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Mobile Nursing in Rare and Paediatric Disease Studies

A case study

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What makes rare disease patients difficult to manage in a research study?

- Difficult to find and hard to retain.
- Patients may be geographically located far from an investigative site.
- Patients may be too ill or debilitated to travel.
- The protocol may require numerous visits to site for the patient.
- Emotional time for both the patient and their family.
- Financial commitment.
- Study interventions are more often extreme and invasive than other known research studies.



The use of Mobile Research Nursing services

- As patients may be rare and spread all over the globe, travel to a study site can be onerous and inconvenient.
- Using an in-home service will minimise disruption, caused by a clinical trial, to the patient's life.
- Home visits can provide solutions for the most common challenges in clinical trials: recruitment, retention, compliance and satisfaction of the patient.

Home visits are:

- convenient
- flexible
- less invasive
- less demanding for the subject



Optimizing the use and management of home healthcare

- Procedures that can be conducted in the home are substantially underestimated.
- Virtually all procedures carried out at the investigator site can be performed in the patient's home, school or place of work.
- Assessments according to the protocol may include:
 - AE/SAE assessment
 - Vital signs/ECG recording
 - Venepuncture and centrifugation/processing of samples (including dry ice shipments & even refrigerated centrifugation)
 - IMP administration
 - Questionnaires, training and education
 - Documentation of source data/CRF completion



DMD Case Study: “Rescue Study”

Study Design

A phase IIb, open-label study to assess the efficacy, safety, pharmacodynamics and pharmacokinetics of multiple doses of IMP in subjects with Duchenne muscular dystrophy.

Dose- escalation phase and then up to a 2 year treatment phase.

Once weekly administrations of IMP by subcutaneous Injection.

Biweekly blood sampling and sample preparation.



DMD Case Study: “Rescue Study”

- Issues: Children withdrawing from the study. The protocol required them to attend weekly hospital visits leading to a major loss of time at school, impact on education and a loss of earnings for their parents due to lost time from work and general inconvenience.
- Solution: Mobile nursing services to deliver and administer study drug and draw blood samples for patients at home or school.



Case Study: Drop Out Rate

This study was awarded in-home services after the project suffered
'significant drop out problems'

After initiating the home research nursing service for 2 years there was
ZERO drop out.

Feedback from a Family

QUOTE FROM A PATIENT

James said “the nurses make me feel happy and I don’t miss too much school.” Although James missed more school when we travelled to London, with the research nurses it was only half a day.

QUOTE FROM THE PARENT

My son, James was on a clinical trial for 3 years. We live on the Isle of Man and on a weekly basis we travelled to Great Ormond Street Hospital in London. When we were told that our visits to London would change to a monthly basis, the whole family were delighted. James still received his injection weekly but research nurses came to our home. It is marvellous, they were trained to follow all the protocols exactly as they were carried out at the Hospital. The nurses were more than giving the injections and taking urine and blood samples. I found the research nurses friendly, professional, energetic and extremely caring towards my son. It was like having a ray of sunshine helping us all.



Any Questions?



For further information about the services offered by Illingworth Research Group, please contact:

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Thank You

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