



Joint Transnational Call for Proposals 2022 (JTC 2022)

"Novel translational approaches to tackle the challenges of hard-to-treat cancers from early diagnosis to therapy"

Call Text

Submission deadlines

Pre-proposals: 18 July 2022 at 12:00 CEST

Full proposals: 15 December 2022 at 12:00 CET

Electronic proposal submission system: <u>https://ptoutline.eu/app/transcan2022</u> (Online submission will be possible from 6 June 2022)

> For further information, please visit http://www.transcan.eu/ or

> > contact the Joint Call Secretariat (JCS) at: Alliance Against Cancer, Italy

> > > Valentina Trapani E-mail: jtc2022@transcan.eu



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1. MOTIVATION

The EU has been working to tackle cancer for decades and its strategic actions, for example on tobacco control and protection from hazardous substances, have saved and prolonged lives. Along with incidence, mortality, and prevalence, survival is a key indicator for cancer surveillance: it allows to assess the overall improvement in cancer patients' prognosis, resulting both from initiatives implemented to diagnose cancers at earlier stages or to improve cancer care, and from therapeutic progresses. Survival rate for most cancers has doubled over the past 40 years, with 50% of patients surviving to 10 years or longer. However, progress has not advanced equally for all forms of cancer. According to the most authoritative cancer epidemiology registries in the Western world (e.g., the NIH Surveillance, Epidemiology, and End Results (SEER) Program, https://seer.cancer.gov or the IARC Cancer Survival in High-Income Countries (SURVMARK-2) project. https://gco.iarc.fr/survival/survmark), survival for some types of cancer is lagging behind, due to the lack of successful treatment. For some Hard-To-Treat Cancers (HTTC), the 5-year survival rate is still lower than 35% and little or no improvement has occurred in the past decades; these include tumours arising in the oesophagus, liver and annexes, pancreas, lung/pleura, and brain.

The causes of therapeutic failure can be multiple: late detection due to lack of advanced diagnostics, absence of appropriate biomarkers and/or targeted approaches, tumour heterogeneity, acquired drug resistance, problematic drug development due to the rarity of some tumour types, as well as tumourand site-specific hurdles. For example, glioblastoma has ill-defined boundaries, which complicates surgical removal, while the blood-brain barrier hampers drug penetration into the tumour. Drug penetration is also problematic in mesothelioma and pancreatic tumours, due to their fibrous outer layers. Oesophageal cancer is characterised by early lymph node metastases, due to the anatomy of the mucosa, and multifocal lesions, which increases heterogeneity.

Tackling the manifold challenges presented by HTTC is a key priority in the translational cancer research arena, very relevant to the European Commission's Cancer Mission and the Europe's Beating Cancer Plan, which together aim to prevent cancer and to ensure a high quality of life for cancer patients through action on crucial areas such as early detection and diagnosis, treatment and follow-up. In addition, during the European Meetings of the French National Cancer Institute (INCa) held on February 3rd and 4th 2022, European stakeholders gathered to propose concrete actions building on the objectives of Europe's Beating Cancer Plan and the Horizon Europe Cancer Mission. In this context, poor prognosis cancer was identified as one of the five priorities in the fight against cancer which can most benefit from increased European cooperation and coordinated actions.

Against this background, it appears essential to develop translational research at European level and beyond, to build new paradigms that could radically transform the prognosis of these cancers. TRANSCAN-3 aims at promoting highly innovative and ambitious collaborative projects in translational cancer research at European and international level, and considers that, based on the previous grounds, it is timely and relevant to foster the translation of a better understanding of HTTC into clinical practices.



Therefore, the TRANSCAN-3 partners have agreed to focus their second Joint Transnational Call for proposals (JTC 2022) on

"Novel translational approaches to tackle the challenges of hard-to-treat cancers from early diagnosis to therapy"

The following national/regional funding organisations have agreed to participate in the JTC 2022:

- Austrian Science Fund (FWF), Austria
- Research Foundation Flanders (FWO), Belgium, Flanders
- Fund for Scientific Research FNRS (F.R.S.-FNRS), Belgium, French speaking community
- Estonian Research Council (ETAg), Estonia
- French National Cancer Institute (INCa), France
- ARC French Foundation for Cancer Research (ARC Foundation), France
- Federal Ministry of Education and Research (BMBF), Germany
- National Research, Development and Innovation Office (NKFIH), Hungary
- Health Research Board (HRB), Ireland
- The Chief Scientist Office of the Ministry of Health (CSO-MOH), Israel
- Ministry of Health (IT-MOH), Italy
- Alliance Against Cancer (ACC), Italy
- Tuscany Region (TuscReg), Tuscany, Italy
- Fondazione Regionale per la Ricerca Biomedica (FRRB), Lombardy, Italy
- Latvian Council of Science (LCS), Latvia
- National Research Fund (FNR), Luxembourg
- Research Council of Norway (RCN), Norway
- Norwegian Cancer Society (NCS), Norway
- National Centre for Research and Development (NCBR), Poland
- Executive Agency for Higher Education, Research, Development and Innovation Funding (UEFISCDI), Romania
- Slovak Academy of Sciences (SAS), Slovakia
- National Institute of Health Carlos III (ISCIII), Spain
- The Scientific Foundation of the Spanish Association Against Cancer (FCAECC), Spain
- Ministry of Science and Technology (MoST), Taiwan



2. AIM OF THE CALL

The JTC 2022 focuses on:

"Novel translational approaches to tackle the challenges of hard-to-treat cancers from early diagnosis to therapy"

