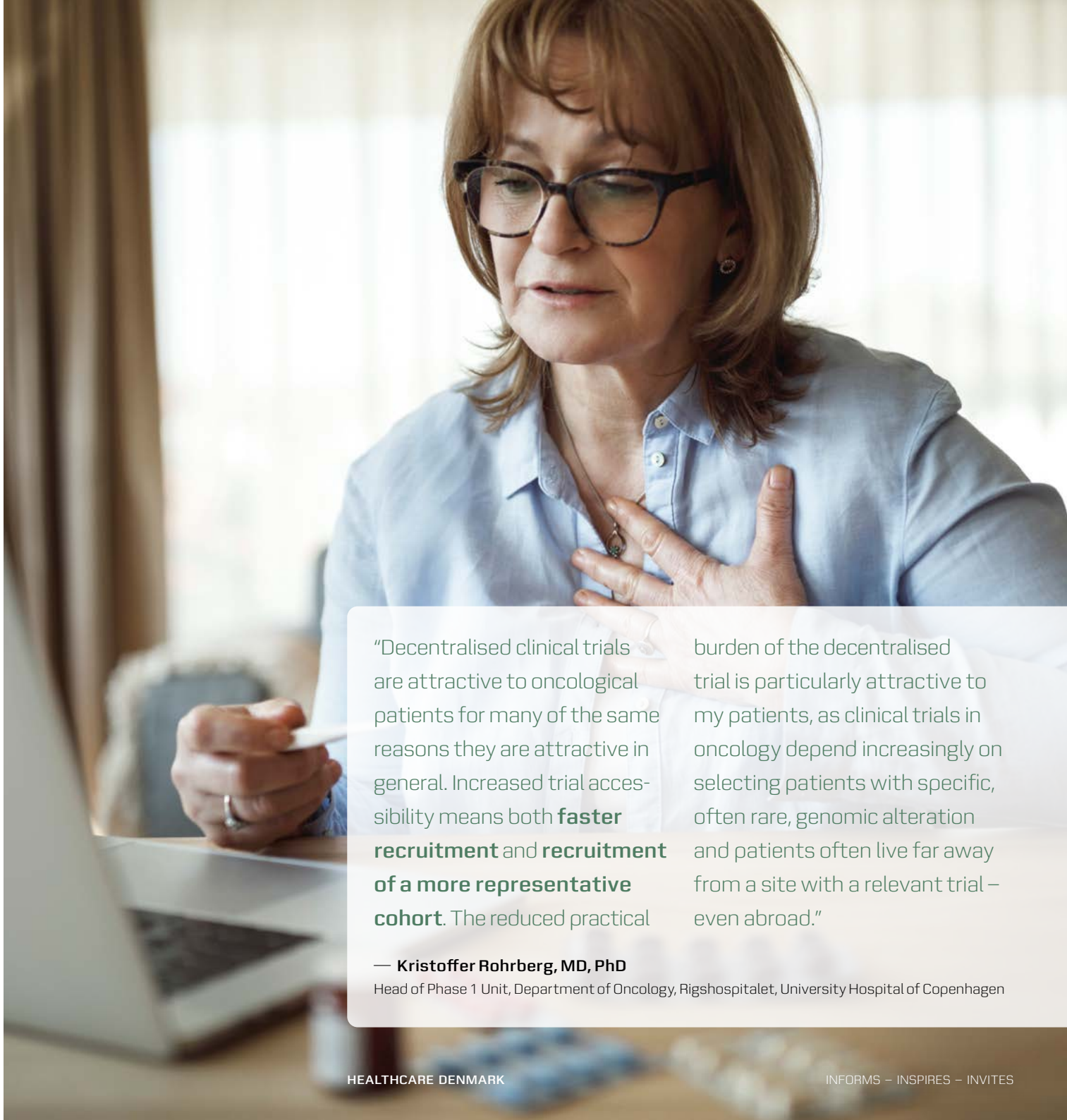
Definition of Decentralised Clinical Trials

A decentralised clinical trial uses digital tools and innovative processes to bring the clinical trial to the patient. This way, the patient does not have to go to the hospital physically as frequently as for a traditional clinical trial. The digital tools include, for example, digital recruitment, electronic consultations, electronic systems for data collection, wearables, and direct-to-patient shipment.

