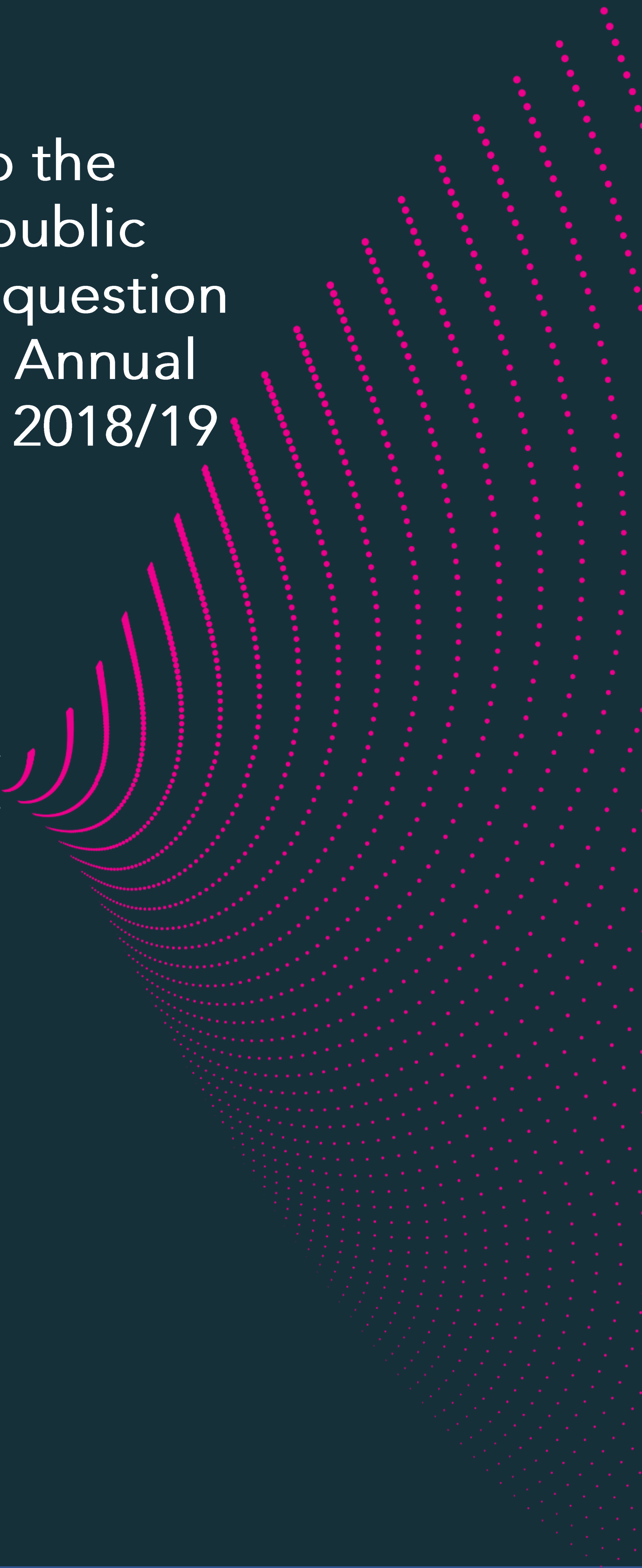
Responses to the patient and public involvement question in the ECMC Annual Report Form 2018/19



ecmc
Experimental
Cancer
Medicine
Centres

Contents

Background

The Experimental Cancer Medicine Centres (ECMC) network is an initiative funded in partnership by Cancer Research UK and the four health departments of England, Scotland, Northern Ireland and Wales. Launched in 2007 with a total investment by the funders of over £100million, this infrastructure award supports a network of 18 adult centres of excellence and 11 paediatric locations throughout the UK. By bringing together world-class scientific and clinical expertise the ECMC network advances the boundaries of cancer care.

All recipients of ECMC funding provide the ECMC Programme Office (PO) with an annual report detailing activity and progress made in the previous financial year. Annual reports provide valuable information that allows the ECMC PO to review performance, communicate the activities of the ECMC network and respond to requests for information from the ECMC Funders.

There is a patient and public involvement (PPI) question in the annual report that requests the following information:

Please provide a summary of any progress or challenges against the patient and public involvement objectives detailed in the ECMC Review application.
Please consider including in this response any updates to/further information on your objectives, the impact of this activity, any feedback from research partners, any publications/communications from this activity or links to any reports with further information.
Involve definition of what public involvement is/isn't

You should liaise with your staff representative on the ECMC network PPI Group to complete this section

ECMCs could also include an optional PPI case study.

This document contains the responses to the PPI question from the adult ECMCs.

Summary of responses

As previously reported in the *ECMC Network PPI Activities 2017-18* report, all ECMCs recognise the importance of involving people affected by cancer in their work and the positive impact it can have on research taking place in their locations. At the annual meeting of the ECMC Network Patient and Public Involvement (PPI) Group in June 2019 members were taken through some of the themes that had been identified from the Annual Report Form responses. This discussion then allowed for the informal sharing of learnings and best practice which is one of the reasons for collating and sharing the PPI work taking place across the ECMC network.

Themes identified

Co-production

Increasing diversity
(of PPI members)

Information resource
(for patients – reviewed by PPI members)

Training
(for PPI members and researchers)

Monitoring / assessing impact

PPI in translational research

Surveying early phase trial participants about their experiences

Barts ECMC

Barts: response

Ms Hannah Payne continues to lead the running of the Barts annual Clinical Trials Day event, which coincides with the International Clinical Trials Day. The day is supported by members of the Barts ECMC delivery group, who take this opportunity to promote clinical trials and work carried out at Barts via various interactive resources/games/information. In this year's event researchers from CRUK will join our local team to give talks to patients and the public about the journey from the bench to bedside. These events are generally well attended by the public. A leaflet to raise patient awareness of the fact that Barts offers clinical trials to patients and what they should expect when they attend our clinics is under review by the Trust.

Ms Payne is also establishing links with the existing Queen Mary University PPI Group (QMTAG). She aims to revamp the group, establish regular meetings and use her experience from the CRUK Patient Safety Review Board to guide PPI members through the review of trial related documentation.

Finally, the team is working on a newsletter to raise awareness on the trials open to recruitment at Barts as well as the research activity currently being undertaken. We aim to circulate our first copy in Q3 2019.

Belfast ECMC

Belfast: response

Objective 1: Promote Personal and Public Involvement (PPI)

Our objective to incorporate Belfast Experimental Cancer Medicine Centre (ECMC) within our new Strategy for PPI in Cancer Research in Northern Ireland 2019-2024 is complete. The strategy, launched on 26 March 2019, will kick-start a number of new activities, however notable progress promoting PPI has already occurred during the reporting year:-

Admin support: Since 01 September 2018 a Graduate Intern works with the NI Cancer Trials Network (NICTN) / Belfast ECMC PPI Lead, to facilitate PPI communications, documentation and development.

NI Cancer Research Consumer Forum (NICRCF) membership: New recruitment materials were designed and disseminated. There are three new NICRCF members this year, bringing current total membership to twenty-four.

Training: The NICRCF and Centre for Cancer Research and Cell Biology (CCRCB), Queen's University Belfast (QUB), have commenced work exploring bespoke PPI training for doctoral and post-doctoral students. Access to 'Building Research Partnerships' workshops twice a year is on-going.

Recognition: i) We congratulated Margaret Grayson, NICRCF Chairperson, awarded a MBE in the Queen's Birthday Honours for services to cancer research and the Iris Colvin Lifetime Achievement Award for health. ii) PPI funding from the Department of Health (NI) was awarded via Belfast Trust towards the cancer research PPI strategy launch event and a 'thank you' meal, 07 March 2019, for members of the NICRCF.

PPI Awareness/Outreach: Awareness and outreach were facilitated through a number of NICRCF research and PPI information stands hosted by NICRCF members and NICTN / Belfast ECMC PPI Lead: i) Irish Association of Cancer Research Conference, Belfast, 20 February 2019. ii) International Clinical Trials Day, NI Cancer Centre, 18 May 2018. iii) CCRCB Open Day, Belfast, 16 February 2019 (>240 attend). iv) Public information and strategy launch event, 26 March 2019 (> 85 attend). In addition, Margaret Grayson's story was published in the Belfast Telegraph, 26 March 2019.

Publications: PPI poster presentations i) National Cancer Research Institute (NCRI) Conference, Glasgow, 4-6 November 2018. ii) International Perspectives on Evaluation of PPI in Research Conference, Newcastle, 15-16 November 2018.

Objective 2: Study Quality / Biomarkers and **Objective 3: Studies on time and target**

Some highlights this year are:-

- Meetings of the NICRCF PPI Prostate Cancer Research Advisory Group covering CASPIR*, SPORT*, ADRRAD* and ASTRad* studies were held during the reporting year (see case study below).
- NICRCF member Hazel Carson, CIBRAC* Trial Management Group member and co-ordinator of BRCA Link NI played an instrumental role in a study amendment, approved recently, to maximise access to the study population. Hazel was also instrumental in ethically approved study awareness pathways through BRCA Link NI.

- An amended Patient Information Sheet (adopting MRC alternative template) and Consent Form for the Prospective Radiotherapy Collection* study was implemented in June 2018. The study is now recruiting high-dose radiotherapy patients.
- Margaret Grayson, member of NICTN Executive and Steering Group, and Geoff Hill, NICRCF member and member of the Belfast ECMC Strategic Group, continue to embed PPI within research infrastructure. During the year, Geoff was involved in a Strategic Group activity including small grant research funding decisions.
- NICRCF members continue to contribute to the NICTN / Belfast ECMC portfolio adoption review process, including early phase trials such as Avail-T*, BET Constellation*, CCS1477* this year.
- Members of the NICRCF Bowel Cancer Interest Group are members of the Belfast S:CORT (Stratification in Colorectal Cancer) group meetings.
- The NICRCF continues as patient partner for MErCuRIC 1* [European Community's FP7 (Framework Programme Seven) programme (contract #602901)]. Ruth Boyd, Cancer Research UK Senior Nurse and NICTN / Belfast ECMC PPI Lead, presented an update of the patient initiative at the annual plenary meeting in Torino, Italy, November 2018.

