TRANSCAN-3

ERA-NET: Sustained collaboration of national and regional programmes in cancer research

Joint Transnational Call for Proposals 2021 (JTC 2021)
co-funded by the European Commission/DG Research and Innovation:

"Next generation cancer immunotherapy: targeting the tumour microenvironment"

Call Text

Submission deadlines

Pre-proposals: 29 June 2021 at 12:00 CEST

Full proposals: 20 December 2021 at 12:00 CET

Electronic proposal submission system: https://ptoutline.eu/app/transcan2021
(Online submission will be possible from 20 April 2021)

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

contact the **Joint Call Secretariat (JCS)** at:

Ministero della Salute - Istituto Superiore di Sanità, Italy

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1. MOTIVATION

In the last decades the understanding of the molecular mechanisms responsible for cancer development and progression has significantly improved. This led to the introduction in the clinic of a wealth of targeted therapeutic agents with a corresponding increase in survival and improvement in the quality of life of cancer patients. In this context, a major breakthrough is represented by the clinical validation of the concept that the immune system is capable of recognizing cancer cells and controlling tumour growth, which paved the way to the introduction of immunotherapeutic agents in clinical practice. Cancer immunotherapy, in particular with checkpoint inhibitors, and more recently with adoptive CAR-T cell therapy, has revolutionized outcomes for an increasing number of cancer patients and cancer indications over the past ten years.

However, the high proportion of cancer patients resistant to and suffering from debilitating side effects of cancer immunotherapy still remains a huge issue. In this context, it is now becoming evident that resistance is largely influenced by the composition of the tumour microenvironment (TME). The TME is a complex milieu that contains heterogeneous populations of cancer cells, non-malignant cells of various origin and non-cellular components which all together orchestrate complex and dynamic dialogs. Among the cellular components, the immune cells play an important role in tumour growth and progression, and strategies to target them are expected to increase the chance of success of new and pre-existing cancer immunotherapies. Recently, the composition of different gut and tumour microbiome as well as the virome have been identified as being able to mediate anticancer immune surveillance. Understanding the complex and dynamic interactions of TME components should allow to identifying appropriate targets and developing predictive biomarkers to measure treatment outcome and drug resistance. It is reasonable to predict that targeting the TME will yield the next breakthroughs in cancer immunotherapy.

Molecular and functional phenotypes of diverse TMEs should be achieved by strategies directed to combine technologies, resources and data, highlighting the needs of developing integrated approaches. For instance, but not limited to, single-cell/multi-omics approaches are technologies providing unique opportunities for elucidating TME dynamic dialogs especially for the improvements in spatial mapping and quantification approaches. Also, there is growing evidence from pre-clinical and clinical research that women and men differ significantly in susceptibility to common cancers, and demonstrate differences in immune and treatment responses. This appears to be a relevant issue in the management of the disease, and studies investigating the role of sex and gender are extremely urgent and could contribute to the development of patient-centered and personalized cancer immunotherapy treatments. To achieve this, research groups should find the best way to share, integrate and combine tools and data in order to optimize their use and to obtain robust results directly transferable to the clinic.

Against this background, the TRANSCAN-3 partners have agreed to focus their first Joint Transnational Call for proposals (JTC 2021) on:
"Next generation cancer immunotherapy: targeting the tumour microenvironment"

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 new knowledge on TME functions into clinical practices.

The expected impact of the call is to improve the efficacy of personalized treatment of cancer patients through the development of new tools and targeted immunotherapy strategies, based on a better understanding of TME functions and of their impact on the disease course.

The following national/regional funding organizations have agreed to participate in the TRANSCAN-3 JTC 2021; in addition, the European Commission (EC) will contribute to JTC 2021 in accordance with the ERA-NET Co-fund scheme of the Research Framework Programme “Horizon 2020”.

- Austrian Science Fund (FWF), Austria
- Research Foundation - Flanders (FWO), Belgium, Flanders
- Fund for Scientific Research (F.R.S.-FNRS), Belgium, French speaking community
- Canadian Institutes of Health Research (CIHR), Canada
- 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
- Ministry of Universities and Research (MUR), Italy
- Alliance Against Cancer (ACC), Italy
- Tuscany Region (TuscReg), Tuscany, Italy
- Fondazione Regionale per la Ricerca Biomedica (FRRB), Lombardy, Italy
- State Education Development Agency (VIAA), Latvia
- Research Council of Norway (RCN), Norway
- Norwegian Cancer Society (NCS), Norway
- National Centre for Research and Development (NCBR), Poland
- Foundation for Science and Technology (FCT), Portugal
- 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
- The Foundation for the support of the Applied Scientific Research and Technology in Asturias (FICYT), Spain
- Ministry of Science and Technology (MoST), Taiwan
- The Scientific and Technological Research Council of Turkey (TUBITAK), Turkey

