ERA-NET: Aligning national/regionaltranslational cancer research programmes and activities

TRANSCAN-2

Joint Transnational Call for Proposals 2014 (JTC 2014)

co-funded by the European Commission/DG Research and Innovation:

"Translational research on human tumour heterogeneity to overcome recurrence and resistance to therapy"

Full Proposal Application Form

Project title

Acronym (max. 10 characters)	

Project duration		**months**

Total requested funding	€

Keywords: Please indicate three to seven keywords representing:the scientific content [(type of cancer; specific aim(s) and topic(s) (see Call Text, chapter 2. Aim of the call)]; the methodological and technological approach(es).

Publishable project abstract (maximum 2,000 characters including spaces, equivalent to about half an A4 page)
Please note that this abstract will be published on the TRANSCAN website if your project is selected for funding

Project coordinator (= partner 1)

Last name	
First name	
Institution	
Department	
Address	
Post code	
City	
Country	
Phone	
Fax	
E-mail	

Partner X (to be duplicated as required)

Last name	
First name	
Institution	
Department	
Address	
Post code	
City	
Country	
Phone	
Fax	
E-mail	

Project description

Please note: if a proposal comprises a clinical trial the section 16 of this form should be completed, in addition to the others.

1.0 Background and rationale (maximum 2000 characters including spaces, equivalent to about half an A4 page)
Medical need and present state of the art in the research field(s).

2.0 Specific aims, research hypothesis and preliminary data, experimental design and working plan (maximum 8.000 characters including spaces, equivalent to about 2 A4 pages).

This section should contain:

2.1 Project specific aims for a maximum of 3 (either primary or secondary).

2.2 Research hypothesis and supporting preliminary data in a more detailed fashion compared to the homonymous sections of the pre-proposal.

2.3 Experimental design, intended as the strategy that directs researchers towards the study aim/s.

Experimental Design AIM 1

Experimental Design AIM 2 (if applicable)

Experimental Design AIM 3 (if applicable)

2.4 Working plan, including a general overview of the entire consortium, and the rationale of the work packages.

2.5 Synthetic description of the working plan at the work package level

WP No.	WP: Brief Task Description	Participant(s) responsible for the WP (the participation should be consistent with the financial plan)
1		
2		
3		
4		
N		

3.0 Methods, power calculation and statistical analysis, expected outcome and risk analysis. (Maximum 8000 characters including spaces, equivalent to about 2 A4 pages).

3.1 Methods: This section should include a detailed description of the project methodology extended, whenever applicable, to all the following issues: study design, population(s) as defined by clearly stated inclusion and exclusion criteria, intervention/exposure, group/s of comparison and outcome of interest. Specific details on the procedural aspects will be added depending on the adherence of the proposal to the specific scopes, aims and topic of the call, as specified in the pre-proposal application, section 8, i.e., “Adherence of the proposal to the scope, aims and specific topics of the call”. With specific regard to studies with a mixed design, the applicants are required to be clear about which parts of the study will be retrospective (i.e. based on patient data already collected and stored biological specimens), and which would include patients (and their specimens) to be recruited prospectively; and indicate the number of patients (or samples) in each of these groups.

Details have to be provided regarding the planning for the management and retention of biological samples, specifying whether cooperation with existing or creation of new biobanks is envisaged.

3.2 The proposed sample size has to be clearly supported in terms of power calculation. Details on the strategic plan for statistical analysis are required. With specific regard to clinical trials, interim analyses and stopping rules have to be anticipated and appropriately motivated.

3.3 A referral to the expected outcome has to be included. In specific regard to the intervention trials, this section has to include some justification for the expected treatment outcome.

3.4 This section will be integrated by contingency plan including potential bias, anticipation of problems and possible solutions.

4.0 Novelty and originality of the proposal (maximum 2000 characters including spaces, equivalent to about half an A4 page).

5.0 Project feasibility, consortium governance and management of project coordination (maximum 5000 characters including spaces).

This section should include:

5.1 A Description of the infrastructures and resources relevant to the implementation of the work plan, concept of data and material acquisition and storage, availability of biological resources, data management and elaboration.

5.2. A Description of the research consortium governance and management and of project coordination. This should include: a description of the governance and management structure and of project coordination planning (meeting, monitoring, etc.); ii) an outline of responsibilities and project effort (expressed in person months) of each participating research group per work package.

6.0 Potential impact on cancer recurrence and resistance to therapy in reference to the development, dissemination and use of the project results (maximum 3000 characters including spaces, equivalent to about ¾ of an A4 page).

