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EUCROF is happy to welcome you to this WEBINAR!

IMPACT – Improving and Acting for a stronger European Clinical Trials environment

Mapping National Initiatives to Enhance the Clinical Trials Environment in Europe

08 July 2025 from 16:00 to 17:30 (CEST)

- The meeting will start at 16:00 o'clock.
- Audio is available either through your computer or through phone connection (dial – in).
- Your line will be kept on mute.
- At the end, there will be time for questions and you can submit your questions through the chat box.
- After the webinar, connect to the EUCROF eLearnIN platform (https://eucrof.eu/my-account/) to retrieve materials, customer satisfaction survey and certificate of attendance.
- At the end of the webinar, a Forum Discussion will be opened on the eLearnIN platform (https://eucrof.eu/my-account/) to ask further questions to the speaker or start an open discussion on the topic of the webinar.

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IMPACT – *Improving and Acting for a stronger European Clinical Trials environment*

Mapping National Initiatives to Enhance the Clinical Trials Environment in Europe

Webinar 8 July 2025

Agenda

- Introduction of speakers
- Introduction to EUCROF
- IMPACT
  - Background and introduction
- Overview of National initiatives to strengthen Europe's Position
  - France
  - Germany
  - Spain
  - Italy
  - Netherlands
  - Czech Republic
  - Poland
  - Slovakia
  - Sweden
  - Denmark
- Conclusion and next steps

Presenters

Helena Lüning, Executive board member in EUCROF and Chairman of ASCRO

Christophe Clément, Business Development Director at ICTA

Ursula Türcke M.Sc., Senior Director Clinical Operations and Shareholder of FGK Clinical

Monica Bermejo Senior Clinical Research Leader at Advanced Clinical.

Maria Gómez Director Quality Audits at Syneos Health

Jocelyn Dröge, Associate Director Clinical Operations at IQVIA and secretary at ACRON

Amanda Balzo, Senior CRA, Syneos Health

Martin Hovorka, Senior Legal Counsel, Syneos Health

Per Gradin, Senior Project Manager ICON

Yazmin Nivhede In-House Clinical Research Associate ICON

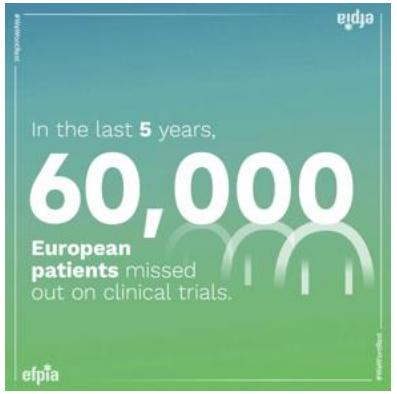
EUCROF -Introduction

- EUCROF is the European CRO federation founded in 2005
  - 13 National associations as full members
  - 23 associated and partner members
  - 30 countries represented
  - 450+ affiliated CROs

- EUCROF's mission is to enhance the quality and impact of Clinical Research by cultivating excellence among CROs

Background to IMPACT

- IQVIA report for EFPIA and Vaccines Europe October 2024
- Despite global clinical trials increasing by 38% the last decade, the European Economic Area´s (EEA) share has halved
- Industry sponsored clinical trials has reduced from **22%** 2013 to **18%** 2018 and to **12%** 2023
- This translates to 60 000 fewer patients accessing a clinical trial in EEA
- Currently approximately 70% of all clinical trials globally are supported by the involvement of CROs. EUCROF is a collective voice for a significant portion of CROs operating in Europe



EUCROF's position and ambition for IMPACT

- Positioning **EUCROF** as a **thought leader** in this topic:

  EUCROF should be one recognized stakeholder when the issues about clinical trials in Europe are on the agenda

Outcome for EUCROF as thought leader

By addressing the issues raised in the EFPIA report, EUCROF can position itself as a leading voice advocating for a revitalized clinical trial environment in Europe. Its proactive measures would not only combat the decline in clinical trial sites but also enhance Europe's global competitiveness in clinical research.

We are not inventing the wheel – we will connect and strenghten the voice of EUCROF to make Europe attractive for sponsors, CROs and others performing clinical trials in humans.

Overview of National initiatives to strengthen Europe's Position

- Collect relevant information about key activites
- What are individual countries doing?
- Can countries learn from each others?
- What are the success factors?
- Conclusions

