



Emergency Scientific & Medical Services

CASE STUDY

ARTHRITIS PREVENTION IN THE PRE-CLINICAL PHASE OF RA WITH ABATACEPT Rheumatoid Arthritis

Lead Sponsor

King's College
London

Co-Sponsor

Guys & St Thomas'
NHS Foundation Trust

Overview

ESMS Client and top ten UK university in the world, King's College London - approached ESMS to support their phase IIb trial to investigate Arthritis prevention in the pre-clinical stage by providing a 24/7 emergency unblinding and medical support service supporting 206 patients for 5 years.

Situation

The King's team approached ESMS as they needed a solution to provide support to healthcare professionals looking after trial patients in medical emergencies and perform codebreaking as required in order to satisfy the following ICH-GCP E6-R2 and MHRA GCP guidelines:

"...medical personnel should be readily available to advise on trial-related problems or medical questions..."

"...Where investigators need urgent medical advice related to subject participation, they are able to access a medically qualified doctor 24 hours a day"

"...In blinded trials, the coding system for the investigational product(s) should include a mechanism that permits rapid identification of the product(s) in case of a medical emergency..."



Solution

ESMS has been providing 24/7 medical response service supporting patient safety for King's Health Partners for several years across a range of trials. Initially ESMS worked closely with the APIPPRA study team to price a solution that met the client's needs and funding.

We are aware, during planning stages that trial design often changes and are able to provide multiple quotations as required so that academic institutes can review their options and choose the best direction for their trial, whether this is running a smaller trial for a longer duration or vice versa.

ESMS experienced Project Managers are available to support the team through all the setup steps to customise ESMS service for the trial.

The finalised trial design went live with ESMS services December 2014 with the ESMS team of Information Scientists providing a rapid response service with instant access to trial documents and ESMS Consultant Physicians available for clinical discussion.

An example enquiry involved ESMS receiving an enquiry from a Principle Investigator wishing to unblind for a patient. Strict criteria for unblinding are agreed between ESMS and the client. For the APIPPRA trial these included:

- The medical management of the patient is dependent on knowing the treatment allocation.
- Not breaking a code if the patient has died as it will not influence their management.
- Requests for codebreak solely on the grounds of pregnancy should be referred to the Clinical Trial Investigator.

Since this request for unblinding came to the Principle Investigator via Coroner it clearly fell outside the above criteria and was escalated to the Chief Investigator for authorisation.

After discussion ESMS were approved by the Chief Investigator to perform the requested unblinding. In order to protect the data integrity and avoid unblinding the study team, ESMS provided the unblinded information directly to the Coroner.

The details of the enquiry were captured, fully documented and the associated SAE and code break were reporting to the King's pharmacovigilance team in blinded format within 24 hours of the enquiry receipt allowing the safety situation to be assessed for reporting to the MHRA.

Outcome

ESMS provide a GCP compliant robust 24/7 service to supporting patients and the healthcare professionals responsible for treating them. Provided by our team of qualified scientific team of Information Scientists and experienced, practicing Senior Consultant Physicians from the UK's largest teaching hospital. The team have immediate access to trial documents and a medical response time within 15 minutes. All enquiries are audio recorded, quality checked and reported to the client within 24 hours.

Client Feedback

"We have been very pleased with your service and we found you very professional in handling last year unblinding request."

Dr Mariam Al-Laith, Clinical Trials Manager

"A big thank you from me too, as CI. An exemplary service and very professional when we needed that one off unblinding – which was handled in a very innovative way."

Professor Andrew Cope, Chief Investigator and Professor of Rheumatology

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