2. AIM OF THE CALL

Based on the considerations mentioned in the previous section, the EC co-funded call of TRANSCAN-3 (JTC 2021) focuses on:

"Next generation cancer immunotherapy: targeting the tumour microenvironment"

Despite advances in immunotherapies, obstacles and challenges, including limited response rates, the inability to predict clinical efficacy, and potential side effects such as autoimmune reactions or cytokine release syndromes, remain and hinder further applications of immunotherapies in clinics. Thus, a deeper understanding of the TME, able to dissect distinct classes and subclasses of it, is essential for deciphering new mechanisms of immunotherapies, defining new predictive biomarkers, and identifying novel therapeutic targets.

In the context of translational research, this topic at the intersection of laboratory and clinical research in immuno-oncology will comprise two general aims which concur to the possible clinical applications. Proposals will have to cover at least one of the six (6) specific sub-aims listed below. Approaches should be directed to draw up a multidimensional TME map paving the road for new efficacious immunotherapy strategies. Projects should be built from a solid and established hypothesis and should be relevant with regards to the possible improvements in clinical practice.

Aim 1: Identification and validation of TME subclasses and their contribution to the resistance mechanisms: Translational research using tumour samples collected from retrospective and/or prospective cohorts of patients.

1.1 Dissection of tumour cells/tumour-infiltrating immune/stromal cells and identification of TME subclasses (single-cell analyses, mass cytometry, imaging, multidimensional immunohistochemistry, etc.) for TME studies (3D culture systems; patient-derived organoids; patient-derived xenografts; syngeneic, genetically modified and chemical carcinogenesis-induced mouse models, etc.).

1.2 Definition of the contribution of TME to resistance mechanisms and identification of new therapeutic targets through multiomics (epigenomic, transcriptomic, proteomic, metabolomics, study of the microbiome and virome, etc.) to assess functional characteristics of TME-tumour cell interplay within the primary tumour and/or metastases (e.g the underlying signaling, the transcriptional landscape, the cell-cell communication, the network regulation of immune cells, etc.), to identify candidate TME targets and to assess the activity of pathway-targeting agents.

1.3 Development of tools capable of predicting treatment efficacy and tumour recurrence using minimally- or noninvasive techniques (generation of algorithms modelling the network dynamics, predictive models based on artificial intelligence, integrating -omics data and network approaches). Development of robust noninvasive biomarkers of disease course (radiomics, cell-free circulating tumour DNA, miRNA signatures, circulating tumour cells, etc.). Sex/gender impact must be

considered.

Aim 2: Targeting TME to improve efficacy of immunotherapy in human patients.

2.1 Development of new precision therapeutic strategies that may prevent human tumour recurrence or resistance (T-cell-based cancer immunotherapies, immune checkpoint blockers (ICBs), chimeric antigen receptor (CAR)-T-cells, preventive and therapeutic vaccines, etc.).

2.2 Evaluation in translational studies of the impact of TME on treatment efficacy and patient outcome (clinical utility of specific TME feature detections or identifications, clinical utility of specific intratumour or peripheral blood immune biomarkers, sex/gender impact, etc.).

2.3 Phase I and II clinical trials (combinations of available treatments, new therapeutic strategies, new administration schemes, etc.) targeting, or preventing resistance of multiple TME features. Particular attention should be given to gender balance inclusion in order to intercept sex/gender differences and to determine if there is an association between sex/gender and treatment response.

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

- Analysis of preclinical models (cell lines and animal models) only, except if the specific research leads to first-in-man application
- 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 of 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 the 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 2021.

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 activities component.

3. APPLICATION: Eligibility criteria

Joint transnational research proposals may be submitted by applicants belonging to one of the following categories depending on national/regional eligibility rules 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 eligibility criteria 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 partner (representing research groups) will be funded by the funding organisation from their country/region that is participating in the TRANSCAN-3 JTC 2021 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, eligible for funding, coming from different countries whose funders participate in the call.

- 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 Latvia, Slovakia and Turkey, 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 this JTC (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.
- 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 eligibility check before the pre-proposal submission is mandatory for: Ministry of Health (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.
- Please note that the Italian Ministry of Universities and Research (MUR) requires the submission of a mandatory national application by the same deadline of the pre-proposal phase (see Annex 1. Contact information of the national/regional funding organisations).
- Please note that TUBITAK requires the submission of a mandatory national application by 5 July 2021 via (https://uidb-pbs.tubitak.gov.tr/) for pre-proposal phase.

