Mini-Clip:
Clinical Trials in Horizon 2020
Proposal Preparation

Fit for Health 2.0

Support to SMEs & Researchers in FP7 and Horizon 2020 health-oriented projects

www.fitforhealth.eu

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Clinical trials in H2020 projects

A clinical study

- can be the core of a project, or part of a project
- Can be included in a project responding to a topic that specifically asks for a clinical study, or be planned even if not asked for in the topic description

→ A large number of H2020 projects will include clinical studies

Contract Research Organizations (CROs)

It is possible to delegate the management of a clinical study within your project to a CRO

- Core CT expertise needs to be available in consortium
- BUT: specialized services e.g. for PK, regulatory support, professional trial monitoring etc. from CROs might be needed / ensure professional support and smooth CT implementation (NOT replacing any of the usual project management needs and structures; CT specific)
- 'Academic CROs' exist (e.g. ECRIN network) – involvement as a beneficiary suggested by the EC (alternatively: provide guidance/support as part of an advisory board?)
- Inclusion of 'regular' CROs as beneficiaries also possible (in that case: full partners, i.e. involved from the planning phase on and active partners in study design)
- Some CROs that work on a 'for profit' basis might not be willing to become a beneficiary → in these cases, subcontracting could be an option
- BUT: In most cases, only limited part of the action can be subcontracted

Budget

CT are even more prone to under-budgeting than ‚regular' H2020 projects

- Careful to include all needs
- EU FP budgeting is done by adding up of individual components, not by giving a safely estimated overall total (e.g. a 'per patient fee') as profit margins are not allowed
- Equally challenging as a comprehensive list of all activities in one day... hardly ever complete
- Additional challenges: How to adapt (number of) recruiting centers during the project? How to deal with drop-outs? How to avoid slow-down of activities due to cashflow issues?
- Unit costs vs actual costs, example for unit costs in the template for clinical trials, p. 4f.

Time planning

Don‘t be over ambitious!

Experience has shown that almost 50% of all FP7 projects were not finished in the originally planned time. Proper time planning is even more of a challenge for clinical trials activities:

- Project start date ≠ start of the study… esp if ethical approval still needs to be obtained (which is usually the case if a new/additional approval is needed for work under the project)
- Include enough time for protocol development (proposal includes draft protocol only.. development of final protocol may take some time, esp if initiated after start of the project as part of the workplan)
- Estimate recruitment speed carefully and realistically!

Description of the trial

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

- "Template for essential information to be provided for proposals including clinical trials"… where mandatory (currently: for all clinical studies included in a single-stage- or stage-2 proposal submitted to topics PHC-2, PHC-3, PHC-11, PHC-14, PHC-15, PHC-16, PHC-18, PHC-22, PHC-24, PHC-33 and HCO-6)
  - in standardized format, in great detail, one description per study
  - new clinical trial template for download

- Proposal body... in any case
  - in condensed format, summarizing the essence
  - as part of the overall description of the planned work, and
  - in parts in the WP description
  - with cross references to the study template / Annex

Ethics

Ethics Issues Table
online
AND
Proposal section 5.1:

In section 5.1

In sub-sections of section 5.1
(one for each issue ticked… see **EC guide**)

In Annex „supporting docs“

5.1 Ethics

If you have entered any ethics issues in the ethical issue table in the administrative proposal forms, you must:

- submit an ethics self-assessment, which:
  - describes how the proposal meets the national legal and ethical requirements of the country or countries where the tasks raising ethical issues are to be carried out;
  - explains in detail how you intend to address the issues in the ethical issues table, in particular as regard:
    - research objectives (e.g. study of vulnerable populations, dual use, etc.)
    - research methodology (e.g. clinical trials, involvement of children and related consent procedures, protection of any data collected, etc.)
    - the potential impact of the research (e.g. dual use issues, environmental damage, stigmatisation of particular social groups, political or financial retaliation, benefit-sharing, malevolent use , etc.).
- provide the documents that you need under national law(if you already have them), e.g.:
  - an ethics committee opinion;
  - the document notifying activities raising ethical issues or authorising such activities

⚠ *If these documents are not in English, you must also submit an English summary of them (containing, if available, the conclusions of the committee or authority concerned).*

⚠ *If you plan to request these documents specifically for the project you are proposing, your request must contain an explicit reference to the project title.*

Ethics Guide

For each item in checklist:

- **Info** to be provided **in section 5.1**
- **Documentation** to be provided in Annex **"supporting documents"**

Section 2: HUMANS		YES/ NO		Page	Information to be provided	Documents to be provided
Does your research involve human participants?		☐	☐		Confirm that informed consent has been obtained. plus:	Informed Consent Forms + Information Sheets (see text box below). plus:
If YES:	- Are they volunteers for social or human sciences research?	☐	☐		Details on recruitment, inclusion and exclusion criteria and informed	Copies of Ethics Approvals (if required).
	- Are they persons unable to give informed consent (including children/minors)?	☐	☐		Details on your procedures to obtain approval from guardian/ legal representative. Details on the measures you intend to take to ensure that there is no coercion on participants.	Copies of Ethics Approvals.
	- Are they vulnerable individuals or groups?	☐	☐		Details on the type of vulnerability. Details on recruitment, inclusion and	Copies of Ethics Approvals.

Info and support

Sources of advice and support:

- National Contact Points
- FAQs concerning the H2020 societal challenge “Health, demographic change and wellbeing” http://ec.europa.eu/research/participants/portal/doc/call/h2020/h2020-hco-2015/1637625-2015_01_15_sc1_h2020_faq_en.pdf
- EU IPR helpdesk: www.iprhelpdesk.eu
- FFH 2.0 CT factsheet
- FFH 2.0 support