ERA-NET TRANSCAN-3 Joint Transnational Call (2023) "Translational research on cancer epigenetics"

Guidance Notes

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Key Dates & Times	
Call Open	09 May 2023
Online Electronic Submission System Open	29 May 2023 @ 15:00 (IST, UTC+01:00)
Application Closing Dates Pre-proposals Full proposals	 21 July 2023 @11:00 (IST, UTC+01:00) 15 December 2023 @11:00 (GMT)

Applications must be completed and submitted through the PT-Outline Electronic Submission System: https://ptoutline.eu/app/transcan2023*, and this system will close automatically at the stated deadline and timeline listed above.*

This document provides additional guidance to researchers based in Ireland applying to this call as part of a transnational consortium. A summary of the call is presented herein along with eligibility criteria for Irish applicants requesting HRB funding.

This document must be read in conjunction with the call documents provided on the main TRANSCAN-3 JTC 2023 webpage, and the HRB FAQ for this call on the HRB call website.

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1 Introduction

The Health Research Board (HRB) Strategy (2021-2025)[1] sets out a lead role of the HRB to invest in research that delivers value for health, the health system, society, and the economy, as well as to foster and enhance European and international coordination, collaboration, and engagement.

In the last decades the understanding of the molecular mechanisms responsible for cancer development and progression has significantly improved. In particular, a lot of progress has been made regarding the genetics of cancer that has led to the discovery and implementation into the clinic of numerous treatments as well as many biomarkers to improve screening, diagnosis and prognosis of cancers, leading to an increase in survival and improvement in the quality of life of cancer patients.

Despite these significant advancements, there is still much to be learned about cancer. It is commonly accepted now that cancers are as much epigenetic as they are genetic diseases. It remains to be understood to what extent these epigenetic alterations influence the development of a cancer and what their importance in tumour growth is.

Epigenetic changes can be observed between healthy and cancerous cells. Large-scale cancer epi/genome sequencing efforts have currently revealed a very large number of epigenetic marks and genetic alterations in cancer cells and tissues. They may have clinical utility as potential tumour biomarkers to help identify specific cells and target the cell of origin of a given tumour or classify tumour type. Epigenetics thus represents an important tool for the improvement of early detection and the prediction of the disease. Epigenetics and epigenomics therefore have significant potential for clinical application as they can help clinicians diagnose certain types of tumours and could help determine the efficacy of treatments.

Treatment targeting epigenetics is becoming an attractive and promising strategy for anticancer therapy. Indeed, unlike genetic alterations, which are irreversible, epigenetic modifications are reversible. This field of research thus offers great opportunity for new therapeutic approaches and has paved the way for the development of new therapeutic compounds, so-called epidrugs. Some new drugs directed at epigenetic modulators have already been developed and are available.

However, apart from a few cases, the clinical applications of epidrugs, alone or in combination with radiotherapy, chemotherapy or immunotherapy, are still far from common practice, particularly for solid tumours. It is therefore necessary to translate the fundamental knowledge of this emerging field into concrete clinical applications.

Considering this background, the TRANSCAN-3 partners have agreed to focus their third Joint Transnational Call for proposals (JTC 2023) on:

“Translational research on cancer epigenetics”

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 previous grounds, it is timely and relevant to focus its funding on this topic.

2 Aim and Objectives

The expected outcome of the call is to improve the efficacy of current detection, diagnosis, prognosis and treatment of cancers, through the development of novel approaches based on a better understanding of cancer epigenetics. The specific objectives of this funding opportunity are to stimulate new partnerships between researchers and clinicians and support original, high-quality projects, with significant clinical impact.

In the context of translational research, this topic will comprise two general aims, each with several specific aims, which align with the possible clinical applications. Proposals should cover one or several of the specific aims listed below and should be built from a sound hypothesis.

Aim 1) The role of epigenetics in cancer initiation and progression. These studies may aim to validate novel epigenetics-based biomarkers to improve detection, diagnosis, prognosis of cancers or response to therapies (using recently developed innovative approaches, multiomic approaches, single-cell analysis, patient-derived organoids, patient-derived xenografts, tumour samples collected from retrospective and/or prospective cohorts of patients or clinical trials).

- Specific aim 1.1: To understand cancer initiation and progression by characterisation of the epigenetic landscape.
- Specific aim 1.2: To define epigenetic features of cells in the tumour microenvironment that may promote tumour progression (e.g., immune cells, vascular cells, microbiota).
- Specific aim 1.3: To study the role of epigenetic modifications as predictors of cell persistence or treatment resistance.
- Specific aim 1.4: To validate epigenetic markers useful to improve early detection and diagnosis by exploring the correlation between epigenetics and clinical cancer manifestation.

Aim 2) Validation of new epigenetics-based therapeutic strategies to limit cancer progression, prevent relapse/recurrence or increase the efficiency or reduce toxicity of existing anti-cancer therapies.

- Specific aim 2.1: To validate novel therapeutic targets (novel targets should be evaluated in translational studies with regard to their impact on treatment efficacy, safety and patient reported outcomes).

- Specific aim 2.2: To study the potential use of epigenetic modulators to overcome resistance to anti-cancer therapies.

