# The digital Experimental Cancer Medicine Team

## Engaging patients, Driving decisions

## 2019 Report

Digital Experimental Cancer Medicine Team

MANCHESTER 1824 The University of Manchester

CANCER RESEARCH UK | MANCHESTER INSTITUTE

NHS The Christie NHS Foundation Trust

# Contents

World leading scientific research, including pioneering work in precision medicine and cancer treatment is brought together through the Manchester Cancer Research Centre (MCRC) partnership, a unique collaboration that brings together the expertise, vision and resources of its partner organisations: Cancer Research UK Manchester Institute, The University of Manchester and The Christie NHS Foundation Trust, all of which have formidable individual reputations in the field of cancer research.

# Introduction



2019 was the fourth full year of operations for the digital Experimental Cancer Medicine Team (digital ECMT). Based within the Cancer Research UK Manchester Institute, which is part of The University of Manchester, the digital ECMT seeks ***"to innovate and apply digital science to transform decision-making in early clinical trials and the patient's role in these trials"***. This goal is very much enabled by having our Design Lab within The Phase 1 unit at The Christie NHS Foundation Trust, providing direct patient contact with juxta-positioning to the Experimental Cancer Medicine Team (ECMT) – a team of over 60 staff dedicated to supporting early phase cancer clinical trials.

The application of digital science to transform decision making in early clinical trials continues at pace. eTARGET, our decision-support solution which was published in Nature Medicine in 2019* continues to be an integral part of the ECMT monthly cancer Molecular Tumour Board, which seeks to integrate the patient's genomic profile with their clinical characteristics and identify the most suitable clinical trial. During the year, we commenced work to make eTARGET available to other experimental cancer medicine centres across the UK to allow researchers based in many locations to meet virtually and review and annotate in real-time the details for each patient.

The team has also developed and applied a decision-making algorithm to a mobile device for the early detection of kidney toxicity which has now been used on the first patient recruited into the clinical study ("IN-HOME") which will appraise the clinical utility of this digital healthcare product. This will allow patients to conduct their own creatinine assessments several times each week, with the aim of enabling those patients with impaired but stable renal function to access clinical trials from which they are currently excluded due to the standard inclusion criteria.

During 2019 we also completed new visualisations for clinical trial data analysis and interpretation, which enables us to significantly extend the functionality of REACT, including integration with cBioPortal to allow interrogation of comprehensive genomic profiles. We have now secured permissions to release REACT as an open source digital healthcare product during 2020.

A key achievement during 2019 has been the awarding of the UpSMART Accelerator award, funded through a partnership between Cancer Research UK (CRUK), Associazione Italiana per la Ricerca contro il Cancro (AIRC), and Fundación Científica de la Asociación Española Contra el Cáncer (FC AECC). This 5 year "accelerator programme" seeks initially to identify digital healthcare products which are proving valuable to either/both of clinical trial data acquisition and data interpretation from the network of (currently 23) participating experimental cancer medicine centres/ early drug development units across Europe. The UpSMART Accelerator has funding to develop the most promising of these digital healthcare products to be open source accessible products; free of license fees to use.

Detailed within this report is the continued deployment during 2019 of PROACT (Patient Reported Opinions About Clinical Tolerability/Trials), to other cancer centres within the ECMC network. PROACT provides direct reports from the patient of their experience on an early clinical trial.

**Professor Andrew Hughes**
*Chair of Experimental Cancer Medicine,*
*The University of Manchester*

*Rothwell et al. Utility of ctDNA to support patient selection for early phase clinical trials: The TARGET Study. Nature Medicine 25,738-743 (2019)

> "Our mission is to innovate and apply digital science to transform decision-making in early clinical trials and the patient's role in these trials"

digitalECMT – 2019 report – Introduction

# Our research and centres of excellence partners

The digital ECMT brings researchers, clinicians, technology and patients together to innovate in early clinical trials. Our aim is for patients, carers and families to work in partnership with clinical researchers on clinical trials and new digital healthcare technologies.

We are an innovative clinical digital research group, based in the Cancer Biomarker Centre within Cancer Research UK Manchester Institute (CRUK MI), part of The University of Manchester and closely aligned to the Experimental Cancer Medicine Team (ECMT) at The Christie. We focus on:

- Putting patients at the centre of early clinical trials
- Applying digital science to improve decision-making
- Forging collaborations that improve outcomes for patients and the development of new medicines
- Conducting research that improves decision-making in early clinical trials by:
  - Developing new care pathways that involve new methods for empowering patients and clinical teams
  - Changing the role of the patient from a passive recipient to an active participant and co-researcher
  - Clinical algorithm development and application of machine learning techniques to identify and alert to safety signals

World leading scientific research, including pioneering work in precision medicine and cancer treatment is brought together through the Manchester Cancer Research Centre (MCRC) partnership, a unique collaboration that brings together the expertise, vision and resources of its partner organisations, Cancer Research UK, The University of Manchester and The Christie, all of which have formidable individual reputations in the field of cancer research.

