







### Capital Markets Day 17 July 2024

**Ticker: HVO** 

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#### Dr Yamin 'Mo' Khan Chief Executive Officer

Dr Yamin 'Mo' Khan has over 25 years of experience in clinical research and the CRO industry. Mo previously worked as a Consultant assisting CROs to develop growth strategies and helping prepare companies for future expansion, both organic and through M&A activity. In addition Mo worked with Private Equity firms providing insight in identifying potential targets and conducting due diligence in preparation for M&A activity. Prior to this Mo had a variety of senior roles at Pharm-Olam where he played a pivotal role in growing a small niche clinical monitoring business to a global full-service CRO with offices across all continents. In his time at Pharm-Olam Mo had leading roles in Clinical Operations, Project Management, Business Development and Executive Management functions. As a key member of the Executive Team Mo participated in the successful sale of the company in 2017, delivering substantial returns to its shareholders. Prior to this he worked at Innovex and Quintiles (IQVIA).

Mo holds a PhD in Biochemistry from the University of Southampton, UK, and a Bachelor's degree in Biochemistry from the University of Liverpool, UK.



#### **Stephen Pinkerton** Chief Financial Officer

Stephen is a chartered accountant with over 25 years of experience in a range of leadership positions in industries covering publishing, technology, exhibitions, and clinical research. The roles have covered both small to large international listed businesses, providing strong technical and commercial experience. Prior to joining hVIVO, he worked in Thomson Reuters for eleven years in various senior roles. He did his articles with Deloitte following the completion of an Honours Degree in Bachelor of Commerce and a Bachelor's Degree in Accounting and Finance from the University of Cape Town.

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#### Alex Mann Senior Director Clinical Science

Alex Mann is a clinical scientist with over 25 years experience working in infectious and respiratory disease clinical research at hVIVO.

He has significant expertise in design, execution and analysis of human challenge models for vaccine, antiviral and immunomodulator efficacy testing against various pathogens such as influenza, RSV, Rhinovirus as well as SARS-Cov2.

One of Alex's major focuses has been on innovation within Precision Medicine, building translational bridges between omics biomarker and target discovery with applied clinical research. He was previously lead researcher and inventor of omics-based patents that were demerged from hVIVO.

Alex is a strong research professional with an MSc focused in Medical Microbiology from St Bartholomew's School of Medicine & Dentistry, Queen Mary University of London.



### Eglė Pavydė Director of Business Development

Eglė Pavydė is an experienced business development professional with a strong scientific background. Eglė is a Pharmacist by training and holds a PhD in regenerative medicine. She has done an intership at the University of Pittsburgh, Stem Cell Research Center. She has won over 10 different national and international awards for scientific achievements and is an author of four scientific publications. Prior to joining hVIVO, Eglė spent nearly seven years at Biomapas, an international CRO focused on early clinical development. Eglė served in a variety of roles including Head or Regulatory Affairs and Head of Business Development.

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#### Melanie Smyth Director, Clinical Operations

Melanie Smith joined hVIVO in 2023 as Director of Clinical Operations. Prior to that, she built an impressive nursing and health technology career over 15 years which is invaluable experience for her role at hVIVO.

During the COVID-19 pandemic, Melanie worked with and implemented crucial and life-saving triaging systems and patient facing apps to aid care delivery across the UK.

Her many years spent on the frontline of Urgent Care/Emergency care led her to conduct her own independent clinical research into the diagnosis and management of sepsis across workforce types.

Since joining hVIVO, Melanie has focused on building a strong clinical team and positive work culture. She strives for safety and quality, so that our volunteers have a safe and comfortable stay in our state-of-the-art facilities, and our clients get valuable and detailed results from our studies.

Melanie has a BSc in Adult Nursing and an MSc in Advancing Clinical Practice.



#### Sohail Nawaz Senior Director, Patient Enrolment & Retention

Sohail Nawaz joined hVIVO in 2022 to lead the transformation of FluCamp which is the hVIVO participant recruitment and enrolment arm.

His experience of leading at a senior level end to end engagement and complaints handling operations within the Life science and FMCG sectors puts him in an enviable position to drive a fundamental change in the way participants are typically recruited into clinical trials.

Under his leadership Sohail has brought the FluCamp contact centre back in house from an outsourced model, implemented a new end to end Volunteer Management System and changed the marketing strategy all leading to improved conversion and overall cost per lead.

He has a keen passion to simplify processes through technology and implemented the first validated web chat service for Healthcare professionals to support prescribing decisions as part of his role for the UKs largest pharmaceutical organization.

He holds a BSc with Hons degree in Pharmacology.





#### Marianne Derricott Associate Director Laboratory Operations

Marianne joined hVIVO in 2012 and has held various positions within the laboratory team. She is currently Associate Director, Laboratory Operations. Over her time at hVIVO, she has been involved in key company projects including setting up the site and study for the first SARS-CoV-2 human challenge model in the world. Marianne focuses on operational delivery, staff training and quality.

Prior to joining hVIVO, she worked for Boehringer Ingelheim, focusing of veterinary products Quality Control, particularly on virus inactivation in final products.

Marianne studied at the University of Lyon (France), and gained a Degree in Biochemistry, followed by a Masters in Biotechnology and Biochemical Engineering.



#### Alison Boyers Director, Laboratory Project Operations

Alison joined hVIVO (formally Retroscreen Virology) in 2002 and now heads up the hLAB Department overseeing laboratory study management, operational delivery, development & validation, and proposal generation. Throughout her time at hVIVO she has additionally worked cross functionally with other departments spending time as a clinical project manager and leading some key hVIVO challenge agent development programs including SARS-CoV-2.

Alison holds a degree in Biomedical Science and a Masters in Immunology from the University of Nottingham.

### **Guest Speakers**





#### Professor Stephen Gordon Professor of Respiratory Medicine at Liverpool School of Tropical Medicine

Stephen has conducted clinical and translational research in the UK and Africa since 1993. His current research focuses on defence against respiratory infection using a pneumococcal challenge model, to explain the relative lack of herd immunity following vaccine implementation in Malawi. New studies focus on more resistant serotypes, at-risk populations, and new immunomodulatory agents and new vaccines. As Director of the Malawi Liverpool Wellcome programme (2015-2022), Stephen led with a vision of "research to benefit health and training the next generation of researchers". Prior to that, he developed the Pan African Thoracic Society research training programme. Stephen leads the CREATOR (Clinical Research Excellence and Training Open Resource) programme, a £10m project aiming to change the paradigm of clinical specialist and research training in Africa.

Stephen is now Director of Experimental Medicine at the Infection Innovation Consortium (iiCON, www.infectioninnovation.com), focusing on innovation and progressing the development of new products to result in global health impact.



#### Stephen Lockhart Former Vice President, Vaccine Clinical R&D Europe and Asia-Pacific Head, Pfizer

Stephen qualified in Medicine from the University of Oxford in 1980. After working around the UK in hospital medicine and research, he joined the pharmaceutical industry in 1986. Stephen is a Fellow of the Faculty of Pharmaceutical Medicine and a Fellow of the Academy of Medical Sciences. For over 30 years he has been engaged in global vaccine clinical R&D across all phases, in Lederle, Wyeth, Emergent BioSolutions, sanofi-pasteur MSD, and most recently Pfizer. Stephen's experience covers a range of clinical development methods, including controlled human infection models. Stephen was involved with bringing some major vaccines to the clinic, including the first pneumococcal and the first meningococcal conjugate vaccines as well as a modRNA COVID-19 vaccine. Stephen is currently a consultant with Hurst Grange Associate.

