

**New Partners – Japan Clinical Oncology Group (JCOG):** We are excited to announce that JCOG has recently joined IRCI as a new partner.

## IRCI Relapsed/metastatic anal cancer group



**InterAACT:** A phase II International multicentre randomised advanced anal cancer trial comparing cisplatin plus 5FU vs. carboplatin plus weekly paclitaxel in patients with relapsed or metastatic disease (IRCI 003)

Chief Investigator: Dr Sheela Rao - Royal Marsden Hospital, UK  
Lead coordinating center: The Royal Marsden  
There are currently 89/90 patients recruited across 60 open sites in 4 countries. The trial is open in the UK, US, Norway and Australia. The study is near completion and the team hopes to present the study in an abstract at the ASCO 2018 meeting.

**General group update:** The group is currently discussing the design of a follow-on trial to InterAACT and plans to meet at the upcoming annual 2018 GI ASCO symposium.

## IRCI Gynaecological sarcoma group



**uLMS:** The trial has closed due to low recruitment.  
**HGUS:** A randomized phase II study evaluating the role of maintenance therapy with cabozantinib vs placebo in High Grade Uterine Sarcoma (HGUS) after stabilization or response to CT following surgery or in metastatic 1st-line treatment (IRCI 006)

Chief Investigator: Prof Isabelle Ray-Coquard - Léon Bérard Cancer Center  
Lead coordinating center: EORTC HQ  
There are 7/54 patients recruited across 11 sites in 7 countries. The trial is open in Belgium, the Netherlands, Germany, France, Spain, Italy and the UK. The trial has been amended to include all high-grade uterine sarcomas, following closure of the uLMS study.

## IRCI Small bowel adenocarcinoma group



**The BALLAD study:** A global study to evaluate the potential benefit of adjuvant chemotherapy for small bowel adenocarcinoma (IRCI 002)

Chief Investigator: Dr Richard Wilson - Belfast/ Dr Jeff Evans - Beatson  
Lead coordinating group: Glasgow Clinical Trials Unit  
Recruitment now stands at 66/580 across 65 open sites. The trial is open across the UK, France, and Japan recently opened the study via a parallel protocol. Discussion is currently underway regarding opening in Denmark, the Netherlands, Germany and Portugal.

**General group update:** A multicenter phase II study of MK-3475 in metastatic patient is currently running in the US. If a significant signal of monotherapy activity is seen in this pilot study, an international phase III randomised controlled trial developed by the IRCI group is planned. The group are also currently in discussions around running a companion pilot trial in metastatic patients in the UK and Europe.

## IRCI Salivary cancer group



**EORTC1206-HNCG:** A randomised phase II study to evaluate the efficacy and safety of chemotherapy vs. androgen deprivation therapy in patients with recurrent and/or metastatic, androgen receptor expressing, salivary gland cancer (IRCI 007)

Chief Investigator: Dr Lisa Licitra - Istituto Nazionale dei Tumori, Milan, Italy  
Lead co-ordinating center: EORTC HQ  
There are currently 23/152 patients recruited across 25 sites in 7 countries. The trial is currently open in Austria, Belgium, France, Germany, Hungary, Italy and the Netherlands. The UK, Greece and Portugal are currently in set up, and Japan has expressed initial interest to participate. Abstracts were presented at ESMO and ESP in 2017.

## IRCI Penile cancer group



**InPACT:** International Penile Advanced Cancer Trial (IRCI 004)

Chief Investigator: Dr Steve Nicholson – Locum Consultant  
Lead co-ordinating center: Institute of Cancer Research, UK  
The trial is now open and recruiting in the UK and US. There are discussions under way to open the study in Japan, Canada, Colombia and continental Europe.  
**General group update:** The group leads are planning a meet in 2018 to discuss future trials ideas (potentially using an immunotherapy approach).

## IRCI Rare melanoma group (inc. Merkel cell carcinoma group subgroup)



**General group update:** The group is planning a full day meeting alongside the 2018 Society for Melanoma Research conference in October, hosted in Manchester UK, at which future trials will be discussed. The Merkel cell carcinoma subgroup are also currently collaborating to develop a clinical trial in this space.

## IRCI groups that have closed



The Rare Brain Tumour group, Desmoplastic Small Round Cell Tumour (DSCRT) group, and the Thymoma group have closed in the absence of a viable international interventional clinical trial concept at this time. Group leads were encouraged to get back in touch should new information come to light that would enable the design and consensus for an international clinical trial.

