The ROYAL MARSDEN
NHS Foundation Trust

ICR The Institute of Cancer Research

Introduction to clinical research support and infrastructure

NHS
National Institute for Health Research

Contents

Introduction

Welcome to The Royal Marsden NHS Foundation Trust and The Institute of Cancer Research, London (ICR) – together we are ranked in the top four centres for cancer research and treatment worldwide. We are a National Institute for Health Research (NIHR) Biomedical Research Centre (awarded in 2006), the only one in England dedicated to cancer. Our aim is to conduct pioneering research into prevention, diagnosis and treatment, and translate research into patient benefit. We are making a significant impact on improving patient outcomes through precision treatment.

We are proud to be a world leader, using NIHR funding to drive progress in cancer treatment. Our work is split, broadly, into two key areas: cancer therapeutics and the molecular classification of disease. Our activities are diverse and include areas such as drug development.

The Royal Marsden also hosts the south west London component of Division 1 (Cancer) of the Clinical Research Network: South London.

The Royal Marsden and The Institute of Cancer Research (ICR) sponsor a large number of studies, with many sponsored clinical trials running under a trials unit. The Royal Marsden also hosts a large number of studies which are delivered through tumour specific clinical research teams.

We hope you find the information in this pack useful as an introduction to the specialist support and infrastructure that make The Royal Marsden and the ICR a great place to conduct clinical research. If you require further information or training in any aspect of research support then please email/telephone the main contact given who will organise this for you.

“Working at The Royal Marsden gives you the opportunity to learn a lot; to experience personal growth; to lead while following. You are part of a relentlessly compassionate and continuously evolving team that refuses to give up when it comes to tackling cancer but remains loyal to providing first class care to patients.”

Alexander Kabagambe
Clinical Trials Auditor

Clinical Research and Development Operational Team

The Clinical Research and Development (R&D) team is responsible for ensuring that all clinical research undertaken at The Royal Marsden and the ICR has undergone the appropriate approvals and that there is the capacity and capability to undertake it. The team members support the various committees and researchers through the research pathway.

Our team

The R&D Operational Team is based in the R&D Offices at The Royal Marsden in Sutton. The team comprises of:

- R&D Facilitator
- R&D Coordinators
- R&D Administrators
- Administrators
- Edge Administrator.

How we do it

- Allocating a Royal Marsden and ICR research study specific number to each study, sponsored and hosted and maintaining a database of these, including current status, amendments etc
- Supporting research teams and individuals in taking their study through the research pathway and provide guidance and training
- Ensuring all research has the correct approvals in place and that researchers are aware of their responsibilities
- In liaison with the support services (Finance, Contracts, Pharmacy, Radiology, Labs etc) provide assurance to sponsors that the study can be undertaken at The Royal Marsden and the ICR
- Administration of the various committees/ meetings that support clinical research: -

  Committee for Clinical Research – To obtain approval of sponsorship by The Royal Marsden and the ICR

  Trial Set-Up Meeting – To review capacity and capability to undertake interventional research

  Clinical Unit Research Leads Meeting

  Genetic Modification Safety Committee

  Immunotherapy Governance Group

  In addition the R&D Operational Team manages service evaluations in The Royal Marsden.

Contact us
Research.development@rmh.nhs.uk

Good Clinical Practice Team

The GCP team is responsible for ensuring that clinical research undertaken by The Royal Marsden and the ICR, and in particular The Royal Marsden and the ICR sponsored Clinical Trials of Investigational Medicinal Products (CTIMPs), are set up and run in accordance with Good Clinical Practice, the international standard for running clinical trials, and any other relevant legislation.

Our team

The GCP Team is based in the R&D Offices at The Royal Marsden in Sutton. The team comprises of:

- Quality Assurance Manager
- Senior Clinical Trials Auditor
- Clinical Trial Auditors
- Pharmacovigilance Officer
- GCP Compliance Officer.

How we do it

- Maintaining and developing a suite of generic Standard Operating Procedures for clinical research which are available on The Royal Marsden and the ICR intranets
- Risk assessing projects/research units/ support services
- Intelligence gathering – from reports on Datix involving clinical research (The Royal Marsden system for reporting incidents), internal and external monitoring reports, attending The Royal Marsden and the ICR governance and risk committees etc
- Conducting audits based on risk assessments and intelligence and ensuring that corrective and preventative actions are implemented
- Working with investigators in the development of CTIMP protocols and reviewing information provided to patients/participants
- Providing advice on the conduct of clinical research
- Engaging an external trainer to provide GCP training (see The Royal Marsden Learning and Development website for details). Providing regular training on The Royal Marsden and the ICR processes.