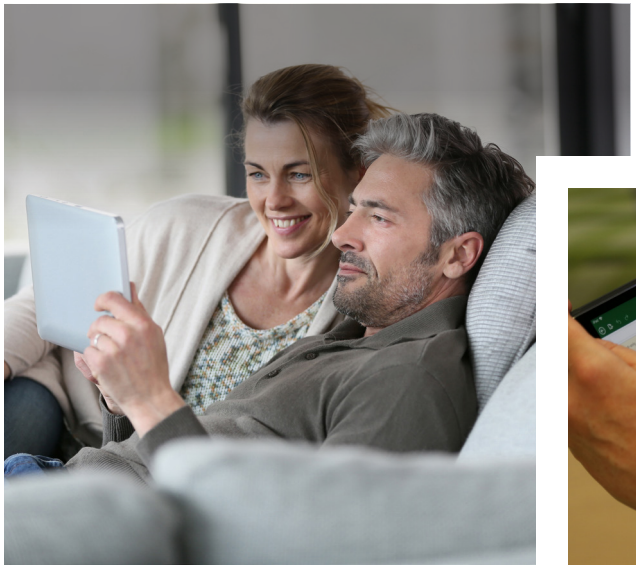
The Oglesby Cancer Research Building, home of the MCRC

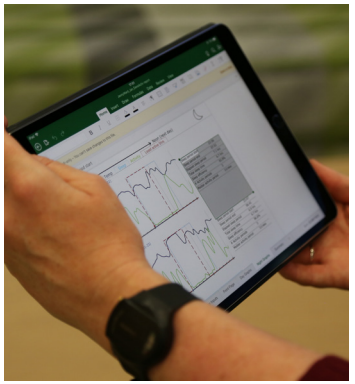


# The Technology Clinical Trial

## Delivering tomorrow's clinical trials today







The widespread and general acceptance of the internet, mobile technologies, home test-kits and sensors, brings with it the opportunity to make changes to patient care pathways and fundamentally change the culture of early clinical trial delivery. We are challenging the current thinking about how clinical trials are delivered and argue that the clinical trials of the future need to be reframed to engage more purposefully with patients. Digital technologies offer the potential to realise our ambition to transform early clinical trials and the patient's role. For optimal benefit these digital-transformations need to be developed and assimilated into new care pathways that are scientifically tested under clinical trial conditions as part of a new type of trial - the *Technology Clinical Trial*.

Our *Technology Clinical Trials* are designed to address the limitations of current clinical trial designs, which are designed around the ergonomics of a centralised clinical trial site, reflected by the application of an outpatient-type schedule of assessments, which limits the amount of patient information that can be captured. This leads to a low density of intermittently captured data, particularly in the first cycle of treatment.

Our goal is to change study conduct through formally testing our technology research through the rigour and lens of a formal clinical trial before it is used in standard clinical practice or potentially incorporated into a Clinical Trial for an Investigational Medicinal Product (CTIMP). Most importantly, the technology clinical trial must also test the viability of the newly created care pathway enabled by the chosen technology to fully assess how it directly impacts the patient, how it affects existing healthcare processes and culture and ultimately whether it is fit to be incorporated into normal clinical practice for clinical decision making.

The patient *Design Lab*, based in The 'NIHR Manchester Clinical Research Facility' at The Christie enables the digital ECMT to directly interact with patients and discuss technologies, their impact and effect directly with patients. This is supported with broader Face-to-Face (F2F) discussions with larger groups of patients at the hospital to discuss new opportunities or research themes with them and solicit structured feedback through a more formal meeting environment and described in further detail in the "Patient Voice" section of this report on page 12.

One of the challenges of delivering *Technology Clinical Trials* is the current regulatory environment and the associated labyrinthine processes where digital technology (devices, software and algorithms) development guidance is not yet fully developed. During 2019, the digital ECMT developed an approach for assessing and determining the best and optimal regulatory path to guide the correct regulatory path for a technology clinical trial to follow. During the year, this framework approach has been discussed and shared with the MHRA.

An example of a technology clinical trial, which the digital EMCT has developed (in close conjunction with Professor Sandip Mitra and Dr. Leanne Phillips from the renal medicine team at the Manchester University Hospitals NHS Foundation Trust UK), is the "*In-Home: Home monitoring of creatinine in cancer patients: assessing acceptability and clinical benefit*" study. This study addresses a clinical unmet need where recruitment to cancer trials is usually limited to patients with good kidney function, therefore excluding significant numbers of patients with renal impairment. At present over 80% of patients with renal impairment are excluded from current clinical trials based on current renal eligibility criteria.

