RSV Human Challenge Study
as a tool for a break-through designation

CASE STUDY

Introduction

An international biotech company, headquartered in the EU approached hVIVO to explore the possibility of performing a **RSV Phase IIa challenge study.** The investigational product was a novel recombinant modified vaccinia virus Ankara **RSV vaccine candidate.** The company wanted to obtain proof of efficacy and additional safety data by Dec-21, (building on data from their initial "In-Human" study) before launching a global Phase III programme.

The challenge

The client's aim was to speed up the development process. In order to do this, they needed to achieve a quick proof of efficacy so that they could move forward with further regulatory discussions. There were certain challenges related to achieving this goal. First of all, time was limited, as the client needed to obtain study data before moving forward into their Phase III clinical trial. It was necessary to have the top-line data available before the **2021-2022 RSV season** in the Northern hemisphere (December-February). Secondly, there were a number of challenges related to recruiting healthy volunteers for the study. The study was to be conducted in the **middle of the COVID-19 pandemic,** and a positive COVID-19 result was one of the exclusion criteria. Moreover, the study design mandated a **quarantine period** of 15 days, a requirement which may have discouraged healthy volunteers. Volunteers also had to be sero-suitable to be included in the study, therefore, **less than 25-30%** of all volunteers screened could be enrolled.

The solution

hVIVO took on the role of conducting the **Phase IIa, double-blinded, placebo-controlled human challenge trial** to assess the vaccine candidate fully aware of the challenges that laid ahead. The goal for hVIVO was to provide proof of efficacy data to the client in an expedited manner. Our extensive experience in conducting human challenge studies allowed us to complete **the protocol and ICF development** process in a little over a month. The CTA review process which normally takes 60 days was also reduced to 47 days as a result of the input of our regulatory experts who have a wealth of experience dealing with MHRA and Ethics committee requirements.

23-Sep-20	06-Nov-20	06-Nov-20	22-Dec-20	22-Feb-21
Study Award	Final Protocol	Ethics/Regulatory Committee Submission	Ethics/Regulatory Committee Approval	First Subject First Vaccination
11-May-21	03-Nov-21	03-Aug-21	17-Dec-21	21-Feb-22
Last Subject Last Vaccination	Last Subject Last Visit	Priority TFLs/	Database Lock	Final TFLs

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The recruitment of volunteers' challenge was overcome by utilising FluCamp's generic screening program. FluCamp is hVIVO's web-based in-house recruitment arm and recruits volunteers through Social Media (Facebook, Instagram & Google), Radio advertising, Metro advertising and email campaigns within our volunteer database (+250,000 volunteers). The key advantage of Flucamp is its ability to conduct a thorough Generic Screening Program even prior to the Regulatory/ EC approval of the protocol. As soon as the relevant approvals were received Flucamp had a number of volunteers ready for the Protocol-specific Screening process. Even with the challenging recruitment conditions at the time, hVIVO managed to enrol all volunteers well within the timeframe required. In total, 73 volunteers were enrolled and **62 volunteers** participated in the study conducted at hVIVO's state-of-the-art facility in Whitechapel, in London. The first volunteer came into quarantine on the 8th of March and the last volunteer left on the 26th of May.

47 days to obtain CA/EC approval

62 volunteers recruited on time

11 weeks to recruit volunteers with a 85% screen-failure rate

The results

Despite the global pandemic, the RSV challenge trial was performed within the allocated timelines and provided the sponsor with the data required to make a confident decision to start their phase 3 programme.

The challenge study found a significant reduction in viral load in vaccinated subjects versus the placebo. Vaccinated subjects showed a significant reduction in clinical symptoms typically associated with RSV infections. The study demonstrated a vaccine efficacy of up **to 79% in preventing symptomatic infections** and no vaccine-related serious adverse events were observed.

Furthermore, the successful results derived from the human challenge trial played a pivotal role in the data package presented to the FDA to receive a **breakthrough designation** in 2022. This designation then allowed the client to advance the development of their RSV vaccine under the "accelerated" approval program.

- 79% efficacy in preventing symptomatic infections
- Break-through designation
- De-risk Phase III clinical trials

"I was really impressed by the professional and timely implementation of this trial, helping us to bring our RSV vaccine candidate into late stage development. The collaboration with your team was really enjoyable, everyone in your team was highly supportive." – Dr. Med. Heinz Weidenthaler (VP, Clinical Strategy)

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Read more about the study by scanning here:

hvivo.com