Contact us
GCPComplianceTeam@rmh.nhs.uk
Ext 6510 (71 6510 from ICR)

Research and Development Finance Team

The R&D Finance team is responsible for ensuring that all new clinical trials (both commercial and non-commercial) and all grant applications (including applications for BRC funding) are costed appropriately and financial implications discussed with the relevant research team or individual. This also includes studies that are set up and run via the ICR but have an impact on The Royal Marsden resources and finance.

We also provide traditional financial management style monitoring and reporting of the on-going financial status of studies and research units; this is routinely reported monthly, with larger strategic meetings with research unit leads held quarterly.

Our team

The Research and Development Finance team is part of the Finance Directorate at The Royal Marsden and are based in Friese Green House, Chelsea, but also in The Centre for Molecular Pathology (CMP 3), Sutton. The team comprises of:

- Finance Business Partner
- Assistant Finance Manager
- Management Accountant
- Clinical Trial Funding and Invoicing Co-ordinator.

Our Process

- For all new clinical trials and grants please contact the R&D finance team via the generic email address R&DBusinessFinance@rnh.nhs.uk and you will be allocated a member of the team to help with your costings
- For clinical trial costings, typically we would expect to receive a costing template (completed as fully as possible), either the NIHR standard template for commercially sponsored studies or the local Royal Marsden template for non-commercial studies as well as a copy of the protocol (if applicable)
- For grants please include as much detail as possible in your request so that we are able to cost the grant accurately (ie grade of staff, site based, length of funding, WTE to be funded, non-pay items). If there are costs to be incurred elsewhere which have already been included please include the source of these costings (i.e. email from supplier, confirmation of salary cost). It is also helpful to forward any specific instructions that are attached to the grant to ensure we include all appropriate costs
- Similarly, for any training needs the same email address R&DBusinessFinance@rmh.nhs.uk can be used
- For any training or guidance on using SBS (Shared Business Services) for procurement, raising invoices, credits notes and other transactional processes please contact the SBS help desk on NHSSBSHelpdesk@rmh.nhs.uk.

Contact us
R&DBusinessFinance@rmh.nhs.uk
Sutton ext 6591 (71 6591 from the ICR)
Chelsea ext 2164 (71 2164 from the ICR)

Clinical Trial Contracts Team

The Clinical Trial Contracts team is responsible for reviewing, negotiating and facilitating the execution of clinical trial agreements and ancillary contracts, for clinical research undertaken by The Royal Marsden and the ICR.

Each contract will fall into one of three categories, which are:

- Sponsored Clinical Trials (further details can be found in the “Guidance on Contracts Review Process – Sponsored Trial”,
- Hosted Commercial Clinical Trials (further details can be found in the “Guidance on Contracts Review Process – Hosted Commercial Trials” and,
- Hosted Non-Commercial Clinical Trials (further details can be found in the (“Guidance on Contracts Review Process – Hosted Non-Commercial Trials”)

Our team

The Clinical Trials Contract team is part of the Enterprise Unit at the ICR and are based in Sutton. The team comprises of:

- Head of Clinical Trial Contracts
- Contract Managers.

Our process

- In the subject line of your email, please include the following:

  [CCR Number] [Protocol/Project Name] [Hosted Commercial] OR [Hosted Non-Commercial] OR [Sponsored Trial]
- Once a new project has been sent to the clinical trial contracts central inbox, the sender will be notified as quickly as possible and in any case within 48 hours which contracts manager has been allocated to the project
- Please note that contract managers will be allocated to specific projects and will work on all agreements associated with that project to allow for consistency and transparency
- Where contracts have been provided an initial contract review will take place and turnaround time for this is 10 working days
- Following this review, contract negotiations will commence with the relevant parties. Please note: review will be delayed in instances where insufficient or incorrect information has been provided or where accurate project timelines were not stated
- Please note before any project/study information is shared or exchanged externally, ensure you have a Confidentiality Agreement in place.

Contact us
ClinicalTrialContracts@icr.ac.uk
Ext 4572 (78 4572 from The Royal Marsden)

Clinical Trial Pharmacy Team

The pharmacy team is responsible for ensuring that all pharmacy aspects of clinical trials are carried out to the highest practicable standards of ICH Good Clinical Practice Guidelines and statutory national guidance.

Pharmacy's principle role in clinical research is to safeguard subjects, healthcare professionals and the Trust by ensuring the investigational medicinal products (IMPs) are appropriate for use and are procured, handled, stored and used safely and correctly.

Who we are

The Pharmacy Team are based in the main pharmacy department, on both the Sutton and Chelsea sites. The team comprises of:

- Associate Chief Pharmacist Clinical Research & Development
- Clinical Trial Pharmacists
- Senior Clinical Trial Technicians
- Clinical Trial Funding & Invoicing Co-ordinator
- Assistant Technical Officers.

If you are interested in visiting our department to gain a bit more insight into how we operate, please make an appointment.