Proposals must be centred on one or more of the HTTC subtypes characterised by very poor prognosis (5-year survival rate<25%) and for which survival has not improved significantly over the last decades, which are listed in the table below:

	5-year survival rate (2017)	Average absolute change 2006-2017
Glioblastoma	5.7%	0.1
Pancreas	10.9%	0.6
Pleural mesothelioma	11.5%	0.3
Gallbladder	19.4%	0.4
Oesophagus	19.9%	0.4
Liver and bile ducts	20.3%	0.7
Lung/bronchus	21.7%	0.5

Source: https://seer.cancer.gov

The specific objectives of this funding opportunity are to stimulate new partnerships between researchers and clinicians and support original, high-quality projects, which have the potential for significant clinical impact on HTTC prognosis. The expected outcome of the call is to improve the efficacy of current diagnosis, prognosis and treatment of HTTC, through the development of novel personalized approaches based on a better understanding of the peculiarities of HTTC.

Current difficulties include the inadequacy of standard diagnostic tools or established early detection methods in the general population, but also the inefficacy of available treatment options, due to intrinsic resistance and/or ineffective drug delivery. In the context of translational cancer research, this call for proposals comprises three specific aims. Proposals will have to cover at least one of the undermentioned aims or sub-aims.



<u>Aim 1</u>) Identification/validation of novel early diagnostic approaches. Early detection and diagnosis (ED&D) research seeks to detect and diagnose consequential precancerous changes and cancer at the earliest possible point at which an effective intervention might be made, reducing the burden of late-stage disease. Any of the areas identified below can be eligible for funding:

- Identification and validation of novel biomarkers/signatures for HTTC, to better understand disease trajectory of very early/pre-cancerous lesions and help patient stratification in terms of risk, diagnosis/prognosis, response to treatment;
- Non-confirmatory clinical trials of ED&D technologies or approaches, in particular data and computation-driven approaches.

Proposals may include hypothesis-driven studies on a variety of biomarkers, e.g. structural, functional, molecular, genetic biomarkers; digital biomarkers are eligible only in combination with other biosignatures. In all cases, a clear pathophysiological correlate and studies on human participants or tissue should be included in the proposal.

<u>Aim 2)</u> Identification/validation of novel therapeutic approaches. Although ED&D may significantly reduce the disease burden, HTTC are often characterised by an intrinsic resistance to available treatments. Therefore, it is of foremost importance to understand the biological processes that make these cancers "hard to treat", and consequently to elaborate more effective therapeutic strategies, also to improve the patients' quality of life. We welcome proposals aimed at:

- Identification and validation of novel therapeutical targets, based on better insights on resistance mechanisms, tumour heterogeneity, cellular plasticity, tumour microenvironment, immune responses, metastatic process, tumour dormancy. Novel targets should be evaluated in translational studies with regard to their impact on treatment efficacy and patient benefits. Any in-vitro model systems must closely relate to the human disease.
- Development of novel therapeutics/therapeutic approaches, through phase I and II clinical trials investigating combinations of available treatments, e.g. targeting multiple pathways, including immune/inflammatory, neoangiogenic and proliferative pathways, new therapeutics, new administration schemes, nutritional support, and other measures to maximise patient outcome and quality of life.

<u>Aim 3)</u> Development of novel drug delivery strategies. The overarching challenge associated with effective treatment of any cancer is to minimize undesired effects while maximizing therapeutic benefits. For HTTC two additional issues arise: (i) traditional targeted drug delivery strategies suffer



from limited capacity of the delivery vehicles preventing sufficient drugs reaching the cancer site which restricts the efficacy of treatment; and (ii) to access the tumour the drug needs to cross endogenous barriers, such as the blood brain barrier and tissue stroma. Therefore, we welcome proposals that aim at developing novel drug delivery systems for HTTC by:

- achieving site-specific targeting; and/or
- controlling release rate.

Interdisciplinary approaches that combine polymer science and nanotechnology, pharmaceutics, bioconjugate chemistry, and molecular biology are particularly supported.

An essential pre-requisite for all proposals is the clinical relevance of the planned work.

Proposals addressing one or more of the above challenges with spatial transcriptomic, single-cell/multiomic approaches are strongly encouraged, as well as other innovative approaches (artificial intelligence, radiomics, etc.) or strong biomedical components (e.g. organoids, cancer vaccines, etc.). We particularly welcome applications that propose novel interdisciplinary approaches from relevant fields of engineering, informatics, physics in addition to biology and medicine, provided that they are mindful of potential clinical need, patient and population impact.

The following types of research projects are excluded from the call:

- Analysis of preclinical models limited to cell lines and animal models;
- Phase III and IV clinical trials;

• Studies not compliant with the COMMISSION REGULATION (EC) No 800/2008 (http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:214:0003:0047:en:PDF), with specific reference to the articles 30, 31, 32, and 33. For full reference, please see also the COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS dated 20.12.2011

(http://ec.europa.eu/services_general_interest/docs/comm_quality_framework_en.pdf);

• Studies not compliant with the Commission Regulation (EU) No 651/2014 of 17 June 2014 http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2014:187:FULL&from=EN.

