



Emergency Scientific & Medical Services

CASE STUDY

Outsourcing Clozapine Monitoring Service Support

ESMS provide a 24/7 emergency medical response service for Clinical Trials and Medical Information to many of the world's leading pharmaceutical companies. With global contracts across 80 countries, speaking 45 languages, our background and culture is built on providing support in emergency situations.

Overview (Introduction)

Since 2008, ESMS have provided a robust, rapid and cost effective Out of Hours solution to a Global Pharmaceutical company in supporting their clozapine monitoring service in the U.K.

The Challenge

Clozapine is an antipsychotic medication used in treatment resistant schizophrenia and psychosis in Parkinson's Disease. Treatment with clozapine comes with a risk of agranulocytosis.

Since the introduction of the monitoring of white blood cell counts in clozapine patients, the incidence of those developing agranulocytosis has decreased markedly. When a clozapine monitoring service is not used, evidence suggests a mortality rate from agranulocytosis of 0.3%. This is in comparison with a mortality rate of 0.01% when clozapine is used in conjunction with a monitoring service.

It is now a regulatory requirement in many markets that blood monitoring should be carried out in clozapine patients in alignment with specific official recommendations, including daily blood monitoring in patients that fall below a certain threshold.

Given the frequency of testing of clozapine patients, often urgent need to access support for the service, and complexity of the testing protocols, the client was in need of robust and high quality Out of Hours support solution.

The Solution

Together with the client, ESMS implemented an Out of Hours call centre solution to support the Office Hours support provided in house by the client.

ESMS Information Scientists all hold a minimum qualification of a life science degree (including toxicology, pharmacology and pharmacy). Information scientists are rostered on shifts around the clock 24/7/365 to ensure that a call handler is always readily available.

ESMS worked with the client to understand the intricacies of the monitoring protocols and develop a detailed process for the handling of enquiries which was aligned with the client's internal processes. A bespoke training programme was also created to ensure that Information Scientists had a thorough understanding of the monitoring service, testing protocols, online system and specific pharmacovigilance requirements.



Together with the client, we have established a clozapine monitoring support service including the following features:

- + Ongoing updates to Out of Hours procedure to maintain process alignment.
- + Immediate support provided to nurses, pharmacists and physicians in entry and confirmation of results in the clozapine monitoring database.
- + Accurate guidance for healthcare professionals with regards to testing protocols.
- + Administrative support for online monitoring system users.
- + On-call access to the client's haematologist with back-up support provided by the ESMS medical team.
- + Regular support provided during office hours when required.
- + Accurate and timely reporting of Adverse Events and Product Complaints.
- + Calls answered in a timely manner (98% of calls answered within 30 seconds).
- + All calls recorded and all cases logged into ESMS's validated enquiry database.
- + Triage of enquiries regarding technical support for Near Patient Testing (NPT).

Outcome & Benefits

We take pride in our ability to offer a bespoke service for all our clients and their respective services offering 24-hour support.

Choosing us as the single provider for this service provided patients with access to experienced, well trained staff 24/7.

A high quality Out of Hours service has been provided by ESMS since 2008. During this time the Marketing Authorisation Holder has changed twice. The service has been consistently tested and described by the customer as an outstanding service. ESMS have since launched a similar service for a pharmaceutical company marketing clozapine in Ireland.

Other benefits included:

- + Expertise in the setup and management of a bespoke scientific call centre service.
- + Confidence of Healthcare professionals in being able to access support outside of office hours.
- + Security in knowing that high quality, professional support for the client's monitoring service was available around the clock.
- + Agility to change and improve processes throughout the life of the service.
- + Flexibility to utilize ESMS for office hours support to handle call surges and 'out of office' periods.

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CLINICAL TRIALS | MEDICAL INFORMATION

24/7 | 365

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