Objective 4: Effective working across the Network and between Universities and Trusts

Partnership working is established, and Belfast ECMC PPI opportunities are primarily referred from QUB or Belfast Trust. Activities promoting PPI (See Objective 1) have also fostered good working relationships and development. Education sessions about PPI have linked Medical, Nursing and Allied Health Professional students to NICTN / ECMC PPI Lead and NICRCF chair and members.

Objective 5: PPI monitoring/review

PPI activities are reported at quarterly NICRCF meetings. PPI metrics are being aligned with the NCRI Consumer Forum measures and a new Researcher Feedback form was introduced recently. Across researcher respondents thus far, 100% reported the NICRCF had been '**very**' helpful, and 100% reported NICRCF input led to **changes**. Research/funding outcomes are pending

Belfast: case study

NI Cancer Research Consumer Forum (NICRCF) Prostate Cancer Research PPI Advisory Group

The NICRCF Prostate Cancer Research Personal and Public Involvement (PPI) Advisory Group was formed in April 2016, as a sub-group of the NICRCF to meet PPI needs of local investigator-led clinical studies in prostate cancer. PPI Representative Role Profiles and Terms of Reference were devised. Meetings are held twice a year and involve researcher presentations about study progress/issues and discussion across the group.

During the reporting period the following study reported results and dissemination:

- **CASPIR** - Calcifications as an alternative to surgically implanted fiducial markers for Prostate Image guided Radiotherapy: A prospective feasibility study

The following studies reported successful on-going recruitment:

- **ADRRAD** - Neo-adjuvant **A**ndrogen **D**eprivation Therapy, Pelvic **R**adiotherapy and **RAD**ium-223 for new presentation T1-4 N0/1 M1B adenocarcinoma of prostate
- **SPORT** – A Randomised Feasibility Study Evaluating Stereotactic PrOstate RadioTherapy in High-Risk Localised Prostate Cancer with or without Elective Nodal Irradiation

This year illustrated the additional benefit of an established group in that discussions associated with the concept and design of a new study were brought to the group at an early stage - prior to protocol development. The **ASTRad Study** 'A Phase 1 dose escalation study of ASTX660 in combination with prostate radiotherapy in hormone sensitive metastatic prostate cancer', is now at the final stages of protocol and patient documentation development and Advisory Group members are already familiar with, and excited about this study, having been part of study design discussions.

Dr Ciaran Fairmichael, co-investigator stated; *"The comments and support from the advisory group gives reassurance that the trial answers a valid question and is likely to successfully recruit once open. Being able to say it has got PPI feedback has also added momentum to the trial development."*

At the NICTN / Belfast ECMC / NICRCF cancer research PPI strategy launch and associated public information event 26 March 2019, Dr Ciaran Fairmichael presented the Belfast investigator-led prostate cancer portfolio and profiled NICRCF Prostate Cancer Research PPI Advisory Group involvement. Following this, Dr Fairmichael and Advisory Group member Ken McBride joined together on the Q&A panel. Feedback was very positive.

*Full Study Titles

- CASPIR: Calcifications as an alternative to surgically implanted fiducial markers for Prostate Image guided Radiotherapy: A prospective feasibility study
- SPORT: A Randomised Feasibility Study Evaluating Stereotactice PrOstate RadioTherapy in High Risk Localised Prostate Cancer with or without Elective Nodal Irradiation
- ADRRAD: Neo-adjuvant **A**ndrogen **D**eprivation Therapy, Pelvic **R**adiotherapy and **RAD**ium-223 for new presentation T1-4 N0/1 M1B adenocarcinoma of prostate
- ASTRad: A Phase I dose escalation study of ASTX660 in combination with prostate radiotherapy in hormone sensitive metastatic prostate Cancer
- CIBRAC: Chemoprevention in BRCA1 mutation carriers – a proof of concept study
- Prospective Radiotherapy Collection: How does radiotherapy affect immune signaling and the tumour microenvironment in men with Localised Prostate Cancer?
- Avail-T: A Phase IIa trial of Avelumab, an anti-PD-L1 antibody, in relapsed and refractory peripheral T-cell lymphoma (PTCL)
- BET Constellation: A Phase I/II Study of CPI-0610, a Small Molecule Inhibitor of BET Proteins: Phase I (Dose Escalation of CPI-0610 in Patients with Hematological Malignancies) and Phase II (Dose Expansion of CPI-0610 with and without Ruxolitinib in Patients with Myelofibrosis)
- CCS1477: An open-label Phase I/IIa study to evaluate the safety and efficacy of CCS1477 as monotherapy and in combination with patients with advanced solid/metastatic tumours

- MErCuRIC 1: A Sequential Phase I study of MEK1/2 inhibitors PD-0325901 or Binimetinib compared with cMET inhibitor PF-02341066 in Patients with *RAS* Mutant and *RAS* Wild Type (with aberrant c-MET) Colorectal Cancer

Birmingham ECMC

Birmingham: response

Patient and Public Involvement (PPI) is a developing area at the Birmingham ECMC. As defined by Involve, the partnership organisation established by the National Institute for Health Research (NIHR), PPI within research is defined as working in partnership 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them. The centre recognises that involvement of patients and the public is an 'active partnership' process to have a positive impact upon cancer research.

The CRUK Senior Research Nurse and a local PPI representative are members of the ECMC PPI steering group and have contributed to the national steering group objectives by attending annual face to face meetings and teleconferences; sharing information amongst colleagues to raise awareness of the ECMC PPI Advisory Service; involvement in the development of a training booklet to support people affected by cancer who are taking part in PPI activities in early phase (Phase I and II) cancer research, along with a new project to look at measuring the impact of PPI at ECMCs.

Throughout the last 12 months the Birmingham ECMC has developed key collaborations across the Birmingham Health Partners NHS teams linking PPI leads across these organisations to drive forward PPI activity. One success of this collaboration has been to establish a programme of workshops which are now available to research staff and members of the public on a regular basis. Targeted workshops for clinical trials unit staff have also been delivered with a view to looking at this staff group's particular learning needs. The CRUK Senior Research Nurse continues to share best practice at the West Midlands Public Involvement and Lay Accountability in Research group (PILAR), has facilitated the ECMC plans for a PPI group and ensures the sharing of best practice, keeping updated on developments in PPI on a national level.

An '**I**nvolvement and Engagement in **C**ancer **R**esearch at **B**irmingham' (ICRB) group has now been established, meeting four times since forming in April 2018. The group covers a diverse range of patients, carers and members of the public. The group also has patients from a wide range of cancers including haematology and parents of children who have had cancer. Forty four representatives are registered and receive invites for the group; on average 9-10 attend each meeting. Ideally this group would be best placed to comment on projects that are in the design/early stage and we can provide researchers with a letter of support/comments for grant submission etc. It may not be that the group will follow the trial/project through its lifespan, but they are available to give their comments.

A strategy has been developed for Patient and Public involvement & Engagement (PPIE) in Cancer Research at the University of Birmingham. The strategy and direction of the ICRB group will be developed further by patients and the public throughout 2019. The group will be invited to contribute to individual projects, work alongside researchers to prioritise research, offer advice as members of relevant project steering groups and comment on and develop research materials. A key objective will be to involve members of the group with the governance and strategy of the centre, with a presence on the ECMC executive board in the coming 12 months.

It is our ambition to lead and work with the ECMC network to develop PPI skills and partnerships to promote the involvement of patients in experimental cancer medicine research.

Birmingham: Case study

The CRUK Senior Research Nurse is a member of the ECMC PPI Steering Group, and in June 2018 was able to host an ECMC PPI Steering Group meeting in Birmingham. This was an opportunity to showcase innovative trial design in clinical trials at the Birmingham ECMC. It was felt by the steering group that a workshop on innovative clinical trial design in early phase trials would be helpful for the PPI Steering Group, as it is a developing area of discussion that group members may be asked to comment on, but do not always fully understand.

Members of the Cancer Research UK Clinical Trials Unit (CRCTU) Biostatistics team (a member of the team is funded through the Birmingham ECMC), developed a workshop covering:

- Introduction to Phase I dose-finding trials
- Differences between conventional 3+3 and the Continuous Response Method
- ECMC trials including SeluDex
- Interactive Audience participation

The session was attended by approximately 20 people, made up of PPI named leads from centres, accompanied by a PPI representative. It was very well received, with one member of the group stating 'she had never really understood the trial methodology in this depth before'. It was discussed how important this understanding is for PPI representatives collaborating with early phase and translational researchers.

The interactive audience participation exercise had a powerful impact upon the team delivering the session who have since developed a greater awareness around involving patients, carers and members of the public in trial design. The team have since presented to the ICRB group, and recruited interested members to collaborate on an MRC-NIHR Methodology Research Programme application. The proposal is a translational methodological project in dose-finding trials, with the central aim of improving the reporting of such trials via a consensus-driven extension to the CONSORT guidelines and the Statistical Analysis Plan guidelines; as well as facilitating the uptake and implementation of innovative designs with the creation of a dose-finding design toolkit. Involvement with the ICRB group has helped to focus the team on the patients' perspective and how such research can impact on patients' health. A longer-term aim is that the ICRB group members will become informed advocates to really help push more of such efficient designs to be implemented in the trials they are involved in.

Separately the team have also delivered a workshop at an NIHR early phase trials meeting in February 2019, attended by CRUK Clinical Trials Unit staff. To prepare for this, the team presented to the ICRB group to gather their views on early phase clinical trials. The ICRB group held an informative discussion with the team on how they view dose finding trials, stating a need for 'trials to be more patient friendly'. One theme that stood out was a strong desire to disseminate clinical trial results (good and bad). PROGRESS was a word re-appearing throughout the discussion - there is a real need to communicate progress with the public and there was an understanding that this could be negative results or decisions, but it was still important to share. One member of the group said, "You can't get enough information, and you don't want to hear just the good things". This was a powerful learning experience for the biostatistics team, who are ideally placed to champion PPI in early phase trials at the Birmingham ECMC.