- Specific aim 2.3: **(Note that Irish partners are not eligible for funding to cover this activity.)** To develop novel epidrugs/therapeutic approaches, through phase I and II clinical trials (investigating combinations of available treatments, new therapeutics, new administration schemes, etc.) to improve safety and efficacy of treatments (objective responses; patient reported outcomes regarding morbidity and quality of life; …).

- Specific aim 2.4: To develop novel theranostic approaches involving epigenetics of cancer. Approaches combining diagnostic (imaging technics) and targeted treatment to detect cancer

cells and assess treatment efficacy (radionuclide, radiopharmaceuticals, nanoparticles, nanomaterial, …).

Particular attention should be given to gender balance inclusion in order to intercept sex/gender differences and to consider the role of these differences in the addressed questions.

3 Scope of Call

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

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.

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 2023.

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): exchanges/mobility of investigators (especially young investigators) between teams and countries participating in the project; short term training of scientists, operational staff, etc.; training through technical workshops dedicated to relevant aspects of the scientific work planned in the project; short training (one or few weeks) of several partner teams by one expert. Activities related to the dissemination of results such as hosting a symposium, conferences etc. are out of the scope of this capacity building component.

3.1 Excluded approaches and topics

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.

In addition to the exclusions above, Irish Partner(s) are not eligible for HRB funding for:

The following research areas are **explicitly out of scope** and **will not be supported** under this call:

- Aim 2.3: To develop novel epidrugs/therapeutic approaches, through phase I and II clinical trials (investigating combinations of available treatments, new therapeutics, new administration schemes, etc.) to improve safety and efficacy of treatments (objective responses; patient reported outcomes regarding morbidity and quality of life; …).
- Proposals seeking to evaluate a pilot or feasibility study[1].
- Proposals seeking to evaluate a definitive intervention[2].
- Proposals involving basic biomedical research.
- Research intended to create human embryos solely for the purposes of research or for the purposes of stem cell procurement, including by means of somatic cell nuclear transfer.

Where an application is outside the scope of the scheme, the application will be deemed ineligible and will not be accepted for review.

[1] **Feasibility studies:** For the purposes of this scheme, we adopt the concept of feasibility as described by Eldridge et al (2016). Eldridge describes 'feasibility' as an overarching concept, within which we distinguish between three distinct types of studies (1) randomised pilot studies (2) non-randomised pilot studies and (3) feasibility studies that are not pilot studies.

[2] **Definitive interventions: Intervention studies** of any appropriate design, including randomised controlled trials and non-randomised trials, are designed to assess the efficacy, effectiveness, cost and broad impact of a therapy or intervention. Interventions can be on individual human participants (patients or healthy volunteers), or alternatively could involve an intervention on an element of the health system, e.g. testing an intervention on healthcare setting, healthcare pathway, with the aim being to improve how healthcare is delivered. **Definitive interventions** have potential for immediate use for decision makers in everyday clinical practice or policy, have supporting feasibility information, and have a basis in evidence that has been synthesised systematically.

4 Funding Available, Duration and Start Date

Please note: Project partners will be funded by their relevant national/regional funding organisations. **Eligible costs and funding rules may vary** between the respective funding organisations (see Annex 3 of the core call text).

For applicants based in Ireland, the HRB plans to commit in the region of up to **€370,000** (inclusive of overheads) to the TRANSCAN JTC2023 awards. Additional funding of up to €130,000 will be made available for coordination activities (excludes equipment and consumables), bringing the total maximum funding to **€500,000 for applicants who take on the role of coordinator**. Quality permitting a minimum of one award will be funded. Awards will have a duration of 36 months.

The award will offer research related costs for:

a) Personnel
    a. Salary-related costs in line with the IUA most recent scale for funded personnel
    b. Stipends and fees (EU rate only)
b) Small equipment costs (not expected to exceed €10k)
c) Direct running costs (including travel, mobility costs, patient-related costs
d) FAIR data management costs: Data stewardship costs (e.g., service/fees from data steward, access to secondary data, costs of making data FAIR, etc). Please refer to Appendix I for additional guidance on FAIR data management costings.
e) Dissemination and knowledge exchange activities (including dissemination-related travel)
f) Overheads contribution

Please refer to Appendix I below for further guidance on costs.

Funding available is inclusive of overheads and pension contributions.

Note: The TRANSCAN JTC 2023 award will not fund the salary and related costs of tenured academic staff within research institutions (including buy-out from teaching time etc.).

The budget requested and the award duration **must** reflect the scale and nature of the proposed research, and reviewers will assess the level of funds and timeframe requested when reviewing the application.

Projects are expected to start from September 2024. Please refer to the call timeline on page 1 of these guidance notes for further information.

5 Eligibility Criteria

This call is not open for Host Institutions in Northern Ireland.

Please also refer to Section 3 for excluded approaches and topics. All Annexes referenced herein can be found in the main TRANSCAN-3 JTC 2023 call text.

Please note that **additional conditions might apply at national level** (see Annex I of the core Guidelines for applicants document).

5.1 Consortium Composition

Only transnational projects will be funded. **There is a partner search tool available for this call:** https://partfinder.ncbr.gov.pl/

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 of the core call text. Note that Irish partners must be based in a HRB Host Institution (see sections 5.1.1 and 6 for further information).

- 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.

