Open Orphan

H1 2022 Financial Results

September 2022

LSE : ORPH

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Presenters

Dr. Yamin ‘Mo’ Khan
CEO

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CFO

Open Orphan plc becoming hVIVO plc

Open Orphan becoming hVIVO

hvivo
formerly Open Orphan plc

Why?

1. hVIVO is the operating brand
2. hVIVO brand is globally recognised by pharma, biotech, academics, and the media
3. hVIVO is a long standing, trusted partner to the biopharma industry for its unparalleled expertise and world class capabilities in human challenge trials

Further details	
Completion Date 26th October 2022	**ORPH** ticker will become **HVO**
www.openorphan.com will become www.hvivo.com	Our **ISIN** will remain unchanged

Our Brands

Venn Life Sciences
part of hVIVO

hVIVO

FluCamp
Clinical Trials Recruitment

hVIVO

formerly Open Orphan plc

Who we are?

World leader *in* ***testing infectious & respiratory disease products*** *using human challenge studies addressing the* growing infectious disease market

10+ Challenge Study Models

66 Completed Human Challenge Studies

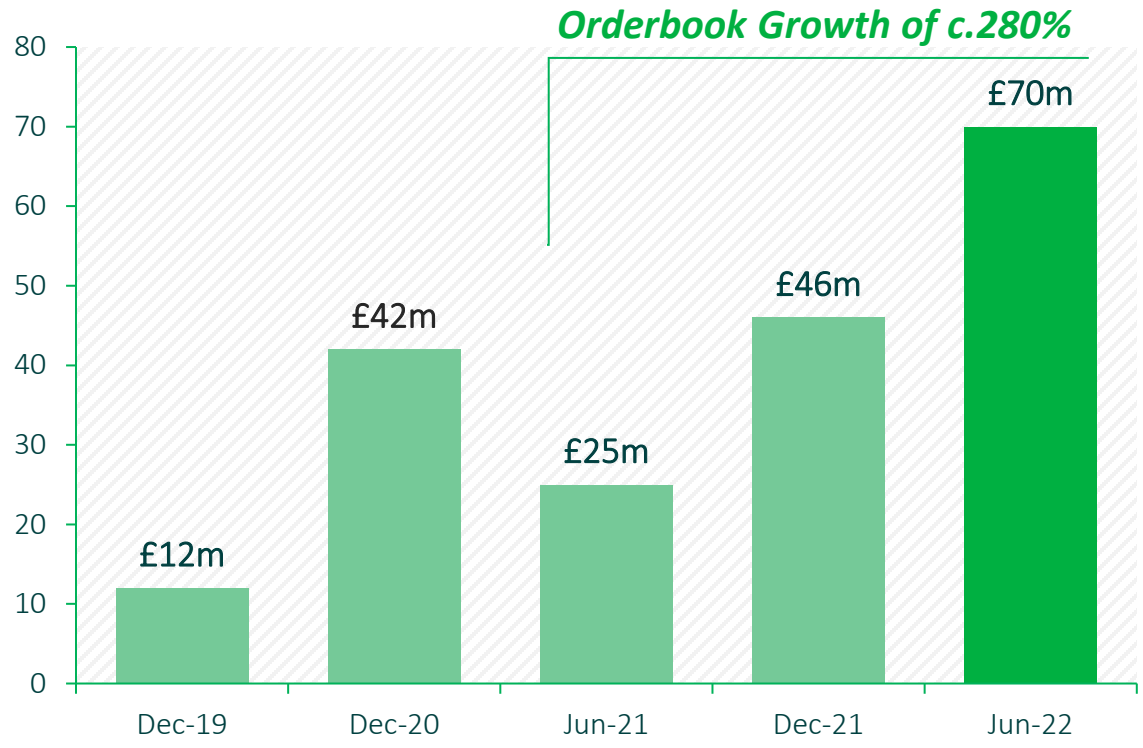
3500+ Volunteers Inoculated

hVIVO – H1 Performance Summary

formerly Open Orphan plc

Steady Performance in H1	**£18.9M** H1-2022 Revenue	**£2.3m** H1-2022 EBITDA 12.1% EBITDA Margin	**£15.9m** H1-2022 Cash Balance
Well Positioned for Growth in 2022	**£50m** Reaffirm Revenue Target £9m Revenue in Jul/Aug'22	**13-15%** Target EBITDA Margin	**80%** FY23 Revenue Contracted as at 1 Sept 2022
Strong Foundations	**£80m +** Contracted Orderbook as 1 Sept 2022	**1,000+** Increased Weekly Onsite Screening Capacity	**4 of Top 10** World's Largest Biopharma as Active Clients
Future-proofing our Operations	**New Models** Influenza, Omicron and Malaria models	**New Revenue Streams** Expanded into Additional Areas	**New FluCamp** Screening Centre in Manchester

Record Contracted Orderbook



As at 1 Sept 22:

- *Contracted orderbook of £80m*
- *Reaffirm £50m revenue guidance for 2022*
- *c.80% FY23 Revenue Contracted*