The concept of decentralised clinical trials

The concept of DCTs involves building the trial around patients in their home and community, which offers new possibilities for making clinical research more patient-centric. Building the trial around the patient's needs is not only beneficial for the patients, but also for the health of the society as trial-related costs are reduced, while equity and inclusion in trials are improved.

The onset of the global COVID-19 pandemic, and the subsequent heavy restrictions and infection risk, has demonstrated that decentralised elements can be implemented rapidly across the healthcare system. The digital meeting between patients and the healthcare system as seen during the COVID-19 pandemic has not only revolutionised clinical research in Denmark, but also in the rest of the world. When the patient and study personnel do not necessarily need to be in the same room, or when the patient does not need to travel to research facilities to participate in clinical trials, taking part in a study becomes more convenient.



"Decentralised clinical trials are attractive to oncological patients for many of the same reasons they are attractive in general. Increased trial accessibility means both **faster recruitment** and **recruitment of a more representative cohort**. The reduced practical burden of the decentralised trial is particularly attractive to my patients, as clinical trials in oncology depend increasingly on selecting patients with specific, often rare, genomic alteration and patients often live far away from a site with a relevant trial – even abroad."

— **Kristoffer Rohrberg, MD, PhD**
Head of Phase 1 Unit, Department of Oncology, Rigshospitalet, University Hospital of Copenhagen

Decentralised clinical trials **meet patients where they are**

Clinical trial designs

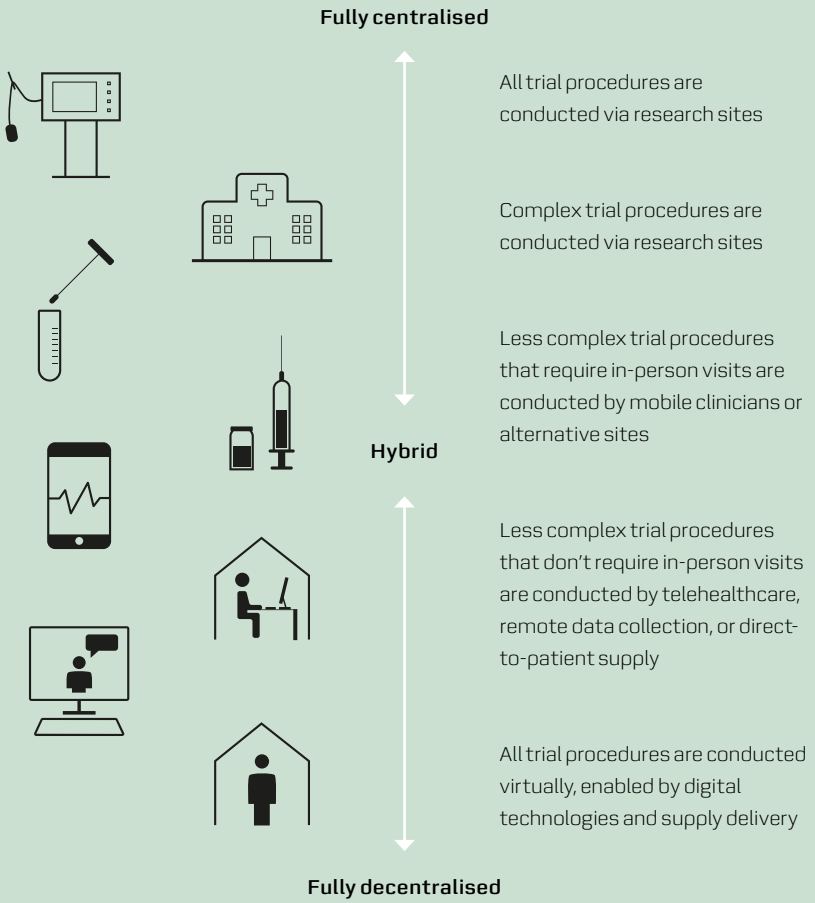


Figure 2 – Spectrum of decentralisation in clinical trials[8]

The degree of decentralisation

DCTs exist as a spectrum where the degree to which a trial is decentralised depends on how many of the elements in the trial are remote or site dependent. Figure 2 illustrates the magnitude of decentralisation and how the various elements create a spectrum of decentralised trial designs.

