

Case Study - Epidermolysis Bullosa

Mobile Research Nursing and Medical Photography in this Challenging Condition

With this disease, management of the blistering of the skin is essential but very burdensome for the patient and family. Travelling back and forth to a site for study visits is extremely difficult as the skin is so fragile and the condition is often painful.



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Illingworth Research Group (Illingworth) were contracted to provide off-site research nursing and medical photography services for a first in human study in Epidermolysis Bullosa (EB). Our experienced research nurses visited the subjects at home and our medical photography department managed the imaging elements of the study. This combination of niche services is totally unique and ideal for studies with an imaging endpoint where travel to site is challenging for subjects and/or their family members.

The study involved patients in the US as well as Europe and included both adults and paediatrics. The protocol allowed for up to 6 of the study visits to be performed in the patients' home, making participation much less stressful for the individual and their family.



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Set Up Activities

Our research nurses acted as an extension to the study sites and met the site team and signed the delegation log prior to commencing any off-site activity. The off-site research nurses attended the site initiation visit so that they received the same in-depth imaging training as site staff. It also allowed the off-site nurse to build a rapport with the site team. Illingworth ensured that the mobile research nurses met their assigned patients at the site, prior to the first visits to the home. That way, the patients were introduced to the concept of off-site visits, met the specific nurse who would be visiting them and were able to ask questions about the service.

We believe that it is very important to introduce ourselves to the patients before turning up at the home, especially in rare disease and paediatric trials. We have child friendly information as well as stickers the children can choose from when they have completed their visits. These small adaptations make a big difference to the children involved.



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The study had an assigned Research Nursing Project Manager (RNPM) to co-ordinate with the Sponsor, site staff, mobile research nurses and logistics companies involved, such as couriers. The RNPM compiled an off-site nursing manual outlining all the tasks to be performed. This manual was reviewed and approved by the Sponsor prior to finalisation. In addition, nurses complete a source data sheet at each visit, which is reviewed and approved by the RNPM. This is then shared with site staff electronically and followed up with hard copies for the hospital notes.

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Study Specifics

The off-site nurses were trained on the selected image capture system so that they were able to create a tracing of the total wound area as well as capturing serial images of the wounds. In addition to this camera system, the patients or carers took weekly pictures of their wounds in between study visits using an app on their phone prior to using the topical investigational drug and redressing the wounds.

The patients or carers, depending on the patient's age, completed a wound specific questionnaire via an ePRO device (Electronic Patient-Reported Outcome). After successful image capture, the Illingworth off-site nurses uploaded study images into a dedicated bespoke imaging eDC system (Electronic Data Capture) for our medical photography department to perform quality checks prior to assessing the wounds. Illingworth managed the image quality control and expert central reader assessment. Illingworth works with many imaging devices that also offer integrated eDC/wound measurement systems.



This study included the collection and processing of numerous urine specimens for various biomarkers. Our nurses were required to process up to 10 different samples involving centrifugation of some of the samples which were then transported to the central laboratory. Some samples were couriered at ambient temperature, some chilled and some on dry ice.

Every Illingworth nurse carried standard kit, including a centrifuge for this purpose. If any repeat blood samples were required, our nurse performed venepuncture and processed the blood samples at home for couriating to the laboratory. Competency in venepuncture, especially with children, is critical and is a skill all our nurses have extensive experience conducting.



Additionally the nurses supported unscheduled visit requests, such as helping to provide support to patients with their ePRO device, if the patient was having user or technical issues at home. Nurses also helped when the patients total wound area needed to be remarked appropriately following their screening visit at site.

Quality Standards

All our nurses are indemnified to work in a home, work or even school setting. We have a full set of standard operating procedures (SOPs) in place for the off-site nursing service and have been audited by multiple Sponsors and inspected by Regulatory Bodies.