Fit for Health 2.0

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

Fit for Health 2.0 – International Training on Clinical Trials in Horizon 2020: Challenges & Best Practices

Introduction to H2020 Clinical Trials

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What is a 'clinical study' in H2020?

Or more specifically: What needs to be described as a ‚clinical study' in a H2020 proposal?

*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 or study subjects.*

*This includes **different types of studies** (such as observational studies, interventional studies, and other) **as well as all phases** (Phase I – IV), and is not limited to clinical studies & trials in the sense of the* EU Clinical Trials Directive (2001/20/EC) and the Regulation (EU 536/2014).

A ‘clinical study’ in H2020 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**
- …a **highly relevant issue** for many proposals to be submitted **under Societal Challenge 1**

Clinical Studies – potentially relevant for SC1 Topics (2016/2017)

2-stage topics (Deadline: 04 October 2016 + 11 April 2017)

- SC1-PM-02-2017: New concepts in patient stratification
- SC1-PM-07-2017: Promoting mental health and well-being in the young
- SC1-PM-08-2017: New therapies for rare diseases
- SC1-PM-10-2017: Comparing the effectiveness of existing healthcare interventions in the adult population

Single stage topics

- SC1-HCO-07-2017: Global Alliance for Chronic Diseases (GACD) prevention and management of mental disorders (11 April 2017)
- SC1-PM-11-2017: Clinical research on regenerative medicine (11 April 2017)

Why clinical studies?

The implementation of clinical studies 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 studies 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.

Collaborative, transnational approaches also bear challenges…

…with clinical studies even more

Typical challenges I

Even among 'regular' FP7 projects:

- ~ 50% of grants were not completed in time & had to be extended through an amendment

Clinical studies

- are known to be particularly complex
- literature: up to 85% of clinical studies in general are not completed in time
- delay often leading to cost increase

Typical challenges I

BUT

declared goal under Horizon 2020 **timely completion** of projects & **quick translation** of research results into application is a

→ **project extension not generally granted**

- maximum EC contribution per project is fixed

Typical challenges II

There are many parallel and competing factors/challenges when preparing for and conducting clinical studies:

- …around coordination of manufacturing activities (timely availability of study medication,…)
- ...around site involvement/initiation, patient recruitment and management (study protocol, ethics/ regulatory reviews,…)
- ...around data collection and management
- …around financial management
- …integration into rest of the H2020 project

…within fixed project time frame

Good planning needed during proposal phase…

…to ensure smooth implementation of H2020 clinical study within the projects life time

To not only address the clinical study challenges in theory…

…but more **holistic from different perspectives**, we invited:

- **experts from the EC** (*DG Research & Innovation, Health Research Strategy*) to elaborate on the challenges encountered in H2020 projects involving clinical studies
- **experts directly involved in the practical clinical studies work in H2020 projects** who will share their practical experience, encountered challenges and how to cope with these (best practice solutions) in the field of:
  - Realistic time and financial planning, site involvement, recruitment planning, availability of study medication
  - Ethical aspects & approval procedures
  - Data Management

Agenda

09:15 – 10:00	**Registration**
10:00 – 10:05	**Welcome to H2020 Clinical Trials training** *Dr Ines Haberl, Austrian Research Promotion Agency (Austria)*
10:05 – 10:20	**01- Introduction to H2020 Clinical Trials** *Dr Birte Kretschmer, European Research and Project Office GmbH (Germany)*
10:20 – 10:35	**02- EC Perspective: Challenges in H2020 Clinical Trials** *Dr Cornelius Schmaltz, DG Research & Innovation, HoU Health Research - Strategy, EC &* *Dr Mark Goldammer, DG Research & Innovation, Health Research - Strategy, EC*
10:35 – 11:10	**03- Planning a multinational H2020 Clinical Trial: experience & best practice from ECRIN** *Dr Christine Kubiak, Operational Director ECRIN, Paris (France)* *Partner in several H2020 projects* *(~25 minutes presentation & 10 minutes discussion)*
11:10 – 11:25	**Coffee break**
11:25 – 12:00	**04- Ethical Aspects & Approval Procedures in H2020 Clinical Trials: challenges & best practice** *Prof. Jens Kastrup, Cardiac Stem Cell Centre, Copenhagen (Denmark)* *Coordinator of the H2020 SCIENCE project* *(~25 minutes presentation & 10 minutes discussion)*
12:00 – 12:35	**05- Data Management in H2020 Clinical Trials: challenges & best practice** *Dr Corinna Engel, Center for Pediatric Clinical Studies, Tübingen (Germany)* *Coordinator of the H2020 ALBINO project* *(~25 minutes presentation & 10 minutes discussion)*
12:35 – 12:40	**Wrap-up and closure with a lunch** *Dr Birte Kretschmer, European Research and Project Office GmbH (Germany)*

Conclusion

- H2020 provides challenges but also great opportunities for the implementation of clinical studies
- Good planning during the proposal phase will ensure a smooth implementation of clinical studies in H2020 projects
- Be careful but don’t be scared

Info and support

Sources of advice and support:

- FFH 2.0 support (FFH 2.0 CT factsheet, workshops, webinars, FAQs …)
- National Contact Points
- FAQs concerning the H2020 societal challenge "Health, demographic change and wellbeing"

  https://ec.europa.eu/research/participants/portal/doc/call/h2020/sc1-pm-03-2017/1730125-faqs_v5_august2016_en.pdf
- Commission Decision C(2014) 1393 on Unit Costs
- EU IPR Helpdesk: www.iprhelpdesk.eu

The webinar will provide an overview on the CT-related aspects to be considered during proposal planning (e.g. consortium composition, budget issues, time planning) and writing (e.g. where to describe the study, introduction to ethical aspects) as well as project implementation.

http://www.fitforhealth.eu/event-created/webinar-clinical-trials-horizon-2020-projects-0

Thank you!

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