Significant contracts in H1 2022

- £7.2m (RSV) – challenge trial with top 5 global pharma client
- £7.3m (Influenza) – challenge trial with European biotech
- £5m (RSV) – challenge trial with European biotech
- £14.7m (Influenza) - manufacture, characterisation and challenge study for top 5 global pharma client
- (Omicron) – development of COVID-19 challenge model for Omicron challenge trial with Vaxart

Post 30 June 2022

- £6.2m (Influenza) – challenge study with US biotech Cocrystal
- £10.4m (Influenza) – manufacture and challenge trial for top 5 global pharma client

Expanding our Portfolio of Models

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Growth in our portfolio of models with particular emphasis on full-service contracts for our Big Pharma clients

High Value Full-Service Contracts

New Omicron Model

- Developing Omicron COVID-19 model with Vaxart Inc.
- Intention to conduct Omicron challenge studies from 2023 onwards

Bespoke Influenza Model

- First full-service influenza challenge programme with an existing for a top 5 global pharma client
- Characterisation and challenge study worth £14.7m

New Influenza Model

- Manufacturing a new Influenza model with an existing top 5 global pharma client
- Agreement worth £10.4m to include challenge study

Launched New Models

Asthma Model

- First Asthma Study currently underway with global pharma client
- Pipeline of asthma opportunities growing

Malaria Model

- Malaria human challenge model launched in H1-2022
- Anti-parasite challenge studies to commence in near future

Opportunity for further challenge models to attract additional clients

FluCamp Recruitment Platform

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Patient recruitment is the #1 problem for all CROs

Our FluCamp recruitment platform has an experienced track record of delivering successful recruitment to our trials

250,000+
Active Volunteers in Existing Database

100%
Trial Recruitment Success

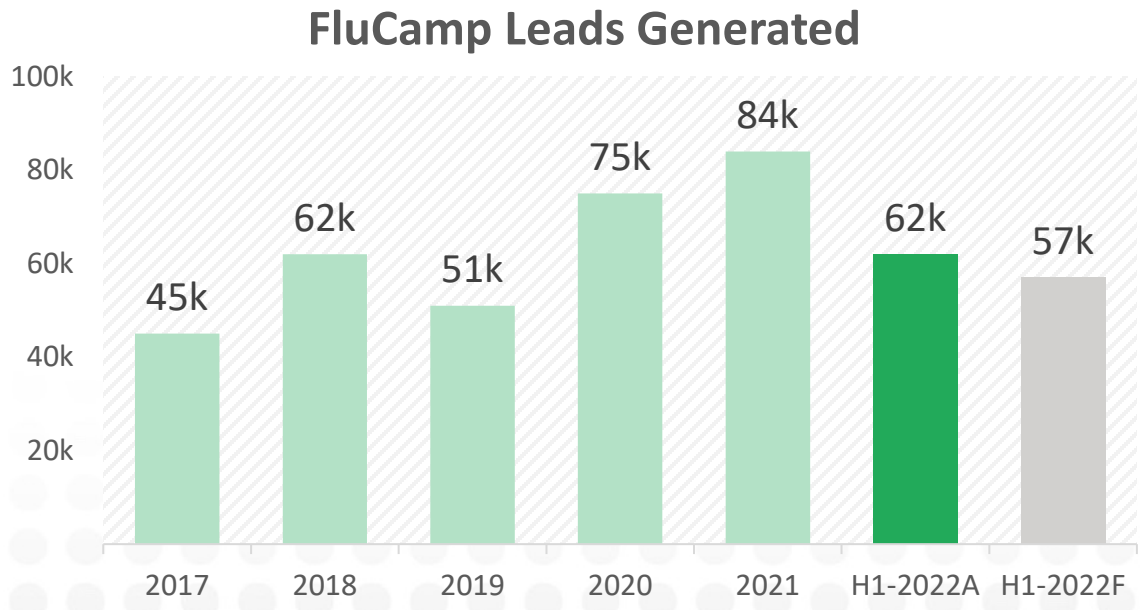
c.85%
FluCamp Volunteers can be utilised in non-challenge trials