The purpose of the "In-Home" clinical trial is to explore the potential for personalised risk-based monitoring for cancer patients utilising adaptive renal eligibility criteria. A point-of-care (PoC) device, the Novo Biomedical Creatinine StatSensor, enables patients with impaired renal function to measure their own creatinine in their home and report the results back to the hospital through a smartphone app. The data is securely transmitted from the app to the digital ECMT secure Azure cloud environment where a NICE-based Acute Kidney Injury Algorithm (AKI) is applied and the results used to notify both the patient and the hospital of changes in their renal function. The scheduling of the home creatinine measurements is three times a week, which delivers a total of twelve readings per cycle (4-week) compared with only two readings when taken within a hospital visit in a traditional trial design. This increase in data density will enable closer monitoring of renal function on an ongoing clinical trial. This technology clinical trial tests the integration of technologies, patients and a new care pathway to solve a clinical unmet need in enabling patients with renal impairment to access clinical trials.

> "By patients performing their kidney tests more often at home, we hope to show that we can pick up kidney problems earlier and monitor patients more closely to allow them access to clinical trials in the future"
>
> **Dr Leanne Phillips**
> *Digital ECMT, Clinical Research Fellow and IN-HOME trial CI*

# Clinical trial in the home


One of our key goals is to change the patient's involvement in a clinical trial from that of an almost passive bystander to having the option of becoming an active member of the research team. One of the areas that we have been exploring is using technology to deliver aspects of an early clinical trial outside of the hospital and taking the clinical trial to the patient. The potential benefits include:

1. adaptive eligibility criteria through improving risk monitoring for patients
2. greater data capture of key clinical variables in the first cycles of treatment for enhanced decision-making
3. potential to develop predictive analytics and new endpoints

As detailed in the previous section, our home-based clinical trial "In-Home" achieved regulatory and ethical approval in 2019. Working with health care professionals and patients to understand the potential and acceptability of a home-based approach using point of care creatinine meters and digital science to enable risk-based monitoring, a clinical trial protocol was developed which is split into two parts:

- Part A) assessing the feasibility and acceptance of patients measuring at home and
- Part B) understanding the potential for earlier diagnosis of changes in renal function through intensive home-monitoring

Part A of the trial is now live and open to recruitment of Head and Neck cancer patients at The Christie. It is testing a home-based monitoring approach using a device, data capture via a smartphone, and risk-categorisation through an Acute Kidney Injury (AKI) algorithm.

During 2019, the digital ECMT developed a second protocol for an at home cytokine sampling study called "NOTION". Working closely with patients, this study was developed to help assess and measure the impact of side effects of immunotherapy treatment. Immunotherapy has provided remarkable outcomes for patients with melanoma and renal cancers, however, there is a very high risk of developing immune related adverse reactions from the treatment. These immune reactions are numerous and can, at their worst, result in death, especially in patients on combinations of checkpoint inhibitors. Changes in blood cytokines have been shown to be predictive of patients who are likely to develop these adverse reactions during immunology treatment The "NOTION" study was developed to identify those patients who are likely to have these immune related adverse events by measuring their cytokine profiles. Through strong collaborations with The Christie and CRUK MI's Cancer Biomarker Centre the "NOTION" trial aims to first answer the question of whether we can collect cytokine data from patients in the home. Patients will take a pin prick of blood and using a simple device, create a dry blood spot. The dry blood spot will then be posted to a central analytical facility where it will be reconstituted for cytokine analysis. If we can demonstrate the feasibility of this approach, it will open the opportunity for several studies that can benefit patients about to commence all types of immunotherapies.

Throughout 2019 our home based clinical trial capability has developed and we now have the following:

- A Technology Clinical Trial to objectively test a home-based monitoring approach, developing a potential new care pathway with patient-centric sampling at home using a device
- Data capture via a mobile phone app
- Machine-based risk assessment using an automated clinical NHS rules-based algorithm
- Robust plans to expand this approach, during 2020, into further trials in areas of unmet clinical need

**IN-HOME Study Patient quotes:**

"It records the time, date...then it's the in-app photograph, put the number in, and send it and away you go."

"I found it easy...It takes end to end 15 minutes at the most, it's not a great deal out of your day."

# Patient Voice in early clinical trials



Modern day research is being changed by the advent of new technologies and we want to make sure that patients and clinical teams are driving that change. Our aim is to fundamentally change the dynamics of early clinical trials. Putting patients at the centre of early clinical trials transforms their role from that of a passive subject to an active participant and potential co-researcher with us. We are empowering patients in early clinical trials and providing a way for them to directly contribute to drug development on their own terms.

Patient-centric drug development means that researchers and sponsors need to listen to the experience of patients on clinical trials.

Dependent on the research question, we have a variety of methods we can employ to gather, iterate and incorporate this valuable input. We may host focus groups, hold 1:1 interviews with those attending their hospital appointments or send an online survey via our colleagues in The Christie Marketing and Engagement Team. The method of engagement chosen depends upon the research questions being asked, the method of development, and the type of information required.

## Putting patients at the centre of early clinical trials

One of our first Technology Clinical Trials was ongoing throughout 2019: a methodological study of how the PROACT (Patient Reported Opinions About Clinical Tolerability) system can be deployed at site to enhance trial participants' voices in their clinical studies. Developed with patients and carers, PROACT allows direct, secure communication between clinical trial patients and their medical team. Using a mobile phone app or website, patients can record personal video, audio, or text messages to say how they are feeling and functioning while taking part in a clinical trial, including 'real-life' insights about how adverse events affect them.

