



newsletter

May 2011 | Issue 3

Latest Analysis of the ECMC Portfolio

ECMC funding has supported a large and varied portfolio of clinical trials including complex early phase, proof of concept, biomarker and new technology studies.

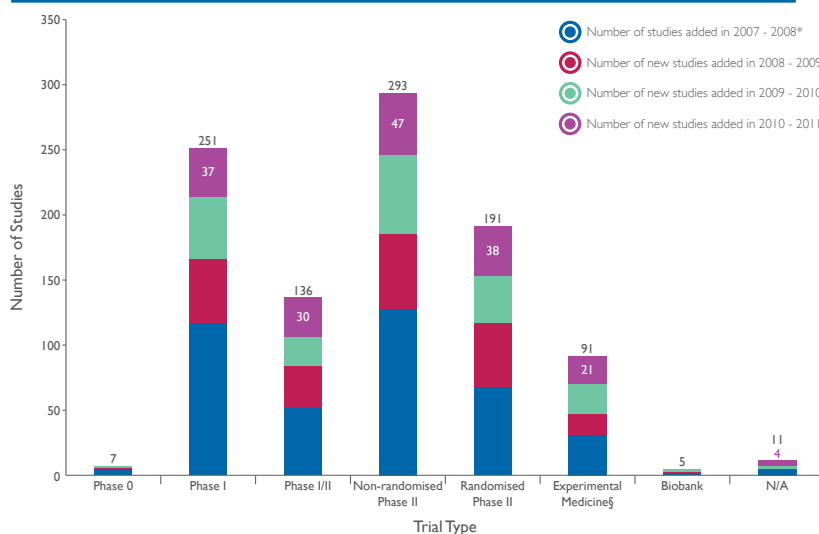
Centres have established or expanded their facilities for early phase trials and ECMC resources have helped these units to

- support more clinical studies,
- increase their cancer clinical trials portfolio and
- focus on efforts to recruit patients to these trials.

Between 1 January 2010 and the end of November 2010 (clinical trial reporting period for Year 4), 177 new early phase studies were added to the ECMC portfolio. 96% of these studies were reported as being either in set-up or open to patient recruitment. 65% of all new studies added to the portfolio in Year 4 were industry funded studies (includes industry sponsored/funded and trust sponsored/industry funded).

The total number of early phase studies hosted by the ECMC Network since the Initiative commenced (2007 – 2011) currently stands at 985. 371 of these studies are currently open to patient recruitment. 64% of all the studies currently on the ECMC portfolio are funded by industry.

Number of new studies hosted by the Network in Year 4 in addition to studies reported in Years 1, 2 & 3



*Year 1 data includes studies started in Year 1 as well as studies started prior to 2007

§Experimental medicine studies are studies that include an experimental medicine component

Experimental Cancer Medicine Centres

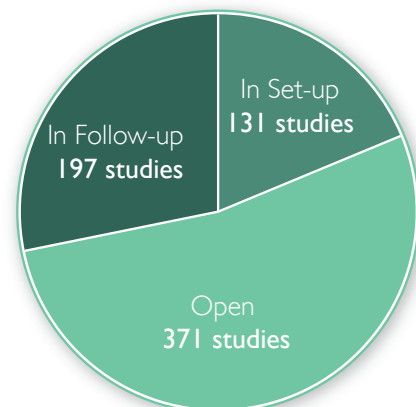


Barts	Leeds
Belfast	Leicester
Birmingham	Liverpool
Cambridge	Manchester
Cardiff	Newcastle
Edinburgh	Oxford
Glasgow	Sheffield
ICR	Southampton
Imperial	UCL
KCL	

ECMC Quinquennial Review 2011

This is the fifth and final year of the current ECMC Initiative. In June 2011, all existing ECMCs will undergo a quinquennial review to determine future ECMC status and allocation of funding beyond March 2012. The review will also involve the assessment of applications from new sites wishing to join the ECMC Network. An international panel of scientific experts along with representatives from the four devolved Health Departments and Cancer Research UK has been assembled to undertake the review.

Status of studies currently supported by the ECMC Network (2011)



Llywodraeth Cynulliad Cymru
Welsh Assembly Government



ECMC selection for the Cancer Research UK Stratified Medicine Programme

Following a call for applications, a number of ECMCs will shortly be invited to establish Clinical Hubs and collect tumour and blood samples from cancer patients for the Programme.

In early March, many strong proposals were submitted by Centres to become clinical facilities for the Stratified Medicine Programme. A peer-review process has now been completed and an announcement on which ECMCs have been selected will be made on the ECMC website (www.ecmcnetwork.org.uk) in due course.

Cancer Research UK will work with selected Centres and three Technology Hubs (genetic testing laboratories, to be selected in the Summer 2011) to demonstrate a scalable model of molecular diagnostic testing, linked to research, for use in the NHS. It is hoped that this is an initial step towards routine molecular profiling of cancer patients' tumours to inform treatment decisions and support future research.

