



Experimental Cancer Medicine Centre Network

# Annual Report

## 2015-16



The Experimental Cancer Medicine Centre Initiative is jointly funded by Cancer Research UK, the National Institute for Health Research in England and the Health Departments for Scotland, Wales and Northern Ireland.

# CONTENTS

<b>INTRODUCTION</b>	<b>4</b>
<b>A NETWORK SUPPORTED BY SCIENTIFIC EXCELLENCE</b>	<b>5</b>
The Network Groups: Enhancing the UK's capacity in experimental cancer medicine	8
The UK Therapeutic Cancer Prevention Network (UKTCPN)	8
Junior Investigators Network Group (JING)	9
Cellular and Molecular Pathology (CMP) Network Group	10
Research Nurses Network Group	11
Patient and Public Involvement Group (PPI)	12
Quality Assurance and Translational Science Network Group (QATS)	12
CRUK, ECMC and UK Radiopharmacy Group Taskforce (CERT)	13
Working together to drive delivery and maximise the Network's capacity	14
<b>WORKING IN PARTNERSHIP WITH INDUSTRY</b>	<b>16</b>
Improving processes to support delivery	17
Streamlining industry liaison processes through the ECMC Trial Harmonisation Programme (ETHP)	17
ECMC Non-Disclosure Agreement (NDA) template	17
Working on a national level to streamline R&D processes across the Network	19
Platforms embedded in our Network	20
ECMC Combinations Alliance	20
CRUK Stratified Medicine Programme 2 (SMP2)	22
The National Lung Matrix Trial (NLMT)	23
<b>DISSEMINATING THE SUCCESSES OF THE NETWORK</b>	<b>24</b>
Attendance to conferences and meetings	24
Annual Network meeting	24
UK Clinical Research Facility (UKCRF) Conference	25
National Cancer Research Institute (NCRI) Conference	25
Disseminating ECMC achievements through our communications tools	26
New ways of communicating our work	27
<b>PREPARING FOR THE NEXT QUINQUENNIUM</b>	<b>28</b>
The ECMC Strategy (2017-22) receives the support from the funders	28
Progress on the ECMC Collaboration Agreement	30
The CRUK Centres and ECMCs Quinquennial Review	30

Figure 1:	The Adult and Paediatric ECMC Networks	4
Figure 2:	The number of new ECMC-supported studies in the Adult and Paediatric Networks in 2015/16	5
Figure 3:	Range of cancer types in the Adult and Paediatric ECMC Networks in 2015/16	6
Figure 4:	Range of treatment modalities in the Adult and Paediatric ECMC Networks in 2015/16	6
Figure 5:	Examples of some of the innovative studies that run through the ECMC Network	7
Figure 6:	Frame shot from JING video featuring Dr Stuart Williamson	9
Figure 7:	The words used by 2016 JING residential attendees to describe their experience	9
Figure 8:	CM-Path Initiative overview, outlining the four central work streams	11
Figure 9:	Bringing cancer treatments faster through the translational pathways	14
Figure 10:	The collaborative nature of the ECMC Network facilitates the delivery of world-class early phase research	15
Figure 11:	Number of new non-commercial and commercial trials in the ECMC portfolio in 2015/16	16
Figure 12:	Number of new ECMC-supported studies per financial year with the proportion of commercially-funded trials	16
Figure 13:	Examples of ECMC-supported trials that have attracted industry sponsorships	18
Figure 14:	Timeline showing the different partners of the ECMC Combinations Alliance	21
Table 1:	Number of ongoing trials in the ECMC Combinations Alliance portfolio	22
Figure 15:	Overview of the National Lung Matrix Trial	23
Figure 16:	The ECMC stand at the NCRI 2015 Conference	25
Figure 17:	#MultiMarvin featuring at NCRI 2015	25
Table 2:	Objectives for the Adult and Paediatric ECMCs for the next five years (2017-2022)	29
Figure 18:	Timeline for the CRUK Centres and ECMC quinquennial review	31

# INTRODUCTION

Launched in October 2007, the Experimental Cancer Medicine Centre (ECMC) Network is funded in partnership by Cancer Research UK (CRUK) and the Health Departments for England, Scotland, Wales and Northern Ireland. Through collaboration across the experimental medicine community, the ECMC Network's vision is to bring together laboratory and patient-based clinical research to speed up the development of better treatments for cancer patients.

The current quinquennium commenced in April 2012, providing a total of circa £35 million over five years to support 18 ECMCs (specialising in adult cancers) across the UK. In addition, the Paediatric ECMC Network is supported by the National Institute for Health Research (NIHR) (see Figure 1).

Each ECMC is a partnership between an NHS Trust or Board and a university, which enables the best health researchers and clinicians to work together to generate novel treatments for cancer patients. Investigators have used the ECMC award creatively to leverage additional funding from NHS Trusts, universities and commercial funders. This has helped to generate further income, which has been invested back into the centres to strengthen their capacity and capability. Locally, this has enabled ECMCs to expand the range of treatments offered to patients. Nationally, it has strengthened the translational research infrastructure of the UK, ensuring that it remains a competitive location for conducting clinical trials.

The ECMC Network is able to maximise its impact on patients by utilising the extensive cancer infrastructure available in the UK. The long-standing commitment of the Departments of Health of the UK Nations on clinical research infrastructure allows the Network to bring together scientific and clinical expertise and speed up the flow of innovation from bench to bedside.

The interaction with commercial partners remains a significant priority for the Network, with over 58% of all ECMC-supported studies involving a commercial partner as a sponsor and/or funder. As demonstrated by the many examples throughout this report, commercial partners are attracted by the ability of the Network to deliver early phase clinical trials and the access they are afforded to world-class translational infrastructure.

The success of the Initiative is endorsed by our five funding partners, who have all committed funding to the 2017-22 quinquennium. Thus, this year has seen preparations put in place for the next five-year funding period, starting in April 2017. Central to this has been the development of a new strategy for the Network, which the Secretariat has been leading. The strategy will clarify the role of the ECMC Network alongside other clinical research infrastructure. The strategy not only sets the scientific direction for the ECMC Network but also details the proposed operational framework and governance provisions that will underpin the Network.

Preparations have also begun for the quinquennial review itself, which will take place in October 2016. The review will be held jointly with CRUK Centres, to promote a unified cancer research strategy in the different sites. The review will ensure that the future ECMC Network is comprised of those centres with the scientific credibility, collaborative nature and track record of delivering complex studies to time and target. This annual report is not an exhaustive list of all activity at every centre; the case studies presented here are representative highlights of the important scientific and clinical achievements delivered by the ECMC Network in 2015/16.



Figure 1: The Adult and Paediatric ECMC Networks

# A NETWORK SUPPORTED BY SCIENTIFIC EXCELLENCE

The ECMC Initiative was created to speed up the development of better treatments for patients in the UK. To do this, the Initiative works around 3 objectives:

- ⦿ Delivering innovative treatments for cancer patients
- ⦿ Making the UK the place of choice to deliver trials
- ⦿ Building the capacity of the Network

This year we have seen incredible progress against all three objectives, demonstrating how the Networks have matured and become established, well-recognised places to deliver experimental cancer medicine.

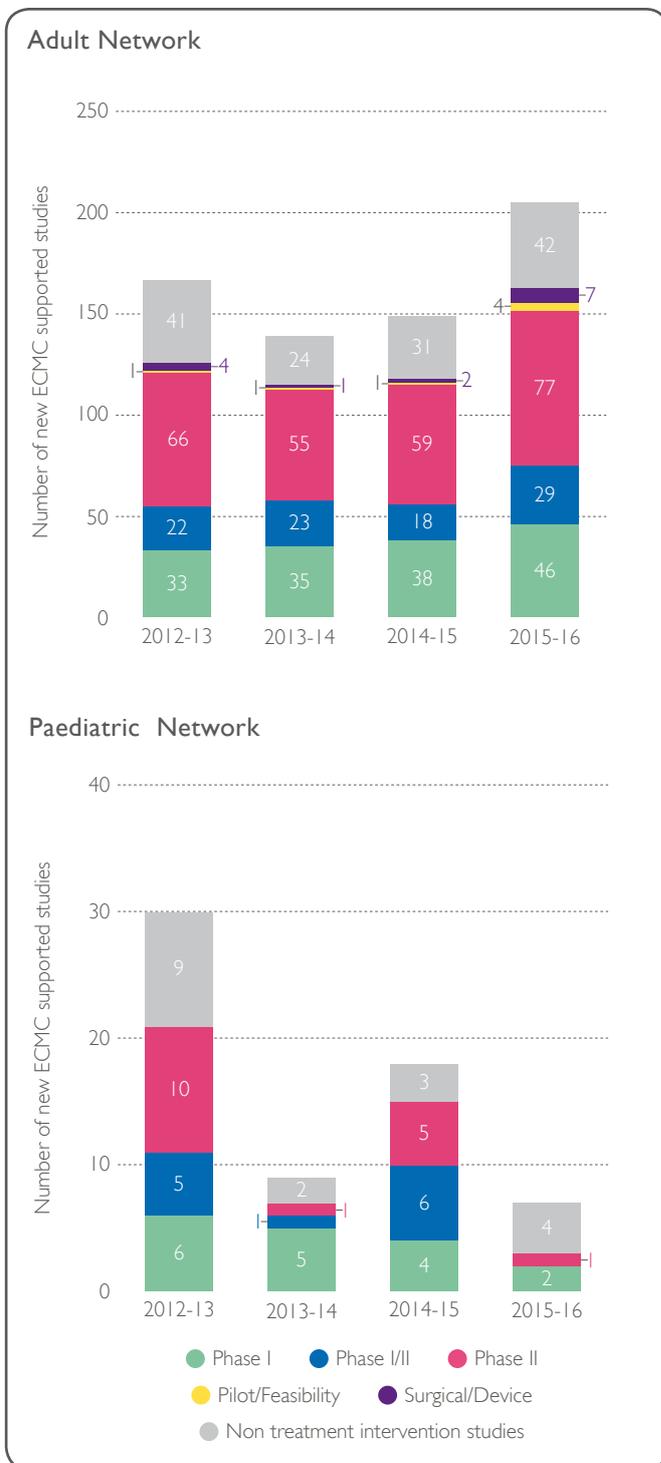
The impressive portfolio of trials recorded over the past year are too many to mention, see Figure 2 for some selected highlights from the ECMC Adult and Paediatric Networks. The breadth of expertise available at the ECMCs linked to access to patients through the associated NHS Trust/Board is clearly reflected in the ECMC portfolio.

During 2015/16 the Adult ECMC Network has continued to grow, with **over 150** new treatment interventional trials being reported and more than **2,000** patients recruited to **over 600** active trials. Most of the increase is due to the number of phase I/II and II trials, with a **38%** increase of trials reported compared to 2014/15.

When looking at the new cancer studies that both ECMC Networks have used ECMC support for, we observe a good spread of cancer types with over 20 different cancers available in the Adult ECMC portfolio and four in the Paediatric portfolio (Figure 3).

Whilst the Paediatric Network is specialised in the most common cancers affecting children, we can see that the Adult Network covers a broad range of cancers from the most prevalent ones (e.g. lung, leukaemia, breast cancers) to some rare types such as sarcoma or brain cancer.