How we do it

All new clinical trial protocols are reviewed by a pharmacist, who attends the Committee for Clinical Research and Trial Set Up Meeting. The feasibility review involves clinically reviewing the protocol, assessing any capacity or resource requirements, assessing complexity of the study – identifying any issues. We work closely with R&D, the clinical research teams and CRAs/ sponsors to ensure smooth and timely set up and opening of the study.

We are also required to ensure that IMPs are managed and dispensed to patients in accordance with the trial protocol and that all pharmacy clinical trials procedures comply with relevant guidelines and regulations.

We maintain a comprehensive Quality Management System, including a suite of Pharmacy clinical trial specific standard operating procedures (SOPs), validation of processes and accurate recording of Corrective and Preventative Actions (CAPAs) events. Ensuring all equipment and facilities are qualified, maintained and operated in such a way as to ensure compliance with the appropriate specifications.

Contact us

Anita McWhirter, Associate Chief Pharmacist
Anita.McWhirter@rmh.nhs.uk

Victoria Sjolin, Chief Technician
Victoria.Sjolin@rmh.nhs.uk

Ext 1725 or 1078 (71 1725 or 71 1078 from ICR)

Radiopharmacy Team

The Radiopharmacy holds a Manufacturers Specials licence and the IMP Manufacturer's Authorisations issued by the Medicines and Healthcare Products Regulatory Agency (MHRA). The team is responsible for the manufacturing and supply of diagnostic and therapeutic radiopharmaceuticals in accordance to Good Manufacturing Practice and Good Clinical Practice. Our main customers are The Royal Marsden and the ICR as well as several local hospitals.

Our team

The Radiopharmacy unit is part of the Pharmacy Department, although it is physically located in Nuclear Medicine – first floor of the main hospital building in Sutton. The team comprises of:

- Head of Radiopharmacy
- Principal Radiopharmaceutical Scientist
- Senior Radio-pharmacist
- Radiopharmacy Technicians.

How we do it

- Dispensing and quality control of diagnostic and therapeutic radiopharmaceuticals and in - vitro measurements
- Maintaining and developing a suite of generic and clinical trial specific Standard Operating Procedures (SOP)
- Performing initial impact assessment of new clinical trials submitted to the Radiopharmacy for resource evaluation
- Maintaining a comprehensive Radiopharmacy Quality Management System, including SOPs, validation of processes and accurate recording of CAPA events
- Providing advice to end users of issues relating to the safe and effective use of radioactive medicinal products, including storage conditions, formulation and potential adverse reactions
- Ensuring all equipment and facilities are qualified, maintained and operated in such a way as to ensure compliance with the appropriate specifications.

Contact us

Joseline Tan, Principal Radiopharmacist
Joseline.tan@rmh.nhs.uk
Ext 3292 (71 3292 from ICR)


Staple chemotherapy proforma here
NHS

Radiology: IRMER Assessment and Capacity Review

The majority of clinical trials will involve imaging procedures. IRMER is about the safety and governance of this and ensuring that patients are accurately informed of the radiation exposures they will receive and any associated risks. The governance and procedures to follow are detailed below.

The Ionising Radiation (Medical Exposure) Regulations (2000, 2006 and 2011) IRMER

IRMER requires that all medical exposures to ionising radiation which take place as part of a research study are:

- approved by a Research Ethics Committee
- justified prior to the exposure being made
- carried out on consenting participants who have been accurately and clearly informed about the associated radiation risks
- and controlled by a research dose constraint.

Setting up a Clinical Trial where IRMER applies

Examples of Imaging procedures are: X-Rays, CT, Bone, MUGA, PET/CT scans, CT Guided Biopsies and radiotherapeutic exposures.

When setting up a trial where any of the above procedures (amongst others) are mentioned in the supporting documents, an IRMER assessment will be required to:

- confirm what image is routine clinical care and what is research
- confirm that the trust and the responsible staff will be able to comply with IRMER when carrying out the procedures
- determine whether an ARSAC certificate is required to carry out any of the nuclear medicine procedures
- provide documented confirmation that the trial is IRMER compliant
- confirm The Royal Marsden's capacity to manage the imaging procedures according to the imaging manual or the trial protocol.

Contact us
Nuclear Medicine
Research.RadiologyReview@rmh.nhs.uk
Ext 6624 (78 6624 from ICR)

Ensuring IRMER compliance

The responsibility for compliance with IRMER rests with the Trust, radiologists, radiographers, imaging technologists, nuclear medicine physicians, radiotherapists and medical physics experts, NOT the study sponsor.