A fully decentralised clinical trial is operated at a remote location where communication is performed solely with digital tools and trial-related supplies are delivered directly to the patient. However, the most common form is a hybrid approach where the trial is partially decentralised. This means stakeholders and participants decide where it is appropriate to implement digital tools in the trial design[7]. The hybrid solution is a customisable approach that offers the patients a choice, which a traditional clinical trial does not offer to the same degree.

"An important aspect of decentralised clinical trials is the ability to **give the patients a choice**. Giving them more say in creating the trial protocol allows for more patient-friendly trials and the patients will experience an increase in their quality of life. Also, by not demanding so much from them, such as transport to research sites, it makes it possible to include patients who have limited resources or energy, which makes trial results more representative."

— **Morten Freil**
CEO Danish Patients

Guidance: **From Idea to Trial** in Denmark

When locating your decentralised clinical trial in Denmark, the first step is to consult the Danish Medicines Agency (DKMA) DCT Guideline[1] as well as the Guidance on decentralised clinical trials[5] from the Danish National Centre for Ethics (DNCE) and amend relevant changes to your draft protocol. After this, both the DKMA and DNCE encourage you to begin an initial dialogue with them, respectively. The DKMA specifically encourages DCT applicants to seek scientific advice from them. Moreover, the regional Good Clinical Practice (GCP) units provide DCT-guidance for non-commercial researchers[9]. In parallel, you are encouraged to contact relevant and experienced Danish clinicians for a clinical feasibility process. Trial Nation provides a highly coordinated national feasibility process, free of charge. Figure 3 provides an overview of the process for placing your DCT in Denmark.

With guideline compliance, medical and ethical pre-dialogue, and a guided clinical feasibility process, you should now find yourself in a better position to file for approval of your study with the DKMA and the MREC, through the pan-European Clinical Trial Information System (CTIS)[10].

"Decentralised clinical trials are the **next evolutionary leap forward**, and Danish clinicians are becoming experienced DCT investigators. We can generate much better data as it's continuous rather than disparate. We can match patients better with trials because DCTs are more attractive and more accessible. And we can offer a **much better and safer experience** for patients because DCTs involve less transport and logistics on one hand and individual access to trial results on the other."

— **Simon Francis Thomsen, Professor, MD, PhD**
Head of Department of Dermatology, Bispebjerg Hospital

