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# FINTRIALS

## National Operating Model for Clinical Trials

**Sitra Memorandum**



**FinTrials – National Operating Model for Clinical Trials**

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# Foreword

Clinical trials are an essential part of healthcare development. Their impact extends from individuals to the health of the entire population and the strengthening of the national economy. Finland has long been known for its high-quality healthcare and strong research expertise. We have also been a much more significant player in clinical research than one would expect given the size of our country.

However, the number of clinical trials conducted in Finland has clearly decreased in recent years. International competition for clinical trials has intensified, and Finland's position as a research country has been weakened by structural barriers, such as fragmented operating models and insufficient coordination.

Many other European countries, especially the Nordic countries, have shown that national cooperation is an effective solution for increasing medical research. National cooperation enables more efficient use of resources, expertise and infrastructure, as well as shared ways of working between different actors.

The need to strengthen national cooperation and thus create better conditions for the growth of clinical trials has also been identified in Finland. At the mid-term policy review in spring 2025, the Government confirmed this direction by deciding to establish a 'one-stop shop' service in Finland modelled on Denmark's Trial Nation. The aim is to bring together the services and actors involved in clinical trials into a coherent and coordinated system.

To address this need, at the beginning of 2025, Sitra launched a research project at the request of the Ministry of Social Affairs and Health to prepare a proposal for a national collaboration model, with the working title **FinTrials**. The model is intended to support the implementation of commercial clinical trials in wellbeing services counties and to strengthen cooperation between different actors.

National cooperation is important, but not the only prerequisite for increasing clinical research. It is also necessary to ensure that hospitals have sufficient resources for clinical trials. Incentives for engaging in research should also be developed in both universities and hospitals. In addition,

Finland must keep pace with its peer countries in the introduction of new medicines, as clinical trials require that comparative treatments meet the standards of other advanced healthcare systems.

This study has been carried out in extensive cooperation with university hospitals, the Ministry of Social Affairs and Health and other key actors. The work was supervised by a steering group consisting of research directors from university hospitals and the Ministry of Social Affairs and Health. In addition, public healthcare providers, interest groups, agencies, and representatives of the pharmaceutical industry were extensively consulted during the preparation process through interviews and workshops. During the implementation phase, the details of the model will be further refined in collaboration with key stakeholders.

We hope this study will provide clear direction and tangible solutions for improving the implementation of clinical trials in Finland. Through cooperation and national coordination, we can ensure that Finland strengthens its position as an internationally competitive research country, benefiting patients, researchers and society as a whole.

Helsinki, 27 April 2026

**Petri Lehto**
Leading Specialist
Sitra

# Summary

Clinical trials sponsored by pharmaceutical companies are a central part of the development process for new innovative medicines. These trials assess the efficacy and safety of medicines in patients, with their significance extending beyond the treatment of individual patients to the advancement of the entire healthcare system and the national economy.

However, in recent years, the number of clinical trials conducted in Finland has declined significantly. This is due to several structural, legislative, and economic challenges that hinder Finland's ability to attract clinical trials. The crucial issues include fragmented operating models, insufficient national coordination, and slow, complex processes that hinder the creation of an internationally competitive research environment.

Pharmaceutical companies are seeking smoother, faster, and more cost-effective operating environments where the initiation and execution of clinical trials can proceed reliably. One example of such an environment is Denmark, where the Trial Nation model has been developed. In contrast, Finland's current model, where each hospital unit operates according to its own practices, fails to provide a clear or predictable service pathway. Without unified national procedures and stronger collaboration among stakeholders, Finland will continue to risk its competitive edge to countries that have already streamlined their processes.

This report proposes a national collaboration model that strengthens Finland's position as an attractive location for commercial clinical trials. The model builds on existing structures, such as ongoing practices and procedures within the wellbeing services counties. At the heart of the model is a centralized "one-stop shop" approach. This includes national coordination, shared processes and metrics, and regional research units (Clinical Trial Offices), all forming a unified research network. The aim is to create a cohesive, transparent, and competitive operating environment that enables an increase in the volume of clinical trials, greater investments, and improved access for patients to new treatments.

Key areas of development within the FinTrials model include standardizing and accelerating feasibility assessments, boosting national collaboration and clarifying division of responsibilities, and strengthening the infrastructure for clinical trials. Additionally, the model aims to establish a set of metrics to track the number, quality, and impact of trials, and to develop incentives at both the organizational and individual levels. Crucially, the implementation of customer relationship management and feasibility systems is proposed to provide a real-time overview of research capabilities and demand for trials. The report also includes a cost estimate and funding options for the proposed operating model.

# 1. Introduction

The number of clinical trials conducted by international pharmaceutical companies in Finland has declined significantly in recent years. This declining trend is partly due to a pan-European phenomenon in which the number of clinical trials has decreased in almost all European countries. However, it has also been noted that national factors have contributed to Finland's declining competitiveness.

## 1.1 Background and objectives of the study

The number of clinical trials conducted by international pharmaceutical companies in Finland has declined significantly in recent years. This declining trend is partly due to a pan-European phenomenon in which the number of clinical trials has decreased in almost all European countries. The most important single factor identified is new EU-level regulation, particularly the new Clinical Trial Information System (CTIS), which is expected to slow the clinical trial approval process. This is expected to weaken Europe's competitiveness in a situation where countries and continents compete globally for new research (Figure 1). Several national factors have also contributed to the decrease in the number of clinical trials in Finland. These factors are discussed in more detail in Chapter Two.

The declining trend in the number of clinical trials has created a consensus among experts and decision-makers that new measures are needed to remedy the situation. Strengthening national collaboration in medical research has been identified as one of the key measures. Other Nordic countries, especially Denmark with its Trial Nation model, already developed models several years ago, providing Finland with useful lessons. Sweden has recently refined its cooperative model for supporting clinical trials (SweTrial), and its government has allocated significant national funding to it. The same trend is also evident in Norway (NorTrials).

The aim of this study was to prepare a proposal for a national collaboration model, called **FinTrials**. This model would support the implementation of commercial clinical trials in wellbeing services counties and strengthen collaboration between different actors. In addition, the model would improve the competitiveness and attractiveness of Finland's research environment internationally.

**Figure 1: In recent years, the European Economic Area (EEA) has lost ground as a target region for commercial clinical trials**