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France

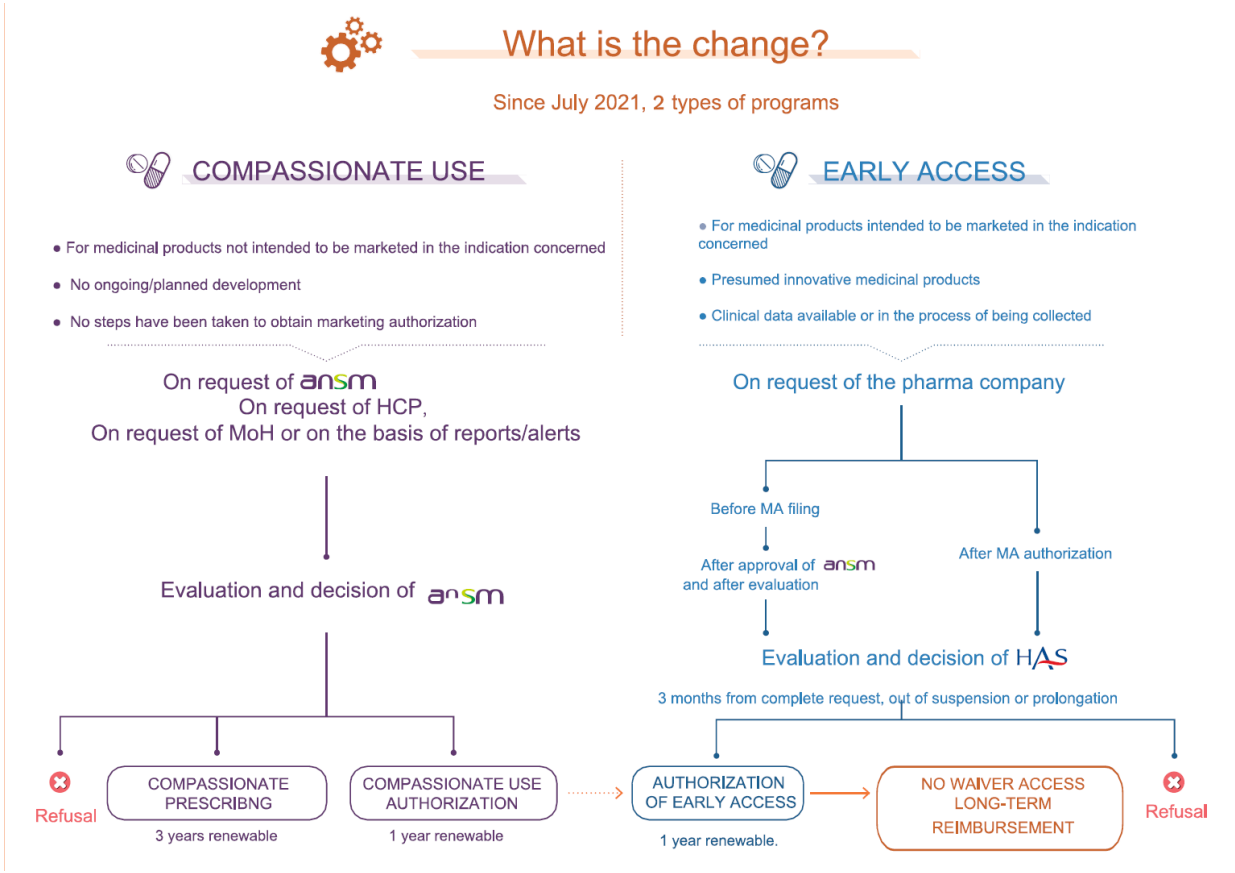
Christophe Clément

French Ministry of Health: ANSM

- Guichet Innovation Santé: service proposed by ANSM to get contacted by Sponsors who need to receive scientific, technical, legal advices
  - A certain level of innovation should be respected to allow to contact ANSM
  - The scientific advices will then speed up the review by ANSM if the project comes to a submission since there are pre-submission meetings

https://ansm.sante.fr/vos-demarches/industriel/guichet-innovation-et-orientation-gio

French access to innovative drugs



National Research Coordination Center

Objectives

- Public entity which represents public Hospital centers; Involved in several taskforces with public and private stakeholders

➔ National contract template & budget grid

- Edited in 2016 : target to speed contract execution, and limit number of contract per site
- Results:
  - CTA signature delay reduced (more than 120 days to around 80 days)
  - Bottlenecks: issues in budget preparation and invoicing due to very complex budget grid
  - CNCR is having regular consultation with stakeholders: (CROs, Pharma industry, hospital administrations, ministry of health...) to update the national template

➔ Invoicing initiative

- Objective to simplify invoicing process due to complexity of the budget grid template
- Current working group with Ministry of Health, CNCR, Hospital administrations and CROs:
  - Tools & good practices sharing,
  - Result expected: Propose simplified invoicing process and/or budget grid for future version of CTA

Patient's basic information about Clinical Trials

- https://notre-recherche-clinique.fr/a-propos/

- French website developed to provide clinical trials to public
- Developed & maintained with public and private stakeholders
- Podcasts
- Articles

French ranking in the clinical trial industry

- AFCROs: yearly barometer about clinical trials
  - displayed on social media and through press releases
  - Set of recommendations provided by AFCRO to improve the situation
  - All clinical trials: drugs & medical devices, academic & industrial
- Leem: yearly survey about clinical trials
  - Set of data especially the delays for 1st site activated and 1st patient in following submission
  - Only industrial and excluding Medical Device

- Results:
  - Gain in visibility
  - Being included in taskforces as CRO representatives directly with main stakeholders
  - AFCROs barometer have been named in 'Le Monde' as a reference regarding clinical trial environment and changes needed

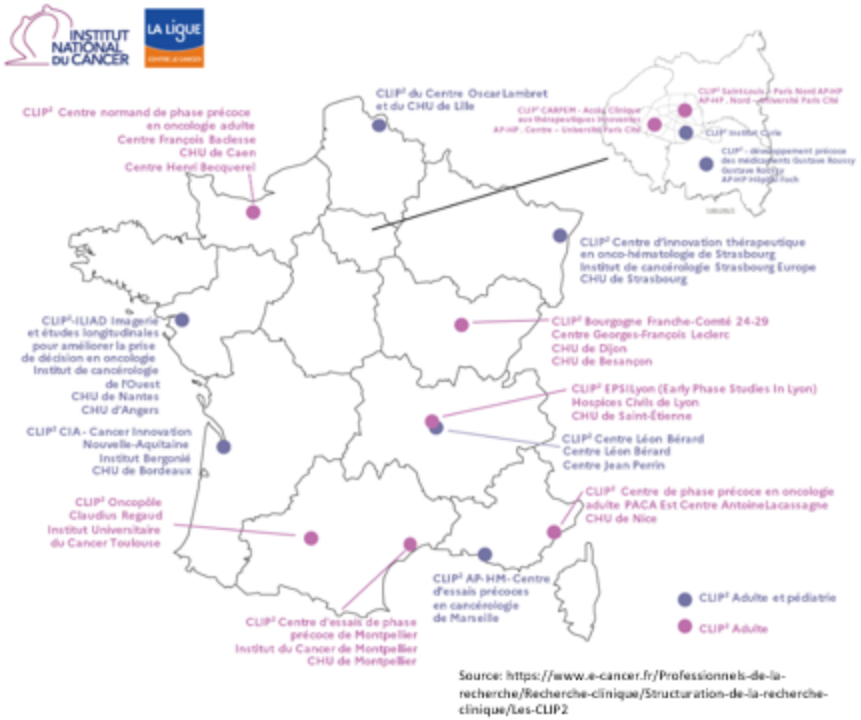
Oncology

CLIP²

early-stage trials expert sites

new pharma, biotech drugs academic research

university hospitals & oncology centers



Source: https://www.e-cancer.fr/Professionnels-de-la-recherche/Recherche-clinique/Structuration-de-la-recherche-clinique/Les-CLIP2

Unicancer

20 dedicated oncology centers
KOLs and technical means dedicated to oncology

Patient's pathway around innovation and expertise

unicancer

Source: https://www.unicancer.fr/fr/espace-patients/trouver-les-coordonnees-du-centre-le-plus-proche-2/

Results: France 1st country in Europe in terms of # trials in Europe

F-CRIN precursor for EU-CRIN

F-CRIN FRENCH CLINICAL RESEARCH INFRASTRUCTURE NETWORK

F-CRIN – French Clinical Research Infrastructure Network

- Since 2012
- Supports and structure national research
- Cross-cutting national community that select, supports and assists French clinical research network & connects platforms and clinical research

Rare Disease

France: A pioneering position

February 1958: Creation of the French Muscular Dystrophy Association (AFM-Telethon)

February 1997: Orphanet created in France before becoming a European endeavour from 2000