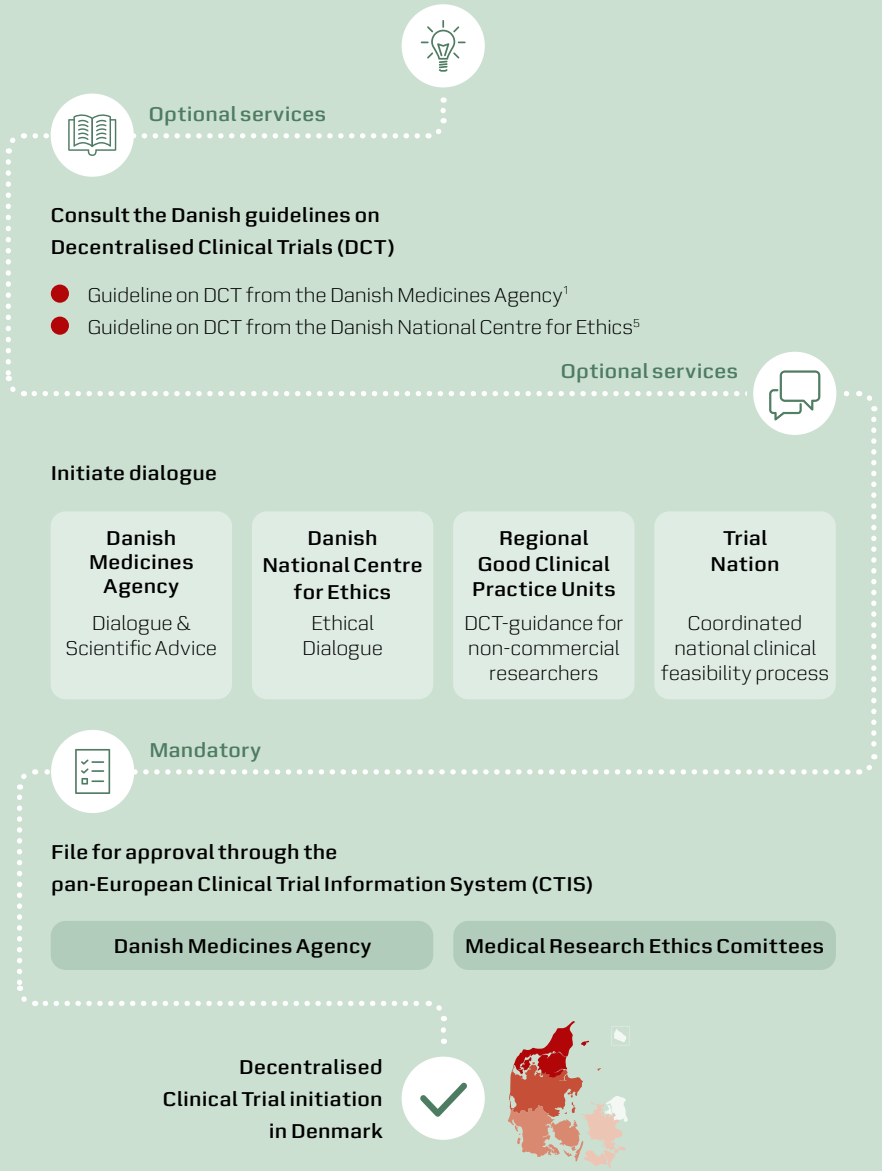


Figure 3 – The flowchart illustrates an overview of the points of contact and activities available to initiate a decentralised clinical trial in Denmark.

Invest in **Denmark**

Invest in Denmark is part of the Danish Ministry of Foreign Affairs and provides confidential and tailor-made solutions for foreign companies looking to accelerate business growth by setting up or expanding their life sciences activities in Denmark. Invest in Denmark can help connect businesses with key local stakeholders, arrange fact-finding tours and provide comprehensive background information on doing business in Denmark.

Read more on
investindk.com

An international outlook
The Danish approach to decentralised clinical trials is inspired by international learnings and experiences.

In 2022, Innovation Centre Denmark published a DCT outlook report with highlights from USA[7].

"We have been working with direct-to/from patient delivery for more than 20 years, delivering medicine to the patient and blood samples to a CRO/CMO. Right now, we see a global trend that this area is **rapidly expanding** – not least due to the COVID-19 pandemic. Based on the feedback we get from sponsors, we anticipate decentralised trials to be a feature of clinical trial design in the future. Due to its small geographical size, **Denmark is an ideal country** in which to perform direct-to/from-patient delivery and it is relatively easy to incorporate this decentralised element in clinical studies."

— **Andrea Zobel**
Senior Director,
Personalized Supply Chain, World Courier

Examples of Decentralised Clinical Trials in Denmark

CASE: Psoriasis DCT

Purpose
LEO Pharma is planning their first fully decentralised psoriasis clinical trial in 2022, where participants will perform their assessments and collect study data from the comfort of their own homes.

Study setup
The study will include the following DCT elements:

- Recruitment via social media campaigns
- Telehealth – talking to their investigator via video calls when needed
- Reviewing and signing of the consent form electronically via a qualified electronic signature
- The delivery of study medication directly to their home
- Performing severity assessments via images taken via their own phone
- Capturing patient reported outcomes (ePRO)
- Reporting of potential adverse events

The study protocol is approved by the health authority and ethics committee in Denmark and by the German health authority. Planned enrolment and conduct through 2022 with a target enrolment of 105 participants.

Learnings
LEO Pharma has implemented new processes for key clinical trial aspects such as informed consent, data monitoring and cleaning, safety reporting, verification of eligibility, medical history, and critical data endpoints. These novel methods have been discussed actively with regulators up front to ensure acceptance.