In terms of treatment modalities (Figure 4), small molecule trials remain the most common treatments although there is a good variety of combinations trials where more than one modality is tested. These trials are more complex and the increasing number being reported in the ECMC portfolio shows the expertise in the ECMCs that form the Networks (Figure 5).



**Figure 2: The number of new ECMC-supported studies in the Adult and Paediatric Networks in 2015/16**

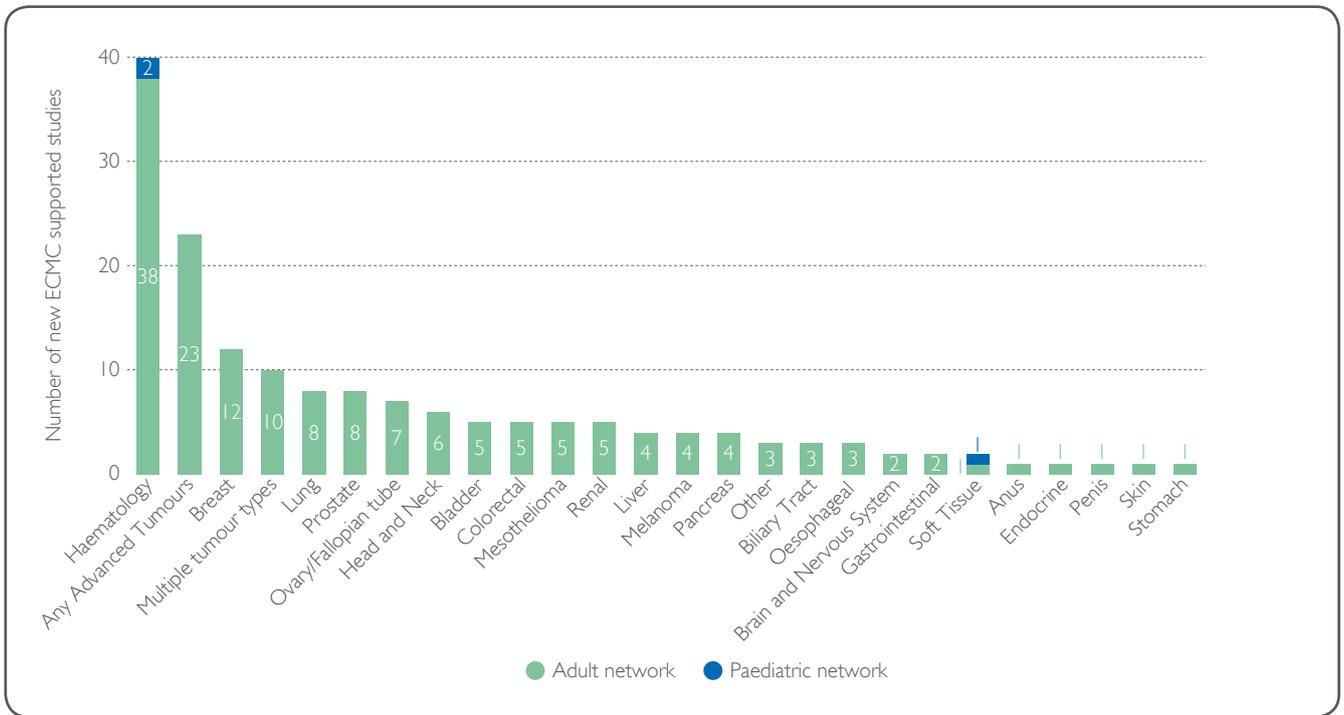


Figure 3: Range of cancer types in the Adult and Paediatric ECMC Networks in 2015/16

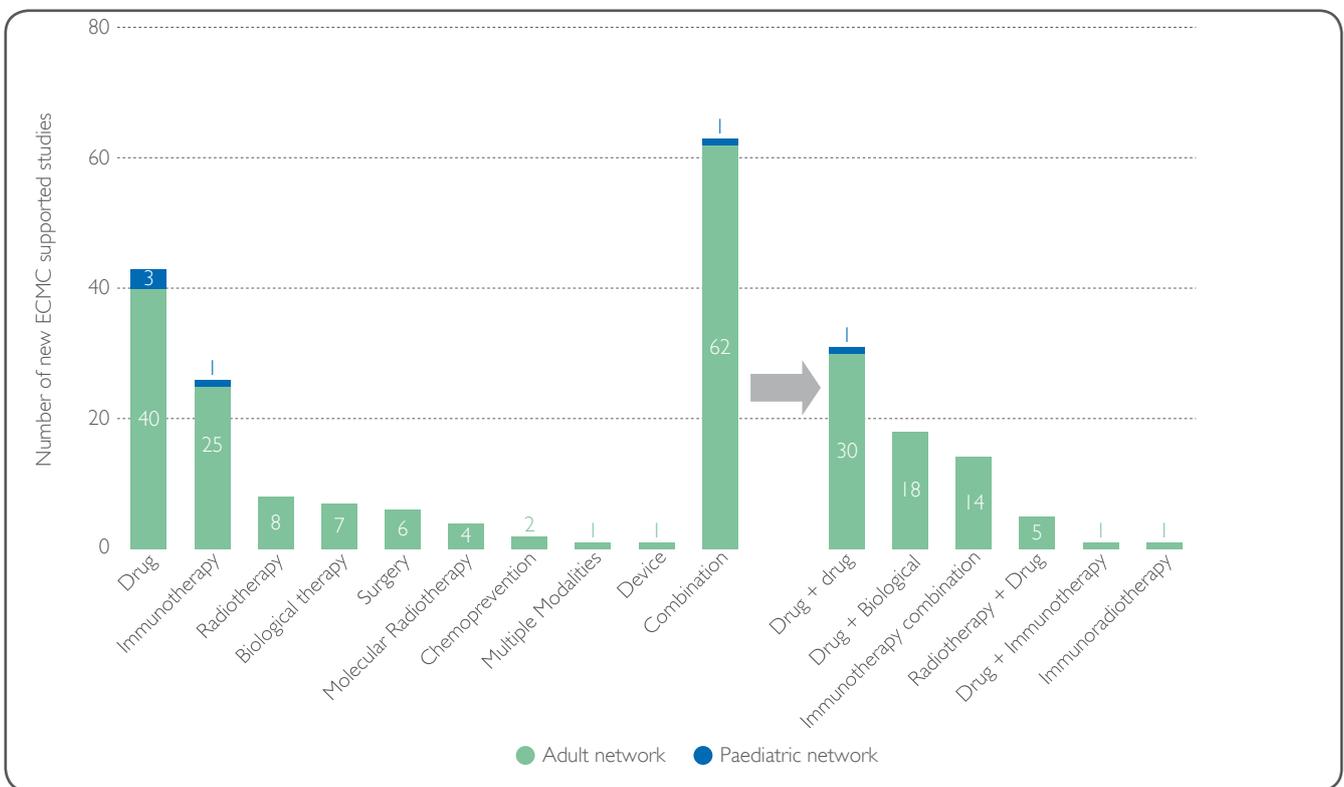


Figure 4: Range of treatment modalities in the Adult and Paediatric ECMC Networks in 2015/16



Figure 5: Examples of some of the innovative studies that run through the ECRC Network



We are delighted that our ECMC Network is continuing to help cancer patients around the country benefit from world-leading research taking place here in the UK



**Sir Harpal Kumar**

CEO of Cancer Research UK

**The Network Groups: Enhancing the UK's capacity in experimental cancer medicine**

A key objective of the ECMC Initiative is to build on the expertise available across our ECMC locations, by bringing together and connecting members of the Network. The Network Groups are central to achieving this, and some of their achievements are detailed below.

**The UK Therapeutic Cancer Prevention Network (UKTCPN)**

The UK Therapeutic Cancer Prevention Network (UKTCPN) group was established in 2013 to bring together a unique blend of expertise for research in cancer prevention including basic and translational scientists, clinicians, epidemiologists, statisticians and specialists in primary care, diet and nutrition.

With a core steering committee of 18 members across the ECMC locations and beyond, and a circulation list of more than 90 professionals in various disciplines related to cancer prevention, this year the group has delivered important milestones.

In November 2015 the group hosted the parallel session **'Prevention is better than cure: cancer chemoprevention in 2015'** at the 2015 National Cancer Research Institute (NCRI) Conference in Liverpool.

The session was attended by more than 80 people and drew on examples spanning from bench to bedside to highlight emerging areas, and reflecting on lessons learnt and past achievements in chemoprevention studies. It was hosted by Prof Jack Cuzick, with talks by national and international speakers and a lively panel debate with UKTCPN members. Given the success of the session, the group is now planning to propose a plenary session for future NCRI events.

Since November 2014 the group has also strengthened the interaction with Department of Health (DH) to provide scientific and clinical knowledge in the debate on drug repurposing. In January 2015, two group representatives took part in the DH roundtable on drug repurposing with George Freeman, Minister for Life Sciences.

The UKTCPN Steering Committee has also been working on the organisation of the two day conference in Bristol, **'Therapeutic interventions for cancer prevention – the way forward'** (18th – 19th July, 2016) jointly supported by the British Association of Cancer Research (BACR) and the ECMC Secretariat. The aims of the conference are to review the current state of the field, discuss the various challenges associated with developing therapeutic interventions for cancer and encourage collaboration that would facilitate the delivery of prevention strategies.

This meeting is expected to attract in excess of 100 attendees, including researchers (basic scientists interested in mechanistic pathways relevant to carcinogenesis, translational scientists working on chemoprevention), clinicians, epidemiologists, statisticians and geneticists undertaking clinical prevention trials.

The range of expertise available at the UKTCPN group makes it uniquely positioned to collaborate in multi-stakeholders projects, like the National Institute of Health Research (NIHR) led initiative on **'Cancer and Nutrition'**. The report on the first year of this initiative was published in July 2015, with a launch meeting in November 2015.

**UK therapeutic**  
**cancer prevention network**  
*collaborating to prevent cancer*

## Junior Investigators Network Group (JING)

The ECMC Junior Investigators Network Group (JING) is an established peer network of junior investigators from across clinical and scientific backgrounds, created in 2012 to bring together and help develop junior investigators across all disciplines of translational research within the ECMCs.

To ensure that the ECMC Network continues to drive the agenda for experimental cancer medicine in the UK, we need to encourage and support the leaders of tomorrow across all relevant scientific disciplines, and this is exactly what JING does.

In January 2016 the group hosted the 4th JING Training the Next Generation event in Newcastle. The two day residential course was attended by 49 junior investigators and supported by a faculty of 30 experienced researchers from the ECMC Network (senior clinicians, translational scientists, statisticians), and 6 patient representatives.

The programme was developed by junior investigators for junior investigators, with a wide range of topics for developing early phase and translational studies (e.g. trial design, use of appropriate biomarkers, combination studies).

For the first time, we also collected feedback from faculty, patient representatives and trainees during the event, and produced a short video to summarise trainees and faculty experience (Figure 6).



Figure 6: Frame shot from JING video featuring Dr Stuart Williamson

This video was released in the February ECMC Newsletter and proved very popular with our immediate Network and further online Twitter community.

