**ERA-NET on Translational Cancer Research (TRANSCAN)**

**Joint Transnational Call for Proposals 2013 (JTC 2013) on:**

**"Translational research on tertiary prevention in cancer patients"**

**Pre-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.**

**1a. Project title**

**1b. Project acronym**

**2. Project duration**

**3. Project coordinator (research partner 1 in the consortium):**

|  |  |
| --- | --- |
| Name |   |
| Country  |  |
| Position |   |
| Institution/Department  |   |
| Address |   |
| Phone + Fax |   |
| E-mail address |   |
| Type of entity (tick as appropriate) | ☐ Academia (universities or other higher education or research institutions)☐ Clinical or Public Health (hospitals/public health and/or other health care settings and health organisations)☐ Small and Medium-sized enterprises (SME) or Industry |

**4. Other research partners**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **No.** | Country | Name of research partner (principal investigator) | Institution, department & full address | Phone & Fax | Email address | Type of entity |
| Academia | Clinical or Public Health | SME or Industry |
| **2** |   |   |   |   |   |  |  |  |
| **3** |   |   |   |   |   |  |  |  |
| **4** |   |   |   |   |   |  |  |  |
| **5** |   |   |   |   |   |  |  |  |
| **6** |   |   |   |   |   |  |  |  |

**5. Total requested funding:** €

**6. Keywords**

Please indicate three to seven keywords representing: the scientific content [(type of cancer; specific aim(s) and topic(s) (see [Call Text](http://www.transcanfp7.eu/transcan/file.php/1/Calls/JTC-2013/Call_text_TRANSCAN_JTC-2013.pdf), chapter 2. Aim of the call)]; the methodological and technological approach(es).

**7. Project abstract** (max. ½ page)

**8. Adherence of the proposal to the scope, aims and specific topics of the call** (see [Call Text](http://www.transcanfp7.eu/transcan/file.php/1/Calls/JTC-2013/Call_text_TRANSCAN_JTC-2013.pdf), chapter 2. Aim of the call). Please, tick the boxes as appropriate.

Impact of health behaviours on clinical outcomes in cancer patients:

[ ]  A. Development of tools to assess health behaviours and validation against biomarkers among cancer patients and survivors.

[ ]  B. Evaluation of health behaviours in relation to clinical cancer outcomes, including treatment efficacy and toxicity.

[ ]  C. Characterization of mechanisms linking health behaviours to cancer progression and prognosis.

[ ]  D. Clinical trials testing the effects of health behaviours modifications on cancer-related clinical outcomes and biomarkers.

Optimisation of the quality of life of cancer patients:

[ ]  A. Identification and/or validation of the molecular mechanisms of the long-term side effects of cancer treatments.

[ ]  B. Clinical trials (Phase I-II) aimed at reducing disabilities or restoring functionalities caused or lost due to a previous cancer or anticancer treatment.

[ ]  C. Testing the influence of co-morbidities on cancer patients’ clinical outcomes, including survival..

Prevention of recurrence and second cancer:

[ ]  A. Identification and/or validation of the genetic, molecular and cellular mechanisms of the metastatic process

[ ]  B .Identification and/or validation of biomarkers predictive of tumour recurrence

[ ]  C. Assessment of interventions designed to prevent tumour recurrence and/or second cancer.

[ ]  D. Early phase clinical studies assessing the effectiveness of innovative and low toxicity interventions designed to prevent tumour recurrence and/or second cancer.

**9. Project description** (once converted into PDF document: max. 5 pages)

This part should contain:

1. Description of the project rationale, in terms of medical need, and of the present state of the art in the field(s).
2. Description of the research hypothesis(es), of the project objectives, and of the work program, including methodology, with particular regard to the study design, the study population(s), and the statistical and biostatistical analysis and power calculations. This section should highlight the innovative approach, originality and feasibility of the project.
3. Information about: the experience of the research consortium partners in the field; the management structure and related implementation plan; added value of the proposed transnational collaboration.
4. Information about potential impact on cancer prevention and control with reference to the development, dissemination and use of project results.
5. References (one page maximum) and diagrams, figures, etc. (one page maximum) should be added in an appendix.

**Please note: if the proposal comprises a clinical trial, the section 12 of this form “Clinical trial description”, should be completed, in addition to the project description.**

**10. Capacity building and training activities (optional section)**

Please specify whether the project will include capacity building and training activities. If so, please describe briefly the nature and purpose of the planned activities taking into account information described in the [Call Text](http://www.transcanfp7.eu/transcan/file.php/1/Calls/JTC-2013/Call_text_TRANSCAN_JTC-2013.pdf). The separated budget will have to be mentioned in the financial plan (sections 13 and 14) in the appropriate line.