80% *More than 80% of clinical trials in the US fail to meet their patient enrolment timelines[1]*

55% *Patient recruitment issues account for 55% of cancelled clinical trails[2]*

H1-2022 FluCamp Improvements

- Online Self Booking
- New CMS system
- Online screening for patients
- Expanded marketing channels – up to 3x more leads



Note (1): Sources: Perspective in Clinical Research
Note (2): Sources: GlobalData

Delivered on Key Value Adding Initiatives in H1

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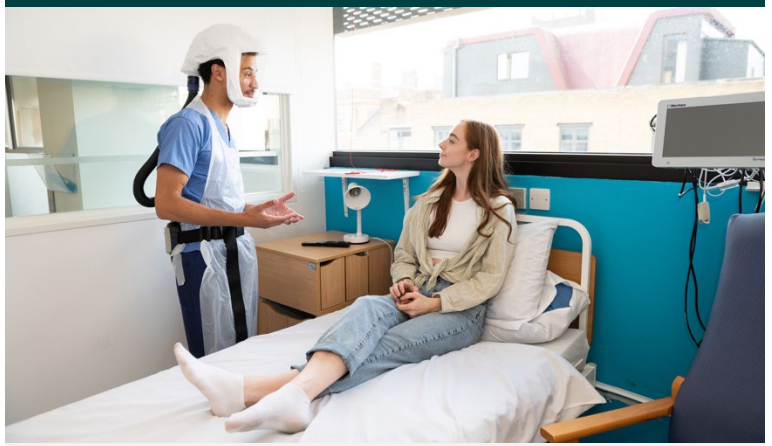
Continuing to develop new revenue streams to offer new and existing clients additional services

Expanding Lab Services

- Increased volume of lab services contracts with external clients
- Received CAP accreditation, increasing the marketability of our lab services to external clients

Launch Research Site Services



- Leveraging our upgraded infrastructure at Plumbers Row for use as a clinical site
- First contract signed with Global Pharma company in H1

Recruitment Strategies

- Marketing FluCamp to provide trial recruitment as standalone service utlising volunteers not suitable for a challenge study

Venn is a Key Driver of the Business

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Venn offers an integrated package of consulting services from preclinical through late phase and approval; accelerating the development of its clients' products

Expanding our Core Offering

1

- Expansion within our key clients ("land-and-expand")
- Growth into ATMP clinical development services
- Key strategic hires to expand our service offering

Cross selling opportunities within hVIVO

2

Client 1 - £5m RSV human challenge study contract stemming from multi-year early clinical development

Client 2 - Secured our first site study award with a Venn client with 20+ year relationship

Venn Life Sciences

part of hVIVO

Venn Life Sciences Services Offering

Drug Development Consultancy	**Clinical PK & Pharmacometrics**	**Non-Clinical Development**	**CMC Consulting**	**Medical Writing & Regulatory Affairs**
Trial Management	**Data Management**	**Statistics, Study Design & Methodology**	**RTSM**	**Training**

