RICHMOND Pharmacology

Early Phase Clinical Trial Excellence

Our Specialist Services at a glance

Richmond's long established partnership with a world-class Scientific Advisory Board provides medically driven outcome based solutions and puts us at the forefront of the industry globally

About us

As a research organisation run by healthcare professionals, Richmond Pharmacology makes a meaningful contribution towards bringing new medicines to market. We interact with healthy research volunteers, patients, clinical and academic specialists in their respective fields, to ensure our research meets the highest regulatory, scientific, quality and ethical standards. We are personable, flexible, adaptive to change to meet clients' expectations and transparent in the process.

The new clinical facilities by the campus of Guy's Hospital and Kings College London offers state-of-the-art premises ideally positioned to provide the infrastructure and expertise to conduct complex studies safely. The new site, formally known as Guy's Drug Research Unit, adds a world-renowned university and large acute teaching hospital trust to our portfolio, in addition to St. George's where we have been based since our foundation in 2001. Richmond's long established partnership with a world-class Scientific Advisory Board provides medically driven outcome based solutions and puts us at the forefront of the industry globally.

Our accreditation by the Medicines and Healthcare Products Regulatory Agency provides assurance that you will be working with a credible organisation that conforms to only the highest of clinical and regulatory standards.

Richmond Pharmacology - 15 years of outstanding achievement

For 15 years, Richmond Pharmacology has delivered clinical excellence from design to delivery of early phase clinical trials, going from strength to strength in a fiercely competitive market place. Our new research facility is the fourth clinical research unit we will have designed and operated and its blueprint is the result of 15 years expertise in running early phase clinical research. It combines the long-standing tradition of the site with our working practices to match the needs and expectations of innovative sponsors.

We have experience that is held by our long serving management team and are reputed for our customer focus, flexible approach and strong project management. We have conducted over 300 Early Phase Studies. We have developed an efficient approach that allows us to combine different designs into one protocol, leading to objectively faster development times from First in Human to Proof of Concept studies. Our integrated platform is designed to streamline every aspect of Early Phase trials with quality, integrity and accuracy.

What makes us special

We are well established in a competitive market place and are a recognised stakeholder on a national, European and global level, helping drive the clinical research sector forward. We are intellectually engaged, adding value by working with our clients to achieve the best possible outcomes for them. We are small enough to care and to be personable, yet large enough to perform well in the largest of studies.

We are highly specialised in Adaptive Phase I, QT studies, Japanese and Patient studies. Richmond's volunteer database is the single largest of its type worldwide with over 225,000 registered volunteers actively seeking to take part in a clinical trial. The intelligence we gather enables us to make firm commitments and to adhere to agreed timelines. We are attentive and thorough in our attitude. We deliver a professional and courteous service establishing long-term working relationships with our clients.

Full service offering:

- Clinical pharmacology consulting
- Medical writing
- Regulatory applications
- CRF design
- Clinical conduct
- In-house volunteer catering
- Drug Free Plasma
- Pharmacy
- Laboratory
- ECG core laboratory
- Data management

TQT and iQT

Thorough and intensive QTc Studies

Richmond Pharmacology has a globally, well recognised expertise in providing consultancy and expert reports on cardiac safety, the clinical conduct of intensive ECG studies, core laboratory services such as adjudication and the cardiology over-reading of automated interval measurements. We have expertise in statistical analysis concentration-effect modelling (CEM), reporting and publishing. We have a 10 year track record in conducting QTc studies. We can conduct ICH E14 TQT studies or use CEM during Japanese bridging and/or early SAD and MAD studies eliminating the requirement for a dedicated TQT study.

Richmond Pharmacology provides their clients with FDA compliant state of the art analysis methods, and provides the option to include a non-pharmacological method of proving assay sensitivity. Richmond's unique and innovative approach means that we conduct our studies and prove assay sensitivity as a standard feature. This has provided quality data in many non-TQT studies eliminating the need for a dedicated TQT study.

