



## Emergency Scientific & Medical Services

# CASE STUDY

## Telephone Diary Support Service

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

**During a review meeting, an ESMS client raised and shared with us a challenging and problematic issue that they were facing with the implementation of an eDiary with a group of patients taking part in one of their trials.**

This was a phase 3, randomised, double blind trial investigating treatment of Clostridium difficile infection, with a senior patient pool across 28 countries.

### Challenge

**The study design required that participating patients were to make daily entries about the study medication and their bowel movements into an electronic diary.**

Due to the nature of the therapeutic area being investigated, the patient population had an average age of 60 years.

Our client had been encountering some reluctance from patients to use the eDiary being provided with some patients choosing not to enrol on the study if the eDiary was mandatory.

As a result, this was having a major impact on the rate of recruitment of patients into the study.

Our client was looking to implement a protocol amendment that would allow for an alternative support service for collection of this vital data to be recorded on a daily basis, by contacting patients directly over the telephone instead of requiring them to complete the electronic diary. This would then allow for the recruitment process to grow for patients who would otherwise not be able to participate in the study.

An additional problem that they were facing was how to overcome subsequent language barriers as the patient pool was spread across 28 countries.



## Solution

**ESMS had been providing 24/7 emergency medical response services for this trial since it began. With existing telecoms and language support infrastructure already set up across the required 28 countries, coupled with experience in providing patient support services, the Telephone Diary Support Service was a straightforward and seamless addition to the services already provided to the client.**

ESMS worked with the client to develop the scope of the service and created SOPs, scripts and documentation describing how data would be collected from the patient, captured and transferred to the client database.

ESMS Information Scientists (IS) all hold a minimum qualification of a life science degree to include toxicology or pharmacology. The IS would call patients daily to talk through and collect the information for the eDiary questionnaire and facilitate patients by inputting the relevant data onto the software on their behalf.

Patient centricity - engagement and experience, was at the forefront of our discussions. Both ESMS and the client prioritised keeping the service streamlined and consistent for the patient, while also allowing the flexibility required for a service to fit into the patients' daily lives.

As discussions continued and the project scope evolved, ESMS adapted to the changing environment and worked closely with the client to ensure all requirements for the service were met.

**Together with the client we created a bespoke Telephone Diary Support Service including the following features:**

- + ESMS arrange a daily schedule of telephone calls with the patient in their local language.
- + ESMS call the patient at agreed times to check in and collect the required data.
- + Data collection method is designed to avoid bias.
- + Appropriate triage of patient queries unrelated to the Telephone Diary Support Service.

- + ESMS submit patient data into the client database (eCRF) as required.
- + Appointments made to suit all patients across all time zones as ESMS operates a 24/7 support service.
- + All Serious Adverse Events fully captured by ESMS and reported to the client PV within the required time frame.

## Outcome & Benefits

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

Choosing ESMS as the single provider for this service provided our client's patients with access to experienced, well-trained staff 24/7. Using our interpretation facility ensured that language barriers were neither an issue nor encountered.

**Other benefits included:**

- + Recruitment of patients who would otherwise not be eligible for the study.
- + A Direct to Patient, friendly, 'Non-IVRS system' outbound Telephone Diary Support Service.
- + Rapid submission of patient data by ESMS into eCRF means power of timely entry into eDiary is not lost by using this service.
- + Patients reassured that their valuable data would still be retained and eligible for the study without facing technical constraints.
- + Potential to reduce study timelines and associated costs due to improved recruitment.
- + The highly experienced team are trained to recognise adverse events and direct the caller to the most appropriate resources, if needed.
- + A more cost-effective alternative to commissioning such a service at each site.