HNN 3.0
HEALTH-NCP-NET

# Health NCP Net

## Partner Search

## ANNEX 1:

Partner Search Tips for proposals with Clinical Studies

www.healthncp.net

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*This Annex complements the "Guidelines for Partner Search", available at https://hnn30.healthncp.net/hnn-30-supporting-tools as part of the Supporting Tools for applicants developed by the project Health-NCP-Net 3.0 (HNN 3.0).*

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## About Clinical Studies in Horizon Europe

In the context of Horizon Europe and according to the application form INFORMATION ON CLINICAL STUDIES, a clinical study covers **clinical studies/trials/investigations/cohorts** and is defined as *any systematic prospective or retrospective collection and analysis of health data obtained from individual patients or healthy persons in order to address scientific questions related to the understanding, prevention, diagnosis, monitoring or treatment of a disease, mental illness, or physical condition.*

It includes, but it is not limited to:

- clinical studies as defined by Regulation 536/2014 (on medicinal products),
- clinical investigation and clinical evaluation as defined by Regulation 2017/745 (on medical devices),
- performance study and performance evaluation as defined by Regulation 2017/746 (on in vitro diagnostic medical devices).

Applicants envisaging to include clinical studies have to provide details of their clinical studies in the dedicated annex using the template "INFORMATION ON CLINICAL STUDIES" provided in the submission system.

For further information and tips how to fill out the "INFORMATION ON CLINICAL STUDIES" template, have a look at our annotated template and recorded webinar.



## How to integrate Clinical Centers in Cluster 1 'Health' projects?

**There are several options for involving the clinics and centers in which the study participants are recruited**. Although each center can become a partner (**beneficiary**) in the project, this often leads to a great deal of management effort in large multicenter studies. Especially, if the centers do not play any scientific role in the project other than recruiting and treating patients, it may make sense to involve them as **subcontractors** or so-called **third parties** (contributing in-kind). Other possibilities would be to include the centers via "other goods, works and services" or via "implementation of actions tasks", if they are affiliated entities.

In the case of complex multicenter studies, it can make sense to draw on the expertise of Clinical Research Organizations (CROs) for study management. If they only take on limited tasks (up to 50%), they can act as a subcontractor. Before integrating clinical centers, it might be useful to discuss following questions:

- Do the centers want to be strongly involved in the project? (→ beneficiary)
- Is there a permanent connection? (→ affiliated entity)
- Do they want to make profit? (→ subcontractor)

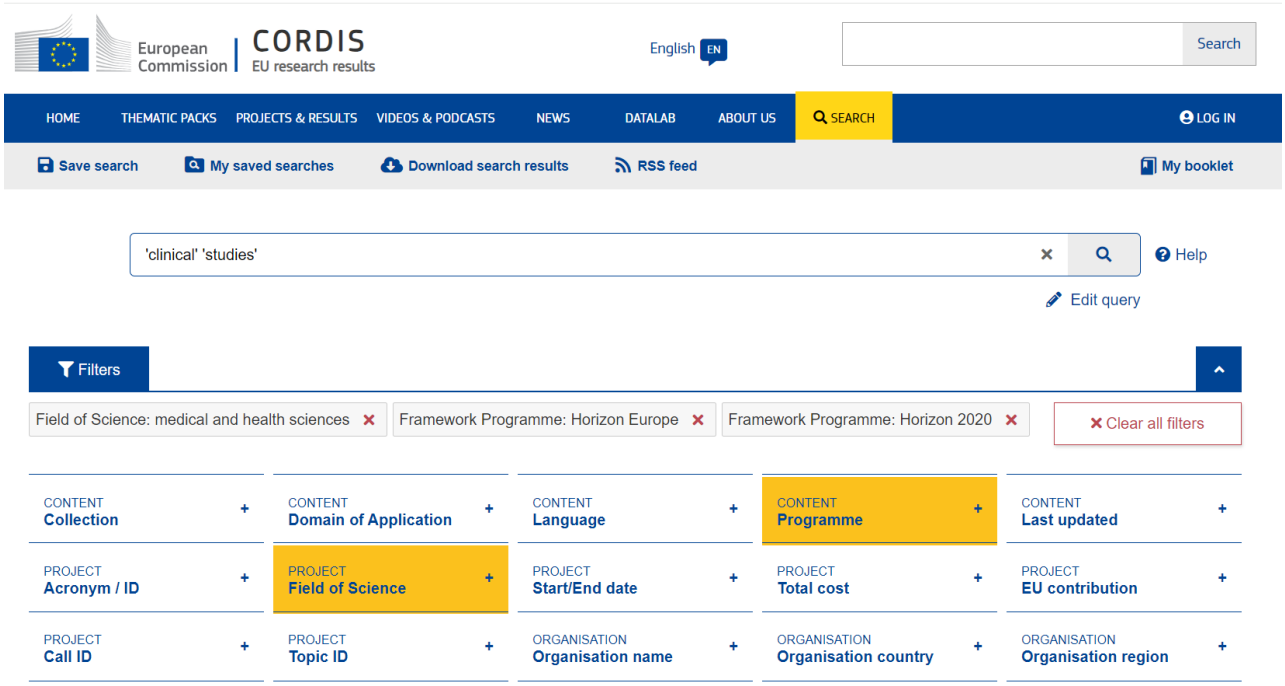
## Where to search for experienced Clinical Centers?