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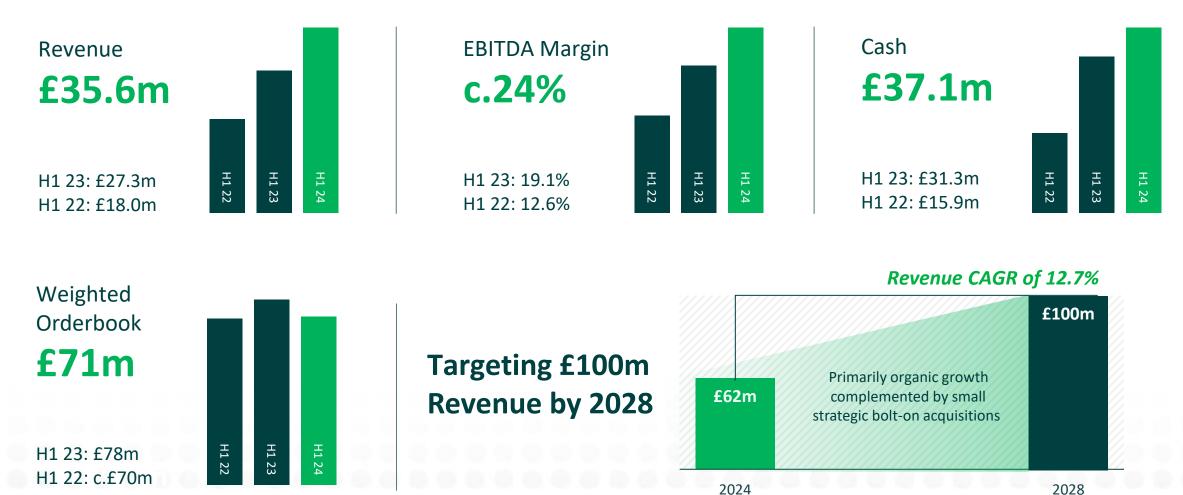
**Chief Executive Officer** 

### Welcome and introduction

### Record H1 revenue and EBITDA margin

hvivo

#### **Building a Long-Term Sustainable Growth Model**



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### Agenda



Time	Subject	Speaker	Title	
10.00	Tea / Coffee			
10.15	Welcome and Introduction	Dr Yamin 'Mo' Khan	Chief Executive Officer, hVIVO	
10.30	hVIVO's Growing Human Challenge Service Offering	Alex Mann	Senior Director Clinical Science, hVIVO	
10:45	The Role of Human Challenge Trials in Drug Development	le of Human Challenge Trials in Drug Development Dr Stephen Lockhart		
10.55		Dr Stephen LockhartFormer Vice President, Vaccine Clinical R&DAsia-Pacific Head, Pfizer		
	Fireside Chat Chaired by Dr Yamin 'Mo' Khan: Biopharma Insights - Why do a Human Challenge Trial?	Professor Stephen Gordon Professor of Respiratory Medicine at Liverpool S   Tropical Medicine		
		Alex Mann	Senior Director Clinical Science, hVIVO	
11.25	Break			
11.40	The World's Largest Human Challenge Trial Unit	Melanie Smyth	Director, Clinical Operations, hVIVO	
11.50	FluCamp - The Leading Volunteer Recruitment Platform	Sohail Nawaz	Senior Director, Patient Enrolment & Retention, hVIVO	
12.00	hLAB - New State-of-the-Art Labs Facilitating a Growing Service Offering	Marianne Derricott Alison Boyers	Associate Director Laboratory Operations, hVIVO Director, Laboratory Project Operations, hVIVO	
12.10	Expanding Services	Eglė Pavydė	l <b>ė Pavydė</b> Director, Business Development, hVIVO	
12.20	Trading Update Q&A	Dr Yamin 'Mo' Khan Stephen Pinkerton	Chief Executive Officer, hVIVO Chief Financial Officer, hVIVO	
12.40	Lunch & Group Tours			





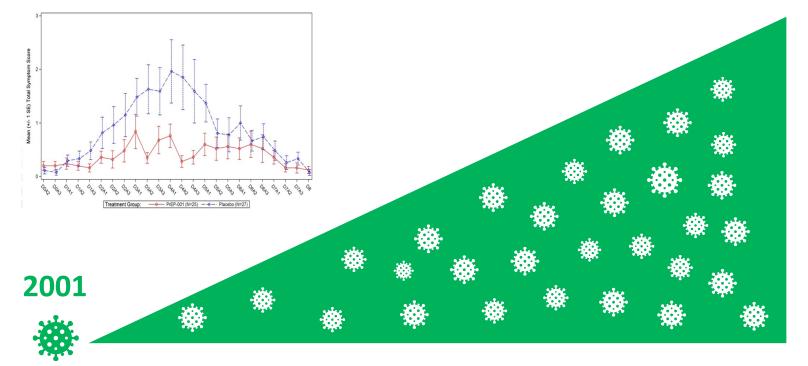


Senior Director, Clinical Science

### hVIVO's Growing Human Challenge Service Offering

### Building Sustainable Growth





### 2024

- 35 influenza challenge studies completed
- Multiple different influenza challenge strains
- New H3N2
- New H1N1
- New flu B strains
- Purpose built 50 bed unit

- hVIVO's first challenge study
- Influenza challenge
- Hotel converted to temporary unit

### Inoculations to date

Virus	HRV	Influenza	Malaria	RSV	SARS-COV-2	Total
# Clinical Studies	9	35	1	30	1	76
# Inoculated	420	2,222	2	1,947	36	4,733

# hvivo

### **Ehe New York Eimes**

# Bird Flu Is Infecting Cats (and the Occasional Dog). Here's What to Know

A few "reasonable precautions" can help people keep their pets safe from the H5N1 virus, experts say.