Cambridge ECMC

Cambridge: response

In the last year, the Cambridge Experimental Cancer Medicine PPI group has successfully recruited six new members, held four group meetings, and been involved with reviewing seven research projects. The activities of the group so far have included:

- Review of one large grant application, which has since been announced as successful;
- Review of participant-facing information for four experimental cancer trials (including two phase I trials and one phase IIa);
- Review of clinician scientist fellowship application;
- Review of grant application for potential new brain cancer trial;
- Engagement with other projects running on the biomedical campus (without formal review by the whole group), for example a department-level patient leaflet.

The members have been involved with reviewing relevant documents and providing comments/suggestions to improve the language and/or format. Where projects have also been presented at the PPI group meetings, the members have questioned the researchers on decisions that have been made and guided the research and study structure.

When setting up the group, we had consulted with patient representatives to determine how the group should be advertised/set-up, what the format of the meetings should be, and what training may be required. We had decided, based upon this advice, to host "training" at each of the meetings to enhance the members' knowledge and we discuss with the members at each meeting to identify future training requirements, as well as suggest potential topics by the PPI group leads.

The CRUK senior research nurse and ECMC programme manager are writing a strategic document for the PPI group, and will work in collaboration with the PPI group to author this. Some of the current challenges and ways to address these include:

- Increased size of the group – update advertising materials, working in collaboration with our current members; contact local network/support groups;
- Increased diversity of the group – liaising with equality & diversity teams at the hospital and the university to identify routes to advertise the groups in areas where we need to improve diversity;
- Continue to promote the group locally – engage with communications contacts to promote the group, engage with researchers and programme managers to identify potential projects, engaging with the CTU team to embed PPI within their processes for new trials;
- Assessing impact of the group – developed feedback forms that are now mandatory for all projects, identifying metrics that can be measured.

We also held a patient- and public-facing engagement day: Experimental Cancer Medicine Demystified. The aims of the day were to promote the experimental cancer research carried out by Cambridge ECMC and to promote PPI in this area. We had ~ 80 attendees come to this free all-day event, and covered topics including: PPI, early detection, imaging & radiotherapy, Personalised Breast Cancer Program (PBCP), pancreatic cancer, and urological cancer. Each of these sessions included talks by researchers/clinicians, nurses/allied health professionals, and patient representatives. The feedback after the event was extremely positive, with approximately one-quarter of participants completing a feedback survey. Of these, 18 (82%) rated the event "very satisfactory" and 3 (14%) rated the event "satisfactory". The feedback included questions such as what was liked most and least about the event, any additional topics that could have been covered, and how regularly the event should be run. Based on the results from the feedback, we have decided to run this event annually and each year will cover different topics based on the feedback received.

The PPI group leads have also advised other teams locally on the process of PPI and assisted when researchers/programmes were looking to identify patient representatives (e.g. for project steering committees).

We have also continued to be engaged with the ECMC Programme Office PPI Working Group, and have been involved with the researcher feedback tool. Additionally, Cambridge will be hosting the next working group meeting in June.

Cambridge: Case study

As outlined above, PPI has been a real focus of the Cambridge ECMC and the team has made significant progress over the last year to embed the group within the local experimental cancer research structure. Throughout 2018/19 (to date), the Cambridge Experimental Cancer Medicine PPI group has been involved with reviewing seven projects, and the review of the WIRE trial provides an example as to how the group has been involved with developing the upcoming and novel experimental cancer research conducted in Cambridge.

Trial Background

Window-of-opportunity clinical trials platform for evaluation of novel treatment strategies **RE**nal cell cancer (**WIRE**)

The WIRE trial will investigate the effect and safety of three different cancer drugs, individually or in combination, in patients with clear cell renal cell cancer (CCRCC). In this trial, the window-of-opportunity is the time between the decision to operate and the kidney removal operation ("nephrectomy").

Patient and Public Involvement

The WIRE trial management team requested a slot at the next PPI meeting to present the trial and requested input from the PPI group. Prior to the meeting, the PPI members were sent the current drafted version of the participant information sheet and informed consent form (PIS/ICF) to review. This was to enable them to gain an understanding of the trial before the presentation, and provided the members an opportunity to question information in the PIS/ICF specifically during the meeting.

Three members of the trial management team attended the PPI group meeting: Mr Grant Stewart (Chief Investigator, CI), Richard Skells (senior trial coordinator for urology cancer and device trials), and Amanda Walker (trial coordinator for WIRE). Grant Stewart provided an overview of the trial, including the rationale and trial design, and all three were available to answer questions. Throughout the presentation, the PPI members were encouraged to ask questions and raise points for discussion. All discussions were minuted and the minutes circulated to the PPI members for review prior to finalisation. After the meeting, the PPI group were also requested to conduct an additional review of the PIS/ICF in light of the discussions from the meeting. Additional comments/suggested changes were received from two of the six members, and were fed back to the WIRE trial management team with the approved minutes from the meeting.

The CI and the trial management team provided positive feedback regarding the PPI process and the comments the members made. As part of their feedback, the team confirmed that most of the suggested changes had been made and, where changes had not been made, an explanation was provided.

Our local policy (based upon discussions during the group set-up with the patient representatives) is to provide all feedback to the PPI group members, as we aim to be open with the changes that are made based on their review. It is important to explain where changes have not been incorporated (and the reason why) as this develops the members' skills set and knowledge as PPI reviewers. One of the common criticisms that PPI members have is that they do not always get feedback for the projects they review, which can make them feel undervalued.

Specifically, some of the changes incorporated include:

- PPI group encouraged the trial management team to detail whether the participants are likely to benefit from participating in the study;
- Clarification on long-term side effects of the drug(s) used;
- Terminology changes to make the participant information more understandable (such as form study treatment "arms" to "groups"), and being clearer on the meanings of the different acronyms.

The PPI group members were pleased to have had the trial management team attend the meeting in person, as well as being given a chance to review the participant-facing documentation. Based upon the experience at this meeting, the team now encourages all new projects to be presented at a meeting (where feasible) to allow a dialogue between the research team and the PPI members.

Cardiff ECMC

Cardiff: response

PPI has continued to play an integral role in the work carried out in Cardiff ECMC and, in line with this approach, we have sought feedback from one of our public contributors for this summary. Our aim of aligning PPI activities with the ECMC and Wales Cancer Research Centre (WCRC) has continued, strengthening our links with the PPI and research community. The PPI Group in the ECMC mirrors that of the WCRC, cementing links and ensuring consistency. The group consists of a Lead Lay Partner, Dr. Jim Fitzgibbon, an Academic PPI Lead, Prof. Annmarie Nelson and a part-time PPI Officer funded by the ECMC, Kate Cleary. The role of a funded PPI Project Officer in the PPI work stream has been recognised as a unique and key role to the continued success of the PPI model and has been highly commended by the WCRC's External Advisory Board.

There is a true commitment to have PPI representation in the governance of ECMC and the ECMC Lay Partner continues to attend and contribute to the Cardiff ECMC Senior Staff meetings. We actively seek opportunities for our public contributors to be involved in opportunities that will inform the direction of research in Wales. These opportunities include recruiting public contributors to the Cancer Research Strategy for Wales (CReSt Cymru) to ensure that the strategy will reflect the views of the members of the public in Wales. Our public contributors have also been involved in the Short Life Working Group on Innovations in Oncology group; this group includes academics and healthcare professionals across Wales who deliver cancer care and research to look at a number of challenges.

There is a recognition of the importance of adhering to the National Standards for Public Involvement: WCRC has signed up as a freestyle project with the Public Involvement Standards Development Partnership and as part of this network, will feedback best practice to the research community. An audit tool was created, based on the National Standards for Public Involvement and measured activities against the standards. Similar trends were noted between the groups: there was a recognition that more work is needed to address inclusive opportunities and the national issue of representing diverse communities. Links have been created with the NIHR to look at the issue on a national level and we are also working with the Wales School for Social Care Research and the School of Population Medicine at Cardiff University to produce case studies to support our, and others', approach to achieving diversity in our PPI.

Another focus area highlighted from the audit is the importance of measuring impact and a working group has been created to develop an impact measuring tool. This will build on the existing online diary cards which provide an opportunity for public contributors to voice their thoughts and opinions on their activities as well as enabling the team to qualitatively collect data. The aim of the working group is to create a practical framework to record impact and reflect on possible improvement in practice.

The PPI Project Officer has developed links with the ECMC Programme Office and is the Deputy Chair for the ECMC network PPI Group. She was also a member of working sub-group which reviewed a resource booklet for patient and public involvement in early phase cancer research.

After carrying out a scoping report, it was identified that translational research may be best served by a lay faculty and one was developed in collaboration with an existing lay faculty in Cardiff University School of Medicine's Division of Infection & Immunity. This lay faculty is engaging with the community by developing interactive workshops that focus on the importance of PPI, using writing lay summaries as an example of PPI. Elements of these workshops have been developed with the Public Involvement team at CRUK following discussions at the Junior Investigator Network Group (JING) conference.

We have organised various public engagement activities throughout the year, for example: on the 9th of October 2018, we held a celebratory event at the Welsh Assembly to mark over 10,000 patients being recruited to the STAMPEDE trial, making it the biggest cancer trial in the world. The event featured patient Tim Driscoll and generated news coverage and enabled us to engage with key politicians.

To mark World Cancer Day we joined forces with members of the Wales Cancer Partnership to present a live Q and A on Facebook with a panel of cancer experts and a patient. The Q and A was put together in collaboration with the Wales Cancer Research Centre, Tenovus Cancer Cancer, Macmillan Cancer Support, Cancer Research UK, Cancer Research Wales and the University of South Wales featuring Dr. Alan Parker and Kay Wilson from the ECMC.

