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Clinical Trials in FP7 Projects

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European Legislation on Clinical Trials

L 121/34 EN Official Journal of the European Communities 1.5.2001

DIRECTIVE 2001/20/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 4 April 2001
on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

9.4.2005 EN Official Journal of the European Union L 91/13

COMMISSION DIRECTIVE 2005/28/EC
of 8 April 2005
laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products
(Text with EEA relevance)

http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm

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Clinical Trial topics

Total EC contribution to these projects: ~€100 million
4 + 2 topics, with several projects to be funded in each topic

Purpose:

- to bring discoveries into clinical testing, to advance development of new approaches and to compare treatments
- Most topics are for investigator-driven clinical trials (IDCTs), complementing development of new drugs by industry

Scope:

- Is specified in each topic
- Needs to consider available budget
- Expected to be mostly phase II, but also all other phases depending on the topic

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Clinical Trial topics

Guiding principles:

- Two-stage submission/evaluation
- EC contribution: max. € 6m/project for all but one topic
- Number of partners: as appropriate (with minimum 3 from 3 diff. Member States/Associated Countries)
- Duration of projects: no minimum or maximum duration
  - Maximum EU contribution needs to be considered
  - Evolution of consortium (e.g. including of additional clinical centres) possible but no additional EU contribution
- Patient representation in consortium is highly encouraged
- Ethical and regulatory framework (EU and national)
- Outsourcing/subcontracting possible but…….

See also orientation paper, introduction page 9

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Key Message for 2012 Calls

Flexibility

Some basic rules and guidelines, but:

- Size of consortium (beyond min. 3)
- Composition of the consortium
- Duration of the project

} are for the applicants to decide

E.g.: a small- or medium-scale Collaborative Project with a € 6m ceiling can involve just 3 or 4 partners for only two years with a budget of € 4m

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SME Involvement and International Cooperation

- SME* participation encouraged for all clinical trial topics
  - Will be considered in the evaluation of the proposals
  - Most topics with additional eligibility criterion for min. % EU funding going to SME or industry
- All topics open for international Cooperation
  - Opportunity to involve partners from anywhere in the world
  - US participation in the Health Theme as in previous calls

*SME Definition
http://ec.europa.eu/enterprise/policies/sme/facts-figures-analysis/sme-definition/index_en.htm

User Guide
http://ec.europa.eu/enterprise/policies/sme/files/sme_definition/sme_user_guide_en.pdf

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Successful Proposals for Clinical Trial Projects

Clinical trial methodology needs to be properly addressed, e.g.

- Control, number of patients, inclusion/exclusion criteria, etc.
- Statistical plan
- Strategy and status of obtaining ethical and regulatory clearance
- If applicable, sourcing of the medicinal product, device, etc.

Clear indication needs to be given already at the first stage; full proposals must contain all relevant information in detail

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Ethical issues and Good Clinical Practice

- Information about ethics issues on Cordis website at: http://cordis.europa.eu/fp7/ethics_en.html#ethics_cl « informed consent » document has references to the main documents, such as:

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI
Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53rd WMA General Assembly, Washington 2002 (Note of Clarification on paragraph 29 added)
55th WMA General Assembly, Tokyo 2004 (Note of Clarification on Paragraph 30 added)
59th WMA General Assembly, Seoul, October 2008

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Ethics check list

Informed Consent
- Does the proposal involve children?
- Does the proposal involve patients or persons not able to give consent?
- Does the proposal involve adult healthy volunteers?
- Does the proposal involve Human Genetic Material?
- Does the proposal involve Human biological samples?
- Does the proposal involve Human data collection?

Research on Human embryos/foetus
- Does the proposal involve Human Embryos?
- Does the proposal involve Human Foetal Tissue/Cells?
- Does the proposal involve Human Embryonic Stem Cells?

Privacy
- Does the proposal involve processing of genetic information or personal data (eg. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical convinction)?
- Does the proposal involve tarcking the location or observation of people?

Research on Animals
- Does the proposal involve research on animals?
- Are those animals transgenic small laboratory animals?
- Are those animals transgenic farm animals?
- Are those animals cloning farm animals?
- Are those animals non-human primates?

Research Developing countries
- Use of local resources (genetic, animal, plant, etc.)?
- Benefit to local community (capacity building ie access to healthcare, education, etc.)

Dual Use
- Resarch having potential military/terrorist application

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Informed Consent

When is it needed?

Review at EU level

- ***When Children involved***
- ***Developing Countries***

Screening
- ***Healthy volunteers***
- ***Human genetic material***
- ***Human biological samples***
- ***Human data collection***

INSURANCE!!!!!!!!

What must be in Consent form ? State + explain

- ***That it is research***
- ***Purpose+duration+descriptio n***
- *foreseen risks*
- *benefits*
- ***Alternative***
- ***confidentiality***
- *Treatment/compensation +information*
- *contact for rights/claims*
- ***contact for injury to the subject***
- ***Voluntary participation***
- ***No penalty or loss on stopping***

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Privacy and Data Protection

Refers to relation between tech and the right to privacy

- identifiable data collected and stored,
- Improper or non-existent disclosure control

Data affected by privacy issues

- Health information.
- Criminal justice.
- Financial information.
- Genetic information.
- Location information.
- Data privacy / share data while protecting identifiable information.

How to Deal with Data Protection and Privacy?

- describe the procedures for informed consent + confidentiality
- inform consent for **duration** +
- code or **anonymised** banked biomaterial, security for storage and handling
- Fairly and **lawfully** processed
- **limited** purposes
- Adequate, relevant sufficient
- Accurate
- Timely storage
- Processed in due form subject's rights
- Secure
- Not transferred abroad unprotected

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Research in Developing Countries – DOUBLE Standards

- Does the research project provide **benefit to the local community** (in terms of access to healthcare, education, allocation of property rights, etc.)?
- Does the research project **use local resources** (genetic resources, animal, and plants)? Result in their benefit?
- Standards Equal or Similar to EU Member States

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To be considered for negotiations

Explanation on page 9 of the orientation paper for health research 2012*

- Clinical trials can be carried out internally by a participant or outsourced to a third party
- When carried out internally by a participant (beneficiary):
  The participant may either charge his actual costs of the trials; or where it is difficult to substantiate each of the actual costs involved for each individual test, the participant may opt to charge an average cost per patient or test or type of test, calculated with a methodology based on its actual costs and that is auditable

* http://cordis.europa.eu/fp7/health/home_en.html

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To be considered for negotiations

- The participant may also propose to outsource the performance of (some aspects) of the clinical trials to a third party
- On a commercial basis, for which a price is agreed upon by the participant and the third party (subcontract)
- Or on a cost basis, on a non–commercial basis, that is where the third party charges only its costs to the participant who reimburses them fully and is in turn reimbursed by the Commission according to the applicable funding rate

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To be considered for subcontracts

- best value for money, for example by providing the various offers requested, or, if a long term-cooperation with that third party to carry out such tests pre-exists (e.g university and university hospital)
- Participants that are public bodies are reminded that the selection of such a third party has to follow their internal rules and applicable legislation, in particular those related to public procurement
- According to the FP7 rules for participation, core tasks of a project can not be subcontracted

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Thank you very much for your attention! Questions ?