2005: 1st National Plan for Rare Diseases (NPRD) 4th plan started in Feb 2025

orphanet

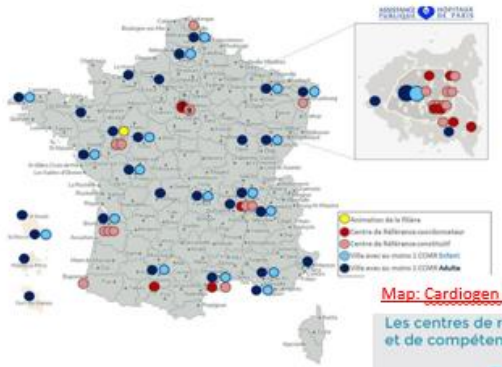
Results:
France is involved in:

- **43% of European clinical trials** for rare disease (all phases)
- **50% of European clinical trials** for rare cancers (all phases)

Clinical Research Infrastructure and Capabilities Rare Diseases

- **1st country to develop country specific rare disease plans**
- Rare diseases structured in different therapeutic areas (24 different branches)
- Objectives:
  - Improve identification, diagnostic, access to innovation and patient's FU
  - Develop reference centers with different responsibilities (coordination, expertise, research…)

Map: BRAIN-TEAM rare disease reference centers



Map: Cardiogen for cardiac diseases hereditary or rare

Map: FAI²R (autoimmune & autoinflammatory diseases) reference centers

Source:filieres_rapport_activite_des_filieres_2018.pdf (sante.gouv.fr)

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Germany

Ursula Türcke

Development of a National Pharma Strategy

- On 13 December 2023 the German Federal Government officially published a Strategy Paper for a new Pharma Strategy. **This new national Pharma Strategy aims to improve the policy environment for the pharmaceutical sector in Germany and to make Germany more attractive for pharmaceutical R&D and manufacturing**.

Germany Pharma Strategy Paper

Medical Research Act (MRA)

- **An important part of the National Pharma Strategy is the Medical Research Act (in German: Medizinforschungsgesetz, MFG)** which came into force on 30 October 2024. **The aim of this law is to increase Germany's attractiveness as a location for innovative medical research.** More specifically, the MRA (MFG) will improve the legal framework for conducting clinical trials, simplify bureaucratic processes and approval procedures for clinical trials and authorization procedures, and facilitate access to research data.

Medical Research Act

Medical Research Act (MRA)

The most important regulatory changes in the Medical Research Act are:

- **Simplified radiation protection procedure** for clinical trials ("single-gate-approach")
- **Standard contractual clauses** for clinical trials (should be implemented mid of 2025)
- Authority/**guideline competence of Association of Medical Ethics Committees** in Germany
- **Specialized ethics committee** for ATMPS, first-in-human, and complex trials
- **Reduction of processing times for mono-national clinical trials**
- Regulatory facilitation of **decentralized clinical trials**
- **Simplification of the labeling** of investigational and auxiliary medicinal products
- **Research incentives** are being set
  - -> For medicinal products with a relevant proportion of clinical trials in Germany, scope for reimbursement amount negotiations (“guardrails” from the Statutory Health Insurance Financial Stabilization Act) is being reopened.
  - -> This is the case if the proportion of subjects in German sites in the clinical trials of the medicinal product conducted by the pharmaceutical company amounts to at least **five percent** of the total number of test subjects.

Initiative Study Location Germany (ISD)

The ISD was set up in November 2023 and is discussing possible improvements for conducting clinical trials at the study location Germany. **Overall, the aim of the ISD is to make Germany more attractive as a study location at all levels and thus to attract more studies to Germany. The ISD currently consists of a total of over 25 organizations from the clinical research environment including all main stakeholders from medical universities, academia, science, industry and ethics committees.**

The ISD has now 5 working groups as follows:

- Political framework and strategy
- Administrative aspects
- Study centers/Medical staff: Training, promotion, young talent/talent engagement
- Industry related aspects
- Study registry

Initiative Studienstandort Deutschland

Clinical research is supported by various advice procedures in Germany

- Kick-off meeting through the Innovation Office
- Advice during development ("Scientific Advice")
- Advice prior to Clinical Trial Application ("Pre-CTA Advice")
- Advice prior to Marketing Authorization Application ("Pre-submission Advice")
- Joint Advice through the BfArM and the Federal Joint Committee (G-BA)
- Portfolio meetings

Scientific Advice BfArM
Scientific Advice PEI

Federal Institute
for Drugs
and Medical Devices

Paul-Ehrlich-Institut

Bundesinstitut für Impfstoffe
und biomedizinische Arzneimittel

Network of University Medicine

All activities of the **Network of University Medicine (NUM)** contribute to the following three overarching goals:

- **Establish a nationwide, comprehensive study and data space** for clinical research that includes data from routine patient care documentation as well as additional data collected, for example, in prospective clinical and clinical-epidemiological studies
- **Prepare the biomedical research landscape for future pandemics** and other major public health crises
- **Create a central point of contact** for clinical research at a national level that provides stakeholders with fast and efficient access to all academic medical centers in Germany

German network of university medicine

netzwerk universitäts **medizin**

Various national networks for specific indications

With the German Centers for Health Research (DZG), the Federal Ministry of Education and Research (BMBF) has established powerful structures to better identify, treat and prevent these diseases.

- German Center for Neurodegenerative Diseases (DZNE)
- German Center for Diabetes Research (DZD)
- German Center for Infectious Diseases (DZIF)
- German Center for Cardiovascular Research (DZHK)
- German Center for Lung Diseases (DZL)
- German Cancer Consortium (DKTK)
- German Center for Mental Health (DZPG)
- German Center for Child and Adolescent Health (DZKJ)

Various German networks for specific indications

DEUTSCHE ZENTREN DER GESUNDHEITSFORSCHUNG

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Spain

Monica Bermejo and Maria Gómez

Collaboration is key: 2 main entities

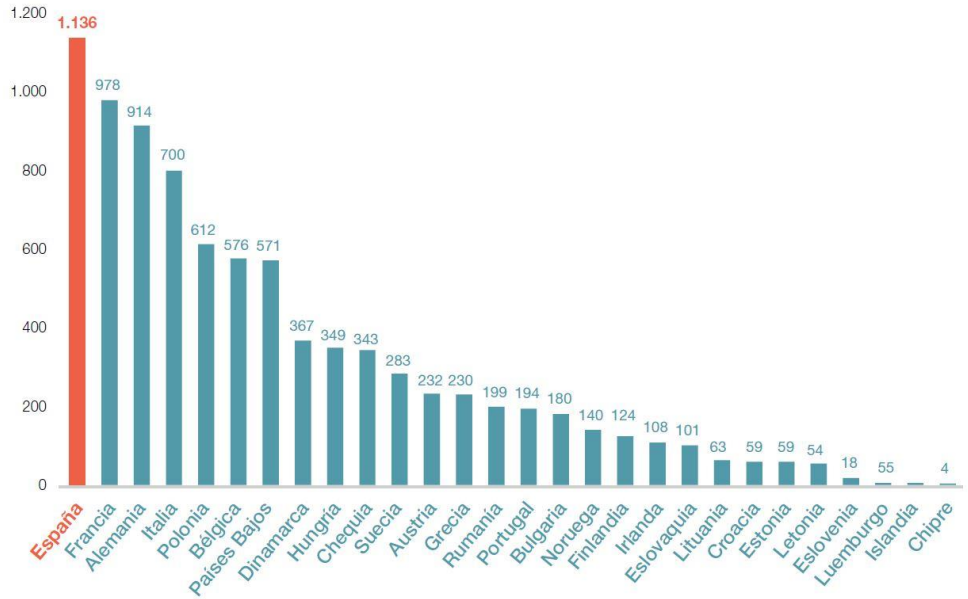
https://www.aemps.gob.es/medicamentos-de-uso-humano/investigacion_medicamentos/