In accordance with the NRES guidance "Approval for research involving ionising radiation" (version 2, 2008), Medical Physics Experts (MPEs) and Clinical Radiation Experts (CREs) with expert knowledge of the exposures required by the trial determine whether a study is IRMER-compliant or not. Occasionally a sponsor may select an external MPE and CRE to carry out the lead assessment for the IRAS application, but for all trials The Royal Marsden will need to perform a local IRMER assessment. The Royal Marsden has a small bank of voluntary MPEs and CREs. There is also a team of Radiology superintendents who are able to determine the capacity to manage research. In the case of Nuclear Medicine, capacity is assessed by the Deputy Service Lead or Radioisotope Services Manager.

MPEs are Royal Marsden-employed physicists who are registered with the Health & Care Professions Council. MPEs specialise in diagnostic radiology, nuclear medicine or radiotherapy, but may have expert knowledge across more than one speciality. Their key contribution to the IRMER assessment is to assess and confirm the radiation doses and associated risk are accurately described across all documents and to set research dose constraints to be used at The Royal Marsden during the trial. Additionally they are expert advisors on matters relating to radiation protection and they play a pivotal role in determining patient dosimetry and quality assurance.

CREs are Royal Marsden-employed consultant radiologists, nuclear medicine physicians or radiotherapists. Consultant radiologists and radiotherapists additionally specialise in specific cancer sites. CREs are registered with the General Medical Council. CREs examine the clinical aspects of the trial to determine whether the imaging requirements are justified and clearly communicated to the consenting patient.

Administration of Radioactive Substances Advisory Committee (ARSAC)

ARSAC is an advisory non-departmental public body, sponsored by the Department of Health, advising government on the certification of doctors and dentists who wish to use radioactive medicinal products on patients.

All imaging/procedures that expose patients to radioactive substances require ARSAC certification before they can be conducted. Consultants within the Department of Nuclear Medicine & PET/CT (along with a few specialist Consultants outside the unit) hold certificates for all routine diagnostic and therapeutic procedures conducted within the Trust. Additionally, a research ARSAC certificate is required for clinical trials involving patients being administered radioactive substances for imaging considered above that expected from routine clinical care; this is determined during the review process described above. The radiopharmaceuticals used for nuclear medicine imaging/procedures are provided by the Radiopharmacy unit.

The Radiology IRMER assessment described above provides sufficient information to enable the sponsor to apply for overall ARSAC approval Trial coordinators must liaise with the Nuclear Medicine Trials Administrator to submit site applications once the IRMER assessment is complete. All imaging requirements undergo a stringent capacity assessment to ensure The Royal Marsden can meet the sponsor's expectations to secure a successful trial. The Royal Marsden request a copy of the sponsors imaging manual for all trials but will refer to our standard imaging protocol when necessary.

Generic Biobank

Housed in the Centre for Molecular Pathology is one of the UK's largest biobanks dedicated to cancer set up with the help of the National Institute for Health Research funding due to our status as a Biomedical Research Centre. The Biobank's -80°C freezers and liquid nitrogen units have the capacity to store and preserve up to 900,000 frozen samples well into the future.

The Biobank will serve as a vital, clinically relevant tissue resource available to researchers for both basic and translational studies, thereby facilitating the identification and development of new personalised treatments for cancer.

The Royal Marsden treats a variety of cancers, so the Biobank has samples from some of the rarest tumour types.

How we collect samples

Successful sample acquisition relies on close collaboration between surgical, clinical and radiology teams working via trained, unit-based, generic tissue collectors and appropriate Histopathologists.

The Biobank is Human Tissue Authority compliant and has a team of four bio specimen co-ordinators to manage the sampling process, from gaining patient consent at registration to sample collection from the theatre or clinical, then processing samples in the laboratory for storage in the Biobank.

How do you access samples from the Biobank?

The Generic Biobank Steering Group, chaired by the Director of Clinical Research, has strategic oversight of the Biobank. Membership includes the Clinical Research Executive Group, surgeons, pathologists and key research scientists across The Royal Marsden and the ICR. Applications for samples go through a stringent peer-review process to ensure full benefit can be derived. Details of the process can be found in:

– The Royal Marsden NHS Foundation Trust and The Institute of Cancer Research, London Generic Biobanking and Sample Access Policy (2061).

Contact us
Janine Salter, Tissue Bank Manager
Ext 4512 (71 4512 from ICR)

Performance Metrics

The Royal Marsden and the ICR sponsor and host a large number of clinical trials and we are required to provide metrics as indicators of our ability to initiate and deliver on them.

The Government provide funding for health research through the National Institute of Health Research (NIHR). The NIHR wish to see a dramatic and sustained improvement in the performance of providers of NHS services in initiating and delivering clinical research. The aim is to increase the number of patients who have the opportunity to participate in research and to enhance the nation's attractiveness as a host for research.

