GUIDE FOR APPLICANTS

Version 05 July 2012

COLLABORATIVE PROJECT

Two-stage submission process

Annexes 1-5, specific to call:

Call identifier FP7-HEALTH-2013-INNOVATION-2

This part of the guide contains the annexes for the specific call and funding scheme shown above. It should be read in conjunction with the general part of the guide, published as a separate document, which contains the general information for applying to FP7 under this funding scheme.

July 2012

Annex 1:

Timetable and specific information for this call

- The **work programme** provides the essential information for submitting a proposal to this call. It describes the content of the topics to be addressed, and details on how it will be implemented. The work programme is available on the Participant Portal call page. The part giving the basic data on implementation (deadline, budget, additional conditions etc.) is also posted as a separate document ("call fiche"). You must consult these documents.

- **Indicative timetable for this call**

Publication of call	*12 July 2012*
Deadline for submission of stage one proposals	*25 September 2012, 17:00:00 Brussels time*
Evaluation of stage one proposals	*Finalised by end of October 2012*
Letter to coordinators of successful stage one proposals; invitation to submit a full stage two proposal	*By 31 October 2012*
Coordinators informed of results of rejected stage one proposals	*By mid-November 2012*
Deadline for submission of stage two proposals	*11 December 2012 , 17:00:00 Brussels time*
Evaluation of stage two proposals	*Finalised by beginning of February 2013*
Coordinators informed of results of stage two proposals	*February 2013*
Invitation letter to successful coordinators to launch grant agreement negotiations with Commission services	*February 2013*
Letter to unsuccessful applicants	*February/March 2013*
Signature of first grant agreements	*Mai/June 2013*

- **Further information and help**

The Participant Portal call page contains links to other sources that you may find useful in preparing and submitting your proposal. Direct links are also given where applicable.

Call information

Participant Portal http://ec.europa.eu/research/participants/portal/ *(select tab "FP7 calls")*

Self-Evaluation forms

General sources of help:

The Commission's FP7 Enquiry service http://ec.europa.eu/research/enquiries

National Contact Points http://cordis.europa.eu/fp7/ncp.htm

National Contact Points in third countries http://cordis.europa.eu/fp7/third-countries_en.html

Contact person :

A list of contact details of Commission officers can be found on a separate document on the call page.]

Specialised and technical assistance:

eFP7 Service Desk http://ec.europa.eu/research/participants/portal/page/contactus

Electronic Submission Services help desk
http://ec.europa.eu/research/participants/portal/page/contactus
E-mail: DIGIT-EFP7-SEP-SUPPORT@ec.europa.eu

IPR help desk http://www.ipr-helpdesk.org

Ethics help desk http://cordis.europa.eu/fp7/get-support_en.html

Generally, you may also wish to consult the following documents that can be found at:
http://ec.europa.eu/research/participants/portal/

FP7 Legal basis documents generally applicable

- Decision on the Framework Programme
- Rules for Participation
- Specific Programmes
- Work Programmes

Legal documents for implementation

- Rules for submission, evaluation, selection, award
- Standard model grant agreement
- Rules on verification of existence, legal status, operational and financial capacity

Guidance documents

- Guidance Notes on Audit Certification Guide for beneficiaries Guide to Financial Issues
- Guide to IPR
- Checklist for the Consortium Agreement
- Negotiation Guidance Notes and Templates for Description of Work

Other supporting information

- Brochure “The FP7 in Brief”
- European Charter for researchers and the Code of Conduct for their recruitment
- International cooperation
- Risk Sharing Financing Facility and the European Investment Bank

Ethics Review

- Ethics check list
- Supporting documents

Open Access (when relevant)

- Leaflet "Open access pilot in FP7"
- OpenAIRE website (Open Access Infrastructure for Research in Europe: www.openaire.eu)
- Model cover letter for amendment to publishing agreement
- Model amendment to publishing agreement

Annex 2:

Evaluation criteria and procedures to be applied for this call

1. General

The evaluation of proposals is carried out by the Commission/Agency with the assistance of independent experts.

Commission/Agency staff ensures that the process is fair, and in line with the principles contained in the Commission's rules[1].

Experts perform evaluations on a personal basis, not as representatives of their employer, their country or any other entity. They are expected to be independent, impartial and objective, and to behave throughout in a professional manner. They sign an appointment letter, including a declaration of confidentiality and absence of conflict of interest before beginning their work. Confidentiality rules must be adhered to at all times, before, during and after the evaluation.

In addition, an independent expert will be appointed by the Commission/Agency to observe the evaluation process from the point of view of its working and execution. The role of the observer is to give independent advice to the Commission/Agency on the conduct and fairness of the evaluation sessions, on the way in which the experts apply the evaluation criteria, and on ways in which the procedures could be improved. The observer will not express views on the proposals under examination or the experts' opinions on the proposals.

2. Before the evaluation

On receipt by the Commission/Agency, proposals are registered and acknowledged and their contents entered into a database to support the evaluation process. At each stage, eligibility criteria for each proposal are also checked by Commission/Agency staff before the evaluation begins. Proposals which do not fulfil these criteria will not be included in the evaluation.

For this call a proposal will only be considered eligible if it meets all of the following conditions:

The eligibility criteria below apply to both first and second stage proposals:

- It is received by the be Commission/Agency via the Electronic Submission Services before the deadline given in the call fiche
- It involves at least the minimum number of participants given in the call fiche
- It is complete (i.e. both the requested administrative forms and the proposal description are present). To satisfy this condition, part B of the proposal must be readable, accessible and printable.

[1] Rules for proposals submission, evaluation, selection and award procedures (posted on the Participant Portal .

- The content of the proposal relates to the topic(s) and funding scheme(s), including any special conditions set out in the relevant parts of the work programme

- For each funding scheme there are limits on the requested EU contribution (for details please refer to the Work programme and the topic you are applying to). **It is important to note that the upper funding limits will be applied as eligibility criteria at stage 1 and stage 2. Proposals that do not respect these limits will be considered ineligible.**

- The additional eligibility criterion for INNOVATION-2 topics requesting at least 50% of the EU-funding going to SMEs will be assessed only at stage 2, however, as the level of SME participation is specified in the call text, SMEs need to be also listed in the proposal at stage 1 even though the SME status will only be analysed in depth for successful second stage proposals.

Where maximum numbers of pages have been indicated for a section of the proposal, or for the proposal as a whole, the experts will be instructed to disregard any excess pages.

The Commission/Agency establishes a list of experts capable of evaluating the proposals that have been received. The list is drawn up to ensure:

- A high level of expertise;
- An appropriate range of competencies;

Provided that the above conditions can be satisfied, other factors are also taken into consideration:

- An appropriate balance between academic and industrial expertise and users;
- A reasonable gender balance;
- A reasonable distribution of geographical origins;
- Regular rotation of experts

In constituting the lists of experts, the Commission/Agency also takes account of their abilities to appreciate the industrial and/or societal as well as innovation dimension of the proposed work. Experts must also have the appropriate language skills required for the proposals to be evaluated.

Commission/Agency staff allocates proposals to individual experts, taking account of the fields of expertise of the experts, and avoiding conflicts of interest.

3. Evaluation of proposals

The evaluation of a stage 2 proposal can involve experts that evaluated the corresponding stage 1 proposal as well as new experts.

At the beginning of the evaluation, experts will be briefed by Commission/agency staff, covering the evaluation procedure, the experts' responsibilities, the issues involved in the particular area/objective, and other relevant material (including the integration of the international cooperation dimension as well as the innovation dimension).

Each proposal will first be assessed independently by at least three experts.

The proposal will be evaluated against pre-determined evaluation criteria.

Evaluation criteria applicable to **Collaborative project proposals**		
S/T QUALITY (stage 1 and stage2) **"Scientific and/or technological excellence (relevant to the topics addressed by the call)"**	**IMPLEMENTATION (stage 2 only)** **"Quality and efficiency of the implementation and the management"**	**IMPACT (stage 1 and stage 2)** **"Potential impact through the development, dissemination and use of project results"**
• Soundness of concept, and quality of objectives • Progress beyond the state-of-the-art • Quality and effectiveness of the S/T methodology and associated work plan	• Appropriateness of the management structure and procedures • Quality and relevant experience of the individual participants • Quality of the consortium as a whole (including complementarity, balance) • Appropriateness of the allocation and justification of the resources to be committed (staff, equipment …)	• Contribution, at the European [and/or international] level, to the expected impacts listed in the work programme under the relevant topic/activity • Appropriateness of measures for the dissemination and/or exploitation of project results, and management of intellectual property.

Stage 1 proposals will be evaluated only against the criteria of S/T QUALITY and IMPACT.

Stage 2 proposals will be evaluated against the criteria and sub-criteria as indicated in the corresponding table above.

Only those proposals achieving all thresholds at stage 1 will be invited to submit a full stage 2 proposal. While proposers successful at stage 1 will not receive an ESR (only a letter of invitation to participate in stage 2) unsuccessful proposers will receive an ESR consisting of numerical scores and an explanation of these.

The stage 2 evaluation of the full proposal is an independent evaluation against each of the criteria for that submission. It is not a complementary evaluation. Scores achieved by the stage 1 proposal are not taken into account at the stage 2 evaluation.

Evaluation scores will be awarded for each of the relevant criteria, and not for the sub-criteria. The sub-criteria are issues which the expert should consider in the assessment of that criterion. They also act as reminders of issues to raise later during the discussions of the proposal.

For proposals failing to achieve a threshold for a criterion, the evaluation of the proposal will be stopped at the first criterion failing a threshold. Therefore for such proposals the ESR (evaluation summary report) will not contain marks and comments for the remaining criteria.

The relevance of a proposal will be considered in relation to the topic(s) of the work programme open in a given call, and to the objectives of a call. These aspects will be integrated in the application of the criterion "S/T quality", and the first sub-criterion under "Impact" respectively. When a proposal is partially relevant because it only marginally addresses the topic(s) of the call, or if only part of the proposal addresses the topic(s), this condition will be reflected in the scoring of the first criterion. Proposals that are clearly not relevant to a call ("out of scope") will be rejected on eligibility grounds.

Each criterion will be scored between 0 and 5. Half marks can be given.