Texas, CDC say bird flu detected in person exposed to dairy cattle



# Former director of the CDC predicts the next pandemic will be from bird flu

While mortality from Covid-19 was 0.6 per cent, Robert Redfield says bird flu mortality likely to be 'somewhere between 25 and 50 per cent'



U.S. dairy farm worker infected as bird flu spreads to cows in five states

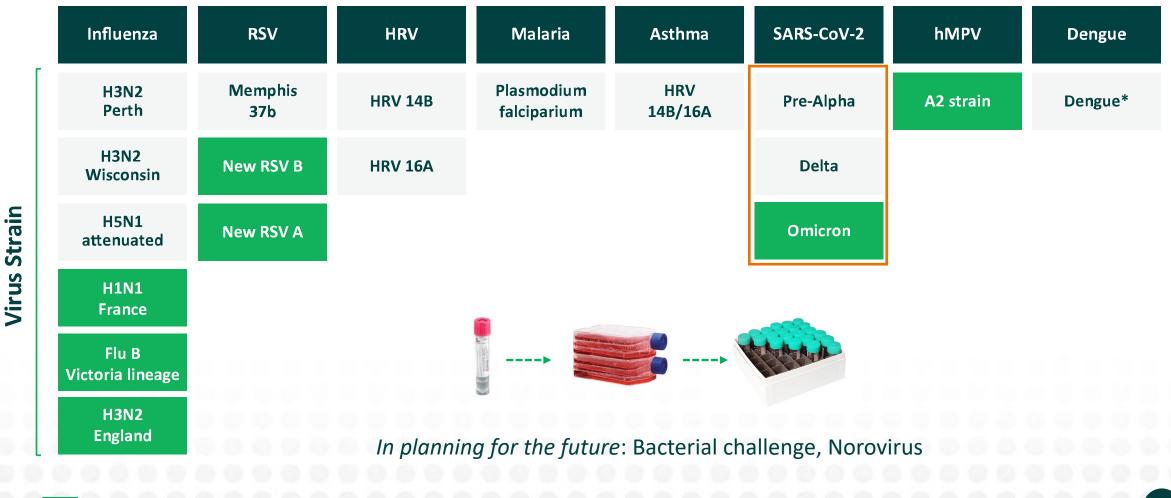
Unexpected H5N1 outbreaks in cattle raise difficult questions about how to protect herds and people

### hVIVO's Expanding Challenge Agent Portfolio



10 challenge agents manufactured in the past three years – investing in sustainable growth

New to hVIVO in the past 2 years



\* In development

### Expanding Our Service Offering



#### New facility enables hVIVO to offer new services which were not previously possible

- Biosafety Level 3 pathogens both in laboratories and quarantine unit
  - $_{\odot}\,$  Previously used Royal Free Hospital for SARS challenge and rented BSL-3 lab
  - $_{\circ}\,$  Now all under one roof at hVIVO
- Bacterial challenge studies with on-site laboratory support

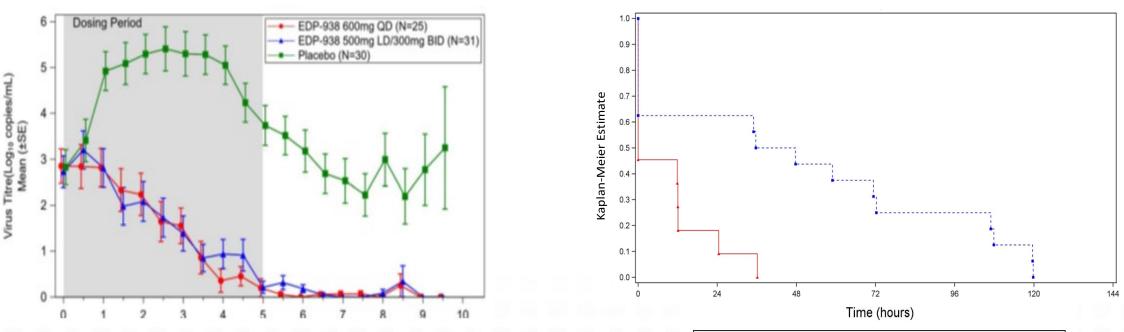
#### • Transmission studies

- Inoculate donor volunteers and directly test if a vaccine or drug intervention is able to prevent transmission to a recipient volunteer
- Utilising flexible space linked to quarantine unit, specifically designed to be able to control conditions appropriate for transmission studies



### Enanta's EDP-938 RSV treatment

### SAB-176 influenza symptom resolution



Treatment Group: \_\_\_\_ SAB-176 (N=11) --- Placebo (N=16)

### Benefits of Human Challenge Trials



- Generates invaluable dosing, safety and stentific efficacy data
- Helps optimise for larger field trials
- De-risks Phase III programs

### **Financial**

- Significant valuation uplift for Biotech sponsor
- Quick, cost-effective data in a tight funding environment
- Allows products to "Succeed fast" or "Fail Fast"

**Benefits of** Human Challenge **Trials** Regulatory Financial

Clinical D

elopment

### **Clinical Development**

- Requires fewer subjects
- Significant time savings
- No seasonal dependence

### Regulatory

- Potential for Fast Track or Breakthrough designation - accelerating time to market
- Potential approval and Emergency Use **Authorisation**



### Stephen Lockhart

Former Vice President, Vaccine Clinical R&D Europe and Asia-Pacific Head



The Role of Human Challenge Trials in Drug Development



# **Stephen Lockhart** MA, BM BCh, DM, FFPM, FMedSci



- Worked on vaccines including Haemophilus influenzae type b, pneumococcal conjugate (7, 13, 20), meningococcal conjugate and nonconjugate, Anthrax, paediatric combinations, HPV, influenza, COVID-19, Clostridoides difficile, RSV and others
- Phase 1 through 4 vaccine trials, including human challenge studies

