

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

TRANSCAN-2

Joint Transnational Call for Proposals 2017 (JTC 2017) on:

“Translational research on rare cancers ”

Full Proposal Application Form

Project title (maximum 150 characters, including spaces)

Acronym (max. 10 characters)

Project duration

months

Total requested funding

€

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 2000 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.

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	
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	

* The maximum number of 7 research groups can be increased with partners from Estonia, Latvia, Slovakia and Turkey, up to a maximum of 4 additional partners from the 4 countries, to reach a maximum total of 11 research groups in a proposal (See Call text, section 4.1).

Project description

Please note: if a proposal comprises a clinical trial the section 17 of this form should be completed, in addition to the others.

1. Background and rationale, i.e medical need and present state of the art in the research field(s).(maximum 4000 characters including spaces, equivalent to about one A4 page)

2. Preliminary results obtained by the consortium members, if applicable (maximum 3000 characters including spaces, equivalent to about ¾ of an A4 page. Figures related to the preliminary results, one page maximum, must be uploaded as a separate pdf file).

3. Specific aims, research hypothesis and preliminary data, experimental design and working plan (maximum 12.000 characters including spaces, 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 risk analysis. (Maximum 8000 characters including spaces, equivalent to about two A4 pages).

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 9, 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 endpoints, discontinuation of participation by human research participants, possible bias regulatory aspects, or future funding.

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

6. Project feasibility, consortium governance and management of project coordination (maximum 4000 characters including spaces, equivalent to about one A4 page).

This section should include:

- a. 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.
- b. A description of the research consortium governance and management as well as of project coordination. This should include: i) 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.
- c. 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 2000 characters including spaces, equivalent to about half an A4 page).

8. References (maximum 4000 characters including spaces, equivalent to about one A4 page)

9. Timeline and milestones (maximum 2000 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. 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 uploaded as a separate pdf document.

10. Diagram which compiles the work plan, the contribution of the partners to each work package and their interactions (PERT diagram to be uploaded as a separate pdf document).

The diagram must be uploaded as a separate pdf document.

11. Added value of the collaboration in the proposed transnational project (maximum 3000 characters including spaces, equivalent to about $\frac{3}{4}$ of an A4 page).

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: title, 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 3000 characters including spaces, equivalent to about $\frac{3}{4}$ of an A4 page).

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 3000 characters including spaces, equivalent to about $\frac{3}{4}$ of an A4 page).

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 4000 character including spaces, equivalent to about one A4 page for each partner).

16. Capacity building activities (optional section) (maximum 4000 characters including spaces, equivalent to about one A4 page)

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	<ul style="list-style-type: none"> • First name, last name, academic title • Institution and department (complete name) • Postal address • Telephone • Fax • E-mail address • Describe your experience in conducting clinical trials (maximum 300 characters)
Title of clinical trial	
Clinical trial type and phase	<i>e.g. randomized/non-randomized, type of masking, type of controls (active/placebo), parallel/factorial/cross-over, prognostic, diagnostic</i>
Objective(s)	<i>Which principal research questions are to be addressed? Specify clearly the primary hypotheses of the trial that determine sample size calculation.</i>
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 collected:
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: 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: 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:

17.2 Trial flow chart. **The chart must be uploaded as a separate pdf document.**

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/regional 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	Partner 8*	Partner 9*	Partner 10*	Partner11*
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.

*Columns 8, 9, 10 and 11 have to be filled only when the maximum number of 7 research groups is increased with partners from Estonia, Latvia, Slovakia and Turkey, up to a maximum of 4 additional partners from the 4 countries, to reach a maximum total of 11 research groups in a proposal (See Call text, section 4.1).

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 (€)		<i>Please indicate the number of PMs, indicating the project tasks that justify the inclusion of that number of PMs</i>
Consumables (€)		<i>Please identify the consumables to be included, and their importance within your projects' tasks and objectives</i>
Equipment (€)		<i>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.</i>
Study/Clinical trial (€)		<i>Please indicate the concrete participation/work package(s) in the study/clinical trial.</i>
Travel (€)		<i>Please give an estimate on the number and main reasons for the travels within the project</i>
Capacity building (€)		<i>Please indicate the type of capacity building and necessary efforts (PMs, travel etc.).</i>
Other direct costs (€)		<i>May include subcontracting, fees, insurances, etc. Please justify each predicted expenditure with relation to project tasks and objectives</i>
Overheads (€)		<i>Please refer to your national/regional regulations before calculating overheads</i>
Total budget (€)		

19.2

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

19.3

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

19.4

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

19.5

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

19.6

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

19.7

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

19.8*

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

19.9*

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

19.10*

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

19.11*

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

* **Sections 19.8, 19.9, 19.10, 19.11** have to be filled only when the maximum number of 7 research groups is increased with partners from Estonia, Latvia, Slovakia and Turkey, up to a maximum of 4 additional partners from the 4 countries, to reach a maximum total of 11 research groups in a proposal (See Call text, section 4.1).

20. 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 undersignedPartner 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 undersignedPartner 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.