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

- 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.
- Each consortium must involve a **minimum of three (3) and a maximum of six (6) partners (including the project coordinator) eligible for funding**.
- 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 four (4), coming from three (3) different countries).
- The maximum number of partners may be increased to seven (7):
    - if the consortium includes one partner from the following participating countries: Hungary, Latvia, Slovakia and Turkey.
    - as a consequence of the widening process aimed at including one team from underrepresented countries/regions, as detailed in Section 10 of the main call text.
- Partners not eligible for funding by one of the organisations participating in the JTC2023 (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.
- 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.

5.1.1 Applicants based in Ireland

Note that HRB use the terms 'Lead Applicant' and 'Co-Applicant' (where applicable) to refer to a coordinator or partner applying for HRB funding. See below for the distinction between these roles.

Lead Applicants

The following will apply to partners seeking HRB funding – i.e., Lead Applicants based in Ireland.[3] The **Lead Applicant** will serve as the primary point of contact for the HRB during the review process and on the award, if successful. The Lead Applicant will be responsible for the scientific and technical direction of the Irish research programme. They have primary fiduciary responsibility and accountability for carrying out the research within the funding limits awarded and in accordance with the terms and conditions of the HRB. Where more than one Irish partner exists, the Lead Applicant is the partner who will coordinate the Irish budget.

Note that, where an Irish coordinator exists, this person **must** be nominated as the Lead Applicant.

Co-Applicants

A second Irish partner (named co-applicant) may be located at a different eligible Irish Research Institution than the Lead Applicant. In this case, the grant will be administered through the Research Institution of the Lead Applicant only – i.e., HRB will contract only with the Lead Applicant who must distribute the funds appropriately (via collaboration and/or consortium agreements). Note that, if research teams are based in more than one institution, they must be entered as separate partners for the purposes of this call.

All Applicants based in Ireland **must**:

Hold a post (permanent or a contract that covers the duration of the award) in a HRB recognised Host Institution in the Republic of Ireland (the "Host Institution") as an independent investigator. For clinicians, an adjunct position in a HRB recognised Host Institution is acceptable (an accompanying letter of support is required in these cases, as well as in the case of contract positions – see Section 6 below).

OR

Be an individual who will be recognised by the Host Institution upon receipt of an award as an independent investigator who will have a dedicated office and research space for the duration of award, for which they will be fully responsible (an accompanying letter of support is required in

[3] In view of the overwhelming evidence that both active and passive smoking of tobacco are injurious to health, the HRB is unwilling to fund applications from individuals applying for, holding, or employed under a research grant from the tobacco industry.

these cases – see Section 6 below). Applicants do not necessarily need to be employed by the Host Institution at the time of the application submission.

They **must** show evidence of achievement as an independent researcher in their chosen research field by:

a) Demonstrating a record of research output, with at least three publications of original research in peer reviewed journals. Where appropriate, they should also provide evidence of other outputs (e.g., published book chapters, reports to government, research data and datasets, research materials, databases, audio/video products, national and/or international reports, patents, models and protocols, software production, evidence of influence on health policy and practice, outreach and/or knowledge exchange activities, media coverage or other relevant activities) and/or any other relevant outputs that have resulted in a significant impact in their field.

b) Demonstrating record of independence by showing that they have secured at least one peer-reviewed research grant for a research project/s, as either the Lead Applicant or a Co-Applicant. Funding received for travel to seminars/conferences and/or small personal bursaries will not be considered in this regard.

c) Show evidence that they possess the capability and authority to manage and supervise the research team.

Each applicant can submit only one application as coordinator but can be involved in multiple proposals as partner.

Applicants must demonstrate that they meet the eligibility criteria by 1) including the relevant information in the application form (CV) or 2) by submitting additional documentation via email (eujointprogrammes@hrb.ie) to the HRB in advance of call submission deadline.

Where an applicant fails to meet the eligibility criteria, the application will be deemed ineligible and will not be accepted for review. The Joint Call Secretariat will contact the consortium in the event that this situation arises.

6 Host Institution

A HRB Host Institution is a research performing organisation that is approved by the HRB for the purpose of receiving and administering HRB grant funding and is responsible for compliance with all general and specific terms and conditions of awards. HRB Host Institution status is a requirement to submit an application under all HRB award schemes. The **Host Institution for the award** is that of the **Lead Applicant** based in Ireland. In order to be eligible to apply for funding, an Institution must be an approved HRB Host Institution no later than two calendar months before the closing date of a call. A list of currently approved HRB Host Institutions and information on the application process for research performing organisations to be approved as HRB Host Institutions can be found on the HRB website[4].

[4] http://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-approval-of-host-institutions/

Please note that this call is not open to HIs from Northern Ireland.

Host Institution Letters of Support must be provided for **(1) all Lead Applicants in a contract position and (2) Adjunct Professors not directly employed by the HI.** These must be emailed to eujointprogrammes@hrb.ie before the pre-proposal submission deadline. The formal letter on headed notepaper, dated and signed by the Head of School/Research Centre/Hospital must include the following information:

- Case (1): [*Host Institution - insert name*] which is the host institution of [*applicant - insert name*] confirms that [*applicant - insert name*]: (i) holds an employment contract which extends until [*insert date*] or will be recognized by the host institution upon receipt of the HRB [scheme] award as a contract researcher; (ii) has an independent office and research space/facilities for which they are fully responsible for at least the duration of the award, and (iii) has the capability and authority to mentor and supervise the research team.
- Case (2): [*Host Institution - insert name*] confirms that [*applicant - insert name*] has the authority and resources allocated to hold and manage a grant under their Adjunct status for at least the duration of the award.