https://www.farmaindustria.es/web/

Spanish Ministry of Health: AEMPS

- AEMPS is aware that **Spain has very good numbers in clinical trials**, being competitive at both the European and global levels, but it could be affected by the negative trend in Europe.

The clinical trial, which in the vast majority of cases (almost nine out of ten in Spain) is driven by the pharmaceutical industry, represents the final stage of a complex, lengthy, and risky marathon that is the R&D of new drugs. This process begins when researchers identify a promising compound in the preclinical stage and concludes 10–12 years later when, if all goes well, the new drug becomes available to patients.
Thus, of the 2,491 clinical trials authorized in the European Union through the new centralized registration system CTIS (which began on January 31, 2022, but only became mandatory in 2023), Spanish centers have participated in 1,136—45.6% of the total—surpassing France with 978 and Germany with 914 (see chart).



https://www.farmaindustria.es/web/reportaje/estas-son-las-10-razones-por-las-que-espana-es-un-lider-mundial-en-ensayos-clinicos/

Spanish Ministry of Health: AEMPS

Contact: Juan Estévez (Head of Clinical Trials)

- The implementation of Royal Decree 1090/2015 on clinical trials in 2015. It was not strictly necessary since the Regulation is directly applicable, but their **proactive approach** in anticipating the Regulation with the Royal Decree was key to **ensuring all stakeholders in the country were prepared**. Especially the Ethics Committees, with the integrated evaluation by a **single committee.**

- The **creation of a coordination group** between the Agency and approximately 25 committees, to unify evaluation, safety, and Part II authorization criteria.

- **Spain's healthcare infrastructure,** with integrated coverage for patients from care to participation in clinical trials. This is complemented by the **expertise of healthcare professionals**. **This is evident in the pharmaceutical industry's preference for Spanish centers,** often returning to the same centers and investigators from early phases

Spanish Ministry of Health: AEMPS

Contact: Juan Estévez (Head of Clinical Trials)

- AEMPS has opted for a rigorous yet **flexible framework in interpreting unclear articles of the regulation**, issuing a **public Q&A document** now in its 19th edition, with the 20th edition in progress for after the summer. This document reflects the **interaction between the Agency and the industry**, the Agency's interest in understanding the challenges faced by different stakeholders, and in providing solutions. The Q&A document is a consensus document, not legislative, but it clarifies aspects that are not clearly defined in the regulation.

- In terms of **data protection,** in the absence of a clear directive, **AEMPS, Farmaindustria, the Ethics Committees, and the Data Protection Agency have worked together** to **establish criteria and agree on including data protection consent within the patient's consent f**or the trial, which adds agility and protection. Other countries require a separate consent.

- **The largest or most important centers in the country have clinical trial units or research support units.** AEMPS also has a research support office. This shows the centers' interest in participating in trials and in facilitating the bureaucratic aspects for researchers.

- Looking ahead, AEMPS is working on expanding the **Fast Track.** This will depend on resources, but it is a priority for the Agency.

FarmaIndustria *(Contact: Amelia Martín- Director of the Clinical Research Department)*

KEYS TO SPAIN'S LEADING POSITION IN CLINICAL TRIALS

1 PIONEERS IN REGULATION

Our country was the first in Europe to adopt the Clinical Trials Regulation, through Royal Decree 1090/2015, which entailed the simplification, streamlining and harmonization at national level before any other Member State.

2 AEMPS: A COMMITTED REGULATORY AGENCY

Its pioneering and proactive attitude to promote and preserve research activity (thus guaranteeing patient safety) and constant dialogue with the pharmaceutical industry.

3 A STRONG NATIONAL HEALTH SYSTEM

Almost 13,000 health centers and 800 public and private hospitals, plus 35 health research institutes accredited by the Carlos III Health Institute, spread across 13 autonomous communities and employing more than 29,000 researchers in total.

4 TOP-NOTCH HEALTHCARE PROFESSIONALS

Spain has highly qualified healthcare professionals who can face the challenge of clinical research with the highest quality standards thanks to their commitment to continuous training and patient care.

5 PATIENTS INVOLVEMENT AND GENEROSITY

Patients' participation in clinical trials is a great example of altruism, solidarity and generosity, and without the cooperation of patients there is no research.

6 AN ACTIVITY BASED ON ETHICS AND TRANSPARENCY

In Spain, there are currently more than 65 Ethics Committees, and the efficient performance and professionalism of its members have contributed significantly.

7 A STRONG FOOTPRINT IN SPAIN

For many pharmaceutical companies, Spain is already the second-most active country in the world in clinical trials, only behind the United States, and participates in one out of every three trials launched in Europe.

8 PROJECT BEST

A strategic project bringing together all public and private stakeholders to create a platform for excellence in clinical research.

9 A HARMONIZED EUROPEAN SYSTEM

Since 31 January 2022, the new Clinical Trials Information System (CTIS) has been operational. CTIS harmonizes the assessing and monitoring of clinical trials.

10 A MODEL BASED ON PUBLIC-PRIVATE COLLABORATION

Public-private collaboration between health authorities, hospitals, researchers and healthcare professionals, patients and pharmaceutical companies is a key driver in promoting biomedical research in Spain.