Attractive Market Dynamics

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$46.7B+	*The global clinical CRO market was estimated to be worth $46.7bn in 2021 and to grow at a 10% CAGR to 2024[1]*
$5.5B+	*The infectious disease clinical trial market is projected to reach over $5.5 billion by 2027[2]*
£700m+	*The estimated market size for challenge study CRO services by 2028[3]*
2,500+	*Active vaccine, anti-viral and respiratory compounds currently in development – 86% increase from 2019 to 2021[4]*

Our Challenge Trials have Supported Breakthrough Therapy Designation with the FDA

Bavarian Nordic

Bavarian Nordic's RSV vaccine candidate, MVA-BN® RSV received Breakthrough Therapy designation in 2022

Top 5 Big Pharma

Breakthrough Therapy designation received following successful phase 2a RSV challenge trial in over 60s

Impact of COVID-19 on Funding for Infectious Disease

- Pandemic Preparedness
- Increased funding for vaccines and anti-virals

Note (1): Sources: Results Healthcare (2021) CRO Sector M&A drivers and market trends
Note (2): Sources: Global Market Insights
Note (3): Sources: Liberum
Note (4): Sources: Pharmaprojects; Citeline

Why do a Human Challenge Trial?

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SCIENTIFIC

- Generates invaluable dosing, safety and efficacy data
- Helps optimise for larger field trials

CLINICAL DEVELOPMENT

- Requires fewer subjects
- Significant time savings
- De-risk Phase III program

REGULATORY

- Potential for Fast Track or Break Through designation
- Potential approval and Emergency Use Authorisation

FINANCIAL

- Significant valuation uplift for Biotech sponsor
- Allows products to “Succeed fast” or “Fail Fast”

Partner of Choice for Big Pharma

formerly Open Orphan plc

Preferred partner for 4 of the top 10 global biopharma[1]

3
Active Challenge Studies
with Big Pharma in H1-2022

2
Full-Service Challenge Programmes
value exceeding £25m

8
Challenge Studies
signed with Big Pharma since 2018

100%
Repeat Customers
Percentage of our Big Pharma customers are repeat customers

c.40%
Contracted Orderbook
relates to our Big Pharma clients

hVIVO's Biotech Clients

- hVIVO work with a large number of biotechs – challenge studies are a key inflection point
- c.60% of our orderbook relates to our biotech customers
- Omicron model developed with key customer
- 3 new biotech challenge clients in H1-2022 (further win in August)
- c.80% repeat business for Venn's biotech clients

[1] Active customers for 2021-2023+

hVIVO

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Financial Performance & Outlook

Summary Financial Highlights

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£'m	H1-2022	H1-2021	Comment
Revenue	18.9	23.2	✓ H1-2022 revenues of £18.9m ✓ 2022 revenue weighted to H2 ✓ Reaffirm revenue guidance of £50m for 2022 ✓ Revenue for July & August 2022 of c.£9m ✓ hVIVO division is the core growth driver representing over 80% of H1-2022 revenue ✓ Venn division is expanding services & increasingly supporting hVIVO studies
EBITDA	2.3	2.1	✓ EBITDA margin increased to 12.1%
Cash	15.9	14.9	✓ Strong working capital management ✓ Cash of c.£20m as at 1 Sept. 2022
Order Book	70	25	✓ Orderbook increased almost threefold year-on-year ✓ Increased to c.£80m as at 1 Sept. 2022