Over two years, Clinical Hubs are expected to jointly collect up to 9,000 patient samples across six tumour types (breast, colorectal, lung, prostate, ovary and malignant melanoma) with

matching blood samples. These will be sent to three central, quality assured Technology Hubs (testing labs) where nucleic acid will be extracted and tested for a prioritised set of genes and mutations. The results of analysis will be made available to clinical teams involved in patient care as well as being securely stored for future studies.

James Peach, Director of Stratified Medicine at Cancer Research UK explains 'We need to start work now to ensure that the NHS is ready to deal with the emerging generation of targeted treatments. The genetic information collected by the programme will be linked to information on treatments and outcomes, building a translational research database. Our hope is that as this scales up, this information can be used to help develop the personalised cancer drugs of the future.'

A series of teleconferences and workshops will be organised by Cancer Research UK in the next few months to agree minimum standards and share best practice across the Clinical and Technology Hubs. This collaborative work will continue throughout Phase One establishing the processes required to routinely test molecular characteristics of patient's tumours.

ECMC Finance Meeting

Finance is always a topic of interest across the ECMC Network and so for the first time, the ECMC Secretariat engaged with the ECMC finance community, bringing together Centre staff and their associated Trust and R&D departments at a meeting held in March 2011. The aims of the meeting were to:

1. Address some of the broader cancer research financial issues (both the hosting and coordinating of studies)
2. Share best practice in approaches for costing different categories of early phase trials
3. Consider the grey areas and key considerations that could influence practice moving forward

Clarification of NIHR CRN (Clinical Research Network) support eligibility criteria was provided by Dr Helen Campbell (NIHR). Christopher Burdette (NCRN) gave an overview of industry costing and contracts and explained how the costing template worked for Industry and the NHS. Paul Godden (Oxford Dept of Oncology Early Phase Hub) presented a finance case study and highlighted the complexity of the funding environment for trials, explaining that Excel-based tools were of limited use and that there would be a need for comprehensive trial finance modules. During the breakout group sessions, attribution of costs was discussed and it was agreed that as this was an extremely complicated area and training was required. If there is enough demand for this, the ECMC Secretariat will organise training on this topic. A frequently asked questions document on finance will be circulated to across the Network.

Sample Handling Guidelines Published

Patient tissue samples are extremely valuable and optimal handling can have a direct impact on the robustness of the data and success of a study which ultimately contributes to patient benefit. The ECMC Network has published guidelines on handling patient samples, to share best practice with the research community. Titled 'Sample Handling Guidance Document for Research Nurses and Junior Clinical Laboratory Staff', the document describes key requirements for the sample collection and the handling process and explains the important roles research nurses and lab staff both play. It provides staff with a general overview detail, checklist, flowchart and regulatory appendices.

The guidelines were developed as a result of the workshop, 'From Collection to Analysis - A Practical Approach to Sample Management', held in May 2010, which brought together the ECMC Early Phase and Translational Research Nurse, Bioanalysis and Quality Assurance, and Operational Network Groups. A need for guidance was identified at the meeting and Pam Baxter (Exeter), Anne Croudass (CR-UK), Linda Jones (Cambridge ECMC) of the ECMC Early Phase and Translational Research Nurse Network Group collaborated with members of the other Network groups to produce the document which can be found at:

<http://www.ecmcnetwork.org.uk/news-events/news/ecmc-sample-management-guidance?>

Joint ECMC/ CTRad Conference in Association with the LH Gray Memorial Trust

The ECMC Initiative and the Clinical and Translational Radiotherapy Research Working Group (CTRAd) held a collaborative day of presentations and discussion as part of the 22nd International LH Gray Conference in February 2011. The meeting brought together basic and translational scientists with clinicians to highlight the biological consequences of combining radiation with molecularly targeted drugs, and the potential for improving patients' response to cancer treatment. The ECMC / CTRad day focussed on the development of drug-radiation combinations in early phase clinical trials, optimising their design and potential application. The conference was well attended by CTRad and ECMC members, other UK and international experts and industry representatives. Professor Ian Stratford, Co-Chair of the Science Base CTRad Workstream, will write a conference report for submission to a journal.

For more information on other ECMC events, please visit our website: www.ecmcnetwork.org.uk

Cambridge ECMC Open Day

Cambridge ECMC hosted a successful open day at the Cancer Research UK Cambridge Research Institute in November 2010 with an attendance of over 200. It showcased some of the vital work taking place at the Centre and gave members of the public the opportunity to meet the nurses, scientists and clinicians who work there.



Delegates heard presentations on early detection of oesophageal cancer; imaging and the testing of drugs of the future. A patient who had participated in a clinical trial gave a very moving account of their experience of cancer and treatment. Many nurses prepared posters and these were displayed over lunch, along with a number of demonstrations (e.g. delegates were able to view cancer cells under the microscope).



Students viewing one of the many displays

Combinations Alliance update

Due to the overwhelming response received to the second ECMC Combinations Alliance Expression of Interest (EOI) call, two workshops



were held; the first attached to the ECMC Leads meeting on 24th November 2010 and the second attached to the NCRN meeting on 10th February 2011. The format of both workshops was interactive and provided the ECMC clinicians with the opportunity to present and discuss their ideas with key AstraZeneca (AZ) personnel. The Joint Steering Committee (JSC) have since reviewed and identified which proposals to progress to formal New Agents Committee (NAC) applications.