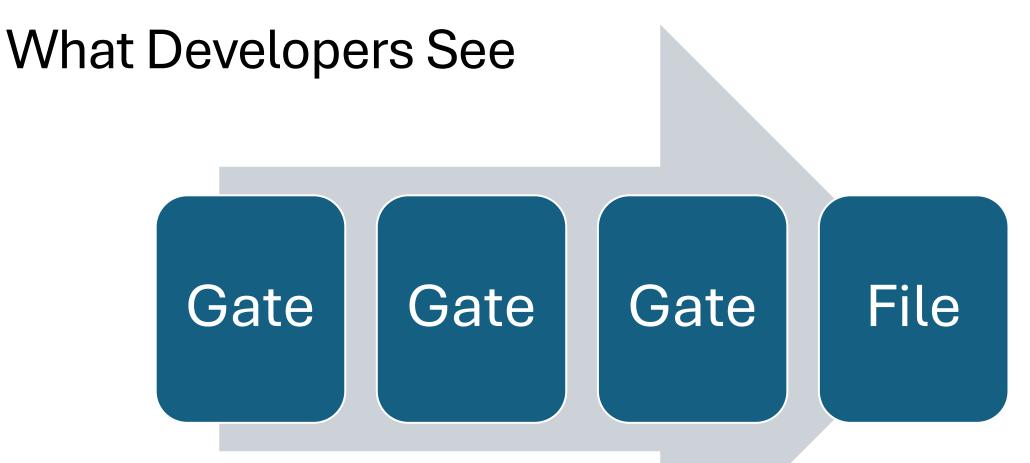






# What the World Sees





### EVER INCREASING INVESTMENT

# Methods to Inform Investment Decisions

### Confidence and Cost Increase in Parallel

Human Efficacy Against Natural Disease

Human Challenge

Human Antibodies and T-cells

**Animal Challenge** 

**Animal Antibodies and T-cells** 

In Vitro

# **Challenge Trial Endpoints**

### **PRIMARY OBJECTIVE:**

• IMP effect vs. placebo



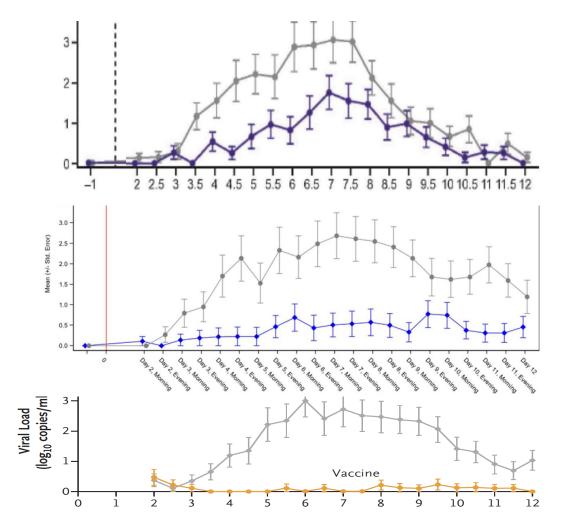
### **POSSIBLE ENDPOINTS:**

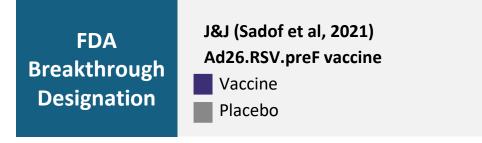
- Reduction of viral load AUC
- Reduction of Peak Viral load
- Clearance of viral load
- Reduction of total symptoms score AUC
- Reduction of disease incidence
  - Subjects with Total symptom score (TSS)  $\ge x$  at single time point
  - Symptomatic infected (PCR confirmed infected subjects with TSS ≥ 2 at single time point)
  - Subjects with Total symptom score (TSS)  $\ge x+y$  at single time point
  - ≥ grade 2 symptoms
  - Modified symptomatic infected: PCR confirmed infected subjects with symptom of ≥ grade 2
  - ILI: fever and or x TSS symptom level in infected subjects

# Universal Flu Vaccine as an Example

- Current vaccines use haemagglutinin antigen (HA) which rapidly evolves and is matched to current viruses
- ✓ For new HA-based vaccines antibodies predict effectiveness
- "Universal" flu vaccine uses new, conserved antigens but we have no clear predictor
- "Universal" flu vaccine efficacy trial will be very large, very expensive and high risk
- Human challenge study greatly mitigates risk

# **Regulatory Benefits**





FDA<br/>Breakthrough<br/>DesignationBavarian Nordic (corporate website Sep 2021)MVA-BN RSV vaccineVaccinePlacebo

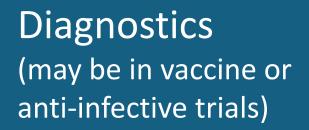
FDA Breakthrough Designation Pfizer (Schmoele et al, 2022) RSVPreF vaccine Vaccine Placebo

# Applications

 $\bigcirc$ 









Basic biology studies by publicly funded academic groups



# Biopharma Insights: Why do a Human Challenge Trial?



Fireside Chat



# Chaired by Dr Yamin 'Mo' Khan, CEO



Stephen Gordon

Professor of Respiratory Medicine

LIVERPOOL SCHOOL OF TROPICAL MEDICINE



#### Stephen Lockhart

Former Vice President, Vaccine Clinical R&D Europe and Asia-Pacific Head





Alex Mann Senior Director, Clinical Science







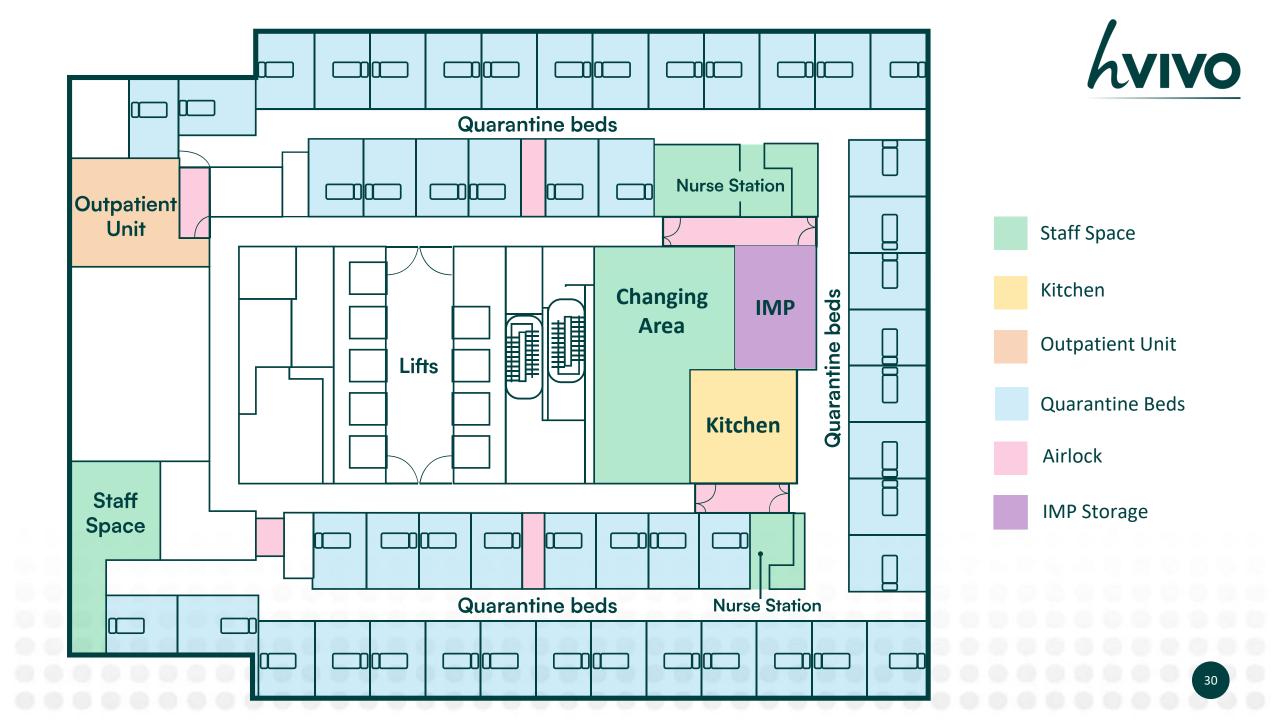






Director, Clinical Operations

### The World's Largest Human Challenge Trial Unit





# Conducting Trials with Hazard Group 3 Pathogens

Rooms are built to hospital isolation standards with HEPA filters on all air extracts in each isolation room

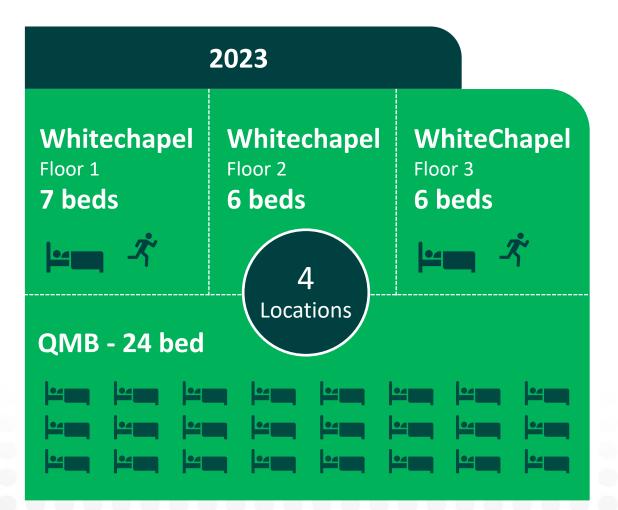
#### **Air Handling Unit**

- Maintains negative pressure in each room
- Between -5 and -15 pascals
- 8-10 air changes per hour
- The failover system

