



# 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	BSL 2 & BSL 3	Human Biosamples	Long Term Storage	Bio-Logistics	
Consulting Services	Non-Clinical	CMC	Clinical	Regulatory & Medical Writing	Pharmacology	Study Design
Biometry Services	Data Management	Biostatistics	Medical Writing			



### Key metrics

**13+**  
Challenge Study Models

**50+**  
IMP Studies

**80+**  
Studies Completed

**5,000+**  
Subjects Inoculated

### Key metrics

**1,850+**  
Trials Completed

**45+**  
Years of Experience

**GCP & FDA**  
Inspected

**37,000+**  
Subject Pool

### Key metrics

**25**  
Years of Experience

**GLP**  
Facilities Inspection Passed

**Long-term Partnerships**  
Repeat Customer Base

### Key metrics

**70,000+**  
Assays Per Year

**500,000+**  
Biobank Samples

**85,000+**  
Samples Processed Per Year

**Level 2 & 3**  
Biosafety

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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	2,002
HRV	9	420
SARS-CoV-2	2	51
hMPV	1	28
Global Health		
Malaria	1	2
Respiratory Diseases		
Asthma, COPD, Cough	4	114
<b>TOTAL</b>	<b>81</b>	<b>5,002</b>

## 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