The scores indicate the following with respect to the criterion under examination:

0 -	*The proposal fails to address the criterion under examination or cannot be judged due to missing or incomplete information*
1 -	*Poor. The criterion is addressed in an inadequate manner, or there are serious inherent weaknesses.*
2 -	*Fair. While the proposal broadly addresses the criterion, there are significant weaknesses.*
3 -	*Good. The proposal addresses the criterion well, although improvements would be necessary.*
4 -	*Very Good. The proposal addresses the criterion very well, although certain improvements are still possible.*
5 -	*Excellent. The proposal successfully addresses all relevant aspects of the criterion in question. Any shortcomings are minor.*

No weightings will be applied.

Thresholds will be applied to the scores as follows:

Evaluation criteria and **thresholds for stage 1** proposals:

	Minimum threshold/Possible score
S/T quality	4/5
Impact	4/5
Overall threshold required	8/10

Evaluation criteria and **thresholds for stage 2** proposals:

	Minimum threshold/Possible score
S/T quality	4/5
Implementation	3/5
Impact	4/5
Overall threshold required	12/15

Examples of the evaluation forms and reports that will be used by the experts in this call will be made available on the Participant Portal

Conflicts of interest: Under the terms of the appointment letter, experts must declare beforehand any known conflicts of interest, and must immediately inform a Commission/Agency staff member if

one becomes apparent during the course of the evaluation. The Commission/Agency will take whatever action is necessary to remove any conflict.

Confidentiality: The appointment letter also requires experts to maintain strict confidentiality with respect to the whole evaluation process. They must follow any instruction given by the Commission/Agency to ensure this. Under no circumstance may an expert attempt to contact an applicant on his own account, either during the evaluation or afterwards**.**

4. Individual evaluation

This part of the evaluation will be carried out on the premises of the experts concerned ("remote evaluation").

At this first step the experts are acting individually; they do not discuss the proposal with each other, nor with any third party. The experts record their individual opinions in an Individual Evaluation Report (IER), giving scores and also comments against the evaluation criteria.

When scoring proposals, experts must *only* apply the above evaluation criteria.

Experts will assess and mark the proposal exactly as it is described and presented. They do not make any assumptions or interpretations about the project in addition to what is in the proposal.

Concise justifications will be given for each score. Recommendations for improvements to be discussed as part of a possible negotiation phase will be given to successful stage 2 proposals, if needed.

The experts will also indicate whether, in their view, the proposal raises research ethics or security issues.

Signature of the IER also entails a declaration that the expert has no conflict of interest in evaluating the particular proposal.

Scope of the call: It is possible that a proposal is found to be completely out of scope of the call during the course of the individual evaluation, and therefore not relevant. If an expert suspects that this may be the case, a Commission/Agency staff member will be informed immediately, and the views of the other experts will be sought.

If the consensus view is that the main part of the proposal is not relevant to the topics of the call, the proposal will be withdrawn from the evaluation, and the proposal will be deemed ineligible.

5. Consensus meeting

Once all the experts to whom a proposal has been assigned have completed their IER, the evaluation progresses to a consensus assessment, representing their common views.

The consensus process (virtual or on-site in Brussels) is moderated by a representative of the Commission/Agency. The role of the moderator is to seek to arrive at a consensus between the individual views of experts without any prejudice for or against particular proposals or the organisations involved, and to ensure a confidential, fair and equitable evaluation of each proposal according to the required evaluation criteria.

The moderator for the group may designate an expert to draft the Consensus Report ("rapporteur"). The experts attempt to agree on a consensus score for each criterion and on suitable comments to justify the scores. Scores and comments are set out in a consensus report. Evaluators also come to a common view on the questions of scope, ethics and security.

If during the consensus discussion it is found to be impossible to bring all the experts to a common point of view on any particular aspect of the proposal, the Commission/agency may ask up to three additional experts to examine the proposal.

Ethics issues: If one or more experts have noted that there are ethics issues touched on by the proposal, the relevant box on the Consensus Report (CR) will be ticked and an Ethics Issues Report (EIR) will be completed stating the nature and type of ethics issues involved. Exceptionally for this issue, no consensus is required.

Outcome of consensus

The outcome of the consensus step is the Consensus Report. This will be signed/approved (either on paper, or electronically) by all experts, or as a minimum, by the "rapporteur" and the moderator. The moderator is responsible for ensuring that the consensus report reflects the consensus reached, expressed in scores and comments. In the case that it is impossible to reach a consensus, the report sets out the majority view of the experts but also records any dissenting views.

The Commission/Agency will take the necessary steps to assure the quality of the consensus reports, with particular attention given to clarity, consistency, and appropriate level of detail. If important changes are necessary, the reports will be referred back to the experts concerned.

The signing of the Consensus Report completes the consensus step. At stage 1 all proposals at threshold or above will be invited to present a full proposal for stage 2 but not receive an Evaluation Summary Report[2] , therefore no panel meetings are needed.

Evaluation of a resubmitted proposal

In the case of proposals that have been submitted previously to the Commission/Agency, the moderator gives the experts the previous evaluation summary report (see below) at the consensus stage. If necessary, the experts will be required to provide a clear justification for their scores and comments should these differ markedly from those awarded to the earlier proposal.

6. Panel review (only applied at stage 2)

This is the final step involving the independent experts. It allows them to formulate their recommendations to the Commission/Agency having had an overview of the results of the consensus step.

The main task of the panel is to examine and compare the consensus reports in a given area, to check on the consistency of the marks applied during the consensus discussions and, where necessary, propose a new set of scores.

The panel comprises experts involved at the consensus step, new experts and /or a mixture of the two. Several panels will cover the different indicative budget lines of this call.

The tasks of the panel will also include:

- reviewing cases where a minority view was recorded in the consensus report
- recommending a priority order for proposals with the same consensus score;

[2] See annex C of the "Rules for submission of proposals, and the related evaluation, selection and award procedures"; COMMISSION DECISION of 28 February 2011

If necessary, the panel will determine a priority order for proposals which have been awarded the same score within a ranked list. Whether or not such a prioritisation is carried out will depend on the available budget or other conditions set out in the call fiche. The following approach will be applied successively for every group of *ex aequo* proposals requiring prioritisation, starting with the highest scored group, and continuing in descending order:

(i) Proposals that address topics not otherwise covered by more highly-rated proposals, will be considered to have the highest priority.

(ii) These proposals will themselves be prioritised according to the scores they have been awarded for the criterion *scientific and/or technological excellence*. When these scores are equal, priority will be based on scores for the criterion *impact*. If necessary, any further prioritisation will be based on other appropriate characteristics, to be decided by the panel, related to the contribution of the proposal to the European Research Area and/or general objectives mentioned in the work programme (e.g. presence of SMEs, international co-operation, public engagement).

(iii) The method described in (ii) will then be applied to the remaining *ex aequos* in the group.

- making recommendations on possible clustering or combination of proposals.

The panel may be chaired by the Commission/Agency or external experts. The Commission/Agency will ensure fair and equal treatment of the proposals in the panel discussions. A panel rapporteur will be appointed to draft the panel's advice.

At stage 2 the outcome of the panel meeting is a report recording, principally:

- An Evaluation Summary Report (ESR) for each proposal, including, where relevant a report of any ethics issues raised and any security considerations;
- A list of proposals passing all thresholds, along with a final score for each proposal passing the thresholds and the panel recommendations for priority order per indicative budget as listed in the call fiche.
- A list of evaluated proposals having failed one or more thresholds;
- A list of any proposals having been found ineligible during the evaluation by experts;
- A summary of any deliberations of the panel; the report may contain multiple lists according to the different indicative budget lines.

The panel report is signed by at least three panel experts, including the panel rapporteur and the chairperson.

Following the final scoring and ranking by experts, the Commission/Agency will apply any other rules set out in the work programme for this call:

7. Ethics Review of project proposals

Under Theme Health an ethics review of above-threshold proposals (on the short list and reserve list) will be organised by the Commission/Agency. The Ethics Review is carried out by independent experts with a special expertise on ethics. Reviewing research projects on ethical grounds at the EU level is a legal requirement under FP7. The Ethics Review asesses several aspects of the design and methodology of the proposed research such as intervention on humans, animal welfare, data protection issues, terms of participation of children, vulnerable populations and dual use.

The drafts an Ethics Review Report that summarises its opinion on the ethical soundness of the project proposal under consideration. The requirements put forward by the Panel are taken into account in any subsequent negotiations on the grant agreement, and may lead to obligatory provisions in the conduct of the research.

The Ethics Review process is described in detail in the Rules for submission, evaluation, selection and award procedures[3]

[3] Commission Decision (2011/161/EU, Euratom)

amending Decision C(2008) 4617 related to the rules for proposals submission, evaluation, selection and award procedures for indirect actions under the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) and under the Seventh Framework Programme of the European Atomic Energy Community (Euratom) for nuclear research and training activities (2007-2011)

(Text with EEA relevance)

(2011/161/EU, Euratom)

Annex 3:

Instructions for completing "Part A" of the proposal

Proposals in this call must be submitted electronically, using the Electronic Submission Services of the Commission. The procedure is given in section 3 of this guide.

In Part A you will be asked for certain administrative details that will be used in the evaluation and further processing of your proposal. Part A forms an integral part of your proposal. Details of the work you intend to carry out will be described in Part B (annex 4).

Section A1 gives a snapshot of your proposal, section A2 concerns you and your organisation, while section A3 deals with money matters.

Completion of Part A at Stage 1 is a relatively simple process involving only the coordinator. Direct input from other partners is not required at stage 1

Please note:

At stage 1:

- Only the coordinator completes the A-forms (A1, A2 and A3)
- In form A3, only a single set of budget figures and the corresponding requested EU funding is required for the whole project (Form A3.1). These figures should represent the combined total project budget for **all** partners and should be submitted as the coordinators costs. (See guidance in section A3 below). The figures should match the totals presented in the budget table in Part B of the stage 1 proposal.
- Do not complete additional A2 and A3 forms for the other partners

At stage 2:

- The coordinator fills in sections A1 and A3.
- The participants already identified at the time of proposal submission (including the coordinator) each fill in their respective section A2.
- Subcontractors should not fill in section A2 and should not be listed separately in section A3.
- The estimated budget planned for any future participants (not yet identified at the time of the proposal) is not shown separately in form A3 but should be added to the coordinator's budget. Their role, profile and tasks are described in Part B of the proposal.