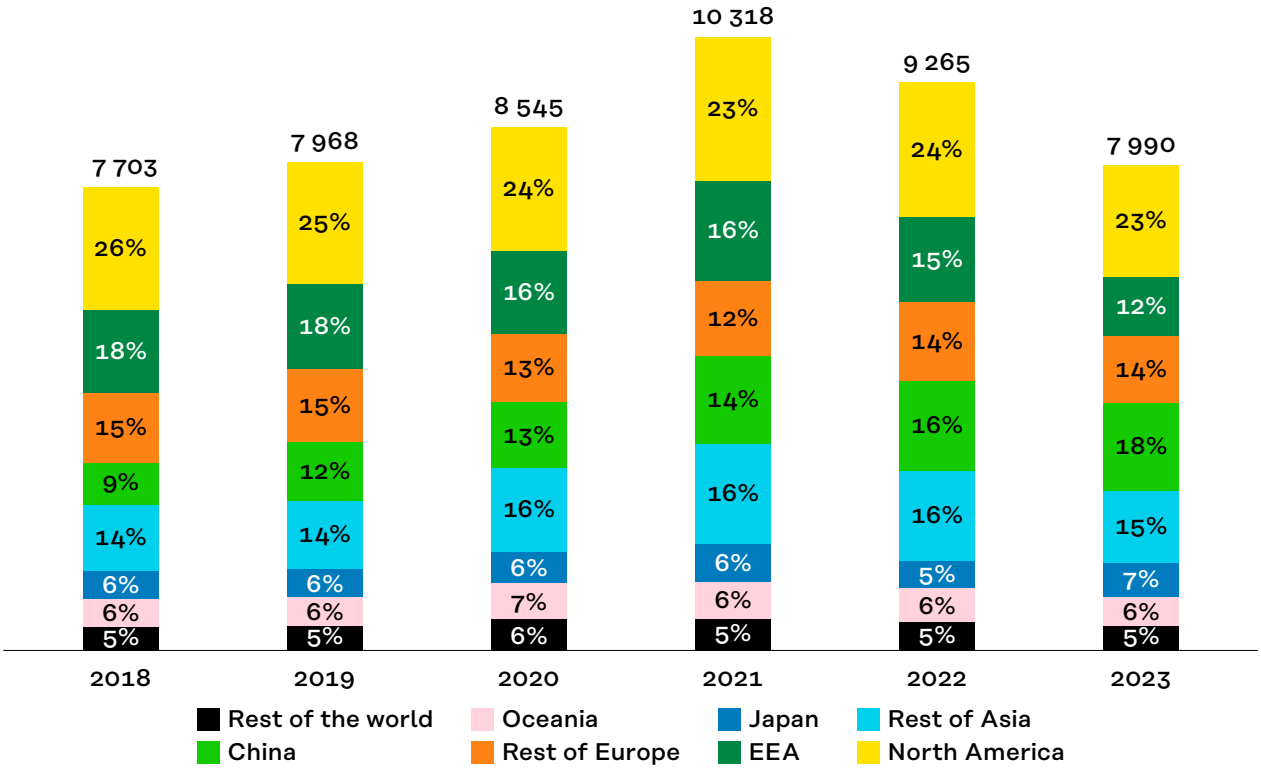



Image borrowed and adapted from: IQVIA ja EFPIA-VE: Assessing the Clinical Trial Ecosystem in Europe. August 2024

The study focused on the structures involved in clinical trials, excluding vaccine studies in healthy populations, as Finland already has operating models in place for their coordination and implementation. However, the comparative data used in the study (Finland, the EU and global statistical data) include all categories of medical research, so the numbers of vaccine studies are also included.

In particular, the report focused on the following areas:

- **Developing research feasibility (a term used subsequently in this report) and feasibility assessment**: an efficient and reliable assessment process for feasibility is one of the key factors Finland needs in order to regain its appeal as a research country from the perspective of international pharmaceutical companies. Feasibility assessments are closely related to the development of what are referred to as 'feasibility services'.
- **Organising national collaboration and the division of labour**: a national network and standardised processes and operating methods will streamline the conduct of clinical trials at all stages. On the one hand, national collaboration strengthens existing structures and, on the other, creates new opportunities to improve competitiveness. Existing research structures also need to be strengthened.

- **Defining performance indicators**: Finland must be able to respond to international competition by means of clear, measurable indicators. This will allow it to demonstrate its capabilities and gain a competitive advantage over other countries. Indicators also help in developing operations.

## 1.2 Importance of clinical trials for Finland

Clinical trials play a significant role in public health, science, and the economy in Finland. They are an integral part of the development process for new medicines and are used to determine the efficacy and safety of medicines before they are widely introduced. Patients participating in studies may have the opportunity to access new treatments even before the medicines are on the market, which may offer additional treatment options, especially for difficult-to-treat diseases.

Clinical trials also support the development of healthcare expertise. Healthcare professionals can familiarise themselves with the latest pharmaceutical treatments and research methods, which is usually reflected in high-quality clinical care and positively affects job satisfaction among healthcare personnel. Clinical trials also provide healthcare professionals with an opportunity to develop their skills as investigators in clinical trials and, more broadly, in other areas of clinical research. Clinical trials can thus also serve as part of personal skills development, which can be an important retention and attraction factor in the challenging situation regarding the healthcare workforce. They also help researchers build both national and international networks. An economically significant factor is that medical research brings financial benefits to healthcare organisations, as compensation for research activities is paid according to the studies conducted.

In terms of the national economy, clinical trials bring significant foreign investment and create jobs. They also strengthen Finland's position in international research and innovation. At best, a broad ecosystem will be built around clinical research, creating new companies, services and technological solutions. Good examples of this are companies offering clinical research services that were established in Finland and have since expanded internationally.

The pharmaceutical industry in Finland has succeeded in establishing a reasonably strong market position internationally, even though the domestic market is small. The sector mainly employs a highly educated workforce; pharmaceutical research attracts international investment to the country; and research collaboration between universities, hospitals, and companies is strengthening. In practice, all this means that Finland not only consumes pharmaceutical innovations, but also benefits economically

by participating in their development. This means that the majority of the global value chain in this sector will remain in Finland. As research and production increase in the country, it will, in turn, create high-productivity jobs, tax revenues and new business opportunities. Based on the cost-benefit analysis carried out in Pohjois-Savo, an investment of one euro in clinical trials yields up to a fourfold return (Väätäinen et al., 2023). A study conducted a few years ago showed that the added value of the pharmaceutical industry in Finland increased from EUR 1.3 billion in 2008 to EUR 2.8 billion in 2019 (80%), while the added value of the entire corporate sector decreased by 3 per cent. Investments in research generate benefits in the development of pharmaceutical treatments and other healthcare services, bring external research funding to the region, and increase the health benefits for the population (QALY). Therefore, investments in clinical trials are not just healthcare costs, but investments that strengthen the competitiveness of the entire economy in the long term.

## 1.3 Clinical trials in Finland, in Europe and internationally

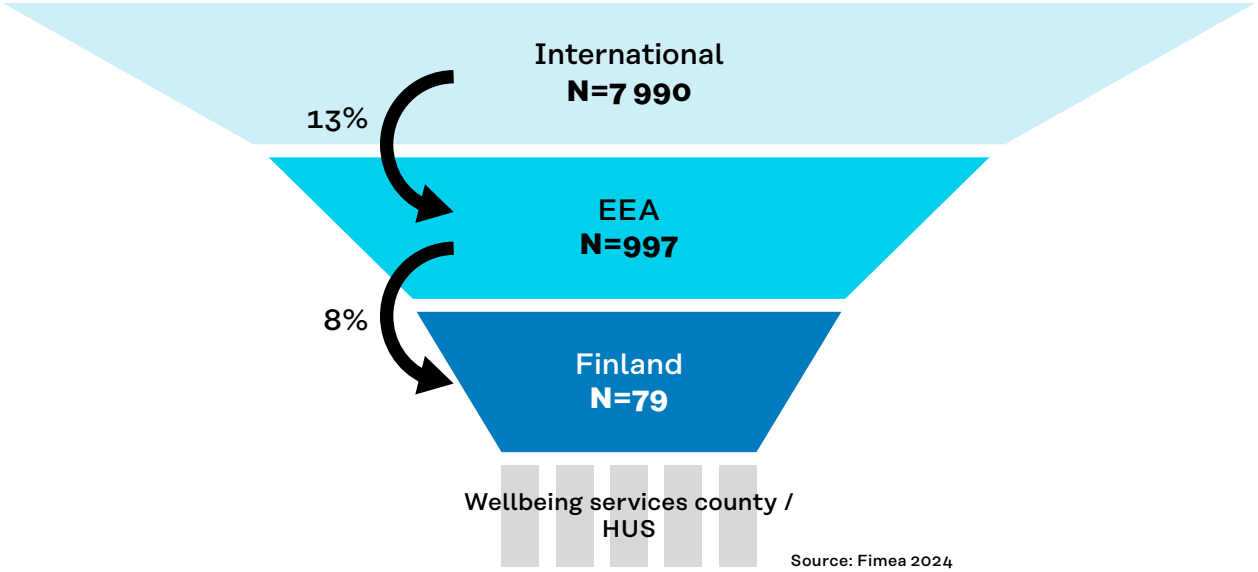
The number of commercial clinical trials in Europe has declined in recent years, with Europe losing market share to Asian markets, particularly China, where trial volumes are increasing. In 2023, 7,990 commercial clinical trials were initiated worldwide, of which only 997, or about 13%, were conducted within the European Economic Area (EEA).

In Europe, the relative initiation rate of studies has decreased by six percentage points between 2018 and 2023. Based on the literature and interviews conducted for this project, the EU Clinical Trials Regulation (EU CTR) is considered the most important single factor, as it changed the approval process for trials and caused delays and uncertainty during the transition phase.

