PORTFOLIO NEWSLETTER

DECEMBER 2021

# NIHR University College London Hospital Clinical Research Facility Cancer Trials


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## COVID-19 and Early Phase Cancer Trials at UCLH

Whilst COVID-19 restrictions have eased across the country, we're very much aware that some cancer patients remain vulnerable to COVID-19 even if they have been vaccinated.

As a result we are continuing to take full precautions for the safety of our patients and staff. Our early phase clinical trials programme is fully open and we are happy to take referrals, please contact the PI for the study of interest to gauge timelines for enrolment. The pandemic has led to delays in a number of trials opening; however over the next few months we hope to open a significant number of new cancer trials.

Thank you for your patience and support in performing local blood/ COVID tests during this exceptional time. We're looking forward to getting back to having a full portfolio of studies open.

*Dr. Rakesh Popat, Consultant Haematologist*

*Cancer Lead NIHR UCLH Clinical Research Facility*

## How to refer a patient

***By Post:***
NIHR UCLH Clinical Research Facility,
University College London Hospitals NHS Foundation Trust, 4th Floor, 170 Tottenham Court Road,
London, W1T 7HA

***By Telephone:***
Reception: 020344 72929/72930
Reception Fax: 020344 72994

***By Email*:***
*When referring patients, ensure you use nhs.net emails. Patient identifiable data *should not* be sent to/ via non-NHS email accounts.

### Principal Investigators

Prof. John Bridgewater

Dr. Martin Forster

Prof. Daniel Hochhauser

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Dr. Heather Shaw

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Dr. William Townsend

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*As it appears in alphabetical order*



## Latest News

### CO41942 Trial Presented at an International Conference

December 2021 saw the 63rd American Society of Haematology (ASH) Annual Meeting and Exposition.

CRF Cancer Principal Investigator Dr. William Townsend (Consultant Haematologist) was lead author on an abstract presented at this international conference on the CO41942 clinical trial.

The on-going Phase Ib study is evaluating the safety and activity of Mosunetuzumab (M) in Combination with Lenalidomide (Len) in Refractory/Relapsed Follicular Lymphoma (R/R FL) patients who have received at least one prior line of therapy.
The oral presentation concluded M+Len has a manageable safety profile and encouraging activity in patients with R/R FL. The study is open for recruitment at the UCLH CRF.

We would like to congratulate Dr. Townsend on this achievement. The abstracts can be viewed on the ASH meeting website.

### UCLH Find a Study

To find more information on UCLH CRF Early Phase Cancer Clinical Trials visit the UCLH Find a Study database:

**https://findastudy.uclh.nhs.uk/#/trial**

Using the 'Study Name' and/or 'Local Project Reference' (LRP).

# NIHR UCLH Clinical Research Facility
# Cancer Trials Open to Recruitment

For more information on a trial, including eligibility criteria click the hyperlinked **Local Project Reference (LRP)** ID.

## Gastro-Intestinal

| Study Acronym/ Full Title | LPR | PI | Drug Class/ Tumour Target |
|---|---|---|---|
| **DESTINY-Gastric 03**<br>A Phase 1/2b Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (DS-8201a) Monotherapy and combinations in Adult Subjects with HER2 Overexpressing Gastric Cancer. | 137677 | Prof. Daniel Hochhauser | **Topoisomerase I Inhibitor**<br><br>HER2-Overexpressing Gastric Cancer |
| **FIDES-03 (DZB-CS-202)**<br>A Phase 1b/2 study of derazantinib as monotherapy and combination therapy with paclitaxel, ramucirumab or atezolizumab in patients with HER2-negative gastric adenocarcinoma harboring FGFR genetic aberrations (FIDES-03) | 133317 | Prof. John Bridgewater | **FGFR Inhibitor**<br><br>Stomach or Gastro-esophageal Adenocarcinoma harbouring FGFR2 genetic aberrations |
| **PORCUPINE2 (RXC004/0003)**<br>A Modular, Phase II, Open-Label, Multicentre Study to Assess the Preliminary Efficacy and Safety of RXC004, in Patients with Advanced Solid Tumours that have Progressed following Therapy with Current Standard of Care | 138861 | Prof. John Bridgewater | **FGFR Inhibitor**<br><br>Pancreatic Ductual Adenocarcino-ma (PDAC) or Biliary Tract Cancer (BTC) |
| **PORCUPINE1 (RXC004/0002: REACT)**<br>A Multi-arm, Phase II, Open-Label, Multicentre Study to Assess the Preliminary Efficacy of RXC004 in Monotherapy and in Combination with Nivolumab, in Patients with Ring Finger Protein 43 (RNF43) or R-spondin (RSPO) Aberrated, Metastatic, Microsatellite Stable, Colorectal Cancer who have Progressed following Therapy with Current Standard of Care | 137631 | Prof. John Bridgewater | **FGFR Inhibitor +/- PD-1 inhibiting IgG4 Monoclonal**<br><br>RNF43/RSP Colorectal Cancer |

