

Finalisation of the IRCI Methodological paper: Following the Methodological meeting held alongside the ECCO 2013 meeting, the meeting co-chairs Jan Bogaerts and Matt Sydes have been working with the IRCI statisticians and clinicians on a publication that exemplifies the possible approaches to designing credible trials in rare cancers. This has been published by the European Journal of Cancer: [http://www.ejancer.com/article/S0959-8049\(14\)01063-6/abstract?cc=y](http://www.ejancer.com/article/S0959-8049(14)01063-6/abstract?cc=y)

Expansion of the Ocular melanoma group: The IRCI Board has approved the expansion of the IRCI Ocular melanoma group to cover all rare melanomas, including Merkel cell carcinoma.

NCIC CTG- New Partner: We are excited to announce that The National Cancer Institute of Canada Clinical Trials Group (NCIC CTG) has agreed to join IRCI as a partner organisation.

IRCI Relapsed/metastatic anal cancer group



InterAACT: There are currently 10 patients recruited across 12 UK sites. The study has also opened in Oslo University Hospital, Norway. Sites are also in set up in Denmark and it is anticipated that Germany, France and Portugal will participate through the EORTC. The US cooperative group ECOG has submitted the trial to NCI-CTEP for review. The AGITG has approved, and is providing funding for, the trial in 7 Australian sites. It is anticipated that recruitment in Australia will begin in Q1 2015.

IRCI Rare melanoma group



Ocular melanoma GSK Trametinib +/- GSK795: Following a thorough review of the phase I safety data of the trametinib and GSK795 combination, the GSK leadership team are discontinuing further investigation of the combination. The trial will continue to the interim analysis stage in the US centres, however will not be activated in sites within mainland Europe and the UK. Drawing on the strength of the international collaboration developed, the group is in discussions regarding their next IRCI trial/s.

IRCI Small bowel adenocarcinoma group



The BALLAD study: Glasgow CTU is close to finalisation of the protocol, which will then be shared with the collaborators. The French Ministry of Health has approved funding for this study. There is continued interest from Japan and other individual European sites to join the trial. Consideration is being given to whether this study can be sponsored in the US through a large cancer centre.

Metastatic study: A proposal for an international trial in patients with metastatic small bowel adenocarcinoma is currently in development.

IRCI Penile cancer group



InPACT: The protocol for this study is currently in development with the international community. The ICR CTSU plan to submit to UK Regulatory Authorities in Q1 2015. The US co-operative group ECOG is planning to submit the protocol to the GU Steering Committee before submitting to CTEP. The EORTC Headquarters has kindly agreed to assist the ICR administratively with the set up of sites in mainland Europe.

IRCI Gynaecological sarcoma group



uLMS: 13 patients have been recruited in the US. In mainland Europe the first site has now activated in Norway. Site approvals are pending in Belgium, France, the Netherlands, Spain and Germany. In the UK, the first site opened to recruitment in September.

HGUS: It is anticipated that the first site will open in Belgium in Q1 2015. Regulatory/site contracts are pending in Belgium, Italy, Spain and the Netherlands. In the UK, Glasgow CTU is pending Regulatory Authorities approval. A future submission to CTEP is being considered.

IRCI Salivary cancer group



ADT in advanced SGCs: The EORTC PRC has now approved the protocol, and submissions to Regulatory Authorities have commenced in mainland Europe. It is anticipated that the study will open in France and Belgium imminently. The study is also currently in set up in the UK. The NCI CTEP has decided not to participate in this study.

IRCI Desmoplastic Small Round Cell Tumour (DSRCT) group



Following a Working Group meeting held alongside the ECCO 2013 Annual meeting, a study outline has been developed for consideration of the wider IRCI DSRCT group. The IRCI DSRCT group met alongside the CTOS 2014 conference in October 2014 to discuss the proposal to develop a clinical trial with an initial registration phase followed by randomisation likely to maintenance treatment.

IRCI Thymoma group



PORT: Following an initial review by the NCI-CTEP, a revised Letter of Intent was requested. The ECOG Steering Committee has approved the revised proposal and a resubmission has been made to the CTEP Thoracic Malignancy Steering Committee. The trial has been approved for participation by the French Rhythmic Intergroup and has also been endorsed in Australia. There also continues to be interest to participate in the UK and Asia (which will be further pursued following confirmation of the US approval). The EORTC will not participate in this study.