#### **Back up Power**

- Building is connected to 2 separate power station via 4 power lines
- Should the power from all 4 lines fail, there are back-up generators on the roof

#### Improved resource utilisation





### **Operational Improvements**

**Two- way call bell systems** - easy communication among staff and volunteers

- Faster communication and therefore faster problem resolution for volunteers
- 3 tier alert system that priorities the calls according to need

**Pneumatic chute system** - samples transported to the lab in ~30 seconds

 Previously this would require to be resourced and could take 7-8 minutes depending on the site of collection



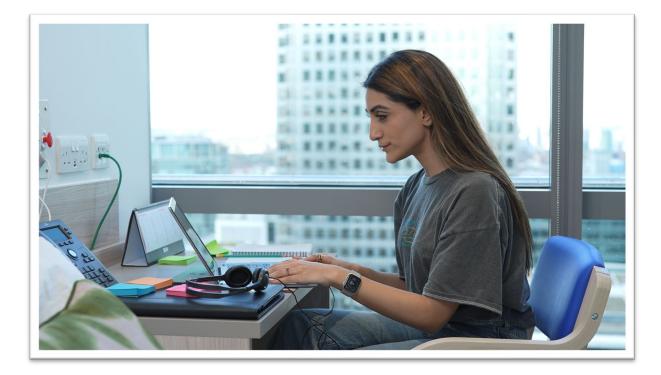




### Participant Comfort



#### State-of-the-art clinical trial unit – designed to maintain infection control



"The thing that I liked about this FluCamp trial was that there were lots of improvements since my last trial. E.g. There was more variety on the menu and also I had a kettle and snacks in my room this time. The night light was good too."

- Air conditioning unit within each room
- PS5 & 43" Smart Television
- High grade hospital furniture
- Highest comfort mattresses
- Freshly prepared food on-site



### Staff Wellbeing and Retention



#### State-of-the-art clinical trial unit – designed to maintain infection control



Better storage and having stock easily accessible is a win!

The opportunity to put our acquired knowledge and skills into practice manifested in the design and build phase of our purpose-built facility at CW and is already reflected in the quality and increased output at the site.



Staff wellbeing area has beautiful views and light.

Corridors are nice and spacious in comparison to QMB, first thing I commented on when I saw the pics.







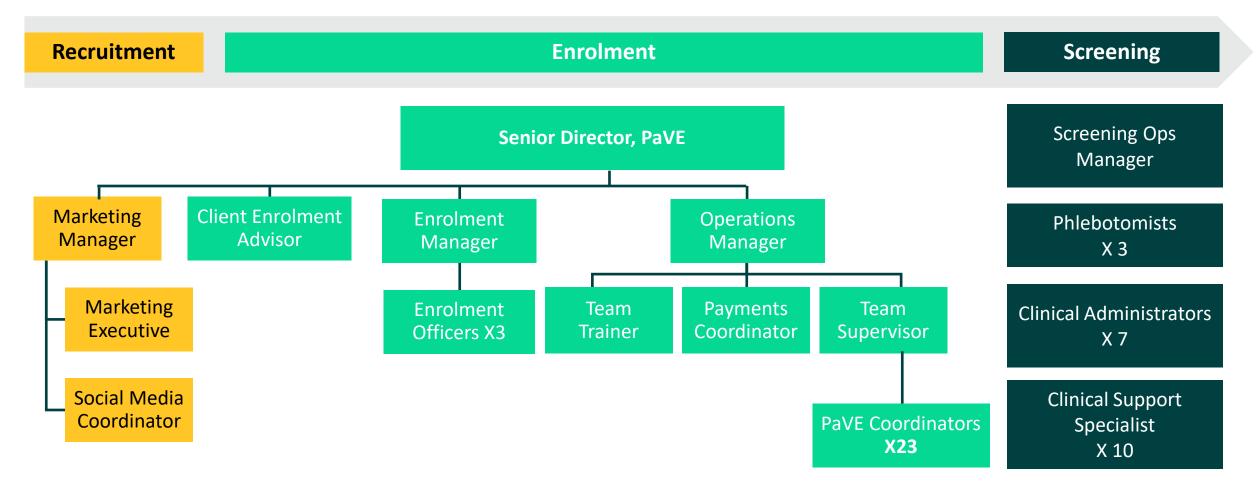
#### FluCamp - The Leading Volunteer Recruitment Platform

# TRANSFORMING RECRUITMENT



# **FLUCAMP ENROLMENT TEAM**

#### Team of >100 people working towards the successful enrolment of participants



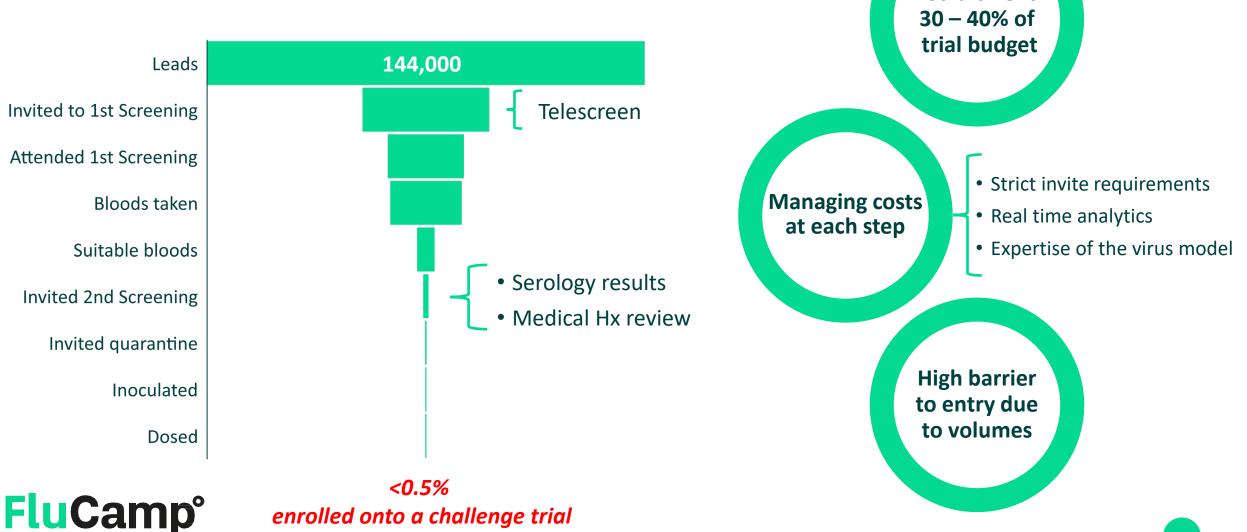


Generic Screening Protocol (Asthma & Healthy) Screening 5+ days per week – Capacity 1,000+ per week