Check that your budget figures are correctly entered in Part A. Make sure that:

- *Numbers are always rounded to the nearest whole number*
- *All costs are given in Euros. Do not express your costs in thousands of Euros ("KEUROS") etc. this can affect decisions on the eligibility of your proposal*
- *You have inserted zeros ("0") if there are no costs, or if no funding is requested. Do not leave blanks*
- *Costs do not include value added tax.*

Note:
The following notes are for information only. They should assist you in completing Part A of your proposal. On-line guidance will also be available. The precise questions and options presented via the Electronic Submission Services may differ slightly from these below.

COLLABORATIVE PROJECTS

Section A1: Summary	
Proposal Acronym	The short title or acronym will be used to identify your proposal efficiently in this call. It should be of no more than 20 characters (use standard alphabet and numbers only; no symbols or special characters please). The same acronym should appear on each page of Part B of your proposal.
Collaborative Projects	For each type of Collaborative Projects, please refer to the work programme.
Proposal Title	The title should be no longer than 200 characters (with spaces) and should be understandable to the non-specialist in your field.
Duration in months	Insert the estimated duration of the project in full months.
Call (part) identifier	[pre-filled] The call identifier is the reference number given in the call or part of the call you are addressing, as indicated in the publication of the call in the Official Journal of the European Union, and on the call page. A call identifier looks like this: *FP7-HEALTH-2013-INNOVATION-2*
Topic code(s) most relevant to your proposal	Please refer to the topic codes /objectives listed in the work programme call fiche. All activities and topics of FP7 have been assigned unique codes, which are used in the processing of data on proposals and subsequent contracts. The codes are organised hierarchically. The choice of the first topic code will be limited in the drop-down menu to one of the topics open in this call. Select the code corresponding to the topic most relevant to your proposal. The choice for the second code is also limited to topics open in the call in question. Enter a second code if your proposal also addresses another of these. Select 'none' if this is not the case. Select a third code if your proposal is also relevant to another theme. This time, the available codes will simply correspond to broad themes. Select 'none' if this is not the case.
Free Keywords	Please enter a number of keywords that you consider sufficient to characterise the scope of your proposal. There is a limit of 100 characters.
Abstract	The abstract should, at a glance, provide the reader with a clear understanding of the objectives of the proposal, how they will be achieved, and their relevance to the Work Programme. This summary will be used as the short description of the proposal in the evaluation process and in communications to the programme management committees and other interested parties. It must therefore be short and precise and should not contain confidential information. Please use plain typed text, avoiding formulae and other special characters. **If the proposal is written in a language other than English, please include an English version of the proposal abstract in Part B.** There is a limit of 2000 characters (with spaces). Exceeding this limit may block the submission of your proposal.
Similar proposals or signed contracts	A 'similar' proposal or contract is one that differs from the current one in minor ways, and in which some of the present consortium members are involved.

Section A2/ Participants *(Only the coordinator should complete this section at stage 1)*

Participant number	The number allocated by the consortium to the participant for this proposal. The **co-ordinator** of a proposal is always **number one**.
Participant Identification Code	The Participant Identification Code (PIC) enables organisations to take advantage of the Participant Portal. Organisations who have received a PIC from the Commission **must** use it when submitting proposals. By entering a PIC, parts of section A2 will be filled in automatically. An online tool to search for existing PICs and the related organisations is available at http://ec.europa.eu/research/participants/portal. **Organisations not yet having a PIC must self-register (at http://ec.europa.eu/research/participants/portal) before submitting the proposal so that the coordinator could insert in the 'Parties' screen the PIC received at the end of the self-registration. Failure to do so will block the submission of your proposal.**
Legal name	**For Public Law Body,** it is the name under which your organisation is registered in the Resolution text, Law, Decree/Decision establishing the Public Entity, or in any other document established at the constitution of the Public Law Body; **For Private Law Body,** it is the name under which your organisation is registered in the national Official Journal (or equivalent) or in the national company register. **For a natural person**, it is e.g. Mr Adam JOHNSON, Mrs Anna KUZARA, and Ms Alicia DUPONT.
Organisation Short Name	Choose an abbreviation of your Organisation Legal Name, only for use in this proposal and in all relating documents. This short name should not be more than 20 characters exclusive of special characters (./;…), e.g. CNRS and not C.N.R.S. It should be preferably the one commonly used, e.g. IBM and not Int.Bus.Mac.
Legal address	For Public and Private Law Bodies, it is the address of the entity's Head Office. For Individuals it is the Official Address. If your address is specified by an indicator of location other than a street name and number, please insert this instead under the "street name" field and "N/A" under the "number" field.
Non-profit organisation	Non-profit organisation is a legal entity qualified as such when it is recognised by national or, international law.
Public body	Public body means any legal entity established as such by national law, and international organisations.
Research organisation	Research organisation means a legal entity established as a non-profit organisation which carries out research or technological development as one of its main objectives.
NACE code	**NACE** means " Nomenclature des Activités économiques dans la Communauté Européenne". Please select **one** activity from the list that **best** describes your professional and economic ventures. If you are involved in more than one economic activity, please select the **one** activity that is **most** relevant in the context of your contribution to the proposed project. For more information on the methodology, structure and full content of NACE (rev. 1.1) classification please consult EUROSTAT at: http://ec.europa.eu/eurostat/ramon/nomenclatures/index.cfm?TargetUrl=LST_CLS_DLD&StrNom=NACE_1_1&StrLanguageCode=EN&StrLayoutCode=HIERARCHIC .

Small and Medium-Sized Enterprises (SMEs)	SMEs are micro, small and medium-sized enterprises within the meaning of Commission Recommendation 2003/361/EC in the version of 6 May 2003. The full definition and a guidance booklet can be found at http://ec.europa.eu/enterprise/enterprise_policy/sme_definition/index_en.htm To find out if your organisation corresponds to the definition of an SME you can use the on-line tool at http://ec.europa.eu/research/sme-techweb/index_en.cfm
Dependencies with (an) other participant(s)	Conditions for dependency and independence are stipulated in Article 6 of the FP7 Rules for Participation. Two participants (legal entities) are dependent on each other where there is a controlling relationship between them: – A legal entity is under the same direct or indirect control as another legal entity (**SG**); or – A legal entity directly or indirectly controls another legal entity (**CLS)**; or – A legal entity is directly or indirectly controlled by another legal entity **(CLB)**. ***Control:*** Legal entity A controls legal entity B if: – A, directly or indirectly, holds more than 50% of the nominal value of the issued share capital or a majority of the voting rights of the shareholders or associates of B, or – A, directly or indirectly, holds in fact or in law the decision-making powers in B. The following relationships between legal entities shall not in themselves be deemed to constitute controlling relationships: (a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50 % of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates; (b) the legal entities concerned are owned or supervised by the same public body.
Character of dependence	According to the explanation above, please insert the appropriate abbreviation according to the list below to characterise the relation between your organisation and the other participant(s) you are related with: • **SG**: Same group: if your organisation and the other participant are controlled by the same third party; • **CLS**: Controls: if your organisation controls the other participant; • **CLB**: Controlled by: if your organisation is controlled by the other participant.
Contact point	It is the main scientist or team leader in charge of the proposal for the participant. For participant number 1 (the coordinator), this will be the person the Commission/Agency will contact concerning this proposal (e.g. for additional information, invitation to hearings, sending of evaluation results, convocation to negotiations).
Title	Please choose one of the following: Prof., Dr., Mr., Mrs, Ms.
Sex	This information is required for statistical and mailing purposes. Indicate F or M as appropriate.
Phone and fax numbers	Please insert the full numbers including country and city/area code. Example +32-2-2991111.

Section A3/Budget

Stage 1 of a two-stage process	**A simplified version of the budget is all that needs to be submitted here at stage 1 of a two-stage process**. This simplified version summarises the totals and the requested EU funding which are also presented in the budget table in Part B of the stage 1 submission. For each Type of Activity, enter the total anticipated costs against the first cost heading (i.e. Coordinator's "Personnel Costs"). It is not necessary at stage 1 to make any entry against "Subcontracting", "Other direct" or "Indirect Costs". For each Type of Activity, enter the Requested EU Contribution for the full proposal. The following instructions in this table elaborate the requirements for completing Section A3 of a stage 2 proposal.
Indirect Costs	Indirect costs are all those eligible costs which cannot be identified by the participant as being directly attributed to the project but which can be identified and justified by its accounting system as being incurred in direct relationship with the eligible direct costs attributed to the project. They may not include any eligible direct costs.
Method of calculating indirect costs	**Summary description (as displayed on EPSS)** • Participants who have an analytical accounting system that can identify and group their indirect costs in accordance with the eligibility criteria (e.g. exclude non-eligible costs) must report their **actual indirect costs** (or choose the 20% flat rate option referred to below). • For the purpose of calculating the actual indirect costs, a participant is allowed to use a **simplified method** of calculation of its full indirect eligible costs. • Optionally, participants may opt for a **flat rate** for indirect costs of **20%** of the direct costs (minus subcontracting and third party costs not incurred on the premises of the participant. • A specific **flat rate of 60%** of the direct costs is allowed for **non-profit public bodies, secondary and higher education establishments, research organisations and SMEs**, which are unable to identify with certainty their real indirect costs for the project when participating in funding schemes which include research and technological development and demonstration activities. For **Coordination and Support actions**, whichever method is used, the reimbursement of indirect eligible costs may not exceed 7% of the direct eligible costs, excluding the direct eligible costs for subcontracting and the costs of reimbursement of resources made available by third parties which are not used on the premises of the participant. **Further guidance** In FP7 all departments, faculties or institutes which are part of the same legal entity must use the same system of cost calculation (unless a special clause providing for a derogation for a particular department/institute is included in the grant agreement). Under FP7, there are no cost reporting models. 1. Participants which have an analytical accounting system that can identify and group their indirect costs (pool of costs) in accordance with the eligibility criteria (e.g. exclude non-eligible costs) must report their **actual indirect costs (**or choose the 20% flat rate option under 2. below). This method is the same as the "full cost" model used in previous Framework Programmes. For the purpose of calculating the actual indirect costs, a participant is allowed to use a **simplified method** of calculation of its full indirect eligible costs. The simplified method is a way of declaring indirect costs which applies to organisations which do not aggregate their indirect costs at a detailed level (centre, department), but can aggregate their indirect costs **at the level of the legal entity**. The simplified method can be used if the organisation does not have an accounting system with a detailed cost allocation. The method has to be in accordance with their usual accounting and management principles and practices; it does not involve necessarily the introduction of a new method just for FP7 purposes. Participants are allowed to use it, provided this simplified approach is based on actual costs derived from the financial accounts of the last closed accounting year. There is no "standard model"; each legal entity will use its own system. The minimum requirements for it to be considered a simplified method for FP7 purposes are the following: - the system must allow the participant to identify and remove its direct ineligible costs (VAT, etc.); - it must at least allow for the allocation of the overheads at the level of the legal entity to the individual projects by using a fair "driver" (e.g. total productive hours); - the system applied and the costs declared according to it should follow the normal accounting principles and practices of the participant. Therefore, if the system used

by a participant is more "refined" than the "minimum" requirements mentioned here, it is that system which should be used when declaring costs.