## Haematology

| Study Acronym/ Full Title | LRP | PI | Drug Class/ Tumour Target |
|---|---|---|---|
| **AML1001**<br>A Phase 1, First in Human (FIH), Dose Escalation Study of JNJ-74856665 (dihydroorotate dehydrogenase [DHODH] Inhibitor) in Participants with Acute Myeloid Leukemia (AML) or Myelodysplastic Syndrome (MDS) | 135994 | Dr. Jenny O'Nions | **Dihydroorotate Dehydrogenase (DHODH) Inhibitor**<br><br>Acute Myeloid Leukemia (AML) or Myelodysplastic Syndrome (MDS) |

# Haematology (II)

| Study Acronym/ Full Title | LRP | PI | Drug Class/ Tumour Target |
|---|---|---|---|
| **BP41072**<br>An Open-Label, Phase I Study To Evaluate The Safety, Pharmacokinetics And Preliminary Antitumor Activity Of Ro7227166 (A Cd19 Targeted 4-1bb Ligand) In Combination With Obinutuzumab And Incombination With Ro7082859 (Cd20-Tcb) Following A Pre-Treatment Dose Of Obinutuzumab Administered In Participants With Relapsed/ Refractory B-Cell Non-Hodgkin's Lymphoma. | 129333 | Dr. William Townsend | **Ro7227166 (CD19-directed 41BB ligand) + Obinutuzumab (anti-CD20 Monoclonal Antibody) or Glofitamab (CD3-CD20 T-Cell Bispecific Antibody)**<br><br>Relapsed/Refractory B-Cell Non-Hodgkin's Lymphoma |
| **CC-220-MM-001**<br>A Phase 1B/2A Multicenter, Open-Label, Dose-Escalation Study to Determine the Maximum Tolerated Dose, Assess the Safety and Tolerability, Pharmacokinetics and Preliminary Efficacy of CC-220 Monotherapy and in Combination with Dexamethasone in Subjects with Relapsed and Refractory Multiple Myeloma. | 16/0336 | Dr. Rakesh Popat | **Cereblon E3 Ligase Modulator**<br><br>Relapsed and Refractory Multiple Myeloma |
| **CC-92480-MM-001**<br>A Phase 1 Multicenter, Open-Label Study to Assess The Safety, Pharmacokinetics And Preliminary Efficacy of CC-92480 in Combination With Dexamethasone in Subjects With Relapsed And Refractory Multiple Myeloma. | 18/0040 | Dr. Rakesh Popat | **Cereblon E3 Ligase Modulator**<br><br>Relapsed and Refractory Multiple Myeloma |
| **CCS1477-02**<br>An open-label Phase I/IIa study to evaluate the safety and efficacy of CCS1477 as monotherapy in patients with advanced haematological malignancies | 121140 | Dr. Jenny O'Nions | **P300/CBP Inhibitor**<br><br>Advanced Haematological Malignancies |
| **CL1-65487-003**<br>Phase I / II, open label, dose escalation part (phase I) followed by non-comparative expansion part (phase II), multicentre study, evaluating safety, pharmacokinetics and efficacy of S65487, a Bcl2 inhibitor combined with azacitidine in adult patients with previously untreated acute myeloid leukemia not eligible for intensive treatment. | 136715 | Dr. Jenny O'Nions | **BCL-2 Inhibitor**<br><br>Previously Untreated Acute Myeloid Leukaemia, not eligible for Intensive Treatment |
| **CO41942**<br>Ph1b study of bispecifics with lenalidomide in relapsed/ refractory FL. | 130416 | Dr. William Townsend | **CD3-CD20 Bispecific Antibody**<br><br>Relapsed or Refractory Follicular Lymphoma |
| **DREAMM-6**<br>A Phase I/II, Open-label, Dose Escalation and Expansion Study to Evaluate Safety, Tolerability, and Clinical Activity of the Antibody-Drug Conjugate GSK2857916 Administered in Combination with Lenalidomide Plus Dexamethasone (Treatment Arm A), or Bortezomib Plus Dexamethasone (Treatment Arm B) in Participants with Relapsed or Refractory Multiple Myeloma. | 18/0571 | Dr. Rakesh Popat | **Humanised Monoclonal Antibody (anti-BCMA)**<br><br>Relapsed or Refractory Multiple Myeloma |
| **EP0042-101**<br>A Modular, Multipart, Multi-arm, Open-label, Phase I/IIa Study to Evaluate theSafety and Tolerability of EP0042 Alone and in Combination with Anti-cancerTreatments in Patients with Advanced Malignancies. | 134892 | Dr. Jenny O'Nions | **FLT3 inhibitor & Aurora Kinase Inhibitor**<br><br>Acute Myeloid Leukaemia (AML) or Myelodysplastic Syndromes (MDS) |