Particularly well received by the trainees were the more interactive sessions on developing their own study ideas and learning to engage patients in their research. The feedback on the value of the event has been extremely positive, with some attendees acknowledging this as one of the most useful events they ever attended (Figure 7).



Figure 7: The words used by 2016 JING residential attendees to describe their experience

In the last year, the group has also built a portfolio of bursary schemes to support the participation of junior investigators of the Network in external training schemes. During 2015/16 three trainees were supported to take part in the NCRI Clinical Studies Groups (CSGs) Trainee Scheme, with the opportunity to experience the workings of a national CSG. This year we extended the bursary to up to 10 successful applicants for the September 2016 intake.

In February 2016 we launched a shadowing scheme with Cancer Research UK's New Agents Committee (NAC); one trainee attended the first meeting in February and two more will be attending the June and October meetings.

After the success of last year, we have made funding available to junior investigators in the ECMC Network to cover participation fees for the 'ECCO, AACR, EORTC & ESMO Methods in Clinical Cancer Research course', taking place in Zeist, Netherlands in June 2016.

## TRAINING THE NEXT GENERATION:

### Dr Matt Ahearne (Leicester ECMC) attended the NCRI CSGs Trainee Scheme



Last year the ECMC Network provided support for junior investigators to attend the NCRI Clinical Studies Groups (CSGs) Trainee Scheme. The scheme offers the opportunity to experience the workings of a national CSG in the trainees' area of interest.

Dr Matthew Ahearne of Leicester ECMC was awarded ECMC funding support, and attended meetings of the Lymphoma Clinical Studies Groups. During these meetings, he was involved in the discussion of ideas for the next national front-line T-cell lymphoma trial and successfully submitted two grant applications alongside other CSG members.

After attending the trainee scheme, Dr Ahearne said that he had found the experience invaluable:

**'I learned to understand the challenges faced with trial design, pharmaceutical engagement, set-up, and recruitment.'**

Following on from previous successes, the ECMC Network is providing support for up to 10 ECMC junior investigators to attend this year's Trainee Scheme, beginning in August 2016.

All of these activities are designed to give junior investigators a better understanding of all the different elements that are required in a successful grant application.

The Group's Steering Committee is currently reviewing the work plan and deliverables to identify further ways to improve the skills of junior investigators in the Network, and is considering other training and mentoring opportunities for both clinical and non-clinical trainees.

### Cellular and Molecular Pathology (CMP) Network Group

**The Cellular & Molecular Pathology Network Group was set up in May 2014 to scope out the extent of the expertise gap in cellular pathology in the UK. With this understanding of the current landscape of pathology, the group aims to create a culture of innovation and up-skill the cellular pathology workforce in the Network.**

During 2014-2015 the group developed the Cellular Molecular Pathology (CM-Path) Initiative proposal for a five-year programme, under the guidance of Dr Bridget Wilkins and in collaboration with National Cancer Research Institute (NCRI).

The programme aims at reinvigorating pathology research in the UK, and is articulated in four work streams (WS) with overlapping cross-cutting themes (Figure 8).

During the opening ceremony of the 2015 NCRI Conference in Liverpool, the NCRI Director - Dr Karen Kennedy - announced that NCRI had committed £635,000 to the CM-Path Initiative over five years.

In February 2016 Dr Karin Oien (Glasgow ECMC) was appointed Chair of the CM-Path Initiative, and recruitment is on the way to appoint the workstream leads.

The formal launch of the CM-Path Initiative is expected in June 2016, and it will act as an occasion to celebrate the achievements of the ECMC CMP Network Group in shaping the programme.

The launch will also mark the opportunity to look towards the future of the Initiative and cellular and molecular pathology in the UK. As a healthy pathology community is vital to the delivery of experimental cancer medicine, we will continue to assist the CM-Path programme as required.

## Research Nurses Network Group

The Research Nurses Network Group promotes quality care for patients taking part in early phase research through peer support, training and guidance for research nurses working in early phase and translational research.

This year, the steering committee of the Research Nurse Network Group organised a workshop at the ECMC Annual Network meeting in May 2015 entitled ‘Use of IT and Social Media by Health Professionals’.

This workshop gave delegates a chance to hear about innovative uses of IT in the research setting and how social media is being used to raise the profile of research and increase engagement. On the day delegates heard from speakers discussing dynamic consent, Cancer Research UK’s Citizen Science Programme, using social media, TED talks and patient blogs.

In addition, a poster was presented at the NCRI Cancer Conference in November 2015 showcasing the results

of the survey (undertaken in March 2015) to better understand the experience of patients participating in early phase trials. Patients were overwhelmingly positive about their experience of participation in early phase clinical trials. Individual centres received their results for local actions and some centres have already implemented actions in response to their survey results. For example, Oxford ECMC produced a film to highlight research in the local area, and after Newcastle received comments on how uncomfortable the chairs were, a new set of chairs was purchased for the Sir Bobby Robson Cancer Trials Research Centre.

Whilst no issues on substantive Network-wide areas for improvement were identified by the survey, it was agreed that the survey would be repeated in a few years’ time in order to ensure that standards are maintained.

Following the positive feedback of the one-day course ‘An introduction to early phase cancer trials: everything you wanted to know but were too afraid to ask’ delivered in London in 2014, it was run for a second time in Birmingham in February 2016.

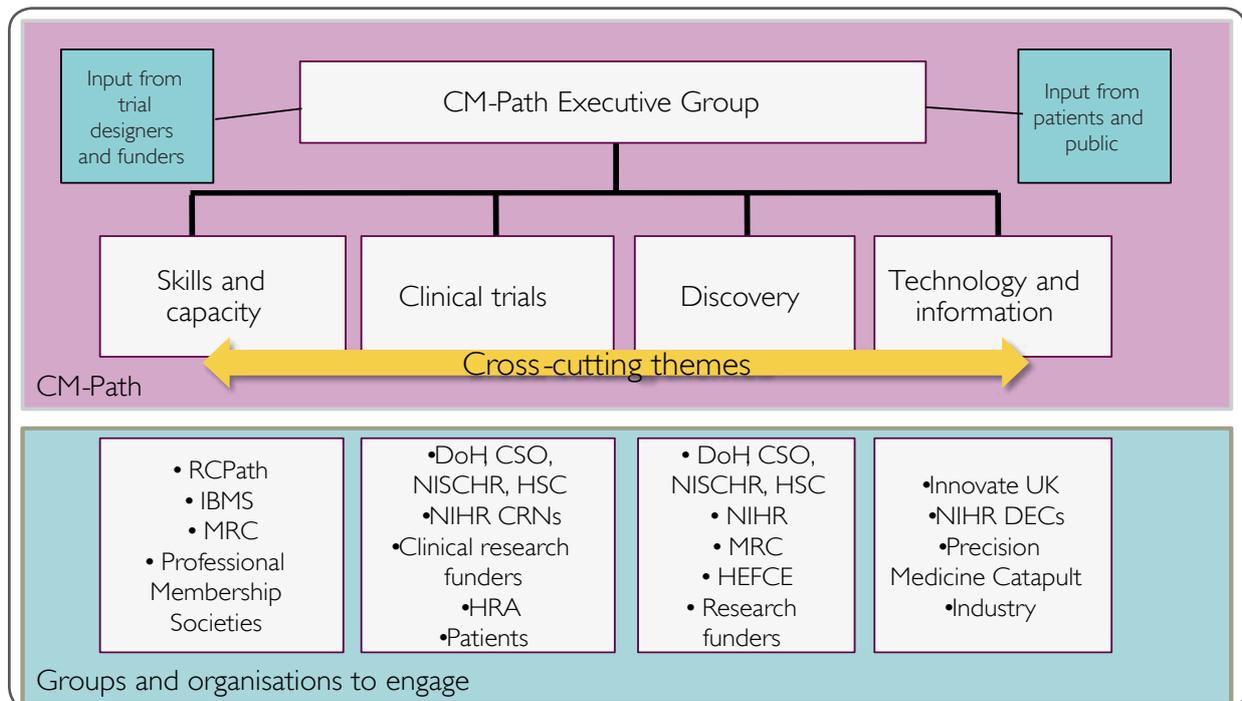


Figure 8: CM-Path Initiative overview, outlining the four central work streams



The purpose of this training day was to equip new early phase nurses with the skills needed to deliver quality, patient-centred care within the clinical trial regulatory framework. Topics covered on the day included clinical development of a protocol, preparations to start a trial, running of a trial, and end of study.

Participants from this year's event had a range of experience in early phase cancer trials, with over 50% of the attendees having worked in early phase cancer research for under a year. The course was able to cater to all needs, as despite the different experience in this field, 96% of them found the training useful. The Group's steering committee will discuss how to take this training day forward; for example whether it should become an annual event or if content should be available online for local inductions.

### Patient and Public Involvement Group (PPI)

**The ECMC Patient and Public Involvement (PPI) Group was developed to act as advisory group for the whole ECMC Network on issues involving patient and public involvement.**

By reviewing and overseeing the project specific working groups including group objective setting, the PPI group feeds updates and shares activities from across the Network. When required, the group can act as a sounding board for local initiatives and can assist on areas that require collective opinion.

Despite being in existence for only one year, the group has been extremely proactive. Some of the Group's activities during 2015/16 have included:

- Agreed the remit for the ECMC PPI Group. This remit and the membership of the group will be

reviewed in March 2017, at the end of the current quinquennium.

- Shared a baseline matrix of each location's PPI activities. In future, the group will be privy to the responses given by each ECMC location to the PPI questions in the ECMC Annual Report Form.
- Established a working group to look at training/education issues specific to PPI in early phase cancer trials. This group is working on pulling together some resources that can be used by anyone looking at involving people affected by cancer in early phase cancer trial activity.
- Commented on the PPI question in the ECMC Quinquennial Review paperwork. This is to ensure that patients are involved with the work carried out throughout the ECMC Network.
- Started to jointly work with the ECMC Research Nurse Network Group. This aims to look at the issues of repeat and multiple tumour biopsies in experimental therapies.

### Quality Assurance and Translational Science Network Group (QATS)

**The Quality Assurance and Translational Science (QATS) Network Group supports and enables ECMCs to conduct translational research to the appropriate levels of quality and regulatory compliance, utilising validated, cutting-edge techniques.**

The decision was taken last year to split the group into two subgroups – Quality Assurance (QA) and Translational Science (TS) – in order to better tackle the diverse set of priorities of both groups.

# Molecular radiotherapy was identified as a technique requiring further research in the report of the Independent Cancer Taskforce

Since then, the QA subgroup has been working hard to engage the ECMC QA community on setting their priorities. Initial ideas for the group's work plan were to identify at least one QA contact in each ECMC location. Once this was done, a survey was sent out to identify the needs of the group to help develop the group's work plan.

The steering committee who took on board the feedback from the survey and in response, developed a monthly communications update which provides details on forthcoming workshops and meetings, information on meetings attended by Network members and any regulatory updates.

An 'Areas of Expertise' document was sent out with this communication as well as being on the ECMC website. The purpose of this document is to make the QA contacts aware of others working in QA within the ECMC Network and to give them an idea of whom they could contact with certain queries.

