

## **Clinical Trials in Horizon 2020 – Overview**

Horizon 2020 has opened its gates to clinical trials. Check out this extensive post covering the highlights of clinical trials in Horizon 2020.

To generally explain, clinical trials in Horizon 2020 are funded via the Research and Innovation Actions (RIA). The funding via RIA is always to the extent of 100% of the project's budget. The typical budget in these projects is usually around 6 million euro (but can vary). Check out the basics of funding clinical trials in Horizon 2020 below.

## **Understanding the Horizon 2020 topics**

The Horizon 2020 work program, published once every 2 years, specifies the list of specific topics and areas in which the EC welcomes clinical trials. When reviewing the topics, note that there are topics in which clinical trials are mandatory, while in other topics the clinical trial might be optional.

## **Clinical trials in Horizon 2020: working in consortium**

Like any other Horizon 2020 collaborative project, clinical trial projects are performed as a consortium of partners. It may include a combination of sponsor, medical centers (sites), research organisations, Contract Research Organisation (CRO), patient interest groups, and more.

The structure of the consortium should be in line with the clinical trial structure, its protocol, the patient recruitment plan, and other specifications mentioned in the call for proposals. The consortium should be flexible enough to perfectly enable the execution of the clinical trial. Unique to clinical trials within Horizon 2020, [enhanced implementation of sub-contracting](#) is allowed, but should be planned with care.

Learn about [possible consortium structures for clinical trials in Horizon 2020](#).

Participation of US-based organisations is allowed. Note that there might be some regulatory conflicts between the US and EU clinical trial legislations that should be addressed.

## **What kind of clinical trials and studies can be funded in Horizon 2020?**

The answer is rather simple: practically any type of clinical trial can be funded:

- Categorized by Methodology:
  - Observational
  - Interventional
  - Randomized
  - Longitudinal
- Categorized by type of intervention:
  - Medicinal products
  - Medical devices
  - Advanced therapies
  - Surgery
  - Education/Training
  - Psychotherapy
- Categorized by phases:
  - Phase 0' to 'Phase 4'

Although all of the above can be funded, the proposed clinical trial project must **corresponds to the content of a specific topic regarding the type of clinical trial**, as published in the Horizon 2020 work program.

## **What should be included in the Horizon 2020 application?**

The Horizon 2020 application for funding clinical trial consists of a **regular Horizon 2020 RIA application**, a **complementary “Essential information for clinical trial annex”** and an **“Ethical annex”**.

In general the full application should be protocol-driven and address the following issues (non-exhaustive list):

- Study design and endpoints
- Study Subjects / Population – Inclusion / Exclusion criteria
- Patient recruitment plan
- Scientific advice / protocol assistance / communication with regulatory / competent authorities / ethics committees
- Statistical analysis planning and power calculation
- Cumulative safety information
- Orphan Designation, if relevant to topic/proposal
- Payments structure
- ‘Unit cost’ per patient break-down, if relevant
- And more

Think you are ready to move forward with a Horizon 2020 clinical trial proposal?  
We have a selection of services that can be relevant. [Check them out here.](#)