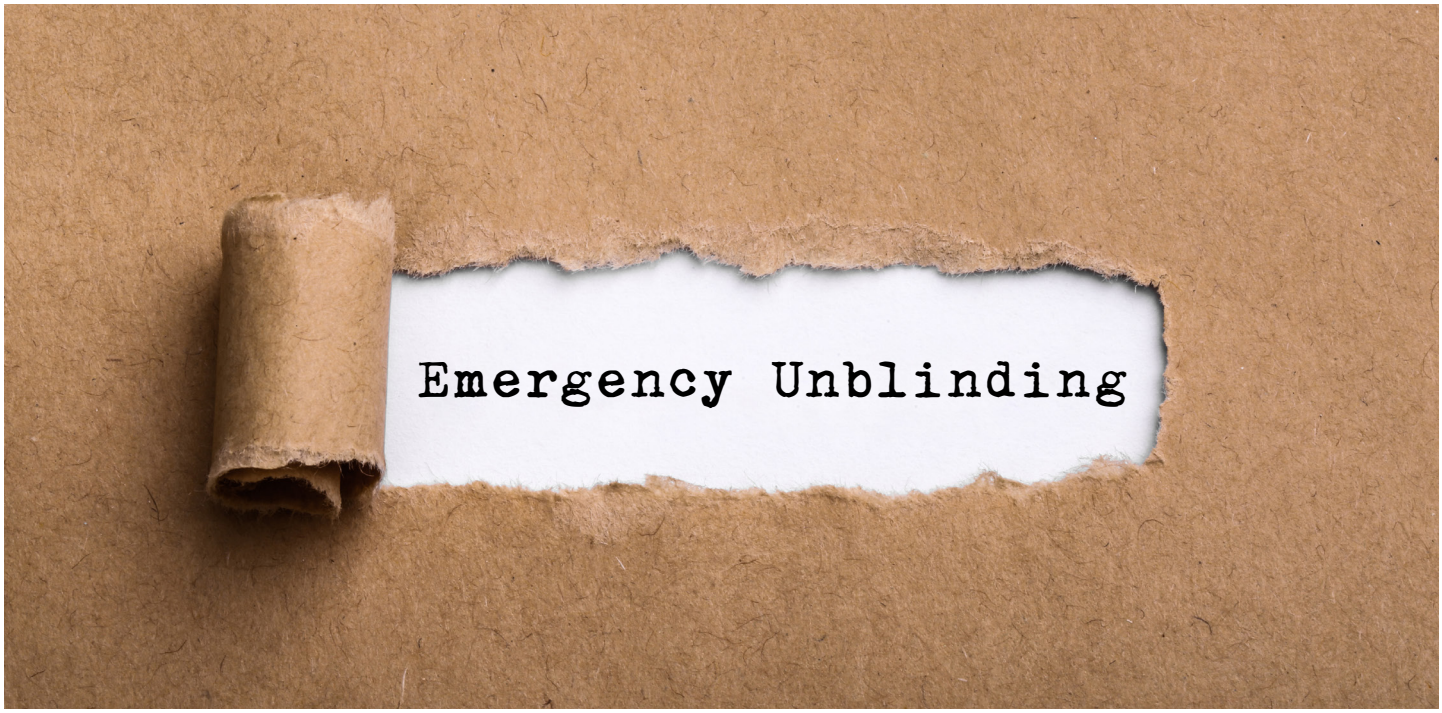

Emergency Scientific & Medical Services

CASE STUDY

Performing Emergency Unblinding

ESMS provide a 24/7 emergency medical response service for Clinical Trials and Medical Information to many of the worlds 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

In an emergency medical situation, the treating physician usually wants to know what study medication the patient is taking, and many of the calls that ESMS receive start with a request for unblinding.

While it is often possible to prevent unnecessary unblinding, in some cases it is essential for unblinding to be performed quickly, to ensure safe management of the patient.

However, it is crucial to ensure that the unblinding request is from an authorised user (usually the treating physician), and that the emergency management of the patient is indeed dependent upon knowing the treatment allocation.

In the following example, ESMS ensured these GCP-compliant, client-agreed criteria for unblinding were met and successfully unblinded the patient within the required rapid timelines.

Challenge/Situation

ESMS received a call at 10:57 from a study coordinator in Belgium, about a patient who was participating in a randomised, double-blind, placebo-controlled, phase III study investigating treatment of head and neck squamous cell carcinoma.

The patient had been admitted to an intensive treatment unit (ITU) that day with worsening pneumonia. Their treating physician had requested that the patient was unblinded, as they believed the pneumonia may be related to the study treatment.

The study coordinator stated that the treatment given to the patient would differ depending on whether they were receiving the investigational medicinal product (IMP) or placebo. However, they did not know which treatment the physician was intending to administer.

Solution

The ESMS Information Scientist (IS) reviewed the study protocol and Investigator's Brochure, and discussed the following information with the study coordinator:

- Pneumonia has been reported as an adverse event previously during studies involving this IMP
- Restricted concomitant treatments included additional experimental treatments and erythropoietin
- Caution should be exercised when combining the IMP with P-glycoprotein modulators

Based on this information, it was confirmed that it may not be necessary to unblind the patient. This would depend on the specific treatments the physician wanted to administer.

The IS requested that the treating physician call ESMS to further discuss the patient's treatment.

The treating physician called ESMS at 11:14. They confirmed that the patient had already been treated with methylprednisolone, moxifloxacin and clarithromycin for interstitial pneumonitis.

From the study documentation, the IS confirmed that administration of clarithromycin (a potent P-glycoprotein inhibitor) may increase exposure to the IMP.

The patient was successfully unblinded at 11:30 and the treatment allocation was relayed to the caller.

The SAE was fully captured and reported to the Sponsor Pharmacovigilance within 24 hours. An enquiry report was provided to the client within 24 hours for oversight. The report documented that the patient had been unblinded, but no details of the treatment allocation they were receiving were revealed.

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 24/7. Furthermore, using our interpretation facility ensures that language barriers are not encountered.

Other benefits included:

+ Information scientists are trained on strict unblinding criteria to prevent unnecessary unblinding.
+ Ability to rapidly perform emergency unblinding when this is required for safe management of the patient.
+ Immediate access to consultant physicians if a further clinical discussion is required.
+ The highly experienced team at ESMS are trained to recognise adverse events and ensure all SAEs are reported to PV within agreed time frames.

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