To secure patient centricity, LEO Pharma worked with a CRO and vendors to better understand patient needs. All stages of the clinical trial implementation were focused on optimising the patient experience and enhancing the use of technology.

During the preparation and protocol writing for the study, there have been several interactions with both the Danish and German authorities to discuss challenges, concerns, and suggested mitigations. In parallel, the DKMA has developed the guidance for sponsors on decentralised clinical trials, and LEO Pharma has contributed heavily to these considerations both during the study-specific interactions and during participation in the DCT Dialogue Forum.

CASE: Multiple Sclerosis DCT

Purpose
In February 2021, Merck Denmark initiated their first phase IV decentralised clinical trial for multiple sclerosis (MS) with the purpose of facilitating easier patient recruitment and reducing dropout rates.

Study setup:
The study includes the following DCT elements:

- Remote monitoring and communication with participants
- Use of ePROs for health-related quality of life and physical function questionnaires
- The ePROs will be migrated to an app-based solution
- Participants answering questionnaires from their homes
- Tablet devices for patients to input answers to the questionnaires
- Remote reporting of potential adverse events

The study protocol is approved by the Danish Medicines Agency and ethics committees in Denmark. Worldwide, up to 320 patients will be enrolled from Q1 2021 to Q1 2024. Trial publication is expected in Q3 2025.

Learnings
In Denmark, Merck Group's learnings so far are that if DCTs are to succeed, it is crucial that the public and private sectors cooperate closely. In time, new learnings will hopefully show that DCTs can facilitate easier patient recruitment, improve retention, and reduce travelling costs to specific sites.

This will potentially reduce dropout rates, decrease paperwork, and perhaps even ensure that patients receive innovative medicines faster. Therefore, Merck encourages other patient-directed companies to have a decentralised approach to their clinical trial design.

CASE: Oncology DCT

Purpose
In 2022, Roche Denmark will implement a decentralised trial design for a complex oncology study in Denmark, which is set to end in 2026. The study aims to confirm that this type of oncology study can be operationalised in a decentralised setup where patients across the country can potentially be included in a study even though they reside far away from the main site.

Study setup:
The study will include the following DCT elements:

- Mobile doctor and nurse to perform all safety and efficacy-related assessments
- Video conferencing between mobile doctor, patient, or the principal investigator
- Reviewing and signing of the consent form electronically via a qualified electronic signature
- The delivery of study medication directly to their home
- Blood sampling in the patient's home by home nurse
- Capturing patient-reported outcomes (ePRO)
- Scanning performed at the hospital closest to the patient to avoid travelling to the main site
- Reporting of potential adverse events

Learnings
During the preparation for the study, there have been several fruitful interactions with the DKMA to discuss challenges, concerns, and suggested mitigations. As the DCT oncology study at Roche is in a planning phase, the learnings are so far limited.

Roche finds several reasons for incorporating a decentralised trial design in their studies. First, to have more diversity in recruiting as patients living far from university hospitals can be included without spending too much time on travelling between research sites.

Furthermore, DCTs will accommodate the needs of future clinical trials as they reduce hospitalisation of patients and thus the burden for healthcare personnel. Increasing the use of technology in clinical trials is a part of re-thinking patient treatment and a way of meeting patient needs.

CASE: Type 2 Diabetes – A decentralised observational study

Purpose
Studies&Me executed an observational decentralised clinical study in collaboration with Novo Nordisk in 2021. The study was fully decentralised, i.e., all study visits and data sampling were handled remotely.

The goal of this pilot study was to investigate the operational feasibility of using DCT design elements to recruit, enrol, and engage patients with Type 2 Diabetes. The pilot was made in preparation for a more extensive DCT in Type 2 Diabetes, which will be conducted by Novo Nordisk and Studies&Me in 2022.

Study setup
The time frame of the study was three weeks and included 26 participants who were monitored remotely via digital devices. Hence, the study was completely siteless, which meant that participants did not have to physically attend the clinic at any time.