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

6 April 2021	**Publication of the call**
20 April 2021 at 16:00 (CEST)	**Opening of the on-line submission system for pre-proposals**
29 June 2021 at 12:00 (CEST)	**Deadline for pre-proposal submission**
5 November 2021	**Communication of the results of the pre-proposal assessment and invitation for full-proposal stage**
19 November 2021	**Opening of the submission system for full proposals**
20 December 2021 at 12:00 (CET)	**Deadline for full-proposal submission**
Expected for May 2022	**Communication of the funding decisions to the applicants**
October/November 2022	**Expected project start (also subject to regional/national procedures)**

5. SUBMISSION OF JOINT PROPOSALS

TRANSCAN-3 JTC 2021 will be implemented through a two-stage submission procedure: pre-proposals 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 electronic submission system 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 from the electronic submission system or from the TRANSCAN website (http://www.transcan.eu/). 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 **29th June 2021, at 12:00 (Central European Summer Time, CEST)**. The information relating to the selected pre-proposal will be communicated to the coordinators on 5 November 2021.

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 **20th December 2021 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 proposals evaluation meeting will be communicated to all the (successful and unsuccessful) coordinators in May 2022. The coordinators of the full proposals will receive a summary of the 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 2021. 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. SEC members are not allowed to submit or participate in proposals within this call, and must sign declarations on conflicts of interest and confidentiality. In the second step of evaluation (full proposals stage), in addition to the SEC members, external experts chosen for their knowledge in specific fields covered by the proposals will also contribute to the evaluation.

An independent expert will be appointed by the CSC as observer, to assess the conformity of the implementation of TRANSCAN-3 JTC 2021 and, in particular, review the proper implementation of the independent international peer review conducted by the SEC and the establishment of the ranking list of projects.

The JTC 2021 will adhere to the EC evaluation procedures and rules for the co-funded calls.

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.).

b. 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 the clinical trial 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 the clinical trial 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 proposals 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. Please note that half-marks may be given.

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 of “excellence” and then of “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; the pre-proposals not considered eligible will be rejected without further review. The coordinators of the 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 the SEC members have no conflict of interest for those proposals that they are asked to review. The 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 at least 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 the pre-proposals respective merit. Then, the CSC will decide, based on the SEC

recommendations and budget consideration, how many pre-proposals will be invited to submit a full proposal. 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, with possible recommendations on the project from the SEC and the JCS.

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

An eligibility check of the full proposals will be performed by the JCS so as to ensure that they meet the formal criteria of the call 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 the proposal objectives or the 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 organization 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 two (2) SEC members, possibly those who had reviewed the corresponding pre-proposal, and to two (2) external reviewers. One of the SEC members will be appointed as rapporteur. The SEC members and the external reviewers will independently assess the full proposals according to the evaluation criteria mentioned above, and will deliver their evaluation reports to the JCS (via an electronic evaluation system). In preparation of the second SEC meeting, all SEC members will get access to the evaluation reports. During this second SEC meeting, each full proposal will be discussed by the SEC member on the basis of the 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.

11. 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. This joint selection list of the projects to be funded, as well as the ranking list of the projects, the observers' report on the evaluation, and a formal signed commitment from each CSC member on availability of funds for the selected projects, will be communicated to the European Commission for review, so as to activate the cofund mechanism.

The JCS will communicate to all project coordinators the final decision along with a summary of the evaluation conclusions.

12. FINANCIAL AND LEGAL ISSUES

Funding model and funding details

The TRANSCAN-3 JTC 2021 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. In accordance to the ERA-NET Cofund model, the European Commission can contribute additional funding (up to 33% of the cumulated national/regional funding actually spent on research project), which will be distributed to the research

teams through the national/regional funding agencies.

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 November 2022.** 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 2021 funding organisations.

Results and new IPR resulting from projects funded through the TRANSCAN-3 JTC 2021 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 2021 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.

13. 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 and the EC 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.

14. 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 pluri-disciplinarity. 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.

15. CONTACT AND FURTHER INFORMATION

The JCS is set up at the Ministero della Salute-Istituto Superiore di Sanità, Italy.
The JCS will assist the CSC during the implementation of JTC 2021 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 call evaluation. The JCS will be the primary contact referring to the TRANSCAN-3 JTC 2021 procedures between the research consortia, the funding organisations (CSC) and the peer reviewers (SEC members and external experts).