A Sustainably Profitable & Cash Generative Business

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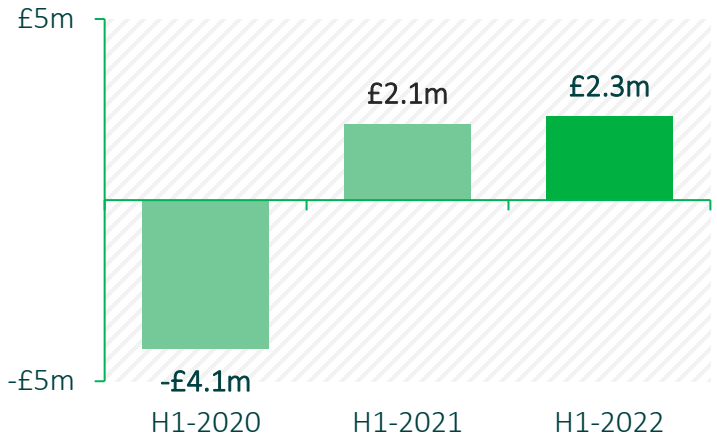
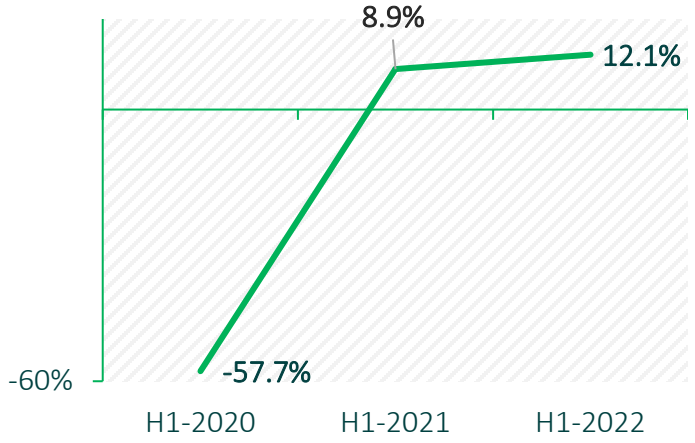
EBITDA



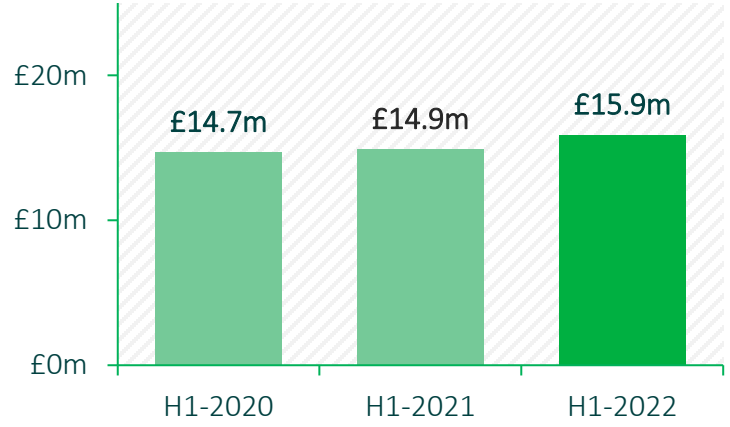
- Increased H1-2022 EBITDA of £2.3m
- Improved productivity gains in operations & overhead efficiency

