



Emergency Scientific & Medical Services

CASE STUDY

Medical Device 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.

Introduction

Where medical devices are used in clinical trials, direct-to-patient technical support is often required to ensure correct usage of the device and to allow for rapid identification of faults or associated adverse events. Subsequently, having the correct level of support can help to maintain patient retention.

Our client, a major pharmaceutical company with a global presence, conducted an oncology study across 50 sites in several different countries.

The study required patients to receive medication as a continuous rate infusion, via an ambulatory pump worn 24 hours a day. The client had a requirement to provide a 24/7 technical advice and support service for the device, with the ability to screen and report adverse events.

The Challenge

The client requested that ESMS set up and provided tollfree telephone lines to provide a comprehensive, 24/7 technical advice and support service for patients and healthcare professionals across all 50 global sites.

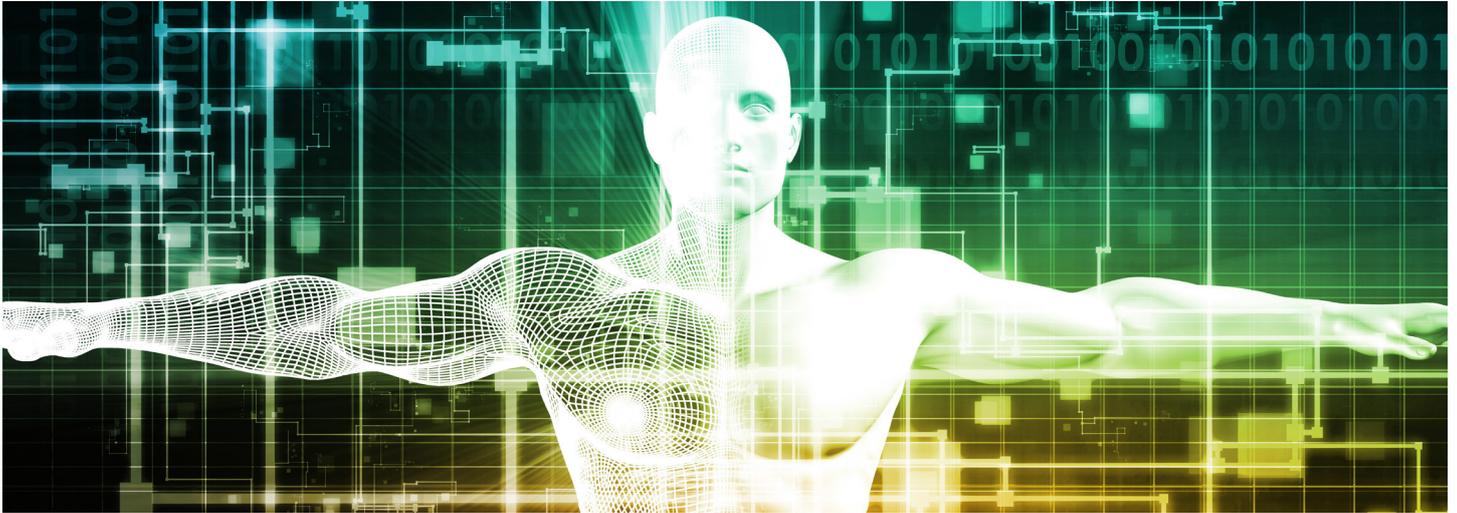
The support provided was tailored to the specific enquirer type. This was essential to ensure patients had access to the support they needed in a language they understood, while allowing additional information to be shared in sufficient detail with healthcare professionals. For example, when the alarm on the pump sounded, ESMS was required to be available to troubleshoot with the patient to resolve the issue.

The Solution

ESMS set up a dedicated network of telephone lines for the associated countries, with language support provided by interpreters covering more than 45 different languages.

Our highly-trained scientific and medical team were available 24/7 from our secure, manned office to provide clear and accurate information and to document and report adverse events.

Immediately after receiving an enquiry, an ESMS Information Scientist had a highly-qualified interpreter available on the line, facilitating a three-way conversation to answer the query with confidence. All staff were trained in using the device and were able to screen the enquiry for adverse events.



Solution cont'd

ESMS Information Scientists provided technical support based on the enquirer type:

Enquiries from Healthcare professionals

- Guidance provided included; locking/unlocking, priming and programming the pump.
- Checks in place after each enquiry to prevent accidental reprogramming by patients.

Enquiries from patients

- Patients provided with information from the Patient Materials.
- Patients referred to the research site or a local medical facility as appropriate.

Any adverse events or product complaints were fully documented and reported to the Sponsor immediately.

Monthly reconciliation reports ensured the client received details of all enquiries in a cohesive and reliable manner.

Case Study:

Call on day 1 from a patient concerned because their pump alarm was sounding with an error message.

- The ESMS Information Scientist assisted the patient to correct the pump using information from the Patient Materials. .
- Patient reassured that they could call back if there were any further problems.

Call on day 2 from the same patient – the error message and alarm had returned.

- The Information Scientist walked through the steps to correct the pump from the Patient Materials, however the error message remained.
- Patient advised to contact their site, so that the Investigator could contact ESMS for further assistance if there were still issues.

Call later on day 2 from the patient's investigator

- The Information Scientist talked the investigator through the steps required to unlock and re-prime the pump.
- The Investigator re-primed the pump successfully, the error was fixed and the patient was discharged from hospital.

Outcome & Benefits

We take pride in our ability to offer bespoke services to our clients and their respective clinical trials offering 24-hour support.

Choosing us as the single provider for this service provides patients with access to experienced, well-trained staff 24 hours a day, seven days a week. Using our interpretation facility ensures that language barriers are not encountered.

Other benefits included:

- + Patients and healthcare professionals can access technical advice and support at the appropriate level of detail, at any time.
- + Patient safety is improved whilst reducing the logistical challenge of tracking safety information from multiple sites.
- + A more cost-effective alternative to commissioning such a service at each site.
- + The highly experienced team are trained to recognise adverse events and direct the caller to the most appropriate resources.
- + Patients are fully supported in their homes 24 hours a day reducing unnecessary trips to site.

EMERGENCY SCIENTIFIC & MEDICAL SERVICES

CLINICAL TRIALS | MEDICAL INFORMATION

24/7 | 365

For more information, please contact:
Rita Fitzpatrick on +44 (0)20 7113 7878
 rita.fitzpatrick@esmsglobal.com
www.esmsglobal.com