FarmaIndustria *(Contact: Amelia Martín- Director of the Clinical Research Department)*

Farmaindustria's strategy to strengthen Spain's leadership in clinical research

Spain has a competitive advantage over other countries to underpin its leadership in clinical trials. However, there are challenges and improvement areas in the development of new drugs:

01 **Streamlining and reducing clinical research management processes**
- Prioritizing Fast Track for First in Human
- Promoting harmonized contract clauses
- Addressing Combined Trials - IVDs

02 **Promoting Clinical Research in Primary Care in Spain**

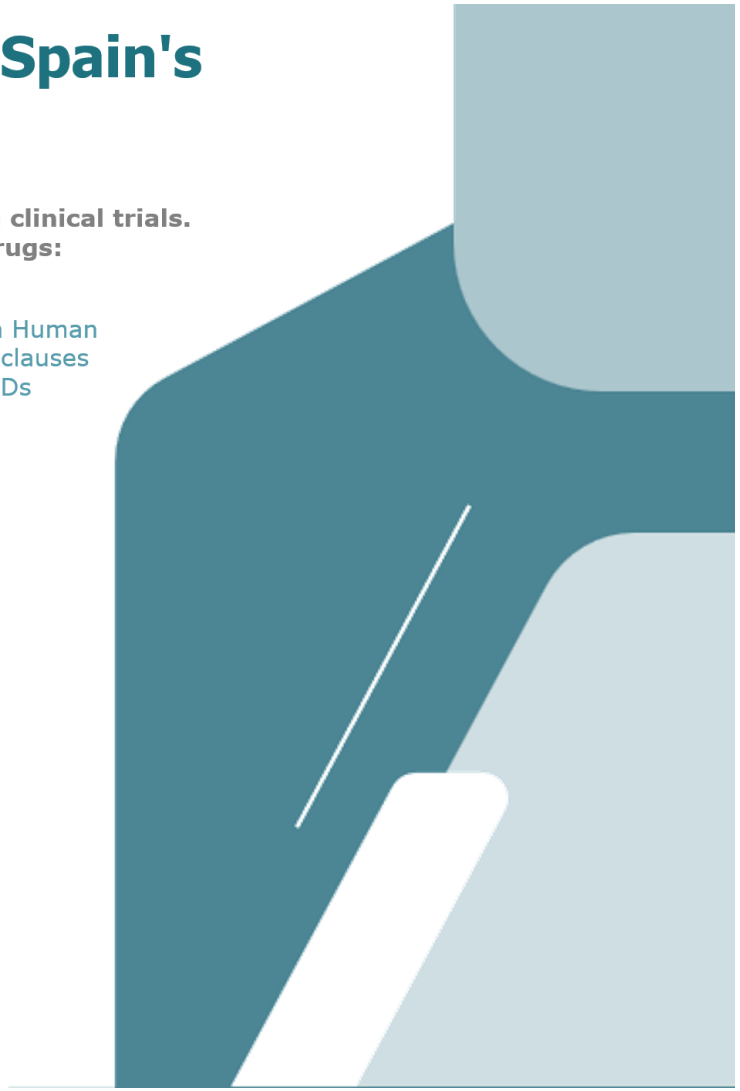
03 **Advancing Decentralized Clinical Trials**

04 **Enhancing Diversity in Clinical Trials**

05 **Guideline for Clinical Trials in Hospital Pharmacy**

06 **Patient Participation in Biomedical R&D**

07 **Fostering RWD, RWE, AI and EHDS**



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Notes from some media

https://www.diariomedico.com/farmacia/industria/espana-1-ensayos-competencia-desafios-amenazan-liderazgo.html?emk=NPSFAR1&s_kw=1T

Strengths of Spain in Clinical Trials

- Highly qualified healthcare professionals and top-tier hospitals.
- Strong support from health authorities and regulators.
- Active patient participation and major pharmaceutical investment.
- In 2023, Spain led Europe in new clinical trials, surpassing Germany.
- Recognized for its reliable infrastructure and professional research teams.

Areas for Improvement

- Reduce bureaucracy (e.g., contract signing delays).
- Expand fast-track evaluations beyond Phase I.
- Prevent talent loss by improving career opportunities.
- Train professionals in AI, biotech, and personalized medicine.
- Promote decentralized trials and include more regions and Primary Care.
- Increase investment in early-phase and translational research.

Summary

Spain is a European leader in clinical trials due to its infrastructure, coordination, and public-private collaboration. To stay ahead, it must simplify processes, invest in talent and innovation, and expand trial access across the country

Other Resources

NETWORKS

- **RECLIP (Spanish Network of Pediatric Clinical Trials)**: https://www.reclip.org/
- **Spanish National Cancer Research Center (CNIO):** https://www.cnio.es/en/
- **SPANISH NETWORK OF CANCER REGISTRIES:** HTTPS://REDECAN.ORG/EN
- **Cooperative Health Research Networks Oriented Toward Results:** https://www.isciii.es/en/financiacion/ricors
- **Research networks in primary care:**

  REAP – Red Española de Atención Primaria

  reap.es

  RIAPAd – Red de Investigación en Atención Primaria de Adicciones

  riapad.es

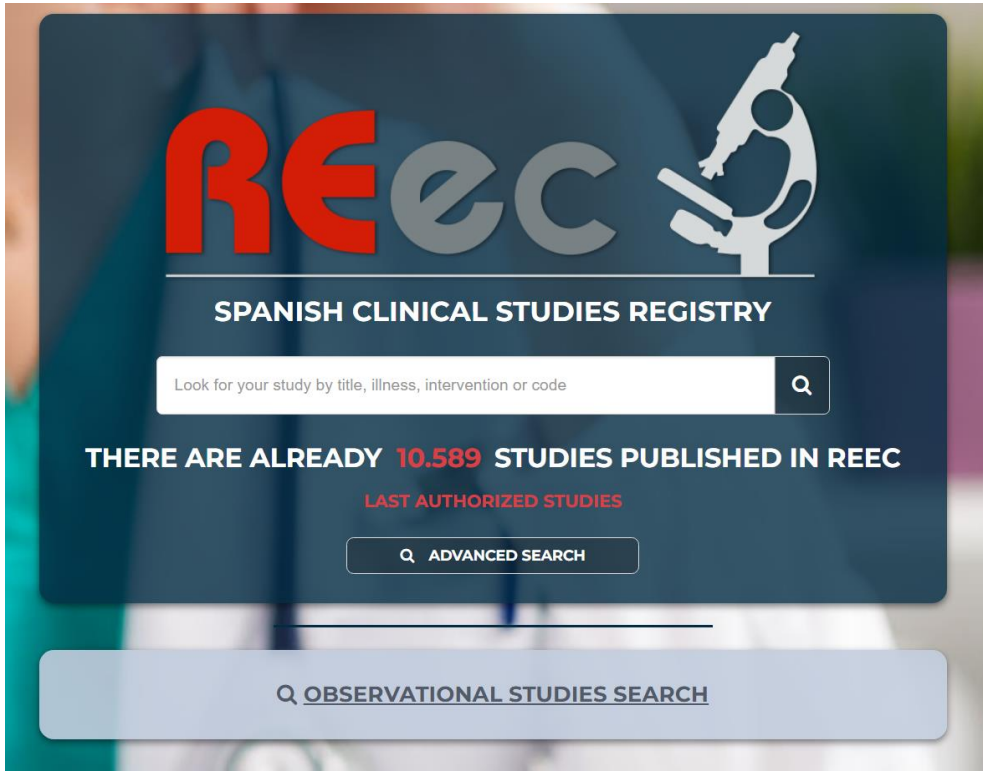
  RICAPPS – Red de Investigación en Cronicidad, Atención Primaria y Promoción de la Salud

  iacs.es

Other Resources

Patient's basic information about Clinical Trials

- **Spanish Registry of Clinical Studies:** https://reec.aemps.es/reec/public/web.html