7.0 References (maximum 4000 characters including spaces, equivalent to about 1 A4 page).

8.0.Timeline and milestones (maximum 2500 characters including spaces, equivalent to about half an A4 page).

This section should include a graphic representation of the project time plan and the milestones (Gantt chart) on a 12-month basis, that is, at 12, 24 and 36 months.

The chart must be uploaded as a separate PDF document.

9.0 Diagram which compiles the work plan, the contribution of the partners to each work package and their interactions (Pert diagram).

The diagram must be uploaded as a separate PDF document.

10.0 Added value of the collaboration in the proposed transnational project (maximum 2000 characters including spaces, equivalent to about half an A4 page).

This section should describe the quality of the transnational research consortium, illustrating:

i) the level of expertise of the individual partner research teams in the field(s) of the proposal (team scientific track record, publications, patents, etc.

ii) the quality of the collaboration between the research teams and added value of the research consortium with respect to the individual teams.

11.0 Description of past and ongoing research projects of each participating group related to the present topic.

Specify funding or co-funding from other sources (include at least: ID number, amount and duration of funded project; funding agency) and possible overlaps with the proposal, if applicable

Project title	ID number (project number or application date	Amount (€)	Duration of funded project (start-end date)	Topic and correlation to the requested proposal	Funding agency

Participation in former TRANSCAN calls:

JTC 2011: ☐ JTC 2012: ☐ JTC 2013: ☐ NO: ☐

12.0 Description of existing or potential patents (own or third party) and present/future position with regard to intellectual property rights, both within and outside the consortium (i.e. freedom to operate, barriers to sharing materials or results), if applicable (max 2500 characters including spaces, equivalent to about half an A4 page).

13.0 Ethical and legal issues. Please provide confirmation that the study complies withlocal, national and EU regulations, concerninginformed consent and other legal requirements for human experimentations, data protection, material transfer obligations and use of animals, if applicable (max 2500 characters including spaces, equivalent to about half an A4 page).

14.0 Brief CVs for each research partner (i.e. the project coordinator and each principal investigator) including a description of the main domain of research and a list of the five most relevant publications within the last five years, demonstrating the competence to carry out the project (maximum 4000 character including spaces, equivalent to about 1 A4 page).

15.0 Capacity building activities (optional section) (maximum 4000 characters including spaces, equivalent to about 1 A4 page)

Please refer to the Call Text for the specific modalities of this section

- Description of capacity building activities and relevance to the objectives of the proposal
- Description of the candidate: CV, background (scientific, medical, etc.); scientific production; current work; and coherence of the training with the CV
- Description of the host team (expertise in the field and qualification in research of the responsible person)
- Justification of the additional separate budget needed for these specific activities.

16.0 Clinical trial description (if applicable)

16.1. Clinical trial synopsis:

Principal/Coordinating Investigator	• First name, last name, academic title • Institution and department (complete name) • Postal address • Telephone • Fax • E-mail address
Title of clinical trial	
Clinical trial type and phase	*e.g. randomized/non-randomized, type of masking, type of controls (active/placebo), parallel group/cross-over*
Objective(s)	*Which principal research questions are to be addressed? Specify clearly the primary hypotheses of the trial that determine sample size calculation.*
Intervention(s)	Experimental intervention /index test: Control intervention /reference test: Duration of intervention per patient: Duration of follow-up per patient:
Key inclusion and exclusion criteria	Key inclusion criteria: Key exclusion criteria:
Endpoint(s)	Primary endpoint(s): Secondary endpoint(s):
Sample size	Number of patients to be assessed for eligibility: Number of patients to be allocated to the trial: Number of patients to be analyzed:
Statistical analysis	Efficacy / test accuracy: Summary Description of the primary efficacy / test accuracy analysis and population: Safety endpoints: yes/no Secondary endpoints:
Trial duration	First patient in to last patient out (months): Duration of the entire trial: Recruitment period (months):
Participating centres	Total number: Official name of the individual centres and respective location:

16.2 Trial flow chart

The chart must be uploaded as a separate PDF document.

17.0. Global financial plan: sum of year 1-3. Please describe the requested budget only.
(Please note that eligibility of costs is subject to national/regional rules and regulations: refer to the Annex 1 of the "Guidelines for Applicants").

