

# ECMC Paediatric Oncology and/or Haematology Drug Development Clinical Fellowship

Contact and submission of applications to: ECMC Office – sumair.nizamuddin@cancer.org.uk

<u>How to apply</u>: Please send a two-page CV and a letter of intent why you would like to undertake this fellowship to above email address.

With your emailed application, please rank, in order of preference, your choice of ECMC centres from those who have offered to host a fellow from 1 (top choice) to 5. Those ECMCs who have put themselves forward to host a fellow for this round of applications are listed in Appendix 1 of this job advert.

## Informal enquiries:

Generic and oncology: Dr. Lynley Marshall (Lynley Vanessa. Marshall@icr.ac.uk)

Haematology: Dr. Donna Lancaster (<u>Donna.Lancaster@rmh.nhs.uk</u>)

Deadline for application: 14 January 2025

The ECMC Paediatric Network brings together clinicians and translational scientists to run early phase clinical trials for children and young people with cancer across the UK. Formed of 12 paediatric phase I/II centres (including 1 centre in Scotland (Glasgow) and 1 centre in Wales (Cardiff)), the network functions as a single virtual centre to improve patient recruitment and expand geographical access to novel anticancer agents.

The paediatric ECMC network were successful in renewing their funding for another 5 years in 2023. The funding for the paediatric network is 6.6 Mio GBP and is provided through the partnership of CRUK, NIHR and the Scottish government, match-funded by the Little Princess Trust and Health and Care Research Wales (https://www.ecmcnetwork.org.uk/news/announcement/funding-boost-experimental-treatments-cancer).

One core element of the renewed funding is the sponsoring of several 12 months Paediatric Oncology/ Haematology Drug Development fellowships.

The aim of the Fellowship is to provide the candidate with the opportunity to work in one or more of the ECMC paediatric centres within the oncology and haematology drug

development team to gain exposure to children undergoing participation in early phase trials. Alongside this clinical exposure the candidate will have the opportunity to follow a specific site prepared educational package specific to the unique site set up/collaboration partners. The package will include aspects of drug discovery, preclinical testing, genomics and personalized medicine, biomarkers, pharmacokinetic/pharmacodynamics/pharmacogenetic concepts, trial designs, protocol development, regulatory and ethical aspects. The anticipated duration of the clinical training will be 12 months. The fellow will be expected to participate in the ECMC-JING: training the next generation workshop (https://www.ecmcnetwork.org.uk/jing-tng) and will have the opportunity to participate in the regular paediatric ECMC meetings.

Training will be expected to deliver experience in early Phase trials for solid, CNS and haematological malignancies. Fellows will have the opportunity to further develop an area of interest in one of these sub-categories.

The training centres will be responsible for all contractual and employment arrangements with the fellow. Candidates will have a choice of ECMC centres which have put themselves forward to host a fellow. The ECMC will provide an educational grant to support the fellowship but will hold no legal responsibility for the employment of the fellows.

The fellowship is intended for doctors in training who are committed to becoming paediatric haematologists / oncologists in the UK and want to further extend their expertise in drug development. The candidates should be at least half-way through their paediatric haematology/oncology training, i.e. have a solid understanding of the core principles of paediatric oncology/haematology when embarking on this role.

One fellowship will be available to **start in September 2025** although earlier start dates may be possible. Depending on flexibility and mobility of the candidates a split experience between two centres is possible – please see attached centre descriptions for further information on centres which have put themselves forward to host a fellow in this round (appendix 1).

#### **Timeline**

- → <u>Deadline</u> for application **14 January 2025.**
- $\rightarrow$  Shortlisted candidates will be informed by early February 2025, with online interviews arranged shortly after.
- $\rightarrow$  Selection made no later than end of March 2025.

#### **Funding:**

The total funding available per 12 months Fellowship is:

• Salary scale is £55,500 - £68,000 depending on individual's level of experience

### **Appendix 1—host centre descriptions**

## University of Birmingham (UoB) and Birmingham Children's Hospital (BCH)

This ECMC Drug Development Fellowship opportunity is a shared arrangement between the Cancer Research Clinical Trials Unit (CRCTU) of the University of Birmingham (UoB) and the Birmingham Children's Hospital (BCH) which is part of the Birmingham Women's and Children's NHS Foundation Trust.