Capacity building activities

Translational research has the ambition to remove barriers to multidisciplinary and multi-professional collaboration. It is envisioned that clinicians, researchers and operational staff from various sectors (academia, industry, regulatory bodies) will effectively work together to expedite the translation of scientific discoveries to clinical application and to more rapidly fuel research directions with observational or clinical findings. In fact, the complexity of the process requires, at the individual and



collective levels, the creation of translational medicine research interfaces/infrastructures. To reach that goal, TRANSCAN-3 supports capacity building activities to promote the formation and upgrading of multidisciplinary teams in an integrated process: i) exchange/mobility of individual researchers/professionals in order to bring new expertise to an existing multidisciplinary translational team; and/or ii) recruitment of individual researchers/professionals by a translational research team in order to cover expertise and "know-how" unavailable in the existing team. These types of activities, when present, will be supported within the projects, which will be selected for funding under TRANSCAN-3 JTC 2022.

Thus, applicants may add an additional part to cover these activities (eventually with an associated separate budget, in compliance with the rules of the respective national/regional funding organisations). Capacity building activities have to be fully coherent with the objectives of the research project, and aimed at strengthening the ability of participating team(s) to perform the work detailed in the project plan as well as to improve, in the long term, the quality and potential of the translational research performed by the team(s). Depending on the project these activities could be (the following examples are indicative only, and neither exhaustive nor prescriptive): 1) exchanges/mobility of investigators (especially young investigators) between teams and countries participating in the project, 2) short term training of scientists, operational staff, etc., 3) training through technical workshops dedicated to relevant aspects of the scientific work planned in the project, 4) short training (one or few weeks) of several partner teams by one expert, etc. Activities related to the dissemination of results such as hosting a symposium, conferences etc. are out of the scope of this capacity building component.

3. APPLICATION: Eligibility criteria

Joint transnational research proposals may be submitted by applicants belonging to one of the following categories <u>depending on national/regional eligibility rules</u> as specified in Annex 3:

- Academic research groups (from universities or other higher education or research institutions).
- Clinical/public health sector research groups (from hospitals/public health and/or other health care settings and health organisations).
- Enterprise's research groups (depending on national/regional eligibility rules), with particular emphasis on small and medium-sized enterprises.

The applicants are subject to <u>eligibility criteria</u> of national/regional funding organisations (see "Guidelines for applicants") and are advised to contact their respective national/regional contact points (see Annex 1).

Please note that non-compliance with the eligibility rules detailed below will lead to the rejection of the entire proposal without further review.

• Only transnational projects will be funded.



- Applications will be submitted by the coordinator. The coordinator and each of the individual project partners (representing research groups) will be funded by the funding organisation from their country/region that is participating in the TRANSCAN-3 JTC 2022, and are therefore subject to national/regional eligibility rules.
- Each research consortium must involve a minimum of three (3) and a maximum of six (6) partners (comprising the project coordinator) eligible for funding, coming from different countries whose funders participate in the call. The maximum number of partners can be increased to 7 in the full proposal stage as a consequence of the widening process aimed at including one team from underrepresented countries/regions, as detailed in Section 10.
- The partners must be **from at least three (3) different countries participating in the call**. In addition, a consortium must not involve more than two (2) research groups from the same country (in such cases the minimum number of groups must be 4, coming from 3 different countries).
- A wide inclusion of research teams from all the countries/regions participating in the call is encouraged, with a particular attention to research teams from Hungary, Latvia, and Slovakia, in order to strengthen the European translational cancer research area.
- Each consortium is represented by a coordinator responsible for the scientific management (such as controlling, reporting, intellectual property rights issues, etc.) and for all the communications with the JCS.
- Partners not eligible for funding by one of the organisations participating in the JTC2022 (e.g. from non-funding countries or not fundable according to the regional/national regulations of the participating funding organisations) may participate in projects provided that they demonstrate, with the full-proposal submission, that their economic and human resources have already been secured and will be available at the start of the project. No more than one partner with its own funding is allowed in consortia with at least three partners eligible for funding. Partners with their own funding must be comprised in the maximum number of six partners.
- Applicants should refer to the annexes of the document "Guidelines for Applicants" containing all the specific national/regional eligibility criteria and should contact their respective national/regional funding organisation contact points for additional clarification (see Annex 1. Contact information of the national/regional funding organisations).
- Please note that an <u>eligibility check before the pre-proposal submission is mandatory</u> for: Ministry of Health (IT-MOH), Italy; Fondazione Regionale per la Ricerca Biomedica (FRRB), Lombardy, Italy, Tuscany Region (TuscReg), Italy, Alliance Against Cancer (ACC), Italy and Chief Scientist Office - Ministry of Health (CSO-MOH), Israel.

Each consortium must involve at least one basic or pre-clinical research team and one clinical team. It is also recommended to include an expert team in methodology, biostatistics or bioinformatics, depending on the type of work planned. The consortium may also involve other teams with specialised skills and know-how (biobanks, model systems, technological platforms, etc.) or expertise



(epidemiology and molecular epidemiology, early phase clinical trials, public health, ELSI, etc.). The consortium should have sufficient critical mass to achieve ambitious scientific, technological and medical goals and, along with the particular contribution of each research team, should clearly demonstrate its transnational added value. The translational nature of the research results is the key goal of TRANSCAN-3, therefore the consortium should also clearly demonstrate a knowledge transfer towards clinical, public health and/or industrial applications.

The duration of the projects shall not exceed three (3) years.