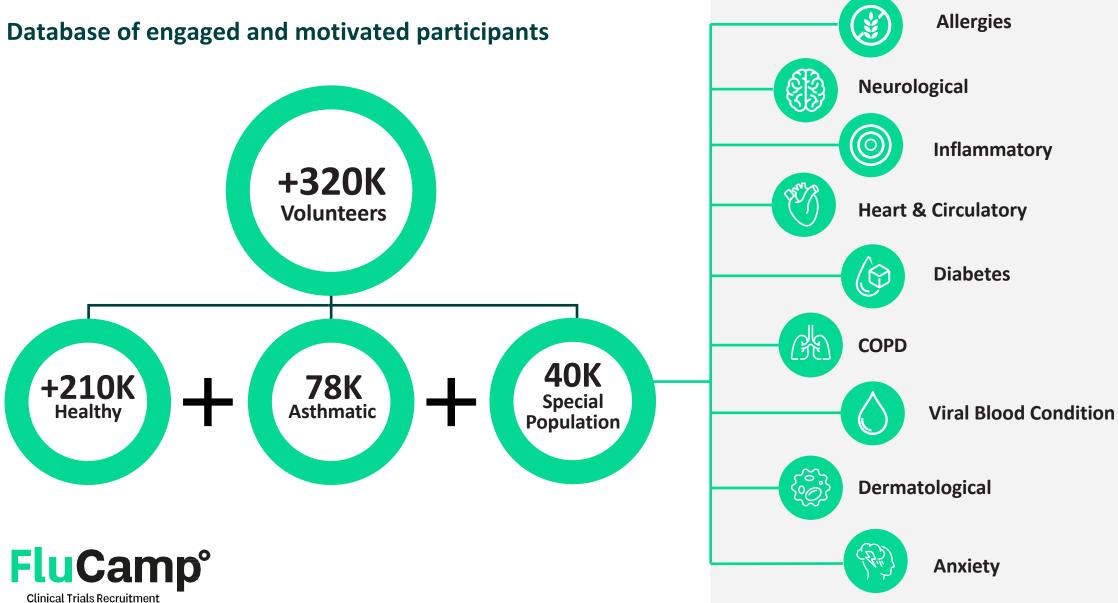
#### Lead to inoculation - 2023

**Clinical Trials Recruitment** 



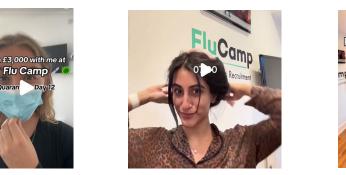
Recruitment

# **FLUCAMP DATABASE**



# FLUCAMP AS A SERVICE

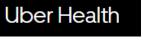
- Loyal volunteer community
- Collaborate on material generation
- 135 User Generated Content





#### Key partnerships

 Access to 7 million primary care patients





National Institute for Health Research NIHR

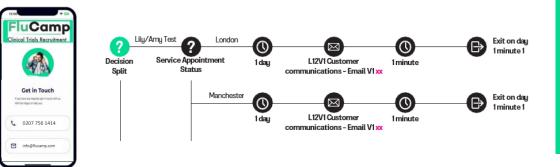






• Latest technological solutions





**EMIS** 

# FLUCAMP PORTAL

## Launch 2024!



#### LIVE DATABASE ACCESSIBLE BY CLIENTS



# TIERED RECRUITMENT OFFERING



## **CASE STUDY - RECENT CONTRACT**

FluCamp approached by a large Global CRO to support with a difficult to recruit population

Target of 50 referrals

**FluCamp**°

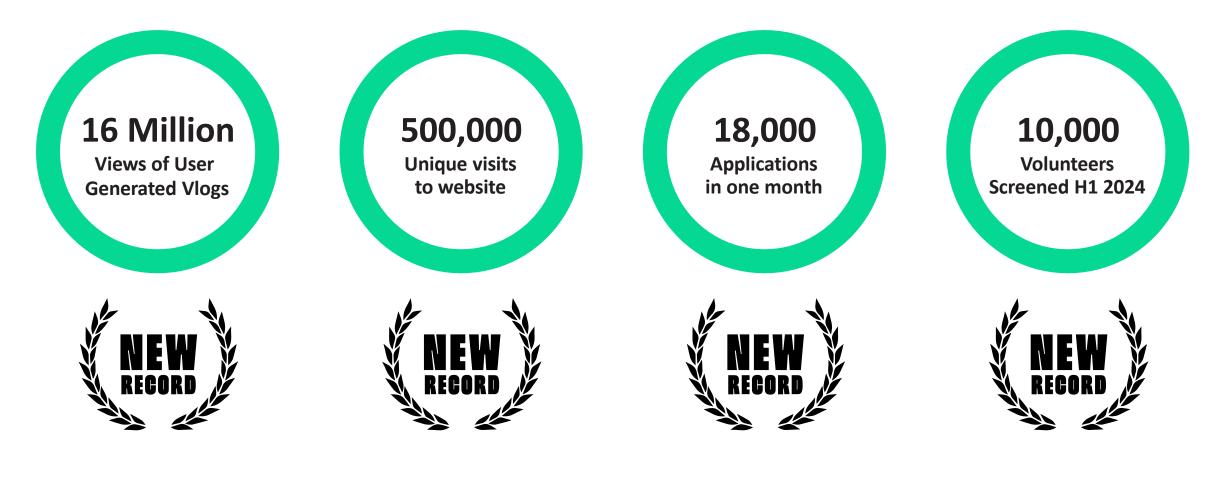
**Clinical Trials Recruitmen** 

- Essential package database review & outreach
- 98% of participants engaged gave consent
- ✓ All 50 referrals completed within 4 weeks
- Discussion on moving to Advance model





# KEY STATS JAN - JUNE 2024











**Scan for Video** 





# Alison Boyers & Marianne Derricott

Director, Laboratory Project Operations & Associate Director, Laboratory Operations





