

↘ Definitive QTc studies at Richmond Pharmacology Ltd

QTc studies at Richmond Pharmacology in collaboration with St George's University of London and Professor AJ Camm

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↘ Our goal

An integrated solution to your Phase I-IV Clinical Trial requirements

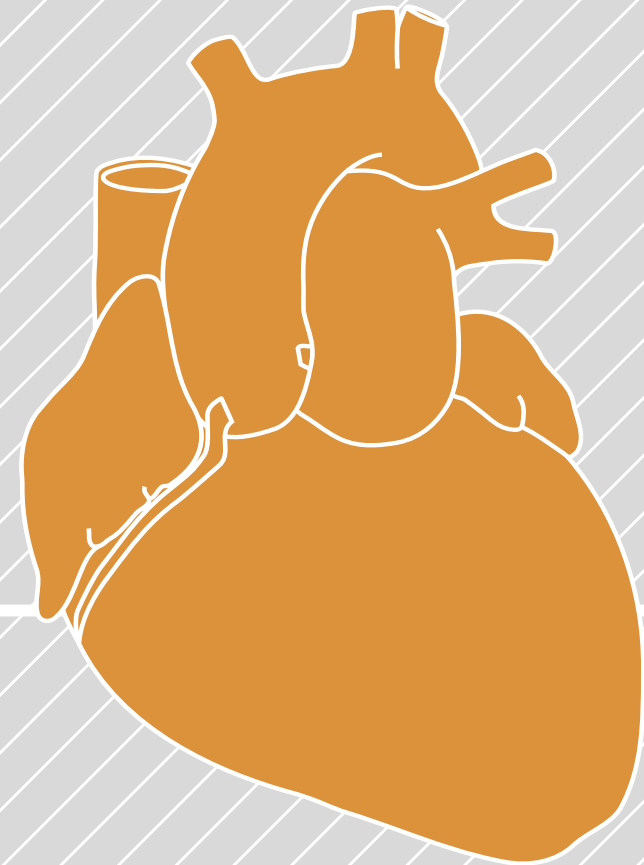
“Our goal is to deliver full service clinical solutions, swiftly, efficiently, and to the highest clinical standard. Our integrated set-up is designed to manage your Early Phase clinical study within the controlled environment of Phase 1. We compliment this through our out-patient facilities offering flexibility through the Early Phases in clinical trials.

Richmond Pharmacology is the UK's only Early Phase Clinical Research Organisation (CRO) to conduct trials from within 2 acute NHS Teaching Hospitals. We are based within St George's Hospital, St George's University London and Mayday University Hospital.

Through our unique NHS Trust surroundings, we provide innovative Early Phase clinical and SMO (Site Management Organisation) solutions to 7 of the world's top 10 pharmaceutical companies.

Finally, our on site access to consultants across an unrivalled range of therapeutic areas ensures your study is designed and delivered to the highest clinical standard, from protocol to report”

Dr Jörg Täubel, Managing Director,
Richmond Pharmacology



↘ The definitive QTc study

Two organisations working in collaboration for all your QTc study needs from study conception, clinical conduct, ECG data management, QTC measurement and analysis, through to the final study report.

Our unique fusion of clinical and technical expertise, ensures we are the world's only Clinical Research Organisation (CRO) running a digital MUSE platform connected to 85 stations uploading ECG data files instantly to our core ECG laboratories.

We have a special interest, and unique set up to run high volume intensive ECG studies, in collaboration with St George's University of London, a centre of excellence in ECG analysis pioneered by Professor AJ Camm, world leading cardiologist.

We offer expert advice on study concept and protocol design, and have in house clinical expertise, coupled with ECG data analysed on site by world leading cardiologists in our ECG laboratories.

This combination provides clients with the ultimate QTc study.

