Proven expertise: Delivering large scale outpatient vaccine trials

CASE STUDY

hVIVO's World-leading Expertise in Challenge Studies Supports the Successful Delivery of a Large-scale Outpatient Vaccine Study in Healthy Participants.

Study Requirements & Objectives

A US-based biotech company intended to conduct a large-scale outpatient vaccine study involving approximately 5,000 healthy participants in the US and UK. Our objective was to recruit approximately 1,000 participants in the UK before the start of the influenza season and complete a 26 week influenza-like illness follow-up. The study aimed to complete dosing prior to the start of the influenza season, leveraging the later onset of the influenza season in the UK compared to the US to fit better with the client's timelines. The US-based biotech company, already operating in the US, contracted hVIVO as its exclusive UK-based site as it offered greater efficiency in terms of both time and operations.

Timelines were challenging, with recruitment being scheduled to start in September 2024. In early June 2024, the protocol was delivered and hVIVO promptly completed the feasibility assessment.

Operational Execution

The success of the study was attributed to close collaboration between internal hVIVO teams (including pharmacy, laboratory staff, site personnel, and recruitment teams), the sponsor, and an external team of clinical research associates embedded with the sponsor. This team of CRAs worked onsite to facilitate close cooperation with hVIVO staff and sponsors. Flexibility was crucial, with the team optimising clinic hours and running extended dosing sessions, including during weekends, to maximise the numbers of participants being dosed.

Clinical Process Optimisation

The aim was to have 20 participants per dosing session, but unpredictable turnout of participants required constant adjustments to optimize efficiency. To accommodate the varying numbers of participants, hVIVO implemented three dosing sessions per day (i.e., 7:30 AM, 10:30 AM, and 1:30 PM). Each session involved at least three nurses, seven clinical study support (CSS) personnel, five doctors, and one phlebotomist.

Before the start of the actual study, dry runs were conducted to optimise facility utilisation, ensuring smooth operational flow on treatment days. The clinical administration team managed case books, consent verification, paperwork filing, and coordinated triggered assessments when participants experienced acute respiratory infections. The enrolment team coordinated follow-up visits to maintain participant engagement, while the data management team transferred all source data into the sponsor's electronic data capture system.

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Screening and Dosing Process Flow

Consent
Group consent session followed by individual consent

Participants complete medical questionnaire

Screening
Blood samples • Pregnancy tests • Drug screening • Vital signs/ECG • BMI

Laboratory Tests
Blood and respiratory samples tested in central lab

Further Screening
Physician review
Medical questionnaire review

Eligibility Criteria Confirmed

Participants trained on e-diary card completion and provided with home assessment kit (thermometer, flu swab)

Pharmacy prepares IMP

IMP Dosing
Followed by post-dosing observation period.

Study Schedule Flowchart

Day 1
Screening and dosing

Day 8
Follow-up visit (blood tests, safety/ AE review, and e-diary checks)

Days 15 & 57
Follow-up phone calls

Days 29 & 85
Follow-up visits

Day 169
Final follow-up phone call

Day 197
Final follow-up visit

Day 280
End-of-study visit per UK MHRA regulations

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Challenges & Solutions

Our proactive and expert knowledge and input helped resolve issues that could be a disadvantage for the study success. Challenges included unpredictable participant turnout, ranging from as few as 1—2 to as many as 43 per session, necessitating real-time staffing adjustments. Dry runs helped to manage the large workflow, ensure efficient space utilization, and minimize overlap between screening and dosing teams. To mitigate waiting times and prevent dropouts, snacks were provided to keep participants engaged.

Our specialist virology scientists, facilities, and services were invaluable in running this vaccine study, providing expertise on how to collect, manage, and analyse specialist virology samples, ensuring robust and maximal study data was obtained. We provided scientific advice to update the laboratory protocols for all study sites to ensure optimal sample preservation, as well as guidance on the IMP and blinding process. Our integrated clinical trial site and laboratory services ensured a seamless and efficient process throughout the study.

Our vast experience in running challenge trials also allowed us to model data, predicting everything from required staffing levels and resource allocation to recruitment run rates. Our predictions allowed us to deliver on expectations and address challenges proactively. We were also able to monitor, measure, and adjust processes where necessary, providing highly agile services.

Key Metrics and Achievements

On average, hVIVO screened approximately 170 participants and dosed around 130 participants per week. In just over 6 weeks, hVIVO screened over 1,100 participants, of whom 817 (74%) were successfully dosed with follow up currently underway. Among those who failed screening, approximately 40% were excluded due to self-reported medical history, 15% due to positive drug tests, and 25% failed due to factors such as out-of-range body mass index, ECG, or vital signs.

Conclusion

hVIVO's expertise in virology and clinical operations enabled seamless trial execution despite significant challenges. In just over 6 weeks, hVIVO successfully dosed 817 subjects, a remarkable achievement given the study's complexity and the unpredictable nature of participant turnout. The team's ability to rapidly adapt to fluctuating numbers, optimize resources, and ensure high-quality clinical execution was instrumental in meeting the trial's ambitious goals.

This successful outcome highlights hVIVO's position as a premier clinical research site in the UK, capable of efficiently recruiting for and managing large-scale vaccine studies. The ability to screen, dose, and follow up on such a high volume of participants within a constrained timeframe is a testament to hVIVO's operational excellence, agile methodology, and deep scientific expertise.

Our team of scientists, clinicians, and expert clinical trial staff combined with our integrated site and lab facilities and our impressive participant capacity could help accelerate the development of your vaccine or antiviral product.

hVIVO

Learn more about our Vaccine Trial Services

hvivo.com