### IRCI partner organisations:



## IRCI Expression of Interest call 2018 for new rare cancer working groups

The driving mission of the International Rare Cancers Initiative is to facilitate the development and delivery of hypothesis-driven, interventional clinical trials for patients with rare cancer. The initiative to date has convened 9 groups and opened 7 trials. In recognition of the requirement to coordinate trial development internationally (to optimise funder dialogue and delivery success), IRCI is calling for further expressions of interest from researchers who are interested in establishing international rare cancer trials. Future IRCI groups/studies will benefit from the broad international reach of the IRCI partner members, and application of key lessons learnt from the initial set of IRCI trials.

IRCI is running an Expression of Interest (EOI) call for new working groups who wish to develop an international trial in a rare cancer. If the EOI is successful, IRCI will support the lead researchers to make international connections to establish a group of interested parties, will coordinate the logistics of working group meetings alongside ASCO or other international conferences, and will be able to provide information and advice on how to approach parallel funding applications and feasibility aspects of the study.

### EOI submission

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

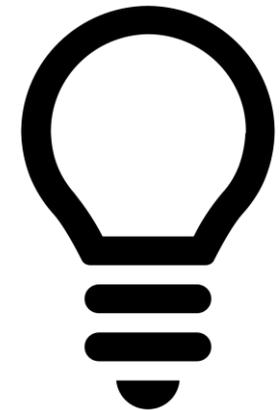
- Read the Terms and Conditions associated with establishing a new rare cancer group, visit [\[link\]](#).
- Complete the EOI form [\[download link\]](#)
- Send EOI form to [IRCI@cancer.org.uk](mailto:IRCI@cancer.org.uk) by **5th April 2018**.

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

### Next steps

At ASCO 2018 the IRCI Board will assess the level of shared interest to collaborate internationally and the scope to subsequently deliver a feasible, hypothesis-driven practice changing clinical trial. Feedback will be provided after ASCO 2018 to advise if your proposed IRCI rare cancer group has been selected to be taken forward.

Should you wish to discuss further, or if you have any questions, please contact [IRCI@cancer.org.uk](mailto:IRCI@cancer.org.uk)



#### IRCI partner organisations:



National Cancer Institute (USA)  
National Institutes of Health



Canadian Cancer  
Trials Group



Groupe canadien  
des essais sur le cancer



## International activity in rare cancers - non IRCI

Please note, the below studies have not been developed by IRCI working groups but have been included below for your information as part of the broader rare cancer activity taking place across the countries who participate in IRCI.

### **SPECTArare: Screening Patients With Rare Tumors for Efficient Clinical Trial Access (Belgium, France, Poland, UK)**

**Europe, PI: Vassilis Golfopoulos**

SPECTArare is a program aiming at establishing a quality assured platform for collecting clinicopathologically annotated biological material from patients with primary rare tumors (6 new cases/100,000/year) to support biospecimen-based translational research and biomarker discovery.

### **MASTER KEY Project (Marker Assisted Selective ThERapy in Rare cancers: Knowledge database Establishing registry Project)**

**Japan, PI: Kenichi Nakamura**

Tokyo's National Cancer Center Hospital has teamed up with pharmaceutical companies for a project to research genomic information of patients with rare cancers and develop new drugs to fight the diseases. The project is designed to collect genomic information from patients with rare cancers such as sarcoma and malignant brain tumors as well as their treatment information and create a database to advance understanding of what causes rare cancers and how they progress.

### **Molecular Screening and Therapeutics clinical trials**

**Australia, PI: David Thomas**

The Genomic Cancer Medicine Program has developed targeted approaches to inhibit tumor growth and immunotherapies to stimulate an immune response that delivers long-lived tumor destruction. The Genomic Cancer Medicine Program will use genomic information in novel ways to understand further the genetic contribution to cancer risk and identify new therapeutic opportunities for individual patients, with a view to improving outcomes.

### **DART (Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors)**

**USA, PI: Sandip Patel**

DART is managed by SWOG, and sponsored by the NCI. The trial is being conducted under the NCI collaborative agreements with Bristol-Myers Squibb for ipilimumab and nivolumab. Razelle Kurzrock and Francis J Giles are the DART Senior Study Chairs, providing guidance on the trial design and protocol.

### **NCI-MATCH Trial (Molecular Analysis for Therapy Choice)**

**USA, PI: Barbara Conley**

Co-designed by ECOG-ACRIN Cancer Research Group and the NCI, and led by ECOG-ACRIN, NCI-MATCH is the most sweeping precision medicine trial in the United States. NCI-MATCH uses a customized tumor gene testing method to match patients with any solid tumor, along with lymphoma and myeloma, to multiple targeted treatments. 25% of the screening has been reserved for rare cancers and during a recent interim analysis on 645 patients, common cancers accounted for 36% of tumors so there is currently a higher proportion of rare cancers.

#### IRCI partner organisations:



National Cancer Institute (USA)  
National Institutes of Health



Canadian Cancer  
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