Example: if a participant's accounting system distinguishes between different overhead rates according to the type of activity (research, teaching...), then the overheads declared in an FP7 grant agreement *should follow this practice and refer only to the concerned activities (research, demonstration...)*

The simplified method does not require previous registration or certification by the Commission.

2. Optionally, participants may opt to declare their actual direct costs plus a **flat rate** for indirect costs of 20% of the direct costs (minus subcontracting and third party costs not incurred on the premises of the participant). This flat rate is open to any participant whatever the accounting system it uses. Accordingly, when this option is chosen, there is no need for certification of the indirect costs, only of the direct ones.

3. Also, a **specific flat rate** is allowed for certain types of organisations.

The use of this flat rate is subject to three cumulative conditions :

(i) Status of the organisation

The flat rate is reserved for:
- non-profit public bodies
- secondary and higher education establishments
- research organisations
- SMEs

(ii) Accounting system of the organisation

The flat rate provided for organisations which are unable to identify with certainty their real indirect costs for the project. How will it be proved that an organisation is unable to identify with certainty their real indirect costs for the project? The participant (for example, an SME) does not have to change its accounting system or its usual accounting principles. If its accounting system can identify overall overheads but does not allocate them to project costs, then the participant can use this flat rate if the other conditions are fulfilled.

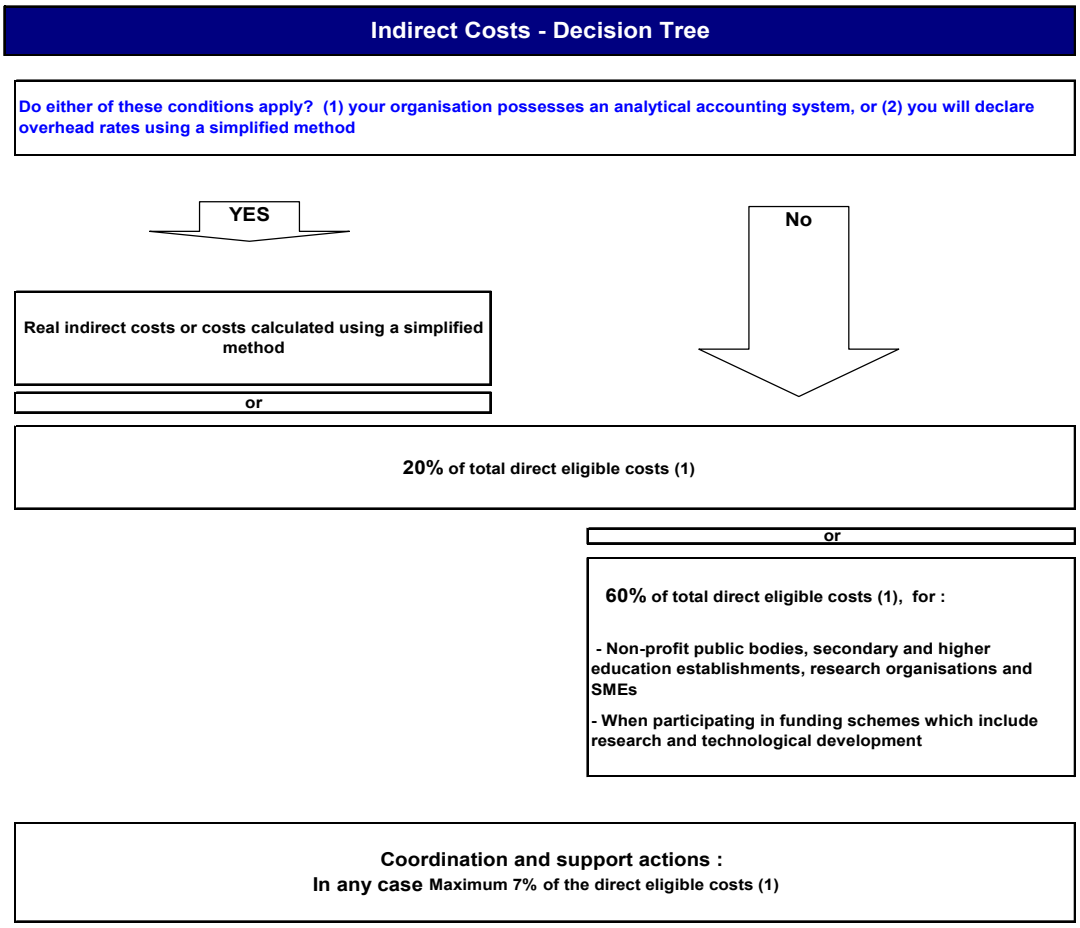
Example:
A University, which in FP6 has used the "additional cost" basis because its accounting system did not allow for the share of their direct and indirect costs to the project to be distinguished may under FP7:
- either opt for the 60% flat rate, or
- introduce a cost accounting system "simplified method" by which a basic allocation per project of the overhead costs of the legal entity will be established, or
- introduce a full analytical accounting system.

Following this, an organisation which used the "full cost" model under the Sixth Framework Programme is presumed to be in a situation to be able to identify the real indirect costs and allocate them to the projects. Accordingly, this organisation would not in principle be able to opt for the 60% flat rate for FP7.

An organisation which can identify the real indirect costs but does not have a system to allocate these indirect costs can opt for this 60% flat rate. The choice of this specific flat rate lies within the responsibility of the participant. If a subsequent audit shows that the above-mentioned cumulative conditions are not fulfilled, all projects where this participant is involved might be reviewed.

(iii) Type of funding scheme

The flat rate is reserved to funding schemes which include research and technological development and demonstration activities: Network of Excellence and Collaborative projects (including research for the benefit of specific groups – in particular SMEs). The basis for the calculation of the flat rate excludes the costs for subcontracting and the costs of resources made available by third parties which are not used on the premises of the participant because in these two cases, the indirect costs are not incurred by the participant but by the subcontractor or the third party. When a participant opts for the specific flat rate of 60 % for its first participation under FP7 it can opt afterwards for the actual indirect costs system for subsequent participations. This change does not affect previous grant agreement. After this change, this organisation cannot opt again for a flat rate system (either 60% or 20% flat rate).



(1) excluding direct eligible costs for subcontracting and the costs of reimbursement of resources made available by third parties which are not used on the premises of the beneficiary

International Cooperation Partner Country (ICPC)	International Cooperation Partner Country means a third country which the Commission classifies as a low-income, lower-middle income or upper-middle-income country and which is identified as such in Annex I to the work programmes.
Lump sum funding method	Legal entities established in an ICPC may opt for lump sums. In that case the contribution is based on the amounts shown below, multiplied by the total number of person-years for the project requested by the ICPC legal entity. • Low-income ICPC: 8,000 Euro/researcher/year • Lower middle income ICPC: 9,800 Euro/researcher/year • Upper middle income ICPC 20,700 Euro/researcher/year The maximum EU contribution is calculated by applying the normal upper funding limits shown under "requested EU contribution". This amount is all inclusive, covering support towards both the direct and the indirect costs. More information on ICPC lump sums can be found in the section II.18 of the "Guide to financial issues" on the Participant Portal http://ec.europa.eu/research/participants/portal/page/home

Type of Activity	• **RTD and innovation activities** means activities directly aimed at creating new knowledge, new technology, and products including scientific coordination. • **Demonstration activities** means activities designed to prove the viability of new technologies that offer a potential economic advantage, but which cannot be commercialised directly (e.g. testing of product like prototypes). • **Other activities** means any specific activities not covered by the above mentioned types of activity such as training, coordination, networking and dissemination (including publications). These activities should be specified in the proposal Part B. **Management activities** are part of the other activities. They include the maintenance of the consortium agreement, if it is obligatory**,** the overall legal, ethical, financial and administrative management including for each of the participants obtaining the certificates on the financial statements or on the methodology, the implementation of competitive calls by the consortium for the participation of new participants and, any other management activities foreseen in the proposal except coordination of research and technological development activities.
Personnel costs	Participants may opt to declare average personnel costs if these fulfil the four acceptability criteria defined by the Commission in its Decision of 24th January 2011 on the three simplification measures for FP7 (http://ec.europa.eu/research/participants/portal/page/fp7_documentation). Detailed explanation can be found in the FP7 Guide to Financial Issues (http://ec.europa.eu/research/participants/portal/ShowDoc/Extensions+Repository/General+Documentation/Guidance+documents+for+FP7/Financial+issues/financialguide_en.pdf). For the particular case of personnel costs to be claimed by SME owners and natural persons not receiving a salary, the Commission has set up a mandatory flat rate system. Detailed information on this flat-rate system can be fund in the FP7 Guide to Financial Issues).
Sub-contracting	A subcontractor is a third party which has entered into an agreement on business conditions with one or more participants, in order to carry out part of the work of the project without the direct supervision of the participant and without a relationship of subordination. Where it is necessary for the participants to subcontract certain elements of the work to be carried out, the following conditions must be fulfilled: - subcontracts may only cover the execution of a limited part of the project; - recourse to the award of subcontracts must be duly justified in Part B of the proposal having regard to the nature of the project and what is necessary for its implementation; - recourse to the award of subcontract by a participant may not affect the rights and obligations of the participants regarding background and foreground; - - Part B of the proposal must indicate the task to be subcontracted and an estimation of the costs; Any subcontract, the costs of which are to be claimed as an eligible cost, must be awarded according to the principles of best value for money (best price-quality ratio), transparency and equal treatment. Framework contracts between a participant and a subcontractor, entered into prior to the beginning of the project that are according to the participant's usual management principles may also be accepted. Participants may use external support services for assistance with minor tasks that do not represent per se project tasks as identified in Part B of the proposal. If applicable, actual direct costs and real overhead costs of third parties that make available to the proposal resources otherwise unavailable within the consortium, can also be included under the category of subcontracting costs (provided that these costs are not related to proposal's core tasks).
Other direct costs	Means direct costs not covered by the above mentioned categories of costs.