EBITDA Margin



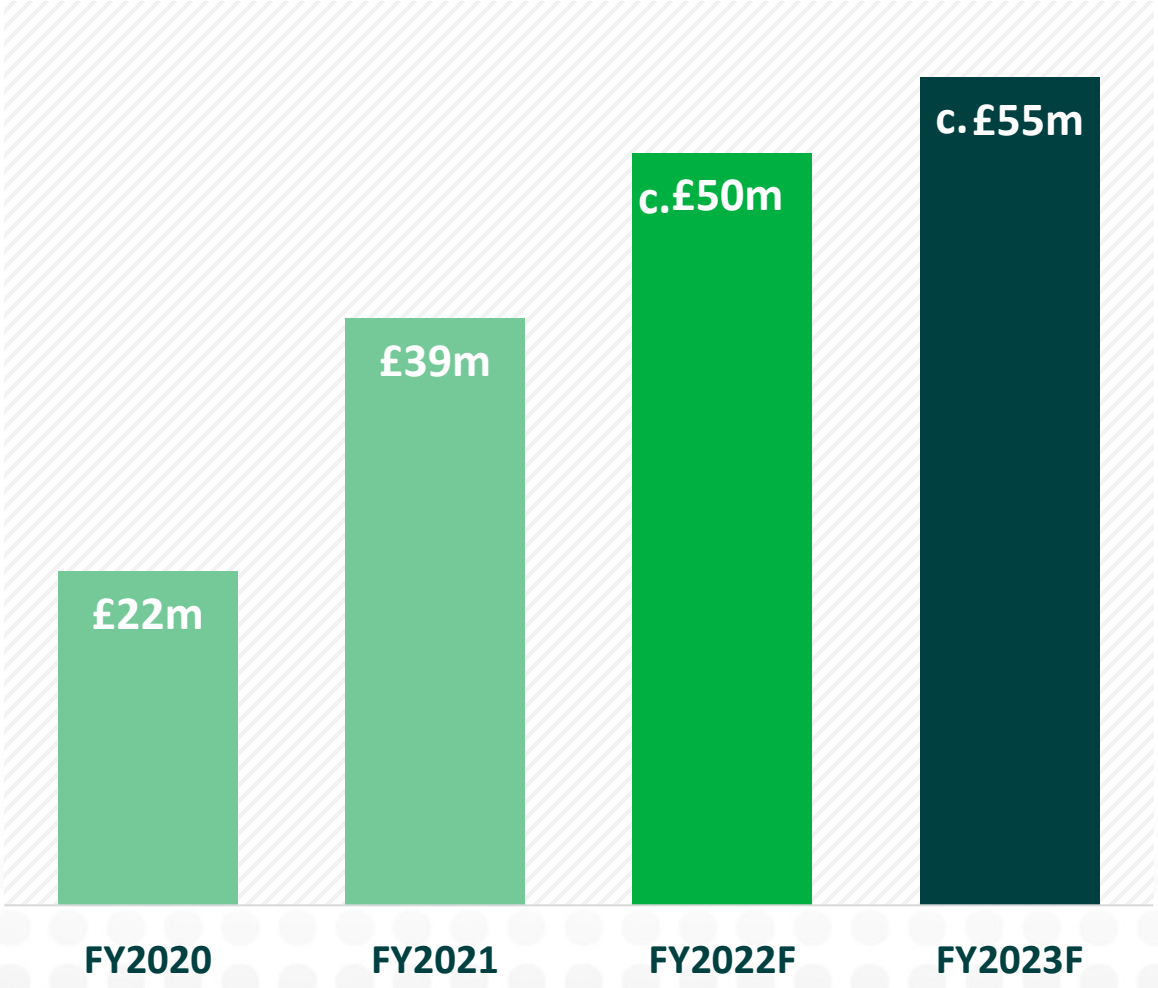
- H1-2022 EBITDA Margin increased to 12.1%
- Growth towards sustainable double digit EBTIDA margin of 13–15%

Cash



- Strong cash position with £15.9m as at 30 June 2022
- Cash generative with modest investments made to improve infrastructure
- Cash balance as at 1 Sept. 2022 of c.£20m

Market Consensus



Revenue

- Full year guidance remains at c.£50m revenue for 2022 (revenue for July & August 2022 of c.£9m)
- Drive efficiencies and productivity to achieve double digit EBITDA margin for full year 2022
- Focus on orderbook conversion into 2023 targeting c.£55m of revenue – c.80% of 2023 revenue already contracted
- Continue to close strong sales pipeline and progress development of new revenue streams

Investment Case

01 Strong Market Dynamics

- Attractive market dynamics across rapidly growing infectious disease space
- World leader in challenge trials for infectious and respiratory disease
- Increased adoption of challenge trials by Big Pharma

02 Scalable Infrastructure

- Investment in the operational infrastructure to deliver further growth
- Increased bed capacity
- Expansion of FluCamp screening platform

03 Trusted Partner

- Repeat revenue with big pharma; a trusted “go-to” partner; served 4 of top 10 global biopharma in H1-2022
- Increased volume of biotech awards

04 Orderbook Growth

- Record order book of c.£80m as at 1 September 2022
- Growth in new models; expansion of pipeline
- Growth into new revenue streams e.g. site services, lab services

Support continued revenue growth and long term, sustainable profitability

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Questions

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Appendix

What is a Human Challenge Trial?