## Birmingham Children's Hospital

The Haematology/ Oncology department at BCH is one of the largest paediatric haematology/ oncology services in the UK seeing 200-250 new cases of childhood malignant disease each year. A team of 15 NHS consultants, 3 academic consultants and 14 post-graduate doctors in training, provide care through 5 cancer MDTs including solid tumours, neuro-oncology, leukaemia, stem cell transplant and retinoblastoma. BCH is one of the 5 First-in-Child ECMC early Phase trial centres in the UK and multiple early Phase trials - including the platform trials GlO-BNHL and Determine - are either open or will have opened by the time the post holder is appointed. We have a range of industry and academic trials. The fellow will have a dedicated fellow role in the Early Phase trials team, be sub-investigator on all Phase I/II trials and gain experience across all aspects of early Phase clinical trials conduct.

#### Cancer Research UK Clinical Trials Unit

The CRCTU is the largest paediatric cancer clinical trials unit in Europe. Prof. Amos Burke, who is part of the BCH oncology consultant team, has been director of CRCTU since December 2023. The CRCTU has 4 dedicated Children's Cancer teams which together deliver the broad CRCTU portfolio of international, academic children's cancer trials. The fellow will have the unique opportunity to work alongside one or more of these teams. Several of these trials are large platform trials with innovative Bayesian, multi-arm, multi-stage designs. Prominent examples include the FaR-RMS platform trial for newly diagnosed and relapsed rhabdomyosarcoma and the highly innovative GLO-B-NHL trial Phase I/II platform trial for relapsed/ refractory B-NHL with several treatment arms all delivering to filing standards in collaboration with different Pharma partners. In this environment, trials can be experienced through their whole life cycle from idea generation and new business meetings to trial setup/ protocol writing, regulatory application and authorisation, trial opening and monitoring, as well as trial closure.

## **Great Ormond Street Hospital for Children NHS Foundation Trust (GOSH)**

Great Ormond Street Hospital for Children NHS Foundation Trust (GOSH) is an international centre of excellence in child healthcare. Together with our research partner, the UCL Great Ormond Street Institute of Child Health, we form the UK's only academic Biomedical Research Centre specialising in paediatrics. In partnership with six other NHS trusts, we are the lead provider for North Thames Genomics Medicine Centre, part of the national 100,000 Genomes Project. Team members of two CRUK Grand Challenge teams focusing on childhood cancer.

The ECMC Paediatric Oncology Drug Development fellow will join the GOSH Experimental Cancer Therapeutics programme, which aims to improve the efficiency of introducing novel targeted agents (including biological therapies) into children with cancer. GOSH/UCL have established a team of doctors, research nurses and data managers to conduct translational and clinical research. The programme will offer the following:

- Cover whole range of early phase trials across oncology and haematology.
- GOSH/UCL has unique expertise in developing CAR-T cell therapies in leukaemia, solid
  and brain tumours providing ward experience in managing these patients, opportunity to
  spend short period in the pre-clinical CAR-T cell teams.
- Expertise in developing academic trials in neuro-oncology including novel drug delivery systems.
- Assist in development and writing of regulatory submissions.
- Join team coordinating the CRUK funded StratifiedMedicinePaediatric2 National Molecular Profiling programme.
- Will be support in participation in the ECMC-JING: training the next generation workshop (<a href="https://www.ecmcnetwork.org.uk/jing-tng">https://www.ecmcnetwork.org.uk/jing-tng</a>) and paediatric ECMC.

## Southampton

The Southampton Children's Hospital Paediatric Oncology Unit has particular expertise in early phase immunotherapy and neuroblastoma trials. It is co-located with the University of Southampton Centre for Cancer Immunology, where there are a number of projects involving the pre-clinical evaluation of novel immunotherapies for neuroblastoma. Depending on the experience and interests of the candidate, the post will offer opportunities to be involved in a pre-clinical project as well as aspects of trial design, set up and delivery, and recruitment and management of patients recruited to trials. In addition, there will be the opportunity to help with the analysis, correlation with clinical data and publication of immunological data from current immunotherapy trials.

For more information, please contact Professor Juliet Gray jcgray@soton.ac.uk.