4. TIMELINE of the CALL

23 May 2022	Publication of the call
6 June 2022 at 16:00 (CEST)	Opening of the on-line submission system for pre- proposals
18 July 2022 at 12:00 (CEST)	Deadline for pre-proposal submission
3 November 2022	Communication of the results of the pre-proposal assessment and invitation for full-proposal stage
17 November 2022	Opening of the submission system for full proposals
15 December 2022 at 12:00 (CET)	Deadline for full-proposal submission
Expected for April 2023	Communication of the funding decisions to the applicants
September 2023	Expected project start (also subject to regional/national procedures)

5. SUBMISSION OF JOINT PROPOSALS

TRANSCAN-3 JTC 2022 will be implemented through a two-stage submission procedure: preproposals and full proposals. Both pre- and full proposals must be written in English and submitted to the JCS by the coordinator through the PT-Outline <u>Electronic Submission System</u> exclusively.

In preparing the proposals, applicants must strictly follow the rules described in this call text and in the document entitled "Guidelines for Applicants", and use the application forms available on the TRANSCAN website (<u>http://www.transcan.eu/</u>) and on the electronic submission system. Applicants should take note of individual national/regional rules, and contact their national/regional contact points for specific questions.

The pre-proposals must be submitted to the electronic submission system no later than the **18th July 2022, at 12:00 (Central European Summer Time, CEST)**. The information relating to the selected pre-proposal will be communicated to the coordinators on the 3rd November 2022.

The information provided in the pre-proposal application is binding for the entire application process. Thus, any substantial changes between the pre-proposal and the full proposal (e.g. composition of the



consortia, objectives of the project, etc.) must be communicated in advance to the JCS with detailed justification and will only be allowed by the CSC under exceptional circumstances.

The invited full proposals will have to be submitted to the electronic submission system not later than the **15th December 2022 at 12:00 (Central European Time, CET)**. Please note that full proposals will only be accepted from applicants explicitly invited by the JCS to submit.

The decision on the results of the full proposal evaluation meeting will be communicated to all (successful and unsuccessful) coordinators in April 2023. Coordinators will receive a summary of the full proposal evaluation conclusions in due time.

6. CALL IMPLEMENTATION BOARDS

The Call Steering Committee (CSC) and the Scientific Evaluation Committee (SEC) will manage the evaluation procedure of pre-proposals and full proposals and the final selection of research projects, with the support of the Joint Call Secretariat (JCS).

The CSC is composed of one single representative from each national/regional funding organisation participating in TRANSCAN-3 JTC 2022. The CSC will supervise the preparation and the implementation of the call and will take all decisions concerning the call. Based on the ranking list established by the SEC, the CSC will take the final decision on the proposals to be funded. Members of the CSC are not allowed to submit proposals to this call.

The SEC is a panel of internationally recognised scientific experts in charge of the evaluation of submitted pre- and full proposals. In the second step of evaluation, additional experts chosen for their knowledge in specific fields covered by the proposals may also be invited to join the SEC. The selection of reviewers will not be restricted to countries participating in TRANSCAN-3, on the contrary international membership will be actively sought. A balance of gender and national representation will also be sought. Reviewers do not represent the funding organisations and are appointed for their own scientific expertise; their evaluations must be based on the evaluation criteria for this call. Reviewers are not allowed to submit or participate in proposals within this call and must sign declarations on conflict of interest and confidentiality.

7. EVALUATION CRITERIA

Pre-proposals and full proposals will be assessed according to following criteria.

1. Excellence

- a. Scientific quality of the proposal: soundness of the rationale including transdisciplinary considerations, clarity of the objectives, expected progress beyond the state-of-the-art, international competitiveness.
- b. Relevance of the project regarding the topic and the overall objective (translational cancer research) of the call; availability and quality of preliminary data.



2. Impact

- a. Potential impact with reference to the development, dissemination and use of project results: potential impact of the expected results on cancer control, in terms of translation into public health or clinical practices (enhancing innovation capacity and integration of new knowledge) and/or into pharmaceutical/industrial applications; appropriateness of measures for the dissemination and/or exploitation of project results including socio-economic aspects and anticipation of intellectual property issues (patenting, industrial exploitation, marketing, etc.).
- Impact with reference to strengthening the translational capacity building activities: This sub-criterion will be assessed at the level of the full proposal only and solely for the scientific proposals recommended for funding.

The assessment of the capacity building component and associated budget will be performed under this sub-criterion after the scientific assessment of the proposal: hence, a proposal could be recommended for funding without the part related to capacity building activities if this part is evaluated as "poor".

The assessment under this sub-criterion will be performed independently using the following:

- Content: relevance and coherence of the capacity building activities with the proposal objectives.
- Candidate: background (scientific, medical, etc.), coherence with the CV, scientific production.
- Host team: expertise of the host team in the field, research qualification of the responsible person.

3. Quality and efficiency of the implementation

- a. Coherence and effectiveness of the work plan: appropriateness and feasibility of the methodology (including clinical trials if applicable) and associated technologies used, with particular regard to the study design, the study population(s), study endpoints.
- b. Statistical/bio-statistical aspects and power calculation (including clinical trials if applicable): study design; sampling calculations; appropriateness and robustness of statistical analyses: adequateness of endpoints.
- c. Quality of the transnational research consortium: experience of the research partners in the field(s) of the proposal (for young teams: appropriateness of their current work and training of their members); quality of the collaboration between the research teams and added value of the research consortium as a whole.
- d. Appropriateness of the management structures and procedures, including risk and innovation management.
- e. Appropriateness of the allocation of tasks and resources to be committed (personnel, equipment, etc.) and of the estimated budget.
- f. Compliance with ethical rules and regulatory aspects



8. SCORING

Range and interpretation of the scores

A scoring system from 0 to 5 will be used to evaluate the proposal performance with respect to each evaluation criteria, as follows:

0 – Failure. Proposal fails to address the criterion or cannot be assessed due to missing or incomplete information.