Cardiff: Case Study

A Patient Sounding Board was created by the ECMC team in Cardiff as part of our ambitions to deliver earlier clinical interventions for poor outcome haemopoietic stem cell transplant patients. This patient subset has a particularly poor prognosis and represents a key area for developing novel drug design and early phase trials. We have directly involved Bone Marrow Transplant (BMT) patients and their carers as stakeholders who can provide a 'lived in' experience, through our BMT patient sounding board where there is an opportunity to feedback on lay summaries, grant applications, research updates, patient information and consent forms and logistics of sample collection for the study.

The Board now receives comments from a broader spectrum of people involved in cancer care that often sit on funding committees for local and national funding bodies. This input has changed the way Researchers write their research and design their science. Whereas previously the focus may have been on chasing a brand new avenue in science which would benefit the public in longer term, this Board is shifting that focus so the Researchers also look to improve stratification, delivery and monitoring of current treatments which has more immediate impact on the public and healthcare system and gives hope to those patients currently undergoing cancer therapies.

The public involvement community (organised by Health and Care Research Wales) have fully supported us in this endeavour to develop skills in this area and raise awareness in the research community of the benefits for patient involvement.

Edinburgh ECMC

Edinburgh: response

The Edinburgh Cancer Centre's Patient and Public Involvement Group (ECCPPI) was established in July 2016, supporting research staff from across NHS Lothian, SESCRN, Cancer Research UK, and Edinburgh's ECMC. Since it began, we have supported a number of local researchers with PPI input and received very positive feedback from our researchers who have used the service. We have developed a robust and detailed database, documenting our members details and subsequent activity. The database has been risk assessed for data protection and is registered on an NHS asset register.

We currently have a group of 7 representatives. Consisting of:

- 3 Patients with Breast Cancer
- 1 Patient with Prostate Cancer
- 3 Carers

Our activity since our last report has included:

- PPI involvement in the redesign of the Edinburgh Cancer Centre
- Representation on a breast cancer trial focus group - CardiacCARE
- PPI representation at 2 cancer conferences
- PPI involvement of the Peer review of the Scottish Referral Guidelines for suspected Cancer
- PPI attendance at CRUK's Annual Parliamentary Reception

Working with other ECMCs and CRUK Centres Aaross the UK:

Vivienne Wilson and Sarah Thomas, CRUK Senior Nurse and Research Engagement Manager deliver a significant number of public engagement activities within the cancer centre and across Scotland. Examples in the last year include fundraising events, lab tours, science festivals and legacy events.

We also regularly host staff from other ECMCs and CRUK Centres, sharing ideas, challenges and common practices. Vivienne routinely networks with the other CRUK senior nurses from the other UK cancer centres and Sarah does the same in her capacity as Research Engagement Manager. In the last 12 months, both have independently hosted ECMC and CRUK Staff from across the UK and regularly visit the other UK cancer centres.

There is a particularly close relationship with the Glasgow Centre, collaborating on multiple initiatives including fundraising and PPI. Both centres have supported each other to find suitable and additional PPI representatives for their respective research activities.

Glasgow ECMC

Glasgow: response

Patient and Public Involvement (PPI) is a key component of Glasgow's ECMC activity and consumer representatives are involved across our ECMC translational and clinical programmes.

This includes PPI representation on:

The ECMC Steering Committee which has oversight of all of our ECMC activities and strategy.

- IHTAB (In-House Trials Advisory Board) which assesses ideas from researchers and develops these into clinical trial protocols that can be submitted for external funding or support our existing funding (ECMC, Clinical Trials Unit CRUK Grant). These protocols may involve medicinal products or other therapeutic interventions, or may be entirely translational in nature (e.g. biomarker studies in blood or tumour tissues).
- CTEC (Clinical Trials Executive Committee) which assesses established clinical trial protocols that are brought by investigators, including those developed through the IHTAB route, for consideration of support from our clinical research infrastructure (including from our ECMC funding and resources).
- Umbrella Trials Steering Group which has oversight of the CRUK Clinical Trials Unit's studies including many of those within the ECMC Combinations Alliance that are led from Glasgow.

Through membership of these committees, our consumers are involved in assessing and developing the ECMC strategy and shaping research questions for specific projects, reviewing clinical and translational research protocols, and reviewing the SOPs of the Clinical Trials Unit and Clinical Research Unit.

During the past 12 months, in collaboration with members of our PPI group, we have undertaken reviews of our research strategy and our clinical trial delivery processes at the Beatson West of Scotland Cancer Centre (BWoSCC). This has included:

- Development of a BWoSCC research strategy with a specific focus on PPI/E across the Centre
- Review and evaluation of patient experiences of participating in early phase clinical trials within Glasgow ECMC. Over an 8 week period (Sept-Oct 2018) 55 patients involved in clinical trials running at the Beatson West of Scotland Cancer Centre were consulted and asked to feedback on their experiences of trial participation and suggest areas of improvement. It is planned that we will develop a PPI working group to take these recommendations forward and guide improvements across the unit

In addition to the above activity one of our consumer representatives (Elspeth Banks) and our CRUK Lead Research & Information Nurse (Laura Rooney) are members of the ECMC Patient and Public Involvement working group. Both have contributed to the development of the 'Early Phase Cancer Research: A reference guide for patient and public involvement members' booklet.

Over the next 12 months we plan to continue to promote PPI across our Centre and add new consumers to our group with a key focus on increasing diversity within the group. We are also collaborating with colleagues from our PPI group, Cancer Research UK, NHS Greater Glasgow and Clyde and the University of Glasgow to develop a PPI symposium in June 2019.

We have also involved consumers in our activities including our International Clinical Trials Day symposium, through presentations to the public and to CRUK fundraisers (through open evenings) and presentations to the media. A series of three documentaries (The Cancer Hospital) was commissioned by BBC Scotland and were aired in April and May 2018. This series included interviews with ECMC researchers and patients participating in phase I clinical trials.

Imperial ECMC

Imperial: response

The Imperial Patient and Public Involvement Group for cancer has supported numerous projects and researchers over the last year. The group meets four times a year. At these meetings, researchers present their projects/requests and feedback is given at the meeting. When researchers are unable to attend a meeting or a deadline falls in between meetings, requests are shared by email and the PPI group reports directly to the researcher or the CRUK Senior Nurse who manages this group. One of the highlights of our PPI activity has been the number of young researchers coming forward and involving PPI very early during the research project. Over the last year, the group has supported 42 projects:

- 7 Patient Information Sheet (PIS) reviews
- 15 study feasibilities assessments
- 6 lay summary reviews
- 14 grant proposals

Members of the Imperial PPI group also sit on various Trial Management Groups and Steering Committees:

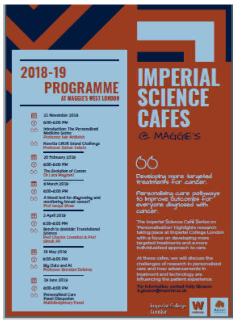
- Rosetta Grand Challenge Management Committee
- REI-EXCISE Trial Management Group
- EBLLIS/Breast Screening Study Management Group
- People Like You Study on personalised medicine
- Deep Mind Breast Cancer Screening Study
- Breast Cancer PhD Project in radiotherapy
- ECMC Steering Committee

The Imperial ECMC hosted eight Imperial Science Cafes in the last year. The first four were:

1. Breast cancer research: resistance to therapy and epigenetics *PhD students*
2. How do cancer risk factors affect your body? *Dr James Flanagan*
3. Prostate Cancer Research at Imperial *Professor Charlotte Bevan & Gareth Jones (PPI Representative)*
4. How a simple blood test can help treat cancer? *Dr Ally Hills*

The cafes listed below were part of a series of six science cafes on personalised medicine (programme attached). These cafes were organised to run alongside a qualitative research study funded by Wellcome called People Like You.

1. Rosetta CRUK Grand Challenge *Professor Zoltan Takats*
2. The evolution of caner *Dr Luca Magnani*
3. A blood test for diagnosing and monitoring breast cancer? *Professor Jacqui Shaw*
4. Bench to bedside: translational medicine. The journey of CDK7 *Professor Simak Ali & Professor Charles Coombes*



2018-19
PROGRAMME
AT MAGGIE'S WEST LONDON

21 November 2018
6:00-8:00 PM
Introduction: The Personalised Medicine Series
Professor Iain McNeish
Rosetta CRUK Grand Challenge
Professor Zoltan Takats

20 February 2019
6:00-8:00 PM
The Evolution of Cancer
Dr Luca Magnani

6 March 2019
6:00-8:00 PM
A blood test for diagnosing and monitoring breast cancer?
Prof Jacqui Shaw

2 April 2019
6:00-8:00 PM
Bench to Bedside: Translational Science
Prof Charles Coombes & Prof Simak Ali

15 May 2019
6:00-8:00 PM
Big Data and AI
Professor Brendan Delaney

19 June 2019
6:00-8:00 PM
Personalised Care
Panel Discussion
Multidisciplinary Panel

IMPERIAL SCIENCE CAFES
@ MAGGIE'S

Developing more targeted treatments for cancer.

Personalising care pathways to improve outcomes for everyone diagnosed with cancer.

The Imperial Science Café Series on 'Personalisation' highlights research taking place at Imperial College London with a focus on developing more targeted treatments and a more individualised approach to care.

At these cafes, we will discuss the challenges of research in personalised care and how advancements in treatment and technology are influencing the patient experience.

For information, contact Kelly Gleason k.gleason@imperial.ac.uk

Imperial College London

Our CRUK Senior Nurse is working with Principal Investigators of People Like You, Professor Helen Ward and Professor Sophie Day, to help evaluate the science cafés; the science café platform has been very successful at Imperial. The science café style engagement is aimed at patients, members of the public and NHS staff. Evaluation of this platform may therefore point to how science cafes could be used in other centres as a means of engaging patients, the public and NHS staff, communicating study updates, disseminating results and recruiting new members to PPI groups.