Additionally, in collaboration with the AstraZeneca Respiratory team, the digital ECMT also deployed PROACT to be used as part of an AstraZeneca exploratory clinical study called "TWINKLE". Digital ECMT are currently evaluating whether advanced video analytic techniques can be used to detect and quantify emotions in clinical trial participants based on video messages submitted through the PROACT platform. We will then evaluate whether there is any correlation between participants' emotions and validated clinical outcomes. The first preliminary results from the study are expected in mid-2020.

> "Changing Care Pathways will only work if we engineer them around the patient. We need to enable giving the patients a voice in all stages of this - from defining what is at issue with the current care pathway, developing and prioritising digital healthcare solutions, and then testing their utility within a Technology Clinical Trial"
>
> **Dr Jenny Royle**
> *PI of the PROACT technology clinical trial*

# UpSMART Accelerator Award

In 2019 the digital Experimental Cancer Medicine Team within the CRUK Manchester Institute Cancer Biomarker Centre, along with our EU colleagues, including those from Fondazione IRCCS Istituto Nazionale dei Tumori Milano and Instituto de investigación Oncologica de Vall d'Hebron, Barcelona were awarded a CRUK Accelerator Award to enable SMART Experimental Cancer Medicine Trials.

The ambition of this new programme, entitled "UpSMART", is to 'digitalise up' experimental cancer medicine centres across the UK, Italy and Spain, providing clinical teams with digital tools for real-time access to a wealth of patient data allowing faster decision making.

The Accelerator Award funding means that the Experimental Cancer Medicine Centres/Early Drug Development Units in the UK, Italy and Spain can use digital healthcare products to enable data acquisition and data interpretation and create digitally enabled Phase 1 centres able to conduct technology clinical trials.

The key areas of the programme will cover:

- training centres on conduct of technology clinical trials
- development of digital tools for clinical trial data capture
- integration of phase I trial data points for decision making
- creation of a digital network coordinating hub

The UpSMART Accelerator programme will test existing digital tools within 23 Phase 1 Units that have joined this aspiring, timely programme. UpSMART will be developing and providing all clinical sites with access to new digital healthcare technology approaches and improvements in trials that enable patients access to tomorrow's medicines today. Our goal is for these and other digital healthcare products to be shared and implemented more widely together with training in digital healthcare product approaches.

CANCER RESEARCH UK | AIRC | FUNDACIÓN aecc INVESTIGACIÓN CONTRA EL CÁNCER | UPSMART ACCELERATOR



As part of the collaboration the digital ECMT will provide expertise and innovation for new digital technologies, developing prototype digital technologies from the centres and enhance existing ones to make them available across the participating centres.

More companies are turning to clinical testing of digital healthcare products and the appraisal of technology under clinical trial conditions. Phase 1 technology clinical trials are different to drug trials and the challenge can be determining the appropriate regulatory pathway and process. We have developed a regulatory framework to facilitate implementation of technology clinical trials and centres will need support and training on how to conduct clinical trials of new digital technologies.

Developments in mobile technologies, home test-kits and sensors mean that data acquisition can be extended outside the hospital to a patient's home allowing more data to be collected and the potential to develop risk-based monitoring approaches.

Being able to visualise and interpret the vast amounts of data generated in an early phase clinical trial in near real-time is key to accelerating drug and technology developments for the benefit of patients. The digital ECMT has developed a research platform- "REACT" to enable the visualisation and interpretation of data.

UpSMART digital clinical trials

> "I am delighted that CRUK have funded this new European network to disseminate digital tools that support early clinical trials, the dawn of a new era – and we aim to be at the vanguard"
>
> **Professor Caroline Dive**
> *Professor of Cancer Pharmacology at the University of Manchester, Deputy Director of the Cancer Research UK Manchester Institute, Director of Cancer Biomarker Centre and PI on the UpSMART Accelerator Award*

# Decision science

## Supporting the way we interpret clinical trials and make decisions

Modern early experimental clinical trials, such as platform studies, produce vast amounts of clinical, investigational, laboratory and scientific data. Approximately 10,000 data-points are gathered at present from each patient enrolled into an experimental cancer clinical trial. Future clinical trials involving the patient will see an exponential increase in the number of individual patient data points collected during their participation on a study. The increase in patient and study data density will mean that clinicians and scientists will require decision support technology to help analyse and interpret these large and complex data sets to help them identify important safety and efficacy signals in near real-time and decide the best future treatment options for their patients. This is where the combination of statistical, Bayesian, AI and Machine Learning methods may be applied to great advantage.

