Mini-Clip:
Clinical Trials in Horizon 2020
Framework Conditions

Fit for Health 2.0

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

www.fitforhealth.eu

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What is a Clinical Trial?

- Research study involving human subjects
  - To answer specific questions about biomedical or behavioural interventions
  - To prevent or treat disease

- Any systematic evaluation of investigational medicinal products (IMPs) or devices in human subjects (patients or healthy volunteers) to discover or verify the effects of IMPs and/or identify any adverse reactions to IMPs and/or to study their absorption and excretion in order to ascertain their efficacy and safety.

Types

- Observational study
- Interventional study
  - Prevention trials
  - Screening trials
  - Quality of life trials
  - Diagnostic trials
  - Trials with Orphan Drugs
  - Pilot Studies (feasibility studies)

Trial Design

- Randomized Controlled Trials (RCT)
  - Each study subject is randomly assigned to receive the study treatment or a placebo
- Blind-trials / Double-Blind trials
  - Investigators and / or subjects do not know which treatment a subject receives

➔ currently, some Phase 2 and most Phase 3 trials are designed as randomized, double-blind and placebo controlled trials, which is the gold standard when conducting CTs

Rules & Regulations: execution of research & protection of patients

- Declaration of Helsinki – international standard for the protection of subject's rights
- International Conference of Harmonization Guidelines for Good Clinical Practice (ICH GCP)
  http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf
- The European Clinical Trials Directive 2001/20/EC
  (and Commission Directive 2005/28/EC of 8 April 2005)
- European Medicine Agency:
  - *Human medicines: regulatory information*
    http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/landing/human_medicines_regulatory.jsp&mid
  - *Clinical Trials in human medicins*
    http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000489.jsp&mid=WC0b01ac058060676f

Rules & Regulations: execution of research & protection of patients

National Legislation

Member States have transposed the requirements of the Clinical Trials directive into national laws, regulations and administrative provisions. **The approval of clinical trial applications is the responsibility of the member states.**

National Medicine Regulatory Authorities ("competent authorities"): *http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&murl=menus/partners_and_networks/partners_and_networks.jsp&mid=WC0b01ac0580036d63&jsenabled=true*

EU proposals including clinical studies - specifics

Challenges, obstacles and problems during proposal preparation or during running project

- Difficulties in controlling Patient recruitment process (e.g. delay in recruitment; requirement to shift to other study sites)
- Necessity of high number of study sites for certain research questions
- Unforeseen increase in drop-out rates or costs
- Different ethical aspects (protocol harmonization; national approvals; etc)
- *See http://www.healthncpnet.eu/jahia/Jahia/pid/26 for help*
- Missing specific expertise in monitoring, biostatistics, regulations, etc.

Template 'Essential information on clinical studies'

- **Mandatory** for certain SC1 topics
- Only **for full proposal** (= second stage of two stage application or single stage application)
- **Template** available in Submission Service (Participant Portal)
  - After selection of topic under topic conditions & documents: PDF for information
  - After logging on: Word doc to be filled in and submitted
- To be **uploaded as separate document** in submission system
- To be completed for **each** clinical study, but **as one single document**

Unit costs per patient

- Unit costs (UC) eligible under Horizon 2020
- Beneficiaries can use different forms of reimbursement (unit costs or actual costs) for different clinical studies
- When using unit costs: needs to be applied for **all** patients of this beneficiary for this particular CT
- Option for any Beneficiary, but not for subcontractors
- Unit costs per patient **set for the entire duration** of the project
- Resources and costs will be **evaluated with the proposal**
- Estimation of resources per patient and task based on historical costs (actual costs recorded in certified or auditable profit and loss accounts of last closed financial year (before proposal submission) of beneficiary)

Unit costs per patient: Eligible Costs

Direct costs of clinical studies*:

a) Personnel (doctors and other medical and technical personnel)
b) Consumables
c) Medical equipment *(depreciation and costs of service contracts necessary for their functioning)*
d) Other specific service contracts necessary for the clinical study

Indirect costs of the clinical study

- 25% of direct costs (sum of unit costs components under a) – c))

* *Travel and subsistence costs of patients are not included (will be reimbursed on the basis of eligible costs actually incurred under the cost category "other direct costs")*

Management: How to involve study sites?

1. **Partner**
   - Preferred option of the EC

2. **Subcontractor**
   - External procurement rules apply
   - Core tasks are not eligible for subcontracting (expertise for conduction of CT needs to be within consortium)

3. **In-kind contributions provided by third parties against payment**
   - No unit costs possible

4. **Affilitated entities and third parties with a legal link to a beneficiary (Art. 14 MGA)**
   - “legal link” often unclear