1 – Poor. The criterion is inadequately addressed or there are serious inherent weaknesses.

2 – Fair. The proposal broadly addresses the criterion, but there are significant weaknesses.

3 – Good. The proposal addresses the criterion well, but a number of shortcomings are present.

4 – Very good. The proposal addresses the criterion very well, but a small number of shortcomings are present.

5 – Excellent. The proposal successfully addresses all relevant aspects of the criterion. Any shortcomings are minor.

The maximum total score for the three evaluation criteria is 15.

Thresholds and weighting

The threshold for individual criteria is 3. The overall threshold, applying to the sum of the individual scores, is 10.

To determine the ranking, in case of equal score, the "impact" score will be considered first, then the score for "excellence" and finally that for "quality and efficiency of the implementation".

9. ELIGIBILITY CHECK OF PRE-PROPOSALS AND FIRST STEP OF EVALUATION

Eligibility check

The JCS will examine all pre-proposals to ensure that they meet the call's formal criteria (date of submission, number of participating countries/regions and groups, inclusion of all necessary information in English, adherence to the application forms, document length). The JCS will forward the pre-proposals to the national/regional funding organisations, which will perform a formal check of compliance with their respective regulations.

After completion of the eligibility check, the CSC will make the final decision; pre-proposals that are not considered eligible will be rejected without further review. Coordinators of non-eligible pre-proposals will be informed by the JCS accordingly.

Evaluation of pre-proposals

Eligible pre-proposals will be reviewed by the SEC panel.



All necessary steps will be taken by the JCS and the CSC to ensure that SEC members have no conflict of interest for those proposals that they are asked to review. SEC members will be required to formally declare that no conflict of interest exists at any time of their evaluation duty and will sign a confidentiality agreement concerning all documents and the entire process.

Each pre-proposal will be allocated to two (2) SEC members (one of whom will act as rapporteur). The SEC will meet, discuss the pre-proposals and establish a ranking list in accordance with each pre-proposal respective merit. Then, the CSC will decide, based on SEC recommendations and budget considerations, how many pre-proposals will be invited to the full proposal stage. The JCS will communicate to each project coordinator the final decision with respect to their own application. Successful applicants will be invited by the JCS to submit a full proposal.

Coordinators of successful pre-proposals might also receive information related to a widening process for the involvement of researchers from underrepresented countries in their own proposal, according to the procedure described below.

10. PROCESS FOR THE INVOLVEMENT OF UNDERREPRESENTED COUNTRIES

For pre-proposals invited to the full proposal stage, a widening process might be implemented to maximise the involvement of underrepresented countries (i.e. countries that will likely not spend their earmarked budget), by providing the opportunity to add a partner from one of those countries to the consortium. Any new inclusion must bring added value and expertise to the project, which overall should not change significantly.

The widening process will be subject to the following conditions:

- Up to one team from an underrepresented country may join a consortium;
- Funding of the new partner must be provided by the respective funding organisation (i.e. the new partner must be able to independently finance their own work package/tasks);
- The work plan of proposals which have already been evaluated must not be changed (i.e. new work packages or tasks should be added and existing work packages must not be modified);
- The addition of partners must be in compliance with the respective national funding rules of involved funding organisations;
- The maximum number of participating partners can increase to seven, in the case that one team from an underrepresented country/region joins a consortium composed of six members.

After pre-proposal evaluation, the CSC will decide on the final list of underrepresented countries for this step, which will be published in the TRANSCAN-3 website. To support the process, coordinators of successful pre-proposals will be informed about the possibility to benefit from inclusion of one team from an underrepresented country in their consortium and will receive the list of the funding organisations that adhere to the process. Coordinators willing to incorporate a new partner in their



consortium will get in contact with the national contact person of the funding organisation concerned in order to:

1. share a summary of their project to disseminate it to the most suitable research groups in the concerned country/region;

and

2. receive contacts and details of expertise of research groups that are interested in participating.

Inclusion of a new partner must be justified on a scientific basis and must provide added value for the consortium as a whole. The widening process will occur on a voluntary basis: inclusion of a research group from an underrepresented country is not mandatory and has no influence on the final assessment, which will be on the basis of pure scientific merit.

11. ELIGIBILITY CHECK OF FULL PROPOSALS AND SECOND STEP OF EVALUATION

An eligibility check of full proposals will be performed by the JCS to ensure that they meet formal criteria and have not changed substantially from the respective pre-proposals. A full proposal may be excluded from further review, if criteria are not met or if proposal objectives or composition of the consortium deviate substantially from the previously submitted pre-proposal. In any case, major changes must be communicated in advance to the JCS, which will contact the concerned national/regional funding organisation to discuss the issue; a formal decision on whether such an exceptional change may be justified will be taken by the CSC.

Each full proposal will be allocated to at least three reviewers, possibly including those who had reviewed the corresponding pre-proposal. If necessary, in consideration of the number of proposals and/or the specific scientific field, additional experts will be invited to join the SEC panel. One of the reviewers will be appointed as rapporteur. The reviewers will independently assess full proposals according to the evaluation criteria mentioned above and will deliver their evaluation reports to the JCS (via an electronic evaluation system). All reviewers will be invited to the second SEC meeting and will have access to evaluation reports. During the meeting, each full proposal will be presented by the rapporteur and discussed on the basis of individual evaluation reports so as to reach consensus scoring. As a result of these discussions and as an outcome of the SEC meeting a ranking list of the full proposals recommended for funding will be established.

