



International Rare Cancer Initiative (IRCI): *2023 Expression of Interest Information Sheet*

International Rare Cancer Initiative Expression of Interest call 2023 for new rare cancer working groups 2023

Background to IRCI:

IRCI is a joint initiative between Cancer Research UK (CRUK), the National Institute of Health Research, the National Cancer Institute (NCI), the European Organisation for Research and Treatment of Cancer (EORTC), the Institut National Du Cancer (INCa), Clinical Oncology Society of Australia (COSA), Japan Clinical Oncology Group (JCOG) and Canadian Cancer Trials Group.

The aim of this initiative is to facilitate the development of international clinical trials for patients with rare cancers to boost the progress of new treatments for these patients. The initiative hopes to encourage the use of innovative methodologies to maximise the potential for answering research questions and to identify and overcome barriers to international trials to allow international collaborative trials to run smoothly.

IRCI supports the facilitation of several working groups to develop trials in specific rare cancer types, with support and input from the IRCI Board, consisting of arrange of international funding & cross organisational expertise. IRCI is now looking to support a small number of new working groups and is inviting Expressions of Interests from any interested parties.

EOI submission

To submit an EOI to establish a new IRCI rare cancer disease group:

1. Read on page two the *Terms and Conditions* for establishing a new rare cancer working group
2. Complete the EOI form
3. Send EOI form to IRCI@cancer.org.uk by **5th April 2023**.

Your EOI will be shared with the IRCI Board and their countries' respective clinical communities.

Next steps

In Summer 2023 the IRCI Board will assess where there is shared interest to collaborate internationally and where there is scope to deliver a feasible hypothesis driven clinical trial. Feedback will be provided post later in 2023 to advise if your proposed IRCI rare cancer group has been selected to be supported. Please note that IRCI does not directly provide funding for trials and will be providing facilitation and secretariat support only.

Should you wish to discuss further, or if you have any questions, please contact IRCI@cancer.org.uk





Terms and Conditions:

Each IRCI working group adds value to the initiative by aiming to design, develop and deliver an innovative trial in a rare cancer area within three years. An IRCI working group participates in bi-annual virtual meetings and works collaboratively by contributing their clinical knowledge, skills, where possible sharing data, and common approaches to overcome barriers to rare cancer research.

A working group involves two-three group leads, each lead comes from a different country and includes various members who range in discipline, geographic location & skills.

For any new working group applying to the EOI please note that IRCI does not expect them to come in with the group fully set up and the Office can help support you in with setting up of the group and identifying wider membership.

<p>IRCI Group Activity</p>	<p>It is expected that IRCI group meetings and virtual conferences should be supplemented by group activity offline.</p> <p>Group leads are responsible for building the broader group membership and self-managing the groups direction, driving progress to design/set up/deliver trial and to seek funding nationally (IRCI does not provide funding for trials).</p> <p>As part of group discussions IRCI Group/trial leads are responsible for ensuring that a trial is feasible to deliver in the participating countries in a timely manner (in terms of patient numbers, treatment available, and trial design) with consideration of statistical contingency plans if the trial is not approved in a planned country. Groups should also ensure trials developed are acceptable to patients and clinicians in participating countries is in line with anticipated funders’ funding schemes/priorities.</p> <p>The EOI application needs to come from at least two different continents. There needs to be proven international engagement from at least two continents. There needs to be cancers of unmet need.</p> <p>Once established, Group Leads will be requested to provide brief annual updates to the Board to indicate progress and to highlight any challenges encountered.</p>
<p>IRCI Secretary Support</p>	<p>The IRCI secretariat will facilitate virtual meetings to support the group’s discussions – including a face-to-face meeting at ASCO each year.</p> <p>No funding is available to support travel arrangements of IRCI group leads or IRCI group members to attend IRCI meetings. Meetings are planned virtually or potentially alongside conferences at which it is expected your colleagues would already be attending.</p> <p>Support with funder level engagement/alignment, signposting and sharing of best practice.</p> <p>IRCI groups will be facilitated for up to 3 years, at which time it would be anticipated that trial set up would be under way and the future of the group will be discussed by the Board</p>





IRCI Board Support

During future Board meetings there will be a standing 20–30-minute agenda item available as an open session for guidance for developing rare cancer trials for IRCI Working Groups members.

Expression of Interest to form a new IRCI Group 2023: International Rare Cancer Initiative (IRCI)

Important note: Before filling in this Expression of Interest (EOI) form please ensure that you have read and understood the eligibility criteria and group expectations which can be found in the information sheet. Your EOI will be shared with the IRCI Board of Directors and their countries' respective clinical communities.

- Please complete this form and send to IRCI@cancer.org.uk (Two-three pages maximum please) by the deadline of **5th April 2023**.

If you have any queries about this, please do get in touch with us by emailing us IRCI@cancer.org.uk

SECTION 1

PROPOSER:

Lead Applicant Name	
Main Institution	
Country	
Email	

INTERNATIONAL CO-APPLICANTS:

International Applicant(s) Name(s)	
Main Institution	
Country	
Email	
Telephone	

(Please copy and paste this box as appropriate for additional international co-applicants)

RARE CANCER POPULATION TO BE STUDIED

As a guide, cancers with a total incidence of between 2-6/100,000/year will be prioritised for inclusion

Cancer type/subtype:	
Approximate incidence (new cases/100,000/yr.):	
Country(ies)/Region(s) of incidence figure provided:	
Approximate incidence (new cases/100,000/yr.) from other countries/regions (if incidence is likely to differ):	





Clinical stage(s) of interest for trial (i.e., primary, adjuvant, relapsed):	
Approximate population of potential trial patients at clinical stage of interest (patients/100,000/yr.):	

OUTLINE CONCEPT (if available)

IRCI facilitates hypothesis-driven interventional trials with one or more treatments of interest for investigation (audits, registries or non-trial tissue collections are not within remit).

If available, please briefly describe any potential clinical trial concepts that you would propose to a new group, including the objectives and a study schema:	
If known, please briefly describe any initial ideas for associated tissue collections or translational research:	
If known, please briefly describe the new clinical data that will result from this group and how such data will be collected, stored, and made available for future use (including the type of consent that is planned)	
Please describe the unmet need for this rare cancer and how IRCI support will drive forward progress	

Please turn to page two for the last question of section 1.

EXISTING COLLABORATIONS & RESEARCH ACTIVITY

Please provide an update if any national/international collaborations exist for this cancer type and any on-going or planned clinical trials relevant for this cancer type (including access to umbrella trials)?



CROSS CUTTING THEMES

Please provide an update on what other things the working group will be focusing on?

Please note if you're interested in setting up a non-disease specific working group to address shared challenges in the rare cancer trials space, we would be happy to discuss this with you. Please do get in touch with us IRCI@cancer.org.uk