#### **Great North Children's Hospital Newcastle-upon-Tyne**

The North of England Principal Treatment Centre for Children and Young People with cancer based at the Great North Children's Hospital Newcastle upon Tyne will be happy to offer fellowship training in Early Phase Clinical Trials through the ECMC Paediatric Oncology and/or Haematology Drug Development Clinical Fellowship. We are a clinical trials team established for 30 years fulfilling all the aspects of early and late phase clinical trials, biological, Pharmacokinetic and quality of life, survivorship studies. Our current early phase portfolio is of 6 interventional trials with a further 10 in start-up. We are closely allied with a much larger adult early phase service which as well as having a larger portfolio of trials and a very high level of activity also has a drug development programme and it's own clinical trials unit.

There is substantial opportunity to get first hand experience of the groups co-ordinating early phase children's cancer research in the UK and Europe. The lead for early phase in Newcastle is the current chair of the UK New Agents Group committee. We are an active site within the European Innovative Therapies in Childhood Cancer (ITCC) and UK Experimental Cancer Medicines Centres (ECMC) paediatric networks. Within ITCC staff from the site sit on both the solid and brain tumour steering committees. We are one of the sites accepted for the ITCC Early Phase trials fellowship programme and we can fulfil all of the training requirements for this programme. We jointly lead a network for the North of Britain and Ireland which comprises Northern England, Scotland, Northern Ireland and the Republic of Ireland – a population of 15 million. This was the prototype for the ECMC Paediatric network relapse MDTS. We hold weekly teleconferences to identify trial opportunities for patients within this network and enable travel between the centres for trial entry.

We offer a comprehensive paediatric oncology, neuro-oncology and haemato-oncology service for the whole population of the North of England up to the age of 18 and for some young adults. This includes Stem cell transplantation both autologous and allogeneic and we have a busy CAR-T programme including CAR-T trials. Within our service we have specialist Neuro-surgery, paediatric surgery, all aspects of sarcoma surgery, Cardiothoracic surgery and Hepatobiliary surgery. We have a photon radiotherapy service and a comprehensive palliative care service which offers 24 hour management at home where necessary.

Our clinical service is closely integrated with a long established preclinical research institute and 6 of our clinicians have substantial preclinical research programmes with world leading research in Neuro-oncology, Leukaemia and Lymphoma, Neuroblastoma and Late effects. A comprehensive range of cutting edge scientific investigatory techniques are routinely practised and can be demonstrated and taught including a mouse hospital. There is a large preclinical scientific community here with abundant experience of training clinical colleagues in scientific techniques. We have a longstanding programme supporting clinical colleagues through preclinical research including PhDs. The UK children's cancer tissue bank is administered from our site and we have a clinical cytogenetics facility providing next generation sequencing facilities. Integral to our service is the national Paediatric Oncology Pharmacology unit which undertakes the pharmacokinetic and pharmacology services for the UK. This service also has a long pedigree of training clinical colleagues in the field of clinical pharmacology.

We are closely engaged with the much larger and busier adult cancer early Phase Sir Bobby Robson Trials Unit within our hospital trust. We conduct our trials collaboratively and make trials from the paediatric oncology unit available for suitable adult patients and where permitted make adult trials available to paediatric patients opening these trials in both allied units. Our

clinical service spans age range and incorporates a Teenage and Young adult service which bridges. We sit in the same MDTs and within the same research group in Newcastle University cancer centre. The SBRF has a much higher volume of trials and recruitment than in paediatric oncology and there will be opportunity to gain experience in this adult setting as well as our paediatric unit.

## The Royal Marsden Hospital & The Institute of Cancer Research (ICR)

#### Background to The Royal Marsden Hospital and the Institute of Cancer Research

The Royal Marsden's 31-bed Oak Centre for Children and Young People is one of the largest comprehensive cancer centres in Europe for children and teenagers. Built as a £20 million purpose-built facility which opened in 2011, the Centre comprises 18 children's inpatient beds, a dedicated 13 bed Teenage and Young Adult (TYA) Cancer Unit, and outpatient and day care facilities including facilities for children's and young people's oncology drug development, the paediatric and adolescent oncology drug development unit (PA-DDU). The Centre sees almost 600 inpatients and more than 5000 day-patients every year, with around 220 new malignant registrations per year including leukaemia, lymphoma, central nervous system (CNS) and extracranial solid tumours. Our PA-DDU is the largest and most active in the UK's Paediatric Experimental Cancer Medicines Centre (ECMC) network and within the ITCC, recruiting around 32% of all UK patients recruited to ITCC trials in the period 2017-22. We are a designated ITCC First-in-Child centre. The Centre has excellent integration with all adult oncology specialities and enjoys the significant benefits of co-location with The Institute of Cancer Research (ICR), a world-leading cancer research centre and a College of The University of London.