The NIHR request quarterly updates on three performance areas relating to the research carried out at the Royal Marsden. The first two areas relate to initiation and delivery performance and the 3rd area looks at the output of the centres within The Royal Marsden that receive direct NIHR funding.

Initiating Clinical Research

This looks at how quickly trials are set-up and recruited to. The Royal Marsden performs well in this area and currently recruits the first patient within 70 days for 90% of our interventional trials. The Trial Set – Up Meeting provides a platform to discuss set up issues with all support services prior to R&D confirmation of capacity and capability. Please see relevant documents and guidance on the Clinical Research and Development page on the intranet or contact the R&D Performance Co-Ordinator.

Delivering Clinical Research

This looks at whether or not we've recruited the target number of patients in the timeframe we said we would as per the Clinical Trial Agreement. Due to many of the rare disease cancer trials which take place at The Royal Marsden, it can be difficult to recruit the target number of eligible patients. However, The Royal Marsden currently recruits to target for 57% of commercial studies.

NIHR Infrastructure Report

This looks at particular areas of NIHR Infrastructure within The Royal Marsden (BRC, CRF and ECMC) and reports the total number of patients recruited to those relevant open studies within the three months of that quarter and also a list of correctly acknowledged publications.

Contact us
Leanne Black, Clinical R&D Performance Coordinator
R&DMetricsandPerformance@rmh.nhs.uk
Ex 6507 (71 6507 from ICR)

West Wing Clinical Research Centre

The West Wing Clinical Research Centre (WWCRC) is a dedicated space for clinical trials activities. It runs phase Ib, II and complex phase III clinical trials.

The Centre comprises of 24 treatment chairs and four recovery couches for patients undergoing research-related tumour biopsies and procedures. There are four consulting rooms in the centre where consent, screening, baseline and on-treatment assessments are carried out. The WWCRC brings together all the various tumour groups within the trust to increase their portfolio and capacity in conducting clinical trials.

Our team

- Matron
- Sister
- Speciality Research doctors
- Staff Nurses
- Health Care Assistants
- Laboratory Technician
- Pharmacist
- Business Manager
- Research Facilitator Administrator.

Contact us

Angela Little, Matron
Angela.little@rmh.nhs.uk

Amber Ratcliffe, Sister
Amber.Ratcliffe@rmh.nhs.uk

Ext 6669 (71 6669 from ICR)

Laboratory

There is a dedicated laboratory for processing, storing and shipping of trial related samples. This is managed by a dedicated Laboratory Technician.

Pharmacy

Trial medications are not stored here but held in bond after release from main pharmacy for treatment the same or next day. This is managed by a dedicated Pharmacist and Technician.

Biopsy room

There is a biopsy service Monday-Thursday 9am-12pm with four dedicated slots each day. The service is run by two dedicated Radiologists and they assess and triage all biopsy and scan requests on Tuesdays and Thursdays 2-3pm in the WWCRC conference room. The biopsy room is an extension of main radiology but the day to day running is managed by the WWCRC Matron/ Sister. This service is offered for research trials conducted on WWCRC.

The Drug Development Unit

The Drug Development Unit (DDU) specialises in conducting Phase I Oncology drug studies and in providing holistic care for patients who are participating in Phase I cancer drug trials. Oak Ward is a nine bedded ward consisting of two single-sex bays with four beds, and one single room for patients who require isolation for medical reasons. The day-care area consists of seven treatment chairs, three consultation rooms and an ECG room. The Unit is fully functional 8am to 8pm Monday-Friday and comprises of a dedicated clinical laboratory to process trial specific biological samples.

The DDU also includes an investigator initiated trials (IIT) team that is dedicated to conduct academic, Phase I multicentred studies.

The DDU is staffed by a variety of disciplines, who are dedicated to supporting all our patients and their families throughout their trial participation.