The expectation is that if you add your details to the document that you will be happy to receive queries on the topics that are indicated as your areas of expertise. The responses from the survey have also helped the group to identify topics for future workshops, such as the workshop on Audits and Inspections planned for April 2016.

The Translational Science (TS) subgroup is currently going through a period of review in order to ensure that it complements the strategic direction of the ECMC Network and any other existing groups working in this area.

The Group's steering committee has been reviewing membership, remit and work plan for the subgroup, and will be meeting again in Q2 to ratify their decision.

## CRUK, ECMC and UK Radiopharmacy Group Taskforce (CERT)

**The CRUK, ECMC and UK Radiopharmacy Group Taskforce (CERT) has the key aim of acting as the primary interface between the molecular radiotherapy/radiopharmacy communities and regulatory authorities.**

An emphasis is placed on creating a common understanding of the regulatory, quality and multi-disciplinary requirements necessary for the development and delivery of clinical trials that involve radiopharmaceuticals, primarily at ECMCs but also at all other relevant UK clinical trial units.

During the previous 12 months, CERT has been pivotal in facilitating and providing support for a national review of molecular radiotherapy (MRT) research in conjunction with the Clinical and Translational Radiotherapy Research Working Group (CTRad).

Seeking to understand the barriers which restrict the UK's ability to perform high quality MRT research, the final report is due to be published by the National Cancer Research Institute during April 2016 and will also be launched by CERT at the Spring Meeting of the British Nuclear Medicine Society (BNMS) being held 18-19 April 2016.

Of note, MRT was also identified as a technique requiring further research in the report of the Independent Cancer Taskforce: **"Achieving world-class cancer outcomes: a strategy for England 2015-2020"**. CERT has also been actively involved in setting up a larger multi-disciplinary group with other key MRT stakeholders under the umbrella of the BNMS.

The remit of this umbrella group is to boost coordination of MRT research, improve standards of preclinical and clinical development, produce best practice guidelines, publish reports/white papers and generally promote MRT activity.

The findings from the national review of MRT will feed directly into this process and should assist with forming the basis of a national strategy and roadmap for MRT research in the UK.

### Working together to drive delivery and maximise the Network's capacity

The ECMC Initiative would not be able to build the capacity in the field of experimental cancer medicine without a real commitment to team work across the Network. Through existing collaborations in the Adult and Paediatric Networks we can see that our ECMCs are able to maximise resources and expertise to bring the best treatments to patients.

This year we have seen some exiting cases on how cancer treatments are now being more speedily brought through translational pathways (Figure 9), and how the collaborations across our ECMCs have consolidated (Figure 10).

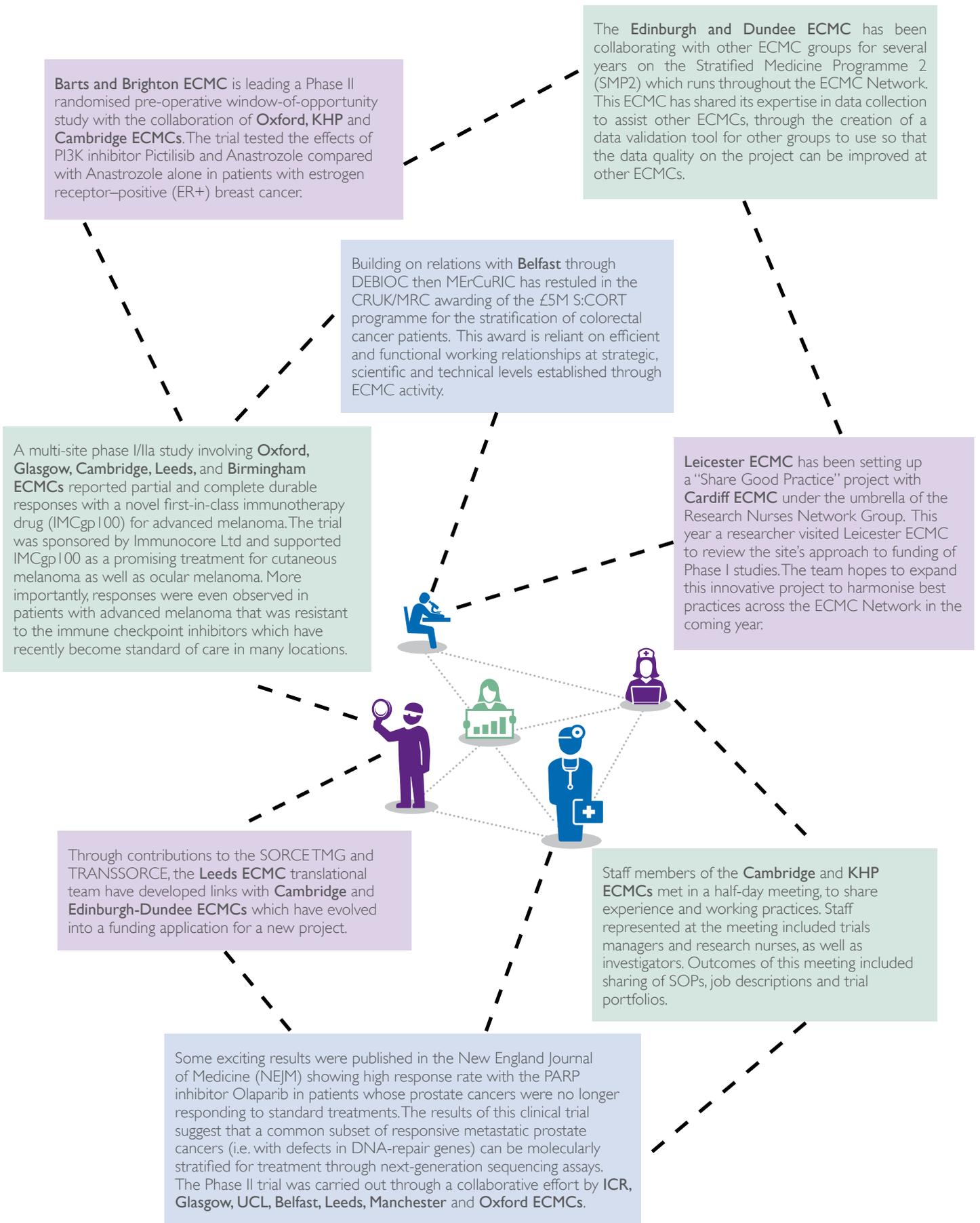
Imperial ECMC have reported excellent progress with the FETONET cohort 2, which has recently expanded recruitment to four ECMCs: ICR, UCL, KHP and Manchester. The study compares 68-gallium labelled somatostatin analogue to a new 18F somatostatin radioligand discovered by Imperial College scientists for staging of neuroendocrine tumours.

Following the successful completion of two ECMC-supported Cytosponge trials (i.e. BEST1 and BEST2), the Cambridge ECMC have successfully secured funding for BEST3. This is a cluster randomised design in primary care for 4,000 patients with reflux symptoms comparing Cytosponge with usual clinical care. It is anticipated that this will be the last trial required for NICE to decide whether this technology can become part of routine clinical care in the NHS.

Barts and Brighton ECMC have made significant progress in developing treatments for malignant mesothelioma. Last year, the team completed the ADAM trial, a Phase II multicentre study of arginine deprivation using ADI-PEG20 which was presented at the ASCO conference. Results from this trial led to the opening of a new Phase I trial: the TRAP trial. This novel trial tests subjects with tumour requiring arginine to assess ADI-PEG 20 with pemetrexed and cisplatin (ADIPemCis) and has recently progressed to Phase II/III trial.

The KHP ECMC led the first in human intra-operative Cerenkov Luminescence Imaging (CLI) to guide surgery in breast cancer. Funded by Innovate UK, it is a proof of principle feasibility trial in partnership with industry. The trial provided evidence that CLI can be safely used to determine margins of tumour resection in real time. The results of this work leveraged £3 million in funding from a Horizon 2020 grant and the Guy's and St Thomas Charity, to proceed to an international multicentre randomised controlled trial.

Figure 9: Bringing cancer treatments faster through the translational pathways



**Figure 10: The collaborative nature of the ECMC Network facilitates the delivery of world-class early phase research**

# WORKING IN PARTNERSHIP WITH INDUSTRY

The ECMC Network is a collaboration between world-class scientists and clinicians across the four UK Nations, which makes it an incredibly attractive business venture for industry partners.

Attracting increased interest from industry is a key objective for the ECMC Secretariat and the Network as a whole. The percentage of trials that are commercially-supported has been maintained in the Adult Network whilst the number of academic trials reported has increased. 60% of trials in the Paediatric Network are commercially supported.

ECMCs have a track record in attracting a significant amount of funding from industry with over 90 new trials in the Adult ECMC portfolio being commercially-supported (Figures 11 and 12). This is clearly associated with the increase of randomised trials reported for 2015/16, with the commercial portfolio representing 58% of the studies. This in turn means that patients in the UK get access to innovative treatments at the earliest opportunity.

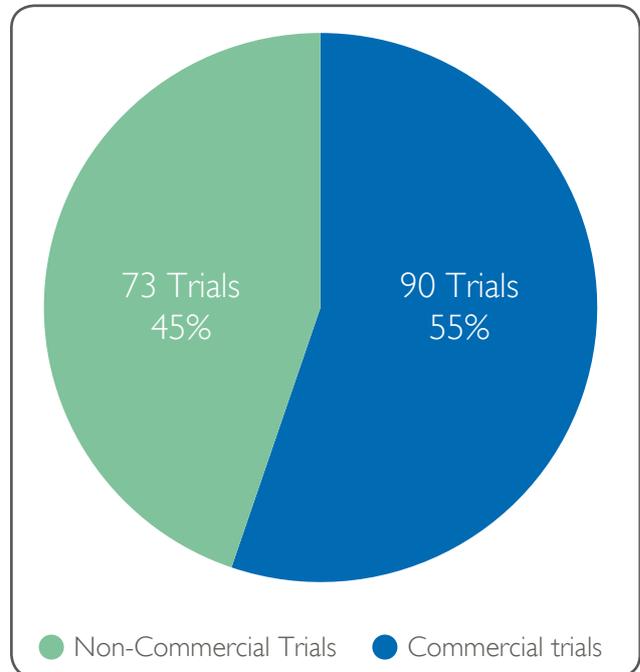


Figure 11: Number of new non-commercial and commercial trials in the ECMC portfolio in 2015/16