Spain is the only EEA country that has managed to keep the number of trials almost unchanged since 2018. There are a number of contributing factors, particularly centralised research centres and an accelerated approval process (known as 'fast-track' processing) for early-stage research. Among the Nordic countries, Denmark in particular has comprehensively developed its operating environment and has maintained almost the same number of clinical trials. Denmark has largely been used as a benchmark for other Nordic countries due to its similar healthcare system and population base.

In 2023, 79 commercial clinical trials were started in Finland (Fimea, 2024). With a total of 997 trials launched in Europe that year, Finland accounted for 8% of all studies initiated in Europe (Figure 2). In that same year, 124 trials were launched in Denmark.

**Figure 2: Distribution of initiated commercial clinical trials in the global market and in Finland in 2023**




Finland has not been fully able to take advantage of the benefits of being a country with a small population. Here, almost all the units involved in research (e.g. the authorities, university hospitals, separate research centres, universities, and smaller companies) know each other and operate according to a set of common rules. This would make it relatively easy to facilitate communication, coordination and joint activities between all units at the national level. Finnish patients also already have a high level of trust in healthcare providers and the authorities.

The majority of clinical trials in Finland are commercial and concentrated in university hospitals, particularly in the Helsinki University Hospital (HUS) area. At present, there is no centralised source of detailed information on research volumes by research unit. This study identified this as one of the significant challenges and areas for future development. In the future, it will be important to obtain a national overview of the distribution of clinical trials among different research units and also by therapy area. Furthermore, it will be important to understand the actual balance between supply and demand in the future. At present, it is also impossible to obtain a comprehensive picture of how many studies are actually offered to Finland and the main reasons why studies are not carried out in certain cases. More accurate statistics will be necessary in the future in order to develop processes.

Finland has traditionally held a strong position in clinical trials relative to its size. Despite a deterioration in recent years, Finland still performs well in certain research areas (for example, vaccines) and therapeutic areas

(for example, cancer) relative to the size of the country. However, the loss of competitiveness can also be seen as growth potential. Exploiting this potential nevertheless requires not only investment in infrastructure but also the development of legislation, a skilled workforce, and the research environment to make Finland more competitive than it is at present.

## The distribution of trials by phase and therapy area differs between countries

Clinical trials are divided into four phases (Phases I–IV), which progress from early-phase studies (Phase I) to large-scale efficacy and safety studies (Phases II and III) and then to efficacy and safety studies based on real-world data conducted after marketing authorisation (phase IV). The phase distribution provides information on the development phases that different countries specialise in and on the expertise and infrastructure required in the research environment.

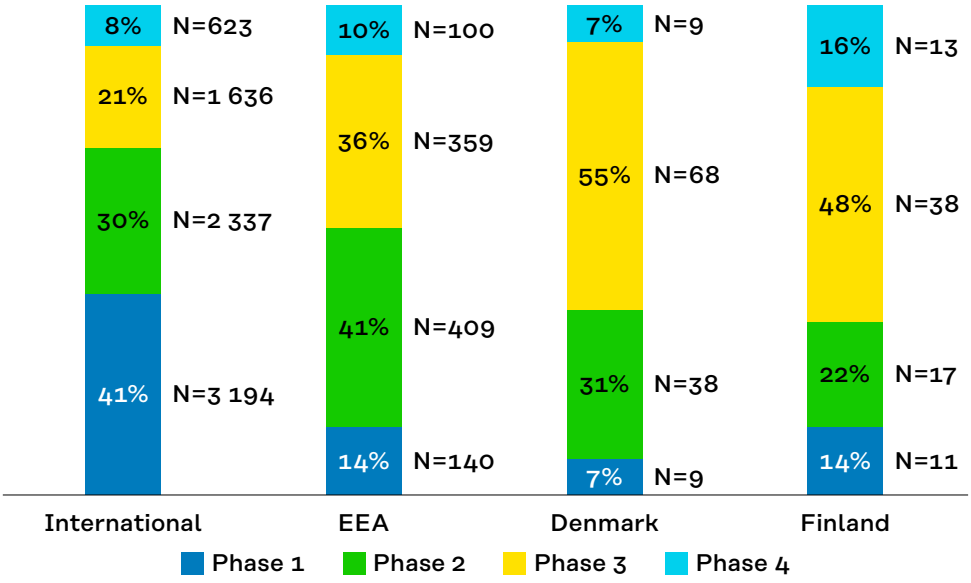
The balanced implementation of clinical trials in phases is important: Phase I trials lay the foundation for pharmaceutical innovation, further development and regional appeal. Their small number may weaken Finland's position as an early-phase research and investment environment. However, Finland has successfully standardised several Phase I centres.

Phase III trials are essentially large-scale studies that provide research units with financial resources and, in turn, give a large number of clinical practitioners the opportunity to participate in research on drug molecules prior to marketing authorisation. Phase IV studies broaden the understanding of the benefits, risks and clinical utility of the drug in a real clinical setting. They are no longer a condition for drug approval in the same way as phases I–III, but they are essential for assessing a drug's overall efficacy and safety at the population level.

In 2023, the majority of trials initiated in the European Economic Area (EEA) were in Phase II (36%) and Phase III (41%). The proportion of Phase I studies was only 14%, which is significantly below the global level (41%). This reflects Europe's weaker position as a location for early-phase research, especially compared to places such as China and North America.

The exact phase distribution of clinical trials in Finland in recent years is not available. The data gap is related to the transition to European-level reporting for clinical trials (CTIS), under which the Finnish Medicines Agency does not report clinical trial phases separately at the national level. The European-level reporting platform is constantly being developed, and the situation may change in the future, when a country-level phase distribution may also become available in more detail. Finland's phase distribution in Figure 3 is based on the average for the available years 2019–2021, which also include academic studies.

**Figure 3: Distribution of clinical trials by phase (%) in 2023**



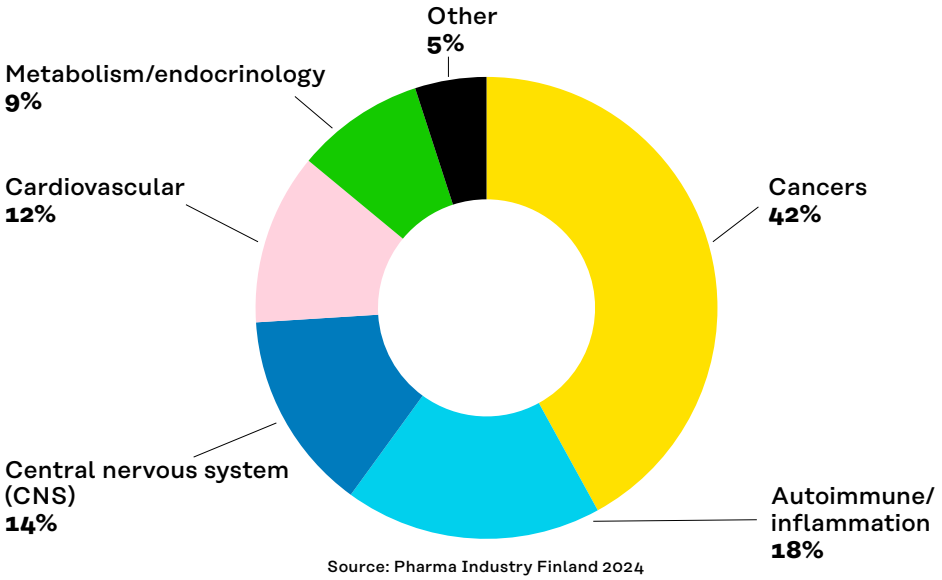

International numbers retrieved from: IQVIA ja EFPIA-VE:
Assessing the Clinical Trial Ecosystem in Europe. August, 2024 / Finland: Fimea, 2024

For the past ten years, Finland has been a pioneer in registry studies based on real-world data, thanks to its unique opportunity to utilise healthcare registers and information from hospital data lakes as data sources. These studies are rarely Phase IV clinical trials, which are mostly conducted to gather post-authorisation data on drug safety (referred to as PASS studies).

