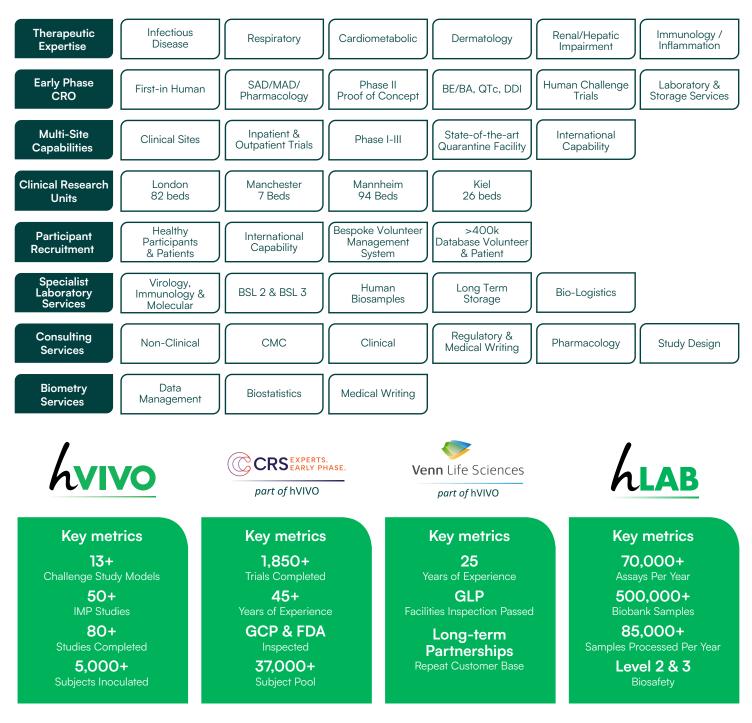


Full-Service Early Phase CRO & World Leader in Human Challenge Trials

At a Glance

hVIVO is an early phase full-service Contract Research Organisation (CRO) and the global leader in human challenge trials. The Company delivers end-to-end clinical development services to a diverse and expanding client base, including seven of the world's top ten largest biopharma companies.



Full-Service Early Phase CRO & World Leader in Human Challenge Trials



Scientific

- Study design
- Protocol writing
- Development of new challenge models
- Clinical study report writing
- Scientific publications



Regulatory

- Interactions with competent authorities
- Scientific advice
- Clinical trial applications
- CA/EC submissions



Clinical

- Human challenge trials
- Phase II-III vaccine studies
- First-in-Human healthy
 participant studies
- Mild condition patient studies
- Primary care indications

hVIVO's Challenge Study Experience

Number of

studies

36

32

9

2

1

1

4

81



Laboratory

- Assay development
- Virology/ microbiology
- Lab services
- Biomarker analysis
- Biobank services

Number

of subjects

inoculated

2.477

2.002

420

51

28

2

114

5.002

Human Challenge Trials

Model

Influenza

SARS-CoV-2

Global Health

Respiratory Diseases

Asthma, COPD, Cough

RSV

HRV

hMPV

Malaria

TOTAL

Viral Infections

FDA grants Breakthrough Therapy and Fast Track designations to influenza candidate April 2023

Data from hVIVO Phase 2a influenza human challenge trial instrumental in FDA decisions

RSV Vaccine Approved May 2023

FDA Breakthrough Designation awarded March 2022

Primarily informed by the positive results of a proof-of-concept human challenge trial conducted by hVIVO

FDA grants Breakthrough Therapy and Fast Track designations to Drug Targeting Influenza June 2023

FDA Breakthrough Designation

RSV Vaccine Human Challenge Trial

FDA Breakthrough Designation

September 2021 RSV Vaccine Human Challenge Trial

Case Studies

RSV Human Challenge Study

47 Days to obtain CA/EC approval

62 Participants recruited on time

11 Weeks to recruit participants with a 85% screen-failure rate

Awarded Fast Track Designation Delivering Large Scale Outpatient Vaccine Trials

> **1,100+** Participants Screened

817

Participants Dosed 6 Week

Period Recruitment

Sole UK Site Selected by Client Multinational Phase 2 Field Study Laboratory Services

> ~60,000 Antibody Assays ~450

> > PCR Assays

Genotyping & Phenotyping

5,000 Volunteers