A notable addition to the digital ECMT this year has been the further expansion of the Artificial Intelligence/Machine Learning (AI/ML) capability to help us achieve our decision science goal. Three new research associates were onboarded as a part of a formal collaboration between digital ECMT and the Department of Computer Science AI systems Group at the University of Manchester, led by Dr. Andre Freitas. The newly formed digital ECMT AI group have started work on existing clinical trial toxicity problems amenable to algorithmic and statistical methods, for instance, Hy's Law, QT prolongation and impaired cardiac output. The group is also developing new AI techniques to support the ongoing technology clinical trials – In-Home study (AKI algorithm), the "NOTION" study (immune toxicity including Cytokine Release Syndrome) and the Opthalmo-oncology study (identification of retinal toxicity). The reach of the AI group will extend beyond clinical trial patients to all cancer patients receiving cancer therapy as we embed these new AI methods as part of newly created patient care pathways. These pathways will see an increase in patient derived data where they will contribute their own data to the clinical trial through Point-of-Care device and smart technologies used by them in their own homes. AI methods will be important in enabling remote patient monitoring and alerting the clinical team to changing clinical parameters in near real-time in the future.

Enabling key information to be made available on an early cancer study allows adaptations made to the clinical trial design remit regarding dose and schedule, patient selection, drug combinations and the selection of potential predictive biomarkers.

These iterations make the trial developmentally challenging and drive the need for near real-time access to emerging trial data to enable decision-making for the benefit of patients. Examples of two systems, which have been developed at the digital ECMT, to support and drive this capability are eTARGET Patient Matching and REACT.

### eTARGET Patient Matching

eTARGET, our decision-support solution continues to be an integral part of the ECMT monthly cancer Molecular Tumour Board, which seeks to integrate the patient's genomic profile with their clinical characteristics. As part of the team's support for the TARGET trial (Tumour chARacterisation to Guide Experimental Targeted Therapy Trial) and precision medicine, the digital ECMT has developed a patient matching system to help clinicians identify the right clinical trials for TARGET patients. The system integrates data from eTARGET with clinicaltrials.gov and other online data sources and generates a bespoke report for each patient that lists potential matching trials based on the patient's cancer type and their tumour genotype. The system has been used to match patients to clinical trials and support decision making during the TARGET Molecular Tumour Board meetings since April 2019 to date. We continue to refine the system based on feedback from TARGET investigators.

> "eTARGET is a perfect example of why the work of the digital ECMT is so important and how they contribute to the holistic goals of the biomarker centre"
>
> **Professor Caroline Dive**
> *Professor of Cancer Pharmacology at the University of Manchester, Deputy Director of the Cancer Research UK Manchester Institute, Director of Cancer Biomarker Centre and PI on the UpSMART Accelerator Award*

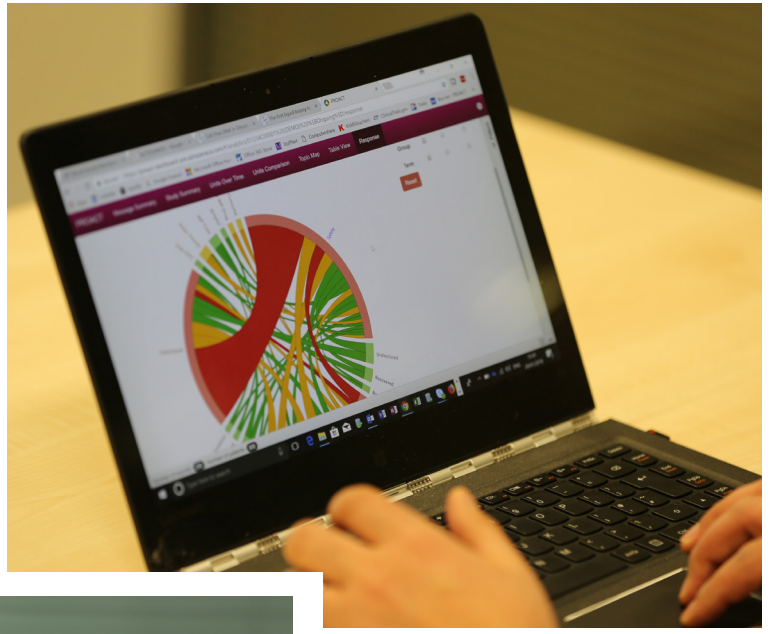
> "eTARGET has transformed the way we undertake our Molecular Tumour Board (MTB) for data visualisation and interpretation. It is a fantastic solution to the challenge of integrating genomic and clinical data"
>
> **Dr Matthew Krebs**
> *Clinical Senior Lecturer in Experimental Cancer Medicine and Honorary Consultant in Medical Oncology*