hLAB - New State-of-the-Art Labs Facilitating a Growing Service Offering

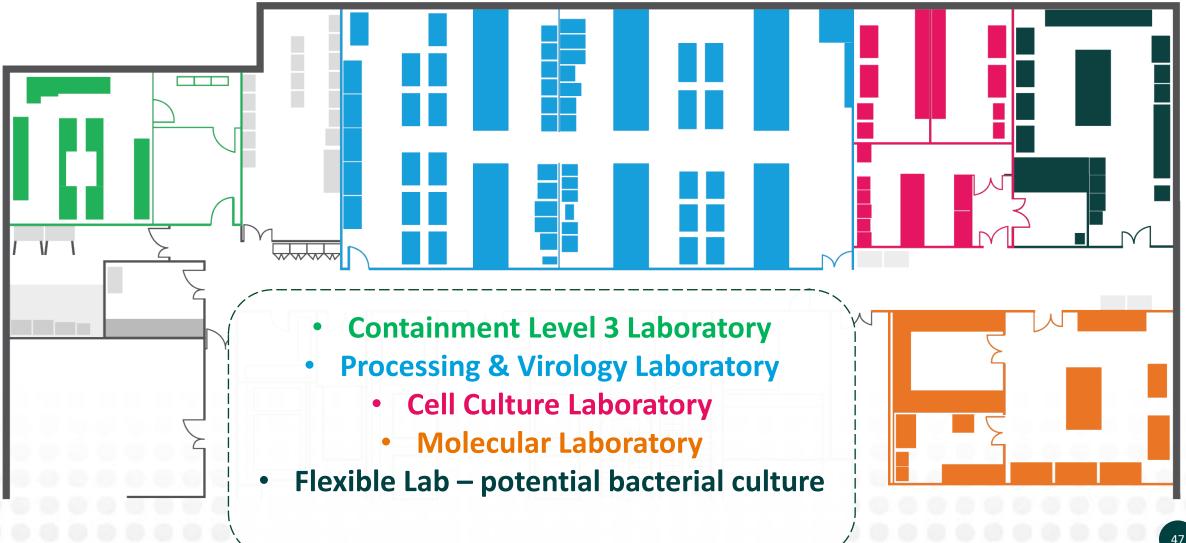


Previous Site	Previous Site	Canary Wharf		
<b>246</b> m <sup>2</sup>	Usable Lab Space	580m <sup>2</sup>		
3 <sup>rd</sup> Party	CL3 Lab	✓ In House		
-	Automated Sample Dispatch	$\checkmark$		
3 <sup>rd</sup> Party	Autoclave Room	✓ In House		
-	Dedicated Storeroom	$\checkmark$		
-	Additional Flexible Lab Space	$\checkmark$		

