



## Off-Site Research Nursing

At Illingworth Research Group (Illingworth), we believe patient centricity is fundamental and developing a strategy with the patient at the centre is key to a successful clinical study. Illingworth have a history of providing highly trained research nurses (including paediatric nurses and midwives) who are able to relieve pressure from the patient by conducting study visits in a convenient location for the patient.

The terminology “off-site” does not necessarily mean “in the home”. It can also refer to the patient’s workplace, school or college, depending on the wishes of the patient and safety considerations from the Investigator. This provides a truly patient-centric solution, making the study fit around the lives of the patients. We have found that this personalised approach is an excellent way to boost patient recruitment, enhance retention, maintain compliance and build an optimum relationship with the patients.

### Overview

For many patient populations, travelling to the hospital site for clinical trial study visits can be a physically and mentally demanding experience. This includes patients who live a significant distance from the study site, suffer from a debilitating disease, have a chronic illness, mobility problems or neurological problems, as well as adults, and children with rare diseases (such as Duchenne Muscular Dystrophy) or patients with terminal cancer. Participation in a trial may cause patients and their carers major anxiety, inconvenience and result in loss of time at work or school caused by the need to physically attend clinic.

Many of the procedures typically associated with a trial visit can be performed off-site, providing the equipment needed is portable and the nurse is qualified to perform the assessments, including:

- ◉ Investigational Medicinal Product (IMP) administration (which may be intramuscular, via an intravenous infusion or bolus injection, central line, oral, topical or via nebuliser or inhaler)
- ◉ Adverse event assessment and safety evaluation
- ◉ Concomitant medication reporting
- ◉ Vital Signs, temperature (tympanic, oral, infra-red)
- ◉ 12-lead ECG recording
- ◉ Intravenous cannula insertion
- ◉ Blood draws (PK, safety labs), sample preparation and centrifugation
- ◉ Urine sample collection and processing
- ◉ Arranging courier collection of IMP and samples including temperature regulated shipments
- ◉ Attaching of monitors e.g. cough and spirometry monitors
- ◉ Diary compliance checks
- ◉ Questionnaire completion
- ◉ Weight and Height measurements
- ◉ Completion of CRF/eCRF and source documentation

### Research Nurse Selection

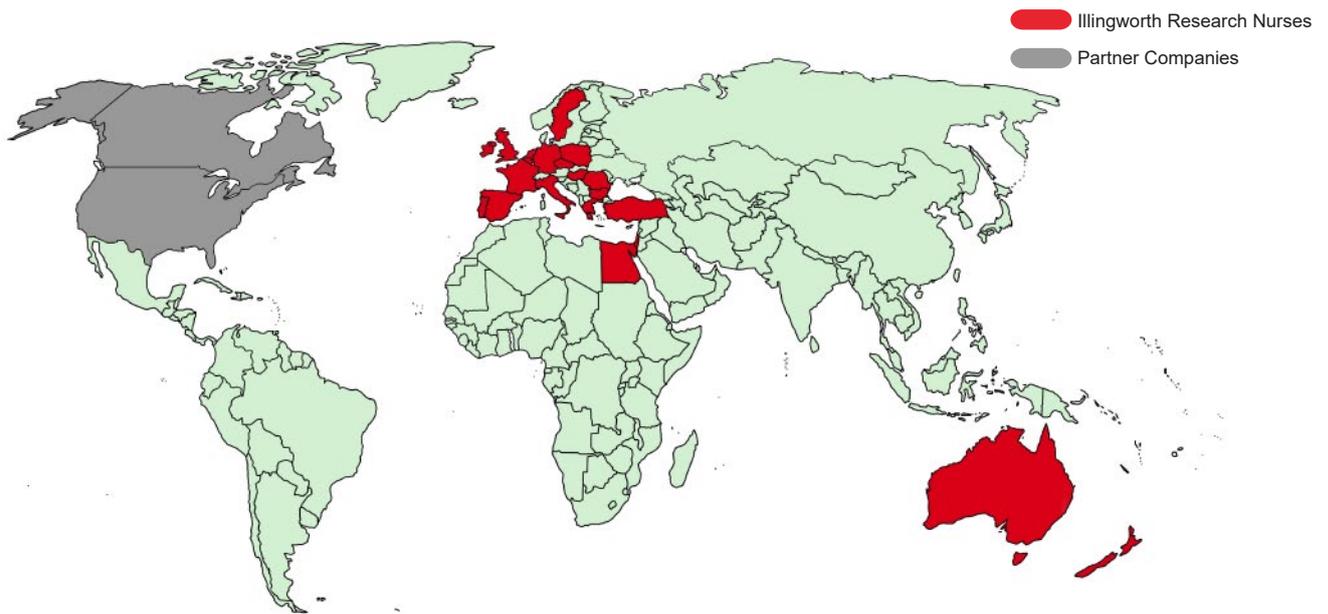
All research nursing staff at Illingworth are subject to a rigorous screening process at the time of interview and during pre-employment checks. Illingworth liaises with all the appropriate governing bodies to ensure the nurse’s documentation and professional qualifications are valid and current to ensure there are no “fitness to practice” or health issues that would affect their ability to perform their roles.

On appointment, we ensure that all nurses are up to date with regulatory and ICH GCP training, basic life support and other key skills. Annual updates are mandatory to ensure nurses can prove their personal and professional development. At the start of the study, all the research nurses will need to be approved formally by the sites. This involves security checks as applicable, including debarment status and registration verification.



## Geographical Reach

Our research nurse coverage is constantly expanding. Illingworth's research nurses are currently located in over 20 countries worldwide. With the appropriate lead time we can identify trained research nurses in many more countries.



## Happy patients increase retention rates

Below are some of the quotes provided by patients and site staff who have utilised our off-site nursing service;

"I see the same nurses all the time and they are very friendly and make me feel at ease. I can also be here when my son comes home from school."

"The best element of receiving home care was saving me having to travel a long distance every two weeks"

"Continuity and quality of care carried out by extremely capable and professional nurses"

"Illingworth Research Group were contracted to provide two nurses to support the patient care within my site for a Phase I, first in human trial in patients with advanced solid tumours. The trained research nurses conducted study visits within the patients' homes, allowing them to minimise the disruption to their lives whilst on the clinical trial. This service means that patients can have 3 visits per week conducted at a convenient location for them which is a major benefit in terms of their quality of life. Both research nurses have liaised well with the site and become an extension of the team at the centre providing the vital care these oncology patients need."

### Professor of Oncology, UK Clinical Research Site

The visits to my home are really convenient. Even though I don't have to drive far to the hospital, it saves me at least 1.5 hours. It is all very well organized and there isn't any waiting involved. It works very efficiently from the participant's point of view.

### Patient in a Chronic Cough Study

## Not forgetting our younger patients

As one of our nurses recalled, "one paediatric patient would happily sit while I gave her intravenous chemotherapy as long as I was dressed as a fairy complete with tiara and wings; she said that I was her "get better fairy" and that the medication was "magic potion". I was very happy to comply!" Home visits result in happier parents and increased compliance.

"When we were told that our on-site study visits at site would change from weekly to a monthly basis, the whole family were delighted. My son 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."

### Mother of Duchenne Muscular Dystrophy patient