The CRUK Senior Nurse and a member of the Imperial PPI Group are also part of the ECMC PPI national group and have attended meetings in London and Birmingham. The number of researchers looking for PPI support for projects and the diversity and complexity of these projects is constantly increasing. For this reason, a review of the PPI support network at Imperial is underway and we will work with our PPI group to develop of PPI strategy to best support our researchers and make PPI an enjoyable experience for patients and the public who choose to offer their support to Imperial researchers.

Imperial: case study

As mentioned in the above report that at Imperial ECMC, it has been very encouraging to observe young researchers coming forward of their own accord and wanting to use PPI at a very early stage in their projects. An example of this is a student who came to the PPI meeting to introduce his research even before he started working officially at Imperial and asked for the PPI group’s input on the project. He is researching on oropharyngeal squamous cell carcinoma using Rapid Evaporative Ionisation Mass Spectrometry and he has since involved the PPI group at various stages in his research. Another young researcher has regularly provided updates of her research to the PPI group and has appointed PPI members in her study management team.

Institute of Cancer Research (ICR) ECMC

ICR: response

- **Identifying important research questions and research prioritisation** – Utilizing/acquiring PPI influence on research prioritization for early trials of novel therapies remains a challenge. However, we are working to generate PPI influence in identifying areas to improve the processes for patients who are participating in Phase I trials.

- **Improving the design of research protocols, information sheets (PIS) and consent forms (ICF) -A PPI Co-production project**. In February 2019, the Drug Development Unit embarked on a co-production project aiming to understand and improve the informed consent process for patients on early trials. The project leads (the ECMC staff PPI rep and a Clinical Fellow) proposed an accelerated experience based co-design framework that adopts a truly multi-disciplinary approach where several members of the team, including clinicians, nurses and trial co-ordinators are working in partnership with patient reps and users of the service to firstly evaluate the current status and then develop tools to aid the patients understanding of the trials and the experience of the informed consent process. The project uses face to face interviews, focus groups and shadowing to collect a breadth of experiences. In terms of PPI the project has a nominated Patient Representative working in partnership as a co-researcher and has so far been instrumental in conducting some of the data collection (interviews). The project is currently in the data collection phase.

- **Reviewing patient focused questionnaires and addressing end user needs** – Building on the findings from last year's PPI work on information and support for patients on trials a quarterly patient forum has been implemented. This forum is open to all patients on trials within the unit and provides well-being support as well as feedback about the trials for patients who want to understand more about what happens to the data generated as a result of their trial participation.

- **Improving methodologies of data collection and analysis** - The ECMC PPI staff rep continues to chair the trust Patient and Carer research review panel. The panel reviews protocols and patient information at varying stages and often contributes to discussion about methodologies in research design. Collected metrics show that over 60 research studies or related documents have been reviewed by the panel in the last twelve months. All of the drug development unit patient-facing documents are reviewed by this patient involvement panel.

Summary

In summary, over the last twelve months the ICR/RM ECMC has built on the well-established structures of PPI in place, with a focus on measuring impact and introducing meaningful co-production work. Two large projects are underway in these areas. On-going PPI activity continues to meet the demands of both researchers and service users. The ECMC staff and patient rep have introduced a governance framework for PPI to ensure that patients, trial sponsors and patient colleagues are protected and supported when conducting PPI in research. PPI colleagues have had the opportunity to disseminate information regarding the PPI work done and to get involved in PPI training.

ICR: case study

The ECMC PPI rep has developed a tool to measure impact of PPI on research. The tool has been developed with patient rep involvement and has been piloted for 6 months within the RM/ICR. Data returned demonstrated that PPI did impact changes within the research and that researcher experience of PPI was positive. The tool needs further refining in response to the pilot findings. The next stage of this project is to roll out nationally in collaboration with other ECMCs. A kick off TC has taken place with some of the key members of the ECMC PPI network and a brief outline of a plan has been formed. There are four other ECMC's interested in collaborating on a broader measurement of impact of PPI.

King's Health Partners (KHP) ECMC

KHP: response

The South East London Consumer Research Panel (SELCRP) supports our researchers with their studies, providing advice on patient information sheets, protocols, and research proposals. Panel members (lay, patient representatives, and active researchers) provide rapid review and feedback to research teams on comprehensibility, terminology used, and patient acceptability of aspects of trial design, and also review draft patient information materials prior to ethics submission.
In addition to this the panel has provided some excellent feedback and ideas supporting researchers in creating their own PPI panels for their own particular projects, such as tips on how to recruit new members to the group, ideas on how best to reward members, and advice on how best to brief the academics who present their research ideas. Some core panel members have also offered to serve on these new project-specific groups to provide experience supporting these new teams.

The Panel also supported an "opt-out" consent strategy for the Guy's Cancer Cohort, which is a REC-approved research database at Guy's and St Thomas' NHS Foundation Trust. The document was developed in collaboration with the Panel ensuring that all information provided is clear to patients. Feedback from SELCRP was aligned with a systematic review of the literature to identify barriers and facilitators of opt-out consent. Overall this work concluded that patients demonstrated a high level of acceptance of participation in observational studies based on the opt-out consent model.

King's Health Partner's (KHP) fourth annual Cancer Survivors' Day event was held on the 24th June 2018 at the Cancer Centre at Guy's, which has been a huge success. The KHP event featured a fashion show modeled by cancer survivors, information stalls, music and entertainment. The day also included a Celebration Walk taking in London's sights to celebrate cancer survivorship along with a series of research lectures and educational activities delivered by our scientists and clinicians, including the KHP ECMC Leads.

As part of the public engagement agenda, two panel members took part in the second speed science event, part of the King's College London K+ programme (http://kplus.london), speaking to K+ students about the impact of cancer research on patients, from a patient perspective. The event was very successful, with 100% positive feedback.

Other PPI highlights:

- Hosted laboratory visits by patients, Dermatology Oncology, e.g. April 2018
- Philanthropy & Partnerships: e.g. Sheffield Haworth Catalyst Club Breakfast, Invited Speaker to support fundraising, Sheffield Haworth, London, 21st Feb 2018;
    - https://www.linkedin.com/company/sheffield-haworth/;
- Interview on immuno-oncology and translating first-in-class antibody to clinic, CRUK Autumn 2018 Newsletter: https://philanthropyandpartnerships.cancerresearchuk.org/ProgressUpdateAutumn2018/
- Hosted 6th Form work experience students;
- King's Stars 2018 Outreach Programme, (July) for 6th Form students; speaker, lab tour host;

- Joined Faculty of the World Hellenic Biomedical Association (6th and 7th Summer Schools in Medical & Biosciences Research & Management, awarded to outstanding PhD students, clinicians & postdocs);
- Invited speaker: e.g. From Bench to Market, PhD training workshop, KCL, December 2018; UK National DermSoc Day, BAD, London, Mar18

Leicester ECMC

Leicester: response

The Patient and Carer Advisory Group has continued to meet throughout the year. Membership has expanded to further reflect age, male/female ratio, ethnicity and disease speciality. New staff members have also joined the group and report an appreciation of the value patient and public involvement and engagement brings to the workplace; this has been especially important whilst considering the development of a paediatric and teenage and young adult work stream.

With the appointment of Dr Harriet Walter as Phase 1 lead consultant, the group has overseen the content requirements of a new section on our website which includes an external referral process. Better provision of information for new patients is now finalised in our 'What is' series which will be included in patient admission packs going forwards.

In conjunction with The East Midlands Centre for Black and Minority Ethnic Health we continue to actively engage with ethnic minority groups. Attendance at a ‘Health Connect’ event within the African Caribbean community triggered the revision of our generic outreach event poster material. More pertinent information relevant to specific populations, with a particular focus on the provision of statistics relating to disease prevalence indicates this approach has heightened cancer awareness and stimulated conversation around 'myth busting'.

As a result of a medical student placement project exploring expected versus actual uptake of clinical trials amongst different ethnicities, we are now in a position to progress to a larger scale study that is to include member(s) of our PPI group as co investigators. Initial responses from colleagues within other ECMCs indicate interest in cross-centre participation.

Liverpool ECMC

Liverpool: response

In January 2019 the Liverpool ECMC Operational Director, Charlotte Rawcliffe, gave an information presentation to the Liverpool Cancer Trials Unit (LCTU) Patient and Public Involvement (PPI) Group regarding the work and development of the Liverpool ECMC. Following this, Dr Philip Bell was selected from a number of keen group members to be the Liverpool ECMC lead patient representative, who will represent Liverpool on the ECMC Patient and Public Involvement Group, replacing Alan Grant, the previous lead.

Dr Bell brings with him a vast amount of knowledge and experience of PPI work, having served in a number of PPI roles and is a strong advocate for cancer trial patients. Dr Bell will work with the Liverpool ECMC Senior Management Team in developing successful grant applications, which reflect the views of patients and the public.

Members of the PPI group continue to support the work of Liverpool ECMC and have provided input into patient facing trial documentation, lay summaries, trial design and grant applications for Liverpool ECMC-led early phase trials.

Ruth Stafferton, Liverpool ECMC staff representative on the ECMC PPI Group, attended and contributed to the 2018 ECMC PPI Subgroup meeting in Birmingham, and has expressed an interest on behalf of the Liverpool ECMC in hosting the 2019 PPI Group meeting in Liverpool, the result of which is awaited. Ruth has participated in and contributed to a teleconference meeting regarding an evaluation tool for researchers to give feedback to PPI representatives. Ruth coordinated the response to the CRUK Senior Patient Involvement Officer, providing feedback for the planned Face to Face PPI Training for Researchers.

Awareness of Liverpool ECMC, the ECMC Network and early phase trials has also been raised externally, through Liverpool ECMC team participation in a number of public facing events.