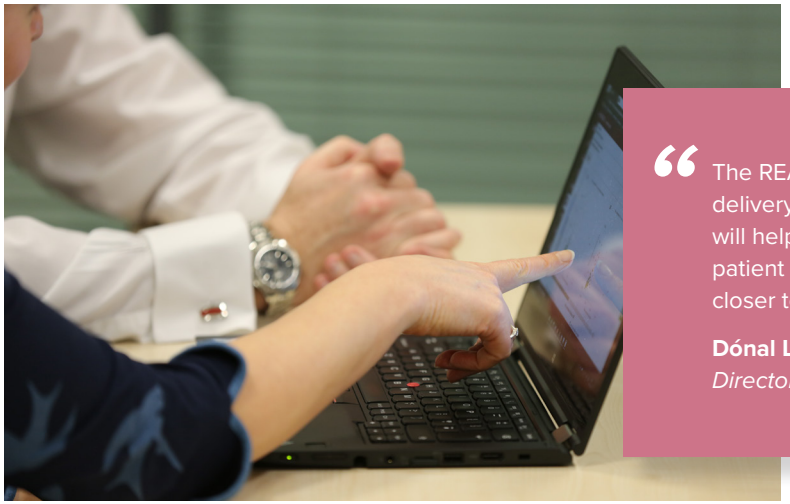
## REACT

Innovation in early clinical trials is key as cancer is not one disease, and we need to understand not just the type of cancer, such as breast or lung, but also the molecular profile of an individual's type of cancer. REACT, a system designed by clinicians and scientists to support clinical trials in early oncology with its primary purpose to keep patients safe, enables:

- earlier science-led decisions and data-driven interpretation
- earlier team-based data evaluation and insight to improve speed and quality of clinical development
- earlier and comprehensive understanding of the patient benefit-risk

REACT has now been successfully deployed and is in use by several organisations who are closely collaborating on improvements and the development of new functionality. Current visualisations include safety, Pharmacokinetics (PK), efficacy, labs, investigations and genomic data. REACT, now under University of Manchester ownership following agreement with AstraZeneca, will be developed as an open source system for use by the clinical and scientific community. Future versions will see additional AI integration into the main platform to help identify and predict important changes in the patient's clinical/genomic profile.





## Research platform to enable adaptive decision-making

> "The REACT research platfom will enable the delivery of our technology clinical trial, which will help us to fundamentally improve our patient care pathway and bring the clinical trial closer to the patient"
>
> **Dónal Landers**
> *Director, digital ECMT*

# Collaborations



## We work together in partnership to transform decision-making and the patient's role

**Lets work together!**
Contact us at info@digitalECMT.org

Achieving patient engagement and digital innovation in early clinical trials requires partnership and expertise. We forge collaborations to bring patients, clinicians, data analytics and innovative digital healthcare products together to change the conduct and interpretation of early clinical trials.

- The digital ECMT delivers the **"iDECIDE"** research programme, a leading 5-year (£11.5M) collaboration between four strategic partners in cancer research; the CRUK MI Centre for Cancer Biomarker Sciences, The University of Manchester, The Christie and AstraZeneca.
- AstraZeneca is also one of nine business partners in the **"iMATCH"** research programme. Set up in March 2018, iMATCH (innovate Manchester Advanced Therapies Centre Hub) is a consortium to coordinate a strategy to scale-up advanced therapies for a range of debilitating conditions. The digital ECMT provides digital science expertise to iMATCH to develop rapid monitoring capabilities and integration into digital algorithms to establish early-warning systems.
- The Digital ECMT also partners with different teams at **The Christie** to deliver Technology Clinical Trials - for example the PROACT Trial has been run with the Experimental Cancer Medicine Team and the In-Home trial is running in collaboration with the Head and Neck team.
- During 2019 the digital ECMT also partnered with different organisations to enable them to use our digital science platform to support visualisation of data from their early phase trials in exchange for feedback and suggested improvements to the system. These partners include: **CRUK Centre for Drug Development** to support CRUK sponsored Phase 1 clinical trials and smaller Biotech companies including **Athenex** and **Carrick Therapeutics.**
- Finally, digital ECMT collaborates with several groups at **The University of Manchester** to enhance our research capability, including the Research IT group and Computer Science group.

Being at the heart of world leading clinical, scientific and academic research excellence means that we can bring together the right experts needed for each individual initiative and project.

# The team

Established in 2016, we are working to change the conduct of clinical trials and the exploration and interpretation of clinical trial data. We are a multidisciplinary digital clinical research group with expertise in patient engagement, data insights, analytics, digital technology, clinical trials and behavioural science.

During 2019, the digital Experimental Cancer Medicine Team extended its core capability in cancer clinical studies by building expertise in the areas of advanced computer science and software engineering. A partnership was built with a team of advanced computer scientists led by Andre Freitas at The University of Manchester. This partnership enables modern Artificial Intelligence (AI) approaches to be applied to cancer challenges. Where these solutions require digital healthcare products to be developed, digital ECMT works with the Research IT team led by Rob Haines. Research IT have expertise in modern software engineering and cloud solution development and have worked with digital ECMT for over three years, extending this partnership during 2019.

The team also expanded to include a Research Practitioner, based within the Experimental Cancer Medicine Team (ECMT) at The Christie, who is dedicated to the delivery of digital ECMT projects on site at The Christie, working closely with the clinical staff and having regular patient engagement.