Our team

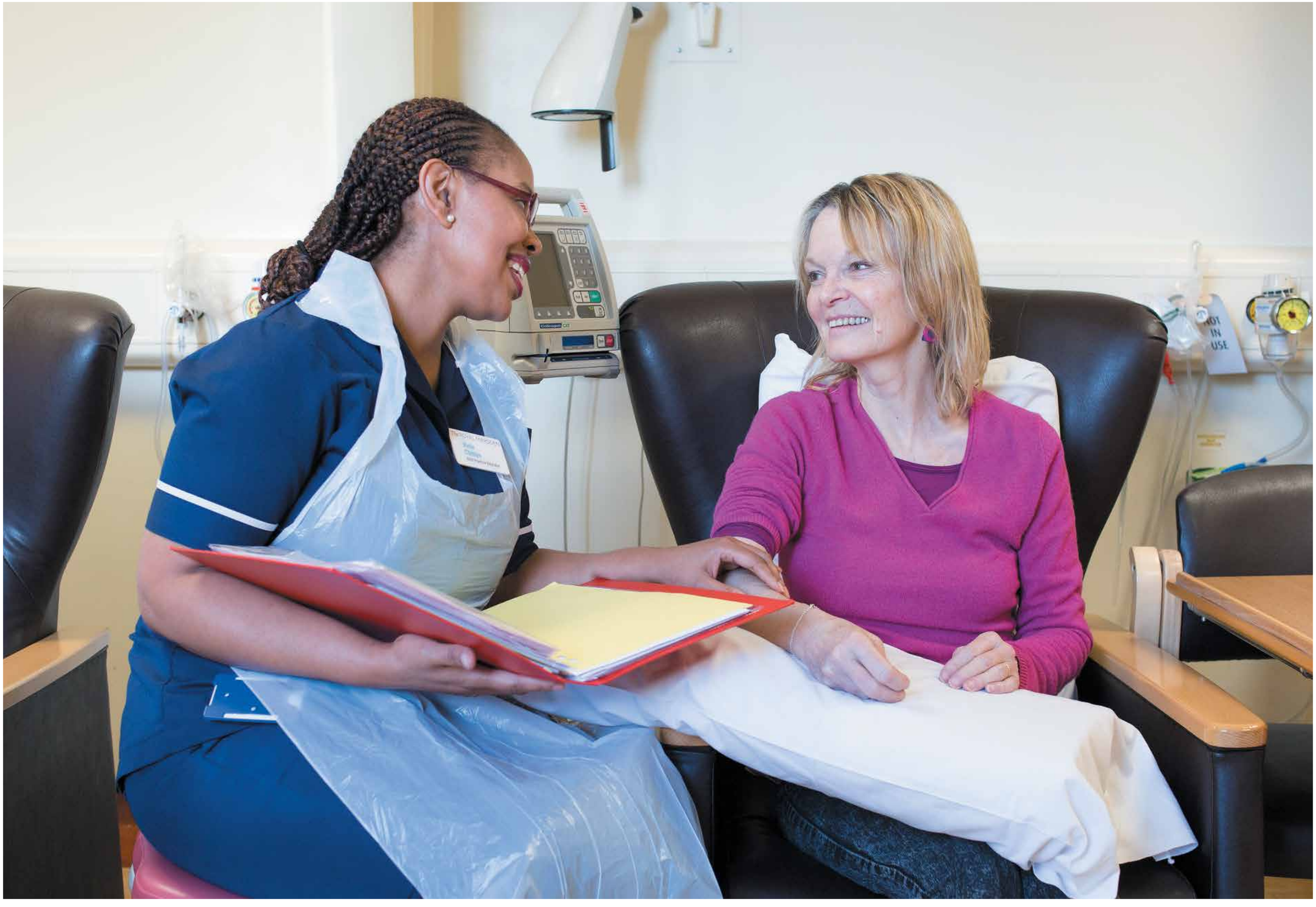
- Professor Johann De-Bono, Unit Director
- Dr Udai Banerji, Deputy Unit Director
- Dr Tim Yap, DDU/Lung
- Dr Juanita Lopez
- Professor Stan Kaye
- Ten Clinical Research Fellows
- Head of Operations
- Regulatory Specialist
- Ten Clinical Data Managers
- Eight Clinical Trial Coordinators
- Matron
- Sisters
- Clinical Nurse Specialist
- Practice Educator
- Staff Nurses
- Health Care Assistants
- Scientific Officers
- Three Ward Clerks
- Good Clinical Practice Manager
- Four Personal Assistants
- Three Ward Clerks
- Biological Speciman Coordinator
- Head of IIT Team
- Nine IIT Team members
- Finance Coordinator
- Administrator.

If you are interested in visiting our unit to gain an insight into Phase I study management, please contact Head Of Operations Or Oak Ward Matron.

Contact us

Dr. Bindu Baikady, Head Of Operations
bindu.baikady@icr.ac.uk
Ext 3524 (71 3754 from ICR)

Angela Little, Matron
Tracy Clark, Ward Sister
Nela Simoes, Day-Care Sister
Ext 6000/6001 (71 6000/6001 from ICR)


DO NOT IN USE

The Royal Marsden Clinical Trials Unit

The Royal Marsden CTU has overall responsibility for all The Royal Marsden sponsored clinical trials. This includes multicentre and single centre clinical trials with Investigational Medicinal Procedures, devices and evaluation of other approaches to treatment eg new radiotherapy regimens.

Our team

- CTU Operations Manager
- Clinical Trial Database Programmer
- Clinical Trial Monitor
- Senior Trial Manager
- Trial Manager.