7 Application, Review Process and Assessment Criteria

7.1 Application

There will be a two-stage application procedure for joined applications. One joint proposal document (in English) shall be prepared by the partners and must be submitted by the Coordinator in electronic format no later than 11:00 (IST, UTC+01:00) on 21st July 2023 via the electronic proposal submission system: https://ptoutline.eu/app/transcan2023 **No other means of submission will be accepted.**

For further details, please refer to the respective submission forms available through the TRANSCAN-3 JTC 2023 website. If you need additional information, please contact the Joint Call Secretariat (JCS). Please refer also to HRB Grant Policies.

Applicants based in Ireland will be required to provide additional information to the HRB at the time of submission of full proposals. This will include justification for their requested budget, and clarification on deliverables assigned to each partner from Ireland. Templates requesting this information will be provided by the HRB after an invitation to submit a full proposal, or upon request. Each partner based in Ireland must provide a budget that has been reviewed and approved by their host institution.

7.2 Review Process

There are four steps of review:

1. **Formal check of proposals:** Conducted against call criteria and national/regional funding organisations regulations. Coordinators of non-eligible pre-proposals will be informed by the JCS accordingly.
2. **Evaluation of pre-proposals:** Eligible pre-proposals will be reviewed by the SEC panel. Successful applicants will be invited by the JCS to submit a full proposal.

3. **Eligibility Check of Full Proposal and second step of evaluation:** Eligibility check performed by the JCS. Each full proposal then allocated to at least three reviewers. Ranking list of the full proposals recommended for funding will be established at SEC meeting.
4. **Funding Decision:** 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, taking into account other priorities (listed in section 13 of the core call text) and maximising use of the available budget.

For full details please refer to the core call text.

7.3 Assessment Criteria

The number of participants and their research contribution should be appropriate for the aims of the transnational research and innovation project and be reasonably balanced in terms of international participation. Each transnational collaborative project should represent the critical mass to achieve ambitious scientific goals and should clearly demonstrate an added value from working together.

Proposals are assessed for scope and provided a mark (from 0–5) for each criterion of excellence, impact and implementation 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 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.

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

8 Timeframe

Date	
09 May 2023	Publication of the call
29 May 2023 at 15:00 (IST, UTC+01:00))	Opening of the online submission system for pre-proposals
21 July 2023 at 11:00 (IST, UTC+01:00)	Deadline for pre-proposal submission
27 October 2023	Communication of the results of the pre-proposal assessment and invitation for full-proposal stage
13 November 2023	Opening of the submission system for full proposals
15 December 2023 at 11:00 (GMT)	Deadline for full-proposal submission
Expected for May 2024	Communication of the funding decisions to the applicants
September 2024	Expected project start (subject to regional/national procedures)

9 Contacts

For further information on the TRANSCAN-3 JTC 2023 call for "translational research on cancer epigenetics" contact:

For general information, please contact the Joint Call Secretariat (JCS):

French National Cancer Institute, France

E-mail: transcan-JTC2023@institutcancer.fr

For country-specific information for Irish Partners, please contact the HRB, Ireland:

Dr Chiara Mizzoni
Email: eujointprogrammes@hrb.ie

Appendix I: HRB Funding Policies and Procedures

Access and support from research infrastructures

Applications availing of the advice, research design, data management services and/or other forms of support from a Clinical Research Facility/Centre (CRF/CRC), other infrastructure (e.g., Centre for Applied Medical Imaging, CAMI, Centre for Support and Training in Analysis and Research (CSTAR), HRB Trials Methodology Research Network (HRB-TMRN), Cancer Groups, National clinical trials office (NCTO), CTNs or a biobank) are required to provide additional information detailing the scope and nature of the engagement (this includes national and international facilities, Units, and networks where justified).

An Infrastructure Agreement form will be requested as part of the application addressing the nature/scope of the service or collaboration, the rationale behind the choice of facility/centre/network and any costs associated with the project (including those provided as in-kind contributions). Applications proposing research with patients which do not detail advice and/or support from a CRF/CRC/CTU will be asked to justify why they have not done so.

Public and Patient Involvement (PPI) in Research

The HRB promotes the active involvement of members of the public and patients in the research that we fund[5]. Public and patient involvement in research means that the public and patients are involved in planning and doing research from start to finish and help tell the public about the results of research. PPI, as defined here, is distinct from and additional to activities which raise awareness, share knowledge, and create a dialogue with the public, and it is also distinct from recruitment of patients/members of the public as participants in research.

PPI represents an active partnership between members of the public and patients and researchers in the research process. This can include, for example, involvement in the selection of research topics, assisting in the design, advising throughout or at specific decision points of the research project or in carrying out the research.

PPI contributors should be actively involved and part of decision making. Involving members of the public in research can improve quality and relevance of research. It can:

- Provide a different perspective - even if you are an expert in your field, your knowledge and experience will be different to the experience of someone who is using the service or living with a health condition.
- Help to ensure that the research uses outcomes that are important to the public.
- Identify a wider set of research topics than if health or social care professionals had worked alone.
- Make the language and content of information such as questionnaires and information leaflets clear and accessible.