### ❖ CORDIS

The Community Research and Development Information Service (CORDIS) is the European Commission's primary source of results for projects funded by the EU's framework programmes for research and innovation.

CORDIS has a single search service that provides a range of simple and more advanced functions.

You can search “clinical studies” and combine it – as below - with filters that apply to all or certain content collections. 'Edit query' allows you to use advanced search syntax by linking the words that are used for the search with AND, OR, NOT.




From there, you’ll find all projects’ details to further explore the partners in the consortium.

### ❖ RePo4EU (Phase I trial sites)

The EU project RePo4EU hosts an online platform for validated precision drug repurposing including a **registry for academic Phase I trial sites in Europe**. They are specialized for drug repurposing approaches, but could serve as partner for your clinical trial. The registry contains the name, country, website and expertise of the trial sites.

## ❖ The European Infrastructure ECRIN

Support is given also by the **European Clinical Research Infrastructure Network (ECRIN)** https://ecrin.org/ that can either be partner in the consortium or also just contacted by the consortium for advice.

ECRIN is a not-for-profit organisation that supports the planning, coordination and conduct of multinational clinical trials in Europe. They have local experts in each Member and Observer country across Europe and they work with national networks of clinical trial units.

Among its **tools and services**:

1. **Clinical operations** – support for the management of multinational clinical trials, from project conception through operational management.
2. **Data center certification** – ensures compliant, effective, and efficient data management services.
3. **Adaptive Platform Trial Toolbox** **-** aims to collect the accumulated knowledge, experience, and resources from multiple projects and trials into a practical and guided toolbox to facilitate planning and conduct of future adaptive platform trials in any therapeutic area.
4. **Clinical Research Metadata Repository** **-** is the online tool to help scientific researchers find documents and data linked to a clinical research study, and to obtain information on the accessibility of those results. ECRIN made the Clinical Research Metadata Repository freely available for all scientific researchers.

## ❖ National Clinical Research Networks

Several countries have **national clinical research networks**, which support clinicians when conducting clinical studies and represent a platform for networking and sharing of high-quality standards. Here are some national examples:

- National Clinical Trials Office
- KKS Netzwerk, Netzwerk Universitäts Medizin
- French Clinical Research Infrastructure Network
- Italian Clinical Research Infrastructure Network
- Spanish Clinical Research Network
- Portuguese Clinical Research Infrastructure Network
- Norwegian Clinical Research Infrastructure
- Greek Clinical Research Infrastructure Network
- Czech Clinical Research Infrastructure Network
- Polish Clinical Trials Network
- Slovak Clinical Research Infrastructure Network
- Swiss Clinical Trial Organisation

If your national network is not listed or you have further questions, please reach out to your Country NCP for further assistance.

## ❖ European Union Clinical Trials Register and Clinical Trial Information System

Start exploring clinical trials in the European Union Clinical Trials Register (EudraCT) or Clinical Trial Information System (CTIS)! The registries include:

- interventional clinical trials that were approved in the European Union (EU)/European Economic Area (EEA) under the Clinical Trials Directive 2001/20/EC (See EudraCT);
- clinical trials conducted outside the EU/EEA that are linked to European paediatric-medicine development (See EudraCT);
- EU/EEA interventional clinical trials approved under or transitioned to the Clinical Trial Regulation (CTR) 536/2014 (See CTIS).

**You will find information like the protocol, sponsor details, and results for each of the registered clinical trials.**

For further information, you can also consult the **list of healthcare professionals' organisations recognized by EMA (European Medicines Agency).** These organisations are not-for-profit, in most cases have a European Union-wide mandate, and include umbrella organisations encompassing a number of smaller or national organisations or organisations with a focus on a specific area.

Eligible organisations receive targeted EMA communications and consultations and frequently assist in the identification of experts for product-specific matters. All of the listed organisations have been evaluated and confirmed to fulfil the eligibility criteria for working with EMA, and may be **able to provide information on clinical trials within various disease areas.**

### ❖ Stakeholders' platform from the ACT EU initiative

The Accelerating Clinical Trials in the EU (ACT EU) initiative aims to develop the European Union further as a competitive center for innovative clinical research. ACT EU seeks to deliver on the clinical trial innovation recommendations of the European Medicines Agencies (EMA) network strategy and the European Commission's Pharmaceutical strategy for Europe. ACT EU builds on the Clinical Trials and Clinical Trials Information System's launched on 31 January 2022.

The European Commission, EMA and Heads of Medicines Agencies (HMA), indeed, launched ACT EU in January 2022 and run the initiative together, establishing a steering group in March 2022.

**ACT EU Priority Action 3** aims to establish a platform where all stakeholders involved in designing, regulating, performing and participating in clinical trials can, through regular dialogue, identify relevant scientific, methodological and technological advances to develop the clinical trials environment in the EU. Through a series of workshops in 2023 and 2024, an **EU Multi-Stakeholder Platform** on clinical trials has been established to advance discussions on priority topics by efficiently incorporating the views, needs and concerns of all parties involved in the process.

This Multi-Stakeholder Platform (MSP) functions as a vehicle for clinical trials stakeholders and regulators to come together, voice their views and collaborate to improve the clinical trials environment for European patients and citizens.