There are three essential components to any clinical study assessing the effects on the QT/QTc interval:

- 1) [The clinical recording of ECGs](#)
- 2) [The measurement and verification of measurements](#)
- 3) [The statistical analysis of potential effects](#)

Of these three, it is essential that the clinical recording of the ECGs is performed to the highest standard, as this provides the foundation for the other two components.

The definitive QTc study can stand alone, or part of your Early Phase clinical research requirements.



↘ Equipment and MUSE platform



Richmond Pharmacology utilise world leading, FDA and industry approved technology for the conduct of thorough QTc studies.

All our studies are performed using MAC@1200 electrocardiographs for ECG acquisition and integrated MUSE CV@ system for digital ECG management and analysis, both manufactured by GE Medical Systems.



GE MAC 1200

To facilitate efficient acquisition of ECG traces in a thorough QTc study, all beds at Richmond Pharmacology are equipped with dedicated 12-lead ECG MAC@1200 machines. The MAC@1200s are networked and connected via Lantronix boxes to the central MUSE server allowing continuous and immediate digital ECG transfer directly from the bedside.



12 Lead ECG Connections

This technology allows Richmond Pharmacology to digitally collect, process, analyse, store and export an almost unlimited number of the highest quality ECG's. The system is fully FDA CFR 21 Part 11 compliant.

ECGs are recoded on MAC@1200s and stored digitally on the MUSE server. They can be viewed and if required edited on the MUSE client terminals.



The MUSE client terminals are based in the Nurse Stations on the Richmond Pharmacology wards and in the designated offices. St George's cardiac sciences analytical suites, also have direct access to the central MUSE server at Richmond Pharmacology via secure link and dedicated MUSE client terminals.