[5] https://www.hrb.ie/funding/funding-schemes/public-and-patient-involvement-in-research/

- Help to ensure that the methods proposed for the study are acceptable and sensitive to the situations of potential research participants.
- Help you increase participation in your research by making it more acceptable to potential participants.

In addition to improving relevance and quality of research, it ensures that research is influenced by broader principles of citizenship, accountability, and transparency. PPI is an ethos as well as a practice. It should be context-specific and should aim to ensure that all voices are heard. Where members of the public or patients are involved, they must be compensated for their time and contributions.

In the application, you are asked to describe any public involvement in your research throughout the various stages of identifying and prioritising the research question, the research design, conduct, analysis, and dissemination. We recognise that the nature and extent of active public involvement is likely to vary depending on the context of each study or award. PPI contributors should be named as Co-applicants where justified by their level of involvement.

For guidance and support on PPI in your research please consult with the PPI Ignite Network Ireland or your Host Institution. The PPI Ignite Network Ireland has offices located in the following seven Host Institutions: DCU, NUIG, RCSI, TCD, UCC, UCD, UL.

FAIR Data Management and Stewardship

Data management/stewardship plans (DMP) are nowadays widely accepted as part of good research practice. The HRB support open research[6] and open publishing directly through the HRB Open Research platform[7]. The HRB is driving the making of research data **FAIR** (**F**indable, **A**ccessible, **I**nteroperable and **R**e-usable) in order to benefit science by increasing the re-use of data and by promoting transparency and accountability.

FAIR data principles[8] provide a guideline for those wishing to enhance the re-usability of their data holdings: these principles put specific emphasis on enhancing the ability of machines to automatically find and use the data, in addition to supporting its re-use by individuals. For researchers, the move to FAIR and open data, where applicable, means researchers should consider data management issues and find suitable data repositories at the research planning stage. Applicants will have to provide information about their plans for data management and data sharing at application stage.

In line with the HRB's policy on management and sharing of research data[9], all successful applicants are required to submit a completed data management plan (DMP) to the HRB on or before three months after the award start date, and a final updated version of the DMP with the last annual report.

[6] http://www.hrb.ie/funding/policies-and-principles/open-research/

[7] https://hrbopenresearch.org/

[8] https://www.nature.com/articles/sdata201618

[9] https://www.hrb.ie/fileadmin/user_upload/HRB_Policy_on_sharing_of_research_data.pdf

The DMP will need to be submitted alongside a certification of completion from the designated representative(s) within the Host Institution.

Applicants will have to provide an outline of their plans for data management and data sharing in the application inclusive of the costs associated to the plan.

The timing for completion and submission of the DMPs must be also included among the objectives and deliverables of the programme.

General Data Protection Regulation

By submitting an application to the call, applicants consent to the use, processing and retention of their data, in line with the above notice and for the purposes of:

- processing and evaluating the application where processing shall be lawful -only if and to the extent that processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;
- administering any subsequent funding award;
- managing the Funding Party's relationship with them;
- analysing and evaluating the call;
- providing aggregate data to regional/national and European surveys and analyses;
- complying with audits that may be initiated by the funding organisations.

The members[10] of the ERA-NET TRANSCAN-3 consortium may share an applicant's data with third parties (some of which may be based outside the European Economic Area) in relation to the above activities including evaluators, auditors and the European Commission (or its agencies).

The members of the ERA-NET TRANSCAN-3 consortium may link the data that applicants provide in the application with regional/national, bibliographic or external research funding data which is available through public subscription-based databases (e.g. Scopus, Web of Science, etc.) or other regional/national/open datasets.

The members of the ERA-NET TRANSCAN-3 consortium may also link the data that applicants provide in their application with future data that applicants provide as part of the ongoing management and reporting.

Data on Funding Parties including contact details of CSC members are kept for the purpose of the call communication. The information will be published with prior consent of the respective management bodies.

Use of personal data by HRB

By participating in this call, you agree to the use of the information you provide (regarding all applicant team members) for HRB to consider your application, contact you about your application,

[10] Canada (CIHR) will not share applicant's data with third parties.

and if you are successful, to manage your grant throughout its lifetime in accordance with HRB general T&C for research awards.

This will include contacting you with regard to monitoring of progress through written reporting and other means e.g., interim review. We will publish some basic information on successful awards including PI, Host Institution, amount awarded and lay summary on our website and may highlight individual awards or researchers in more detail (with specific consent). We will also use the information you have provided to generate general statistics around our current funding portfolio, and to evaluate our funding mechanisms and investment. After your grant has ended, we will continue to keep your information on file (in accordance with HRB policies) to allow us to evaluate the outcomes, outputs and impacts of HRB investment in your research.

Please note that we will also use information associated with *unsuccessful* applications for a number of the purposes outlined above such as generating general statistics around our current funding portfolio, and to evaluate our funding mechanisms and investment e.g., demographics of applicants, research areas of applicants. Similarly, we will use the information provided about people employed on awards to help evaluate our career support and capacity building initiatives.

The Health Research Regulations

Following the implementation of GDPR, a regulation for health research known as the Health Research Regulations 2018 (S.I. 314) has been implemented, with further amendments made in 2019 (S.I. 188) and 2021 (S.I. 18)[11]. These regulations outline the mandatory suitable and specific measures for the processing of personal data for the purposes of health research. They further set out that explicit consent is a mandatory safeguard that must be obtained from individuals when using their personal data for health research. Where it is not feasible to obtain explicit consent, an application for a consent declaration can be made to the Health Research Consent Declaration Committee[12].