A total of 65 EOIs were been submitted in response to the two EOI calls. Twelve of these were identified to progress to the NAC of which two have already received approval. The EOIs submitted were for combinations of specific AZ drugs with other agents in development, marketed agents or radiotherapy and include our first cross company combinations. The cross company collaborations are where the ECMC Combinations Alliance can add value and this will be the first steps towards wider industry engagement. Discussions with other pharmaceutical partners are ongoing.

Given the EOI response, the ECMC Combinations Alliance recently clarified the following study design requirements:

- PRIORITY for these studies is DELIVERY
- STUDY DESIGN
 - Phase Ib/IIa
 - Primary endpoint: Safety, tolerability & Pharmacokinetics of combination
 - Secondary endpoint: Non-statistically powered efficacy (preferably via biomarkers)
 - Dose escalation cohorts: 2 – 4 (3 – 6 pts per cohort)
 - Expansion phase: Randomisation to compare combination vs. standard of care for safety ~ 10 pts per arm
- DELIVERY
 - Locally sponsored across 2 – 4 ECMC sites
 - Ensure CSG awareness via chair

If you would like more information about future workshops or the ECMC Combinations Alliance please contact; Cathy McDowell cathy.macdowell@cancer.org.uk or Lyndall McLellan lyndall.mclellan@cancer.org.uk at the DDO.

Work Experience

Dr Christine Manoharan, Research Manager for the ECMC Secretariat is responsible for undertaking the strategic analysis of the ECMC trials portfolio. The reporting of clinical trial activity and the impact of ECMC funding has become an increasingly important undertaking. In order to gain a better understanding of the work involved in conducting clinical trials and the roles of different staff in the delivery of clinical research, Dr Manoharan undertook a one week work placement at the UCL Department of Gynaecological Oncology. The placement involved shadowing clinicians, research nurses and trial coordinators and learning more about the role of the R&D office and the process of setting up cancer clinical studies. Delivering cost-effective clinical trials means supporting effective trial set-up and recruiting patients to time and target. During the next quinquennium the ECMC Secretariat will work with the Centres to deliver these key parameters.

Press coverage

Since the previous issue of the ECMC Newsletter, there has been further positive press coverage of the ECMC Network:

Cambridge News – 6th December 2010

Following the Cambridge ECMC's Open Day in November 2010, Cambridge News reported on the groundbreaking research taking in place and highlighted the importance of patients participating in trials in a double page feature. Centre Lead, Carlos Caldas, explained the aims of the work, with further quotes from a Research Nurse and two patients who have participated on studies. <http://www.cambridge-news.co.uk/Home/Video-Winning-the-war-against-silent-killer.htm>



The Telegraph Magazine – 4th December 2010

The ECMC Network received extensive coverage in a six page article on the fight against cancer. The feature included stories of a number of cancer patients; looking at the impact that cancer had on them and their families; their treatment journeys and participation in early phase trials. The importance of testing new therapies and the role that ECMCs play was also highlighted. The work of individual ECMCs, namely: Glasgow, Leeds, Newcastle, and Southampton, was also mentioned. <http://www.telegraph.co.uk/health/8176500/The-fight-against-cancer-new-trials-bring-hope.html>

ECMC presentations at 2011 ASCO Annual Meeting

ECMCs will present important new research findings at the 2011 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago in June.

Below is a selection of the 40 abstracts from ECMCs that will be presented at the meeting:

Newcastle

#1523: Single nucleotide polymorphisms and expression/amplification of HER2 in patients with breast cancer. (Nicola Cresti / Mark Verril)

Glasgow

#8527: Assessment of clinical activity of E7080, a multi-targeted kinase inhibitor, in patients with advanced melanoma treated in 2 phase I trials (David Hong/Jeff Evans)

ICR

#3001: A Phase I dose-escalation study of oral MK-2206 in patients with locally advanced or metastatic solid tumours (Tim Yap/Johann de Bono)

Imperial

#83535: Pharmacokinetic (PK)/pharmacodynamic (PD) analysis of escalating repeat doses of the AKT inhibitor GSK2141795 (GSK795) in patients (pts) with ovarian cancer. (H. Gungor/Hanni Gabra)

Oxford

Phase I (Ph) safety, pharmacodynamic (PD), and pharmacokinetic (PK) trial of a pure MEK inhibitor (i), RO4987655, in patients with advanced /metastatic solid tumor. (S Leijen/Mark Middleton)

UCL

#3024: A first-in-human phase I study of JNJ-26481585, a novel oral histone deacetylase inhibitor (HDACi), in advanced cancer patients with evidence of target (Richard Baird/Rachael Kristeleit)

Contact us:

If you have any feedback on this newsletter, or ideas for future articles, please contact Dominique Capostagno (ECMC Secretariat) dominique.capostagno@cancer.org.uk

Further information:

For further information, please visit our website: www.ecmcnetwork.org.uk