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Italy

Amanda Balzo

SIMeF (*Italian Society of Pharmaceutical Medicine*)

- Born on 1964 in Milan as a no-profit scientific society
- Purpose: promote and coordinate scientific initiatives in the field of biomedical sciences applied to the research and development of new therapeutic agents to support scientific research (at the clinical and preclinical level) in Italy.
- Home - Società Italiana di Medicina Farmaceutica
- Initiatives:
  - Webinar
  - Conferences/Seminars
  - Master
  - Training/Educational courses
  - Participation to Clinical Trial Day
  - Focus group

AFI (*Pharmaceutical Association of Industry*)

- Born on 1960 as a no-profit scientific society, founded by professionals with science degrees who work in the pharmaceutical field.
- Purpose: promotion of cultural initiatives, scientific monitoring and practical professional updating, (maintaining a high standard of professionalism).
- AFI – Associazione Farmaceutici Industria Società Scientifica
- Initiatives:
  - Collaboration with Health Authorities and Universities
  - Editorial activities to publish technical-scientific monographs or findings of activities developed from specific meetings
  - Organization of technical and scientific events (conferences, focus group, training/educational courses, etc.)
  - Cultural and operational exchanges with national and international associations inherent to the pharmaceutical world

Associazione Farmaceutici Industria
Società Scientifica

AIOM (*italian association of medical oncology*)

- Born on 1973 in Milan as a no-profit scientific society
- Purpose: bring together medical oncologists to promote progress in the clinical, experimental and social-welfare fields, to foster relations between medical oncologists, general practitioners and specialists in other disciplines, to establish scientific relations with similar Italian and foreign associations and to participate and collaborate with national, regional and local institutional bodies.
- AIOM | Associazione Italiana di Oncologia Medica – Official Website
- Initiatives:
  - Search tool for patients → all clinical studies available to date in Italy are uploaded within the portal, subdivided by Italian regions
  - Webinar "oncology Wednesdays"→ webinars open to all where different topics (always oncology-related) are discussed by doctors/SC/nurses
  - Working groups
  - Conferences/Seminars

IRCCS (*Institute of hospitalization and care with scientific character*)

- Hospital facilities of excellence with a key role in translational scientific research and the application of research results in clinical practice. Benchmark for high specialization and innovation
- **Mission**: to create a bridge between basic science and medicine, transferring research findings into new and more effective treatments and care pathways for patients
- Recognized for their expertise in specific medical areas (e.g., oncology, neurology, cardiology, pediatrics, rare diseases, etc.), where they conduct advanced research and provide highly specialized care contributing significantly to the development of new therapies and the improvement of patient health, thanks to a highly specialized, multidisciplinary and translational research-oriented approach.
- Many IRCCSs have a dedicated Clinical Trial Center (CTC) in-house. These CTC are specialized facilities that manage and support all phases of clinical trials, from initiation to data collection and monitoring.
- Often promoter of no-profit clinical trials, which are critical for exploring new researches, evaluating innovative therapeutic strategies, and addressing clinical needs not covered by commercial trials.

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The Netherlands

Jocelyn Dröge

Dutch Clinical Research Foundation

- The Dutch Clinical Research Foundation, or DCRF for short, is a foundation dedicated to facilitating medical-scientific research involving humans (clinical research), so that valuable knowledge and science can benefit patients as quickly as possible

- The DCRF is a foundation established through collaboration between various stakeholders, such as:
  - University medical centers,
  - Hospitals,
  - Contract research organizations,
  - Pharmaceutical companies,
  - Researchers,
  - Ethics committees,
  - Patient organizations
  - The government

  Representatives of these parties form the board of the DCRF

National Action Plan Clinical Research

The DCRF launched the National Action Plan for Clinical Trials in 2024 and the plan aims to make the Netherlands more attractive for clinical research.

The plan focusses on:

More Effective Execution of Research.

The DCRF aims, during the duration of this action plan, to create the necessary conditions to ultimately reduce the average clinical trial startup time to 50 days.

The Research Participant as a Partner

The DCRF has set the goal that by 2025, patients/research participants will be involved in 80% of clinical trial protocols.

Academic Excellence

The DCRF aims to fully support (new) research networks by 2025, facilitating their development and strengthening collaboration and knowledge sharing.

National Action Plan Clinical Research

Delivery of the action plan:

- Working groups have been established for each focus point
- Working groups have representatives from all stakeholders in the DRCF to ensure that outcomes are endorsed by the clinical research community
- Overseen by DCRF board each working group delivers a detailed plan for the various actions, This also includes the necessary conditions for achieving the objectives, such as the commitment of field parties or relevant legislation and regulations.

Read more: https://www.fast.nl/en/news/national-action-plan-aims-to-further-strengthen-clinical-research/

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Czech Republic

Martin Hovorka

National Strategy to Improve the Environment for Clinical Trials in CZ

- Announced in **mid-2024**
- The **Czech Ministry of Health** (MoH), in cooperation with **CZECRIN**, has been developing a new National Strategy to support the conduct of clinical trials
- The **key coordination and governing document** outlining goals and measures to strengthen the clinical research ecosystem in the Czech Republic
- Objectives:
  - **Increasing the number of patients** enrolled in clinical trials
  - **Supporting research teams** and creating more **favorable conditions** for conducting clinical trials in the country
  - Ensuring that patients gain **access to modern treatments**, **reducing public health insurance costs** by leveraging externally funded medicines during clinical research

National Strategy to Improve the Environment for Clinical Trials in CZ

- **In May 2025,** the MoH presented the National Strategy's **key focus areas**, developed in collaboration with expert working groups:
  - **Simplification of administrative processes**
  - **Digitalization**
  - **Support of study coordinators**
  - **Systematic engagement of patients and healthcare professionals**
  - **Increased support of academic clinical studies**
    - Academic research represents approx. 30% of studies in the country
- Aligned with the MoH's "Health Research Concept to 2030"