Total Budget	*Note: The "total budget" **is not** the requested EU contribution.* A sum of all the eligible costs, under the respective types of activity.
Requested EU contribution	The requested EU contribution shall be determined by applying the upper funding limits indicated below, per activity and per participant to the costs accepted by the Commission/Agency, or to the flat rates or lump sums. **Maximum reimbursement rates of eligible costs** • **Research and technological development = 50% or 75%*** • **Demonstration activities = 50%** • **Other activities (including management) = 100%** (*) For participants that are non profit public bodies, secondary and higher education establishments, research organisations and SMEs.
Total Receipts	*Note: The term "receipts" **is not** the requested EU contribution.* Receipts of the project may arise from: a) Financial transfers or contributions in kind free of charge to the participant from third parties: i. shall be considered a receipt of the project if they have been contributed by the third party specifically to be used on the project. ii. shall not be considered a receipt of the project if their use is at the management discretion of the participant. b) Income generated by the project: i. shall be considered receipts for the participant when generated by actions undertaken in carrying out the project and from the sale of assets purchased under the grant agreement up to the value of the cost initially charged to the project by the participant; ii. shall not be considered a receipt for the participant when generated from the use of foreground resulting from the project. The EU financial contribution may not have the purpose or effect of producing a profit for the participants. For this reason, the total requested EU funding plus receipts cannot exceed the total eligible costs.

Annex 4:

General instructions for drafting "Part B" of the proposal

Collaborative Project (two-stage submission)

A description of this funding scheme is given in section 2 of this Guide for Applicants. Please examine this carefully before preparing your proposal.

This annex provides mandatory templates you must follow to structure your proposal. It will help you present important aspects of your planned work in a way that will enable the experts to make an effective assessment against the evaluation criteria (see annex 2). Sections 1, 2 and 3 each correspond to an evaluation criterion. The sub-sections (1.1, 1.2 etc.) correspond to the sub-criteria.

IMPORTANT: Page limits: at both stages, remember to keep to the page limits where these are specified.
Please remember that it is up to you to verify that you conform to these limits. There is no automatic check in the system. No annexes are allowed outside the page limits, neither as additional document(s) nor as annex within "part B".

Even where no page limits are given, or where limits are only recommended, it is in your interest to keep your text concise since over-long proposals are rarely viewed in a positive light by experts.

Templates for stage 1 and stage 2 proposals are different!

Distinct templates for stage 1 and stage 2 proposals are given below. Even when preparing a stage 1 proposal, you are advised to also read the stage 2 template in order to acquaint yourself with the requirements for a full proposal.

Instructions for drafting "Part B" of the stage 1 proposal

This annex provides a mandatory template you must follow to structure your proposal. It will help you to present important aspects of your planned work in a way that will enable the experts to make an effective assessment against the evaluation criteria (see annex 2). Sections 1 and 2 each correspond to an evaluation criterion. The sub-sections (1.1, 1.2 etc.) correspond to the sub-criteria.

A description of the funding scheme is given in section 2 of this Guide for Applicants. Please examine this carefully before preparing your proposal.

IMPORTANT: Page limits: remember to keep to the page limits as specified.

The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including any footers or headers).

Please remember that it is up to you to verify that you conform to the page limits. There is no automatic check in the system! No annexes are allowed outside the page limits, neither as additional document(s) nor as annex within "part B"!

Make sure that the font type chosen leads to clearly readable text (e.g. Arial or Times New Roman).

As an indication, this layout should lead to between 5000 and 6000 maximum possible characters per page (including spaces).

The Commission will instruct the experts to disregard any excess pages.

Even when preparing a stage 1 proposal, you are advised to also read the stage 2 template in order to acquaint yourself with the requirements for a full proposal.

Template for a B part of a stage 1 proposal

The maximum combined length for sections 1 and 2 is SIX pages. *The cover page, the participant list, the budget table and the table of contents (see below) do not count toward the page limits specified for stage 1.*

At stage 1, all elements of the proposal will be evaluated against the two applicable criteria (Scientific and technological quality and Impact).

Cover Page stage 1

Proposal full title:
Proposal acronym:
Type of funding scheme:
Collaborative Project

Mandatory reference to the work programme topic addressed:

This proposals is addressed to topic (please delete the non-relevant topic for your proposal from this page)

HEALTH.2013.2.3.1-1: Drugs and vaccines for infections that have developed or are at risk of developing significant anti-microbial resistance.

Or to

HEALTH.2013.0-1: Boosting the translation of health research projects' results into innovative applications for health.

If your proposal is submitted under this topic, please clearly indicate the previous project(s) (outcomes may come from more than one previous project) and chose keywords(s) from the list below and/or add free keywords in order to direct your proposal to the corresponding group of evaluators.

This proposal addresses the research outcome(s) of project(s)[1] from either (please delete the non-appropriate!)

1) FP6 "Life sciences, genomics and biotechnology for health"
Or/and
2) FP7 "Theme Health"

Project number of the previous project:
Acronym of the previous project:
Project title of the previous project:

Keywords for this specific proposal under topic HEALTH.2013.0-1* could be*:

List of fixed key words:
1. Vaccines
2. Immunotherapy
3. Diagnostics (biomarker, diagnostics, imaging, lab-on-chip, micro and nanofluidics, statistics, stratification
4. New therapies (gene therapy, cell therapy, tissue engineering, stem cells, regenerative medicine, medical technology, biodevices, bioartificial organs, alternative testing, systems biology / medicine, computational modelling)
5. Clinical trials (pre-clinical and/or clinical drug development; compound screening and/or design; toxicology/carcinogenicity/teratogenicity studies; GMP manufacturing)
6. Omics (adverse drug reactions, animal models, biobank, bioinformatics, gene sequencing, high-throughput screening, microarray, "omics", personalised medicine
7. Any other key words, like paediatric medicine,…….

Name of the coordinating person:

List of participants:
List all the expected members of your consortium. The minimum (3) and maximum (5) number of participants constitute an eligibility criterion, therefore they must be named, otherwise your proposal will be considered ineligible[2].

Participant no.	Participant legal Name	Country	Organisation type*	Name of the scientific person in charge, role(s) in consortium (key words only)

[1] In case of results from several projects you must indicate all these projects with projects number, Acronym and title.

[2] **As at least 50 % of the requested EU funding is required to go to SMEs, SMEs need to be listed in the two tables. The SME status will only be analysed in depth for successful second stage proposals.**

1 (Coordinator)				
2				
3				
(4)				
(5)				

** For example, SME, industry, research organisation, university, hospital, patient organisation, etc.*

Please indicate the estimated budget for the proposed work as accurately as possible.

Estimated budget						
Participant no.	**RTD activities**	**Demonstration**	**Management**	**Other activities**	**Total costs**	**EU contribution**
1						
2						
3						
(4)						
(5)						
Total eligible costs						
Requested EU contribution						
Requested EU contribution for SMEs in % of the total requested						

The "total eligible costs" and the "requested EU contribution" appearing in the table above should be submitted as the coordinator's costs in Form A3.1 of the submission (see annex 3, section A3).

Mandatory table of contents

1: Scientific and/or technical quality, relevant to the topics addressed by the call

1.1 Concept and objectives

1.2 Innovative character in relation to the state-of-the-art

1.3 Outline work plan

2. Impact

2.1 Expected impacts listed in the work programme

2.2. Outline exploitation of project results

Please include page numbers!

Stage 1 proposal content (maximum 6 pages for section 1 and 2 together)

1: Scientific and/or technical quality, relevant to the topics addressed by the call

Applicants are requested to carefully consider any specific requirements set out in the topic description in the work programme. This applies especially to proposals referring to topic HEALTH.2013.0-1 and/or clinical trials.

1.1 Concept and objectives

What are the main ideas that led you to propose this work?

Briefly describe the proposed S&T objectives, the research design and the background information to indicate the soundness of the concept. Show how they relate to the topic addressed. **The objectives should be those achievable and verifiable within the project duration, not through subsequent development.** They should be stated in a measurable and verifiable form, including through the milestones[1] that should be indicated under section 1.3 below. SME participants should carry out activities to validate and exploit the research results.

1.2 Innovative character in relation to the state-of-the-art

Summarise the potential results, and the advance and innovative developments that the proposed project would bring to the area concerned. Describe the international state-of-the-art on which the project's approach is based, by means of a brief description study including, for example, literature, publications, patents, standards and data-base searches. Briefly describe the technical limitations of existing products, processes, technologies, or services and include comments on competing techniques and highlight the unique selling point/competitive advantage, or value against the state of the art of your development.

1.3 Outline work plan

Present an overview of the work plan including milestones and methods for achieving your objectives under 1.1.

2. Impact

2.1 Expected impacts listed in the work programme

Describe how your project will contribute towards the expected impacts listed in the work programme in relation to the topic in question. Mention the steps that will be needed to achieve these impacts. Mention any assumptions and external factors that may determine whether the impacts will be achieved.

2.2 *Outline exploitation[2] of project results*

Provide an overview over the main outcomes of the project and describe the necessary steps and resources required by the SME participant(s) to ensure the development and exploitation of the project outcome(s) towards a marketable product including an indicative timetable.

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[1] Milestones are control points where decisions are needed with regard to the next stage of the project. For example, a milestone may occur when a major result has been achieved, if its successful attainment is required for the next phase of work. Another example would be a point when the consortium must decide which of several technologies to adopt for further development.

[2] Research results should be properly identified. The exploitation of these results has to indicate the "what?" (types of exploitation activities), "how to do it?" (most appropriate means), "when?" (calendar) and the available resources – human and financial.

When defining the exploitation activities, you should also take into account the appropriate target groups (e.g. patients, industry, potential users, policy-makers, interest groups, media and/or the public at large).

Describe briefly how the project will enable the SME participant(s) to expand their markets and their business activities.

Give an estimation of time-to-market for the main outcome(s).