One of the factors contributing to future success may be how well Finland is able to leverage its robust health data environment to support clinical trials, both in Phase IV trials and in feasibility assessments. In the future, the data lakes emerging in wellbeing services counties may give Finland a unique opportunity to offer studies that cannot be carried out elsewhere. Data lakes can also significantly speed up the feasibility process and create a clear competitive advantage over other benchmark countries. The current decentralised model of clinical research cannot fully support the effective use of real-world data and will require closer national collaboration in the future.

Therapy-area-specific reviews provide additional insight into which disease areas studies focus on. At the European level, the largest shares of commercial clinical trials were focused on cancer (28%), neurology (9%), rheumatology (8%) and cardiovascular diseases (7%). In Finland, there are some similarities, but the focus is more pronounced. In 2023, up to 42% of studies focused on cancer, followed by autoimmune and inflammatory diseases (18%), the central nervous system (14%) and cardiovascular diseases (12%) (Figure 4).

**Figure 4: Distribution of clinical drug trials by therapeutic area in Finland**




Source: Pharma Industry Finland 2024

This focus also partly reflects national expertise, the resource base, and the areas to which Finland's research capabilities and patient populations are best suited. It shows that Finland has the potential to raise its profile and focus on specific areas of therapeutic expertise, which could give it a competitive edge in the international research market.

Finland already has centres of expertise in cancer and neurosciences that strengthen and support its clinical research infrastructure. However, the current system may fail to identify other strong areas because of the lack of a national mechanism for comprehensively mapping research potential.

It is possible that certain sectors have also grown thanks to the efforts of outstanding individual experts and centres of expertise, which have steered the allocation of resources. For example, primary healthcare research could become increasingly significant in Finland in the future due to the integration of information systems in wellbeing services counties, but its national scope and potential are not yet fully recognised.

## The role of academic research and its relation to commercial clinical trials in Finland

Academic medical research is a key part of the research and innovation system. It generates new knowledge about the mechanisms of disease, the effectiveness of treatment methods and the development of healthcare practices without any direct commercial objectives. Academic studies are a significant complement to studies funded by the pharmaceutical industry, the main focus of which is on bringing new medicines to the market.

In 2024, 27% of clinical trials in Finland were academic. This is clearly less than in Denmark, for example, where the share of academic studies was 39%. The research environment in Denmark differs from that in Finland partly because several large pharmaceutical companies are owned by foundations, which also increases the number of non-commercially funded trials by allowing them to apply for funding. In addition, in Denmark, pharmaceutical research is more broadly integrated into national research, innovation and economic policies, for which a comprehensive strategy has been developed.

From an international perspective, the number of academic clinical trials conducted in Finland is low. Globally, academic research accounts for 69%, and in the EEA, it makes up about 50% of all research. In Finland, the scarcity of academic clinical research raises the question of whether an increase in the number of commercial trials could also act as a catalyst for the growth of academic research. The same research staff and researchers often work on both commercial and academic projects, and a well-functioning research environment can enable the parallel development of both types of research.

Thus, it is possible that an increase in the volume of commercial clinical trials will improve the conditions for carrying out academic clinical trials, for example, through infrastructure, logistics and the availability of experts. This trend can be strengthened nationally through a conscious strategy to encourage collaborative research between different funding sources and research types.

## 1.4 Economic and societal value of clinical trials

Clinical trials have been shown to provide direct health benefits for patients, as well as indirect cost savings for healthcare and, ultimately, for society as a whole.

Every year, international pharmaceutical companies invest EUR 300 billion in the development of new medicines. According to annual estimates by Pharma Industry Finland, investments in clinical research in Finland exceed EUR 200 million per year. This means significant revenue for healthcare and society as a whole.

According to a report commissioned by Pharma Industry Finland, the direct value of treatment generated by one clinical trial is approximately EUR 1.2 million (including free study drugs, reimbursable treatments for research patients and direct health benefits). However, it is significant that the indirect value (health and cost benefits) generated by clinical research elsewhere in healthcare is nearly nine million euros. Thus, the total societal value of one clinical trial is approximately 10 million euros.

According to data collected by Pharma Industry Finland, in 2024, the pharmaceutical industry invested approximately 460 million euros in Finland, half of which was focused on research and development (R&D). A significant part of the research investments was directed at clinical trials. The Finnish pharmaceutical industry's national goal is to increase investments to one billion euros by 2030. If this happens, investment in clinical trials in Finland could increase by roughly 250 million euros. This means that the number of clinical trials could even double compared to the current level. In order to meet this investment promise made by the pharmaceutical industry, Finland must be able to improve its competitiveness by developing its operating environment for clinical trials.

# 2. The current state and challenges of clinical trials in Finland

In Finland, the implementation of clinical trials currently faces several bottlenecks that weaken the country's position in international competition. The challenges relate both to the initiation and organisation of trials and to their practical implementation, and are particularly visible in the field of commercial clinical trials.

The Finnish system of commercial clinical trials is currently decentralised and localised. Although the national network among academic research communities is relatively well-developed, similar collaboration has not been established in commercially commissioned research. Research organisations operate separately, and there is little interregional coordination or cooperation between them.

From the perspective of a customer, such as a pharmaceutical company, the system appears to be a complex entity in which relevant contacts must be sought from many different research units and among individual researchers. This makes it especially difficult for new actors to find opportunities to engage with suitable research centres and researchers. Decentralised operations can slow down the initiation and implementation of trials, which in turn can lead to a situation where the promised number of patients for the trial cannot be found, or the objectives cannot be achieved within the agreed timeframe. Eventually, this may weaken Finland's position as an attractive country for research and lead to its exclusion from new clinical trials amid fierce international competition.

**Based on interviews, the key challenges for customers, i.e. pharmaceutical companies, initiating new drug trials are:**

1. **Slow contract and budget negotiations**
   Contract and budget negotiations must be conducted separately with each organisation participating in the trial. Each research organisation has its own lawyer, and interpretations and the need for corrections related to the contract text may also vary. Finnish law and related interpretations often necessitate changes to contract templates.

Conversely, the contract processes of pharmaceutical companies themselves can also be cumbersome and slow.

Contract and budget negotiations alone can take so long that, by the time the centres are ready to receive patients, international recruitment targets have already been met, and the number of patients recruited in Finland remains modest.

Harmonising contract and budget negotiations between regions and organisations would require at least some legislative changes, but above all, consistent and jointly agreed national practices. The operating models associated with the contract processes of pharmaceutical companies also need to be reformed to enable smooth collaboration. In the future, the task of the FinTrials coordination unit will be to assess how contract and budget processes could be developed and harmonised.

### 2. Inconsistency and unreliability of feasibility processes

One of the most significant challenges from the customers' perspective relates to the current feasibility assessment process, which is considered inconsistent and unreliable.

When assessing the feasibility of a trial, it is important to quickly gain an accurate understanding of whether it can be carried out in Finland. If implementation is possible, there must also be a realistic estimate of the number of patients available for the study and the relevant timeline. Although there are some excellent units and processes operating in Finland, such as the FINPEDMED network in paediatric studies, the overall picture is still fragmented and the lack of a uniform operating model complicates assessments.

New noteworthy developments include global databases and researcher registries jointly used by large pharmaceutical companies, and increased use of artificial intelligence. They allow companies to connect with individual researchers and centres listed in the registers. In such cases, new offers may be left to individual discretion and thus lead to offers being rejected, as responses cannot be processed at the national level by considering other potentially suitable units and researchers.

During the implementation phase of a trial, it is crucial that the agreed number of patients is enrolled on schedule. This is a critical issue for pharmaceutical companies. If the recruitment of patients for the study remains incomplete, the company must find patients in other countries so that the study design is not compromised. This causes delays and additional costs, which weakens Finland's appeal as a host country for research. If similar problems occur repeatedly, it may significantly weaken Finland's competitiveness in the international research market.