**11. Brief CV for each partner in the research consortium**(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 regarding the proposal (once converted into PDF document: max. 1 page for each partner).**12. Clinical trial description (if applicable):**

a. 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 (single, double, observer blind), type of controls (active/placebo), parallel group/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 | 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 analysed |
| 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: |

b. Rationale, background, evidence and medical need (max. 2 pages).

c. Description and justification of trial design and methodology (max. 6 pages).

* Description of intervention (s): experimental, control, duration of intervention and duration of follow-up (max. 1 page)
* Key inclusion and exclusion criteria (max. 1 page)
* Outcome measures/endpoints: primary/secondary, efficacy/safety etc. (max. ½ page)
* Bias protection: feasibility of randomisation, allocation methods, feasibility of blinding etc. (max. 1 page)
* Statistical justification of proposed sample size and power calculations: number of patients to be assessed for eligibility, to be allocated to trial, to be analysed etc. (including subgroups if applicable) (max. ½ page)
* Feasibility of recruitment: provide the evidence that the intended recruitment rate is achievable (max. ½ page)
* Trial duration and timing: recruitment period, first patient in to last patient out (max. ½ page)

d. Ethical, legal and social issues (ELSI) implications (max. ½ page).

e. Clinical trials management:

|  |
| --- |
| Participants |
|  | Name | Affiliation | Responsibility / Role |
| 1 |  |  |  |
| 2 |  |  |  |
| 3 |  |  |  |

* Participants expertise in clinical trials

(provide a synthetic description and include selected publications; max. 1 page per participant)

* Infrastructural support to the trial

(provide a synthetic description of the available facilities and technological platforms; max. 1 page)

f. Clinical trial financial plan:

|  |
| --- |
| **Total requested budget (€)** |
| Clinical trial management (Personnel) |  |
| Data management and statistical analysis(Personnel) |  |
| Clinical trial drugs/compounds |  |
| Consumables (reagents and other materials) |  |
| Fees, insurance |  |
| Other (specify) |  |
| TOTAL |  |

Co-financing of the trial by a public or private institution or by industry:

[ ]  NO

[ ]  YES (specify the type of co-funding entity and the amount of funding)

For pharmacological interventions, specify trial drug under patent protection:

[ ]  NO

[ ]  YES (until: )

g. References (max. 1 page)

**13. Financial plan: sum of year 1-3. Please describe the requested budget only. 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 2 of the** [**"Guidelines for Applicants"**](http://www.transcanfp7.eu/transcan/file.php/1/Calls/JTC-2013/Guidelines_for_applicants_TRANSCAN_JTC-2013.pdf)**)**

|  |  |
| --- | --- |
| Acronym:   |   |
| No. | Project coordinator | Partner 2 | Partner 3 | Partner 4 | Partner 5 | Partner 6 |  Partner 7 |
| Name (principal investigator) |   |   |   |   |   |  |  |
| Country |   |   |   |   |   |  |  |
| Funding organisation |   |   |   |   |   |  |  |
| Personnel (€) |   |   |   |   |   |  |  |
| Person months**1** |  |  |  |  |  |  |  |
| Consumables (€) |   |   |   |   |   |  |  |
| Equipment (€) |   |   |   |   |   |  |  |
| Travel (€)**2** |  |  |  |  |  |  |  |
| Other direct costs (€)3 |   |   |   |   |   |  |  |
| Overheads (€) |   |   |   |   |   |  |  |
| Total requested budget (€) |   |   |   |   |   |  |  |
| Additional separate budget for capacity building and training activities (section 10) |  |  |  |  |  |  |  |
| **1** Please detail number of person months and current status carrier or employment (Sci: scientist; St: PhD-student; Tech: technician; Oth: other). Please use one cell per person to provide this information.**2** Travel expenses should include the participation of the coordinators and/or principal investigators in an intermediate and/or a final status symposium to present the results of their projects (organised by the Joint Call Secretariat).3 e.g. subcontracting, provisions, licensing fees, clinical trial drugs/compounds, clinical trial fees and insurance. |

**14. 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 2 of the** [**"Guidelines for Applicants"**](http://www.transcanfp7.eu/transcan/file.php/1/Calls/JTC-2013/Guidelines_for_applicants_TRANSCAN_JTC-2013.pdf)**)**