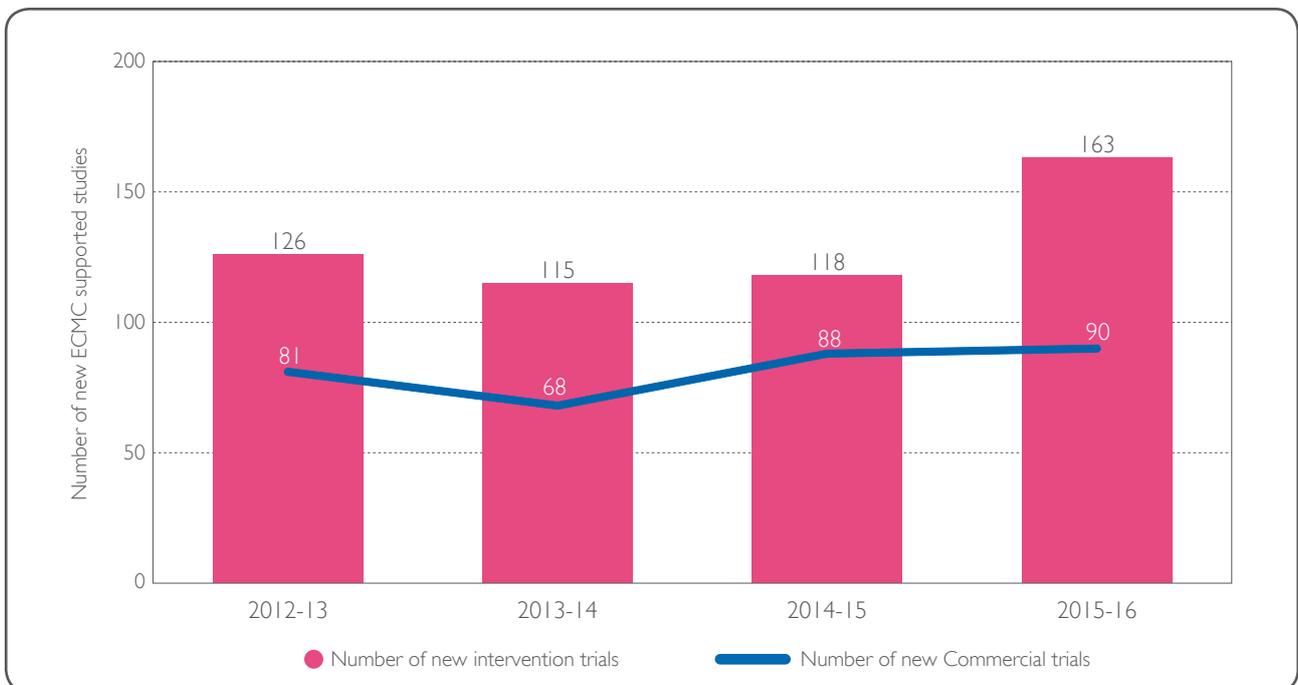


Figure 12: Number of new ECMC-supported studies per financial year with the number of commercially-funded trials

Industry partnerships are vital in driving the development of the cancer treatments for tomorrow (Figure 13). The ECMC brings together world-class pockets of expertise at each of its locations, and provides industry partners the opportunity to collaborate with academia to obtain access to cutting-edge, early-stage innovation, and integration with clinical centres run by outstanding academic leads.

### Improving processes to support delivery

The operational delivery of trials has always been recognised as a challenge and is seen by industry as a bottleneck to investing in the UK.

To help tackle this, the ECMC Secretariat embarked upon the Trial Harmonisation Programme (ETHP). The ETHP has introduced a more collaborative and harmonised way of working towards the delivery of trials across the Adult ECMC Network. These changes are aimed at ensuring that the Network is nimble and responsive, able to maximise all its resources, and that the UK is placed at the forefront of experimental cancer medicine.

### Streamlining industry liaison processes through the ECMC Trial Harmonisation Programme (ETHP)

The common research infrastructure of the ECMC Initiative makes it ideally placed to harmonise and transform the way UK-wide early phase cancer trials are managed across the Network.

The ETHP aims to help build on the current ECMC Initiative and transform it into a UK-wide, world-class Network for the fast and efficient delivery of early phase oncology clinical trials. In order to manage the way industry engages with the ECMC Network, the ECMC Secretariat will transition to a Programme Office in advance of the new quinquennium. The Programme Office will include an operational function to create streamlined processes for industry to liaise more quickly with the ECMC Network.

The work is already underway, and for example, a non-confidential enquiry form is now available through the ECMC Network, where interested industry partners can

submit an Expression of Interest (Eoi) form that is quickly assessed for capacity and capability by the Programme Office.

If the outcome of the Eoi call is a successful one, the Programme Office will work closely with the commercial organisation to guide them through the process, including the signing of a Non-Disclosure Agreement (NDA). Several commercial organisations, major pharmaceutical companies, and small biotechnology companies (both national and international) have already used this route into the Network through the Programme Office.

An evaluation of newly developed industry liaison processes will be planned for later in 2016, as we continue to refine and expand the function of the Programme Office in preparation for becoming fully operational in the next quinquennium. Early signs indicate that the functions that the Programme Office offer are of interest both to large pharmaceutical companies and to smaller biotechnology firms.

### ECMC Non-Disclosure Agreement (NDA) template

It is widely acknowledged amongst ECMC Leads that signing Non-Disclosure Agreements (NDAs) can significantly delay the setup of a clinical trial. The need for a speedy signing-off process between numerous organisations highlights the benefits of a multi-party NDA that allows early access of study opportunities to the Network. To help speed up the discussion process between members of the Network and interested commercial organisations, an agreed ECMC NDA has been delivered through the ECMC Contracts Working Group.

This NDA has been available for use by the Network since December 2015. The ECMC NDA is the first UK-wide compatible template to be used on a per study basis (commercial or non-commercial studies) between ECMC member organisations and a third party. If used in the unmodified form, it allows efficient access for interested ECMC Leads to discuss a study opportunity with a commercial organisation, therefore enabling feasibility assessments to be completed in a timely manner.



Figure 13: Examples of ECMC-supported trials that have attracted industry sponsorship

## CytomX:

### Oxford ECMC to bring the first partnership with industry centralised through the ECMC Secretariat

In order to effectively manage the way industry works with the ECMC Network, the ECMC Secretariat has recently introduced a streamlined approach to quickly engage with ECMC Leads. This will allow the Secretariat to act as a central point of contact to help manage and facilitate initial industry enquiries across the Network. The Oxford ECMC was the first ECMC to notify the Secretariat that a US-based niche pharmaceutical company - CytomX - was interested in developing a multi-centre study using an immunotherapy agent based on the Probody™ technology platform.

A non-confidential enquiry form was completed by the company to allow quick assessment for capability and capacity of potential sites in the Network through an Expression of Interest (EoI) call facilitated by the Secretariat. Outcome of the EoI led to the identification of 11 interested ECMC locations with Oxford ECMC as the lead site. To further engage with the commercial opportunity, the execution of the ECMC Non-Disclosure Agreement (NDA) template in its unmodified form between all relevant parties was done within 3 working days.

The pathway to continue developing this opportunity sits with CytomX to confirm the Clinical Research Office (CRO) for the UK sites. Once confirmed, the Secretariat will progress this opportunity to protocol feasibility assessment and guide CytomX on expediting trial set up timelines by using the model agreement templates which ECMC sites have pre-agreed through the ECMC Collaboration Agreement.

This streamlined process for early engagement with the ECMC Secretariat and the wider ECMC Network has been beneficial in enhancing our reputation in early phase clinical cancer research with commercial partners like CytomX.

To date, CytomX (see case study) has already accepted the ECMC NDA in its unmodified form and a fully executed agreement signed by all interested parties was completed in under four working days.

### Working on a national level to streamline R&D processes across the Network

In 2014 the Health Research Authority (HRA) was tasked with undertaking a complete overhaul of the process for approving studies that use the NHS in England, with a view to having a more transparent and timely approach.

The ECMC Secretariat has been working closely with the HRA to assist in this activity and to help ensure that the new processes meet the needs of the Network. Together with the HRA we designed a streamlined process for pharmacy reviews, which in the pilot period alone, saved 170 duplications of reviews, totalling hundreds of man-hours saved. We expect this Pharmacy Assurance process to be rolled out to all studies nationally in the near future, but in the meantime the HRA will continue to run this

process for all ECMC studies.

A second joint HRA-ECMC streamlined process for medical exposure reviews is also complete. From implementation in January 2015 to the end of October 2015, 16 reviews were completed. These studies underwent a thorough pre-expert check that facilitated faster Integrated Research Application System (IRAS) and site set-up reviews, as a result of reducing queries at later stages of the research approval process.

As with the pharmacy work, assurances around medical exposure to ionising radiation will also form a component of HRA Approval that will aim to remove duplication from sites, freeing the time of researchers, Clinical Radiation Experts (CRE), Medical Physics Experts (MPE) and clinicians whilst maintaining an acceptable level of assurance within the regulatory framework. These collaborations with the HRA are just one example where the influence of the ECMC Initiative has reached well beyond experimental cancer medicine.

# The ECMC NDA is the first UK-wide compatible template [...] between ECMC member organisations and a third party

## Platforms embedded in our Network

The ECMC Network is designed to be a platform to build complex and challenging initiatives upon, such as the ECMC Combinations Alliance (CA) and the Stratified Medicine Programme (SMP). These programmes are pushing ground-breaking work and, in turn, are being seen as supporting the mission of the ECMC Initiative: to provide better and faster treatments to cancer patients in the UK.

### ECMC Combinations Alliance

Over the last year the CRUK Centre for Drug Development (CRUK CDD) has continued to drive the ECMC Combinations Alliance Initiative. Launched in 2010, the Initiative aims to increase novel combination treatment options for people with cancer by bringing academia and industry together.

The Alliance offers academic researchers the opportunity to develop novel ideas while commercial partners are able to realise the further potential of their pipelines. Combinations not typically pursued by drug companies, including radiotherapy trials, cancers of unmet need and combinations involving cross companies, are encouraged in this joint alliance.

During 2015/16, the ECMC Combinations Alliance Joint Steering Committee (JSC) was expanded with the inclusion of a member from each ECMC, providing broader disease expertise as well as a local advocate for the Alliance in each site. In terms of partnerships,

Plexxikon, Immodulon and Acceleron joined the Alliance alongside existing partners AstraZeneca, MedImmune, Biothera, Astex, Lilly, Clovis and Verastem, bringing the total number of partnerships to 10 (Figure 14).

There has been some exciting activity in the Alliance portfolio this year with 24 drugs offered to the ECMC Network via 3 formal Expression of Interest (Eoi) calls. These included Immodulon's immune modulator, Clovis's PARP and PI3 kinase inhibitors, which generated 44 Eoi proposals covering preclinical and clinical stages of development.

A total of 30 studies - 18 preclinical and 12 clinical - were submitted to CRUK's New Agents Committee (NAC) which resulted in two cross-company trials being approved: the FAK-PDI trial on solid tumours involving Verastem and Merck, and the DREW trial in ovarian and endometrial cancers involving Verastem and Clovis. More importantly, the first clinical trial involving paediatrics and adults was approved (SELUDEX) by NAC which will be running through the Paediatric ECMC Network.

Since its launch in 2010, the ECMC Combinations Alliance has seen its portfolio grow, reaching a mature stage, with several trials transitioning from the setup phase to recruiting patients (Table 1). For example, data generated from the TAX-TORC trial was key in the design of the next phase of the trial - the NIHR-funded study OCTOPUS - which is now open.

Finally, the Radiotherapy Drug Consortium (RaDCom), an Alliance-associated initiative, is supporting the progression of more preclinical RT-drug combination projects, with a total of 9 projects awarded funding from the NAC, several in collaboration with industry partners.