## Haematology (III)

| Study Acronym/ Full Title | LRP | PI | Drug Class/ Tumour Target |
|---|---|---|---|
| **GRACE (BP42233)**<br>An Open-Label, Multicenter, Phase I Study Evaluating The Safety And Pharmacokinetics Of Escalating Doses Of RO7425781 In Participants With Relapsed Or Refractory Multiple Myeloma | 137532 | Dr. Rakesh Popat | **T-Cell Engager against GPR5CD**<br><br>Relapsed or Refractory Multiple Myeloma |
| **MajesTEC-2 (64007957MMY1004)**<br>A Multi-arm Phase 1b Study of Teclistamab With Other Anti-cancer Therapies in Participants with Multiple Myeloma | 137973 | Dr. Rakesh Popat | **T-Cell Engager targeting BCMA**<br><br>Multiple Myeloma |
| **NP40126**<br>A Phase 1b Study Evaluating Ro7082859 In Combination With Rituximab (R) Or Obinutuzumab (G) Plus Cyclophosphamide, Doxorubicin, Vincristine, And Prednisone (CHOP) In Participants With Relapsed Refractory Follicular Lymphoma (R/R Fl) Or In Participants With Untreated Diffuse Large B-Cell Lymphoma | 17/0859 | Dr. William Townsend | **Glofitamab (CD3-CD20 T-Cell Bispecific Antibody)**<br><br>Relapsed Refractory Follicular Lymphoma Or Untreated Diffuse Large B-Cell Lymphoma |
| **NVG111-101**<br>NVG111-101: An open-label, phase 1/2, first in human study investigating the safety, tolerability, pharmacokinetics and efficacy of NVG-111 in subjects with relapsed/refractory chronic lymphocytic leukaemia and mantle cell lymphoma. | 135715 | Dr. William Townsend | **Receptor Tyrosine Kinase Like Orphan Like Receptor 1 (ROR1) Bispecific antibody**<br><br>Relapsed or Refractory Chronic Lymphocytic Leukaemia & Mantle Cell Lymphoma |

## Hepatobiliary

| Study Acronym/ Full Title | LPR | PI | Drug Class/ Target |
|---|---|---|---|
| **TAS-120**<br>A Dose Finding Phase I Study of TAS-120 in Patients with Advanced Solid Tumors With or Without Fibroblast Growth Factor/Receptor (FGF/FGFR)-Related Abnormalities Followed by a Phase 2 Study in Patients With Advanced Solid Tumors FGF/FGFR-Related Abnormalities | 17/0474 | Prof. John Bridgewater | **FGFR2 Inhibitor**<br><br>Cholangiocarcinoma harbouring FGFR2 Gene Fusion |

## Sarcoma

| Study Acronym/ Full Title | LPR | PI | Drug Class/ Target |
|---|---|---|---|
| **Afatinib in Chordoma**<br>A phase 2, single arm, European multi-center trial evaluating the efficacy of afatinib as first-line or later-line treatment in advanced Chordoma. | 17/0146 | Dr. Sandra Strauss | **EGFR Small Molecule Inhibitor**<br><br>Advanced Chordoma |
| **ImmunoSARC2(GEIS-52)**<br>Phase I - II trial of sunitinib plus nivolumab after standard treatment in advanced soft tissue and bone sarcomas | 119516 | Dr. Sandra Strauss | **PD-1 inhibiting IgG4 Monoclonal Antibody and RTK Inhibitor**<br><br>Advanced Soft Tissue & Bone Sarcomas |