Research on Research

The HRB is developing its approach to research on research (RoR) with the aim of enhancing the evidence base for HRB research funding practices. We may also collaborate with researchers on request regarding specific RoR questions. Should your application become of interest to such a study, the HRB will seek your consent for the use of your information.

[11] http://www.irishstatutebook.ie/eli/2021/si/18/made/en/pdf

[12] https://hrcdc.ie/

Privacy Policy and Retention Policy

To understand why we collect the information we collect and what we do with that information, please see our Privacy[13] and Retention Policies[14].

Declaration on Research Assessment

As signatory of the DORA Declaration[15], the HRB is committed to supporting a research environment where importance is placed on the intrinsic value and relevance of research and its potential impact in society (HRB - Declaration on Research Assessment).

Additional guidance on Costs

Personnel costs	**Must be listed for each salaried personnel under each of the following subheadings (a-c):**
a) Salary	Gross Annual Salary (negotiated and agreed with host institution). Applicants should use the IUA Researcher Salary Scales. Applicants are advised that public sector pay increases to October 2023 (inclusive) have been agreed. Please apply a salary contingency of 3% per annum from 1st October 2024. Please note this contingency should be applied cumulatively on 1st October year on year. Applicants should include annual pay increments for staff and related costs (pension contribution, employer's PRSI contribution, and overhead contribution) in the budget. Note: The HRB does not provide funding for the salary or benefits of academic staff within research institutions that are already in receipt of salary or benefits. The HRB does not provide salary or buy out time for collaborators
b) Employer's PRSI	Employer's PRSI contribution is calculated at 11.05% of gross salary.
c) Employer Pension Contribution	Pension provision up to a maximum of 20% of gross salary will be paid to the Host Institution to enable compliance with the Employment Control Framework (an additional 5% employee contribution is part of the salary). The level of employer contribution should be in accordance with the model adopted by the Host Institution. If applicable, state the amount of employer contribution based on the pro rata salary and note the % of pro rata salary used to calculate this for reference.

[13] https://www.hrb.ie/about/legal/privacy-policy/

[14] https://www.hrb.ie/fileadmin/user_upload/HRB_Document_retention_policy..docx

[15] Home | DORA (sfdora.org)

	Exceptions apply where Circular letter 6/2007 applies.[16]
Running Costs	For all costs required to carry out the research including materials and consumables, survey costs, travel for participants, transcription costs, etc. Please consult with your Host Institution in relation to trial-related insurance costs. Access to necessary special facilities or services which are not available in the host academic or clinical institutions. i.e., consultancy fees, methodological support, MRI facilities etc. will be considered under running costs as long as they are detailed in an accompanying 'Infrastructure Agreement Form'. Costs associated with compensating PPI contributors involved in your research e.g., consultation workshops, time spent reviewing material, costs of participation in advisory groups, travel expenses, payments for time (in line with your Host institutions policies), etc. should be charged to running costs. Note: Please see a list of costs that fall within the overhead contribution below and which should not be listed under running costs.
Equipment	Funding for suitably justified equipment can be included in this section. We do not expect equipment costs in excess of €10,000. Personal/Stand-alone computers will not be funded as these are considered a standard piece of office equipment, i.e., overhead. Dedicated laptops or similar equipment that is required specifically for the project because of the nature of the research, will be considered where appropriately justified. All costs must be inclusive of VAT, where applicable.
Dissemination Costs	Costs associated with publication of results, seminar/conference attendance (provide details of name and location, where possible) and any other means of communicating/reporting research outcomes as detailed in the dissemination and knowledge exchange plan, as well as costs related to data sharing. Please refer to the HRB policy on Open Access to Published Research[17]. Please list dissemination costs under the following categories: publications, conferences, other activities (expanded as necessary). Publications: The HRB contribution towards publication costs is €1,750/per article or HRB Open Research: rapid open peer reviewed and open access platform for all research outputs, with all publication charges covered

[16] Circular Letter 6/2007 states that the pensions contribution of all Public Health Service employees who, on or after 1 June 2007, are granted secondments or periods of special leave with pay to enable them take up appointments with other organisations, including other Public Health Sector organisations, will be increased to 25% of gross pensionable pay. The rate of 25% of gross pensionable pay referred to in this context is the pension contributions to be paid by the body to which the employee is seconded – it does not include any pension contributions which employees make themselves. Where no such arrangements are in place, the HRB will not be liable for costs.

[17] http://www.hrb.ie/research-strategy-funding/policies-and-guidelines/policies/open-access/

	centrally by the HRB at no expense to the grantee. (www.hrbopenresearch.org) free of charge. Conferences: The HRB contribution to conference costs is €500/year for a national conference and €1,500/year for an international conference.
FAIR Data Management Costs	Costs related to data-related and data management activities in line with best practice of data management and stewardship and the FAIR principles incurred during the lifetime of the project. Please see table below for further guidance.
Overhead Contribution	In accordance with the HRB Policy on Overhead Usage[18], the HRB will contribute to the indirect costs of the research through an overhead payment of 30% of Total Direct Modified Costs (**TDMC excludes student fees, equipment, and capital building costs**) for laboratory or clinically based research and 25% of Total Direct Modified Costs for desk-based research. The following items are included in the overhead contribution: recruitment costs, bench fees, office space, software, contribution to gases, bacteriological media preparation fees, waste fees, bioinformatics access. Therefore, these should not be included in the budget as direct costs.