IRCI Rare brain tumour group



This group is currently collaborating on a trial for patients with Anaplastic meningioma - Dr Pricilla Brastianos' trial concept has been approved by CTEP, and Dr Colin Watts is currently working towards submitting the proposal to the UK Clinical Trials Awards and Advisory Committee. The group is also collaborating on a trial for patients with Adult Medulloblastoma for which Dr Martin McCabe and Dr Gillian Whitfield are leading on development of a concept.

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 co-ordinating centre: Glasgow CTU

US Lead: Dr Rob McWilliams - Mayo Clinic

French lead: Dr Thomas Aparico - Hôpital Avicenne

Japan Lead: Kenichi Nakamura - National Cancer Centre

Metastatic study- name tbc

Chief Investigator: Dr Rob McWilliams - Mayo Clinic

Lead co-ordinating centre: Mayo Clinic

UK Lead: Dr Richard Wilson - Belfast

EU Lead: Dr Arnaud Roth - Hopitaux Universitaires de Geneve

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

Lead co-ordinating centre: Royal Marsden CTU

US Lead: Dr Cathy Eng - MD Anderson

EU Lead: Professor Dirk Arnold - Arcor

IRCI Salivary cancer group

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

Lead co-ordinating centre: EORTC

UK Lead: Dr Kevin Harrington - ICR

US Lead: Dr Alan Ho - MSKCC

IRCI Penile cancer group

InPACT – International Penile Advanced Cancer Trial (IRCI 004)

Chief investigator: Dr Steve Nicholson - Charing Cross

Lead co-ordinating centre: ICR CTU

US Lead: Dr Curtis Pettaway - MD Anderson

IRCI Rare brain tumour group

UK Lead: Dr Colin Watts - Cambridge

US Lead: Dr Eva Galanis- Mayo Clinic

EU Lead: Dr Wolfgang Wick - Heidelberg

IRCI Ocular melanoma group

A randomised phase two-arm phase II study of Trametinib alone and in combination with GSK214795 in patients with advanced uveal melanoma (IRCI 005)

Chief Investigator: Dr Rich Carvajal - MSKCC

Lead co-ordinating centre: MSKCC

UK Lead: Dr Ernie Marshall - Clatterbridge

EU mainland lead: Dr Serge Leyvraz - CHUV

IRCI Gynaecological sarcoma group

HGUS: A randomised phase II study evaluating the role of maintenance therapy with Cabozantinib in High Grade Uterine Sarcoma (HGUS) after stabilisation or response to chemotherapy following surgery or in metastatic first line treatment (IRCI 006)

Chief Investigator: Dr Isabelle Ray-Coquard - Léon Bérard Cancer Center

Lead co-ordinating centre: EORTC

UK Lead: Dr Helena Earl - Cambridge

US Lead: Dr Martee Hensley - MSKCC

uLMS: A phase III randomised trial of gemcitabine plus docetaxel followed by doxorubicin versus observation for uterus-limited, high grade uterine leiomyosarcoma (IRCI 001)

Chief Investigator: Dr Martee Hensley - MSKCC

Lead co-ordinating centre: GOG

UK Lead: Dr Helen Hatcher - Cambridge

EU Lead: Professor Jean Yves Blay - Léon Bérard Cancer Center/Petronella Ottevanger (EU, Radboud University Medical Center Nijmegen)

IRCI Thymoma group

PORT: Randomised phase 3 study of resected stage III Invasive thymoma with or without postoperative radiation therapy

Chief Investigator: Dr Heather Wakelee - Stanford University

Lead co-ordinating centre: ECOG

UK leads: Professor Mike Lind – Hull/ Dr Sanjay Popat - Imperial

IRCI Desmoplastic Small Round Cell Tumour (DSRCT) group

UK Lead: Dr Jeremy Whelan- University College London

US Lead: Dr Paul Meyers/ Richard Gorlick- MSKCC/Einstein

EU Lead: Dr Wynette Van der Graaf – UMC St Radboud