RaDCom has further supported industry engagement through the development of consensus recommendations to increase the number of novel drugs being successfully registered in combination with radiotherapy. The consensus document aims to improve clinical outcomes for patients with cancer and is currently under review at **Nature Reviews Clinical Oncology**.

9

Preclinical RT-drug combination projects progressed from RaDCom

24

Drugs offered to ECMC Network via Combination Alliance formal EoI calls

30

Studies submitted to CRUK New Agents Committee

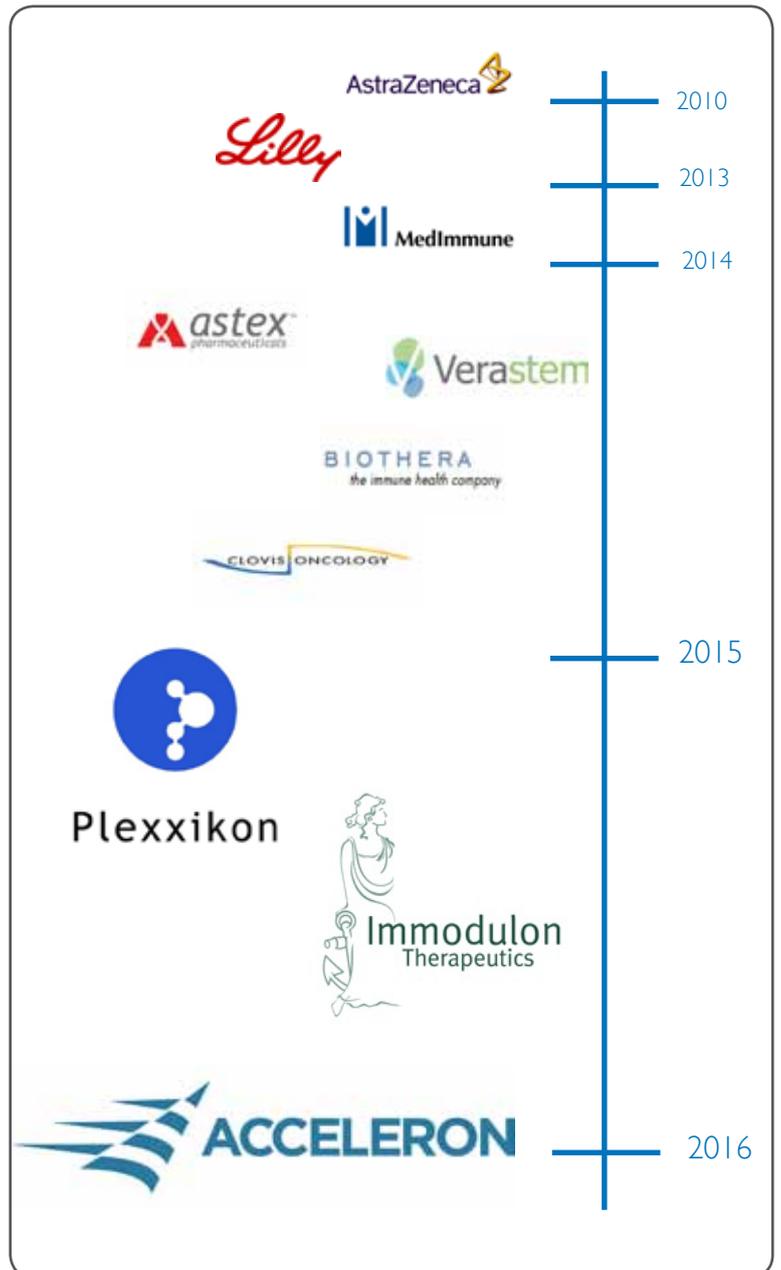


Figure 14: Timeline showing the different partners of the ECMC Combinations Alliance

Project/ Trial	CI	Sponsor	Source/ Partner	Combination	Indication	SetUp	Open	Closed
SELUDEX	Vormoor	Birmingham	AstraZeneca	Selumetinib + Dexamethasone	Paediatric & adult ALL	●		
DREW	Drew	Glasgow	Verastem / Clovis Oncology	PI3K/mTOR inhibitor + PARP inhibitor	Ovarian & endometrial	●		
WISTERIA	Mehanna	Birmingham	Verastem	Wee1 inhibitor + cisplatin + RT	H&N	●		
PARADIGM -2	Chalmers	Glasgow	AstraZeneca	PARP inhibitor + RT/TMZ	GMB	●		
VS6063 + PDI/PDL1	Symeonides	Glasgow	Verastem	FAK inhibitor + anti PDI/PDL1	Solid tumours	●		
SPIRE	Crabb	Southampton	Astex	SGI-110 - Cisplatin/Gemcitabine	Bladder		●	
ORCA2	Forster	UCL	AstraZeneca	PARP inhibitor + Cisplatin + RT	HNSCC		●	
HIRPOC	Glasspool	Glasgow	Lilly	Hedgehog inhibitor + Paclitaxel	Ovarian		●	
PIONEER	Evans	Glasgow	AstraZeneca	PARP inhibitor + Capecitabine + RT	Pancreatic		●	
TORCMEK	Schmid/ Middleton	Barts	AstraZeneca	MTOR inhibitor + MEK inhibitor	NSCLC		●	
DEBOIC	Thomas	Oxford	AstraZeneca	mixed Erb inhibitor + Oxiplatin/ Capecitabine	Oesophogastric		●	
RADICAL	Seckl	Imperial	AstraZeneca	FGFR inhibitor + Anastrozole + Letrozole	Breast		●	
FIESTA	Chester	Leeds	AstraZeneca	FGFR inhibitor + Gemcitabine/ Cisplatin	Bladder		●	
VANSEL	Talbot	Oxford	AstraZeneca	MEK inhibitor + RET, EGFR, VEGF inhibitor	NSCLC		●	
TAX-TORC	Banerji	ICR	AstraZeneca	mTOR inhibitor + Taxane	Ovarian/ Fallopian		●	
ComPAKT	Yap	ICR	AstraZeneca	AKT inhibitor + PARP inhibitor	Oesophogastric		●	
PATRIOT	Harrington	RMH/ ICR	AstraZeneca	ATR inhibitor + RT	Solid tumours		●	
PANtHER	Hochhauser	UCL	AstraZeneca	EGFR inhibitor + FOLFIRI	HN/ abdo/ pelvic/ thorax		●	
VIBRANT	Thirwell/ Sarker	UCL	AstraZeneca	RET, EGFR, VEGF inhibitor + Iodine 131 MIBG	Colorectal			●
FACING	Evans	Glasgow	AstraZeneca	FGFR inhibitor + Cisplatin/ Capecitabine	Phoes & PG			●
DREAM	Saunders	Manchester	AstraZeneca	MEK inhibitor + VEGFR inhibitor	Oesophogastric			●

**Table 1: Number of ongoing trials in the ECMC Combinations Alliance portfolio**

### CRUK Stratified Medicine Programme 2 (SMP2)

Through its Stratified Medicine Programmes (stages 1 & 2), Cancer Research UK is taking ambitious and significant steps towards making targeted therapies available to eligible cancer patients in the UK.

Building on the strong foundations laid by Stratified Medicine Programme 1 (SMP1), SMP2 is a collaborative programme between Cancer Research UK, the ECMC Network, NHS, University of Birmingham Cancer Research Clinical Trials Unit (CRCTU), Illumina (NGS technology

provider), Astra Zeneca and Pfizer (pharmaceutical partners).

SMP2 delivers a national molecular diagnostics service that offers high quality, standardised and cost-effective genetic testing to patients within a clinically useful timeframe. SMP2 supports the national genetic pre-screening that selects lung cancer patients to the multi-arm, multi-stage National Lung Matrix Trial (NLMT). SMP2 is now open to recruitment at 16 Adult ECMCs but through a hub and spoke model, it is able to reach more than 45 hospitals across the UK.

Once patients are consented, their tumour samples will be analysed in the three SMP Technology Hubs (Birmingham, Cardiff and ICR ECMCs). These Hubs will use the Illumina 28-gene panel to test for a number of genomic aberrations that will assess whether a patient is able to join the NLMT.

This year the SMP2 team are pleased to report that through utilisation of the ECMC Network, over 1,000 samples have now been tested through SMP2, with an average Quality Control (QC) failure rate of 32%. Work is underway to optimise the sample pathways especially at sites with a higher than average QC failure rate.

In addition, over 250 patients in the system have been identified who are molecularly eligible for one or more of the MATRIX arms, and work is ongoing to release site specific information to sites on a weekly basis in order to increase the visibility of the results. Finally, following a second comprehensive data audit, the SMP2 team has identified over 20 areas of improvement that span the entire SMP2 pipeline and will be the area of focus for next year. These areas can be grouped in the following themes:

- ⦿ Sample and patient eligibility criteria
- ⦿ Sample processing
- ⦿ Turnaround times

Changes and optimisation of the NGS panel and the optimisation, usability and speed of the bioinformatics pipeline.

### The National Lung Matrix Trial (NLMT)

The National Lung Matrix Trial (NLMT) is a multi-arm umbrella trial in which non-small-cell lung cancer patients with Stage IV disease, or Stage III disease not amenable to surgery or radical radiotherapy, are allocated to their treatment arm according to the molecular phenotype determined by the SMP2 pre-screening programme. The NLMT is, to our knowledge, currently the largest precision medicine trial globally.

The NLMT trial is an academically-led collaborative study between the University of Birmingham, CRUK, Astra Zeneca and Pfizer, sponsored by the University of Birmingham and coordinated by the Birmingham ECMC (Figure 15). The trial utilises a novel adaptive trial design and consists of a series of parallel, single-arm Phase II trials delivered across the ECMC Network.

Each arm tests an experimental targeted drug in a stratified population, with the aim to determine swiftly whether there is sufficient signal of activity in any drug-biomarker combination to warrant further investigation.

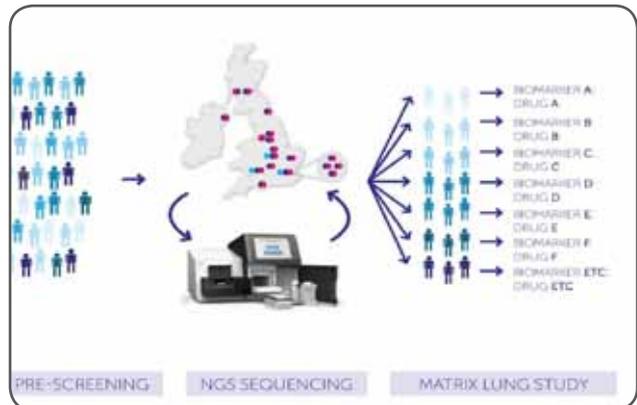


Figure 15: Overview of the National Lung Matrix Trial

The National Lung Matrix Trial opened to recruitment on the 31 March 2015, and currently has 8 arms and 21 drug-biomarker combinations. In the last year we have managed the initial set-up in 11 ECMCs and multiple substantial protocol amendments. The remaining ECMCs will be initiated in summer 2016, as the last few come on board with the setup of the SMP2 pre-screening platform. The NLMT team were very pleased to report that the 50th patient was recruited on the first anniversary of the trial, and as of 7 April 2016, 52 patients have been recruited and have received treatment on all 8 arms of the trial.

