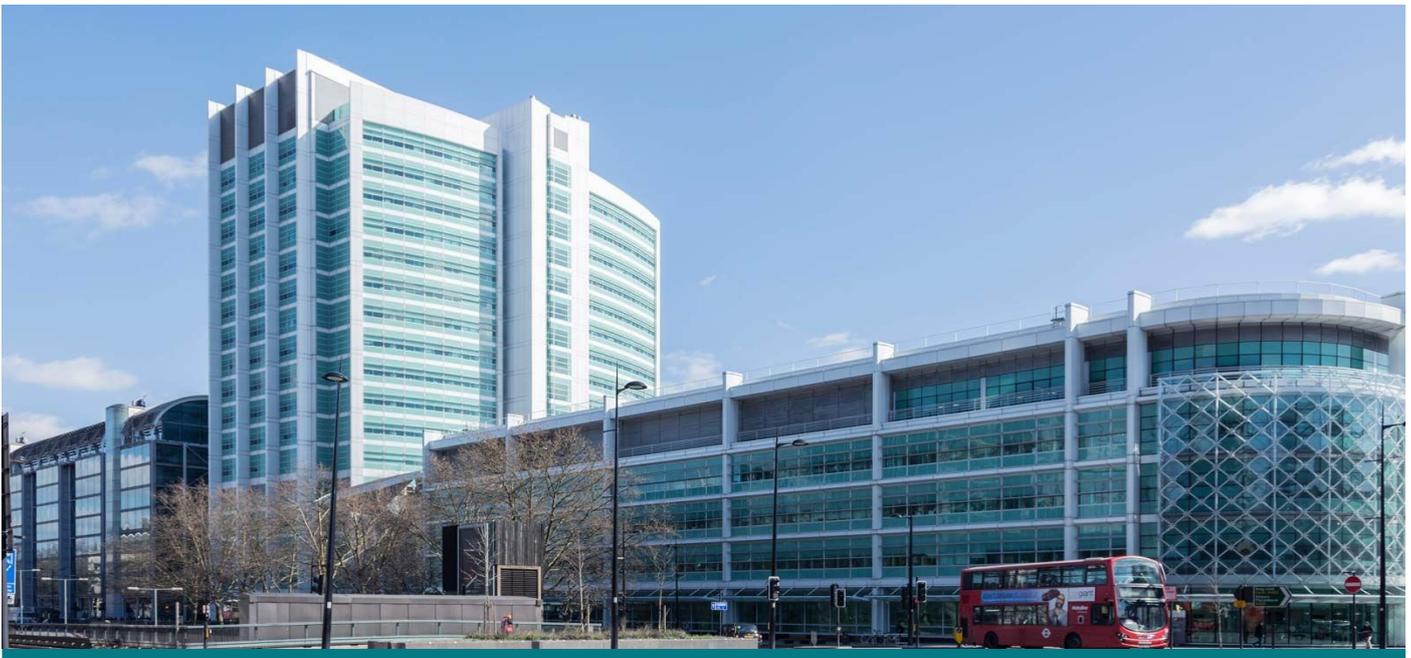


Summer 2022 Edition

UCLH

EARLY PHASE CANCER TRIALS NEWSLETTER



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Latest News & Publications

Welcome to the Summer 2022 Edition

Welcome to the Summer 2022 edition of our new newsletter showcasing early phase cancer trials at the NIHR University College London Hospitals Clinical Research Facility (UCLH CRF).

We are excited to share information and provide updates on early phase cancer trials, share outcomes on these trials, updates from our Principal Investigators, alongside metrics and the latest news and key publications.

THE IMPORTANCE OF EARLY PHASE CLINICAL TRIALS IN CANCER AT UCLH – A PERSPECTIVE

By Dr Kirit Ardeshta

Divisional Clinical Director – Cancer

UCLH has a national and international reputation as a leader in Cancer. Core to this is our strength in clinical trial research which in turn is integral to the way we improve outcomes for our cancer patients. The Cancer Division has a large number of clinicians who are research active ranging from those who undertake laboratory-based research to those undertaking more translational research.



The Cancer Division is currently particularly well set-up to recruit patients into a wide range of clinical trials. We make use of the excellent NIHR UCLH Clinical Research Facility (CRF) run by the Research & Development department on 170 Tottenham Court Road to recruit patients into most of our Cancer Early Phase studies whilst later phase studies tend to be run within the Cancer Division facilities itself in conjunction with our large Cancer Clinical Trials Team (CCTU) (160 staff).