Unmatched expertise

Our core ECG laboratory provides a centralised system for all our studies. It has the longstanding commercial, clinical and academic reputation of excellence of St George's University in London, a world class provider in cardiology. High-precision ECG acquisition in our tried and tested clinic allows meaningful ECG analysis with a smaller sample size, making us the ideal choice for the integration of cardiac safety in FIH and MAD studies.

Richmond Pharmacology's clinical facilities and the on-site core lab are a permanent set-up offering an unmatched focused work environment with no additional costs, thereby delivering value for money to pharmaceutical Sponsors. We are a leading publisher in this area and have publicly accessible credentials. We are proud of our integrity, our professional growth and experience in this field.

Richmond Pharmacology develops optimal and **cost-effective strategies** for TQT waivers

All QTc studies are performed in collaboration with **world renowned opinion leaders** in cardiological analysis

Richmond Pharmacology study data is well respected by regulators such as **FDA, EMA** and **PMDA**

Combined Adaptive Early Phase Trials

One single centre approach for **faster development** to POC-flexible protocols, simple trial logistics, **enhanced data quality**

Phase I programmes from FIH to POC are performed and **completed in 4-9 months**

Richmond Pharmacology has a proven track record of **MHRA and Ethics approval** within 4 weeks of submission

From First-Time-in-Human to Proof of Concept

Richmond Pharmacology actively works to maximise return on our Sponsors' trials, having routinely developed and conducted adaptive protocols to support rational "no-go" or "where to go next" decisions. The benefits of using adaptive design can be best exploited in combined "umbrella" protocols, whereby an entire early phase programme from First-Time-in-Human (FTIH) to Proof of Concept (POC) can be performed within one trial protocol in a single centre. Value can be added by integrating ethnic comparison elements and further drug development can be de-risked by integrating intensive cardiac assessments and other biomarkers into a combined protocol.

Systematic and logical protocols

Our transparent and systematic 3-step approach ensures that all potential adaptive features, their boundaries and study control mechanisms are considered and fully described to allow continuous learning from data that is being gathered. Such a strategy allows us to adapt and modify the trial design without undermining the validity and integrity of the trial.

Competent and Fast Decisions

We have a highly specialised medical team who, in collaboration with our dedicated in-house data management team and multidisciplinary partners, maintain close communication with our Sponsors for competent and fast decision making. Our goal is to constantly review emerging and quality controlled data to modify the study within the pre-approved limits and boundaries to meet the study objectives and guarantee a rapid trial progression while focussing on participants' safety.

Rapid approval

Richmond's established adaptive protocol format enables us to run entire Phase I programmes, including first evaluation of efficacy in groups of patients as part of one protocol and following a single regulatory and ethical approval. We have an excellent track record for starting studies on time and effectively managing ethics and regulatory submissions, with processes that are tailored to ensure a minimum of queries and rejection letters.

Whilst progressing through the various parts of a combined trial, there is no need to share interim data with the competent authority or ethics committee, unless there is intention to go beyond pre-defined and approved adaptive boundaries.

Japanese studies

Bridge the gap in your next clinical study

By gathering Japanese data sets from Phase I, potential ethnic variations can be detected early on adding value to subsequent global development programs. Richmond Pharmacology has the experience and expertise to empower bridging strategies. Through our track record of accepted submissions we have built up a strong relationship of trust with Japan's Pharmaceuticals and Medical Devices Agency (PMDA) and have an in-depth understanding of the specifics needed to submit a complete clinical data package.

Japanese clinical team

Richmond's experienced in-house Japanese team, accounting for 20% of our workforce, includes a Japanese GMC registered doctor, nurses, study managers and recruitment staff who are involved in all aspects of your study. The large contingent of Japanese staff facilitates good communication, accurate reporting of adverse events and helps our volunteers feel comfortable and looked after by a team that understand their concerns and needs.