3. **Lack of proper contacts**
   The current decentralised model highlights the importance of individual contacts and pre-established relationships with research centres. If a sponsor does not already have established contacts with research centres or has outdated information, it can be difficult to find new and appropriate researchers (relevant therapeutic area or expertise) in the current decentralised system. With scattered contacts and multiple contact attempts, a company may end up contacting clinicians who have already retired or moved elsewhere and are no longer conducting research.

4. **Lack of performance indicators**
   In international competition, it is crucial to be able to demonstrate the competitiveness of Finnish clinical research activities with reliable and comparable indicators. Pharmaceutical companies closely monitor how different countries perform in areas such as trial start-up speed, lead times and meeting recruitment goals, and base their decisions about where to conduct future trials on these findings. At present, there are no nationally coordinated performance indicators in Finland, which not only complicates the development of its own operations but also weakens Finland's visibility in international comparisons conducted by pharmaceutical companies.

5. **Slow uptake of innovative drug treatments**
   In recent years, it has been recognised as a challenge that Finland has not approved the same new drug treatments as many other EU countries, or that the introduction of new drugs has been slow. This undermines the ability to participate in studies that use the latest available drugs as a baseline for comparison.

**From the perspective of providers (wellbeing services counties, HUS), the most significant challenges for implementing new trials in research organisations are:**

1. **Lack of performance-based RDI incentives in the criteria for general funding for wellbeing services counties**
   The lack of performance-based incentives effectively discourages RDI investment in wellbeing services counties and has led to a situation where there is virtually no investment in clinical drug and medical device trials in the counties. This is eroding research capability and leading to the loss of clinical drug and medical device trials. Lack of incentives can significantly impair the functioning of the FinTrials network, as the inability to deliver research services that are marketed as effective can lead to failure and thus long-term reputational damage.

2. **Fragmentation of the research environment and shortage of resources, as well as the lack of a centralised research unit (later the Clinical Trial Office, CTO) and hospital-level professional clinical research units (Clinical Trial Unit, CTU) in many areas**
   Research units recognise that they face significant resource challenges, and trials are increasingly being turned down due to a lack of researchers. In particular, recruiting new researchers is challenging due to a lack of incentives for both organisations and individuals. The current funding model for the wellbeing services counties provides no incentives to conduct clinical trials, and doctors do not feel they gain sufficient benefit for the time they spend on research. In addition, CTO/CTU activities are still under development in some university hospitals, and actual clinical trial units are not available everywhere, as therapeutic areas operate quite independently.

3. **Difficulty managing fluctuations in demand**
   The volume of research coming to Finland is modest and strongly concentrated in one or a few units. There is also significant annual variation in the number of research proposals across different therapeutic areas, which makes maintaining permanent resources challenging. It is also difficult to gain a picture of total demand, as there is no uniform system for monitoring demand and supply.

4. **Lack of cooperation, especially between different therapeutic areas and wellbeing services counties**
   At the national level, collaboration between research units is patchy and administratively uncoordinated, and common operating models exist only in isolated cases and between clinicians within specific therapeutic areas.

   In summary, it can be said that the current system needs better national coordination, development of the research environment, measurement of national performance, and stronger incentives for wellbeing services counties, HUS, and individual researchers to participate in commissioned research. Without these changes, Finland will likely continue losing its competitive advantage and thus be excluded from international clinical trials.

# 3. Expectations for clinical trials and international comparison

Actors expect future clinical drug trials to be fast, predictable, and reliable.

The expectations of pharmaceutical companies and providers regarding the future model are similar: the interviews highlighted the need for a clear and simple operating model.

In its target state, Finland operates in a unified, coordinated and transparent manner, providing a competitive, predictable and high-quality operating environment for clinical trials. This requires structural reforms, strong national commitment and a willingness of all parties to cooperate.

The following tables (1–2) describe the expectations of customers and providers regarding the operating model.

## 3.1 Expectations

### Table 1: Key expectations from the customer's (pharmaceutical company) perspective

| Customer expectations | Description |
|---|---|
| Predictability and reliability | The feasibility assessment and the actual implementation of clinical trials must be predictable and efficient. They increase trust in the Finnish system and thus improve competitiveness. |
| Quality | Finland has been and continues to be regarded as a high-quality country for conducting research. However, in most countries today, quality is no longer a real challenge. In terms of competitiveness, maintaining quality is still important, but it is seen as a basic requirement rather than a competitive advantage. |
| Indicators | Internal indicators for clinical trial activities would enable an objective comparison between operational units. They would also provide an opportunity to demonstrate overall performance and compare Finland internationally with other countries. |
| Operating model | The development of the operating model must be iterative and practical. Finland already has several well-functioning research units and centres of expertise, so development should be based on existing structures and their strengths. |

| Customer expectations | Description |
|---|---|
| Costs | For companies, the threat is that the new operating model will create a new layer of actors whose added value will not compensate for the costs incurred. Research budgets are tight, and it is also essential for Finland's competitiveness that it does not fall behind in international competition because of excessively high costs. |

## Table 2: Key expectations from the provider's perspective (wellbeing services counties and HUS)

| Provider expectations | Description |
|---|---|
| Feasibility assessment and key information systems | A centralised, university-hospital-led information system that records all clinical drug trials offered to Finland. It can be used to assess the feasibility of trials in different areas, for example, in terms of resources, expertise and the patient pool. In addition, it supports customer relationship management and directing research to the right units. |
| Network of CTOs | A network of Clinical Trial Offices (CTOs) operating at the level of regional collaborative areas (YTAs) that coordinates and is responsible for the practical implementation of research. |
| Funding | Incentives should be developed both at the organisational level and for individual researchers to prioritise and support research activities. The operating model is expected to align with funding so that financial resources are allocated to research. Performance-based RDI incentives should be created for general funding (e.g. university hospital subsidies or other general funding), and the metrics should include the volume, scope, and economic value of commissioned research. The use of funding through the incentive scheme will be coordinated by the regional CTO. |
| Existing structures | There are already several established units and centres of expertise operating in Finland. It is important to maintain these functioning structures and to draw lessons from them in the development of new ones by increasing cooperation at the national level. |
| EU regulation | The system must comply with EU regulations and legislation. |
| The role of collaborative areas | Strengthening the role of collaborative areas (YTAs) as coordinators and hubs for research activities in areas where they have statutory responsibilities. |
| International networking | Increasing clinical trials in line with the European Competitiveness Report by acting as part of international clinical trials networks, and accelerating scientific innovation and the uptake of innovative drugs. |

## 3.2 International comparison

The FinTrials model is not an internationally unique response to the challenges associated with clinical trials. Similar models for national collaboration have already been introduced in Denmark, Norway and Sweden, which shows that strengthening research activities through national coordination has been widely identified as necessary. Although the models differ, Finland can use these examples to build its own operating model. Below are the solutions from each country and their key features, including budgets.

### Denmark's Trial Nation

Trial Nation's funding is based on both regional and state support. In 2020–2023, all five regions funded activities with a total of 6.4 million euros, or approximately 1.6 million euros per year. In addition, the state supported the organisation with 2.4 million euros in 2020–2021. The total amount of public funding in the initial years was 2.8 million euros, after which it has stabilised at approximately 1.6 million euros per year. Funding is directed at coordination, service development and supporting services, not actual research.

The organisation's core staff consists of 7–10 people, and the regions also fund research resources for 1–2 person-years annually. Trial Nation's network includes all five Danish regions, university hospitals and several research organisations. It acts as a link between the public and private sectors, increasing the quantity and quality of clinical trials.

In 2023, Trial Nation handled more than 100 clinical trial requests, many of which led to actual trials. The organisation has succeeded in attracting international research to Denmark and has strengthened the country's position as an attractive destination for clinical trials.

### Norway's NorTrials

NorTrials is Norway's national public-private partnership that aims to increase the number of clinical trials in Norway and improve patient access to new treatments. NorTrials was established in 2022 as part of the Government's national clinical trials action plan. The model was inspired by Denmark's Trial Nation.

