

Please read on for an update on the key highlights and achievements for each of the IRCI rare cancer groups over the last 6 months. A big thank you to all those involved for their continued hard work and enthusiasm in driving forward the progress of this initiative.

INCa – a new IRCI partner: We are excited to announce that The French National Institute of Cancer (INCa) has agreed to join IRCI as a partner organisation.

Two new groups: The Rare Brain Tumour group and the Desmoplastic Small Round Cell Tumour (DSRCT) group met for the first time alongside ASCO 2013. The Rare Brain Tumour group met again alongside The Society of Neuro-Oncology Annual Meeting in November to further discuss developing trials for patients with Anaplastic meningioma and Adult medulloblastoma. A small DSRCT Working Group met alongside The ECCO Annual Meeting, during which there was a very productive discussion around a potential trial idea, to be further developed and presented to the wider group.

IRCI Small bowel adenocarcinoma group



The BALLAD study: Glasgow CTU is currently in the process of finalising the protocol, which will then be shared with each of the collaborators. There is continued interest from Canada, Japan, Australia and individual EU sites to join the trial, and we are working with Dr Rob McWilliams (Mayo Clinic) and the NCI to identifying a US co-operative group to take on this study.

Metastatic study: Sanofi has agreed to provide aflibercept and support (level to be confirmed) for an international trial in patients with metastatic small bowel adenocarcinoma. The concept is currently with Sanofi for review.

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: The EORTC are currently in the process of finalising the protocol which they plan to have ready imminently. We are pleased to advise that CTAAC have approved the study (subject to conditions) and therefore the study is in set up in the UK. The Alliance co-operative group have agreed to run the trial in the US, and are currently in the process of working on an application to the NCI for funding.

IRCI Relapsed/metastatic anal cancer group



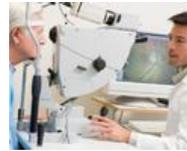
InterAACT: The Royal Marsden has submitted the protocol for UK regulatory approval and is currently awaiting feedback. A telephone conference is being scheduled between the Royal Marsden, the EORTC, the US cooperative group ECOG and the Australian collaborators to progress the application with each of the respective approval bodies. **Lymph node assessment subgroup:** A working group has been initiated with the aim of developing a consensus document on nodal staging. The group is planning to meet at ASCO GI 2014.

IRCI Penile cancer group



InPACT: The protocol for this study is currently in development with the aim of submitting for regulatory approvals in quarter two 2014. The aim is to work towards opening to recruitment in November 2014. We are delighted to announce that the US co-operative group ECOG has agreed to run the study in the US, and an application for funding is being submitted to the NCI for review. The EORTC Headquarters has kindly agreed to assist the ICR with EU site selection and set-up.

IRCI Ocular melanoma group



A randomised two-arm phase II study of Trametinib alone and in combination with GSK214795 in patients with advanced uveal melanoma: This trial has recently opened to recruitment in the US. In the UK, the trial has been approved by CTAAC and is currently in set-up with the aim of opening to recruitment in quarter one 2014. The EORTC has submitted the study to their funding body PRC and are due to receive feedback. The investigators, along with GSK, are currently working on an exciting translational research plan to compliment the trial.

IRCI Thymoma group



Randomised Study of Resected Stage III Invasive Thymoma or Stage II–III Thymic Carcinoma with or without Postoperative Radiation: The US ECOG co-operative group has agreed to run this trial in the US. ECOG recently submitted an application to the NCI for funding. We are pleased to announce that the trial has been supported by the EORTC Executive Committee and the NCRI Lung CSG - applications to PRC and CTAAC are in planning. The trial has also been approved for participation by The French Intergroup.

IRCI Gynaecological sarcoma group



uLMS: This study, which is currently open in the US, has now recruited 3 patients. The contract between the GOG US cooperative group and the EORTC has now been signed, and the contract between the EORTC and Glasgow is very close to finalisation. Therefore it is anticipated that the trial will open in the EU and UK imminently.

HGUS: We are pleased to announce that the study has been approved in the UK by CTAAC (subject to conditions). The EORTC are currently working in collaboration with the UK and US investigators towards finalising the protocol. Upon agreement of the protocol by the collaborators, the trial will be submitted to the GOG US cooperative group for formal review.

ESS: The study outline has been endorsed by EORTC PRC. The EORTC is currently working on the protocol in collaboration with the international investigators.

IRCI Methodological meeting alongside The European Cancer Congress (ECCO): IRCI ran an extremely interesting and very well attended Methodological meeting alongside the ECCO Annual Meeting (co-chaired by Matt Sydes and Jan Bogaerts). The aim of the meeting was to provide an opportunity to consider the statistical approaches and trial designs used for IRCI studies to date, to discuss what approaches have worked well, and to share ideas for future rare cancer trials. The meeting included statisticians and clinicians involved with IRCI who have designed or are currently in the process of designing a rare cancer trial, or who would benefit from the insight this meeting will bring in the future. A publication from the meeting is being planned.

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 Janet Graham – Beatson (deputy)
Lead co-ordinating centre: Glasgow CTU
US Lead: Dr Rob McWilliams - Mayo Clinic
Australian Lead: Professor David Goldstein - Prince of Wales Clinical Centre
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 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)

ESS: Efficacy of aromatase inhibitors in stage III-IV or recurrent endometrial stromal sarcoma: a phase II trial
Chief Investigator: Dr Frederic Amant - U.Z. Leuven,
Lead co-ordinating centre: EORTC
UK Lead: Dr Helena Earl - Cambridge
US Lead: Dr Martee Hensley - MSKCC

IRCI Thymoma group

Randomised Study of Resected Stage III Invasive Thymoma or Stage II –III Thymic Carcinoma with or without Postoperative Radiation Therapy
Chief Investigator: Dr Heather Wakelee - Stanford University
Lead co-ordinating centre: ECOG
UK lead: Professor Mike Lind - Hull
EU Lead: Dr Sanjay Popat - Imperial