Acronym:							
No.	Project coordinator	Partner 2	Partner 3	Partner 4	Partner 5	Partner 6	Partner 7
Name (principal investigator)							
Funding organization							
Personnel (€) - Scientist - PhD-Student - Technician - Other							
Person months - Scientist - PhD-Student - Technician - Other							
Consumables (€)							
Equipment (€)							
Study / Clinical trial (€)[1]							
Travel (€)[2]							
Capacity building (€)[3]							
Other direct costs (€)[4]							
(national/regional) Overheads (€)							
Total requested budget (€)							

[1] If applicable: costs related to participants in the study/clinical trial (e.g. clinical trial drugs/compounds, clinical trial fees and insurance).

[2] Travel expenses should include the participation of the coordinators and/or national group leaders at an intermediate and/or a final status symposium to present the results of their projects (organised by the Joint Call Secretariat).

[3] Separate budget for capacity building activities (if eligible for the funding organization/country).

[4] e.g. subcontracting, provisions, licensing fees,publications.

18.0 Individual financial plan: sum of year 1-3. This table should include the costs of the clinical trial, if applicable (Please note that eligibility of costs is subject to national rules and regulations: refer to the Annex 1 of the "Guidelines for Applicants")

18.1

Partner name:		
Funding organisation		
Country		
	Requested budget	Justification
Personnel (€)		*Please indicate the number of PMs, indicating the project tasks that justify the inclusion of that number of PMs*
Consumables (€)		*Please identify the consumables to be included, and their importance within your projects' tasks and objectives*
Equipment (€)		*Please indicate and justify the equipment to be acquired in accordance to project tasks and objectives. Applicants should also check if equipment is eligible in accordance to their national/regional regulations.*
Study/Clinical trial (€)		*Please indicate the concrete participation/work package(s) in the study/clinical trial.*
Travel (€)		*Please give an estimate on the number and main reasons for the travels within the project*
Capacity building (€)		*Please indicate the type of capacity building and necessary efforts (PMs, travel etc.).*
Other direct costs (€)		*May include subcontracting, fees, insurances, etc. Please justify each predicted expenditure with relation to project tasks and objectives*
Overheads (€)		*Please refer to your national/regional regulations before calculating overheads*
Total budget (€)		

18.2

Partner name:		
Funding organisation		
Country		
	Requested budget	Justification
Personnel (€)		*Please indicate the number of PMs, indicating the project tasks that justify the inclusion of that number of PMs*
Consumables (€)		*Please identify the consumables to be included, and their importance within your projects' tasks and objectives*
Equipment (€)		*Please indicate and justify the equipment to be acquired in accordance to project tasks and objectives. Applicants should also check if equipment is eligible in accordance to their national/regional regulations.*
Study/Clinical trial (€)		*Please indicate the concrete participation/work package(s) in the study/clinical trial*
Travel (€)		*Please give an estimate on the number and main reasons for the travels within the project*
Capacity building (€)		*Please indicate the type of capacity building and necessary efforts (PMs, travel etc.).*
Other direct costs (€)		*May include subcontracting, fees, insurances, etc. Please justify each predicted expenditure with relation to project tasks and objectives*
Overheads (€)		*Please refer to your national/regional regulations before calculating overheads*
Total budget (€)		

18.3

Partner name:		
Funding organisation		
Country		
	Requested budget	Justification
Personnel (€)		*Please indicate the number of PMs, indicating the project tasks that justify the inclusion of that number of PMs*
Consumables (€)		*Please identify the consumables to be included, and their importance within your projects' tasks and objectives*
Equipment (€)		*Please indicate and justify the equipment to be acquired in accordance to project tasks and objectives. Applicants should also check if equipment is eligible in accordance to their national/regional regulations.*
Study/Clinical trial (€)		*Please indicate the concrete participation/work package(s) in the study/clinical trial*
Travel (€)		*Please give an estimate on the number and main reasons for the travels within the project*
Capacity building (€)		*Please indicate the type of capacity building and necessary efforts (PMs, travel etc.).*
Other direct costs (€)		*May include subcontracting, fees, insurances, etc. Please justify each predicted expenditure with relation to project tasks and objectives*
Overheads (€)		*Please refer to your national/regional regulations before calculating overheads*
Total budget (€)		