Before submitting a proposal, it is strongly advised to contact the national/regional funding organisations for any questions regarding JTC 2021 (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 Herbert.Mayer@fwf.ac.at Anita Stürtz Anita.Stuertz@fwf.ac.at
Belgium, Flanders	Research Foundation - Flanders (FWO)	Toon Monbaliu eranet@fwo.be +32 (0)2 550 15 70
Belgium, French speaking community	Fund for Scientific Research (F.R.S.-FNRS)	Mr. Joël Groeneveld, joel.groeneveld@frs-fnrs.be +32 2504 9270 Dr. Florence Quist, florence.quist@frs-fnrs.be
Canada	Canadian Institutes of Health Research (CIHR)	Dr. Rachel Syme rmsyme@ucalgary.ca
Estonia	Estonian Research Council (ETAg)	Argo Soon Argo.Soon@etag.ee
France	French National Cancer Institute (INCa)	Charlotte Gudewicz cgudewicz@institutcancer.fr
France	ARC French Foundation for Cancer Research (ARC Foundation)	Julie Mussard Tel: +33 (0)1 45 59 59 51 E-mail: jmussard@fondation-arc.org
Germany	Federal Ministry of Education and Research (BMBF)	Isabel Aller Isabel.Aller@dlr.de Sebastian Hückesfeld Sebastian.Hueckesfeld@dlr.de Hubert Misslisch Hubert.Misslisch@dlr.de
Hungary	National Research, Development and Innovation Office (NKFIH)	Klára Horváth klara.horvath@nkfih.gov.hu
Ireland	Health Research Board (HRB)	Dr Louise Drudy ldrudy@hrb.ie
Israel	The Chief Scientist Office of the Ministry of Health (CSO-MOH)	Irit Allon irit.allon@moh.gov.it Liron Even-Faitelson liron.ef@moh.gov.il
Italy	Ministry of Health (IT-MOH)	Monica Paganelli m.paganelli@sanita.it; healthresearch@sanita.it Gaetano Guglielmi

		g.guglielmi@sanita.it
Italy	Ministry of Universities and Research (MUR)	Maria Chiara Noto mariachiara.noto@est.miur.it Aldo Covello aldo.covello@miur.it
Italy	Alliance Against Cancer (ACC)	Valentina Trapani trapani@alleanzacontroilcancro.it
Italy, Tuscany	Tuscany Region (TuscReg)	Donatella Tanini Direzione Sanità, Welfare e Coesione Sociale Tel:+39 055 4383256 Claudia Mariut Fondazione Toscana Life Sciences Tel. +39 055 4385431 transcan3@regione.toscana.it
Italy, Lombardy	Fondazione Regionale per la Ricerca Biomedica (FRRB)	Paola Bello Marcello De Amico progetti@frrb.it
Latvia	State Education Development Agency (VIAA)	Dr. Maija BUNDULE Tel: +371 67785423 E-mail: maija.bundule@viaa.gov.lv Dr. Uldis BERKIS Tel: +371 29472349 E-mail: uldis.berkis@viaa.gov.lv
Norway	Research Council of Norway (RCN)	Tine Thorbjørnsen tth@forskningsradet.no
Norway	Norwegian Cancer Society (NCS)	Torunn Elisabeth Tjelle torunn.tjelle@kreftforeningen.no
Poland	National Centre for Research and Development (NCBR)	Dominika Mickiewicz Dominika.mickiewicz@ncbr.gov.pl
Portugal	Foundation for Science and Technology (FCT)	Marta Abrantes Marta.abrantes@fct.pt Anabela Isidro Anabela.isidro@fct.pt
Romania	Executive Agency for Higher Education, Research, Development and Innovation Funding (UEFISCDI)	Mihaela Manole mihaela.manole@uefiscdi.ro Tel: +4 021 30 23 863
Slovakia	Slovak Academy of Sciences (SAS)	Katarina Bibova bibova@up.upsav.sk Martin Novak

		mnovak@up.upsav.sk
Spain	National Institute of Health Carlos III (ISCIII)	Ignacio Baanante Balastegui Email: ibaanante@isciii.es Cándida Sánchez-Barco Email: cbarco@isciii.es
Spain	The Scientific Foundation of the Spanish Association Against Cancer (FCAECC)	Esther Aguilar esther.aguilar@aecc.es Patricia Nieto patricia.nieto@aecc.es
Spain	The Foundation for the support of the Applied Scientific Research and Technology in Asturias (FICYT)	Inés Rey Hidalgo inesrey@ficyt.es Raquel Ochoa González raquel.ochoa@ficyt.es
Taiwan	Ministry of Science and Technology (MoST)	Dr. Ching-Mei Tang Tel: +886-2-2737-7557 Email: cmtom@most.gov.tw
Turkey	The Scientific and Technological Research Council of Turkey (TUBITAK)	Ozge Gozay Ozge.gozay@tubitak.gov.tr Sukran Alpdemir Sukran.alpdemir@tubitak.gov.tr