Additional guidance on FAIR Data Management Costs

People	Staff time per hour for data collection, data anonymisation, etc
	Staff time per hour for data management/stewardship support, training, etc
Storage and computation	Cloud storage, domain hosting charge
Data access	Secondary data access, costs for preparing data for sharing (e.g. anonymisation)
Deposition and reuse	Costs for depositing research data and metadata in an open access data repository
	Defining semantic models, making data linkable, choosing the licence, defining metadata for dataset, deploying/publishing
Others	Please provide explanations.
Notes	*The HRB is currently not covering the cost of long-term preservation of data*
	This list is not exhaustive and aims to provide examples only of eligible costs

[18] http://www.hrb.ie/funding/funding-schemes/before-you-apply/all-grant-policies/hrb-policy-on-usage-of-research-overheads/

Appendix II: Resources/Useful Links

REPORTING

COMET (Core Outcome Measures in Effectiveness Trials) Initiative: development and application of agreed standardised sets of outcomes, known as 'core outcome sets'

http://www.comet-initiative.org/

EQUATOR Network Library for health research reporting: an international initiative that seeks to improve reliability and value of health research literature by promoting transparent and accurate reporting of research studies

https://www.equator-network.org/library/

Registry of Research Data Repositories

http://www.re3data.org/

Zenodo Data Repository (OpenAIR)

https://zenodo.org/about

https://zenodo.org/

EVIDENCE SYNTHESIS

Evidence Synthesis Ireland: aims to build evidence synthesis knowledge, awareness and capacity among the public, health care institutions and policymakers, clinicians, and researchers on the Island of Ireland.

https://evidencesynthesisireland.ie/

The Cochrane Library: online collection of databases in medicine and other healthcare specialties which summarise and interpret the results of medical research.

www.thecochranelibrary.com

The Campbell Collaboration: promotes positive social and economic change through the production and use of systematic reviews and other evidence synthesis for evidence-based policy and practice.

https://www.campbellcollaboration.org/

The Campbell Collaboration UK & Ireland: hub at Queens University Belfast.

https://www.qub.ac.uk/research-centres/CampbellUKIreland/

EQUATOR Network Library for health research reporting: an international initiative that seeks to improve reliability and value of health research literature by promoting transparent and accurate reporting of research studies.

http://www.equator-network.org/resource-centre/library-of-health-research-reporting/

BIOBANKING

Council of Europe Recommendation of the Committee of Ministers to member States on research on biological materials of human origin (2016)

https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168064e8ff

BBMRI-ERIC is a European research infrastructure for biobanking

https://www.bbmri-eric.eu/

OECD Guidelines on Human Biobanks and Genetic Research Databases

http://www.oecd.org/science/biotech/44054609.pdf

ISBER Best Practices for Repositories

https://www.isber.org/page/BPR

Molecular Medicine Ireland Biobanking Guidelines

http://www.molecularmedicineireland.ie/resources/biobanking-guidelines/

NCI Best Practices for Biospecimen Resources (2016 version)

https://biospecimens.cancer.gov/bestpractices/2016-NCIBestPractices.pdf

PUBLIC AND PATIENT INVOLVEMENT IN RESEARCH & RESEARCH PRIORITIES

The National PPI Ignite Network https://ppinetwork.ie/

NIHR PPI resources

https://www.nihr.ac.uk/documents/ppi-patient-and-public-involvement-resources-for-applicants-to-nihr-research-programmes/23437

Patient-Centred Outcomes Research Institute (PCORI)

http://www.pcori.org

Public Involvement Impact Assessment Framework: Provides tools for successful involvement of members of the public in research projects and for assessment of impacts.

http://piiaf.org.uk/

NIHR Payment guidance for researchers and professionals

https://www.nihr.ac.uk/documents/payment-guidance-for-researchers-and-professionals/27392

European Patient Forum Value + Handbook: For Project Co-ordinators, Leaders and Promoters on Meaningful Patient Involvement.

http://www.eu-patient.eu/globalassets/projects/valueplus/doc_epf_handbook.pdf

The James Lind Alliance Priority Setting Partnerships: Research priorities in disease areas set jointly by patients, clinicians, and researchers.

http://www.jla.nihr.ac.uk/

Campus Engage: Supporting Irish HEIs to embed civic engagement in their work. Includes resources, how-to-guides, and case studies for engaged research.

http://www.campusengage.ie/what-we-do/publications/

UK Standards for Public Involvement: The six UK Standards for Public Involvement provide clear, concise statements of effective public involvement against which improvement can be assessed.

https://sites.google.com/nihr.ac.uk/pi-standards/home

The Involvement Matrix: A tool for researchers/project leaders to promote collaboration with patients in projects and research.