NorTrials provides pharmaceutical companies and medical device manufacturers with a 'one-stop shop' that makes it easier and more efficient to conduct trials in Norway. NorTrials has six national research centres located in university hospitals across Norway. Each centre focuses on one

therapeutic area: brain health, cancer, cardiovascular diseases, clinical immunology, gastrointestinal diseases, and medical devices.

The centres act both as national contact points for industrial research and as network hubs that bring together experts and resources from across the country. NorTrials' coordination unit and board of directors are responsible for directing its operations. The board includes both directors of regional healthcare services and industry representatives.

The centres receive annual funding from the state budget for building infrastructure and networks (approximately NOK 2 million per centre annually). In addition, the funding is used for national support activities (10–15 person-years) and for marketing Norway as a research destination.

NorTrials offers an electronic portal through which companies can submit feasibility surveys and find suitable research centres in Norway. NorTrials also helps draft patient information leaflets and consent forms to ensure they meet national requirements.

## Sweden's SweTrial

SweTrial is a Swedish national model similar in structure and purpose to the Danish Trial Nation and the Norwegian NorTrials. A distinctive feature of SweTrial is the Swedish Medical Products Agency's strong role and extensive stakeholder collaboration.

In 2024, SEK 4 million was allocated for the launch of SweTrial, which was increased to SEK 30 million for the following year. From 2026 onwards, SweTrial's annual budget is set at SEK 60 million. The funding is part of Sweden's broader life sciences strategy and budget, which aims to reverse the decline in clinical trials and strengthen the country's international competitiveness.

SweTrial is part of a broader Nordic collaboration that aims to increase the volume and quality of clinical trials across the region and facilitate multicentre trials across national borders. SweTrial collaborates with other Nordic national centres and participates in joint development projects and networks (e.g. Nordic Trial Alliance).

## Conclusions from the comparison

A comparison between Trial Nation in Denmark, NorTrials in Norway and SweTrial in Sweden provides useful guidelines that can be utilised for FinTrials.

Firstly, in all countries, public funding is a key part of the implementation of the model. In Denmark, funding is shared between the regions and the state. In Norway, the government funds centres and support functions, and in Sweden, SweTrial is part of the national strategy.

Secondly, centralised coordination and the 'one-stop shop' model are critical in all examples. They facilitate companies' access to research environments, speed up processes and improve appeal. Finland needs a national coordination unit that acts as a point of contact for companies and provides effective support for initiating trials. In addition, an accelerated approval process, referred to as 'fast-track processing' for early-stage studies, is already in place in countries such as Denmark and Sweden, and is critical to the speed at which trials are initiated.

Thirdly, a regional network and specialisation increase effectiveness. In Norway, the centres focus on different therapeutic areas, and in Denmark, all the regions participate in the collaboration. This enables the targeting of expertise and the establishment of a nationwide network. In Finland, too, regional centres could specialise in forms of therapy and operate as part of a national network.

Fourthly, cooperation between industry and the public sector is an essential part of the success of these models. In Norway, industry participates on the board, and in Denmark, Trial Nation acts as a bridge builder. The Finnish model should ensure industry participation in strategic guidance and operational cooperation so that it genuinely meets the needs of businesses.

In addition, digital tools and services support operations. NorTrials provides an electronic portal for feasibility surveys and document creation, which has accelerated these processes. The Finnish model should include digital services that support the planning and implementation of trials. A practical example of this is the shared electronic platform and service request template for companies, which have been used in the FINPEDMED and NORDICPEDMED paediatric research networks since 2014.

Active and strategic marketing is essential to succeed in international competition as a host country for research. All the models examined seek to strengthen their country's national position as an attractive research destination, and the countries invest systematically in marketing. The Finnish model should also include a strong marketing component that makes Finland a visible and interesting alternative for international research assignments.

In summary, the model to be established in Finland should be publicly funded, centrally coordinated, and regionally connected. Its activities should broadly involve all units providing research services, as well as clinical research organisations from both the public and private sectors. Cooperation should be carried out particularly with existing independent entities, such as Finnish Vaccine Research and the Finnish Drug Discovery Centre, so that Finland can present itself as a unified research area across all sectors and open to all types of research. In the future, competition and concentration of expertise can also be expected in Finland, particularly

through the establishment of centres for advanced therapy medicinal products (ATMP) and new competitive operating models (decentralized clinical trials, cross-border research), once the EU's new Strategy for Life Sciences is implemented. This now requires a national effort from Finland to build a competitive and effective model that promotes the quantity and quality of clinical trials in Finland.

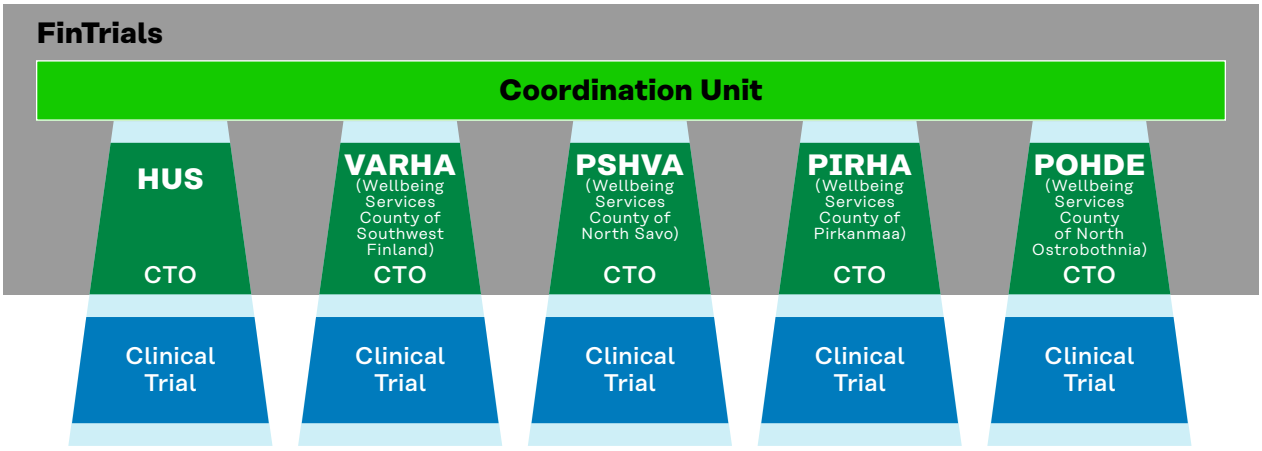
# 4. Proposal: FinTrials – National Operating Model for Clinical Trials

FinTrials is a collaborative network that brings together regional clinical research expertise and national coordination. The model utilises existing structures and brings uniform operating methods, a single point of contact for clinical research, and better visibility for Finland's research capabilities. The aim is to strengthen Finland's position as an attractive and competitive country for clinical trials.

## 4.1 Description of the operating model

The FinTrials model is a nationwide collaborative network based on a clearly organised and uniform operating model. It will make use of existing research structures, especially clinical trials conducted in wellbeing services counties. In the initial phase, the model will focus on university hospitals and the wellbeing services counties that maintain them, as well as HUS. They will be collectively responsible for coordinating research activities (Figure 5). FinTrials' operations will be further developed so that in the future, they will involve all units providing research services and organisations conducting clinical research, both from the public and private sectors.

**Figure 5: National coordination model for clinical trials in Finland**



The FinTrials operating model is built on three main levels:

1. The National Coordination Unit
2. YT Area Clinical Trials Office (CTO)
3. Area clinical research operations (wellbeing services counties and HUS)

The **National Coordination Unit** will support the areas by, among other things, matching the supply and demand for research, maintaining an up-to-date customer relationship management system and availability information system, and coordinating and managing clinical trial contacts and implementation processes. In addition, it will develop feasibility processes, monitor national KPIs, harmonise operating methods and contractual and budgetary templates across the collaborative areas, and market and represent Finland internationally.

**YT Area Clinical Trials Office (CTO)** coordinates and supports the conduct of clinical trials within its collaborative area. The CTO knows the strengths of their area and is responsible for maintaining customer relationship management systems and feasibility information systems. In a YT area, the CTO is responsible for the day-to-day management of clinical trials.