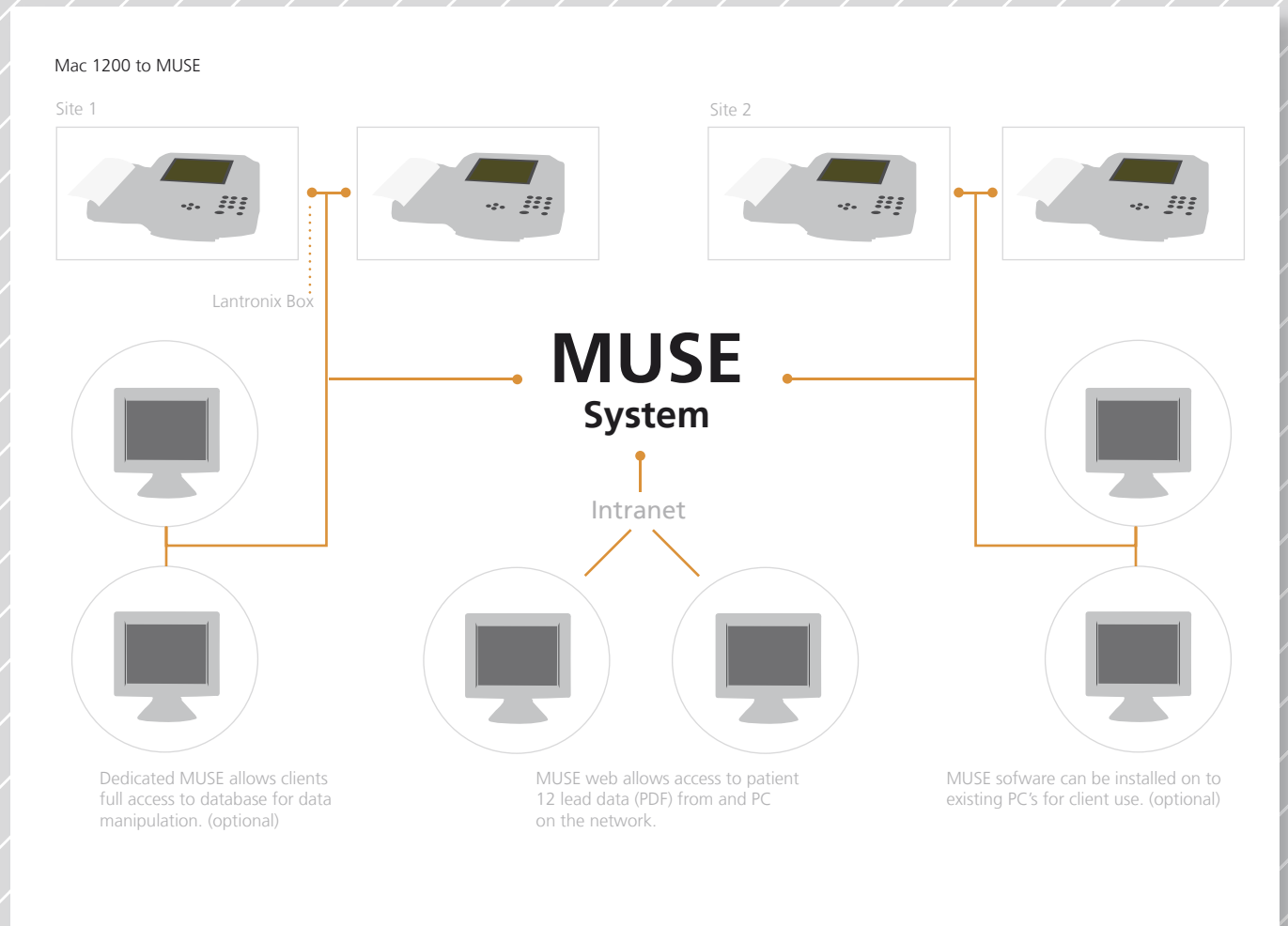


QTC Studies

The MUSE platform also enables Research Physicians to perform safety reviews on screen with immediate access to all ECGs and an editing facility, ensuring consistency between the digital data file and the Case Report Form (CRF).

Upon agreement, ECGs from ongoing studies can be remotely viewed by clients as PDF files, via secure password protected internet access to the digital ECG platform.

Continued



↘ QTC Studies

The MUSE CV® software offers the very latest in digital ECG management including:

- Digital data storage
- User-defined database searches
- Enhanced human review
- Measurement capabilities
- Exported ECG file

Digitally stored ECGs can be exported as .ecg files to external MUSE systems or as XML files to other systems. Equally, ECGs digitally recorded on MAC@1200 and MAC@5000 at external sites can be imported onto the MUSE server via modem or diskettes.

The MUSE server has storage capacity for over 5 million ECGs. The entire content of the server is backed up daily, and the backup tapes are taken off-site.

The ECG files on the backup tapes are in their original (.ecg) format and can be restored on a compatible MUSE system. Additionally, for archiving purposes, all ECGs can be downloaded in XML format, stored onto CD/DVD and kept in a secure off-site archiving facility for the time specified in a study protocol.

