Virtual Phase 4 CTIMP Trial

VCTC Case Study

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Overview

- Fully virtual Phase 4 clinical trial in Europe that required a specialist clinical trial site.
- Study data needed to support product marketing for the next cold season.
- Enrol approximately 125 particpants to be enrolled in 5 months betweeen Nov-22 and Mar-23.
- Participants to be identified and recruited to take part through digital advertising.
- All trial activities to be completed by the participant via a study app downloaded to their mobile phone, and all site activities to be completed via a study portal provided by the CRO.

Sponsors

Blue chip Consumer Health company
Large digital CRO with DCT expertise

Challenges

- **Time-limited consent**
  Participants needed to be identified and consented to within 24 hours of the onset of their first cold symptom.

- **Common cold indication**
  Low interventional study and little benefit for participants as the IP was a medication already available over the counter. This was expected to result in low motivation from participants.

- **Time Rapid IP shipments**
  IP to be delivered to the participants' homes within 6 hours of consent, with baseline activities completed by participants between consent and IP release.

- **Realising the benefits of the study app**
  The study app was a one-stop shop that had everything required by participants to complete the study if they engaged appropriately. Early engagement with the app was important for participants to realise the benefits.

Outcomes

- Streamlined and efficient processes allowed an investigator-led, high-touch model for trial participants, whilst keeping Investigator (site) fees benchmarked against NHS equivalents and the UK NiHR costing model.
- Start-up processes and communication with the CRO and Sponsor team ensured a REC and MHRA submission was made within 2-weeks of being contracted to the study, and our site team expertise resulted in minimal questions received from the authorities.
- Our specialist pharmacy and processes ensured every single box of IP was delivered to the participant on the first attempt.
- Happy participants who completed the trial and would be willing to take part in future research.
- All participants recruited (136 consented and 100 completed) within a four week period.

Tactics

How VCTC overcame these challenges and achieved a successful outcome

High-touch engagement

- High-touch and proactive communications from our medical team, both through the study app chat function and via phone calls, engaged participants without the need for face-to-face contact.
- Having the medical team available both in and outside of normal working hours meant that participants could engage with the trial at a time to suit them.

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Case Study Tactics

Responsive and engaged Principal Investigator

The Principal Investigator on this study, Dr Ravindran, made decisions quickly, was responsive, and attended the Research Ethics Committee (REC).

This ensured that the REC was assured that the study was being appropriately managed in the virtual environment.

We maintained an audit-ready delegation of authority log and any questions that required PI input were addressed quickly.

Medic-led communications

A virtual study does not mean that participants have no contact with the study team. We found that our participants responded very well to regular contact from our study team, particularly our virtual investigators.

Medically qualified Investigators were the first point of contact for the participants. As trained clinicians, they are approachable, friendly and knowledgeable, often able to instantly address participant's concerns.

This was invaluable to provide peace of mind to the participants that a medical professional was on hand to answer questions quickly.

Even when the Investigators didn't know the answer immediately, they received a same-day response from the CRO team, which allowed them to respond to the participants on the same day.

The Investigators had access to the participant-facing app which also allowed them to advise on technical concerns about how to download and answer questionnaires.

Our streamlined and efficient process with an Investigator team, highly skilled in managing patient communication, meant that we could be very efficient with our medics' time but cut out the communication middleman.

This setup was possible due to a team of medics working remotely and would not be achievable at traditional sites.

(the remote working made it feasible for the medics to take on short shifts to cover a full rota).

Competitive Environment

Recruitment activities were seen as a sales-type environment, with easily visible and transparent targets through the study portal, which engaged and motivated the site teams.

The site (VCTC), CRO, and Sponsor all had access to the same data and targets and worked together when the needs of the study dictated an increase or decrease in the intensity of the recruitment outreach.