**YT Area clinical research operations** are responsible for the implementation of an effective research process within the limits of the resources provided.

There must be a strong link between the national and YTA levels, and between YTA levels and area activities, so that information, resources and competence circulate efficiently at all levels. The National Coordination Unit supports activities nationwide, but the actual research work is still carried out locally.

The following table (3) summarises the key elements of the operating model to ensure the competitiveness of the Finnish model in the global market.

## Table 3: Key elements of the FinTrials operating model

| Key element of the operating model | Description |
|---|---|
| 'One-stop shop' model | A coordinated operating model that brings together research processes and functions as a national centre. |
| Customer relationship management and feasibility systems | Shared systems bring together regional research resources, therapeutic priorities, and performance data, enabling an up-to-date overview of research demand and supply in Finland. They support coordinated operations, improve resource efficiency and provide pharmaceutical companies with a predictable and transparent process for conducting business, which strengthens Finland's attractiveness in international competition. |
| Incentive scheme | A performance-based incentive in the wellbeing services county funding model, with the use of funding coordinated by the regional CTO. |
| CTO-network | The YTA-level Clinical Trial Office network coordinates and is responsible for the practical implementation of trials. |
| National feasibility assessment | Time limits are set for feasibility assessments and for the initiation of studies. |
| Indicators | Performance is measured using national KPIs. |
| Harmonised contract processes | Nationally agreed templates (budgeting, contracts, etc.) are in use. |
| Quality | Quality is at internationally competitive levels, with no new cost burdens for payers. |
| Legislation | In line with EU and national legislation. |
| Collaborative areas | The role and importance of collaborative areas (YTAs) are taken into account. Collaboration can be extended to other areas without additional barriers. |
| Global added value | Responding to global demand, generating added value for Finland, accelerating the introduction of innovative drugs and preparing for new research. |

## 4.2 Operating model resourcing

The resource allocation presented below is preliminary and partly based on peer countries as well as the views of the authors. Resourcing depends on the position of the FinTrials organisation within the organisational structure and the available funding. The following activities describe an ideal situation that can be adapted to the circumstances mentioned, such as the Coordination Unit being located in an existing, synergistic clinical trial environment. The aim is to channel most of the funding and resources into regional activities and to keep the National Coordination Unit lean. More detailed resourcing for the operating model will be specified later by the Ministry of Social Affairs and Health.

In the proposal, the **Coordination Unit** includes the director as well as experts who work in support services (financial management and IT, legislative and ethical evaluation, coordination and support for trials) and in investment and procurement (e.g. customer relationship management system, pilots, purchased services).

The Coordination Unit's activities also include a part-time Board of Directors and cooperation committees, which support and harmonise activity across different areas. The cooperation committees are also part-time and can be combined if necessary. The Scientific Committee provides expert support. The Legal Committee evaluates and harmonises contract practices and drafts contract structures. The Finance Committee monitors the commercial terms and the value and economic benefits of research.

Possible tasks of **CTO/CTU activities in the collaborative areas (YTAs)** are to:

- Coordinate and support the clinical trial contact process, feasibility assessment, implementation, and management at the YTA level.
- Collect information about researchers and research in their area.
- Maintain customer relationship management and feasibility systems within a collaborative area.

**Area clinical research** requires resources, such as physician investigators, study coordinators and study nurses. Long-term funding must be reserved for strengthening and resourcing area research activities in order to achieve and maintain a critical baseline.

The resourcing of area CTO (or unit-level CTU) and research activities will be specified together with the collaborative areas, and this process must take into account the strengths and development needs of each area. This report does not take a position on more specific resource allocation for the areas.

The following table (Table 4) describes the entire FinTrials organisation, i.e. the resourcing of the Coordination Unit and the CTO/CTU activities in the collaborative areas.

### Table 4: FinTrials Coordination Unit and CTO/CTU resourcing in the collaborative areas

| Task | Resourcing |
|---|---|
| **Coordination Unit** | |
| **Central staff:** | |
| Director | 1 person-year |
| Assistant | 1 person-year |
| **Research support services:** | |
| Clinical research expert | 1 person-year |
| Finance and IT expert | 1 person-year |
| Legislative and ethical assessment expert | 1 person-year |
| **YTA-level Clinical Trials Office / area** | |
| **Research activities:** | |
| Research coordinator | 1 person-year |
| Study nurse | 2 person-years |
| Research secretary | 1 person-year |
| Total person-year resources in the FinTrials organisation | 25 person-years: 20 for collaborative areas, and 5 for the Coordination Unit |

## FinTrials model cost estimate

The costs of the FinTrials operating model have been estimated at a total of about **2.3–3.4 million euros per year** with the resources outlined above. The cost level depends primarily on the number of resources required in the YT areas.

At this scope, the annual cost of the national coordination unit has been estimated to be approximately **1–1.5 million euros**. This includes administrative costs, support services provided by collaborative committees, marketing and communications, and procurement costs. The annual costs of the customer relationship management system must be assessed separately. The default assumption in these calculations is that national coordination functions will be built from scratch, rather than utilising existing structures.

In addition to annual costs, implementation includes investment in a shared customer relationship management and feasibility service system, the exact cost and distribution of which between the investment and

operating phase costs depends on the selected solution. It is estimated that the customer relationship management system can be launched with a light implementation and updated and expanded as volumes increase.

If the Coordination Unit is placed within an existing organisation working in clinical research, the resulting synergies may help to reduce the costs mentioned above.

## Funding options

The FinTrials organisation has three possible funding models, and a fourth that is a combination of these three models:

1. Funding from the state budget
2. Funded by the areas
3. Commercially funded
4. Hybrid model

In the first option, the Coordination Unit is funded from the state budget. The advantages of this operating model are that it enables long-term planning for operations and emphasises the infrastructural nature of the unit. The model also does not incur additional costs for end customers.

In the second model, the wellbeing services counties fund the activities of the Coordination Unit. The advantages here are close links to the activities in the areas and cost transparency. The biggest challenge is the low willingness of the counties to cover the unit's costs in a constrained economic environment.

In the third model, the funding for the Coordination Unit would come from commercial clinical trials. This funding could be, for example, an administrative fee for commercial research projects. The key advantages of this operating model would be close ties with end customers and a customer-centric approach. This model would also cover its own costs. The challenge here is that total costs to customers could rise, and Finland's attractiveness to customers could decrease.

The fourth model is a combination of the three previously mentioned models. Part of the funding may come from the state budget, and part from commercial activities. The model may also change over time; for example, the budgeted funding is initially higher but decreases as commercial funding grows. The benefits and challenges depend on the particular combination of funding models.

A state-funded model would be a natural way to fund the activities, at least when initially launching them, so they can be initiated and secured in their early stages. Additionally, the model should not increase the total cost to customers. Once the activities have stabilised and become more efficient, funding from the wellbeing services counties can be increased, as they

benefit from the revenue flow generated. Similarly, the share of customer payments (overhead for coordination) can be increased. The legal terms of the funding models must be clarified at the same time as the organisational location of FinTrials is decided.

## 4.3 Customer relationship management and system performance indicators

Shared CRM and feasibility systems form a central part of the proposed FinTrials operating model. They can be used to create an up-to-date overview of the supply and demand for commercial clinical trials in Finland for the first time. The systems bring together the resources, therapeutic priorities, service requests, responses and performance data of the counties, thus enabling a coordinated and efficient operating environment.

Systematic documentation provides comparable data on aspects such as trial start-up speed, the length of contracting processes, recruitment success and patient numbers. This information not only improves the efficiency of resource use and forecasting at the national level, but also enhances Finland's global competitiveness by providing customers with a predictable and transparent service process. In the future, the system would also function as a development tool. It identifies bottlenecks, guides development activities and evaluates effectiveness.

The FinTrials workshop organised by Sitra collected stakeholder views on systemically important indicators.

