



Chronic Refractory Cough Programme Case Study

Chronic Refractory Cough can be a severely debilitating condition that is thought to affect up to 1 in 10 people globally. Sufferers report that it has a devastating impact on their daily lives, affecting their relationships, careers and ability to participate in social activities. In some cases, the severity of the cough can also lead to patients suffering internal damage. There is a huge unmet medical need when it comes to treating this condition.

Study Overview

Illingworth Research Group worked as the CRO partner on a chronic refractory cough programme including 5 studies over a 2-year period providing multiple services, including the identification, set-up, management and monitoring of the UK sites. The programme included a phase I study, 2 cough challenge studies and 2 phase II trials and involved 13 sites in the UK and 37 throughout the USA.

For the larger phase II study the UK made a significant contribution to recruitment and really helped drive the study to come in on time after a slow start in the US. The UK recruited 35% of the total study population in just 4 months and the screen-fail rate was also considerably lower in the UK. In the UK these studies are performed by specialised, regional cough centres whereas in the US the sites are more typically general respiratory sites. Illingworth Research has close links with all the UK specialised centres and also know the the best enrolling sites in the US.

The Illingworth Specialist Cough Team

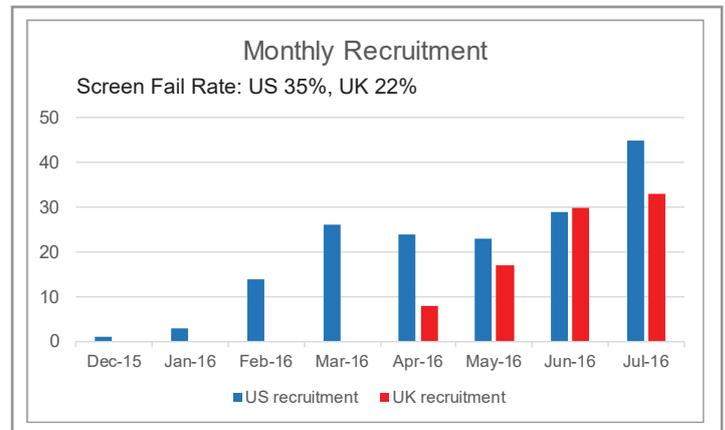
The Illingworth specialist cough team are available to work on other trials and this includes Project Managers, 7 UK based CRAs and 8 US based CRAs. All members of this specialist team have extensive industry experience and experience of working with VitaloJAKs - a 510(K) FDA approved and CE marked custom-built digital recording device (VitaloJAK, Vitalograph Ltd) and currently the only FDA approved cough monitor for use in clinical trials.

Additionally, we have conducted cough challenge studies involving the inhalation of tussive agents/substances such as ATP, Capsaicin, Citric Acid and Distilled Water. These substances were inhaled via a nebulizer, controlled by the KoKo DigiDoser and the number of induced coughs counted.

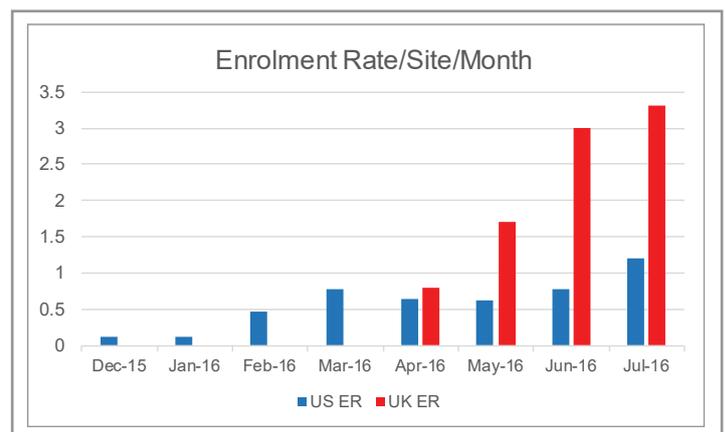
Quote from the Sponsor

"I would consider Illingworth Research experts in this indication and they have established strong relationships with key investigators. They have been a true partner with open, honest communication, exhibiting a high degree of professionalism and flexibility."

Vice President, Clinical Operations



The average patient enrolment rate across the US was 0.56 patients per site per month whereas the UK sites recruited 88 patients with an average of 2.2 patients per site per month.



"Thank you and what a great job Illingworth did for this study!"

Dr Surinder S Biring
Consultant Respiratory Physician and
Honorary Senior Lecturer,
King's College Hospital, London