



Virtual Phase 4 CTIMP Trial Case Study

Overview

A large Consumer Health company contracted with VCTC for a Phase 4 CTIMP Trial of an OTC product to treat the common cold. In this single centre study, 125 participants were to be enrolled over a 16-week recruitment period. Participants could be located anywhere in the UK and were to be identified via digital recruitment. Participants needed to be treated within 36 hours of first cold symptom. The study required rapid start-up to respond to an earlier than expected cold season.

Tactics

- Participant facing team comprised solely of Medics.
- Participants contacted within 1hr of registering interest.
- IP dispensed within 1hr of participant being enrolled.
- End-to-end IP services completed within 6hrs.
- Site team resourcing flexed up and down depending on intensity of recruitment drive.
- Daily follow-up to confirm diary completion.

Outcomes

- Direct to participant shipments of IP.
- Virtual investigator availability: 8am-8pm Mon-Sun.
- Consultant-level emergency medicine Investigator covering 24/7 emergencies.
- VCTC virtual clinical trial site.
- MHRA and Ethics submission.
- Participant screening and enrolment.
- Telemedicine visits with participants.



**Zero participants
lost to follow-up**



**Enrolment of 125 participants
completed within 4-weeks**



**Trial executed 4 months
ahead of schedule**



**100% IP shipment
compliance**