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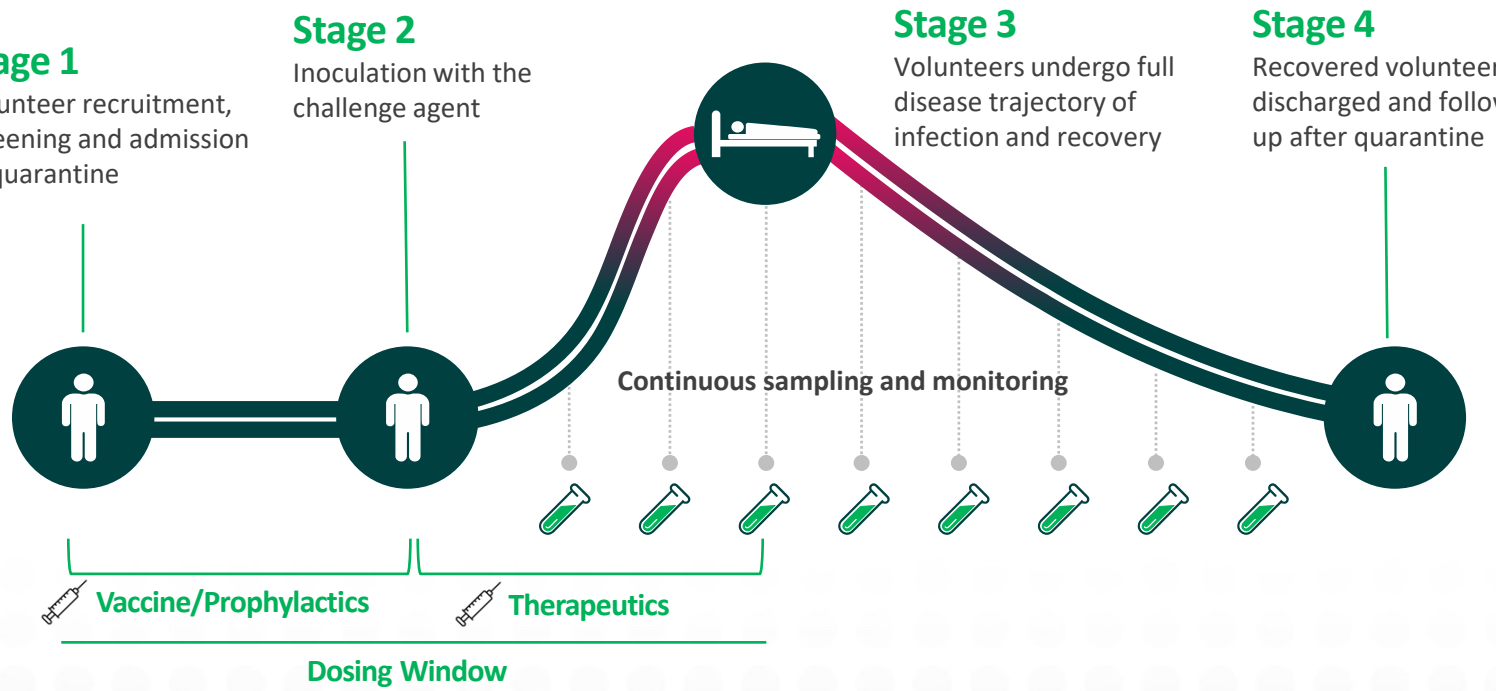
Progression of a Volunteer While in Quarantine During a Typical Human Challenge Trial



- ✓ *Generic screening*
- ✓ *Volunteers are randomly stratified to placebo or active*
- ✓ *All volunteers are inoculated with the challenge agent (virus)*
- ✓ *Trials typically include 50-100 healthy volunteers*
- ✓ *Quarantine duration: 10-15 days*
- ✓ *Outpatient follow-up visits*

History of hVIVO

formerly Open Orphan plc

1945
UK Government establishes the human challenge Common Cold Unit in Salisbury, UK.

1989
Common Cold Unit closes. Retroscreen Virology is founded by Prof John Oxford & Pat Meeking

RETROSCREEN VIROLOGY
CONQUERING VIRAL DISEASE

2001
First human challenge trial takes place

2001-2007
Retroscreen recruits 800+ influenza volunteers

2008
FLUCAMP.COM
Volunteer coins the name FluCamp

2011-2015
Major investment in facilities & challenge model development

2015
hVIVO
Retroscreen Virology rebrands as hVIVO

2019
Open Orphan
hVIVO acquired by Open Orphan

2020
UK COVID CHALLENGE
hVIVO partner with UK Government to conduct world's first COVID-19 challenge trial

2021
POOLBEG PHARMA
Spin out of infectious disease product portfolio: Poolbeg Pharma plc

2022
FluCamp Clinical Trials Recruitment
Expanded facilities to 62 beds; increased lab offering and expanded clinical trial offering; rebrand as hVIVO