Health Research Concept to 2030

- Authored by the MoH, approved in December 2022
- Long-term **strategic framework** for the development, funding, and coordination of health-related research from 2023 to 2030
- **Objective**: to ensure and further develop internationally **competent health research** and the use of its results to improve human health with an impact on healthcare both in the Czech Republic and worldwide
- Key areas of focus include:
  - Digitalization of healthcare
  - Promoting health literacy and patient orientation
  - Research and development in new medial devices and equipment

AIFP Initiatives

- **In May 2024,** the Association of Innovative Pharmaceutical Industry (AIFP) has introduced a complex analysis of the situation for clinical trials in the country in the past years
  - Identified the need for measures to support clinical trials
  - Recommendations to improve the clinical trials landscape include:
    - Creation of a coordinating body
    - Support of a closer collaboration between healthcare organizations
    - Simplification of local procedures
    - Government initiatives
- AIFP operates a **Clinical Trial Helpdesk** – a free online supplementary source of information for patients and volunteers

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Slovakia

Martin Hovorka

Initiatives in Slovakia

- **Roadmap for Academic Clinical Research in Slovakia**
  - Developed by **SLOVACRIN** in collaboration with Slovak research institutions and HCPs
  - Objective: to accelerate and improve access to innovative treatments for patients, support clinical trials, and enhance the scientific recognition of Slovak researchers
  - Contains a **complex overview of the current status of clinical research** in individual public and private sites.
- **MoH Working Group on Clinical Trials**
  - The Ministry of Health of the Slovak Republic has established a clinical trials-focused **working group**
  - Objective: to identify obstacles in the conduct of clinical trials and to propose possible solutions

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Poland

Martin Hovorka

Key Initiatives of the Medical Research Agency

- Established in 2019, MRA's key objective is to support clinical research in Poland
- Since 2019, MRA has signed 300+ co-financing agreements worth over 1 billion USD
- **Governmental Plan for the Development of the Biomedical Sector in PL for 2022-2031**
  - Aims to position Poland as a leader in the biomedical sector in CEE
- **Establishment of dedicated Clinical Trial Support Centres**
  - Outpatient centres improving access to modern clinical trials in Poland
  - Part pf the Polish Clinical Trial Network
  - + Regional Digital Medicine Centres (recognizing the growing importance of digital medicine in modern healthcare delivery)
- **Polish Clinical Scholar Research Training**
  - Part of MRA's Educational Strategy for 2023-2027
  - Aims to train 500 study researchers in study design, data analysis, scientific publication

Other Initiatives - Poland

- **Creation of the Polish Clinical Trials Network (PCTN)**
  - Established in 2021
  - Aims to implement uniform, systemic solutions at clinical trial sites
  - Enhanced, unified infrastructure and standardized processes
  - Supports the training of dedicated clinical trial staff

- **Warsaw Health Innovation Hub**
  - Established in 2021
  - A platform for the cooperation between the MRA, business partners and key stakeholders
  - Creates an innovation ecosystem in Poland

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Sweden

Per Gradin and Yazmin Nivhede

National Strategy for life Science in Sweden

- Swedish government launched a life science strategy in 2019 (updated 2024) with the objective for Sweden to become a leading life science nation
- The strategy has 8 priority areas where clinical trials are clearly outlined as one important part

1. **National Coordination & Partnerships**
2. **Health Data Infrastructure**
3. **Ethical & Safe Policy Development**
4. **Integration of Research in Healthcare**
5. **Technology for Health & Independence**
6. **Research & Infrastructure Support**
7. **Talent & Skills Supply**
8. **Global Competitiveness**

- Government has made financial investments in line with the strategy

Nationell strategi för life science - Regeringen.se

Government Offices of Sweden

Clinical Studies Sweden

- **Kliniska Studier Sverige** was established in **2015** as a national collaboration between Sweden's six healthcare regions, supported by the Swedish Research Council (Vetenskapsrådet)
- Its **purpose is to strengthen the conditions** for conducting high-quality clinical studies within Swedish healthcare

Regional Nodes:
Each healthcare region has a coordination function, "regional node", together forming a national research infrastructure.

National Collaboration:
Working groups with different expert competencies share experiences and develop common tools and support in specific areas.

Feasibility Sweden:
A national service providing researchers and life science companies fast access and responses to study inquiries directed at Swedish healthcare

Trial Units:
Provides clinical trial units that plan and conduct clinical studies on behalf of healthcare, academia, and industry.

[About us | Kliniska Studier Sverige]

Kliniska Studier Sverige

Vetenskapsrådet

NASTRO–Network for Oncology clinical trials

- Network between the 7 University hospitals in Sweden
- Established in 2007
- Regular meetings to adress common issues and facilitate and improve the conditions for oncology clinical trials
- Joint collaboration with RCC (Regional Cancer Centres) in establishing a national database on all ongoing oncology clinical trials in Sweden
- Close collaboration between 4 Phase 1/First In Human units to strenghten Sweden early phase capacity

[Nastro | Nätverket för Universitetssjukhusens Prövningsenheter inom Onkologi]

NASTRO
Nätverket för Universitetssjukhusens Prövningsenheter inom Onkologi

Regional Cancer Centres in Sweden

- Outcome of the Swedish national strategy on cancer treatment - 2009
- Network and support to the hospital regions to increase cancer care quality and improve outcomes
- Mission in clinical research
  - Cancer trial awareness -public database – **www.cancercentrum.se/cancerstudier**
  - Development of registries and databases
  - Coordination of tumour tissue biobanks
  - Sponsoring various innovation project
  - National “task force” group (NAG):
    - Train and educate health care staff on updates in clinical research
    - Collaborate with Kliniska Studier Sweden to strengthen the patient enrollment in clinical trials
    - Develop possibilities for clinical trials in smaller departments

REGIONALA CANCERCENTRUM I SAMVERKAN

HIKS-a web based tool to find clinical studies

- Database of industry initiated clinical trials
- Launched 2023 by Lif-Swedish Pharma Association
- Search function on indication, geographical area and phase
- Contact details to clinical trial sites
- Open and free of charge
- Non-voluntary for Lif members (>95% all pharma companies)

www.hiks.se

HIKS
Hitta Kliniska Studier

Code of Conduct- guidance for oncology clinical trials

- Joint agreement between Lif, ASCRO and NASTRO since 2024
- Guidance document for collaboration between the site, sponsor and CRO in oncology trials
- Call for action from site to reduce the (unnecessary) administrative burden from sites
- Annual update and progress report-ultimate goal to reduce administration and increase patient recruitment

code_of_conduct-english_JAN_2025.pdf

ASCRO

Lif De forskande läkemedelsföretagen

NASTRO
Nätverket för Universitetssjukhusens Prövningsenheter inom Onkologi

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SWETRIAL-a national partnership

- **Government-Led Initiative**
  SweTrial is a national effort launched by the Swedish government in 2023 to address the decline in clinical trials, hosted by the Swedish Medical Products Agency (Läkemedelsverket).
- **Strategic Goal**
  Aims to reverse a decline in clinical trial activity by improving national coordination, infrastructure, and readiness for both academic and industry-sponsored trials.
- **Structure & Scope**
  SweTrial will establishe a central secretariat at the Swedish Medical Products Agency (Läkemedelsverket) to support clinical trial networks across regions, focusing on specific therapeutic areas and trial execution capacity.
- **Public–Private Collaboration**
  Partnering between the life sciences industry, the health care providers, academia, patients and the authorities
- **Long-Term Vision**
  Designed as a sustainable, long-term investment to increase Sweden's global competitiveness in clinical trials
- SweTrial vässar Sveriges konkurrenskraft inom kliniska prövningar | Läkemedelsverket

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Life Sciences Strategy for the Stockholm region

- The Capital Region initiative/strategy compiling 5 areas of focus for Stockholm region to achieve its goal of becoming one of the top five life science regions in the world.

