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

TRANSCAN-2

Joint Transnational Call for Proposals 2016 (JTC 2016) on:

"Minimally and non-invasive methods for early detection and/or progression of cancer"

Full Proposal Application Form

All fields must be filled in using Arial font, size 11, single-spaced.
Applications should be submitted as a PDF file, formatted in DIN-A4.

Please note that full proposals either incomplete, using a different format or exceeding length limitations of any sections will be rejected without further review.

Project title (maximum 150 characters, including spaces)**:**

Project acronym (maximum 10 characters)**:**

Project duration (months)**:**

Total requested funding: € 0,00

Keywords
Please indicate three to seven keywords by using the MeSH vocabulary 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 400 words)

Please note that this abstract will be published on the TRANSCAN-2 website if your project is selected for funding

The abstract should contain:

- Background, rationale
- Hypothesis
- Aims (primary and secondary)
- Methods
- Expected results and potential impact

Project coordinator (= partner 1)

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

Partner X (to be duplicated as required)

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

Project description

Please note: if a proposal comprises a clinical trial the section 12 of this form should be completed, in addition to the sections 1-11.

1. Background and rationale (maximum 600 words).

Medical need and present state of the art in the research field(s)

2. Preliminary results obtained by the consortium members, if applicable (maximum 500 words, figures related to the preliminary results, one page maximum, must be uploaded as an annex).

3. Specific aims, research hypothesis and preliminary data, experimental design and working plan (maximum 2000 words, equivalent to about three A4 pages).

This section should contain:

- Project specific aims for a maximum of 3 (either primary or secondary)
- Research hypothesis and supporting preliminary data in a more detailed fashion compared to the homonymous sections of the pre-proposal
- 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)
- Working plan, including a general overview of the entire consortium, and the rationale of the work packages
- 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		

4. Methods, power calculation and statistical analysis, expected outcome and contingency plan (Maximum 1200 words).

a. 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.

b. 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.

c. 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.

d. Contingency plan: Please describe which problems or risks you may face in executing the project plan and which anticipating actions you will take to make sure your project will run efficiently. Consider for example accomplishment of the specific research objectives of the study, depletion of biospecimens, achievement of critical data end points, discontinuation of participation by human research participants, possible bias regulatory aspects, or future funding.

5. Novelty and originality of the proposal (maximum 300 words).

6. Project feasibility, consortium governance and management of project coordination (maximum 600 words).

This section should include:

- 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.
- A description of the research consortium governance and management as well as 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.
- A description of the data principles, such as storage, accessibility, exchange, and reusability of scientific data and ownership of the data. Please adopt the FAIR data principles.

7. Potential impact in reference to the development, dissemination and use of the project results (maximum 400 words).

8. References (maximum of 30 references).

9. Timeline and milestones (maximum 300 words).

This section should include a graphic representation of the project time plan and the milestones (Gantt chart, see annex 1 of the guidelines for applicants) on a 12-month basis, that is, at 12, 24 and 36 months. A milestone is a critical point in time to ascertain that sufficient and successful progress has been made in the project.

The chart must be included in this application form, as the electronic submission system does not allow the uploading of more than one pdf file.

10. Diagram which compiles the work plan, the contribution of the partners to each work package and their interactions (Pert diagram, see annex 2 of the guidelines for applicants).

The diagram must be included in this application form, as the electronic submission system does not allow the uploading of more than one PDF file.

11. Added value of the collaboration in the proposed transnational project (maximum 500 words).

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

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

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

12. 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: YES: ☐ Please specify:

NO: ☐

13. 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 (maximum 500 words).

14. Ethical and legal issues. Please provide confirmation that the study complies with local, national and EU regulations, concerning informed consent and other legal requirements for human experimentations, data protection, material transfer obligations and use of animals, if applicable (maximum 500 words).

15. 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 600 words, equivalent to about one A4 for each partner)

16. Capacity building activities (optional section) (maximum 1000 words)

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

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

17. Clinical trial description (if applicable)

17.1 Clinical trial synopsis:

Principal/Coordinating Investigator	• First name, last name, academic title • Institution and department (complete name) • Describe your experience in conducting clinical trials (maximum 50 words)
Title of clinical trial	
Clinical trial type and phase	e.g. randomized/non-randomized, type of masking (single, double, observer blind), type of controls (active/placebo), parallel/factorial/cross-over, prognostic, diagnostic
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:
Participants	Key inclusion criteria: Key exclusion criteria: Setting and location where data will be collected:
Endpoint(s)	Primary endpoint(s): Secondary endpoint(s): Describe how and when these endpoints will be assessed
Sample size	Number of patients to be assessed for eligibility: Number of patients to be allocated to the trial: Number of patients to be analysed: If applicable, interim analyses and stopping guidelines
Randomization	Method that will be used to generate the random allocation sequence: Restriction details (e.g. blocking, block size), if any:
Statistical analysis	Efficacy / test accuracy: Description of the primary efficacy / test accuracy analysis and population: Safety: 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:

17.2 Trial flow chart (see the CONSORT flow diagram for an example)

17.3 Please describe the independent trial review (e.g. Institutional Review Board (IRB), Data and Safety Monitoring Board (DSMB), clinical event committee, scientific advisory or steering committee, ethical advisory board) (maximum 200 words).

18. Global financial plan: sum of year 1-3. Please describe the requested budget only.
(Please note that eligibility of costs is subject to national rules and regulations: refer to the Annex 4 of the Call Text).

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							
- 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.

19. 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 4 of the Call Text).

19.1

Partner name:		
Funding organisation		
Country		
	Requested budget	Justification
Personnel (€)		*Please indicate the number of PMs per type of personnel, 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 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 (€)		

19.2

Partner name:		
Funding organisation		
Country		
	Requested budget	Justification
Personnel (€)		*Please indicate the number of PMs per type of personnel, 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 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 (€)		

19.3

Partner name:		
Funding organisation		
Country		
	Requested budget	Justification
Personnel (€)		*Please indicate the number of PMs per type of personnel, 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 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 (€)		

19.4

Partner name:		
Funding organisation		
Country		
	Requested budget	Justification
Personnel (€)		*Please indicate the number of PMs per type of personnel, 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 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 (€)		

19.5

Partner name:		
Funding organisation		
Country		
	Requested budget	Justification
Personnel (€)		*Please indicate the number of PMs per type of personnel, 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 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 (€)		

19.6

Partner name:		
Funding organisation		
Country		
	Requested budget	Justification
Personnel (€)		*Please indicate the number of PMs per type of personnel, 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 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 (€)		

19.7

Partner name:		
Funding organisation		
Country		
	Requested budget	Justification
Personnel (€)		*Please indicate the number of PMs per type of personnel, 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 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 (€)		

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

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

Please note: All the scanned signature pages should be assembled in the single PDF file of this application form, as the electronic submission <u>system does not allow the uploading of more than one PDF file</u>.

<u>PLEASE NOTE</u>

- **Proposals must be sent in <u>one *single* PDF document</u>.**
- **Proposals exceeding the length limitations (of each section) will be discarded without further review:**

<u>Cut-off (incl. all appendices): 60 pages</u>
(80 pages in case of a clinical trial)

Annexes (to be included in this document)

- Diagrams and figures