Our ability to run Early Phase Studies is one of our USP's and in line with this the Cancer Division made the decision to significantly expand the number of clinicians with CRF sessions in their working week. We now have fourteen oncologists covering Lung, Breast, Gynae-Oncology, Uro-Oncology, Gastro-Intestinal Oncology & Skin Cancers and three Haemato-Oncologists covering Myeloma, Lymphoma & Leukaemia/MDS working in the CRF.

On March 2nd 2022 Prince Charles opened our new facility, The Grafton Way Building (GWB). The floors below ground are home to a proton beam therapy centre, one of only two such NHS centres in the UK giving us a great opportunity for academic proton related research.

Above ground is one of the largest centres for the treatment of blood disorders in Europe this has allowed expansion of our adult cancer inpatient beds to 142 in number. GWB also houses a ten bedded Intensive Therapy Unit (ITU) largely for the use of cancer patients.

UCLH is a recognised world leader in Cancer Immunotherapy. We have invested heavily in our Immunotherapy program and in January we opened the Sir Naim Dangoor Centre for Cellular Immunotherapy which houses an 8 bedded inpatient unit, Europe's first dedicated Cellular Immunotherapy research and treatment centre.

UCLH, together with its academic partner UCL, have a shared vision to be a global leader in cancer research. Over the past 10 years we have made great strides to achieve this, and our joint future holds great promise.

We have plans to open four further inpatient beds solely for research patients as we recognise early phase studies are increasingly requiring inpatient stays for patients often repeatedly and for several days at a time, such that the best way to accommodate this is to have dedicated research beds.

I am excited by the prospect of Mount Vernon Cancer Centre becoming part of UCLH. NHS England have been leading a transition support team consisting of clinicians and managers from both sites to create a future for a new Mount Vernon Cancer Centre located on an acute hospital site.

This union would vastly increase the cancer patient population which UCLH serves and the opportunities for research at both sites are immense.

EXPERIENCE, TRAINING AND ROLE OF A SENIOR CANCER RESEARCH NURSE IN EARLY PHASE CANCER TRIALS – A PERSPECTIVE

By Jingle Sanchez

Senior Cancer Research Nurse – UCLH Clinical Research Facility

I started my oncology nursing career in 2002 having completed my nursing degree in the Philippines in 1996. Prior to becoming a Cancer Research Nurse, I worked as a staff nurse for 13 years in an oncology ward and gained experience in chemotherapy administration and palliative care.



My first experience in cancer research nursing followed my ward experience, but a career progression led me to leaving research to become a Prostate Cancer Clinical Nurse Specialist for 4 years.

The uniqueness of cancer nursing has kept me in the same specialism for the last 20 years. In particular, the constant day-to-day challenge in cancer control, the intimate and longstanding professional relationship I have developed with patients and their families, and the personal maturity and self-awareness that I have acquired along the way are only some of the many reasons why I find cancer nursing unique.

Having recently joined the UCLH Clinical Research Facility (CRF) as a Senior Cancer Research Nurse, I am working on developing a more robust implementation of the Holistic Needs Assessment for all the cancer patients in the unit.

I am ensuring all the nurses are trained on how to effectively conduct the holistic needs assessment in a structured way.

Cancer trial patients have an array of information to digest after their initial consultation and during the consent process. My goal is to guide patients to flag the specific areas where they would need additional help and support, with the hope of alleviating some concerns that they may have before the start of their intensive treatment days ahead.

There is evidence to suggest patient's symptoms that are addressed more effectively may allow them to remain and potentially benefit on the clinical trial for longer.

With the emergence of novel cancer clinical trial treatments such as bi-specific antibodies and checkpoint inhibitors, increasing cancer workloads including inpatient requirements for an increasing numbers of clinical trials requiring in-patient hospital admission, cancer research nurses must also navigate the immensely pressured in-patient hospital bed capacity.

It is imperative for cancer research nurses to stay up-to-date with the current trends and research. Alongside self-directed learning opportunities, both formal and informal, it is also paramount to keep up with additional role expectations such as a more autonomous role in patient care and health promotion and to develop a harmonious good working relationship with the hospital and its various departments.