Experts in Japanese recruitment

The Japanese marketing and recruitment process is managed and conducted in-house. This gives us clear oversight and control over the marketing and recruitment campaigns for studies we run with Japanese volunteers. The targeted community outreach campaigns are driven through our longstanding and well-known brand trials4japanese, generating 60-120 new Japanese registrations each month, thereby aiding our on-time recruitment record. Our dedicated in-house Japanese recruitment department provides all Japanese volunteers with a personal experience that results in over 40% returning to take part in further trials.

Richmond Pharmacology's recruitment **database** is the **largest in Europe** containing a panel of over **7,000** 1st generation Japanese volunteers

Richmond has **successfully** completed more than **60 studies** with Japanese volunteers since 2002

Richmond contributes to Japanese annual **scientific meetings** and has a good track record of **publications** in peer-reviewed journals

Participant Recruitment

Richmond has a database of more than **225,000 healthy and patient volunteers**

Richmond's database grows at an average rate of **1,000-2,000 registrants** per month

25 - The average number of calls received per hour from volunteers looking for **clinical trials** to take part in

31.8% (males) and **28.4% (females)** is the average conversion rate of subjects from screening to dosed into trials run at Richmond since 2001

Largest in the UK

Richmond Pharmacology is renowned for our recruitment capabilities. We maintain the largest early phase participant database in the UK with over 225,000 registered and pre-qualified volunteers willing to participate in clinical trials. We have pioneered the use of marketing and recruitment methods, our systems and long standing expertise. This allows us to adapt our recruitment efforts to efficiently screen in excess of 500 volunteers in a month to place up to 150 healthy volunteers and patients into the trials ongoing at Richmond.

Up for the challenge

Our extensive metrics and feasibility assessments offer Sponsors invaluable insight into study acceptability and suitability of the target population. This ensures accurate predictions of recruitment time and attrition rates which benefits the overall timeline planning for the trials we run. As a result, we are able to determine the recruitment effort and identify any potential challenges the study may present at an early stage development, thereby allowing time to address these challenges in a manner that will facilitate study conduct without compromising the scientific quality.

Tried and tested

Our dedicated in-house recruitment teams and personal touch ensure that volunteers are engaged from the first contact to the last appointment.

Our strategic and efficient management, complemented with the ability to modify standard strategies due to the unique demands of individual trials, allows us to:

- Gather homogeneous data with statistical significance in reduced sample size
- Limit participant exposure to what is essential
- Maintain a high (99%) completion rate for volunteers included in trials we run

Patient studies

Complex population panels made easy

We are specialists in recruiting challenging patient panels, bringing these patients to our unit from all over the UK. We have extensive experience of recruiting a multitude of complex volunteer panels including but not limited to patients with diabetic neuropathy, multiple sclerosis, schizophrenia and amyloidosis. One of our proudest recruitment achievements is the recruitment of genetically defined rare disease patients for a global Phase 3 study. Richmond Pharmacology was the first centre worldwide to dose a patient and the largest recruiting centre for this pivotal study.

Reduced variability

A single-centre approach in preference to a multicentre one for the conduct of early-phase patient studies presents numerous benefits:

- Your trials are conducted in a single centre dedicated to clinical research resulting in high quality homogeneous data acquisition.
- This has the potential for requiring fewer patients to demonstrate statistical significance producing valuable data at an early stage of development.
- Our specialised and experienced team work for you to recruit patients in a cost and time efficient manner.

High standard of care

Richmond Pharmacology facilities are adaptable to accommodate the requirements of different patient populations and study procedures. Richmond's clinical wards can accommodate patients for studies requiring long-term in-house stays; creating a safe and research-focused environment, whilst at the same time being a welcoming environment for healthy volunteers and patients.