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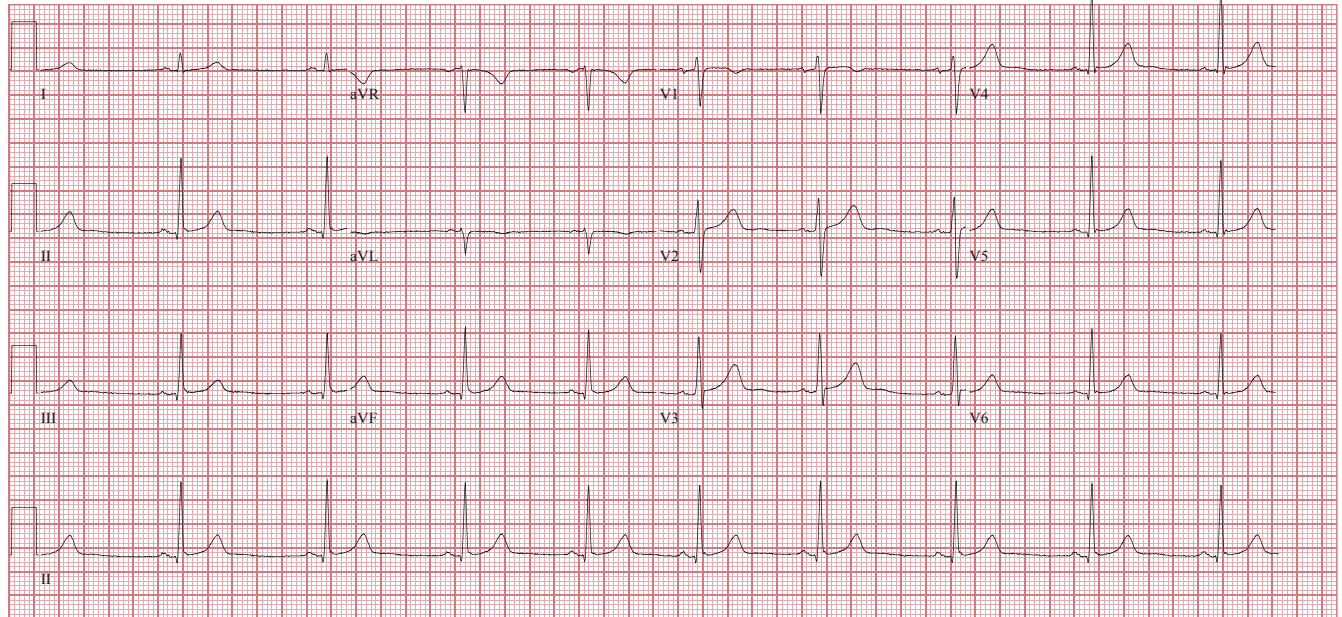
The MUSE system used for ECG management and analysis is validated and fully compliant with the current regulatory requirements for electronic records in clinical research.

This includes secure user name and password controlled access, different user privilege levels and full audit trail in line with the FDA's CFR 21 Part 11. User access on the MUSE system is controlled by the system administrator. For added data security, the server and client stations are based in controlled areas with authorised access only.



Name: ID:022842 02-MAY-2007 00:26:00 C06071-CARDIOLOGIST1
Unknown Vent. rate 57 BPM *** AGE AND GENDER SPECIFIC ECG ANALYSIS ***
PR interval 138 ms Sinus bradycardia with sinus arrhythmia
QRS duration 90 ms Otherwise normal ECG
Loc:5 QT/QTc 428/417 ms Confirmed by MOLINARI, MARIA LOIS (54) on 14-Feb-2007 11:42:04
P-R-T axes 44 78 68

Med: Referred by: TIMEPOINT: Confirmed By: VELISLAV BATCHVAROV
SUBJECT NO: VISIT:



25mm/s 10mm/mV 150Hz 005D 12SL 231 CID: 60

EID:4 EDT: 15:02 09-MAY-2007 ORDER:

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↘ Six steps to the definitive QTc study

1) Concept and QTc Study Design

Expert advice on study concept and protocol design, is available to clients.

Our unique collaboration with the renowned Department of Cardiac and Vascular Sciences at St George's University of London, provides access to world leading Cardiologist Professor AJ Camm and his colleagues for consultation on your QTc study.

2) Clinical Conduct

Richmond Pharmacology has extensive experience in the clinical conduct of highly intensive thorough QTc studies. All study procedures including ECG recordings are performed to very accurate and precise ('to-the-minute') study schedules by trained and highly experienced staff. Due to the complexity of such trials, we have a dedicated

team of nurses, doctors and technicians specialised in the conduct of thorough QTc studies within an efficient and safe hospital setting.

Prior to recording the nurses and technicians will ensure that all pre-requisites for high a quality resting ECG are satisfied. Our skilled staff will make sure that the same standards in skin preparation, lead placement and subject position are consistently adhered to throughout.

