

Explanatory memorandum for innovative clinical trials¹ to verify safety and efficacy

Specific actions under clinical trials will have a major European added value in translating research into clinical practice, increasing therapeutic options for patients, stimulating the implementation of best practices in all Member States (MS) and in establishing the basis for a coherent programme addressing the issue of personalized medicine and improved therapeutic outcomes. Currently, the majority of clinical trials are performed by health-related industries during the development of novel products such as new pharmaceuticals. Nevertheless, clinical trials initiated by academic investigators are of high relevance for public health. The work programme 2011 lists several topics for clinical trials, most being investigator-driven clinical trials. The aim is to strengthen clinical research in Europe in a number of areas with unmet medical needs.

Topics for clinical trials can be found in a number of areas of the work programme including regenerative medicine, brain-related diseases, human development and ageing, antimicrobial drug resistance, cancer, cardiovascular diseases, diabetes and obesity, and off-patent medicines for children.

In areas where the focus is on investigator-driven clinical trials, it is considered that the use of the definition of the typical phases of clinical trials in the context of the development of new drugs (phase I to phase III – approval – post-marketing or phase IV trials) is only of limited utility. For example, clinical trials on life-style interventions do not fit into the phase definitions. Such trials may for example be funded in the topic 2.4.3-1. Where drug interventions will be tested, depending on the individual topic, it is expected that most studies to be funded will be phase II trials, if the intervention to be tested is used outside its approved indication, or phase IV trials if the intervention is used within its marketing authorisation. In particular, it is foreseen that comparative effectiveness trials (phase IV) will be funded in several topics. If evidence warranting advanced clinical testing is already available, phase III trials can also be supported. For topic 1.4-1 it is expected that phase I or II trials will be funded. The topic 4.2-1 "Investigator-driven clinical trials on off patent medicines for children" specifically funds phase III clinical trials. In all cases, the maximum available EU contribution needs to be considered.

As no minimum or maximum duration for projects to be funded under FP7 is foreseen, applicants should properly evaluate the time needed to conclude their study, including relatively short durations, such as 1-3 years, when deemed appropriate; unnecessary addition of participants to projects or inappropriate study duration will be penalised in the evaluation process. As for all FP7 projects, evolution of consortia is in principle possible. However, no additional funding can be made available during the implementation of a project; major changes that cannot be peer reviewed are discouraged, as the fact that the original proposal was evaluated and selected by the experts needs to be considered.

The early involvement of patients² and their advocacy groups in the planning, implementation, and monitoring of a clinical trial is considered important so that patients'

¹ <http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-10/>

² <http://www.eu-patient.eu/Initatives-Policy/Projects/ValuePlus/Resources/Value-Resources/>

needs are appropriately considered. This may also increase the rate of enrolment of trial participants and can have a positive effect on the performance of the clinical trial. All studies must carefully consider the ethical and regulatory framework at European and national level for the conduct of clinical trials.

Implementation guidance

Clinical trials can be carried out internally by a participant or outsourced to a third party (subcontractor).

1) When carried out internally:

- 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.*

2) The participant may also propose to outsource the performance of the clinical trials to a third party by means of a subcontract:

- either on a commercial basis, for which a price is agreed upon by the participant and the third party.*
- 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.*

Participants are reminded that it is up to them to demonstrate that their choice of a third party secures the 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, to demonstrate its added value.

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, as a matter of eligibility.