>80,000 patients across numerous therapeutic indications registered to **our database** and looking to take part in a clinical trial

71 subjects with Relapsing Remitting Multiple Sclerosis included in a trial within **5 months** of initiating recruitment

>99% of subjects included in trials since 2012 have gone on to **complete the trial** they started

47 days - the **longest in house stay** by patients involved in clinical trials with Richmond

Full Service Clinical Trial Management

Richmond Pharmacology believe that effective project management is the key to meeting study timelines. Our team of highly experienced experts meet, plan and document every step of your study providing the following services:

Medical Writing

Richmond Pharmacology's Medical Writing Department has considerable experience in producing Clinical Study Protocols and Study Reports according to ICH guidelines. Each protocol is developed in collaboration with the Sponsor in order to fulfil Sponsor requirements and objectives. All protocols are written by Richmond Pharmacology's medical writing team, with input from Richmond Pharmacology's medical team including the Medical Director. The Clinical Study Report is the final deliverable and the one document for which the study will be remembered. Our experienced Medical Writing Department works alongside the clinical, data management and statistical analysis team throughout the study to ensure accurate representation of data and results of the clinical study.

Regulatory Applications

Richmond Pharmacology undertake all regulatory matters on behalf of our clients, depending on their requirements. In combination with our medical writers, our experienced project management team will compile all necessary documentation, including writing the information for volunteers, informed consent form and completing the on-line IRAS application form. Richmond Pharmacology can obtain necessary documentation and specialist opinions for ethics submissions in order to obtain approvals in a timely manner. We work closely with many ethics committees, local and nationwide, and will select an ethics committee based on study needs. Our Principal Investigators will attend the ethics committee meeting to participate in discussions facilitating a smooth approval process. We also organise and oversee the CTA application to the MHRA if required. We have submitted numerous CTAs to the MHRA on behalf of our Sponsors, often gaining approval after the first review of the study documentation.

Pharmacy

Our clinical trials pharmacy has been designed, commissioned and is operated in compliance with the MHRA best practice and GMP guidelines.

It is staffed by pharmacists and technicians with extensive experience of IMP preparation for clinical trials and supervised by two licensed GMP Qualified Persons (QPs).

As standard we offer to our clients the following pharmacy services:

- IMP manufacture/ assembly of solid, semi-solid and liquid dosage forms
- Batch QP Certifications
- Expert advice and input into IMPD development
- Preparation of study specific Pharmacy Manuals
- IMP label design - MHRA submission ready
- Importation of IMPs from non-EEA countries and issuing QP Declaration of Importation
- IMP dispensing, accountability and reconciliation
- IMP return, destruction and/or retention as required on study completion
- Sourcing of comparators and NIMPs for clinical trials
- Sourcing, preparation and supply of controlled drugs

We have the ability to store IMPs in a wide range of conditions to meet Sponsors product requirements. Ambient and storage temperatures are continuously monitored by a sophisticated temperature control system, which is alarmed as a safeguard against any excursions. The temperature data is exported, signed off electronically and made available to our Sponsors at regular intervals of their choosing.

Richmond Pharmacology Pharmacy Accreditations:

- Licensed by the MHRA for IMP manufacture - MIA(IMP) Licence 21878
- Licensed by the Home Office to possess and supply Controlled Drugs
- Registered with the General Pharmaceutical Council of Great Britain

Data management

Richmond Pharmacology offers a high quality data management service which is flexible, efficient and tailor-made to our clients' needs.

The Data Management department boasts a vastly proficient and integrated team of data managers, programmers and statisticians with many years of experience in the clinical research sector. They work to the highest standards that guarantee delivery of accurate data on time and within budget.

Our 'Under One Roof' approach ensures that the data management works closely, in a co-ordinated manner with the clinic. This reduces query management effort, guaranteeing the fastest time to database lock by eliminating inefficiencies often encountered when these two services are provided separately by different companies.

We offer paper-based and electronic data management services using our Oracle Clinical® platform and a number of EDC systems. Our service is comprehensive, spanning from CRF design, database build, data entry, query management, medical coding, database lock, through to export of final datasets. We are capable of delivering clinical trial data in various formats including CDISC compliant datasets or another format of our client's choice.