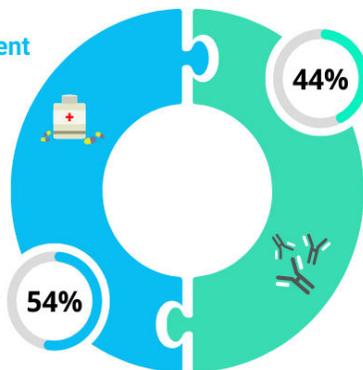
A STORY OF EARLY PHASE CANCER CLINICAL TRIALS IN NUMBERS

Immunotherapy Treatments

Over the past 6 months our portfolio has diversified to ensure we can provide the latest treatment options to patients. Immunotherapy is a type of cancer treatment that helps your immune system fight cancer. Within that T-Cell Engager treatments have acquired much attention as the next generation of antibody-target cancer immunotherapy.

Immunotherapy Treatment

59% (25 Trials) of the cancer portfolio is made up of Immunotherapy Trials



T-Cell Engager Treatment

Within our Immunotherapy trials portfolio, 44% of the trials (11 Trials) utilise T-Cell Engager treatment.



We have recruited 14 participants in the last 6 months to trials using T-Cell Engager treatments. 13 in Haematology trials and 1 in Oncology trials.

OUR CURRENT TRIALS PORTFOLIO

Our growing portfolio of cancer clinical trials ensures access to novel treatments for patients



Over the past 6 months we have opened **12** cancer clinical trials.

Number of Trials currently open to recruitment

35

Number of Trials currently in set-up

33

A STORY OF EARLY PHASE CANCER CLINICAL TRIALS IN NUMBERS

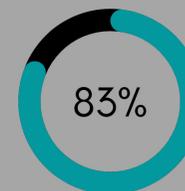
Our Current Cancer Trials Portfolio

ACADEMIC TRIALS



Trials which were developed through academic partnerships

NIHR-ADOPTED COMMERCIAL TRIALS



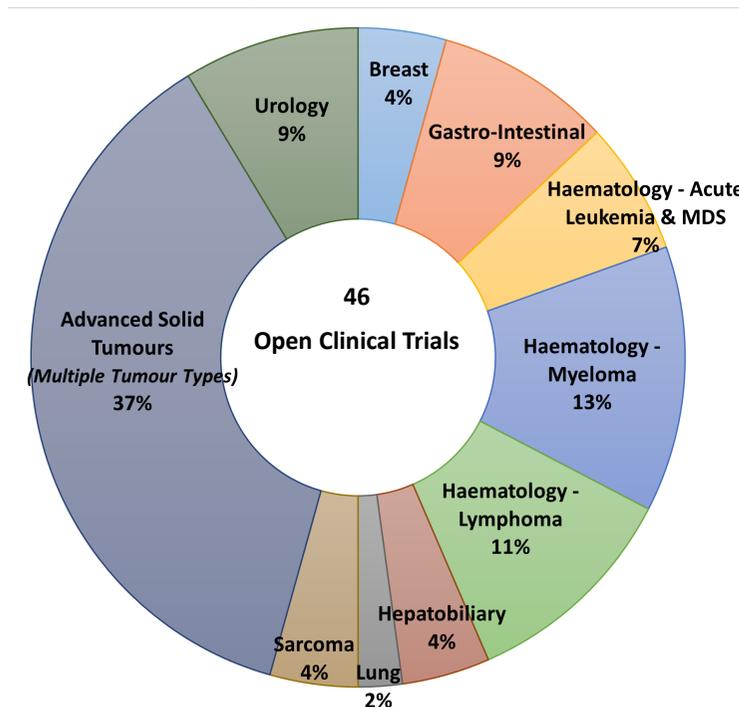
Commercially sponsored trials with NIHR Clinical Research Network (CRN) Support

We are keen to increase the number of academic trials run at UCLH and support Investigators to do so



of our clinical trials in the past 6 months have UCLH as the lead site

Since the start of the year our Cancer clinical trials portfolio per tumour group looked like this:



NEW CANCER PRINCIPAL INVESTIGATORS APPOINTED AT THE UCLH CLINICAL RESEARCH FACILITY

We are excited to announce the appointment of four Principal Investigators in Thoracic Oncology, Gastro-Intestinal Oncology, Uro-Oncology and Gynae-Oncology.