Template for part B of a stage 2 proposal

MANDATORY PAGE LIMITS
(conforming to font and margin sizes mentioned above)

A maximum of 20 pages are allowed for sections 1, 2, 3 and 5 all together, this limit *does not include cover page, table of contents, the Pert diagram under 1.3 i), the Gantt chart under 1.3 ii) or the tables 1.3a-e.*

***NO annexes are allowed outside these limits, n*either as additional document(s) nor as annex within "part B"!**

Please remember that it is up to you to verify that you conform to the page limits. There is no automatic check in the system! No annexes are allowed outside the page limits, neither as additional document(s) nor as annex within "part B"!

Table 1.3-d (work package description) is limited to two pages per work package

No specific limit for section 4

Cover Page

Proposal full title:
Proposal acronym:
Type of funding scheme:

Collaborative Project

If a distinction is made in the call, please state which type of collaborative project your proposal relates to: (i) Small or medium-scale focused research project; (ii). Large-scale integrating project; (iii) Project targeted to special groups such as SMEs and other smaller actors

Work programme topic addressed:

Name of the coordinating person:

List of participants:

Please use the same participant numbering as that used in section A2 of the administrative forms

Participant no. *	Participant organisation name	Country
1 (Coordinator)		
2		
3		

* *Please use the same participant numbering as that used in section A2 of the administrative forms*

Mandatory table of contents

1: Scientific and/or technical quality, relevant to the topics addressed by the call

1.1 Concept and objectives

1.2 Innovative character in relation to the state-of-the-art

1.3 S/T methodology and associated work plan

1.3.1 Detailed work plan[1] , work packages, deliverables, milestones, summary effort table

1.3.2 Significant risks and contingency plans

2. Implementation

2.1 Management structure and procedures

2.2 Individual participants

2.3 Consortium as a whole

2.4 Resources to be committed

3. Impact

3.1 Expected impacts listed in the work programme

3.1.1 Management of intellectual property

3.2 Dissemination and exploitation of project results

3.2.1 Dissemination

3.2.2 Exploitation

3.2.3 Short business plan – how do you intent to exploit the results and potentially the route to market

4. Ethics Issues

5. Consideration of gender aspects

Please include page numbers!

[1] Applicants are requested to carefully consider any specific requirements set out in the topic description in the work programme but also the requirements for statistics as set out on page 10 of the work programme. This applies especially to proposals referring to clinical trials topics (please consult also the work programme page 9 and annex 5 of this guide).

Stage 2 proposal content

1: Scientific and/or technical quality, relevant to the topics addressed by the call

1.1 Concept and objectives

Explain the concept of your project. What are the main ideas that led you to propose this work?

Describe in detail the proposed S&T objectives, the research design and the background information to indicate the soundness of the concept. Show how they relate to the topic addressed. **The objectives should be those achievable and verifiable within the project duration, not through subsequent development.** They should be stated in a measurable and verifiable form, including through the milestones that should be indicated under section 1.3 below. SME participants should carry out activities to validate and exploit the research results.

1.2 Innovative character in relation to the state-of-the-art

Summarise the potential results, and the advance and innovative developments that the proposed project would bring to the area concerned. Describe the international state-of-the-art on which the project's approach is based, by means of a documentary study including, for example, literature, publications, patents, standards and data-base searches. Briefly describe the technical limitations of existing products, processes, technologies, or services and include comments on competing techniques and highlight the competitive advantage[1], or achievement beyond the state of the art of your development.

1.3 S/T methodology and associated work plan

1.3.1 Detailed work plan[2]

This should be presented, broken down into work packages [3] (WPs) which should follow the logical phases of the implementation of the project, and include consortium management and assessment of progress and results. (Please note that your overall approach to management will be described later, in section 2).

Please present your plans as follows:

[1] This is your assessment of why potential customers will choose to buy your product in place of those profiled above. Advantages may include: unique features; price; new technologies or systems; better value to customers in terms of efficiency or ROI or cost/benefit ratios; greater compatibility with existing systems; include any independent validation or case studies

[2] Applicants are strongly advised to carefully consider any specific requirements set out in the topic description in the work programme but also the requirements for statistics as set out on page 10 of the work programme. This applies especially to proposals referring to clinical trials topics (please consult also the work programme page 9 and annex 5 of this guide).

[3] A work package is a major sub-division of the proposed project with a verifiable end-point - normally a deliverable or a milestone in the overall project.

i) Describe the overall strategy of the work plan.

ii) Show the timing of the different WPs and their components (Gantt chart or similar)

iii) Provide a detailed work description broken down into work packages:
- Work package list (please use table 1.3a);
- Deliverables list (please use table 1.3b);
- List of milestones (please use table 1.3c);
- Description of each work package (please use table 1.3d);
- Summary effort table (please use table 1.3e)

iv) Provide a graphical presentation of the components showing their interdependencies (Pert diagram or similar)

v) If relevant to the S/T content of your proposed work, a description of how gender issues will be analysed and taken into consideration[1].

The number of work packages used must be appropriate to the complexity of the work and the overall value of the proposed project. The planning should be sufficiently detailed to justify the proposed effort and allow progress monitoring by the Commission.

1.3.2 Significant risks and contingency plans

Give appropriate detail of the risks associated with project work plan and provide the related contingency plans.

- Identification and classification of potential risks
- Estimation of the probability that these occur
- Strategy(ies) to manage these risks

[1] See http://genderedinnovations.stanford.edu/index.html

Table 1.3 a: Work package list

Work package No[1]	Work package title	Type of activity[2]	Lead participant No[3]	Lead participant short name	Person-months[4]	Start month[5]	End month
	TOTAL						

1 Work package number: WP 1 – WP n.

2 Please indicate one activity per work package: RTD = Research and technological development (; DEM = Demonstration; MGT = Management of the consortium; OTHER = Other specific activities, if applicable in this call including any activities to prepare for the dissemination and/or exploitation of project results, and coordination activities) According to the description of the funding scheme given previously.

3 Number of the participant leading the work in this work package.

4 The total number of person-months allocated to each work package.

5 Measured in months from the project start date (month 1).

Table 1.3 b: Deliverables List

Del. no. [1]	Deliverable name	WP no.	Nature[2]	Dissemination level [3]	Delivery date[4]

1 Please note that each deliverable will have to be submitted as a distinct document/report. In order to keep your deliverables manageable, small related deliverables should be grouped as specified parts (equivalent to 'sub-deliverables') of a single more substantial deliverable. Progress towards achievement of the full deliverable can then be demonstrated in the periodic reports by reference to the smaller parts. The full deliverable will only be submitted when all parts have been -completed. Ideally this will be at the same date as a periodic report. Deliverable numbers in order of delivery dates. Please use the numbering convention <WP number>.<number of deliverable within that WP>. For example, deliverable 4.2 would be the second deliverable from work package 4.

2 Please indicate the nature of the deliverable using one of the following codes in the periodic reports:
R = Report, **P** = Prototype, **D** = Demonstrator, **O** = Other

3 Please indicate the dissemination level using one of the following codes:
PU = Public
PP = Restricted to other programme participants (including the Commission Services).
RE = Restricted to a group specified by the consortium (including the Commission Services).
CO = Confidential, only for members of the consortium (including the Commission Services).

4 Measured in months from the project start date (month 1). It is strongly advised that completed deliverables should have a delivery date corresponding to a periodic report.

Table 1.3 c: List of milestones

Milestones are control points where decisions are needed with regard to the next stage of the project. For example, a milestone may occur when a major result has been achieved, if its successful attainment is required for the next phase of work. Another example would be a point when the consortium must decide which of several technologies to adopt for further development.

Milestone number	Milestone name	Work package(s) involved	Expected date[1]	Means of verification[2]

[1] Measured in months from the project start date (month 1).
[2] Show how you will confirm that the milestone has been attained. Refer to indicators if appropriate. For example: a laboratory prototype completed and running flawlessly; software released and validated by a user group; field survey complete and data quality validated.

Table 1.3 d: Work package description*

For each work package:

Work package number		**Start date or starting event:**						
Work package title								
Activity Type[1]								
Participant number								
Participant short name								
Person-months per participant:								

Objectives

Description of work (possibly broken down into tasks), and role of participants

Deliverables** (brief description and month of delivery)

** Maximum length per work package description: 2 pages*

** Please note that each deliverable will have to be submitted as a distinct document/report. In order to keep your deliverables manageable, small related deliverables should be grouped as specified parts (equivalent to 'sub-deliverables') of a single more substantial deliverable. Progress towards achievement of the full deliverable can then be demonstrated in the periodic reports by reference to the smaller parts. The full deliverable will only be submitted when all parts have been - completed. Ideally this will be at the same date as a periodic report. Deliverable numbers in order of delivery dates. Please use the numbering convention <WP number>.<number of deliverable within that WP>. For example, deliverable 4.2 would be the second deliverable from work package 4.

[1] Please indicate one activity per work package: RTD = Research and technological development (DEM = Demonstration; MGT = Management of the consortium; OTHER = Other specific activities, if applicable in this call including any activities to prepare for the dissemination and/or exploitation of project results, and coordination activities) According to the description of the funding scheme given previously.

Table 1.3 e: Summary of staff effort

A summary of the staff effort is useful for the evaluators. Please indicate in the table the number of person months over the whole duration of the planned work, for each work package, for each participant. Identify the work-package leader for each WP by showing the relevant person-month figure in bold.

Participant no./short name	**WP1**	**WP2**	**WP3**	**…**	**Total person months**
Part.1 short name					
…					
…					
…					
Total					

2. Implementation

2.1 Management structure and procedures

Describe the organisational structure and decision-making mechanisms of the project. Show how they are matched to the complexity and scale of the project. Show how the project management will enable the project to achieve its goals and the SME participants to achieve execution of the project according to their needs and requirements. Demonstrate that there is a satisfactory plan for the management of knowledge, intellectual property and other innovation-related activities arising from the project.

2.2 Individual participants

For this call participants must be at least 3 independent legal entities each of which is established in an EU Member State or Associated Country. No 2 of them are established in the same MS or AC. The maximum number of participants is 5.

Participation of SMEs or SME joint ventures is restricted to entities established in EU Member States and Associated Countries. In addition, SMEs shall fulfil any of the following conditions: 1) be at least 51% owned and controlled by one or more individuals who are citizens of one of the EU Member States or Associated Countries or permanent residents in one of those countries, or 2) be at least 51% owned and controlled by another business that is itself at least 51% owned and controlled by individuals who are citizens of, or permanent residents in those countries.