The study included the following DCT elements:

- Online recruitment through targeted ads on social media
- Electronic consent to participate in the study (eConsent)
- A study app downloaded to the study participant's own mobile phone, which was used throughout the study
- Electronic Patient Reported Outcomes collected through questionnaires (ePROs)
- A continuous glucose monitoring device
- Hybrid smartwatch to monitor heart rate, track activity, GPS, and sleep pattern

Learnings
The online recruitment process, data collection from various electronic devices, and engagement of study participants in the Type 2 Diabetes study were very successful, proving that it is possible to integrate DCT elements in a Type 2 Diabetes study.

In the study, 26 participants were recruited online in just 17 hours from locations in all parts of Denmark. According to post-study interviews, the participants felt confident about participating from home and found it easy to fit the study tasks into their daily routines.

The retention rate of the study was 87%, which indicates a significant willingness among the participants to contribute and engage[11].

Committed National Public-Private Collaboration will **Revolutionise Decentralised Clinical Trials in Denmark**

A newly approved substantial funding decision by Innovation Fund Denmark enables a powerful consortium of Danish life science stakeholders to innovate and develop Denmark as the leading DCT nation.

The €5M project will create a public-private framework that supports implementation of patient-centred decentralised clinical trials in Denmark. The project will reduce the experienced and perceived barriers for patients, healthcare personnel and companies to participate in clinical trials in Denmark and create and implement logistics for general use of decentralised elements in clinical trials. Furthermore, the project will facilitate the development and implementation of public and digital clinical trial tools that empower patients to participate in clinical trials and push the healthcare system towards value-increasing initiatives and patient-centred care. An updated overview about all clinical trials in Denmark will be implemented and made available to clinicians and patients. The ability to register interest in participating in future clinical trials, and then being subsequently matched with a clinical trial, will also be made available for all patients through the implementation of a public digital recruitment platform.

To hear more about this public-private collaboration, please contact Trial Nation.

References & Credits

Editor-in-Chief

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Trial Nation; Michelle Birknow, mrb@trialnation.dk.

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References

1. Danish Medicines Agency (2021, September). The Danish Medicines Agency's guidance on the implementation of decentralised elements in clinical trials with medicinal products. Retrieved October 2021, from: https://laegemiddelstyrelsen.dk/en/news/2021/updated-guidance-on-the-implementation-of-decentralised-elements-in-clinical-trials-with-medicinal-products/
2. Data source: GlobalData, January 2022
3. European Commission (2021). The Digital Economy and Society Index (DESI). Retrieved November 2021, from: https://digital-strategy.ec.europa.eu/en/policies/desi
4. Ministry of Industry, Business and Financial Affairs (May 2021). Agreement on a strategy for life science.
5. Danish National Center for Ethics – Section for the Medical Research Ethics Committees. Guidance on decentralised clinical trials (DCT): https://www.dvmk.dk/~/media/vmk/ansoger/dct/Guidance-on-decentralised-clinical-trials-Version-1-Danish-National-Center-for-Ethics.pdf
6. Danish National Center for Ethics. Experimental programme on new informed consent processes in decentralised clinical trials (DCT): dvmk.dk/~/media/vmk/ansoger/dct/Experimental-programme-on-new-informed-consent-processes-in-decentralised-clinical-trials-Danish-National-Center-for-Ethics.pdf
7. Innovation Centre Denmark, Silicon Vally & Boston (2022). Decentralized Clinical Trials in the USA. Outlook report. Available on www.ufm.dk
8. Inspired by McKinsey (June 2021) No place like home? Stepping up the decentralization of clinical trials. Retrieved September 2021 from: https://www.mckinsey.com/industries/life-sciences/our-insights/no-place-like-home-stepping-up-the-decentralization-of-clinical-trials
9. GCP Enhederne. The Danish GCP units. Retrieved February 2022 from: gcp-enhed.dk/english/
10. Clinical Trials. Clinical trials in the European Union. Retrieved February 2022 from: euclinicaltrials.eu/home
11. Ali Z., Valk J. T., Bjerre-Christensen T., et. Al. Exploring Decentralized Glucose and Behaviometric Monitoring of Persons with Type 2 Diabetes in the Setting of a Clinical Trial. Journal of Diabetes Science and Technology, Sept. 23, 2021. Retrieved January 2022 from: https://journals.sagepub.com/doi/10.1177/19322968211045656

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