Dr Sarah Benafif

*Consultant Medical Oncologist
Thoracic Oncology and Early
Phase Trials*

Dr Benafif completed her medical training at Imperial College London, and subsequent Medical Oncology training in the London Deanery.

In 2020, she gained her PhD in Cancer Genetics from the Institute of Cancer Research, London. As part of her research project, she set up the first trial (BARCODE-1 trial) in the UK to investigate prospective genetic profiling to guide prostate cancer screening.

Having previously worked as a Senior Clinical Research Fellow within the CRF, she has recently been appointed to a consultant position in Medical Lung Oncology and early phase trials in January 2022.



Dr Anuradha Jayaram

*Consultant Medical Oncologist
Uro-Oncology*

Dr Jayaram is a Consultant Medical Oncologist in Uro-Oncology. After completing her medical oncology training in Ireland, she was awarded a Health Research Board grant to pursue a clinical fellowship in Prostate cancer at the Institute of Cancer Research and Royal Marsden NHS Trust where she was awarded a Medical Research Council UK PhD fellowship.

Her research focus is primarily on liquid biopsies, mainly circulating plasma DNA to define the evolutionary complexities that underlie drug resistance and molecularly characterize Prostate cancer. She is co-author of the PARADIGM study: a clinical trial using plasma DNA.

She is interested in running translational based trials that will help predict treatment responses in Prostate cancer patients. Recently appointed as Principal Investigator in Uro-Oncology.



Dr Michael Flynn

*Consultant Medical Oncologist
Gynae-Oncology Cancers*

Dr Flynn is Medical Oncology Consultant at UCLH specialising in Gynae-Oncology and early phase trials.

He completed his PhD in antibody-drug conjugate translational development at University College London and his specialist training at the Royal Marsden Hospital.

Previously, Dr Flynn worked as a Phase I Clinical Research Fellow within our Clinical Research Facility for several years, during which time he was a sub-investigator on a number of first-in-man and later Phase development clinical trials.

He is a now Principal Investigator on Gynae-specific and sub-investigator on tumour-agnostic targeted therapy, immunotherapy and combination trials whilst continuing to expand his trial portfolio.



Dr Khurum Khan

*Honorary Associate Professor &
Consultant Medical Oncologist
Hepato-Pancreato-Biliary and
Gastro-Intestinal Oncology*

Dr Khan is a research-active consultant who trained in medical oncology at the Northern Ireland Cancer Centre and Royal Marsden NHS Trust London. Dr Khan took a substantive consultant position in Gastro-Intestinal Oncology at UCLH in conjunction, after leading Oncology research at North Middlesex University Hospital, he joined Whittington in January 2022.

He is actively involved in translational research and has presented and lectured in international conferences and public forums respectively. He is now a UK Chief Investigator on a phase III study at UCLH, and Principal Investigator on multiple phase II studies.

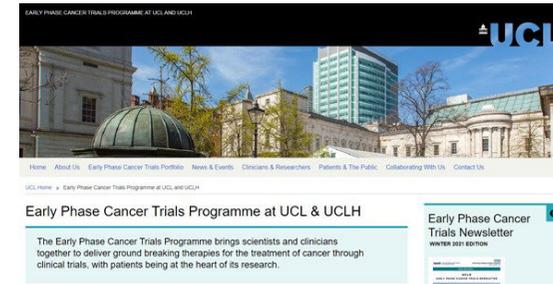
He is currently setting up a number of new early phase clinical trials at the UCLH Clinical Research Facility.

EARLY PHASE CANCER TRIALS PROGRAMME WEBSITE LAUNCH

We are excited to announce the launch of the UCL/UCLH Early Phase Cancer Trials Programme website.

The Early Phase Cancer Trials Programme brings scientists and clinicians together to deliver ground-breaking therapies for the treatment of cancer through clinical trials, with patients being at the heart of its research. The new website will act as the central hub of information for clinicians, researchers, collaborators, patients, and the public.

The website will provide information on our aims, how we operate, our structure, our funders and supporters and will highlight our expertise, and include the latest news and events.



Our goal is to highlight our comprehensive list of early phase cancer trials open to recruitment and provide essential information on these clinical trial, such as;

Trial Name, Full Trial Title, the Principal Investigator leading the study, the name of the Drug(s)/Treatment(s) being investigated and the Patient Population being recruited to the trial.