The ongoing delivery of complex programmes such as SMP2 and NLMT are only possible through collaboration between clinicians, researchers, coordinating staff and pharmaceutical partners. The ECMC Network is the ideal environment to support this collaboration and harnessing the capabilities within the Network is the key to the success of the Stratified Medicine Programme.



# DISSEMINATING THE SUCCESSES OF THE NETWORK

One of the key roles of the ECMC Secretariat is to promote the excellent work undertaken by the Adult and Paediatric ECMC Networks. This year there has been some significant advances in this workstream with particular mention to the improvement of our existing communications tools. We have completed the ECMC website, upgraded the ECMC eNewsletter and have developed new communications materials including the annual highlights booklet and video content.

Nevertheless, the most important communications achievement in 2015/16 has been bringing our ECMC community closer by assembling ECMC communication representatives in each of our locations. This network of individual representatives has facilitated a greater engagement with our community and has meant that we can provide them with the relevant support to disseminate and share communication updates.

An excellent example of the success of this approach has been the steady appearance of ECMC acknowledgment in university and funders' press releases for the first time since the launch of the Initiative in 2007.

Moving forward and with the new quinquennium fast approaching, it is important to target our key audiences with more tailored content. To this purpose, this year we developed the ECMC Communications Strategy that will underpin our communications activity until the end of this quinquennium.

## Attendance to conferences and meetings

There is no better place to disseminate the excellent work taking place in the ECMC Network than at conferences and large meetings. During 2015/16 we organised a series of internal events to promote networking across our ECMC community as well as hosting stands and workshops at external conferences to promote the Network to the wider experimental cancer medicine audience.

## Annual Network meeting

The 6th ECMC Annual Network meeting was held in May 2015. This meeting is an opportunity for those working within the ECMC Network to meet and collaborate. The morning session kicked off with a welcome from Secretariat Head, Dr Aoife Regan, and speakers proceeded to give updates on a range of topics from the ECMC Trial Harmonisation Programme (ETHP) to collaborations with industry.

An overview of the ECMC Patient Satisfaction Survey highlighted the importance of what the ECMC strives to achieve. The parallel sessions in the afternoon brought together staff from across the ECMCs to look at topics such as feasibility, adaptive trial designs, leveraging social media and IT and the future needs of the quality assurance and translational science staff in the Network.

## UK Clinical Research Facility (UKCRF) Conference

Members of the ECMC Secretariat attended the UK Clinical Research Facility (UKCRF) Network Conference in July 2015 and had a stand to showcase the work of the ECMC Network. The 11th Annual UK CRF Conference was jointly hosted by the NIHR Guy's and St Thomas' CRF and the NIHR Wellcome Trust King's CRF.

## National Cancer Research Institute (NCRI) Conference

In November, the ECMC Secretariat attended the annual NCRI Conference, where we hosted a stand (Figure 16) and helped to promote two posters and two parallel sessions. Equipped with some new promotional material (including the 2014/15 highlights booklet), we were delighted to meet and talk with conference attendees, including members of our Network.



Figure 16: The ECMC stand at the NCRI 2015 Conference

In coordination with the announcement of the NCRI funding for the CM-Path Initiative, Dr Bridget Wilkins presented a poster on the ECMC Cellular and Molecular Pathology (CMP) working group's efforts on the CM-Path proposal.

In addition we circulated leaflets detailing the Initiative's work streams, to enthuse the pathology community and encourage professionals to apply for membership in the project.

Similarly, the poster '**Patient Satisfaction: a collaborative approach across the ECMC Network**' was presented, with the results from the patient satisfaction survey conducted across the ECMC Network.

On the final day of the NCRI Conference, the ECMC supported a very well attended parallel session on the latest developments in the ECMC Combinations Alliance, hosted by Dr Hazel Jones from the ECMC Combinations Alliance and Dr Udai Banerji of the ICR ECMC.

Speakers from the Network and industry representatives presented their success stories from studies and lessons learnt, highlighting the importance of collaboration.

Professor Anne Thomas (Leicester ECMC) discussed the DEBIOC trial, which she said was a "**Fantastic example of how the ECMC Network is working**" and Dr Tim Yap (ICR ECMC) summarised his experience with the COMPAKT trial.

From an industry perspective, Professor Anthony Chalmers (Glasgow ECMC) described the collaborative work of Radiotherapy-Drug Preclinical Consortium (RaDCom) with industry to design and deliver studies for novel agents to provide better therapeutic ratios to cancer patients receiving radiotherapy, and Dr Andrew Mortlock (AstraZeneca) highlighted lessons learned from targeting the PI3K pathway.

Finally, NCRI attendees were particularly pleased with the return of our mascot MultiMarvin (Figure 17), with a number of enthusiastic tweets for the duration of the event.



Figure 17: #MultiMarvin featuring at NCRI 2015

## UKTCPN parallel session at NCRI

The ECMC Secretariat supported the UKTCPN hosted parallel session '**Prevention is better than cure: cancer chemoprevention in 2015**'. The aims of the session were to share learnings about current research ongoing in the field of therapeutic cancer prevention in the UK and internationally; to understand how advances in science and technology can complement traditional epidemiology-led prevention studies for the development of effective and safe preventive agents; and to learn about emerging gaps and opportunities in therapeutic prevention research.

The session was well received, with more than 80 delegates turning up to hear from national and international key opinion leaders in cancer prevention like Professor Jack Cuzick (who talked about benefits and harms of preventive therapy for cancer) and Professor Andrew Chan (who discussed molecular risk stratification for aspirin chemoprevention). Professor Karen Brown, Dr Ruth Langley, Dr Farhat Khanim and Professor Tony Howell moderated the lively Q&A discussion that closed the session.

### Disseminating ECMC achievements through our communications tools

This year we have been really busy upgrading our communication tools to ensure that they are fit for our growing communications activity and aligned to the Strategy.

Our ECMC website ([www.ecmcnetwork.org.uk](http://www.ecmcnetwork.org.uk)) has seen significant improvement during 2015/16, most noticeably within the individual centres pages. With thanks to the centres for contributing data and updates, each ECMC location is now more strongly represented on the website.

Another of our key tools is the ECMC eNewsletter that is sent to over 1,100 members of our Network. Based on the statistics gathered over the past year - a 31% open and 36% click-open rate - we are confident that this is a well received publication. Nevertheless, this year we refreshed it to ensure that the content remained relevant and visually appealing.

Our social media presence has improved greatly over the past year, with our [@ECMC\\_UK](https://twitter.com/ECMC_UK) Twitter account reaching 1,000 followers in January. The account tweets on a daily basis, as well as live-tweeting from events that the Secretariat attend, as well as regular interaction with our ECMCs and funders via this platform.

During 2015/16 we also developed new tools to better disseminate our work to our community. Thus for the first time this year we published a Highlights Booklet which

provides a summary of the 2014/15 Annual Report. A shortened overview of the broad activity taking place in that financial year, the booklet celebrated the Network's successes in a visually attractive format. Presented at various meetings and conferences, the booklet garnered praise from many members of our Network and our funders.

Early 2016 saw the ECMC film, edit, and publish the first in a series of short videos. Filmed at our annual JING residential, ECMC Leads and members of the Network were filmed and interviewed to create two videos: the first being a round-up of the JING residential, and the second a snapshot of the landscape of experimental cancer medicine in the UK. The videos were extremely successful in promoting our work during World Cancer Day (4 February), with an increase of 32% page views in our website on the day.

For the first time since its launch in 2007, the ECMC Initiative has been referenced in several national press releases of studies supported by the Network. Most notably, the recent AMG319 trial run through the ECMC Combinations Alliance led by Professor Christian Ottensmeier (Southampton ECMC) and the VAPER cervical cancer vaccine trial, supported by the KHP ECMC and led by Dr James Spicer.

The Secretariat played a key role in ensuring that the work produced in the ECMC community receives maximum attention and we aim to further expand this function next year.

## New ways of communicating our work

Being able to effectively communicate the role of the Networks in the national and international arena of experimental cancer medicine is an integral part of the success of the ECMC Initiative, and a key function of the Secretariat.

To this aim, developing a good flow of communication with our ECMCs was a paramount first step. During 2014/15, we developed a database of ECMC communications contacts at every ECMC and funding body.

This 'comms network' has become the bridge between the ECMC community and the Secretariat and has proven extremely successful: not only have we received an increasing number of updates from our Network that

we have subsequently helped to disseminate, but we have also promoted relevant activities and funding schemes out to both Networks.

The ECMC Communication Strategy for the end of this quinquennium was developed in early 2016 to ensure that we establish relevant communication channels and optimise the use of our tools to disseminate the broadness of work occurring in the Network.

The Strategy establishes new ways of embedding communications to all ECMC activities and allocates resources to relevant areas for our work in the next quinquennium. It will provide guidance on the type of messages and audiences that ought to be prioritised by the Secretariat as well as setting up indicators that will provide a baseline for the next quinquennium.

## NIHR@10: Collaborating with our Funders

Working closely with one of our funders, the National Institute for Health Research (NIHR), we have been supporting their NIHR@10 campaign. Designed to celebrate the 10th anniversary of their launch, the campaign is focused on disseminating the variety of excellent work supported by NIHR to a wider audience.

In line with the NIHR@10 communications around World Cancer Day in February, we released a video with ECMC Leads from the four UK Nations discussing the importance of experimental cancer medicine. The video highlighted how the collaborative nature of the ECMC Network makes the UK a competitive place for such work to be undertaken.

We also aligned to the NIHR Prostate and Ovarian Cancer Awareness month communications, where we published a series of tweets throughout March focusing on several of our ECMC-supported trials in these cancer groups. We choose Twitter as it is the best suited channel to reach the broad community, and it did not disappoint – we had excellent levels of interaction with the Twittersphere, with over 50,000 tweet impressions.





# PREPARING FOR THE NEXT QUINQUENNIAL

The promises of precision medicine to bring the right treatment for the right patient at the right time are slowly reaching the clinic. Nevertheless, these promises also hold significant operational challenges and thus, the need to work collaboratively has never been greater.

The collaborative nature of the Adult and Paediatric ECMC Networks will ensure that resources are maximised for the benefit of patients whilst making the UK a competitive place for industry. The ECMC Initiative is an excellent example of how a successful partnership can make an impact in the UK's field of experimental cancer medicine.

As a result of the Network's ground breaking work, the support pledged to the Initiative was unanimous across all funders as it reached the next funding cycle (2017-22). We are pleased that despite the challenging economic environment, CRUK and the UK's four Health Departments maintained their commitment to the ECMC Initiative. The ECMC Secretariat understands the responsibility it has in making sure the Networks are fit for purpose and has therefore taken this change of funding cycle as an opportunity to improve the way it operates.

To this aim, the scientific focus of the ECMCs will change in the next quinquennium, becoming an interventional Network that will ensure the Initiative gains uniformity which will further facilitate collaboration across sites.

At an operational level, all ECMCs will be working under a

new legal document named the Collaborative Agreement. This document, already signed by all the participating legal entities of the Network, will ensure that we are nimble and responsive to opportunities as well as being able to work collaboratively at both scientific and operational levels.