The recordings are taken and immediately transmitted to the MUSE server within a busy but quiet and orderly environment with no distractions to the study subjects. As they arrive at the MUSE database, the recorded ECGs are reviewed by a research physician on an ongoing basis and signed off electronically.

The review performed by the research physician includes a cardiac safety review and checking the trace quality. Signed-off ECGs will be printed from the MUSE and filed in the subject's Case Report Form (CRF).

3) ECG Data Management

Prior to commencement of the study, all ECG machines used for that particular project are configured to ensure that every ECG data file contains the exact and correct information in a standardised format as per client and protocol requirements. The configuration of an ECG machine is validated which includes acquisition and transfer of test ECGs from the machine's simulator. The entire configuration and validation process is fully documented.

During the study, Richmond Pharmacology's ECG data management team tracks all the

acquired ECGs and applies stringent quality control checks to ensure that all planned and unscheduled ECGs are accounted for, and that the time points, subjects' identifiers and demographic data are properly recorded. This process is done on an ongoing basis during the clinical conduct of the study which allows for the clean ECG data to be available for the analysis almost immediately as the last subject completes the trial.

After the study is completed, our experienced data managers can provide the collected ECG files in any format the clients require including .ecg, XML, SAS or ASCII format.

↘ Continued





4) QTc Measurement and Analysis

As standard, all ECGs are recorded in triplicate at each protocol time point from which the best quality recording is selected by a cardiologist for analysis.

In partnership with Richmond Pharmacology St George's University of London offers client's two main approaches in QT interval measurement and analysis:

- 1) Manual over-read by cardiologists
- 2) Semi-automated method with cardiologist verification

1) Manual over-read

In full manual over-read the QT interval is measured by a highly trained and experienced cardiologist using electronic callipers (MUSE CV® Interval Editor, GE Marquette Medical Systems) with sufficient magnification allowing the measurement precision equal to the storage frequency of 500 MHz, i.e. ± 1 ms.

Details of the analysis can be discussed and agreed with our clients at the study design stage as a matter of routine.

In every ECG a minimum of five consecutive QRS-T complexes that are least noise polluted are selected. For each of them the QT interval is measured in all 12 leads. The median QT interval of the 12 leads is determined for each beat and then the medians are averaged across the selected beats. The resultant QT interval is taken as representative.

2) Semi-automated

Alternatively, if this better suits client's needs we also offer regulatory compliant semi-automated QT interval measurements. In this method, interval markers derived by MUSE CV® Interval Editor are assessed for accuracy by an experienced and fully trained cardiologist. The degree of cardiologist input may vary to meet the client needs.

In line with the current regulatory requirements and at least every six months, all cardiologists at St George's University of London undertake intra- and inter-reader variability tests under blinded conditions to ensure that our measurements are as accurate and reproducible as possible. Furthermore, systematic in-process QC checks are performed by a senior cardiologist during a specific study analysis. All QC checks and any corrective actions are reconciled and fully documented.

The measured and verified QT intervals are corrected for heart rate using conventional population-derived formulae (e.g. Bazett, Fridericia) or an individually derived formula – or both. The QT/QTc interval data are then subjected to a statistical analysis in accordance with the current regulatory guidelines which also includes input and interpretation of the results from experienced cardiological scientists.

5) Report

We will present your data and results of the QTc analysis effectively and in a timely manner both as a 'stand-alone' report and incorporated in the integrated study report, as required. These reports are written by our professional, full time, in-house medical writers with senior cardiologist review and input. Your final, summarised data will be presented on paper as well as electronically.

6) Regulatory Acceptance

We undertake all regulatory matters on behalf of our clients depending on your regulatory requirements. We write and present the ethics submission and CTA application to gain regulatory approval for clinical studies from the relevant Ethics Committee and the MHRA. We attend ethics meetings and present all protocols to facilitate the efficient progression of your application through the regulatory progress.





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