In December 2018, members of the Liverpool ECMC Team (Operational Director, Manager and Senior Trials Coordinator) participated in the Research Insights: Cellular Journeys Event as part of an installation at the Tate Gallery, Liverpool. The team interacted with members of the public providing information about the research taking place in the Liverpool ECMC and the University of Liverpool which is helping to improve diagnosis and treatment of cancer.

In January 2019, the Liverpool ECMC Haematology Lead, Andrew Pettitt, and Lead Haematology Research Nurse, Jane Tinsley, presented at the Chronic Lymphocytic Leukaemia Support Association Conference on clinical trial experience and new developments in treatment.

In collaboration with Nurse Academics at Clatterbridge Cancer Centre, University of Liverpool and John Moore's University, the Liverpool ECMC team are developing a funding application for a PPI project exploring the views and experiences of patients participating in early phase trials, looking at patient views and experiences of early phase trial participation. Initially this will be undertaken locally, with scope to be expanded across other ECMCs. This project will cover all aspects of early phase trial participation, from referral, initial trial discussions and consent through to participation and end of trial experience. This project will be developed over the next 6 months with the contribution of ideas from patients on the LCTU PPI group and Liverpool ECMC PPI representatives.

Liverpool: case study

In 2019, Liverpool ECMC Lead, Daniel Palmer, hosted an Immunotherapy educational evening at the Liverpool Medical Institute, including a keynote presentation by a HCC survivor on the patient perspective of participating in a clinical trial using cancer immunotherapy agents.

This has led to the aforementioned patient collaborating with the Liverpool ECMC on the development of the ARACHNID (phase II, multi-arm, adaptive trial of durvalumab in combination with different radiotherapy modalities for advanced hepatocellular carcinoma) clinical trial. PPI involvement has been pivotal in designing the patient schedules, the consenting process, consideration for the budgeting of patient visits (travel) and the quality of life aspects. The study schedule is demanding, with the requirement of an on-treatment biopsy and, for the proton therapy arm of the study, the requirement to travel across the UK to one of two sites (Manchester or London). We have adapted the trial to allow flexibility for travel and follow-up closer to home based on the patient input.

This has been critical in developing this trial, to allow review of acceptability of the complex schedule from a patient perspective and whether participating in the trial would be in the interest of this specific patient population.

Due to the adaptive nature of this study, close PPI involvement throughout the life cycle will be essential. We plan to build on this involvement with the inclusion of different modalities added during the trial.

Manchester ECMC

Manchester: response

Manchester ECMC is very committed to involving patients and the public in our research work and continues to look for, and create opportunities for patients to participate in the development of protocols and grant proposals. We believe that having a patient voice gives researchers unique perspectives, which in turn influences and shapes cancer research, making it meaningful in the long term. The PPIE collaborative partnership (ECMC, CRUK, The Christie, University of Manchester, Manchester BRC & NIHR Manchester CRF) established in Manchester, ensures the best for our patients in the long term through the involvement (and engagement) initiatives. Examples from the last reporting year include the following:

- Manchester ECMC patient representative (Taylor) sitting on both the local Manchester ECMC steering committee and the ECMC National PPIE group.
- "Behind the labels "event involving patients/public/scientists/nurses and medical staff talking/sharing their stories. This event evolved from an initial concept developed by Manchester ECMC patient representative (Taylor).
- CRUK Senior Research Nurse (Dickinson) is a core member of ECMC National PPIE group and also contributed to the re-drafting of the PPIE booklet and development (on-going) of the Researcher Feedback Tool.
- Manchester ECMC Showcase event was hosted in January 2019. As well as participation in the event, advice was sought from our patient representative to ensure relevant and impactful PPIE was part of the event.
- Re-design of the patient information sheet given to patients at their first new patient appointment with our Experimental Cancer Medicine Team (ECMT). The re-design of this information was conducted with significant input from PPIE representatives from across Manchester ECMC.
- The digital Experimental Cancer Medicine Team (dECMT) hosted a number of focus groups throughout the year, including face-to-face and online focus groups. The groups covered the following areas; nephro-oncology, fatigue and febrile neutropenia. In addition, dECMT hosted a group to discuss how to explain the concept of a platform trial – changing patient's role in clinical trials.
- The dECMT designed and implemented a survey to collect feedback from 'silent patients' collected via a tablet within the NIHR CRF Manchester clinic space. In addition, input was sought via this same route, on a specific point of care device.
- Input to development of protocols for Manchester investigator led studies (ILS) – within the ECMC patient involvement in development of protocols for ILS takes a high priority. Manchester ECMC routinely participates with patient groups, including those supported by The Christie charity and "Maggie's" to involve patients in protocol development and content of patient-related trial materials.

Examples of specific patient and public involvement projects directly funded by ECMC include the following:

- Experimental Cancer Medicine Patient Reported Experience Measure (ECM-PREM) – The study which opened in the second quarter of 2018 aims to develop and pilot test, a Patient Reported Experience Measure (PREM) for experimental cancer medicine clinical trials patients and their family carers. The study has completed stage 1 and is currently finalising data analysis from 24 interviews with patients participating in early phase trials across Manchester ECMC. This will enable the identification of possible questionnaire items to take forward to cognitive debriefing (stage 2). An amendment, following ethical approval, to include carers, has been implemented and recruitment to this group is open. A Manchester ECMC patient representative (Taylor) was heavily involved in the development of this study.

- Pharmacy app - ECMC granted £30k funding towards a pilot project (Patel) to evaluate the use of technology to better inform ECMC patients of their waiting times when receiving IV treatment. The pilot is based on previous feedback from patients that they would benefit from being kept informed of the status of their treatment whilst waiting, to enable them to use their time better. In the first quarter of 2019 the Manchester ECMC (Cook) Trust will roll out a pilot text messaging function for ECMC patients. The aim is to involve up to 100 patients as part of this pilot study.

Manchester: case study

De-mystifying Early Phase clinical trials – an event for patients/carers/public organised by the Experimental Cancer Medicine Team and supported by Manchester ECMC.

The Experimental Cancer Medicine Team (ECMT) hosted a patient and public involvement and engagement event at The Christie NHS Foundation Trust on Saturday 2nd February, entitled **"De-mystifying Early Phase clinical trials"**. The aim was to involve, engage and educate patients and the general public about early phase research and precision medicine. The date was chosen to coincide with World Cancer Day (4th February 2019).

Importantly patient and public involvement (PPI) was considered by the organising team from inception of this event. The ECMT hosted an engagement stand based in the main entrance of The Christie during the week commencing 10th December 2018. The aim of this engagement exercise was to seek valuable feedback from patients, and public insight, and to discuss the aims of the event to ensure the aims, the day and the evaluation were appropriate for the audience.
Examples of feedback received during the engagement week included the following:

- It was evident on the stand that patients and the public more readily approached staff in uniforms, for example nurses. Therefore, staff were requested to wear uniforms at the event.
- A game used on this stand provided a visual explanation of precision medicine, demonstrated limited knowledge amongst the public and also prompted relevant discussions. Therefore, the same game was used at the event.
- A number of people asked about immunotherapy during this week. Therefore, an immunotherapy stall was incorporated into the event, along with a talk on the subject.
- It was clear from the stand that patients and their carers liked the opportunity to engage in conversations about their own medical history with dedicated staff. Therefore, 6 volunteers on the day were assigned to a 'phase 1 trial information stand' which allowed for 1-to-1 conversations with attendees, where required.
- A wide array of printed information was made available on the stand. Some of this prompted relevant conversations about early phase research and precision medicine, whereas other documents caused confusion. The material used later was selected based on this feedback.

Further engagement including additional conversations with patients attending ECMT clinics and clinics with other teams generated important feedback around the planned agenda and theme of the event.

The information gathered from the **De-mystifying Early Phase clinical trials** event was varied and is extremely valuable (examples shown below). The event itself was used as a forum for feedback on the perceptions and understanding of patients and the public about early phase research and precision medicine. This information is now being used by early phase researchers to facilitate conversations with patients who have limited knowledge about the subject, and to influence the way that patients are managed within the team.

Very well organised. Transparent. Educational. Good PR. Easy to follow and understand. Comfortable environment. Lunch looks good… It has taken away some of the fear and mystique. I'm feeling more confident. Very glad I made the effort to come – I didn't feel too good yesterday. Nice to come to the Christie and not have a blood test for a change!

The tour. It was good to see behind the scenes and how everything is done.

Excellent!!!

The laboratory visit was very informative, as was the question/answer panel

I left today with a lot more knowledge and understanding of clinical trials. Congratulations to everyone involved.

Talk more about targeted therapies

"I enjoyed the day immensely. Felt like I have benefited greatly. Learnt about cancer awareness and prevention. Also further insight into careers in clinical research e.g. Pharmacy"

I enjoyed the whole day and was really interested to learn about how targeted therapies are being developed.

An abstract detailing this PPI work has been accepted for a poster presentation at the UKCRF conference, Nottingham, July 2019.

Newcastle ECMC

Newcastle: response

Public engagement work for the Newcastle ECMC involves the whole ECMC team and is ably coordinated by Ben Hood, the CRUK Senior Nurse.

Engagement work

One of the highlights of 2018 was the delivery of the very successful Rucaparib event at the Great North Museum in February. The day comprised of two halves, with 150 invited supporters and PPI group members for the morning and a symposium for 150 scientists and clinicians in the afternoon. The CRUK Supporters heard from several researchers who had been involved in the identification and development of Rucaparib, describing the process from start to finish, and they also learned of the impact it will have for patients. During the intervals, they had the opportunity to try out the PARP Inhibitor engagement activity and to see 'Inhibitor', an incredible audio-visual installation created by artist Ed Carter, which represents healthy and cancerous cells undergoing PARP Inhibition treatment. Feedback from this event was incredibly positive. The turn out and quality of engagement was excellent, with really positive feedback. Some patients who had been on ECMC supported trials of rucaparib opted to attend the event and here the science behind the drug they had received.