What we do

- Protocol design and assistance with funding applications
- Set-up and maintenance of Trial Master Files
- Obtaining relevant approvals eg ethics and regulatory approval
- Case report form (CRF) design or electronic CRF design
- Database specification, design and testing,
- Site initiation and on-going management of trials
- Set-up and coordination of committees to manage multicentre trials eg Trial Management Group (TMG), Trial Steering Committee (TSC) and Data Monitoring Committee (DMC)
- On-going data review and data cleaning
- Preparation of amended documents and obtaining relevant approvals
- On-site or central monitoring of data
- Provision of documents and information to clinical trial site(s)
- Closeout, final analysis and reporting.
- Provision and maintenance of clinical trial databases using Infermed MACRO, a clinical trial database system.
- Monitoring of all institutionally sponsored clinical trials of IMP (CTIMPs) whether they are managed by RM-CTU or coordinated by clinical units.

The Royal Marsden CTU does not generally get involved in site activities which includes but is not limited to, identifying consenting and recruiting patients, managing patient pathway, CRF completion, sample collection and processing and maintenance of investigator site file.

How we do it?

The Royal Marsden CTU has developed a set of unit specific standard operating procedures (SOPs) which are available for review on The Royal Marsden intranet.

Contact us
Sally Ellis, CTU Operations Manager
sally.ellis@rmh.nhs.uk
Ext 6503 (71 6503 from ICR)

Research Data And Statistics Unit

RDSU is a unit within the Clinical Research and Development Directorate and comprises of Statisticians and Clinical Trials Database Programmers. They are mainly based in Orchard House at The Royal Marsden site in Sutton but also have an office in the Dame Unity Building at The Royal Marsden site in Chelsea.

Each clinical unit has a statistician assigned to them and they should be involved in all research projects (audits, service evaluations and clinical trials) sponsored by The Royal Marsden from the very early planning stages right through to publication.

If you are planning a new trial please contact the relevant member of RDSU for help as early as possible as your trial will not be approved unless a Royal Marsden (or ICR) statistician has agreed and signed off the protocol before submission.

What we do

The RDSU team is responsible for ensuring statistical integrity of all clinical research from audits to clinical trials sponsored by The Royal Marsden.

The statisticians should be an integral part of the trial team from early on and provide input into the following aspects of the trial:

- Input and advice on the most appropriate trial design
- Checking / defining endpoints that are statistically robust and relevant to the objective
- Selecting appropriate analysis methods for all endpoints
- Performing sample size calculations to ensure the trial is adequately powered to answer its hypothesis
- Reviewing the CRFs /eCRF drafted by the study team ensuring they are collecting relevant information in order to achieve all endpoints
- Building and testing appropriate databases ensuring appropriate checks are included
- Drafting statistical analysis plans ensuring all analyses are agreed by the trial team prior to any examination of the data
- Preparing trial reports as required for Trial Management Groups, Trial Steering Committees or Safety Review Boards (Phase 1 only) and in-confidence for Data Monitoring Committees
- Completing final analysis reports and reviewing any publications.

Please note that specific RDSU SOPs are found within the RDSU subfolder of the R&D SOPs intranet link within the Clinical Research and Development directorate and need to be followed by all members of the trial team.

Contact us
Clare Peckitt, Lead Statistician and RDSU operations manager
clare.peckitt@rmh.nhs.uk
Ext 6269 (71 6269 from ICR)

The Institute of Cancer Research Clinical Trials and Statistics Unit

The ICR Clinical Trials and Statistics Unit (ICR-CTSU) is a research led, academic trials unit embedded within the Division of Clinical Studies at The Institute of Cancer Research. ICR-CTSU is a Cancer Research UK core funded CTU; it is UKCRC registered and is one of fifteen CTUs recognised by the National Cancer Research Institute (NCRI) for the development and delivery of high quality cancer trials.

Our team

The ICR-CTSU is a multi-disciplinary clinical trials unit, which comprises more than 80 staff including statisticians, trials managers, data mangers and IT and research administration support staff. ICR-CTSU works under the strategic guidance of an independent Clinical Advisory Committee.

What we do

The main objective of the ICR-CTSU is to design, initiate, conduct and analyse national and international randomised clinical trials of cancer treatment which will directly influence routine clinical practice within the NHS and worldwide.

ICR-CTSU's main interests and areas of expertise are multi-centre, phase II/III randomised trials that evaluate new drug treatments and technologies (including radiotherapy) and/or utilise biomarker driven designs to clinically qualify putative predictive biomarkers. ICR-CTSU trials form an important component of the national portfolio of randomised trials in breast, urological and head and neck cancers with further trials in with further trials in rarer cancers including melanoma, sarcoma and ovarian cancer, working closely with the NCRI Clinical Studies Groups.

We collaborate with several other clinical trials units and more than 100 hospitals in the UK and abroad. Fundamental to both the scientific hypothesis, and to the conduct of these trials, is the targeting of treatments towards patients with the most potential for therapeutic gain and with integrated translational and psychosocial research.