**14.1**

|  |  |
| --- | --- |
| 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 regulations.* |
| Travel (€) |  | *Please give an estimate on the number and main reasons for the travels within the project* |
| 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 regulations before calculating overheads* |
| Total budget (€) |   |  |
| Additional separate budget for capacity building and training activities (section 10) |  | *Please describe what type of expenditure is included: travel, tuitions, scholarships, workshops, etc. Applicants should check if their funding agency has committed any budget to this separate activity* |

**14.2**

|  |  |
| --- | --- |
| 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 regulations.* |
| Travel (€) |  | *Please give an estimate on the number and main reasons for the travels within the project* |
| 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 regulations before calculating overheads* |
| Total budget (€) |   |  |
| Additional separate budget for capacity building and training activities (section 10) |  | *Please describe what type of expenditure is included: travel, tuitions, scholarships, workshops, etc. Applicants should check if their funding agency has committed any budget to this separate activity* |

**14.3**

|  |  |
| --- | --- |
| 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 regulations.* |
| Travel (€) |  | *Please give an estimate on the number and main reasons for the travels within the project* |
| 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 regulations before calculating overheads* |
| Total budget (€) |   |  |
| Additional separate budget for capacity building and training activities (section 10) |  | *Please describe what type of expenditure is included: travel, tuitions, scholarships, workshops, etc. Applicants should check if their funding agency has committed any budget to this separate activity* |

**14.4**

|  |  |
| --- | --- |
| 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 regulations.* |
| Travel (€) |  | *Please give an estimate on the number and main reasons for the travels within the project* |
| 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 regulations before calculating overheads* |
| Total budget (€) |   |  |
| Additional separate budget for capacity building and training activities (section 10) |  | *Please describe what type of expenditure is included: travel, tuitions, scholarships, workshops, etc. Applicants should check if their funding agency has committed any budget to this separate activity* |

**14.5**

|  |  |
| --- | --- |
| 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 regulations.* |
| Travel (€) |  | *Please give an estimate on the number and main reasons for the travels within the project* |
| 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 regulations before calculating overheads* |
| Total budget (€) |   |  |
| Additional separate budget for capacity building and training activities (section 10) |  | *Please describe what type of expenditure is included: travel, tuitions, scholarships, workshops, etc. Applicants should check if their funding agency has committed any budget to this separate activity* |

**14.6**

|  |  |
| --- | --- |
| 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 regulations.* |
| Travel (€) |  | *Please give an estimate on the number and main reasons for the travels within the project* |
| 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 regulations before calculating overheads* |
| Total budget (€) |   |  |
| Additional separate budget for capacity building and training activities (section 10) |  | *Please describe what type of expenditure is included: travel, tuitions, scholarships, workshops, etc. Applicants should check if their funding agency has committed any budget to this separate activity* |

**14.7**

|  |  |
| --- | --- |
| 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 regulations.* |
| Travel (€) |  | *Please give an estimate on the number and main reasons for the travels within the project* |
| 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 regulations before calculating overheads* |
| Total budget (€) |   |  |
| Additional separate budget for capacity building and training activities (section 10) |  | *Please describe what type of expenditure is included: travel, tuitions, scholarships, workshops, etc. Applicants should check if their funding agency has committed any budget to this separate activity* |

**15. Reviewers to be excluded from refereeing this proposal (up to five)**

Please note that providing the information below is optional. The CSC will consider these suggestions provided that they do not interfere with the objective and thorough evaluation of the proposal.**16. IF APPLICABLE:** A signed written confirmation that the project partner from TRANSCAN country/region not participating in the JTC 2013 or from non-TRANSCAN country/region has secured his/her funding.

**PLEASE NOTE**

**Proposals that do not meet the national eligibility criteria and requirements will be declined without further review.**

**Proposals must be sent in one *single* PDF document. Proposals exceeding the length limitations of each section will be discarded without further review.**

**USEFUL LINKS**

[**www.transcanfp7.eu**](http://www.transcanfp7.eu)

[**Link to Call Text**](http://www.transcanfp7.eu/transcan/file.php/1/Calls/JTC-2013/Call_text_TRANSCAN_JTC-2013.pdf)

[**Link to Guidelines for Applicants**](http://www.transcanfp7.eu/transcan/file.php/1/Calls/JTC-2013/Guidelines_for_applicants_TRANSCAN_JTC-2013.pdf)

[**Link to electronic proposal submission**](https://www.pt-it.de/ptoutline/application/Cancer13)

(Available from 2 January 2014)