12. FUNDING DECISION

At the end of the evaluation process, based on the ranking list established by the SEC and on the commitment of available funds, the CSC will establish a final list of the projects to be funded. The JCS will communicate to all project coordinators the final decision along with an evaluation summary report.



13. FINANCIAL AND LEGAL ISSUES

Funding model and funding details

The TRANSCAN-3 JTC 2022 uses the "virtual common pot" funding model. This means that funding will be made available by each national/regional funding organisation according to their specific regulations, for research groups in their country/region.

The funding rate will vary up according to national/regional rules to a maximum of 100% of the funds requested. Funding is granted for a maximum of three years according to national regulations.

Each project partner (including the project coordinator) will get a separate funding contract/letter of grant according to national/regional regulations from his/her national/regional funding institutions.

As a general rule, no changes to the composition of research consortia or in budget may occur during the contract/letter of grant. Any minor changes will have to be well justified and the relevant funding organisations will decide upon the proper action to be taken. However, in case of major changes, an independent expert may be consulted to help with the final decision of the funding organisations. The research partners shall inform the JCS and the funding bodies of that project of any event that might affect the implementation of the project.

Depending on the time needed for the administration of granting funds to the respective national/regional research groups, individual projects of a research consortium **are expected to start by September 2023.** The official start date shall be communicated by the project coordinator to the JCS and shall appear in the consortium agreement established in accordance to section below.

Research consortium agreement, ownership of intellectual property rights, ethical issues

It is mandatory for a funded research project consortium to sign a Consortium Agreement (CA), addressing the issues indicated in the document "Guidelines for Applicants", including Intellectual Property Rights (IPR) issues. The research consortium is strongly encouraged to sign this CA before the official project start date. In any case the CA must be signed no later than six (6) months after the official project start date. Upon request, the CA must be made available to the concerned TRANSCAN-3 JTC 2022 funding organisations.

Results and new IPR resulting from projects funded through the TRANSCAN-3 JTC 2022 will be owned by the relevant organisations according to international/national/regional rules on IPR. If several participants have jointly carried out work generating new IPR, they shall agree amongst themselves (CA) as to the allocation of ownership of IPR, taking into account their contributions to the creation of those IPR as well as the European Commission's guidelines on IPR issues.

The results of the research project and IPR created should be disseminated and made available for use, whether for commercial purposes or not, in order to maximize public benefit.



The TRANSCAN-3 JTC 2022 funding organisations shall have the right to use documents, information and results submitted by the research partners and/or to use the information and results for their own purposes, provided that the owners' rights are kept.

Any ethical issues, arising for instance if a research project includes a study on patients, should be addressed at the proposal submission stage, and subsequent authorization presented at the latest, upon request by the national/regional funding organisations, before the process of grant negotiation.

Confidentiality of proposals

Proposals and any relating information shall be kept confidential by the SEC members, the external reviewers and the CSC members. Proposals shall not be used for any purpose other than the evaluation and subsequent monitoring of the funded projects.

Full proposals will be required to include a publishable summary, which will clearly identify the main goals of the project. If a proposal is funded, this information will be published on the TRANSCAN website. All other project details shall remain strictly confidential.

14. REPORTING AND DISSEMINATION

Each coordinator of a funded project, on behalf of all the project partners, must submit annual scientific progress reports (within 2 months after the end of a calendar year), and a final scientific report (within 3 months after the end of the project) to the JCS. All reports must be written in English and comply with the reporting form templates (one for the annual reports and one for the final report) that will be provided to the coordinators of the funded projects in due time.

In addition to these centrally-administered TRANSCAN-3 reports, principal investigators may be asked to submit financial and/or scientific reports to their national/regional funding organisations. Each individual contract/letter of grant will be monitored by the respective national/regional funding organisations.

In case of serious difficulties in the conduct of the research project, the coordinator shall promptly inform the JCS and the relevant funding organisations. These funding organisations will decide upon the proper actions to be taken.

Funding recipients must ensure that all results (publications, etc.) arising from the project include a proper acknowledgement that the project is collectively supported by the national funding organisations under the framework of the ERA-NET TRANSCAN-3 initiative. The coordinators and/or principal investigators may be asked to present the results of their projects at a TRANSCAN-3 symposium. Travel expenses to attend this event should be included in the budget.

15. GENDER EQUALITY

TRANSCAN-3 strives to promote gender equality in scientific research, by facilitating the participation of women scientists and integrating the gender dimension into the research design of the projects.



Integrating the gender dimension in research and innovation is an added value in terms of excellence, creativity, and business opportunities. It helps researchers improve the overall quality of research design, hypotheses, protocols and outputs in an ample variety of fields. It does not only allow to address gender bias and to build more evidence-based and robust research, but also contributes to pluridisciplinarity. As science and innovation are increasingly framed as working for/with society, reflecting the diversity of final users from the early research stage has become a must.

TRANSCAN-3 encourages applicants to explore whether and how the gender dimension is relevant to their research.

When drafting the proposal, applicants will need to pay attention to gender equality from different angles, in terms of:

1. Human resources: balance between women and men in the research teams who will implement the project

2. Content: analysing and taking into account the possible differences between men and women, boys and girls, or males and females, in the research design of the project.

16. CONTACT AND FURTHER INFORMATION

The JCS is set up at Alliance Against Cancer, Italy.

The JCS will assist the CSC during the implementation of the JTC 2022 as well as during the monitoring phase (until 3 months after the funded research projects have ended). The JCS will be responsible for the central management of the evaluation procedure. The JCS will be the primary contact referring to the TRANSCAN-3 JTC 2022 procedures between the project coordinators, the funding organisations (CSC) and the peer reviewers (SEC members).

