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.

Therapeutic Expertise	Infectious Disease	Respiratory	Cardiometabolic	Dermatology	Renal/Hepatic Impairment	Immunology / Inflammation
Early Phase CRO	First-in Human	SAD/MAD/ Pharmacology	Phase II Proof of Concept	BE/BA, QTc, DDI	Human Challenge Trials	Laboratory & Storage Services
Multi-Site Capabilities	Clinical Sites	Inpatient & Outpatient Trials	Phase I-III	State-of-the-art Quarantine Facility	International Capability	
Clinical Research Units	London 82 beds	Manchester 7 Beds	Mannheim 94 Beds	Kiel 26 Beds		
Participant Recruitment	Healthy Participants & Patients	International Capability	Bespoke Volunteer Management System	>400k Database Volunteer & Patient		
Specialist Laboratory Services	Virology, Immunology & Molecular	Extensive BSL-2 & BSL-3 Facilities	Biostorage Facilities & Biospecimen Catalogue	Cell-Based Assays	Bio-Logistics	Assay Development & Validation
Consulting Services	Non-Clinical	CMC	Clinical	Regulatory & Medical Writing	Pharmacology	Study Design
Biometry Services	Data Management	Biostatistics	Medical Writing			

hVIVO

Key metrics

13+
Challenge Study Models

50+
IMP Studies

80+
Studies Completed

5,000+
Subjects Inoculated

CRS EXPERTS. EARLY PHASE.
part of hVIVO

Key metrics

1,850+
Trials Completed

45+
Years of Experience

GCP & FDA
Inspected

37,000+
Subject Pool

Venn Life Sciences
part of hVIVO

Key metrics

25
Years of Experience

GLP
Facilities Inspection Passed

Long-term Partnerships
Repeat Customer Base

hLAB

Key metrics

70,000+
Assays Per Year

500,000+
Biobank Samples

85,000+
Samples Processed Per Year

Level 2 & 3
Biosafety

@hVIVO_UK @hVIVO www.hvivo.com BD@hvivo.com

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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

Laboratory

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

Human Challenge Trials

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
2021
RSV Vaccine Human Challenge Trial

FDA Breakthrough Designation
September 2021
RSV Vaccine Human Challenge Trial

hVIVO's Challenge Study Experience

Model	Number of studies	Number of subjects inoculated
Viral Infections		
Influenza	36	2,477
RSV	32	2,015
HRV	9	420
SARS-CoV-2	2	72
hMPV	1	28
Global Health		
Malaria	1	2
Respiratory Diseases		
Asthma, COPD, Cough	4	114
TOTAL	**81**	**5,014**

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
Analysis
5,000
Volunteers

@hVIVO_UK @hVIVO www.hvivo.com BD@hvivo.com