





## Cross-Border Healthcare Intervention Trials in Ireland Network (CHITIN): PRE-ANNOUNCEMENT OF FUNDING CALL

The Cross-Border Healthcare Intervention Trials in Ireland Network (CHITIN) project has been awarded funding through the European Union's (EU's) <u>INTERREG VA Programme</u>, which is managed by the <u>Special EU Programmes Body</u>.

The CHITIN project will implement 10 Healthcare Intervention Trials (HITs) specifically designed to provide opportunities for people living outside of major population centres in Northern Ireland and an 'eligible area' of the Republic of Ireland to participate in research and ultimately enhance their health and social care.

It will also allow the development and expansion of research infrastructure and capability to deliver R&D, thus creating a legacy for the future across the eligible area.

The project partners, the Health and Social Care Research and Development Division (<u>HSC R&D Division</u>) of the Public Health Agency in Northern Ireland and the Health Research Board (<u>HRB</u>) in Ireland, will issue a call for applications for funding of eligible HITs in August 2017.

All HITs must be completed by mid-2021.

To allow potential applicants adequate time to prepare, the partners are now providing the following pre-call information:

Ten HITs will be funded under this call, provided that the required thresholds for quality and eligibility are reached. Thresholds will be assessed through an external peer review and expert panel review process.

HITs are defined as, "Trials that compare different preventive and/or treatment strategies to show the benefits and risks of specific healthcare interventions."

The types of trials could include:

• **Prevention trials** – which test ways to prevent specific health conditions. For example, prevention trials may test lifestyle changes; therapies; education; drugs; vitamins; or other interventions.







• **Treatment trials** – designed to assess ways of managing specific health conditions. For example, these trials may test educational interventions; management approaches; procedures such as surgery or physiotherapy; medical technology and devices; or drugs/combinations of drugs.

• **Screening trials** – which test ways to detect and diagnose health conditions and diseases.

Applications are expected to address one of the following critical areas, which are not mutually exclusive:

| Critical area                                   | Description   |
|---|---|
| Population<br>health                            | New, cross-border area interventions to support<br>positive health and wellbeing and the prevention of ill<br>health including physical activity; medicines<br>management; self-efficacy; self-management and<br>screening. |
| Primary care<br>and older<br>people<br>services | Interventions supporting caring communities and independent living, including a focus on the rural setting.   |
| Mental health                                   | Interventions to promote cross-border mental/emotional resilience and recovery.   |
| Acute services                                  | Trials testing new models of working both in scheduled and unscheduled care streams by better utilising scarce human, physical and financial resources.   |
| Disability<br>services                          | Trials adopting a social equality approach to<br>promoting social inclusion, citizenship and better life<br>outcomes for disabled people and those with a rare<br>disease.  |
| Children's<br>services                          | Trials of early interventions with vulnerable families (focusing on the under-five years of age population).  |





eHealth interventions to improve data management, disease management or diagnosis, to support new models of care delivery or to target behaviour change, are welcome across all of the critical areas.

Where appropriate, proposals should consider data and systems interoperability which will form part of the assessment process.

Each HIT must be performed on a cross-border basis where evidence is gathered in both jurisdictions. Cross-border is defined as:

- Individual participants crossing the border to participate in the HIT; or,
- The same trial, or different arms of the same trial, being carried out on both sides of the border. This may be used as a natural experiment.

The applications must demonstrate alignment with relevant healthcare strategies and policies.

Proposals extending existing trials into the eligible area where they would not otherwise reach are welcome.

Teams should include a mix of partners from the relevant sectors who are based in the eligible area. A mix of experienced and inexperienced partners is encouraged, along with a plan to ensure development and mentorship. Those with limited experience of leading HITs should demonstrate an aspiration to do so as part of their career path.

Applications will be invited for research study grants up to a maximum value of €700,000 and must be completed by 31 July 2021.

Projects must recruit participants in, and have impact within, the eligible area. However, up to 20% of costs may be spent outside of the eligible area, as long as the remaining spend and impacts are made in the eligible area. Spend outside of the eligible area must be fully justified.

The call will <u>not</u> support:

- applications involving basic biomedical research or using cell lines, animals or their tissue;
- applications which are solely literature reviews; audits; surveys; needs assessments; or, technology development, although these elements may be part of an integrated research study;





- applications which are solely or predominately developing the infrastructure for biobanking; databases; or, patient registers without a predominant research element;
- applications which are solely or predominately health service developments or implementation of an intervention without predominant research element;
- the cost of providing the service or intervention itself;
- applications from individuals applying for, holding, or employed under a research grant from the tobacco industry;
- research intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

For applications including clinical studies that fall within the scope of the EU Clinical Trials Directive, the HSC R&D Division and the HRB cannot take on the role of Sponsor.

Plans for appropriate sponsorship arrangements must be included in the application i.e. letters of support must be provided from Sponsors or potential Sponsors.

Where the scientific and strategic merit of an application is outside the scope of the project, the application will be deemed ineligible and will not be accepted for review.

Please contact Dr Julie McCarroll, Programme Manager, HSC R&D Division, at email: <u>Julie.mccarroll@hscni.net</u> or Dr Donna Tedstone, Programme Manager, HRB, at email: <u>DTedstone@hrb.ie</u> for further information.

## NOTES

- €8.8 million has been awarded to HSC R&D Division and HRB for the Cross-Border Healthcare Intervention Trials in Ireland Network (CHITIN) project by the Special EU Programmes Body.
- This total includes match-funding of 15% provided by the Departments of Health in both Northern Ireland and Ireland.
- The Special EU Programmes Body is a North/South Implementation Body sponsored by the Department of Finance in Northern Ireland and the Department of Public Expenditure and Reform in Ireland. It is responsible for managing two EU Structural Funds Programmes, PEACE IV and INTERREG VA which are







designed to enhance cross-border cooperation, promote reconciliation and create a more peaceful and prosperous society.

- The programmes operate within a clearly-defined area including Northern Ireland, the border region of Ireland and in the case of INTERREG VA, Western Scotland. The INTERREG VA Programme has a value of €283 million and aims to address the economic and social problems which result from the existence of borders.
- For the purposes of the CHITIN project, the eligible area consists of Northern Ireland and the border region of Ireland (counties Donegal; Leitrim; Sligo; Cavan; Monaghan; and, Louth).
- Sponsor is defined as an individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study, as laid out in the Research Governance Framework for Health and Social Care.
- All timelines are subject to change.