  - World-leading access to structured health and care process data
  - Health and social care systems available for interaction with research and innovation and collaboration with business
  - Precision medicine gives patients and residents access to high resolution diagnostics and personalized prevention and treatment
  - Interdisciplinary collaboration creates solutions to complex challenges
  - Life science companies research, develop and grow in the Stockholm region

life-sciences-strategy-for-the-stockholm-region.pdf

Region Stockholm

Fast track assessment

- Swedish Medical Products Agency (Läkemedelsverket) initiative from 1 September 2025
- Mono national trials running in Sweden only
- Assess applications within 26 days of validation
- Approve applications within 30 days, provided no RFIs are issued

Snabbspår för mononationella ansökningar om klinisk läkemedelsprövning | Läkemedelsverket

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

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Denmark

Per Gradin and Yazmin Nivhede

Strategy for Life Sciences until 2030

- Denmark aims to become **Europe's leading life science nation by 2030**
- **Danish government presented the strategy in November 2024**
- 6 strategic priorities
  - Boosting support for life science startups and scale-ups
  - Leveraging health data & AI for research and innovation
  - Promoting innovative, labor-saving health solutions
  - Strengthening framework conditions to attract production & investment
  - Amplifying Denmark's global health diplomacy and exports
  - Driving EU-level advocacy for competitive regulation

Strategy for life science towards 2030 | Ministry of Industry, Business, and Financial Affairs

Trial Nation-a national partnership

- A government and private sector partnership established in 2018 that connects companies, researchers, regions, and patient organisations.
- Offers a single, national entry point for life science companies for clinical trials in Denmark
- Offers streamlined feasibility requests (5-day turnaround), national recruitment strategies, trial performance support, and access to registries—driving a 2.6-fold increase in trials in two years
- Trial Nation is supported by the Ministry of Industry, Business and Financial Affairs, the five Danish Regions and life science company members.

Resources - Trial Nation

Danish Medical Agency

- **Fee Waivers & Cost Incentives**

Since July 2018, commercial sponsors are exempt from all fees for phase I trials, while non-commercial trials already benefit from full fee waivers for applications and annual charges

Better conditions for clinical trials in Denmark

- **Decentralised & Digital Trials Framework**

Since 2020, the Danish Medicines Agency has released national guidelines (2021) and aligned with EU regulations (2022) to enable digital consent, remote visits, home sampling, and wearable devices—aiming to improve access, equity, and lower costs

Decentralised Clinical Trials

- **Regulatory Agility & Pilot Programs**

A 2024 life science strategy targets EU-leading trial volumes per capita. Mono-national trials now benefit from official responses within 31 days. Pilot approvals are available for combined drug–device trials and ATMPs, with new frameworks promoting use of registry data and AI/ML analytics

Clinical trials with medicinal products

Other initiatives

- **National Overview & Patient-Centered Access (PACT Project)**

Launching end-2024, a national clinical trials registry will provide transparent, real-time trial information for patients and clinicians. The PACT project (2022–26) promotes patient-centred trial design, decentralised recruitment (social media, pharmacies, GPs), improved accessibility, and strong public–private coordination

Clinical Trials of Tomorrow - Trial Nation

- **Funding of Investigator-Initiated Trials**

Novo Nordisk Foundation grants (5–20 M DKK over 3–5 years) support Danish-led non-commercial clinical trials, boosting independent research capacity

Investigator Initiated Clinical Trials - Novo Nordisk Fonden

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Conclusions

Helena Lüning

What Are Different Countries Doing That Is Similar?

•National Strategies & Policy Alignment
Countries like Germany, Sweden, Czech Republic, and Denmark have launched **dedicated national strategies** to improve the framework for clinical trials

•Public–Private Collaboration Platforms
Initiatives such as **Trial Nation (Denmark)**, **SweTrial (Sweden)**, **ISD (Germany)** and **DCRF (Netherlands)** demonstrate successful **multi-stakeholder collaboration** across government, academia, and industry

•Focus on Streamlining and Simplification
Several countries are reducing bureaucratic burdens:

- **Germany's Medical Research Act** introduces standard contract clauses, simplified radiation protection processes and reimbursement incentives.
- **France and Spain** simplify invoicing and contract timelines.
- **Denmark** has fee waivers, digital consent, and rapid approvals.

•Patient-Centric & Decentralized Trials
Many are embracing **decentralized models** (Denmark, Spain, Germany) and improving **patient access to information** through national registries (e.g. HIKS in Sweden, REEC in Spain, and upcoming platforms in Denmark)

Success Factors Identified?

- **High-Level Governmental Commitment**
  Strong political backing and national strategies drive structural change (e.g., Denmark 2030, Germany's Pharma Strategy, Sweden's Life Science Strategy)

- **National Coordination Mechanisms**
  Establishing coordinating platforms (SweTrial, ISD Germany, DCRF) enhances alignment, resource sharing, and best practice implementation

- **Speed and Predictability in Start-Up**
  Countries showing reduction in CTA timelines (e.g. France, Spain, Netherlands)

- **Stable Legal Framework with Regulatory Innovation**
  Simplified legislation (Medical Research Act Germany, Spain's Royal Decree) offers clarity and efficiency

- **Engaged Ecosystem & Transparency**
  Platforms that involve industry, ethics committees, and academia (e.g., Spain's Q&A iterations, Denmark's PACT) foster trust and shared responsibility.

Conclusion: From Fragmentation to Coordination – A Path Forward for European Clinical Trials

Europe is responding – not uniformly, but ambitiously.

National initiatives are converging on common pillars: coordination, simplification, speed, and stakeholder engagement.

EUCROF, through IMPACT, can serve as a hub for sharing and amplifying these best practices.

To reverse the decline, Europe needs more than regulation—it needs leadership, agility, and collaboration.


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