Before submitting a proposal, it is strongly advised to contact the national/regional funding organisations for any questions regarding the JTC 2022 (see Annex 1).



ANNEX 1. CONTACT INFORMATION OF THE NATIONAL/REGIONAL FUNDING **ORGANISATIONS**

Country/Region	Funding Organisation	Contact
Austria	Austrian Science Fund (FWF)	Herbert Mayer <u>Herbert.Mayer@fwf.ac.at</u> Kathrina Proschinger <u>Kathrina.Proschinger@fwf.ac.at</u>
Belgium, Flanders	Research Foundation - Flanders (FWO)	Kristien Peeters Tel: +32 (0)2 550 15 95 Toon Monbaliu Tel: +32 (0)2 550 15 70 <u>eranet@fwo.be</u>
Belgium, French speaking community	Fund for Scientific Research - FNRS (F.R.SFNRS)	Joël Groeneveld, <u>joel.groeneveld@frs-fnrs.be</u> Tel : +32 2504 9270 Florence Quist, <u>florence.quist@frs-fnrs.be</u>
Estonia	Estonian Research Council (ETAg)	Argo Soon <u>Argo.Soon@etag.ee</u> Margit Suuroja <u>margit.suuroja@etag.ee</u>
France	French National Cancer Institute (INCa)	Charlotte Gudewicz cgudewicz@institutcancer.fr
France	ARC French Foundation for Cancer Research (ARC Foundation)	Charlotte Audoynaud Tel: +33 (0)1 45 59 58 45 caudoynaud@fondation-arc.org
Germany	Federal Ministry of Education and Research (BMBF)	Isabel Aller Isabel.aller@dlr.de
Hungary	National Research, Development and Innovation Office (NKFIH)	Klára Horváth <u>klara.horvath@nkfih.gov.hu</u>
Ireland	Health Research Board (HRB)	Siobhan Hackett shackett@hrb.ie
Israel	The Chief Scientist Office of the Ministry of Health (CSO-MOH)	Liron Even-Faitelson <u>liron.ef@moh.gov.il</u> Irit Allon <u>irit.allon@moh.gov.il</u>



Italy	Ministry of Health (IT-	Chiara Ciccarelli	
·,	MOH)	c.ciccarelli@sanita.it	
	- /	Simona Bifolchi	
		s.bifolchi@sanita.it	
		Gaetano Guglielmi	
		g.guglielmi@sanita.it	
Italy	Alliance Against Cancer	Valentina Trapani	
	(ACC)	trapani@alleanzacontroilcancro.it	
Italy, Tuscany	Tuscany Region	Donatella Tanini	
	(TuscReg)	Tel: +39 055 4383256	
		Teresa Vieri	
		Tel. +39 055 4383289	
		transcan3@regione.toscana.it	
Italy, Lombardy	Fondazione Regionale	Paola Bello	
	per la Ricerca	Marcello De Amico	
	Biomedica (FRRB)	progetti@frrb.it	
Latvia	Latvian Council of	Maija BUNDULE	
	Science (LCS)	maija.bundule@lzp.gov.lv	
		Tel: +371 26514481	
		uldis.berkis@lzp.gov.lv Tel: +371 29472349	
Luxombourg	National Research	Sean Sapcariu	
Luxembourg	National Research Found (FNR)	sean.sapcariu@fnr.lu	
		Helena Burg	
		helena.burg@fnr.lu	
	Research Council of		
Norway	Norway (RCN)	Tine Thorbjørnsen	
	Norwegian Cancer	tth@rcn.no	
	Society (NCS)		
Poland	National Centre for	Izabela Rzepczyńska	
	Research and Development (NCBR)	Izabela.Rzepczynska@ncbr.gov.pl	
		Joanna Makocka	
		Joanna.Makocka@ncbr.gov.pl	
Romania	Executive Agency for	Mihaela Manole	
	Higher Education,	mihaela.manole@uefiscdi.ro	
	Research, Development	Tel: +4 021 30 23 863	
	and Innovation Funding (UEFISCDI)		
Slovakia	Slovak Academy of Sciences (SAS)	Katarina Bibova	
		bibova@up.upsav.sk	
		Martin Novak	
		mnovak@up.upsav.sk	
		minovak@up.upsav.sk	

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Spain	National Institute of Health Carlos III (ISCIII)	Ignacio Baanante Balastegui <u>ibaanante@isciii.es</u> Cándida Sánchez-Barco <u>cbarco@isciii.es</u>
Spain	The Scientific Foundation of the Spanish Association Against Cancer (FCAECC)	Esther Aguilar <u>esther.aguilar@contraelcancer.es</u> Patricia Nieto <u>patricia.nieto@contraelcancer.es</u>
Taiwan	Ministry of Science and Technology (MoST)	Ching-Mei Tang <u>cmtom@most.gov.tw</u> Tel: +886-2-2737-7557

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ANNEX 2. INDICATIVE FUNDING COMMITMENT OF THE FUNDING ORGANISATIONS PARTICIPATING IN TRANSCAN-3 JTC 2022