International Clinical Trials Day was celebrated with an Open Day in May. The clinical trials unit opening on a Saturday to allow access and showcasing of the clinical trials work without compromising clinical delivery. The majority of ECMC and CRUK Centre staff gave up their Saturday morning to volunteer for this event. The event was very popular with all 60 available places filling quickly and a big success with fantastic feedback from colleagues and supporters.

200 patients and relatives attended the Sunderland Hospital Wellbeing event to mark the 70th anniversary of the NHS. The Research Engagement Manager supported the events by delivering interactive activities and a presentation about the cancer research taking place at Newcastle ECMC and CRUK Centre.

Involvement work

Newcastle ECMC has a thriving early phase cancer PPI group, led by our CRUK Senior Nurse, Ben Hood. There have been three major grant applications where our PPI group has been critical in helping develop the research and also worked to support the research teams, these have been ColoSPEED, a CRUK catalyst application linking ECMCs across the whole of the UK, MEDALLION, an IO toxicity study led from Newcastle and involving Glasgow, Birmingham and Oxford ECMCs. These projects all went to full application and received fundable peer review scores despite there not being funds available to progress them further at present.

The PPI group has been critical to helping develop the CONCORDE platform study, a novel agent/radiotherapy combination study in lung cancer, which is led by Dr Alastair Greystoke from the Newcastle ECMC and is at full application stage at CRUK's Clinical Research Committee.

In addition, the PPI group has worked with Ben Hood on developing a new patient information leaflet- outlined in more detail below

Newcastle: case study

Development of Early Phase Trial generic patient information resources

Cancer patients are referred to the Sir Bobby Robson Cancer Trials Research Centre where the Newcastle ECMC clinical team are based, for early phase clinical trials by their original treating oncologist. All these patients have received the available standard treatments for their cancer, and are aware that they have no proven treatment options left. These patients are referred from a very wide geographical region reaching up to the Scottish Border, including North Cumbria, Northumberland and into North Yorkshire. In addition, the unit accepts patients from a wider region for studies in rare tumour subtypes.

Patients and their carers are therefore, often referred from a considerable distance at a very challenging time in their patient journey, to meet a new team and also discuss often complex trial options. This can be daunting and the research team in the Newcastle CRUK Centre and Newcastle ECMC were keen to understand the issues and help improve the pathway.

This was done in a multi-step process supported throughout by the PPI group, led and coordinated by Ben Hood with the development of a patients' questionnaire, evaluation of the results, development of a patient information leaflet, website resource and phone app – bringing to our patients a wealth of support resources and options.

This research project was instigated by Ben Hood approaching the PPI group and working with them to develop the initial patient questionnaire. This was designed to seek the views of current patients on clinical trials, who were already partway through the journey and, using an open question format as well as specific questions, get their views on how the referral and information pathway currently worked, what the problems were and what might make it better. Views were also sought on the various forms of patient information media that would be preferred.

Working with the PPI group throughout, a cycle of feedback and further "market" research was used to develop initially a paper patient information leaflet.

Patients also indicated that having video content through the trial unit website, with staff members discussing their roles and how the unit worked would be useful. These have been undertaken on the trial unit using a small tripod mounted Smart phone, the content edited and uploaded to the website.

The current third stage of the project is development of a phone app, again aimed at improving access to information and highlighting clinical research activity.

This project has been presented at an international PPI conference, which spanned all disease areas. The development of the patient information booklet and evaluation process with future plans were presented in poster format. This attracted considerable interest at the conference from a wide range of delegates and was awarded the research poster prize overall. This poster acknowledged CRUK and Department of Health support for the Newcastle ECMC/Centre

Oxford ECMC

Oxford: response	
What percentage of your research studies have involved patients or public in their development?	Early Phase: All studies that we run have an element of PPI at development, as public representation on ethics committees prior to approval is a prerequisite.
How have you involved patients or the public in the overall priorities for research within the theme?	Patients are approached on an ad hoc basis at the request of investigators for involvement in various projects as needed. A panel of lay people (mixture of patients and people affected by cancer) was formed to review projects / address requests from other agencies – Oxford Cancer Research (OCR) PPI committee. The ECMC PPI handbook is approaching publication, it will also be released online in the coming months. The handbook will provide comprehensive information on trials, treatment and jargon to better equip patients and the public for engaging with research activities. As a member of the ECMC PPI working group we have been involved in its development, including consulting lay people on its content and design. Early Phase trials unit committee member on OCTO early phase steering committee. Researchers are engaging in consultation as part of the updating of Face to Face PPI research training that is already offered to researchers. Consultation is also underway to create PPI case studies to better demonstrate the direct value of engagement and involvement. Patient / people affected by cancer were asked to attend a meeting concerning the CRUK Grand Challenge proposal looking into colorectal cancer (CRC) and the microbiome. Examples of the above activity are given below: • Two of our CRC patients have agreed to attend a meeting to feed into the development of S: CORT. • One of the EPCTU PPI committee was involved in helping to shape a

	project looking at the promise of precision medicine. - A satisfaction survey of EPCTU patients helped us to understand what was important to our patients and improve our service. - A haematology patient from OCR PPI committee helped the Haematology PPI committee with research proposal review. - Haematology patients were approached to help inform research design for Celgene project at the pharmacological company's request.
What examples are there that research has been reshaped as a result of patient and public involvement?	Member of PAIR committee which is an overarching PPI group hoping to co-ordinate and influence PPI across different themes. Direction of this committee is still evolving.
Steps taken to reach out to patients / public to get them involved in your research?	Posters up in public areas to advertise the existence of the OCR PPI committee. Flyers also available on the EPCTU. Emails are sent out to request feedback on projects either virtually or sometimes meetings are held if this is more appropriate.

Sheffield ECMC

Sheffield: response

The following section was completed by Jacqui Gath, Sheffield ECMC PPI representative and member of the executive committee.

The Yorkshire and Humberside Consumer Research Panel continue their PPI activities and provision of input to ECMC research studies, as well as ancillary activities which have direct and indirect value to the centre.

For example, of special note is the successful work on the postcard for the ZOLMENO study (see the case study section below) which was circulated to the Panel, and Independent Cancer Patients' Voice for comment.

Five studies submitted for funding to Yorkshire Cancer Research (YCR) were enhanced by PPI from the Panel. Topics ranged from a new and sophisticated imaging technique (funded) to nutrition for cancer patients.

Opportunities for involvement in data projects has been taken up, as members feel that the availability of 'big data', and cancer data in particular, offers extensive opportunities for comparison and improvement of treatment and services. Two members of the Panel are involved in the design and implementation of the IQVIA CODE system, being rolled out across the UK, and the EU and under review by Sheffield Hospitals Trust.

HRA is currently revising guidelines regarding involvement and Panel members are helping to shape these, while the MHRA are issuing guidelines for the Early Access to Medicines Scheme where Panel members are similarly involved.

Other activities remain largely as per last year, with training opportunities being taken up, and involvement opportunities being circulated.

Panel members work with researchers from both University of Sheffield and Hallam University. They continue to press nationally for travel expenses to be reimbursed for participants in studies, particularly commercial studies, for the use of comprehensive quality of life measures, and recording of data concerning measures the patient has taken to assist their own recovery.

Sheffield: case study

The PPI group played an active part in the development of a postcard for breast cancer patients to help with recruitment for the ZOLMENO study. We introduce this study to patients just after they have received their initial breast cancer diagnosis, and wanted to provide a simple reminder of the opportunity to take part in a trial at a time when we know patients find it hard to take in all the information they are given. The PPI group participated in several rounds of refinements of the draft postcard, advising us on everything from content to colours and layout. The postcard subsequently obtained ethical approval, providing a new resource to aid recruitment to this trial developed with significant PPI input.

Front of the card

HELP US IMPROVE BREAST CANCER TREATMENT

The bone drug called **ZOLEDRONIC ACID** has more benefit for women with early breast cancer who have gone through menopause.

WHY DOES IT NOT HAVE THE SAME EFFECT ON ALL WOMEN?

You could **help us find out**.

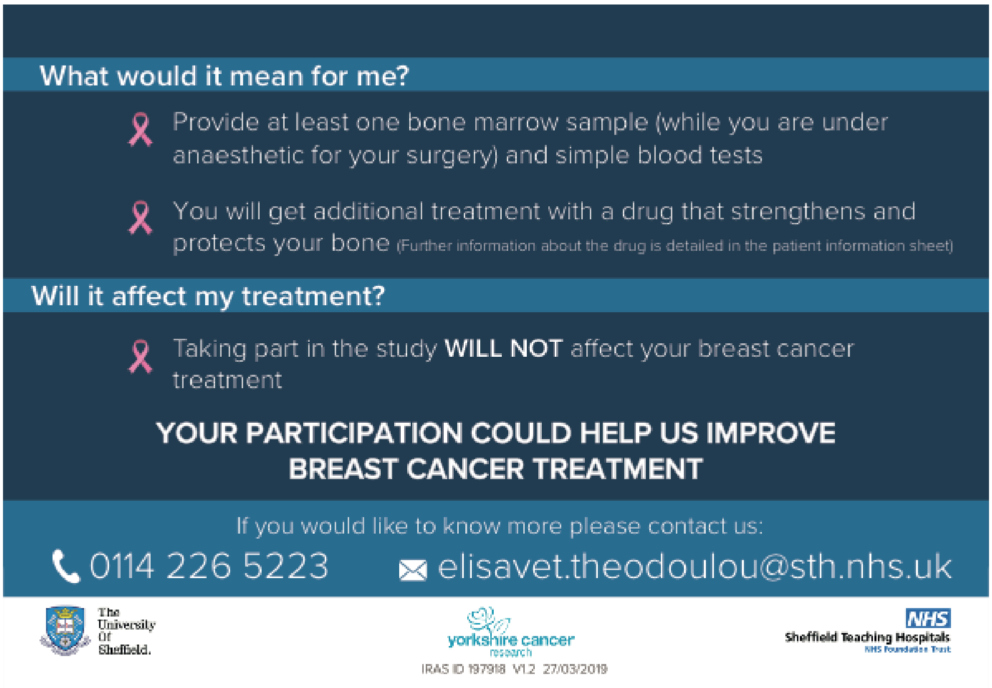
The ZOLMENO study

if you would like to know more please contact us:
☎ 0114 226 5223
✉ elisavet.theodoulou@sth.nhs.uk

The University Of Sheffield.
yorkshire cancer research
NHS Sheffield Teaching Hospitals NHS Foundation Trust

IRAS ID 197918 V1.1 27/02/2019

Back of the card



What would it mean for me?

