Fit for Health 2.0

Clinical trials in Horizon 2020

European Commission

This project has received funding from the European Union's Seventh Programme for research, technological development & demonstration under grant agreement No 602428

What is the challenge?

What is defined as a 'clinical study' in Horizon 2020?

A 'clinical study' in the context of Horizon 2020 means any clinical research involving a substantial amount of work related to the observation of, data collection from, or diagnostic or therapeutic intervention on multiple or individual patients. This includes different types of trials (such as observational studies, interventional studies, and other) as well as all phases (Phase I – IV), and is not limited to clinical trials in the sense of the new Regulation on clinical trials, repealing the clinical trials Directive 2001/20/EC.

Why clinical trials?

The implementation of clinical trials in a collaborative, transnational approach has a clear European added value:

- easier to reach sufficient patient numbers (especially in the case of rare diseases and stratified treatment groups)
- faster recruitment rates
- consolidated expertise

In addition, clinical trials are the ultimate validation step for any innovation in clinical Health Research, bringing innovations to markets and patients – one of the main objectives of Horizon 2020.

Experience has shown that in FP7, meeting the timelines set out in the Grant Agreement was a challenge for a large number of collaborative projects, even without clinical study components. Clinical trials are known to be particularly complex and analyses show that the majority (up to 85%) of clinical trials in general are not completed in time, with site initiation (i.e. the time until a site is ready to start inclusion of patients) and patient recruitment being the most common reason for delays – and/or leading to a cost increase. In an EU project, however, the maximum funding that an initiative can receive is fixed and timely completion of projects - allowing a quick translation of research results into application - is a declared goal under Horizon 2020.

To help overcome these challenges, the European Commission provides clear guidance on how to optimally plan and describe your study in the proposal phase, and has adapted its financial rules in appreciation of the special requirements of clinical trials.

The right consortium

Partner selection & involvement of trial sites

As in any collaborative effort, experienced and responsive partners are the key to success. Your project will greatly benefit from partners who are experienced in planning and implementing clinical trials, and related data management. A thorough enrollment feasibility analysis will help choose the right study sites and estimate patient numbers realistically. The preferred option for involvement of recruiting centers is always the role of a beneficiary, i.e. a full partner to the consortium. However, it is also possible to include such centers as Third Parties, or as subcontractors under 'Societal Challenge 1: Health, Demographic Change and Wellbeing'.

Inclusion of Contract Research Organizations (CROs)

While the core expertise to conduct the planned clinical trial needs to be available in the consortium, specialized services, e.g. for pharmacokinetics, regulatory support, or professional trial monitoring might be needed. In such cases, the inclusion of CROs is explicitly permitted and can help ensure a smooth and timely implementation of the clinical trial elements.

Proper planning

Among the call documents, the European Commission provides a template on 'Essential information on clinical studies' (the Template) which includes sections on the study identifier, study design and endpoints, protocol assistance and regulatory issues, subjects to be included in the study, sample size, statistical methods, conduct, orphan designation and the use of 'Unit costs per patient' for the study (if applicable) – key issues to be considered for a sound planning of your study.

Where in the proposal do I describe my study, and what's the appropriate amount of detail?

The use of this Template in the context of the full proposal submission is mandatory for many of the topics which include clinical studies. Whether or not you have to fill out the Template is clearly indicated in the call. If required, you have to complete the Template providing the requested information for each clinical study, but merged in a single document and uploaded it as separate file together with the other proposal sections. In addition, relevant issues need to be addressed and incorporated in the admin forms and proposal body.

For proposals containing clinical studies submitted to topics where the use of this template is not mandatory it is still advisable to use the points listed as an orientation and provide this information in part B of the proposal.

Ethical issues

While ethical considerations should be an integral part already at the earliest planning stages, these aspects have to be described in detail only in the full proposal. You will find an ethics issues table in the online forms, and a dedicated section in the proposal body. The European Commission provides detailed guidance in the document 'How to complete your ethics self-assessment', a 'how to' guide that provides step-by-step advice on how to deal with classic cases (what to describe, how to describe it and what kind of documentation to add). Ethics issues that are not covered in this document must be dealt with outside the guide. Proposals are evaluated as they are, i.e. only information and documentation that is actually included can be taken into account during the evaluation.

Clinical trials in Horizon 2020

- key element of health research supported in Horizon 2020
- all types of trials are eligible for funding
- proposal process and financial rules adapted to facilitate the implementation of clinical studies within the programme

Budgeting issues

Subcontracting and the introduction of unit costs largely facilitate the budget planning and financial aspects of trial implementation in Horizon 2020. Both were designed to account for the additional challenges that are typical for clinical trials, such as the possible necessity for adaptation of (the number of) recruiting centers during the project lifetime, dealing with drop-outs, or competing studies.

Unit costs

Commission Decision C(2016) 7553 allows the 'reimbursement on the basis of unit costs for actions requiring the conduct of clinical studies under "Societal Challenge 1: Health, Demographic Change and Wellbeing"', as an alternative to the use of actual costs, on voluntary basis (AMGA / v2.2, Annotations ref. Article 6.2F, p.108). If chosen, this method needs to be applied for all patients of this beneficiary and is fixed for the entire duration of the project. In that case, the costs of a clinical study is calculated as the amount per unit set out in Annex 1 (the Template), multiplied by the number of actual units, i.e. patients or subjects. For costs which are not included in the unit costs, reimbursement will be based on actual cost. Resources and costs will be evaluated with the full proposal.

Subcontracting

In Horizon 2020, clinical centers that enroll, treat or follow patients can be included as a subcontractor (MGA Art. 13). However, only a limited part of the action can be subcontracted.

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