Country/Region	Country/Region Funding Organisation		Anticipated number of fundable research groups
Austria	Austrian Science Fund (FWF)	1.2	4
Belgium, Flanders	Research Foundation - Flanders (FWO)	0.35	1
Belgium, French speaking community	Fund for Scientific Research - FNRS (F.R.SFNRS)	0.2	1
Estonia	Estonian Research Council (ETAg)	0.1 (0.15 if the coordinator is from Estonia)	1
France	French National Cancer Institute (INCa)	1.5	5-10
France	ARC French Foundation for Cancer Research (ARC Foundation)	0.7	1-3
Germany	Federal Ministry of Education and Research (BMBF)	3.0	10-12
Hungary	National Research, Development and Innovation Office (NKFIH)	0.3	2-3
Ireland Health Research Board (HRB)		0.37	1-2
Israel	The Chief Scientist Office of the Ministry of Health (CSO-MOH)	0.3	2
Italy	Ministry of Health (IT- MOH)	3.0	14
Italy Alliance Against Cancer (ACC)		0.3	1-2
Italy, Tuscany Tuscany Region (TuscReg)		0.3	1-2
Italy, Lombardy Fondazione Regionale per la Ricerca Biomedica (FRRB)		1.5	



Latvia	Latvian Council of Science (LCS)	0.6	2	
Luxembourg	National Research Fund (FNR)	0.35	1	
Norway	Research Council of Norway (RCN)	0.5	Total for Norway: 2-4 projects (max 300 000 eur/project; 400 000	
	Norwegian Cancer Society (NCS)	0.5	eur/project if the project coordinator is from Norway)	
Poland	National Centre for Research and Development (NCBR)	0.6	3	
Romania	Executive Agency for Higher Education, Research, Development and Innovation Funding (UEFISCDI)	0.5	1-2	
Slovakia	Slovak Academy of Sciences (SAS)	0.12	1	
Spain	National Institute of Health Carlos III (ISCIII)	1.0		
Spain	The Scientific Foundation of the Spanish Association Against Cancer (FCAECC)	0.45	3-5	
Taiwan	Ministry of Science and Technology (MoST)	0.81	2-3	

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ANNEX 3. ELIGIBILITY OF BENEFICIARY INSTITUTIONS FOR THE FUNDING ORGANISATIONS PARTICIPATING IN TRANSCAN-3 JTC 2022

Country/	Funding Organisation	Eligible beneficiary institution ⁽¹⁾		
Region		Academia	Clinical/ Public Health	Enterprise
Austria	Austrian Science Fund (FWF)	Yes ⁽²⁾	Yes ⁽²⁾	Yes ⁽²⁾
Belgium, Flanders	Research Foundation - Flanders (FWO)	Yes	No	No
Belgium, French speaking community	Fund for Scientific Research - FNRS (F.R.S FNRS)	Yes	No (except Sciensano)	No
Estonia	Estonian Research Council (ETAg)	Yes	Yes	Yes (if requirements for research staff are fulfilled)
France	French National Cancer Institute (INCa)	Yes	Yes	No
France	ARC French Foundation for Cancer Research (ARC Foundation)	Yes	Yes	No
Germany	Federal Ministry of Education and Research (BMBF)	Yes	Yes	Yes
Hungary	National Research, Development and Innovation Office (NKFIH)	Yes	Yes	Yes
Ireland	Health Research Board (HRB)	Yes	Yes	No



		X		
Israel	The Chief Scientist Office of the Ministry of Health (CSO- MOH)	Yes	Yes	No
Italy	Ministry of Health (IT-MOH)	No	Yes	No
Italy	Alliance Against Cancer (ACC)	No	Yes	No
Italy, Tuscany	Tuscany Region (TuscReg)	Yes (in partnership with Authorities of the Tuscany Health Service SST)	Yes	No
Italy, Lombardy	Fondazione Regionale per la Ricerca Biomedica (FRRB)	Yes (in partnership with IRCCS or ASST)	Yes	No
Latvia	Latvian Council of Science (LCS)	Yes (must be listed in the Latvian Registry of Scientific Institutions)	Only if listed in the Latvian Registry of Scientific Institutions	Must be listed in the Latvian Commercial Registry, have main activity in Latvia, two-year statements provided
Luxembourg	National Research Fund (FNR)	Yes	Only if an eligible beneficiary of FNR funding	No
Norway	Research Council of Norway (RCN)	Yes	Yes	Yes (max. 50% of the total budget)
	Norwegian Cancer Society (NCS)	Yes	Yes	Yes (max. 50% of the total budget)
Poland	National Centre for Research and Development (NCBR)	Yes, according to national rules	Yes, according to national rules	Yes, according to national rules
Romania	Executive Agency for Higher Education, Research, Development	Yes, according to national rules	Yes, according to national rules	Yes, according to national rules

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	and Innovation Funding (UEFISCDI)			
Slovakia	Slovak Academy of Sciences (SAS)	Yes	No	No
Spain	National Institute of Health Carlos III (ISCIII)	Yes, only under the conditions specified in national rules	Yes	No
Spain	The Scientific Foundation of the Spanish Association Against Cancer (FCAECC)	Yes, if they are endorsed to Spanish Act 49/2002, of 23 rd December	Yes, if they are endorsed to Spanish Act 49/2002, of 23 rd December	No
Taiwan	Ministry of Science and Technology (MoST)	Yes	Yes	No

Please note that the information on this table is only indicative. Applicants are strongly advised to contact their national/regional contact points (see Annex 1) for further information.

(1) The eligibility of companies and institutions is subject to different regulations in the participating country/region. Further details regarding the eligible beneficiaries and other national eligibility criteria and requirements are available on the "Guidelines for Applicants"

(2) Applications for projects from FWF (Austria) may only be submitted by single natural persons. Affirmation of the research institution (academia, clinical/public health, enterprise) of the applicant is mandatory