Research funding for the majority of the trials comes from Cancer Research UK, with further funding from the Medical Research Council and/or the Department of Health. While our trials are non-commercial and academically inspired, for certain trials we work in partnership with the pharmaceutical industry and receive some funding in the form of educational grants.

Contact us
Claire Snowdon, Operations Director
ctsu@icr.ac.uk
Ext 4307/4013 (78 4307/4013 from TRM)

How we do it?

ICR-CTSU staff has expertise in the design, management and analysis of clinical trials, including:

- Statistical design and sample size calculation
- Preparation of protocols
- Preparation of funding applications
- Design of Case Report Forms (CRF)
- Specialist Clinical Trials IT systems
- Data collection and data management
- Data monitoring
- Quality assurance
- Trial management
- Analysis and reporting.

We like to be involved in clinical trials from the outset. We can offer assistance at all stages of trial design and implementation, working in partnership with clinical and scientific colleagues. As part of our role we:

- Review and comment on the options for the trial design taking into account both scientific and pragmatic issues
- Offer statistical advice and carry out sample size calculations
- Identify a protocol working group in collaboration with the Chief Investigator that can determine trial design taking account of additional specialities, eg translational research, quality of life studies
- Carry out a feasibility exercise to ensure study treatment is available, sufficient patients can be recruited, and that the trial can run successfully in the NHS and beyond
- Coordinate applications for funding
- Coordinate submission of a proposal for endorsement by the relevant NCRI Clinical Studies Group
- Coordinate regulatory and ethics applications
- Guided by the principles of GCP, ICR-CTSU work when coordinating the day to day management of trials encompasses:
- Preparation of trial protocol and patient information sheets
- Database design and development
- Quality assurance including Standard Operating Procedures (SOPs)
- Regulatory and Ethics Committee approvals
- Randomisation and registration service 9am to 5pm
- Trial initiation, coordination and management
- Data management, monitoring, analysis and preparation of study reports.

Further information on our current staff, trials portfolio and working with us can be found on the ICR-CSTU internet pages: www.icr.ac.uk/our-research/our-research-centres/clinical-trials-and-statistics-unit

Useful acronyms and abbreviations

Local

CCR	Committee for Clinical Research
BRC	Biomedical Research Centre
DDU	Drug Development Unit
ICR	Institute of Cancer Research
ICR-CTSU	Institute of Cancer Research- Clinical Trials and Statistics Unit
MDU	Medical Day Unit
RDSU	Research Data Management and Statistics Unit
R&D	Research and Development
RM\RMNHSFT	Royal Marsden\Royal Marsden National Health Service Foundation Trust
RM CTU	Royal Marsden Clinical Trials Unit
SBS	Shared Business Services (Finance programmed for NHS)
TSM	Trial Set-Up Meeting (for hosted and sponsored interventional studies)
WWCRC	West Wing Clinical Research Centre

Regulatory and organisations

ARSAC	Administration of Radioactive Substances Advisory Committee
CRN: South London	Cancer Research Network: South London
FDA	Food and Drug Administration (USA)
HRA	Health Research Authority
HTA	Human Tissue Authority
IG	Information Governance
IRAS	Integrated Research Application System
IRB	Institutional Review Board
MHRA	Medicines and Healthcare Products Regulatory Authority
NIHR	National Institute for Health Research
REC	Research Ethics Committee

Job titles

AP	Assistant Practitioner
CI	Chief Investigator
CTA	Clinical Trial Administrator
CTC	Clinical Trial Coordinator
PI	Principal Investigator
SBSC	Senior Biological Specimen Coordinator
SpR	Specialist Registrar
STC	Senior Trial Coordinator
STM	Senior Trial Manager
Sub-I	Sub-Investigator

Trial terminology

General

CAPA	Corrective and Preventative Action
CRF	Case Report Form
CRO	Contract Research Organisation
CTA	Clinical Trial Agreement
CTA	Clinical Trial Authorisation (MHRA)
CTIMP	Clinical Trial of Investigational Medicinal Product
DMC	Data Monitoring Committee
FD	Financial Disclosure
GCP	Good Clinical Practice
IDMC	Independent Data Monitoring Committee
ISF	Investigator Site File
PIC	Patient Informed Consent
PIS	Patient Information Sheet
PSV	Pre Study Visit
SIV	Site Initiation Visit
SOP	Standard Operating Procedure
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

Safety

AE	Adverse Event
DSUR	Development and Safety Update Report
IB	Investigator Brochure
PK	Pharmacokinetic
PV	Pharmacovigilance
RSI	Reference Safety Information (IB, SmPC)
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SmPc/SPC	Summary of Product Characteristics
SUSAR	Suspected Unexpected Serious Adverse Reaction

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