

Why use mobile research nurses in rare disease trials?



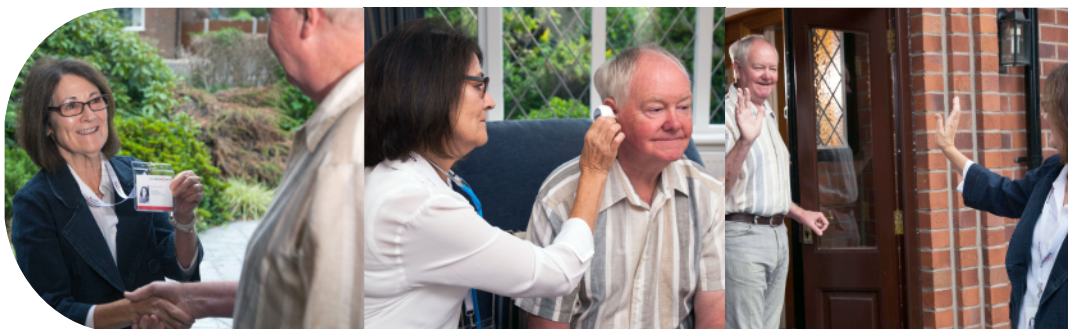
There are a limited number of patients with rare diseases and these subjects tend to be widely geographically dispersed. In addition, the cost per patient for a rare disease trial is typically significantly higher than for a standard, non-orphan drug study. A combination of these factors can mean that enrolment into rare disease clinical trials is challenging and patient retention is critical.

Working with Illingworth Research enables you to design the study in such a way that the patient and family are inconvenienced as little as possible. Utilising our global network of experienced research nurses to visit patients within their home setting also increases outreach to gain access to the limited pool of patients.

Providing Sponsors with this niche service allows patients, at often one of the most challenging periods of their lives, the opportunity to have some of their study visits performed at home, work or at school. Lessening the burden on patients and their families means better recruitment and fewer drop-outs which in turn leads to increased likelihood of a successful trial.

Our experience includes studies in a variety of rare diseases, including:

- Von Willebrand Disease
- Acquired haemophilia A
- Congenital haemophilia A
- Hunter's syndrome
- AA Amyloidosis
- Niemann-Pick Type C
- Graves' disease
- Fabry's disease
- Nelson's syndrome
- MELAS syndrome
- Prader Willi Syndrome
- Cystic fibrosis
- Carcinoid syndrome
- Duchenne muscular dystrophy
- Becker Muscular dystrophy
- Sanfilippo Syndrome
- Epidermolysis bullosa
- Dermatomyositis
- Pompe Disease
- Acquired thrombotic thrombocytopenic purpura
- Myasthenia Gravis
- Isolated hypogonadotropic hypogonadism



Our research nurses are able to carry out many procedures off site, including:

- Adverse Event assessment and safety evaluations
- Concomitant medication assessment
- Abbreviated physical examination
- Vital Signs including weight and height measurements
- 12-lead ECG
- Urine sample collection and processing
- Blood draw (PK, safety labs) and centrifugation process
- IMP administration (SC, IM, IV, central line, oral, nebuliser/inhaler)
- Diary compliance checks
- CRF, eCRF and Questionnaire completion
- Courier collection for samples including temperature regulated shipments
- Attachment/collection of monitors such as cough or spirometry monitors

Our Research Nurses visit patients 365 days of the year to ensure they are not lost from clinical trials - no matter where they live.



Why use mobile research nurses in rare disease trials?

Our research nurse geographical coverage

A large bank of experienced research nurses with years of clinical trial experience

Operating with Illingworth nurses in over 32 countries worldwide

Region	Countries covered by Illingworth
Europe	Austria, Belgium, Bulgaria, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Greece, Netherlands, Norway, Poland, Romania, Russia, Serbia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom
North America	Canada, USA
Australasia	Australia, New Zealand
Middle East	Israel, Egypt, Cyprus, Jordan*, Lebanon* (*in development)

Examples of rare disease trials conducted at home

Epidermolysis Bullosa (EB)

Children required lengthy soaking and removal of wound dressings. Our nurses photographed the skin blisters, redressed the wounds, uploaded the images to Illingworth's secure portal and then our Medical Photography department analysed and reported on the images.



Dermatomyositis

Subjects underwent twice daily sub-cutaneous infusions using a Chrono pump. The infusion sessions lasted up to 7 hours per day split over 2 sessions avoiding the need for the patient to stay in hospital.



Acute Stroke

After a 50% drop out, patients were given the option for Illingworth's nurses to conduct all study visits within the patient's home after discharge from hospital. Both patients and site staff agreed this makes participation in the trial easier and more attractive and drop out rates are now minimal.



Duchenne Muscular Dystrophy

P A Duchenne Muscular Dystrophy (DMD) study being run by a pharmaceutical company required paediatric patients to attend weekly hospital visits over a period of several years.

R The client approached Illingworth Research because of high dropout of patients, predominantly due to travel requirement causing loss of time at school, loss of earnings and general inconvenience for the whole family.

S After amending the protocol to allow flexible visits, Illingworth mobile Research Nurses conducted visits within the child's home or school. Our research nurses visited the children three out of every four weeks.

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

Parents and their children were delighted with the Research Nursing service and rapport developed, resulting in minimal loss of school time, no loss of earnings for parents and general disruption was kept to a minimum.