Below are the most important performance indicators according to the participants:

- Number of trial proposals and total demand by type (phases and therapeutic areas)
- Number and names of the units that have received the trial offer
- Number of units that declined trial offers
- Grounds for refusal (provider level)
- Start speed of the trial (time indicators):
    - How quickly was the availability survey completed?
    - How quickly were contracts drafted and signed?
- Number of patients potentially eligible and recruited for trials
- Availability and speed of recruitment (time indicators)
- Administrative processing times for research, including contracts and permits (time metrics)
- Value of the drugs used in the research in euros
- Direct benefits to patients during the research (quality indicators)

As noted, the system's cost has not yet been estimated, but it is relatively simple in terms of its operational logic and does not store personal or patient data. At its simplest, the system can be built using a spreadsheet program. Of course, it is wise to prepare for future growth and new needs. Connecting the customer relationship management system to the feasibility system should be considered, which would require a more sophisticated system.

## 4.4 Placement options for the Coordination Unit

This study identified three placement options, each with its own advantages and challenges. It should also be noted that the operating model is network-based, that is, the majority of operations take place in the counties in any case.

1. **In connection with a wellbeing services county**
   The FinTrials Coordination Unit can be placed within a wellbeing services county, in which case that particular area serves as the responsible organisation. The advantages of this model include the ability to use existing structures and expertise, proximity to patients, and existing international networks. Challenges may include competition forming between different wellbeing services counties and the development of inequality between them.

2. **Within a national body**
   Another option is placement within a national body, such as a ministry or a subordinate institution or agency (for example, the Finnish Institute for Health and Welfare (THL)). The advantages of this model are fairness and neutrality, national structure and connections to wellbeing services counties. Challenges, in turn, may arise from the distance to practical activities and patients, possible needs to amend legislation, and the fact that there may not necessarily be direct links to key clinical experts.

3. **Breaking away from existing structures**
   The third option is placement as a completely separate organisation, without ties to existing structures, as exemplified by the Finnish Drug Discovery Centre. This makes it possible to plan from scratch and allows for a great deal of freedom in designing structures and operating models. The challenges with this model are a slow start-up, the risks associated with establishing the unit, and the restrictions imposed by legislation, especially if it is placed outside the wellbeing services counties.

At the time of writing this report, no decision has yet been made regarding the placement of FinTrials. That decision must be made in Stage 0 of the roadmap presented below.

# 5. Roadmap to the target state

The introduction of a new operating model for clinical trials in Finland requires step-by-step and systematic implementation. The aim of the roadmap is to ensure that the FinTrials model is built in a controlled way, scales efficiently and meets the expectations of different stakeholders.

The roadmap proposed in the project is divided into six stages, which progress from preparation and piloting to nationwide expansion, evaluation and finally consolidation. Each step has a clear goal and key actions that lay the groundwork for the next stage. The proposal for the roadmap is preliminary and should be refined once the funding channels are clear and key actors have committed to the organisation.

**Stage 0: Preparation (Q4/2025)**
The goal is to organise and plan the resourcing of the well-being services counties/HUS. Stage 0 involves deciding on the organisation's placement and administrative model (e.g. public authority, wellbeing services county, or a separate entity), preparing a plan for resource allocation in the wellbeing services counties/HUS and YT areas, and determining the structure and resource needs of the coordination unit's central staff.

**Stage 1: Start of operations (Q4/2025–Q1/2026)**
Stage 1 involves defining the basic requirements of the collaborative model and initiating activities. This stage establishes the central staff for the coordination unit (director and key personnel), defines the procurement criteria for the customer relationship management system, describes the feasibility process, drafts preliminary KPIs, begins engaging key stakeholders (well-being services counties, the industry, researchers, authorities, ministries) and prepares marketing and communication plans.

**Stage 2: Piloting (Q1–Q2/2026)**
In Stage 2, the customer relationship management system, feasibility process, and indicators will be piloted in select YT areas. At the same time, contract management processes will be developed and data collection initiated (for example, research volumes in CTOs). The first research projects will be launched according to the new model. The aim is to test the structures in practice and create the conditions for nationwide expansion.

## Figure 6: Preliminary Roadmap for the FinTrials Model

| Stage | Q4/ 2025 | Q1/ 2026 | Q2/ 2026 | Q3/ 2026 | Q4/ 2026 | Q1/ 2027 | Q2/ 2027 | Q3/ 2027 | Q4/ 2027 |
|---|---|---|---|---|---|---|---|---|---|
| 0. Preparation | | | | | | | | | |
| 1. Launching | | | | | | | | | |
| 2. Planning and piloting | | | | | | | | | |
| 3. Expansion and harmonisation of processes | | | | | | | | | |
| 4. Evaluation and optimisation | | | | | | | | | |
| 5. Scaling and consolidation | | | | | | | | | |

### Stage 3: Expansion and process harmonisation (Q3–Q4/2026)

Stage 3 expands the use of the customer relationship management system to all YT areas and introduces uniform feasibility processes and time limits. KPIs will be established, and reporting will be carried out with the agreed analytics tool.

### Stage 4: Evaluation and optimisation (Q1–Q2/2027)

Stage 4 involves the first overall evaluation of activities, examining quality, speed and research volumes. Indicators and processes will be updated based on experience, and new value-adding services will be planned. Where possible, national specialist networks (such as FINPEDMED) will be added to the structure. At the same time, the funding model will be optimised and the role of organisational bodies will be strengthened.

### Step 5: Scaling and consolidation (Q3/2027 onwards)

In Stage 5, the system will be consolidated and scaled to also cover value-added services, such as data-based feasibility processes. The aim is to also incorporate health technologies, the private sector and vaccine research. A more comprehensive societal impact assessment will also be prepared.

# 6. Summary and future opportunities

The study identified structural barriers and development needs that slow the implementation of clinical trials, but also strengths on which the new operating model can rely in Finland. The proposed centrally coordinated yet regionally implemented 'one-stop' solution offers a clear direction: national coordination, harmonised operating procedures, a predictable process, and adequate and long-term resourcing. Coordination at the national level, combined with regional expertise, enables not only increased trial volumes and investments but also patient access to the latest treatments. At the same time, it makes Finland a clear and approachable partner for international actors. The model not only enhances information sharing, but also serves as a recognisable and reliable representative of the Finnish research system around the world.

At the same time, FinTrials is a significant step forward in the field of social and health care RDI. It complements other ongoing national development projects, such as studies conducted by the Ministry of Social Affairs and Health and Sitra. For example, Finland's rich health data resources are a competitive advantage internationally and an opportunity to stand out among other countries conducting clinical trials. When health data and availability services are seamlessly integrated, it opens up opportunities to do things that cannot yet be imagined. Research syntheses, the development of new data-driven research designs, and patient-oriented data integration could make Finland a global pioneer in clinical research. This can also create completely new research innovations, companies and solutions for global markets.

In the future, decentralised and virtual studies can be a significant part of research. In addition, it is also possible to create opportunities for cross-border research in Finland. With FinTrials, Finland can lay the groundwork for implementing these in a controlled and scalable manner, providing research opportunities for patients in their daily lives.

The opportunities for medical device research in Finland are also considerable. While the current system does not yet fully support it, FinTrials can build synergy between clinical drug and medical device research. In this way, Finland can establish itself as a comprehensive environment for testing and developing health technologies, which attracts both investments and experts.

Vaccines are already an area in which Finland has strong expertise and demonstrable results. FinTrials can take this expertise to a new level, where

vaccine research becomes a key attractor for international research networks.

FinTrials is not just a new operating model but a unifying platform that accelerates the development of new treatments and innovations, strengthens the national economy and allows Finnish patients to be among the first to benefit from medical advances.

The work will continue with the Ministry of Social Affairs and Health collecting more detailed data, especially in terms of operational resourcing, regional capabilities and process details. The current funding solution is still unclear, and resolving it is a critical part of defining both the implementation model and its scale. When implemented, FinTrials can be a significant turning point in the development of Finland's research environment. The transition from a fragmented system to one that is unified, competitive and forward-looking serves patients, researchers, healthcare and the business community alike.

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