18.4

Partner name:		
Funding organisation		
Country		
	Requested budget	Justification
Personnel (€)		*Please indicate the number of PMs, indicating the project tasks that justify the inclusion of that number of PMs*
Consumables (€)		*Please identify the consumables to be included, and their importance within your projects' tasks and objectives*
Equipment (€)		*Please indicate and justify the equipment to be acquired in accordance to project tasks and objectives. Applicants should also check if equipment is eligible in accordance to their national/regional regulations.*
Study/Clinical trial (€)		*Please indicate the concrete participation/work package(s) in the study/clinical trial*
Travel (€)		*Please give an estimate on the number and main reasons for the travels within the project*
Capacity building (€)		*Please indicate the type of capacity building and necessary efforts (PMs, travel etc.).*
Other direct costs (€)		*May include subcontracting, fees, insurances, etc. Please justify each predicted expenditure with relation to project tasks and objectives*
Overheads (€)		*Please refer to your national/regional regulations before calculating overheads*
Total budget (€)		

18.5

Partner name:		
Funding organisation		
Country		
	Requested budget	Justification
Personnel (€)		*Please indicate the number of PMs, indicating the project tasks that justify the inclusion of that number of PMs*
Consumables (€)		*Please identify the consumables to be included, and their importance within your projects' tasks and objectives*
Equipment (€)		*Please indicate and justify the equipment to be acquired in accordance to project tasks and objectives. Applicants should also check if equipment is eligible in accordance to their national/regional regulations.*
Study/Clinical trial (€)		*Please indicate the concrete participation/work package(s) in the study/clinical trial*
Travel (€)		*Please give an estimate on the number and main reasons for the travels within the project*
Capacity building (€)		*Please indicate the type of capacity building and necessary efforts (PMs, travel etc.).*
Other direct costs (€)		*May include subcontracting, fees, insurances, etc. Please justify each predicted expenditure with relation to project tasks and objectives*
Overheads (€)		*Please refer to your national/regional regulations before calculating overheads*
Total budget (€)		

18.6

Partner name:		
Funding organisation		
Country		
	Requested budget	Justification
Personnel (€)		*Please indicate the number of PMs, indicating the project tasks that justify the inclusion of that number of PMs*
Consumables (€)		*Please identify the consumables to be included, and their importance within your projects' tasks and objectives*
Equipment (€)		*Please indicate and justify the equipment to be acquired in accordance to project tasks and objectives. Applicants should also check if equipment is eligible in accordance to their national/regional regulations.*
Study/Clinical trial (€)		*Please indicate the concrete participation/work package(s) in the study/clinical trial*
Travel (€)		*Please give an estimate on the number and main reasons for the travels within the project*
Capacity building (€)		*Please indicate the type of capacity building and necessary efforts (PMs, travel etc.).*
Other direct costs (€)		*May include subcontracting, fees, insurances, etc. Please justify each predicted expenditure with relation to project tasks and objectives*
Overheads (€)		*Please refer to your national/regional regulations before calculating overheads*
Total budget (€)		

18.7

Partner name:		
Funding organisation		
Country		
	Requested budget	Justification
Personnel (€)		*Please indicate the number of PMs, indicating the project tasks that justify the inclusion of that number of PMs*
Consumables (€)		*Please identify the consumables to be included, and their importance within your projects' tasks and objectives*
Equipment (€)		*Please indicate and justify the equipment to be acquired in accordance to project tasks and objectives. Applicants should also check if equipment is eligible in accordance to their national/regional regulations.*
Study/Clinical trial (€)		*Please indicate the concrete participation/work package(s) in the study/clinical trial*
Travel (€)		*Please give an estimate on the number and main reasons for the travels within the project*
Capacity building (€)		*Please indicate the type of capacity building and necessary efforts (PMs, travel etc.).*
Other direct costs (€)		*May include subcontracting, fees, insurances, etc. Please justify each predicted expenditure with relation to project tasks and objectives*
Overheads (€)		*Please refer to your national/regional regulations before calculating overheads*
Total budget (€)		

19. Signed declaration by the project coordinator and by all the principal investigators, partners in the project, concerning the agreement of their respective team members to participate in the proposal.

This page(s) must be uploaded as a separate PDF file.
If signatures are provided on different pages, all the pages should be assembled in a single PDF document.

I, the undersigned. ..... Coordinator of the Project.....(acronym) declare to keep records with evidence that each of my respective team members agreed to participate in the proposal submitted.

Signature.....

I, the undersigned .....Partner n. 2 of the Project.....(acronym) declare to keep records with evidence that each of my respective team members agreed to participate in the proposal submitted.

Signature.....

I, the undersigned .....Partner n. 3 of the Project.....(acronym) declare to keep records with evidence that each of my respective team members agreed to participate in the proposal submitted.

Signature.....

to be duplicated for all the other partners...