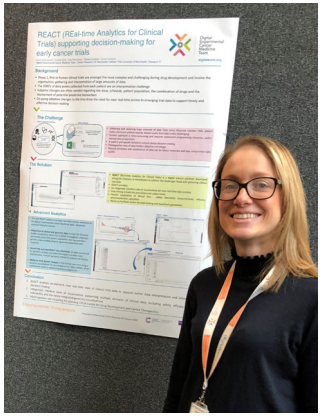
On 2nd Feb 2019, digital ECMT was represented by team members at The Christie 'Making Clinical Research Accessible' Clinical Research Facility open day.

The International Clinical Trials Day at The Christie in May 2019 was another opportunity for digital ECMT team members to promote awareness of our research with both patients and staff.

At the Phase 1 – where science becomes medicine, conference, which took place in Manchester in July 2019, Digital ECMT members Julie Stevenson and Paul O'Regan were awarded poster prizes for their posters detailing their respective work linked to eTARGET and the TARGET (Tumour chARacterisation to Guide Experimental Targeted therapy) trial.

An Overview of Advanced Therapies: The UK Landscape event at The Christie on 22nd October gave the digital ECMT another opportunity to present our research.

Digital ECMT member Laura Stephenson presented at the poster session after the ECMC (Experimental Cancer Medicine Centres) Open Day event in Manchester.







digitalECMT – 2019 report – The team

# 2019 news and research activities



## Conferences/workshops/publications

| Title/Event | Type | Location | Date |
|---|---|---|---|
| **BioData World Congress, Basel, Switzerland**<br>Precision Medicine and Clinical Trials | Invited presentation | Basel, Switzerland | December |
| **PCT Europe 2019**<br>Partnerships in Clinical Trials Europe Conference<br>Technology trials: weaving new technology into care pathways in early clinical trials | Invited presentation | Barcelona, Spain | November |
| **MAP (Molecular Analysis for Personalised Therapy)**<br>Application of variant interpretation software to decipher pathogenicity of mutations for a Molecular Tumour Board (MTB) | Abstract/ poster presentation | London | November |
| **Digital Strategy Oncology Workshop**<br>Internal AstraZeneca event | Invited presentation | London | November |
| **GM conference, Manchester**<br>Implementation of five set research themes as part of the expansion of the Experimental Cancer Medicine Team at The Christie NHS Foundation Trust | Poster presentation | Manchester | November |
| **Kidney Week, ASN (American Society of Nephrology)**<br>5-10 November, Washington, US | Abstract/ poster presentation | Washington, USA | November |
| **NCRI, 4-5 November, Glasgow, UK**<br>• REACT (REal-time Analytics for Clinical Trials): supporting decision-making for early cancer trials<br>• Automated extraction and visualisation of data from the TARGET (Tumour chARacterisation to Guide Experimental Targeted therapy) trial to support interim analysis | Abstracts/ posters | Glasgow | November |
| **Transforming clinical trial experience with patients**<br>AstraZeneca Patient Centricity meeting, Gothenburg | Invited presentation | Gothenburg | October |
| **Patient Summit Europe, London, UK**<br>Roundtable facilitation | Conference Roundtable | London | October |
| **ASCO Breakthrough**<br>11-13 October, Bangkok, Thailand<br>eSOURCE abstract accepted<br>• A multidisciplinary-guided digital solution to data capture in early phase clinical trials | Abstract/ Poster/oral | | October |
| **BioData World West**<br>San Diego, USA | Invited presentation | San Diego, USA | October |
| **Mini-symposium – Clinical trials in the future**<br>Centre for Cancer Biomarkers (CCBBO), University of Bergen | Invited presentation | Bergen | October |
| **ECMC North**<br>Device Trials Interest Group | Presentation & workshop | Manchester | October |
| **CRUK MI Colloquium, Lancaster**<br>Digital tools to support the TARGET (Tumour chARacterisation to Guide Experimental Targeted therapy) trial | Presentation | Lancaster | September |
| **Phase 1 – where science becomes medicine, Manchester, UK** | Session Chair Presentation | Manchester | July |
| **Phase 1 – where science becomes medicine, Manchester, UK**<br>• Clinical trials going digital – technology, research and patient engagement<br>• REACT (Real-time Analytics for Clinical Trials): supporting decision-making for early cancer trials<br>• eTARGET: a digital solution to integrate clinical and genomic data for the Manchester Molecular Tumour Board (MTB)<br>• Automated extraction and visualisation of data from the TARGET (Tumour chARacterisation to Guide Experimental Targeted therapy) trial to support interim analysis<br>• Clinical Trials in the Home: Renal monitoring for Cancer Patients - a decentralised, patient-focused approach | Abstracts/ Poster presentation | Manchester | July |