Continuing to expand offering to drive new streams of revenue

RSV Human Challenge: A tool for a break-through designation

hVIVO
formerly Open Orphan plc

BAVARIAN NORDIC

The Challenge

To speed up the development process by achieving fast proof of efficacy to fast-track regulatory discussions

The Solution

Phase IIa, double-blinded, placebo-controlled human challenge

The Result

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

47 days to obtain CA/EC approval

62 volunteers recruited on time

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

"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)

Facilities Overview

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QMB Clinic

QMB Laboratories

Facilities Overview

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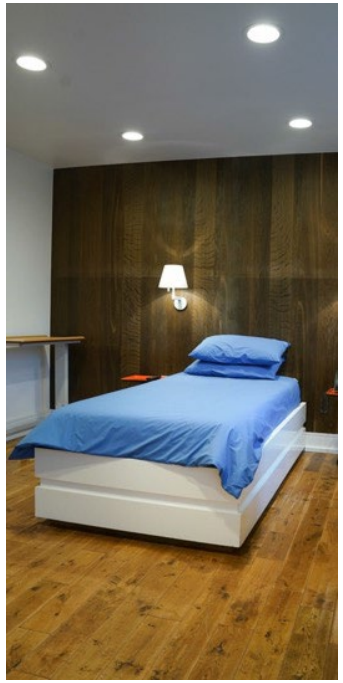
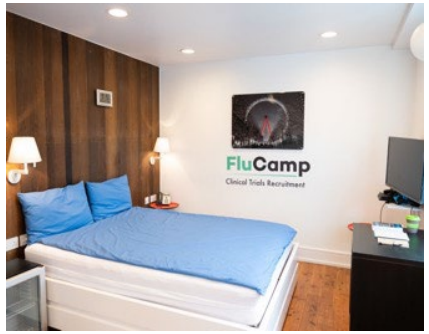
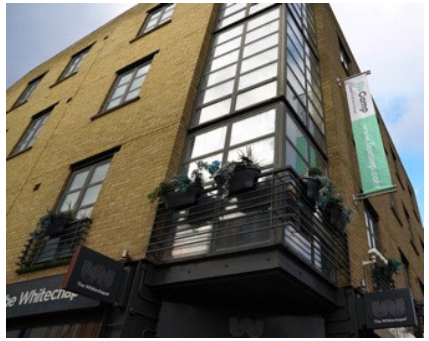
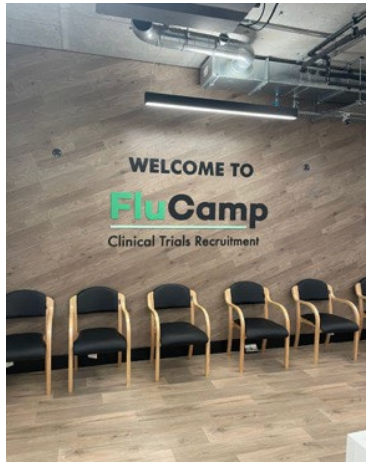
Whitechapel Clinic and Screening Centre

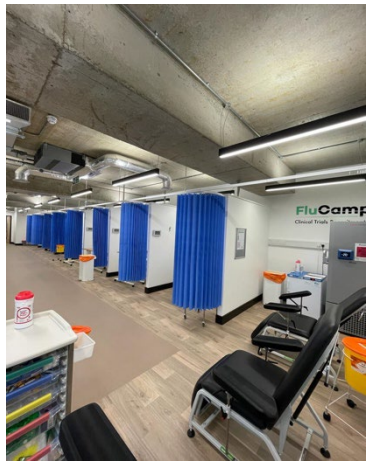






Plumbers' Row Corporate Office & Screening Facility





Manchester Screening Centre

Biobank