# Solid Tumours

| Study Acronym/ Full Title | LPR | PI | Drug Class/ Target |
|---|---|---|---|
| **AGI-134**<br>A phase I/IIa, multicentre, open label study designed to evaluate the safety and tolerability of AGI-134 as monotherapy and in combination with pembrolizumab, in unresectable metastatic solid tumours. | 104916 | Dr. Martin Forster | **Anti-αGal**<br><br>Unresectable Superficial Metastatic Melanoma or Squamous Cell Cancers |
| **20190136: AMG994 & AMG404**<br>A Phase 1, Multicenter, Open-label, Dose Exploration and Dose Expansion Study Evaluating the Safety, Tolerability, Pharmacokinetics and Efficacy of AMG 994 Monotherapy and Combination of AMG 994 and AMG 404 in Subjects with Advanced Solid Tumors. | 134740 | Dr. Rowan Miller | **Bivalent Bispecific IgG1 Monoclonal IgG1 against PD-1**<br><br>Advanced Solid Tumours |
| **BLU-667**<br>A Phase 1 Study of the Highly-selective RET Inhibitor, BLU-667, in Patients with Thyroid Cancer, Non-Small Cell Lung Cancer (NSCLC) and Other Advanced Solid Tumors. | 17/0783 | Dr. Martin Forster | **RET Inhibitor**<br><br>Thyroid Cancer, NSCLC, Other RET-driven Advanced Solid Tumours |
| **BICYCLE Study: BT171/8**<br>A Cancer Research UK Phase I/IIa trial of BT1718, (A Bicycle drug conjugate), given intravenously in patients with advanced solid tumours. | 100211 | Dr Dionysios Papadatos-Pastos | **Bicycle Drug Conjugate**<br><br>Advanced Solid Tumours |
| **D9170C00001**<br>A Phase I/IIa, Open-Label Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy of Ascending Doses of AZD7648 Monotherapy or in Combination with either Cytotoxic Chemotherapies or Novel Anti-Cancer Agents in Patients with Advanced Malignancies | 18/0580 | Dr. Rowan Miller | **DNA-PK Inhibitor**<br><br>Advanced Malignancies |
| **GO42144**<br>A Phase Ia/Ib Dose-Escalation And Dose-Expansion Study Evaluating The Safety, Pharmacokinetics, And Activity Of GDC-6036 As A Single Agent And In Combination With Other Anti-Cancer Therapies In Patients With Advanced Or Metastatic Solid Tumors With A KRAS G12c Mutation. | 140092 | Dr. Martin Forster | **KRAS G12c Inhibitor**<br><br>Advanced or Metastatic Solid Tumours with KRAS G12c Mutation |
| **IMC-F106C-101**<br>A Phase 1/2 First-in-Human Study of the Safety and Efficacy of IMC-F106C as a Single Agent and in Combination with Checkpoint Inhibitors in HLA-A*02:01-Positive Participants with Advanced PRAME-Positive Cancers | 130728 | Dr. Heather Shaw | **PRAME Immune-Mobilizing T-Cell Receptor against Cancer**<br><br>HLA-A*02:01-Positive Participants with Advanced PRAME-Positive Cancers |
| **POTENTIA (CBT307-1)**<br>A Phase 1 Open-Label, Dose Escalation and Expansion Trial to Investigate the Safety, Pharmacokinetics and Pharmacodynamics of CB307, a Trispecific Humabody T-cell Enhancer, in Patients with PSMA+ Advanced and/or Metastatic Solid Tumours (POTENTIA) | 129679 | Dr. Mark Linch | **Trispecific Humabody T-Cell Enhancer**<br><br>PSMA+ (IHC) Advanced or Metastatic Solid Tumours |
| **LOXO-TRK-15002**<br>LOXO-TRK-15002: A Phase II Basket Study of the Oral TRK Inhibitor LOXO-101 in Subjects with NTRK Fusion-Positive Tumors. | 16/0077 | Dr. Martin Forster | **TRK Inhibitor**<br><br>NTRK Fusion-Positive Tumours |