https://www.kcrutrecht.nl/involvement-matrix/

USE OF ANIMALS IN RESEARCH

Experimental Design Assistant (EDA) (online tool for design of animal experiments)

https://www.nc3rs.org.uk/experimental-design-assistant-eda

ARRIVE (Animal Research: Reporting of In Vivo Experiments) guidelines

https://www.nc3rs.org.uk/arrive-guidelines

SYRCLE (Systematic review of animal studies, register 2014-2017)

https://www.radboudumc.nl/en/research/departments/health-evidence/systematic-review-center-for-laboratory-animal-experimentation

PROSPERO (Register for systematic reviews including animal studies 2018)

https://www.crd.york.ac.uk/PROSPERO/

GENDER AND/OR SEX ISSUES IN RESEARCH

Examples of case studies in Health & Medicine where gender/sex in research matters

http://genderedinnovations.stanford.edu/case-studies-medicine.html

Gender Toolkit in EU-funded research for examples and guidance

http://www.yellowwindow.be/genderinresearch/downloads/YW2009_GenderToolKit_Module1.pdf

Sex/Gender Influences in Health and Disease

https://orwh.od.nih.gov/sex-gender/sexgender-influences-health-and-disease

Methods and Techniques for Integrating Sex into Research

https://orwh.od.nih.gov/sex-gender/methods-techniques-integrating-sex-research

NIH Policy on Sex as a Biological Variable

https://orwh.od.nih.gov/sex-gender/nih-policy-sex-biological-variable

DATA MANAGEMENT AND SHARNG AND FAIR PRINCIPLES

Digital Curation Centre: How to develop a data management and sharing plan and examples DMPs.

http://www.dcc.ac.uk/resources/data-management-plans/guidance-examples

FAIR data principles FORCE 11

https://www.force11.org/fairprinciples

UK Concordat on Open Research Data (July 2016)

https://www.ukri.org/wp-content/uploads/2020/10/UKRI-020920-ConcordatonOpenResearchData.pdf

Guidelines on FAIR data management plans in Horizon 2020

http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf

FAIR at the Dutch centre for Life sciences

https://www.dtls.nl/fair-data/

Registry of Research Data Repositories

http://www.re3data.org/

RESEARCH DATA MANAGEMENT PLANS

Data Stewardship Wizard created by ELIXIR CZ and NL

https://dmp.fairdata.solutions/

DMPonline of the Digital Curation Centre (DCC), UK

https://dmponline.dcc.ac.uk/

DMPTool of University of California Curation Center of the California Digital Library (CDL), USA

https://dmptool.org/

RDMO Research Data Management Organiser of the German Research Foundation, Germany

https://rdmorganiser.github.io/en/

Guidelines on FAIR data management plans in Horizon 2020

http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf

KNOWLEDGE TRANSLATION RESOURCES

Health Service Executive Research & Development Main Page

https://hseresearch.ie/research-dissemination-and-translation/

Health Service Executive Research & Development: Knowledge Translation, Dissemination, and Impact A Practical Guide for Researchers

https://hseresearch.ie/wp-content/uploads/2021/04/Tools-and-templates-.pdf

Integrated Knowledge Translation (iKT) NUI Galway

https://www.nuigalway.ie/hbcrg/ikt/

The Canadian Institutes of Health Research: Guide to Knowledge Translation Planning

https://cihr-irsc.gc.ca/e/45321.html

Training Institute for Dissemination and Implementation Research in Health: Open Access Course

https://cancercontrol.cancer.gov/is/training-education/TIDIRC-open-access

IMPLEMENTATION SCIENCE RESOURCES

Centre for Effective Services

https://www.effectiveservices.org/resources/implementation

UCC Implementation Science Training Institute

https://www.ucc.ie/en/cpd/options/medhealth/cpd1778uccimplementationsciencetraininginstitute/

European Implementation Collaborative

https://implementation.eu/resources/

CO-CREATION RESOURCES

ACCOMPLISSH Guide to impact planning

https://www.accomplissh.eu/publications-and-deliverables

Working together to co-create knowledge: A unique co-creation tool – Carnegie UK Trust

https://www.carnegieuktrust.org.uk/publications/working-together-to-co-create-knowledge-a-unique-co-creation-tool/

INFORMATION ON PERSISTENT IDENTIFIERS

DOI: List of current DOI registration agencies provided by the International DOI Foundation

http://www.doi.org/registration_agencies.html

Handle: Assigning, managing and resolving persistent identifiers for digital objects and other Internet resources provided by the Corporation for National Research Initiatives (CNRI)

http://www.handle.net/

PURL: Persistent Identifiers developed by the Online Computer Library Center (OCLC). Since 2016 hosted by the Internet Archive

https://archive.org/services/purl/

URN: List of all registered namespaces provided by the Internet Assigned Numbers Authority (IANA)

https://www.iana.org/assignments/urn-namespaces/urn-namespaces.xml

DATA REPOSITORIES

Registry of Research Data Repositories

http://www.re3data.org/

Data centers accredited by the German Data forum according to uniform and transparent standards (Germany)

https://www.ratswd.de/forschungsdaten/fdz

Zenodo Data Repository (OpenAIR)

https://zenodo.org/

FAIR/OTHER USEFUL LINKS

Main FAIR Principles

https://www.go-fair.org/fair-principles/

UK Concordat on Open Research Data (July 2016)

http://www.rcuk.ac.uk/documents/documents/concordatopenresearchdata-pdf/

Tool that helps to select and apply a license to a resource, provided by Creative Commons

https://creativecommons.org/choose/