# 2019 news and research activities

| Title/Event | Type | Location | Date |
|---|---|---|---|
| **UK CRF network conference**<br>Nottingham, UK. Theme: curing the incurable. Interdisciplinary approaches to research | Abstract submitted | Nottingham, UK | June |
| **ASCO, Chicago, USA**<br>Abstract submitted: eSource | Abstract submitted | Chicago, USA | June |
| **ECMC Network, London**<br>Title: Changing the conduct and interpretation of clinical trials | Presentation | London | May |
| **Alahmadi, A et al. Evaluating the Impact of Pseudo-Colour and Coordinate System on the Detection of Medication-induced ECG Changes**<br>Computing Systems, CHI'19 Proceedings of the 2019 CHI Conference on Human Factors in Computing Systems Paper No. 123 | Conference paper | | May |
| **ECMC North, MCRC, Manchester**<br>• Presentation – digital ECMT achievements and plans<br>• Workshop - Digital Health Technologies in Phase I cancer studies | Presentation and Workshop | Manchester | April |
| **ECMT, The Christie, Manchester**<br>• ECMT workshop – Technology Clinical Trials | Workshop | Manchester | April |
| **CRUK MI –**CBC Quinquennial Review presentation | Presentation and poster | Manchester | April |
| **Rothwell et al. Utility of ctDNA to support patient selection for early phase clinical trials: The TARGET Study Nature Medicine 25,738-743 (2019)** | Publication | | April |
| **Education meeting for Manchester ECMT staff** | Presentation | Manchester | February |
| **CPSA (Clinical & Pharmaceutical Solutions through Analysis), 5-8 Feb, London (Cambridge)**<br>Innovative "real-time" decisions – bench at the bedside | Invited presentation | Cambridge | February |

| Title/Event | Type | Location | Date |
|---|---|---|---|
| **ECMC Manchester Showcase**<br>Oglesby Building, MCRC, Manchester | Poster presentation | Manchester | January |
| **The Life Sciences Innovation Report –**<br>a data-driven view of emerging R&D trends | Report reviewer | | January |
| **Focus Groups** | | | |
| **Patient Focus Group at The Christie**<br>Wearables and continuous monitoring – assessment of devices | Focus group | Manchester | November |
| **Patient Focus Group at The Christie**<br>Home sampling, assessment of devices for home blood sampling | Focus group | Manchester | October |
| **Patient Focus Group at The Christie**<br>Review of Patient Information Sheet relating to Immunotherapy trial | Focus group | Manchester | September |
| **Patient Focus Group at The Christie**<br>Immune response monitoring at home – assessment of new approach and clinical trial | Focus group | Manchester | August |
| **Patient Focus Group at Manchester Royal Infirmary**<br>Monitoring in the home – assessment of devices | Renal Patient Focus group | Manchester | June |
| **Patient Interviews at The Christie**<br>Monitoring in the home – device evaluation and assessment | Patient Interviews | Manchester | June |
| **Patient focus groups at The Christie**<br>Monitoring in the home - assessment of devices<br>Patient and clinic two-way agreement | Focus group | Manchester | May |



digitalECMT – 2019 report – 2019 news and research activities

# 2019 news and research activities

| Title/Event | Type | Location | Date |
|---|---|---|---|
| **Education/awareness** | | | |
| **ECMT new starter induction**<br>Digital ECMT new starter slideset now included | Training | | June |
| **International Clinical Trials Day, The Christie, Manchester Research, technology and you** | Event - display | Manchester | May |
| **Using modern IT in clinical trials – MRes The Christie**<br>How can the smartphone make patients players rather than spectators in their clinical trials | Education lecture | Manchester | March |
| **Using modern IT in clinical trials-** MRes The Christie | Education lecture | Manchester | March |
| **Making Clinical Research Accessible –** Behind the scenes at the Clinical Research Facility at The Christie | Event – display | Manchester | February |

**To get in touch**
please contact us at
info@digitalECMT.org

# Looking to the future

2020 will be a year of change. Our 5 year programme grant "iDECIDE" with AstraZeneca which commenced in 2016 will draw to a close; whilst our 5 year programme grant "UpSMART Accelerator" will commence. The former has provided a portfolio of digital healthcare products, which the latter can disseminate across the participating early phase cancer centres in Europe.

Together, these awards very much realise *"Our mission to innovate and apply digital science to transform decision-making in early clinical trials and the patient's role in these trials"*.

2020 also represents a year when we seek to further broaden our academic independence through grant applications that strengthen our core research into digitally enabled decision science.

## Changing the conduct of clinical trials

Further building our clinical operation capability as we work closely with the ECMT and research teams at the Christie on our "In-Home" study and open the "NOTION" study (see pages 10-11 of this report for details of both studies).

## Changing the interpretation of clinical trials

Advanced precision analytics system to support Technology Clinical Trials - through the open source release of REACT

## Collaboration

Extend our future collaborations and partnerships at a local, national and international level to forge new care pathways and a network of participating UpSMART Accelerator centres

## Technology

Extend our research areas to investigate technologies, patient micro sampling, wireless and patient devices

## Decision Science

Application of predictive science and developing algorithms, machine learning and artificial intelligence (AI) capability with an initial focus upon toxicity alerting and matching patients to appropriate clinical trials based on their molecular profile

# Notes

Digital
Experimental
Cancer
Medicine
Team

MANCHESTER
1824
The University of Manchester

CANCER
RESEARCH
UK

MANCHESTER
INSTITUTE

NHS
The Christie
NHS Foundation Trust