## The ECMC Strategy (2017-22) receives the support from the funders

This year has been pivotal for the future of the ECMC Network as the Secretariat presented an ambitious scientific and operational strategy that was well received by all the funders.

When developing the aims of the Adult and Paediatric ECMC Networks for the next quinquennium, it was agreed that there was a need to homogenise the aims of the Paediatric and Adult ECMCs to facilitate cross-Network collaborations (Table 2). Thus, for the first time since the launch of the ECMC Initiative in 2007, the Adult and Paediatric ECMC Networks will have complementary aims for the 2017-22 quinquennium.

In order to ensure these ambitious aims are achieved, there was a need to clarify the type and direction of the Network's scientific activity. The Secretariat led a thorough quantitative and qualitative analysis of the current activity taking place at the Network between

2012 and 2015. Results of this analysis suggested that the Network is already fairly well aligned to the aims of the ECMC Initiative.

However there is some activity ongoing across ECMCs that would be classified as basic science and discovery work, which is more appropriately supported through other mechanisms such as CRUK Centres or response-mode funding.

As we move towards precision medicine, translational activity still remains a vital component of experimental medicine, which supports the delivery of early phase trials. This is particularly true for “biologically-rich”, science-driven trials that follow the global trend of bench-to bedside-to-bench, where the results from trials directly inform laboratory work to further improve treatments.

Similarly, biomarkers and biobanking are activities that are integral to the delivery of high quality experimental cancer medicine. Thus, both activities still remain in remit of the ECMC Initiative but the activity ought to be linked to prospective clinical trial studies.

Following extensive consultation with the scientific and operational experts in our experimental medicine community, the ECMC Secretariat presented to the funders the proposed scientific focus for the next quinquennium. The emphasis of the ECMC Initiative for activity in the ECMC Networks for the next funding cycle (2017-22) is on:

- ⦿ Translational activity of clinical relevance and aimed at informing treatment decisions;
- ⦿ Biomarker activity directly relevant to prospective early phase clinical trials such as pharmacological (PK) and pharmacodynamic (PD) molecular biomarkers or prognostic/predictive/stratification where the endpoint clearly informs targeted therapies in pre-clinical or clinical studies;
- ⦿ Early phase clinical trials (defined as from Phase 0 up to Phase IIa) with an interventional purpose and/or biomarker-associated activity;

Adult ECMCs	Paediatric ECMCs
1. Drive the design and delivery of translational studies and scientifically-driven, rationally designed early phase oncology trials to the highest international quality, on time and target and to consistently high standards	Drive the design and delivery of translational studies and innovative early phase oncology trials to the highest international quality, on time and target and to consistently high standards
2. Enhance the delivery of early phase trials by increasing capacity, safety and speed, to improve the success rates in developing new therapeutic modalities for patient benefit	Enhance the delivery of early phase trials by increasing capacity, safety and speed, to maximise patient access to novel treatments and improve patient care
3. Maximise therapeutic opportunities for patients through the development and validation of novel molecular and/or imaging biomarker assays to regulatory standards	Maximise therapeutic opportunities for paediatric patients through the development and validation of novel molecular and/or imaging biomarker assays to regulatory standards
4. Ensure effective joint working across the Network and between Universities and Trusts	Support the geographical spread of trials across the UK to facilitate recruitment and ensure effective collaboration with the Adult ECMC Network
5. Increase the attractiveness of the UK as the industry's destination of choice for the development of high impact, innovative treatments, and thereby contribute to economic growth	Increase the attractiveness of the UK as the industry's destination of choice to lead on international paediatric early phase clinical trials
6. Promote patient and public involvement in experimental cancer medicine	Promote patient and public involvement in experimental cancer medicine
7. Ensure that the UK remains at the forefront of international efforts to develop and test new treatments for cancer; built upon outstanding science and optimal trial design	Ensure that the UK remains at the forefront of international efforts to develop and test new treatments for cancer; built upon outstanding science and optimal trial design

**Table 2: Objectives for the Adult and Paediatric ECMCs for the next five years (2017-2022)**

- ◉ Funding may only be used to support late phase trials where there is a significant translational component;
- ◉ Biobanking is within remit of the ECMC award but should not be the core component of any individual site and when appropriate, the use of the NIHR National Biosample Centre is encouraged.

Finally, the Paediatric ECMC Network will also undergo some significant changes in the next quinquennium. Currently funded solely by the NIHR, it is made up of nine UK Phase I oncology centres. The level of activity taking place across the Paediatric ECMC Network is significant, gaining a good reputation across industry for being a platform to perform early phase clinical trials.

The NIHR indicated their commitment to continue to support the current Network, subject to its favourable quinquennial review. In addition, CRUK have indicated that if the review is favourable, they may also invest in the Network.

In summary it has been an exciting year for the ECMC Initiative having received the commitment from all five funders. This support will allow the Adult and Paediatric ECMC Networks to align to the ambitious strategy, tackle existing bottlenecks and deliver our mission to provide better and faster treatments to cancer patients in the UK.

### Progress on the ECMC Collaboration Agreement

To transform the ECMC Initiative into an innovative Network dedicated to early phase oncology clinical trials, the ECMC Secretariat have developed a Collaboration Agreement through the ECMC Contracts Working Group.

The multi-party agreement will formalise the Network between all ECMC member organisations (NHS Trusts/Health Boards and Universities) to:

- ◉ Define the roles and responsibilities of all ECMC member organisations and the Programme Office;
- ◉ Provide an operational framework for all ECMCs and the Programme Office; and
- ◉ Define the new ECMC Network governance structures

It is anticipated that 40 ECMC member organisations along with CRUK will be party to the agreement. Extensive external engagement took place during Summer/Autumn 2015 to ensure that all signing parties understood their commitment to the new ways of working with the Network. The agreement is now at its final iteration with planned signatures of all parties arriving from early March 2016.

Once signed, the expanded functions of the Programme Office will be trialled, refined and embedded in advance of the next quinquennium (from April 2017). During the embedding phase from April 2016, refinement of data reporting, development of Network-wide key performance indicators (KPIs) and implementation of how the Programme Office will engage with various governance and Network Groups will be initiated.

### The CRUK Centres and ECMCs Quinquennial Review

The preparations for the quinquennial review (QQR) that started last financial year reached full speed during 2015/16. The review will take place in October 2016, and will be held jointly with CRUK Centres. This joint review is to encourage the different sites to develop a unified bench-to-bedside strategy for cancer.

The ECMC and CRUK Centres teams have been joining forces to develop a review of the highest quality standards (Figure 18). The expert review panel contains a good mix of disciplines covering the whole spectrum of activity taking place in the CRUK Centres and ECMCs. In addition, a specific Patient and Public Involvement (PPI) panel will assess the PPI sections of the applications and their feedback will be given to the expert QQR panel.

The review panel will meet in London between the 17-21 October 2016, where all the CRUK Centre and ECMC Leads will defend their applications before the panel. Great efforts have been taken to ensure the review is fair and transparent and the results translate into stronger Adult and Paediatric ECMC Networks able to deliver the most promising cancer treatments to patients.

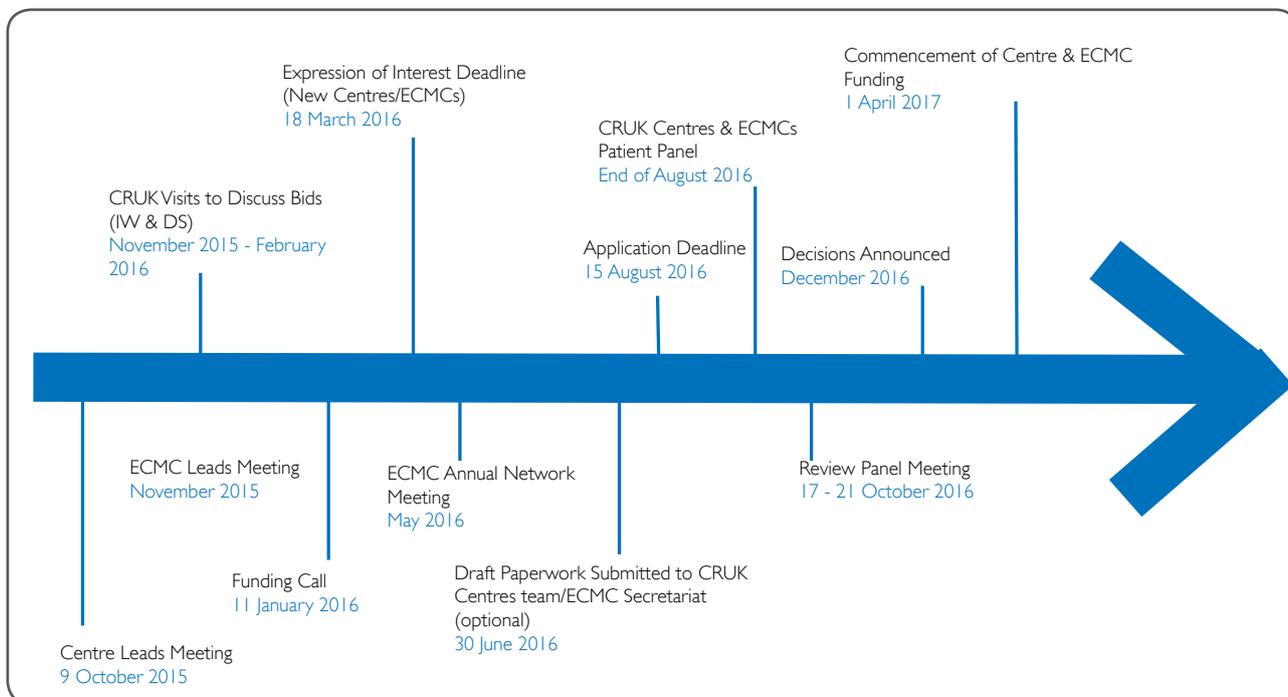


Figure 18: Timeline for the CRUK Centres and ECMC quinquennial review

As part of the preparations for the review, the ECMC Secretariat developed a novel structure for assessing which ECMC applications are better aligned to the vision of the ECMC Initiative.

Whilst scientific excellence is a key component in receiving the ECMC award, to be a successful ECMC in the next quinquennium, sites will be requested to demonstrate their capacity to bring ideas to the clinic, deliver trials to time and target and maximise resources through collaboration across the Network.

Thus, the ECMC QQR will be structured around the three ECMC pillars:

- ⦿ **Pillar 1: Scientific Excellence.** The quality of the science that takes place at the ECMCs has always been a priority and a key driver of the review structure.
- ⦿ **Pillar 2: Operational Delivery.** We asked applicants to demonstrate how they ensure that they have internal processes and structures that support efficient delivery of ECMC supported research.

- ⦿ **Pillar 3: Value to the Network.** Whilst ECMC funding is awarded to individual locations, it is expected that they act collaboratively as a Network. Contribution to the Network, whether this is recruitment to multi-site trials, individual collaborations with other ECMCs, or participation in ECMC Secretariat-led activities, has been included as a key element of the review.

The results of the review will be available Autumn/Winter 2016, and the new funding will come into effect on 1 April 2017.

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