

Fit for Health 2.0

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

Clinical Trials in Horizon 2020



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What is a 'clinical trial' in H2020?

Or more specifically: What needs to be described as a ,clinical study' in the proposal?

- *A 'clinical study' is defined for the purpose [of this template] is 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. It includes but is not limited to clinical trials in the sense of the EU Clinical Trials Directive (2001/20/EC).*
- A clinical study can be the core of a project, or part of a project
- ...included in a project designed in response to a topic that specifically asks for a clinical study, or not
- i.e. highly relevant issue for anyone who is considering a proposal submission under SC1

Content

1. Proposal preparation:
 - a) Planning:
 1. Composition of the consortium
 2. Costs/budget issues
 3. Time planning
 - b) Writing
 1. Description of the trial
 2. Ethics (section 5.1 and annexes)
 3. Changes between stage 1 and stage 2
2. Implementation:
 - a) Management
 - b) Monitoring

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Consortium

Composition of the consortium

- Experienced partners needed! Clinical trials are always a challenge; in H2020 even more so
- H2020 has been adapted to better accommodate the implementation of CT, but is not primarily designed for CT →
 - Different budgeting approach
 - 'No' flexibility regarding duration
 - Unexperienced partners often find EU FP participation a challenge in itself..
- 2 different approaches:
 - make trial visible and living part of the project, full inclusion, EU FP capacity building, investment in one project will pay off in later/other project
 - Trial as data source, outsource in (large) parts
- Recruiting centers as beneficiaries vs subcontractors
- Inclusion of a CRO

Consortium

Inclusion of Contract Research Organizations (CROs)

- 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 (well informed, many times confirmed) overall total
- Equally challenging (if not 'as impossible') as a comprehensive list of all activities in one day.. never complete
- Additional challenges: e.g. plan for adaptation of (number of) recruiting centers, deal with drop-outs, avoid by all means slow-down of activities due to cashflow issues
- Unit costs vs actual costs, tbd

Timeplanning

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 \neq 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)
- 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)
- Slow recruitment
- Stage 1 planning often more ambitious, stage 2 planning more specific/longer duration (still highly ambitious usually.. be careful!!)

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Description of the trial

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

- Studies template... where mandatory
 - in standardized format, in great detail, one description per study

- 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

Where in the proposal do I deal with ethical aspects of my planned work, and what's the appropriate degree of detail?

- Ethics issues table
- Proposal section 5.1
- “Supporting documents”

Ethics

Ethics issues table online:

- collect from all partners
- have coordinator check / complete

THEN

optimally:
have one designated
person in charge of all
ethics aspects in your
proposal
(..and project)

ieses Formular eingegebene Daten speichern.

Proposal Submission Forms

Table Of Contents Validate Form Save And Close

Proposal ID SEP-210200747 Acronym SMARTchemBio Go to

4 - Ethics issues table

1. HUMAN EMBRYOS/FOETUSES		Page
Does your research involve Human Embryonic Stem Cells (hESCs) ?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Does your research involve the use of human embryos?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Does your research involve the use of human foetal tissues / cells?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
2. HUMANS		Page
Does your research involve human participants?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Does your research involve physical interventions on the study participants?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Does it involve invasive techniques?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
3. HUMAN CELLS / TISSUES		Page
Does your research involve human cells or tissues (other than from Human Embryos/ Foetuses, i.e. section 1)?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
4. PERSONAL DATA (ii)		Page
Does your research involve personal data collection and/or processing?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Does your research involve further processing of previously collected personal data (secondary use)?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
5. ANIMALS (iii)		Page
Does your research involve animals?	<input type="radio"/> Yes <input checked="" type="radio"/> No	

Ethics

Proposal section 5.1:

In section 5.1

In sub-sections of section 5.1 (one for each issue ticked.. see 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

EC guide:



How to complete your ethics Self-Assessment

Version 1.0
11 July 2014

Ethics

„How to complete your ethics self assessment“

- Very helpful ‘how to’ guide
- Detailed step-by-step advice on how to deal with classic cases (what to describe, how to describe, what documentation to add)
- Ethics issues that are not covered must be dealt with outside the guide!

Table of Contents

1. Human embryos and foetuses.....	4
2. Humans.....	7
3. Human cells/tissues.....	13
4. Personal data.....	17
5. Animals.....	23
6. Third countries.....	27
7. Environment & Health and Safety.....	31
8. Dual use.....	36
9. Misuse.....	38
10. Other ethics issues.....	40

Ethics

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?		<input type="checkbox"/>	<input type="checkbox"/>		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?	<input type="checkbox"/>	<input type="checkbox"/>		Details on recruitment, inclusion and exclusion criteria and informed consent procedures	Copies of Ethics Approvals (if required).
	- Are they persons unable to give informed consent (including children/minors)?	<input type="checkbox"/>	<input type="checkbox"/>		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?	<input type="checkbox"/>	<input type="checkbox"/>		Details on the type of vulnerability. Details on recruitment, inclusion and exclusion criteria	Copies of Ethics Approvals.