- Provide at least one bone marrow sample (while you are under anaesthetic for your surgery) and simple blood tests
- You will get additional treatment with a drug that strengthens and protects your bone (Further information about the drug is detailed in the patient information sheet)

Will it affect my treatment?

- Taking part in the study **WILL NOT** affect your breast cancer treatment

YOUR PARTICIPATION COULD HELP US IMPROVE BREAST CANCER TREATMENT

If you would like to know more please contact us:
☎ 0114 226 5223 ✉ elisavet.theodoulou@sth.nhs.uk

The University Of Sheffield.
yorkshire cancer research
NHS Sheffield Teaching Hospitals NHS Foundation Trust

IRAS ID 197918 V1.2 27/03/2019

Southampton ECMC

Southampton: response

PPI in the Southampton CRUK Centre has for many years been the remit of the Cancer Research Partnership Group (CRPG) whose strategic main aim was:

To deliver meaningful PPI across Wessex/UHS to support the cancer research pathway in a manner responsive to the evolving nature of the clinical trials landscape and broader PPI development.

We saw considerable change in our PPI activity in the last year with no requests from individual researchers. More members died and we had only 2 attending in person by the end of 2018. Both of these are on TMGs, TSGs, The Oesophageal Consortium and also participate in the CTU Trial Review meeting. The Centre SRN & one patient member belong to the ECMC PPI group.

In response to the changing landscape we are developing a new model for PPI to be delivered locally. This will evolve through close networking with the recently appointed UHS Trust-wide PPI manager and her new team. Our aim is to continue to deliver our CRPG strategy but proactively adapt the way this is achieved. We will retain links nationally through the ECMC PPI group & CRUK PPI team. We will continue our local focus via CTU membership on the Trial Review Group, TMG & TSGs and The Oesophageal Consortium. The Centre SRN met with the UHS Trust-wide PPI manager to discuss how best to achieve this by partnership working. The UHS Trust-wide PPI manager presented to the CRPG meeting on 6/12/18. The group agreed that the current format is not effective & members were willing to have their contact details added to the NHS Trust PPI team's database, to be approached for relevant activity. This database already has several other cancer patients' details and they participate in PPI.

The Centre SRN will facilitate necessary changes to ensure we pursue effective deliverance of our strategy, detailed below:

- *PPI will be integrated into local & regional cancer research strategy, management & projects*
- *Consumers will have a clear pathway for finding out how they can be involved in influencing research*
- *Researchers will have a clear pathway for accessing PPI*
- *Consumers will be supported appropriately to maximise the impact of their involvement*
- *PPI continued learning & development will be supported through regional & national networking*

University College London (UCL) ECMC

UCL: response

a) **Mekala Gunaratnam** was awarded a BRC grant aimed at addressing **PPI in key areas relevant to experimental cancer medicine** – genomics data, routinely collected data and perceptions of risk and benefits of early phase trials. Since the beginning of this award in Apr 2018, a PPI panel consisting of 6 members, both patients and carers, was established. The panel contributed to the development of a questionnaire, including its content, structure and language used which addressed the aims of this project. The final questionnaire was piloted at the Clinical Research Facility, in Dec 2018 for feedback on its content and design. The full survey was conducted among a cohort of patients who had agreed to participate in an early phase/first in man cancer trial. In total, 43 patients completed the questionnaire and data was analysed using the survey tool, which was developed by UCLH Patient Experience Team. A final face-to-face meeting with the group was held on 20 Mar 2019 to discuss the outcome of the survey and to look at options for sharing this with the wider community. Outcomes of this survey, based on data analysis and the discussions held with the PPI panel are:

Collection of genomics data - despite the relative novelty of this aspect of data collection, which might have been expected to increase concerns, none of the respondents disagreed with its use and it was overwhelmingly (88%) accepted. Majority of the participants (75%) however were interested in receiving further information/overview on how the data will be used.

Routinely collected data – again a majority of participants (88%) agreed on the routine collection of anonymised data and further supported use of this data for monitoring cancer incidence in different groups of population, monitoring changes in survival rates and reporting overall cancer levels. When asked about the security of this stored data a third of the participants expressed ‘some’ concerns. The panel felt that this should be recognised and valid reassurance should always be provided when proposing data use or requesting consent.

Perception of early phase trials – participants responded in a very similar manner and all participants agreed that the patient information sheets were easy to understand and that they were given detailed information prior to consenting. The panel pointed out that this is a tribute to the Investigators and study team and may well have influenced the strongly positive overall attitudes noted earlier.

The outcome of this survey will be presented at one of the national meetings following discussions with the PPI panel.

b) Our PPI members provided **feasibility feedback for the CRUK/AZ Alliance study** - Perioperative Immunotherapy with Durvalumab and Tremelimumab for Resectable Hepatocellular Cancer (HCC) at its application stage.

c) In September 2018, the CRUK UCL centre hosted a large-scale weekend **Supporter’s Day** titled **Revealing Research** to celebrate the Cancer Institute’s 10-year anniversary and display the pioneering research and collaborations happening across UCL, from the earliest stages of lab research through to clinical trials. The event was led by the CRUK Research Engagement Manager and content was steered by Centre Directors, the CRUK Senior Research Nurse, ECMC Centre Manager (**Mekala Gunaratnam**) and UCL scientists. Those involved ran drop-in activities including a ‘Researcher Café’, hands-on activities and lab tours.

Feedback from attendees on the day was 100% positive, with most placing emphasis on how insightful the event was in terms of the research and progress being made, and the importance of meeting people working on lifesaving research. For this event, Dr Saioa Lopez and Ariana Hueber of Dr Nicky McGranahan's group developed a new activity to demonstrate the process and importance of genetic sequencing in cancer research, which will be developed into a permanent resource for CRUK engagement. This event was a pilot event for future CRUK supporter open days, which we will now continue to host bi-annually due to the day's success. Below are some comments from attendees:

- "Fascinating and very informative. I can see why research is so important and expensive!"
- "The activities were very engaging and broke down complications into simple terms"
- "Fantastic experience. Thank you to everyone who gave their time for this. It is brilliant to be able to engage CRUK supporters in the work they fund"
- "An amazing experience in the lab. So much information and a chance to get practical"
- "An excellent blend of 'lay speak' with the view into the real science. I feel very optimistic for the future."

Acronyms in the document

AZ	AstraZeneca
BMT	Bone Marrow Transplant
BRC	Biomedical Research Centre
BWoSCC	Beatson West of Scotland Cancer Centre
CCRCB	Centre for Cancer Research and Cell Biology (Belfast)
CCRCC	Clear cell renal cell cancer
CI	Chief Investigator
CRCTU	Cancer Research Clinical Trials Unit
CReSt Cymru	Cancer Research Strategy for Wales
CRC	Colorectal cancer
CRF	Clinical Research Facility
CRPG	Cancer Research Partnership Group (Southampton)
CRUK	Cancer Research UK
CTU	Clinical Trials Unit
CTEC	Clinical Trials Executive Committee (Glasgow)
dECMT	digital Experimental Cancer Medicine Team (Manchester)
ECCPPI	Edinburgh Cancer Centre's Patient and Public Involvement Group
ECMC	Experimental Cancer Medicine Centre
ECM-PREM	Experimental Cancer Medicine Patient Reported Experience Measure
ECMT	Experimental Cancer Medicine Team (Manchester)
EPCTU	Early Phase Clinical Trial Unit (Oxford)
HCC	Hepatocellular Cancer
HRA	Health Research Authority
ICF	Informed Consent Form
ICR	Institute of Cancer Research
ICRB	Involvement and Engagement in Cancer Research at Birmingham
IHTAB	In-House Trials Advisory Board (Glasgow)
ILS	Investigator-led Studies (Manchester)
JING	ECMC Junior Investigator Network Group
KCL	King's College London
KHP	King's Health Partners
LCTU	Liverpool Clinical Trials Unit
MHRA	Medicines and Healthcare products Regulatory Agency
MRC	Medical Research Council
NCRI	National Cancer Research Institute
NHS	National Health Service
NI	Northern Ireland
NICRCF	Northern Ireland Cancer Research Consumer Forum
NICTN	Northern Ireland Cancer Trials Network
NIHR	National Institute for Health Research
OCR	Oxford Cancer Research
OCTO	Oncology Clinical Trials Office (Oxford)
PAIR	Patients Active in Research committee (Oxford)
PBCP	Personalised Breast Cancer Program (Cambridge)
PILAR	West Midlands Public Involvement and Lay Accountability in Research Group
PIS	Patient Information Sheet
PPI/E	Public and Patient Involvement and Engagement (in Northern Ireland it is Personal and Public Involvement)
QMTAG	Queen Mary Trial Advisory Group (Barts)
QUB	Queen's University Belfast

REC	Research Ethics Committee
RM	Royal Marsden Hospital
SELCRP	South East London Consumer Research Panel (KHP)
SESCRN	South East Scottish Cancer Research Network
SOP	Standard Operating Procedure
SRN	Senior Research Nurse
TMG	Trial Management Group
TSG	Trial Steering Group
UCL	University College London
UCLH	University College London Hospital
UHS	University Hospital Southampton
WCRC	Wales Cancer Research Centre
YCR	Yorkshire Cancer Research