A Local Project Reference (LPR) is included linking to the website to the [UCLH 'Find a Study' database](#) which provides additional details on the trial including the eligibility criteria and contact details for the study.

The 'Clinicians & Researchers' page hosts key outputs from the programme such as publication and abstract releases, alongside information on funding calls and link to our portfolio newsletters. Importantly, referral information is included for clinicians to refer patients to our open to recruitment cancer trials.

We include a team profile of all our Principal Investigators who run early phase cancer trials, including information about the various teams, departments and networks that ensure smooth running of these early phase cancer trials.

Patients & The Public

The Early Phase Cancer Trials Programme brings scientists and clinicians together to deliver ground breaking therapies for the treatment of cancer through clinical trials, with patients always at the heart of its research.

Clinical Trials - Source of Information and Support

There is support available who can help talk you through your treatment and being a part of a clinical trial, who are not directly involved as part of the clinical trial team.

Alongside this, the website will contain content for patients and the public, to provide an understanding of how early phase clinical trials are run, information on the latest research, and helpful content.

You can visit the website at <https://www.ucl.ac.uk/early-phase-cancer-trials/>

UCLH CRF CONTRIBUTES TO NOVEL IMAGING STUDY IN LYMPHOMA IMMUNOTHERAPY TRIAL

By Dr William Townsend

Consultant Haematologist

We are proud to have been one of only 2 UK sites selected to treat patients on the NP39488 nuclear medicine sub-study.



Dr. William Townsend is the Principal Investigator on the NP39488 clinical trial ([NCT03533283](https://clinicaltrials.gov/ct2/show/study/NCT03533283)). The trial is an open-label Phase Ib/II of the CD3-CD20 bispecific antibody Glofitamab in combination with Atezolizumab in patients with Relapsed or Refractory B-Cell Non-Hodgkin Lymphoma (B-NHL).

The treatment is a novel immunotherapy approach to treatment of relapsed B-NHL.

The trial incorporates an extremely innovative nuclear medicine sub-study in which a radio-labelled CD8 antibody (89ZR-DF-IAB22M2C) is given and additional scans are performed to evaluate the feasibility of this approach to image the infiltration of CD8+ T-Cells in malignant B-cell lesions before and after treatment with Glofitamab.

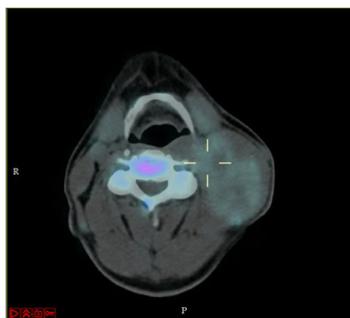
The hypothesis is that these scans may be able to track the movement of CD8+ T-Cells in response to the T-Cell engaging therapy. If successful, this approach may allow prediction of who is most likely to benefit from T-Cell engaging therapy in the future.

We treated our first patient on this protocol at UCLH and it was a huge team effort with a large number of departments involved in making this happen.

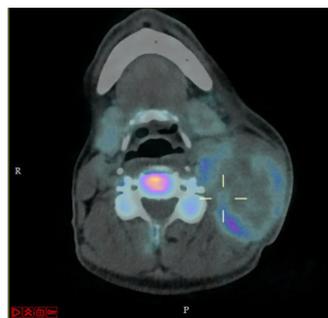
The scans performed before and after the first dose of Glofitamab show increase in signal after treatment indicating infiltration of the periphery of the patient's nodal mass with T-Cells after treatment.

It is too early to know how much this patient will benefit but this trial demonstrates that ability of our unit to work with multiple other departments in the hospital as well as the sponsor to deliver novel and innovative trials of immunotherapy in our patients.

The study is currently open to recruitment at the UCLH Clinical Research Facility.



Pre-treatment scan showing low level uptake in the large nodal cervical mass



Post-treatment scan showing increased uptake in the peripheral of the large nodal mass indicating increased CD8+ T cell infiltration of the tumour

LATEST NEWS & PUBLICATIONS

Phase 1/2 trial for Relapsed or Refractory Multiple Myeloma published in the New England Journal of Medicine

We are pleased to highlight a paper contribution by Dr. Rakesh Popat, Consultant Haematologist and Cancer Lead NIHR UCLH CRF.