Dedicated Study Team

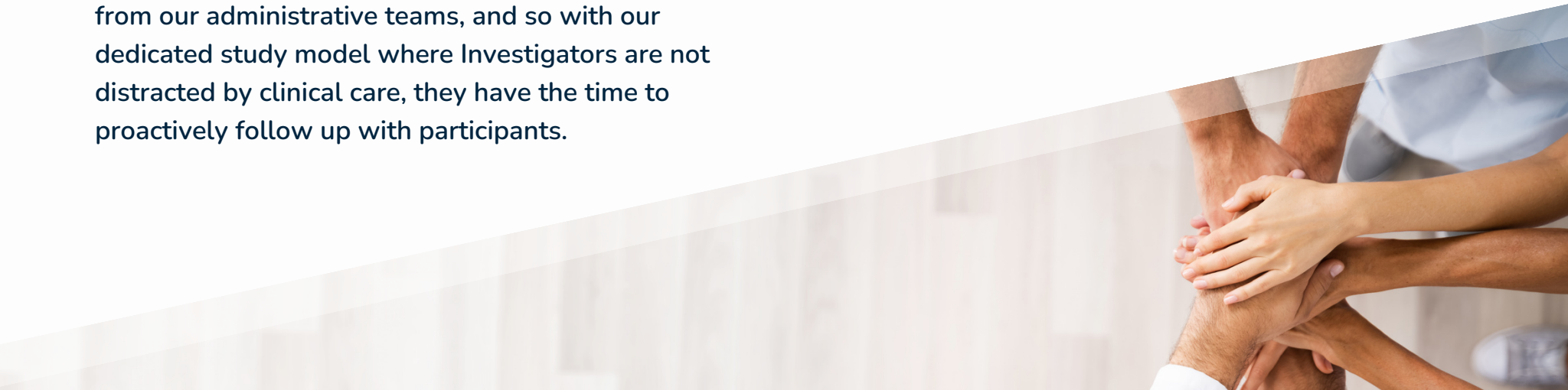
Our investigator team worked on a rota basis covering 8am - 8pm 7 days a week and whilst on shift they focussed 100% on delivering this study.

In traditional site models, Investigators would have more of a passive role in clinical trials as much of the participant communication would be performed by the administrative team.

However, we found that participants responded better to communication from a doctor than they did from our administrative teams, and so with our dedicated study model where Investigators are not distracted by clinical care, they have the time to proactively follow up with participants.

The dedicated study team model also gave us flexibility in our approach and allowed us to quickly ramp up recruitment efforts and react to emerging data of an earlier-than-expected peak in the cold season.

It also ensured that we could use the Investigators to the best of their ability, and they weren't burned out from doing a repetitive job but did multiple different participant-related tasks each shift.



Emulation of clinical medical practices

All our Investigators work in clinical practice alongside their shifts with the VCTC. This meant that they naturally implemented streamlined activities, such as performing handovers between shifts.

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Direct to patient shipping

Our pharmacy are experts in direct to patient shipping, and their efficient processes and trained couriers made IP receipt a streamlined process for participants.

IP was usually shipped to the participants on the same day that they spoke to the investigator and had engaged with the study which enhanced their motivation.

Investigators collected and then confirmed addresses and delivery information with participants, and checked any additional information required (such as how to get into a flat's mail room) to complete the delivery.

Realistic recruitment area

Although the VCTC has geographical coverage across the UK, the IP had to be delivered within 6 hours of consent.

To achieve this, we limited the recruitment area to 4 hours driving distance of the pharmacy, which still included large cities such as Birmingham, Manchester, and London.

Immediate participant payment

Participant payments are important in this type of low-interventional study. Ensuring that participant payments were released immediately on completion of activities motivated participants and gave them the confidence that they would be paid again on study completion.

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Wider team communication

Site staff joined study calls with the CRO and Sponsor which aligned all team members and allowed us to work towards a common goal.

Each group provided their own expertise, and the Sponsor was receptive to the local expertise of our site team.

This was key for REC and regulatory submissions and allowed us to make submissions within 2 weeks of our start date, receive minimal questions from the REC and MHRA, and commence recruitment at the start of the cold season.

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