The research activities of the clinical Unit are closely integrated with the Division of Cancer Therapeutics and The Division of Clinical Services within the ICR. The Paediatric and Adolescent Oncology Targeted Drug Development Programme at the Royal Marsden and the ICR is a comprehensive programme which comprises drug discovery, pre-clinical evaluation in a comprehensive range of model systems, preclinical imaging, and biomarker-rich early clinical trials conducted within the Centre's clinical facility (the Oak Foundation Unit, which is an NIHR Research Facility). In addition to the clinical facilities described above the outpatient and day care unit houses an adjacent 'hot' laboratory on site for pharmacokinetic and pharmacodynamic sample processing. The inpatient unit houses two suites for radioisotope therapy (including MIBG therapy and others) to help facilitate novel studies involving radioisotope components.

**Paediatric & Adolescent Oncology Drug Development Fellowship – Job Description**This position is a key post within the Paediatric and Adolescent Oncology Drug Development Team, which was the first of its kind in the UK when set up in 2007.

Within this clinical post the fellow will work very closely with other members of the multidisciplinary team carrying out early clinical studies of novel agents in children and young people and will be involved in the eligibility assessment and care of children and young people enrolled on early clinical studies of new agents, including first-in-child studies of molecularly targeted drugs, and novel immunotherapy agents, including combination and multi-arm basket trials.

The team has developed excellent links with academic and pharmaceutical industry clinical trial sponsors for clinical trial design and implementation. Patients are referred from other UK centres through the Paediatric ECMC Network via well-defined pathways. The team delivers an excellent level of patient care, providing access to novel therapies, within clinical trials and with strong regulatory levels of pharmacovigilance and practising to the highest standards of Good Clinical Practice (GCP). Where clinical trials are not available, we also deliver a significant programme of compassionate/managed access programmes in partnership with pharma, and these patients are cared for by our team, to the same standards as patients on early phase clinic\al trials.

There will be opportunities for the fellow to be involved in devising and writing early phase clinical studies/study arms and in other projects. The fellow will also have an opportunity to develop a specialist interest of their own if desired, in clinical trials for haematological malignancies, neuroblastoma, neuro-oncology, or sarcoma. The fellow would participate actively in weekly tumour-based multidisciplinary team meetings (MDTs) (1 MDT each for neuro-oncology, solid tumours, haematological malignancies, bone marrow transplantation (BMT), the weekly ECMC regional relapse teleconferences where patients with newly relapsed disease are discussed for consideration of clinical trials eligibility, 1-2 weekly molecular tumour boards, as well as in the weekly drug development clinical planning meeting and the weekly clinical research operational governance meetings and Trust 3 monthly immunotherapy governance group meetings. They would be responsible for and become competent in reviewing patients on Phase I/II clinical trials, both on the ward and in the Paediatric Drug Development clinics, with the research nurse and consultant team members. The post holder will receive training in and be actively involved in liaising with academic and commercial clinical trial sponsors about patients recruited onto trials, new trials and new drugs, collection of clinical trial data to GCP standards and the regulatory aspects of paediatric early phase trials to enable them to work effectively in the set-up of new early phase trials, under consultant supervision. The post holder will link closely with radiology colleagues and receive training in the relevant imaging assessments of patients on clinical trials. Via links with the ICR, a central theme of the programme will be the translation of laboratory research to clinical trials. There is also the opportunity to attend laboratory team meetings at The ICR in tumour area of interest (Paediatric Glioma, Medulloblastoma, Sarcoma, Neuroblastoma or Leukaemia).

The post in paediatric oncology is suitable for trainees wishing to gain experience in paediatric and adolescent oncology drug development and clinical trials. The post holder will have the opportunity to develop their own project(s) in the area of drug development and to contribute to the academic output of the Unit and build on their own academic profile via authorship on publications and presentations at relevant national/international meetings. It may also be a stepping stone to develop a project that could be taken forward in future towards a higher research degree (MD or PhD).

For more information please contact Dr Lynley Marshall: <u>LynleyVanessa.Marshall@icr.ac.uk</u>