



Post-Marketing Medical Device Study in Venous Leg Ulcer Participants

Case Study

Overview

A global medical products and technologies company contracted VCTC to support a post-marketing medical device study of two dressings used to treat venous leg ulcers (VLU). Study data were being collected across multiple sites globally, to support product recertification and future reimbursement activities. In this rescue study, VCTC needed to enrol 40 participants in the UK. Participants were to be identified and treated in specialist NHS VLU clinics, within their standard of care, for the duration of the study.

Tactics

- Digital solutions provided, with all site documentation available electronically.
- A Central PI model that saw VCTC acting as a central hub providing research services to NHS-led VLU clinics.
- A dedicated medical team reviewed and confirmed eligibility information within 10 minutes of the data being submitted.
- Responsive and engaged Principal Investigator.

Outcomes

- Positive feedback from NHS VLU clinics about the new Central PI model.
- Fastest recruiting site globally, with 8.68 participants recruited per month compared to a global average of 1.25 participants / site / month for other sites.
- Recruitment of 42 participants in 4 months.
- Communication with the Sponsor team ensured site set-up was completed in 12 weeks, including submitting and gaining the required regulatory approvals.



Fastest recruiting site globally



42 participants recruited in 4 months



First-of-its-kind agreement to run a central Principal Investigator model with NHS clinics



Digital solutions for all aspects of the study