Data is analysed by Richmond's expert statisticians who are involved in all key aspects of a project from protocol and CRF design to statistical reporting. They have academic backgrounds with vast industry experience in all phases of clinical trials across numerous therapeutic areas.

Richmond's Data Management recognises the diversity of our clients' preferred methods of collecting, analysing and reporting clinical data. By listening and understanding these preferences we are able to adapt our standard processes to meet the needs of our clients. No matter how big or small they are, we provide a bespoke and, more importantly, superior service time after time.

Testimonials

"Please know that it has been an absolute pleasure collaborating with you and that I am most appreciative of the key contributions RPL has made to this project thus far. I hope I have the opportunity to work with RPL again in the very near future."

"We will again rely on your support, and we have every confidence that you will continue to provide the high level of service that you have already done."

"I am very pleased with the Project Management of both studies undertaken on behalf of (blank) and any future studies we have to outsource will automatically be contracted to you."

"We were impressed with Richmond Pharmacology's professionalism and knowledge base/experience with our study type as well as with Richmond's willingness to discuss the safety aspects and study design of our protocol."

Featured Publications

Thorough QT & iQT

Thorough QT study of the effect of intravenous amisulpride on QTc interval in Caucasian and Japanese healthy subjects. Taubel et al. Br J Clin Pharmacol. 2016 doi: 10.1111/bcp.13128

Comparison of digital 12-lead ECG and digital 12-lead Holter ECG recordings in healthy male subjects: Results from a randomized, double-blinded, placebo-controlled clinical trial. Wang et al. Annals of Noninvasive Electrocardiology 2016; 00(0):1-7.

Single Doses up to 800 mg of E-52862 Do Not Prolong the QTc Interval - A Retrospective Validation by Pharmacokinetic-Pharmacodynamic Modelling of Electrocardiography Data Utilising the Effects of a Meal on QTc to Demonstrate ECG Assay Sensitivity. Taubel et al 2015: PLoS ONE, 10(8): e0136369.

Concentration-Effect Modeling Based on Change From Baseline to Assess the Prolonging Effect of Drugs on QTc Together With an Estimate of the Circadian Time Course. Ferber et al. J Clin Pharmacol, 2014, 54(12): 1400-6.

Shortening of the QT Interval After Food Can Be Used to Demonstrate Assay Sensitivity in Thorough QT Studies. Taubel et al. J Clin Pharmacol, 2012; 52:1558-1565.

Insulin at normal physiological levels does not prolong QTc interval in thorough QT studies performed in healthy volunteers. Taubel et al. Br J Clin Pharmacol 2012; 75(2): 392-403.

Adaptive Phase I

Three steps to writing adaptive study protocols in the early phase clinical development of new medicines. Lorch et al. BMC Medical Research Methodology 2014, 14:84

The practical application of Adaptive study design in Early Phase Clinical Trials. Lorch et al. Eur J Clin Pharmacol 2012; 68(5): 543 -551

Japanese Studies

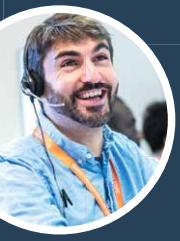
Pharmacokinetics and Pharmacodynamics of Lomitapide in Japanese Subjects. Taubel et al. J Atheroscler Thromb. 2016; 23(5):606-20.

Pharmacokinetics, Safety and Cognitive Function Profile of Rupatadine 10, 20 and 40 mg in Healthy Japanese Subjects: A Randomised Placebo-Controlled Trial. Taubel et al. PLoS One. 2016; 11(9):e0163020.

Recruitment

Benefits of a Single Versus Multicenter Approach in Early-Phase Patient Studies; A case of Multiple Sclerosis Patients. Berelowitz et al. The Monitor 2011 ; 21-25.

Early Phase Japanese Bridging Studies; Their Global Significance and What to Look for when Selecting a Suitable Contract Research Organisation to Conduct these Studies. Berelowitz et al. International Pharmaceutical Industry 3(1); 64-72.



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