## Solid Tumours (II)

| Study Acronym/ Full Title | LPR | PI | Drug Class/ Target |
|---|---|---|---|
| **MULTI-31**<br>An open-label, Phase II, platform trial evaluating safety and efficacy of multiple BI 754091 anti-PD-1 based combination regimens in PD-(L)1 naïve and PD-(L)1 pretreated patient populations with advanced and/or metastatic solid tumours who have had at least one line of systemic therapy | 123071 | Dr. Martin Forster | **Anti-PD-L1 Based Combination Regime**<br><br>PD-(L)1 naïve & PD-(L)1 pre-treated patients with advanced and/or metastatic solid tumours, had at least one line of systemic therapy. |
| **Starpharma CTX**<br>A phase 1/2 dose-escalation study to evaluate the safety, tolerability, pharmacokinetics and preliminary efficacy of CTX-SPL9111 (a cabazitaxel (CTX)-dendrimer conjugate) in patients with advanced solid tumours. | 18/0016 | Dr. Martin Forster | **Drug-Dendrimer Conjugate**<br><br>Advanced Solid Tumours |
| **Starpharma DTX**<br>A phase 1/2 dose-escalation study to evaluate the safety, tolerability, pharmacokinetics and preliminary efficacy of DTX-SPL8783 (a docetaxel (DTX)-dendrimer conjugate) as monotherapy in patients with advanced solid tumours or in combination with nintedanib in patients with non-small cell lung cancer (NSCLC). | 17/0585 | Dr. Martin Forster | **Drug-Dendrimer Conjugate (Tubulin Polymerase Inhibitor)**<br><br>Advanced solid tumours<br>Or non-small cell lung cancer (NSCLC) |

## Urology

| Study Acronym/ Full Title | LRP | PI | Drug Class/ Target |
|---|---|---|---|
| **BXCL701**<br>A Phase 1b/2 Study of BXCL701, a Small Molecule Inhibitor of Dipeptidyl Peptidases (DPP), Administered in Combination with the Anti-Programmed Cell Death 1(PD-1) Monoclonal Antibody Pembrolizumab (PEMBRO; Keytruda®) in Patients with Small Cell Neuroendocrine Prostate Cancer (SCNC; NEPC). | 113103 | Dr. Mark Linch | **Dipeptidyl Peptidases (DPP) Inhibit & Anti-PD-1 Monoclonal Antibody**<br><br>Small Cell Neuroendocrine Prostate Cancer (SCNC; NEPC) |
| **CORT125281**<br>Phase 1/2 Dose-Escalation and Expansion Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of CORT125281 with Enzalutamide in Patients with Metastatic Castration-Resistant Prostate Cancer. | 18/0135 | Dr. Mark Linch | **Glucocorticoid Receptor (GR) Antagonist**<br><br>Metastatic Castration-Resistant Prostate Cancer (mCRPC) |
| **FIDES-02 (DZB-CS-201)**<br>An open-label multi-cohort Phase 1/2 study of derazantinib and atezolizumab in patients with urothelial cancer expressing activating molecular FGFR aberrations (FIDES-02) | 124615 | Dr. Mark Linch | **FGFR Inhibitor & Anti PD-L1 Monoclonal Anti-body**<br><br>Advanced Urothelial Cancer expressing FGFR Genetic aberrations.<br><br>*Substudy 4:*<br>Urothelial progression - FGFR-inhibitor resistant (>12 weeks) & previous chemo and CPI |

| Urology (II) | | | |
|---|---|---|---|
| **Study Acronym/ Full Title** | **LRP** | **PI** | **Drug Class/ Target** |
| **PRO-MERIT**<br>(Prostate Cancer Messenger RNA Immunotherapy): A first-in-human, dose titration and expansion trial to evaluate safety, immunogenicity and preliminary efficacy of W_pro1 in patients with metastatic castration resistant prostate cancer and W_pro1 in combination with cemiplimab and/or goserelin acetate in patients with high-risk, localized prostate cancer. | 122815 | Dr. Mark Linch | **W_pro1 mRNA Cancer Vaccine**<br><br>*Group 1:* mCRPC that have exhausted conventional treatment<br><br>*Group 2:* High-risk, Localized Prostate Cancer prior to Prostatectomy |