'Teclistamab in Relapsed or Refractory Multiple Myeloma' was published on the New England Journal of Medicine on the 5th June, with data from the 64007957MMY1001 (MajesTEC-1) trial (A Phase 1/2, First-in-Human, Open-Label, Dose Escalation Study of Teclistamab, a Humanized BCMA x CD3 Bispecific Antibody, in Subjects With Relapsed or Refractory Multiple Myeloma).

The NHR UCLH CRF and CCTU team at UCLH worked together to make a significant contribution to this study which included in-patient admissions for adverse event management. The study showed Teclistamab resulted in a high rate of deep and durable response in patients with triple-class-exposed relapsed or refractory multiple myeloma. Cytopenias and infections were common as well as mostly grade 1 or 2 adverse events associated with T-cell redirection.

We would like to congratulate Dr. Popat and the trials teams at UCLH for this high impact research, which we hope will lead to wider patient benefit. The paper can be viewed at the NEMJ website ([DOI: 10.1056/NEJMoa2203478](https://doi.org/10.1056/NEJMoa2203478)).

Phase 1 CCR4420 (HyPeR) Trial Paper Accepted in the BMJ Journal for Immunotherapy of Cancer

We are pleased to highlight Dr. Dionysis Papadatos-Pastos, Consultant Medical Oncologist, leads as author on a paper accepted to the BMJ Journal for Immunotherapy of Cancer.

The paper, entitled 'A Phase 1, Dose Escalation Study of Guadecitabine (SGI-110) in Combination with Pembrolizumab in Patients with Solid Tumours', presents data from the CCR4420 (HyPeR) trial (Phase 1, Dose Escalation Study of Guadecitabine (SGI-110) a Second Generation Hypo-Methylating Agent in Combination with Pembrolizumab (MK3475) in Patients with Refractory Solid Tumours).

This academic study was sponsored by the Institute of Cancer Research & Royal Marsden NHS and run as a joint collaboration between the Institute of Cancer Research (Prof. Johann de Bono) and UCLH Clinical Research Facility (Dr. Papadatos-Pastos). The trial began in June 2019 and enrolled 15 patients from UCLH.

We would like to congratulate Dr. Papadatos-Pastos on the achievement and all the team at UCLH. The paper can be viewed on the BMJ website.

PlasmaMATCH Trial Presented at ASCO 2022

We are pleased to highlight an abstract presented at ASCO 2022 Annual Meeting featuring UCLH PI Dr. Rebecca Roylance, Consultant Medical Oncologist. The abstract presented results from Cohort E of the PlasmaMATCH trial - A phase II trial of olaparib and ceralasertib in patients with triple-negative advanced breast cancer.

Cohort E aims to explore the efficacy of the combination of olaparib with Olaparib (AZD6738) in patients with Triple Negative Breast Cancer. Dr. Roylance was Principal Investigator on this Cancer Research UK sponsored trial, making a significant contribution to this study and providing data for this abstract, with responses observed in patients without germline or somatic BRCA1/2 mutations.

We would like to congratulate Dr. Roylance on the achievement and all the team at UCLH. The abstract can be viewed at the [ASCO 2022 page](https://ascopubs.org/doi/10.1200/JCO.2022.40.15_suppl.100).

Analysis of 2 cohorts in the GARNET Trial Presented at ASCO 2022

We are pleased to highlight an abstract presented at ASCO 2022 Annual Meeting featuring UCLH PI Dr. Rowan Miller, Consultant Medical Oncologist. The abstract presented results from two cohorts (Cohort A1 and F) of the GARNET trial - Study of TSR-042 (Dostarlimab), an Anti-programmed Cell Death-1 Receptor (PD-1) Monoclonal Antibody, in Participants With Advanced Solid Tumours.

Cohort A1 enrolled pts with dMMR/MSI-H AR EC and cohort F enrolled pts with dMMR/MSI-H/POLe-mut non-EC solid tumours. Dr. Miller was Principal Investigator, recruiting 12 patients at UCLH. Dostarlimab demonstrated durable antitumor activity across 16 tumour types in patients with dMMR solid tumours.

We would like to congratulate Dr. Miller on the achievement and all the team at UCLH. Cohort F is open to recruitment at the CRF. The abstract can be viewed at the [ASCO 2022 page](https://ascopubs.org/doi/10.1200/JCO.2022.40.15_suppl.100).