Changes between stage 1 and stage 2

Need to be explicitly addressed:

6. Preparation of a stage 2 proposal

If I am successful at stage 1, can I make changes to my proposal when submitting the full version to stage 2?

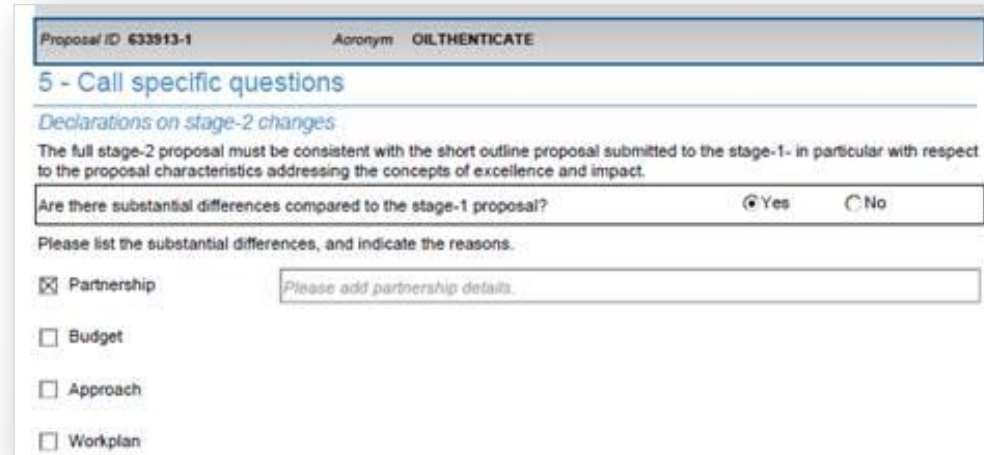
Section III.5.2 of the Horizon 2020 [Grants manual: Section on: proposal submission and evaluation](#) states that for two-stage submission schemes, 'the full proposal must be consistent with the short outline proposal and may not differ substantially'.

This means that changes are not recommended, but if absolutely necessary, they should be clearly explained and the evaluators will determine whether or not these changes are legitimate, and whether or not their insertion compromises the evaluator judgement made at stage 1.

Changes between stage 1 and stage 2

Need to be explicitly addressed

- For some SCs it was possible to address 'Call specific questions (Declarations on stage-2 changes)' in ECAS - this was NOT possible for SC1 (H2020-PHC-2014 topics)



Proposal ID 633513-1 Acronym OILTHENTICATE

5 - Call specific questions

Declarations on stage-2 changes

The full stage-2 proposal must be consistent with the short outline proposal submitted to the stage-1- in particular with respect to the proposal characteristics addressing the concepts of excellence and impact.

Are there substantial differences compared to the stage-1 proposal? Yes No

Please list the substantial differences, and indicate the reasons.

Partnership

Budget

Approach

Workplan

- Instead:
 - highlight at the very beginning of your proposal body, or
 - highlight in the proposal section where it the issue is mentioned (e.g. consortium: on cover page; duration: where mentioned, and as a comment on Pert..)

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Management

Management of a clinical trial is not just an add-on to classical project management

AND

vice versa: the management of your project is not taken care of if including a CRO to look after your trial

- CT is like a project within your project, with its specific set of actions, large number of individuals involved, need for harmonization, communication, coordination... → to be managed by a highly experienced (clinical) partner or CRO
- to be complemented by the management of (and guidance for) ethical issues → by an ethics expert (committee), and
- to be integrated into the H2020 project and regulatory framework → management of interfaces and H2020 project itself by a classical project manager

Monitoring

The CT is to be implemented under H2020, but comes with additional requirements

- Official reporting in H2020: every 18 months, with the possibility of interim reports & additional monitoring activities as the coordinator/management team sees fit to optimize implementation

The same basically applies to clinical trials:

- While specific requirements for CT elements in H2020 proposals, no specific EC requirements for monitoring/reporting
BUT
- closer monitoring and much more (basic) reporting back of information is definitely needed (e.g. monthly reporting of recruitment numbers, monthly TCs with all clinical partners, etc)

Concluding remarks

- Clinical trials implementation is rather new to EU Framework Programmes
- Introduced during FP7
- In H2020, CT are a central issue in SC1; the EC has made great efforts to accommodate the needs of consortia willing to implement clinical studies
- H2020 provides challenges but also great opportunities for the implementation of clinical trials
- Be careful but don't be scared

Info and support

Sources of advice and support:

- National Contact Points
- FAQs concerning the H2020 societal challenge “Health, demographic change and wellbeing”
https://ec.europa.eu/research/participants/portal/doc/call/h2020/h2020-phc-2014-two-stage/1620101-2014_2015_-2014_07_31_sc1_h2020_faq_en.pdf
- EU IPR helpdesk: www.iprhelpdesk.eu
- FFH 2.0 CT factsheet
- FFH 2.0 support



Thank you!

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