For each participant in the proposed project, provide a brief description of the legal entity, the tasks they have been attributed, and the previous experience relevant to those tasks. Short information about the size and structure of participating SME should be given. Show that the SME participants are well suited, have the managerial capacity and how the project fits into the companies strategy. Provide also a short profile of the principle staff members who will be undertaking the work.

2.3 Consortium as a whole

Describe how the participants (from EU Member States and/or Associated countries only) collectively constitute a consortium capable of achieving the project objectives, and how they are suited and are committed to the tasks assigned to them. Show the complementarity between participants. Explain how the composition of the consortium is well-balanced in relation to the objectives of the project.

Describe the industrial/commercial involvement to ensure exploitation of the results, and how the requirement of SMEs having a leading role has been addressed.

i)Sub-contracting: If any part of the work is to be sub-contracted by the participant responsible for it, describe the work involved and explain why a sub-contract approach has been chosen for it. **Please note that core tasks of the project cannot be subcontracted!**

ii) Other countries: If one or more of the participants requesting EU funding is based in a country that is outside the EU, which is not an Associated Country, and is not on the list of International Cooperation Partner Countries[1], explain in terms of the project's objectives why such funding to the third country entity(ies) would be essential for the work described in the proposal.

iii) Additional partners: If there are as-yet-unidentified participants in the project, the expected competences, the role of the potential participants and their integration into the running project should be described. **However, these as-yet-unidentified participants**

[1] See Participant Portal web-site, and annex 1 of the work programme.

will not be counted in the minimum but in the maximum number of participants condition regarding the eligibility of the proposal.

2.4 Resources to be committed

Describe how the totality of the necessary resources will be mobilised, including any resources that will complement the EU contribution. Show how the resources will be integrated in a coherent way, and show how the overall financial plan for the project is adequate.

In addition to the costs indicated in Part A3 of the proposal, and the staff effort shown in section 1.3 above, please indicate any other major costs (e.g. equipment).

Please ensure that the figures stated in part B are consistent with those in Part A.

3. Impact

3.1 Expected impacts listed in the work programme

Describe how your project will contribute towards the expected impacts listed in the work programme in relation to the topic or topics in question. Mention the steps that will be needed to achieve these impacts. Explain why this contribution requires a European (rather than a national or local) approach. Indicate how account is taken of other national or international research activities. Mention any assumptions and external factors that may determine whether the impacts will be achieved.

3.2 Dissemination and/or exploitation of project results, and management of intellectual property

3.2.1 Management of intellectual property

Describe also your plans for the management of knowledge (intellectual property) acquired in the course of the project, and, when relevant, the question of open access when submitting articles for scientific publication. Provide a clear and adequate description of how the participants will organise IPR (intellectual property rights) ownership and user rights (e.g. licences, royalties). The proposal should clearly outline how the consortium intends to protect, share, manage and exploit IPR. Indicate any protection available for your product or service: whether the technology can be or has been patented, whether you can avail of copyright or trademark registration, and intend to build up as a protection against future competition.

3.2.2 Dissemination and exploitation of project results

Describe the measures you propose for the dissemination of project results, and how these will increase the impact of the project. In designing these measures, you should take into account a variety of communication means and target groups as appropriate (e.g. interest groups, media and the public at large, policy-makers).

For more information on communication guidance, see http://ec.europa.eu/research/science-society/science-communication/index_en.htm.

3.3.3 Short business plan – how do you intent to exploit the results and potentially the route to market?

Provide the outcomes of the project and describe the necessary steps and resources required by the SME participant(s) to ensure the development and exploitation of the project outcome(s) towards a marketable product including an indicative timetable.

When defining the exploitation activities, you should also take into account the appropriate target groups (e.g. patients, industry, potential users, policy-makers, interest groups, media and/or the public at large).

Perform an analysis in respect of the following points:

- Where appropriate the impact on the participating SMEs must be clearly addressed in terms of economic growth, employment, market strategy, distribution channels etc. underpinned by quantitative and qualitative indicators.
- Describe how the project will enable the SME participants to expand their markets and extend/internationalise their business activities in practical details;
- Describe the potential areas and markets of application of the project results and the potential advantages of the resulting technologies/ solutions compared to those that are available today.
- Estimation of time/steps-to-market/users/clients for the main outcome(s)
- Benefits[1]

With regard to the innovation dimension (including where appropriate policy makers and public health authorities), describe the measures you propose to increase the likelihood of market uptake of project results, such as: verification, testing, and prototyping; supporting the development of technical standards; identifying and collaborating with potential users; identifying potential partners and sources of finance for commercialisation.

4. Ethics Issues

Describe any ethics issues that may arise in the project. In particular, you should explain the benefit and burden of the experiments and the effects it may have on the research subject(s). All countries where research will be undertaken should be identified. You should be aware of the legal framework that is applicable and the possible specific conditions that are relevant in each country (EU and non-EU countries alike). It is strongly advised that when drafting the research proposal, the local ethics committee or/and relevant competent authorities (Data Protection, Clinical Trials etc) should be contacted for information and, when applicable, guidance. You may also address specific questions to the FP7 Ethics Help Desk (see page 2 in this Annex).

The following special issues should be taken into account:

Informed consent: When describing issues relating to informed consent, it will be necessary to illustrate an appropriate level of ethical sensitivity, and consider issues of insurance, incidental findings and the consequences of leaving the study.

[1] Increase sales? Increase efficiencies? Better health? Save money? Save time? Maximise resources? Reduce errors? Reduce downtime? Improve Customer Service? Reduce churn? Increase loyalty? Reduce health care costs? Impact on policy making?

Clinical Trials: Approvals from national competent authorities are required.

Data protection issues: Avoid the unnecessary collection and use of personal data. Identify the source of the data, describing whether it is collected as part of the research or is previously collected data being used. Consider issues of informed consent for any data being used. Describe how personal identify of the data is protected. Data protection issues require authorization from the national data protection authorities.

Use of animals: Where animals are used in research the application of the 3Rs (Replace, Reduce, Refine) must be convincingly addressed. Numbers of animals should be specified. Describe what happens to the animals after the research experiments. The use of animals requires permits and/or authorizations from the national competent authorities.

Human embryonic stem cells: Research proposals that will involve human embryonic stem cells (hESC) will have to address all the following specific points:

- the applicants should demonstrate that the project serves important research aims to advance scientific knowledge in basic research or to increase medical knowledge for the development of diagnostic, preventive or therapeutic methods to be applied to humans.
- the necessity to use hESC in order to achieve the scientific objectives set forth in the proposal. In particular, applicants must document that appropriate validated alternatives (in particular, stem cells from other sources or origins) are not suitable and/or available to achieve the expected goals of the proposal. This latter provision does not apply to research comparing hESC with other human stem cells.
- the applicants should take into account the legislation, regulations, ethics rules and/or codes of conduct in place in the country(ies) where the research using hESC is to take place, including the procedures for obtaining informed consent;
- the applicants should ensure for all hESC lines to be used in the project were derived from embryo's
    - of which the donor('s)(s') express, written and informed consent was provided freely, in accordance with national legislation prior to the procurement of the cells.
    - that result from medically-assisted *in vitro* fertilisation designed to induce pregnancy, and were no longer to be used for that purpose.
    - of which the measures to protect personal data and privacy of the donor(s), including genetic data, are in place during the procurement and for any use thereafter. Researchers must accordingly present all data in such a way as to ensure donor anonymity;
    - of which the conditions of donation are adequate, namely that no pressure was put on the donor(s) at any stage, that no financial inducement was offered to donation for research at any stage and that the infertility treatment and research activities were kept appropriately separate;

Include the Ethics issues table below. If you indicate YES to any issue, please identify the pages in the proposal where this ethics issue is described. Answering 'YES' to some of these boxes does not automatically lead to an Ethics review. It enables the independent

experts to decide if an Ethics review is required. If you are sure that none of the issues apply to your proposal, simply tick the YES box in the last row.

(No maximum length for Section 4: Depends on the number of such issues involved)

Note:
Only in exceptional cases will additional information be sought for clarification, which means that any Ethics review will be performed solely on the basis of the information available in the proposal.
Projects raising specific ethical issues such as research intervention on human beings[1]; research on human embryos and human embryonic stem cells and non-human primates are automatically submitted for Ethics review.

To ensure compliance with ethical principles, the Commission Services will undertake ethics audit(s) of selected projects at its discretion. A dedicated website that aims to provide clear, helpful information on ethics issues is now available at: http://cordis.europa.eu/fp7/ethics_en.html
Additional information (reference documents, EU and International legislation etc.) can be found in the EUROPA research site:
http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1289&lang=1

[1] Such as research and clinical trials involving invasive techniques on persons (e.g. taking of tissue samples, examinations of the brain).

ETHICS ISSUES TABLE

Areas Excluded From Funding Under FP7 *(Art. 6)*

(i) Research activity aiming at human cloning for reproductive purposes;

(ii) Research activity intended to modify the genetic heritage of human beings which could make such changes heritable (Research relating to cancer treatment of the gonads can be financed);

(iii) Research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer;

All FP7 funded research shall comply with the relevant national, EU and international ethics-related rules and professional codes of conduct. Where necessary, the beneficiary(ies) shall provide the responsible Commission services with a written confirmation that it has received (a) favourable opinion(s) of the relevant ethics committee(s) and, if applicable, the regulatory approval(s) of the competent national or local authority(ies) in the country in which the research is to be carried out, before beginning any Commission approved research requiring such opinions or approvals. The copy of the official approval from the relevant national or local ethics committees must also be provided to the responsible Commission services.