ANNEX 2. INDICATIVE FUNDING COMMITMENT OF THE FUNDING ORGANISATIONS PARTICIPATING IN TRANSCAN-3 JTC 2021

Country/ Region	Participating funding organisation	Envisioned amount of funding (M€ for 3 years)	Anticipated number of fundable research groups
Austria	Austrian Science Fund (FWF)	0.8	2-3
Belgium, Flanders	Research Foundation - Flanders (FWO)	0.7	2-3
Belgium, French speaking community	Fund for Scientific Research (F.R.S.-FNRS)	0.2	1
Canada	Canadian Institutes of Health Research (CIHR)	0.6	2
Estonia	Estonian Research Council (ETAg)	0.1	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)	5	15-17
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)	3.5	14
Italy	Ministry of Universities and Research (MUR)	0.6	
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	2-3
Latvia	State Education	0.42	2

	Development Agency (VIAA)		
Norway	Research Council of Norway (RCN)	0.5	Total for Norway: 1-3 projects (max 300 000 eur/project; 400 000 eur/project if the project coordinator is from Norway)
Norway	Norwegian Cancer Society (NCS)	0.5	
Poland	National Centre for Research and Development (NCBR)	1.2	5-6 (Max. 200 000 eur/project)
Portugal	Foundation for Science and Technology (FCT)	0.1	1
Romania	Executive Agency for Higher Education, Research, Development and Innovation Funding (UEFISCDI)	0.5	1-2
Slovakia	Slovak Academy of Sciences (SAS)	0.24	2
Spain	National Institute of Health Carlos III (ISCIII)	0.75	3-5
Spain	The Scientific Foundation of the Spanish Association Against Cancer (FCAECC)	0.4	
Spain	The Foundation for the support of the Applied Scientific Research and Technology in Asturias (FICYT)	0.2	2
Taiwan	Ministry of Science and Technology (MoST)	0.5	1-2
Turkey	The Scientific and Technological Research Council of Turkey (TUBITAK)	0.5	3 (1,5 Million TL per project excluding overhead costs): 720.000 TL for public research organisations, 1 Million TL for private companies)

ANNEX 3. ELIGIBILITY OF BENEFICIARY INSTITUTIONS FOR THE FUNDING ORGANISATIONS PARTICIPATING IN TRANSCAN-3 JTC 2021

Country / Region	**Participating funding organisation**	**Eligible beneficiary institution** [1]		
		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 (F.R.S.-FNRS)	Yes	No (except Sciensano)	No
Canada	Canadian Institutes of Health Research (CIHR)	Yes	Yes	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
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	Ministry of Universities and Research (MUR)	Yes	Yes	Yes
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 IRRCS or ASST)	Yes	No
Latvia	State Education Development Agency (VIAA)	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 research activity in Latvia
Norway	Research Council of Norway (RCN)	Yes	Yes	Yes
Norway	Norwegian Cancer Society (NCS)	Yes	Yes	Yes
Poland	National Centre for Research and Development (NCBR)	Yes, according to national rules	Yes, according to national rules	Yes, according to national rules
Portugal	Foundation for Science and Technology (FCT)	Yes, according to the national rules	Yes, according to the national rules	Yes, according to the national rules (max. of 50% of the total budget)
Romania	Executive Agency for Higher Education, Research, Development and Innovation Funding (UEFISCDI)	Yes, according to the national rules	Yes, according to the national rules	Yes, according to the national rules
Slovakia	Slovak Academy of Sciences (SAS)	Yes	No	No
Spain	National Institute of Health Carlos III (ISCIII)	Yes, only under the conditions specified in the 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 23th December.	Yes, if they are endorsed to Spanish Act 49/2002, of 23th December.	No
Spain	The Foundation for the support of the Applied Scientific Research and Technology in Asturias (FICYT)	Yes, according to the regional call grant conditions	Yes, according to the regional call grant conditions	Yes, according to the regional call grant conditions
Taiwan	Ministry of Science and Technology (MoST)	Yes	Yes	No
Turkey	The Scientific and Technological Research Council of Turkey (TUBITAK)	Yes (under the conditions specified in the national rules)	Yes (under the conditions specified in the national rules)	Yes (under the conditions specified in the national rules)

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

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