Guidance notes on informed consent, dual use, animal welfare, data protection and cooperation with non-EU countries are available at :
http://cordis.europa.eu/fp7/ethics_en.html#ethics_sd

For real time updated information on Animal welfare also see:
http://ec.europa.eu/environment/chemicals/lab_animals/home_en.htm
For real time updated information on Data Protection also see: http://ec.europa.eu/justice/data-protection/index_en.htm

	Research on Human Embryo/ Foetus	YES	Page
	Does the proposed research involve human Embryos?		
	Does the proposed research involve human Foetal Tissues/ Cells?		
	Does the proposed research involve human Embryonic Stem Cells (hESCs)?		
	Does the proposed research on human Embryonic Stem Cells involve cells in culture?		
	Does the proposed research on Human Embryonic Stem Cells involve the derivation of cells from Embryos?		
	I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		

	Research on Humans	YES	Page
	Does the proposed research involve children?		
	Does the proposed research involve patients?		
	Does the proposed research involve persons not able to give consent?		
	Does the proposed research involve adult healthy volunteers?		
	Does the proposed research involve Human genetic material?		
	Does the proposed research involve Human biological samples?		
	Does the proposed research involve Human data collection?		
	I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		

	Privacy	YES	Page
	Does the proposed research involve processing of genetic information or personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?		
	Does the proposed research involve tracking the location or observation of people?		
	I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		

	Research on Animals	YES	Page
	Does the proposed research involve research on animals?		
	Are those animals transgenic small laboratory animals?		
	Are those animals transgenic farm animals?		
	Are those animals non-human primates?		
	Are those animals cloned farm animals?		
	I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		

	Research Involving non-EU Countries (ICPC Countries[1])	YES	Page
	Is the proposed research (or parts of it) going to take place in one or more of the ICPC Countries?		
	Is any material used in the research (e.g. personal data, animal and/or human tissue samples, genetic material, live animals, etc) : a) Collected and processed in any of the ICPC countries?		
	b) Exported to any other country (including ICPC and EU Member States)?		
	I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		

	Dual Use	YES	Page
	Research having direct military use		
	Research having the potential for terrorist abuse		
	I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		

[1] In accordance with Article 12(1) of the Rules for Participation in FP7, 'International Cooperation Partner Country (ICPC) means a third country which the Commission classifies as a low-income (L), lower-middle-income (LM) or upper-middle-income (UM) country. Countries associated to the Seventh EC Framework Programme do not qualify as ICP Countries and therefore do not appear in this list.

5. Consideration of gender aspects

You may give an indication of the kind of actions that would be undertaken during the course of the project to promote gender equality in your project, or in your field of research. This aspect will not be evaluated, but will be discussed during negotiations should your proposal be successful.

These could include actions related to the project consortium (e.g. improving the gender balance in the project consortium, measures to help reconcile work and private life, awareness raising within the consortium) or, where appropriate, actions aimed at a wider public (e.g. events organised in schools or universities).

More information can be found at www.genderedinnovations.eu

(Maximum length for section 5 – one page)

Annex 5:

Guidance on proposals with clinical trials

The purpose of this document is to provide applicants with additional guidance for the preparation of proposals that include clinical trials, and thus to provide proposal evaluators with the information needed to judge them properly. This structured approach should facilitate the negotiation, implementation and follow-up of successful projects.

Clinical trial proposals submitted in response to a call for proposals are subject to the same formal and legal requirements (including e.g. the mandatory information in part A and the structure and page limitations of part B of the proposal) as any other proposal. This also applies to the electronic submission format. For information on these issues, please consult the other documents contained or referred to in the "information package" on the call website, which take precedence over this guidance.

Given that trials vary in methodology and design, the following should be used according to the particular study type proposed and only those issues pertinent to the trial(s) in question need to be addressed. For example, a first-in-human trial of a new therapy or a device will require different considerations and a different selection of issues mentioned below than a comparative effectiveness trial of two known drugs used within their approved indication. Proposals where the clinical trial starts only later in the project, after preliminary work has been carried out, should address the issues as far as is realistic; however, in addition, they should set out the milestones that need to be achieved and describe the decision points that are necessary for the clinical trial to go ahead.

1. Minimum information to be provided in stage-1 proposals:

The following issues should be considered for each trial envisaged and addressed – if applicable – in part B of the stage 1 proposal **within the given page limitation**:

- background evidence and need for the trial (sections 1.1, 1.2 and 2.1):
  - scientific rationale and primary hypothesis of the trial
  - epidemiology of the underlying disease/disorder
  - magnitude of expected benefits over currently available therapeutic options
  - preclinical and/or preliminary clinical evidence; systematic review evidence
- description and justification of trial design and methodology (Section 1.3)
  - study type[1]: classification by objective (e.g. human pharmacology, therapeutic exploratory, therapeutic confirmatory, therapeutic use), by phase (I-IV), by methodology: randomised/non-randomised, type of masking (none, single, double, observer blind), type of controls (active, placebo), parallel group/cross-over, prognostic, diagnostic etc.
  - proposed setting: number, location and type of centres

[1] cf. European Medicines Agency's (EMA) 1998 note on ICH topic E 6: http://www.ema.europa.eu/pdfs/human/ich/013595en.pdf

- precise description of intervention(s): experimental, control, duration of intervention and duration of follow-up
- key inclusion and exclusion criteria
- outcome measures/endpoints: primary/secondary, efficacy/safety etc.
- bias protection: feasibility of randomisation, allocation methods, feasibility of blinding etc.
- statistical justification of proposed sample size/power calculations: number of patients to be assessed for eligibility, to be allocated to trial, to be analysed etc. (including subgroups if applicable)
- feasibility of recruitment: provide the evidence that the intended recruitment rate is achievable!
- trial duration and timing: recruitment period, first-patient-in to last-patient out, duration of the entire trial

2. Minimum information to be provided in stage-2 proposals:

Part B of the stage-2 proposal should specify the above-mentioned issues in significantly more detail and in particular provide more in-depth justifications, evidence and references. Please note that if an issue is addressed in a specific section, the same issue doesn't need to be addressed again in another (just the reference to the pertinent section).

In addition the stage-2 proposal needs to address the following issues – if applicable – in its part B:

- trial management: distribution of roles (sponsor, principal/coordinating investigator, trial statistician), evidence of trials expertise, specific trials facilities and resources, quality assurance and monitoring strategy (section 2)
- trials expertise of individual investigators/sites (section 2.2)
- plans for data and database management, including location, access and regulatory implications (section 1.3).
- statistical analysis: strategy for (multiple) primary outcome(s), interim/subgroup analyses etc. (section 1.3)[1].
- monitoring of recruitment and contingency planning for recruitment problems (section 1.3)
- pharmacy issues: planning for the good manufacturing practice (GMP) batch production: timeline, facilities, testing, approval; planning for drug dispensing and accountability (section 1.3)
- plans for management and retention of biological samples, cooperation with existing or creation of new bio-banks (section 1.3)
- plans for reimbursement and contractual involvement of patient recruitment sites and trial management, including contract/clinical research organisations (CRO) if applicable: full beneficiaries, "third parties making available their resources", subcontractors (see below) (section 2.3)

[1] The justification of the proposed sample size/power calculations (see section on information to be provided in stage 1) and the statistical analysis are essential elements of the proposal. Proposals without a proper statistical methodology are likely to fail with a below-threshold score for "S+T Quality".

- financial plan (section 2.4): trial (data, clinical) management, case payments/ hospitalisation costs, trial drug(s) or device (including GMP batch production), additional diagnostic procedures, co-financing by industry or other third parties, the distribution of costs between health insurer, hospital and trial sponsor, statistical analysis, insurance, submission fees for regulatory dossiers, data and safety monitoring boards (DSMB) etc.
- provisions and timelines for approval by (which?) ethics committees and (which?) national competent authorities: which regulatory requirements have to be fulfilled, which have already been achieved and what is the status of the others, results of prior discussions with authorities (section 1.3)
- overall timeline of the trial, including preparation time (section 1.3.ii – include in Gantt chart of WPs or provide separate Gantt chart)
- independent trial oversight (section 1.3): e.g. DSMB, clinical event committee, scientific advisory or steering committee, ethical advisory board
- involvement and specific contribution of patients' organisations
- ethics (section 4): risks/benefits, protection of research participants, informed consent process and forms, participants' compensation, confidentiality, data protection, conflict of interests/commercial interests etc.

3. Financing clinical trials under FP7 rules:

3.1. Clinical centres, whose contribution to the project is limited to the recruitment and inclusion of patients into the trial.

Integration into the consortium as *beneficiary*, which is the preferred option for any entity contributing to FP7 projects, might not be practical or feasible in some clinical trial projects because the large number of such centres might make the management of the project cumbersome and/or because these centres themselves consider the responsibilities linked to full beneficiary status not as proportionate to their involvement. In these cases the status of *"third party making available its resources"* or the status of *subcontractor* might offer acceptable alternatives. Please read carefully the sections in the FP7 "Guide to Financial Issues" referring to the respective Articles II.14.2 and II.7 of the grant agreement and Annex VI of the Negotiation Guidance Notes (on subcontracting), which describe the conditions under which these options are applicable and related costs are considered eligible.

- A *"third party making available its resources"* (based on Article II.14.2 of the grant agreement) charges its costs to the linked beneficiary, who reimburses them fully and is in turn reimbursed by the Commission according to the applicable funding rate. Third parties need to be described in section B.2.3 of the Technical Annex (Annex I) to the grant agreement. Third parties are also required to have a *prior* agreement with the beneficiary that defines the frame in which these resources are made available. This can be a longstanding agreement covering a large range of areas of cooperation, but may also be specific to the project and the resources in question. The reimbursement to the third party covers only costs, and there will not be a profit for the third party.
- A *subcontractor* charges an agreed price to the linked beneficiary. Tasks to be subcontracted need to be described in section B.2.3 of the Technical Annex. Any subcontract must be awarded to the bid offering best value for money (best price-quality ratio), under conditions of transparency and equal treatment. Participants that are public bodies are reminded that the selection of subcontractors has to follow their internal rules and applicable legislation related to public procurement in order for the related costs to be eligible.

In cases where it is difficult for beneficiaries or third parties to substantiate each of the actual costs involved for each individual test, the beneficiary or third party may opt to charge an average cost per patient or per test or type of test, calculated with a methodology based on its actual costs and that is auditable.

3.2. Performance of certain tasks in the clinical trial by a clinical/contract research organisation (CRO).

Because of their specialised expertise, CROs are often entrusted with clinical trial tasks, such as GMP production, pharmacokinetic studies, data management or the submission of regulatory dossiers. While the core expertise related to the performance of clinical trials needs to be available in the consortium itself, there might be certain services for which the specialised expertise of CROs is required. CROs are usually for-profit service providers and generally have no intellectual property or other direct interest in the performance of the trial. They might not be able to join the consortium on the basis of a partial reimbursement or co-funding and, as for-profit entities might even be unable to participate as a third party on the basis of a cost reimbursement only.

In view of this situation, the Commission will consider accepting subcontracting for the performance of specialised clinical trials services. The tasks to be subcontracted need to be well described and the reason for subcontracting well justified in section 2.3 of the Technical Annex. The award of subcontracts needs to be carried out under the conditions specified above.