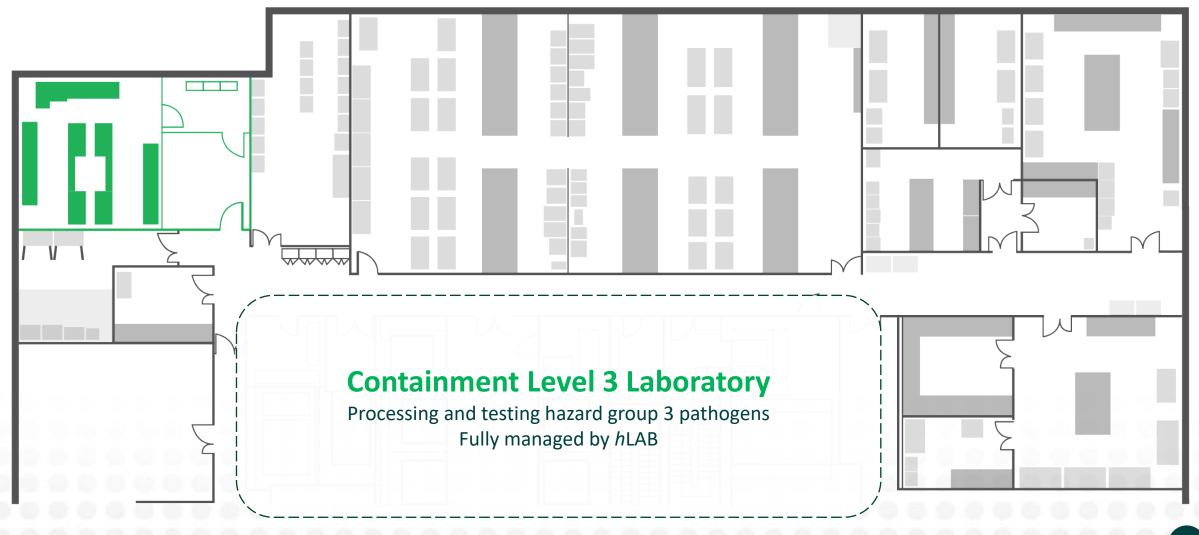




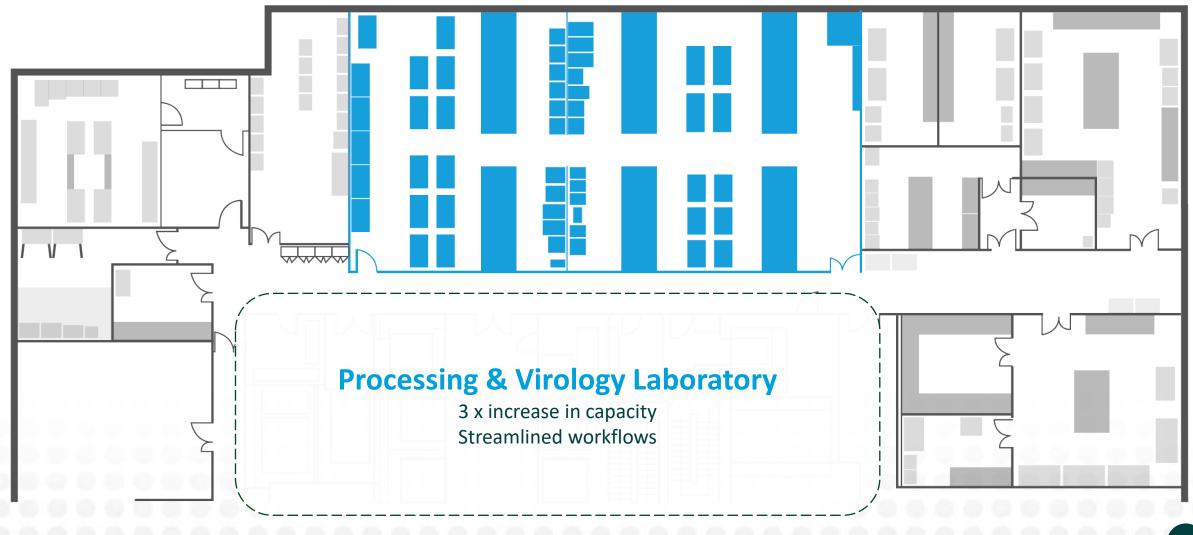




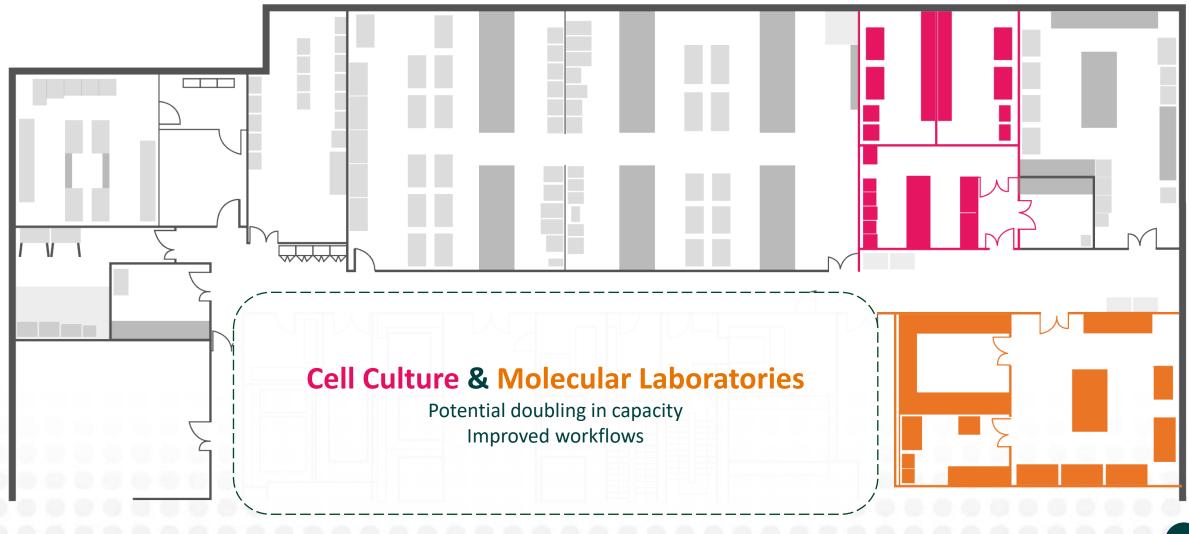




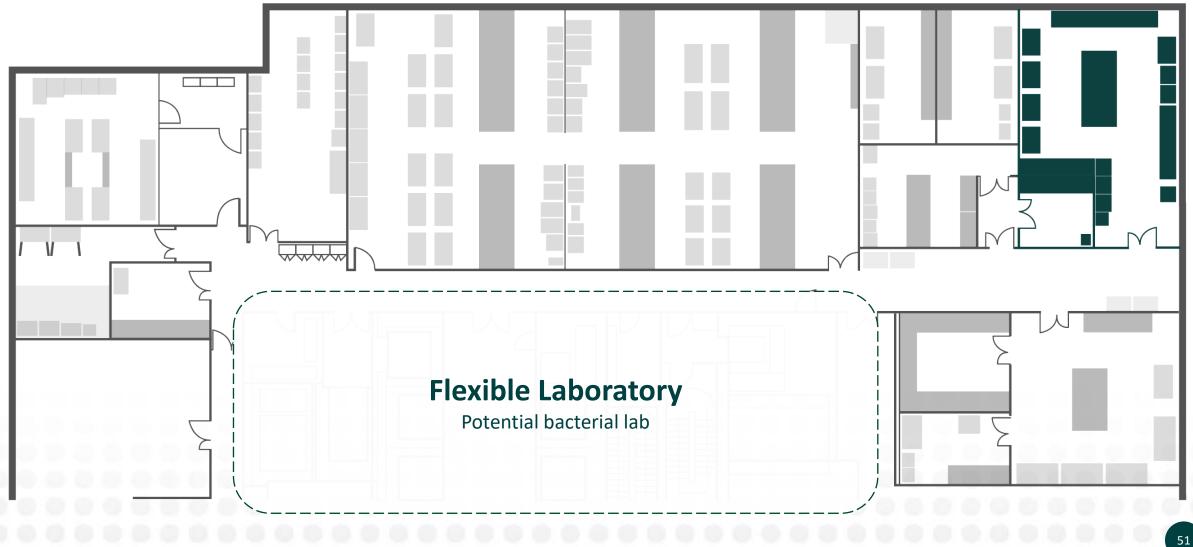
















#### **Brand Awareness**

- Targeted outreach to potential new clients
- Updated marketing materials
- *h*LAB website
- Launch at World Vaccine Congress in Oct

#### Growth

- Larger lab capacity
- Increase in subject matter experts
- New revenue streams
- Lab partnerships



#### **Scientific Expansion**

- Large expansion in assay portfolio to include new specialties
- **Biospecimen Services**
- Lab focused publications

#### ABWARE **Results** Count

#### Systems & Technology

- Increased automation: PCR & Cell culture
- LIMS & eSource integration

# Expansion of Assay Portfolio

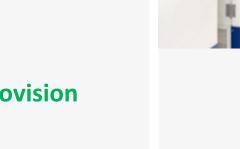




Serology, PCR, Infectivity assays: Influenza A & B RSV HRV SARS pre-Alpha **PBMC Processing** 

**BioMarkers** 

Clinical Trial Kit Provision





**hMPV:** FRNA/PCR/FFA

SARS Omicron: FRNA/PCR/FFA

# Options for the future:

Bacteria Pandemicpotential Influenza Dengue Yellow Fever Zika







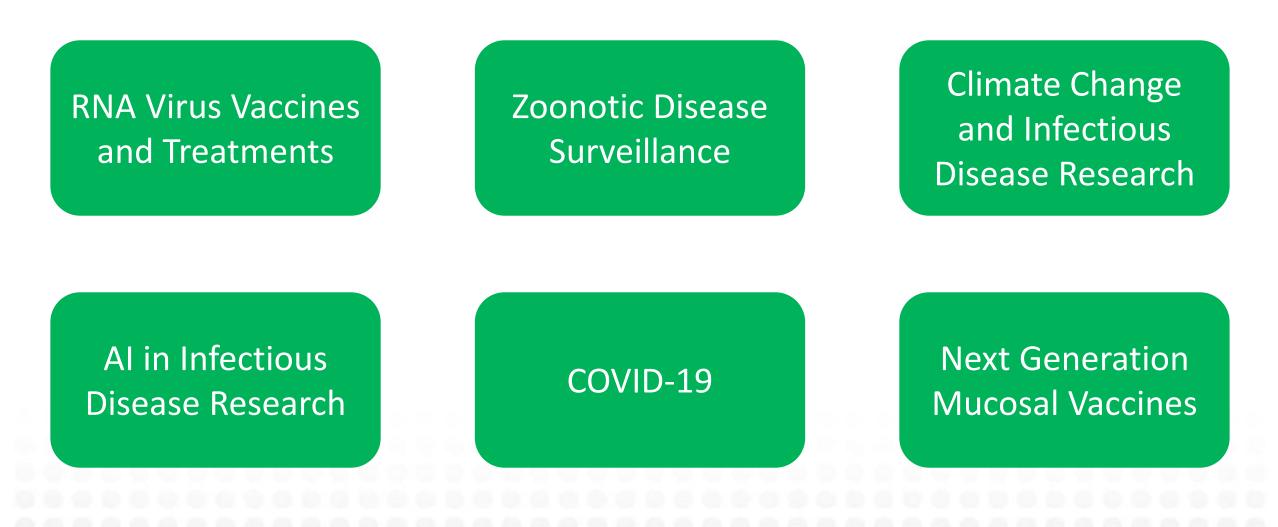




#### Director, Business Development

#### Expanding Services & Driving Efficiency





# A Growing Market





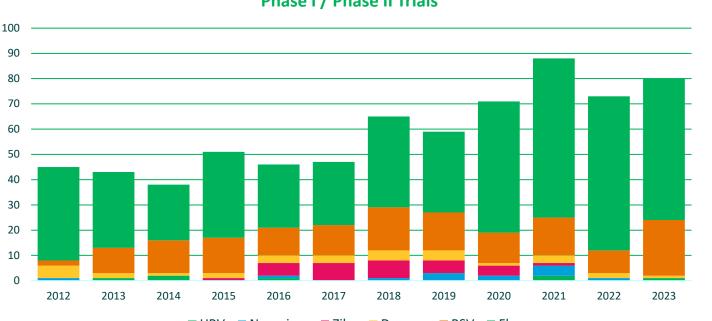
Increase in academic and nonprofit funding



Growing Healthcare Funding: \$13Bn Q1 2024 \$5Bn Q1 2023



Growing number of academic and 'commercial' human challenge units



#### Phase I / Phase II Trials

■ HRV ■ Norovirus ■ Zika ■ Dengue ■ RSV ■ Flu



# hVIVO's Growing & World Leading Services





## End-to-End Human Challenge Trial Services



Patient Recruitment Services



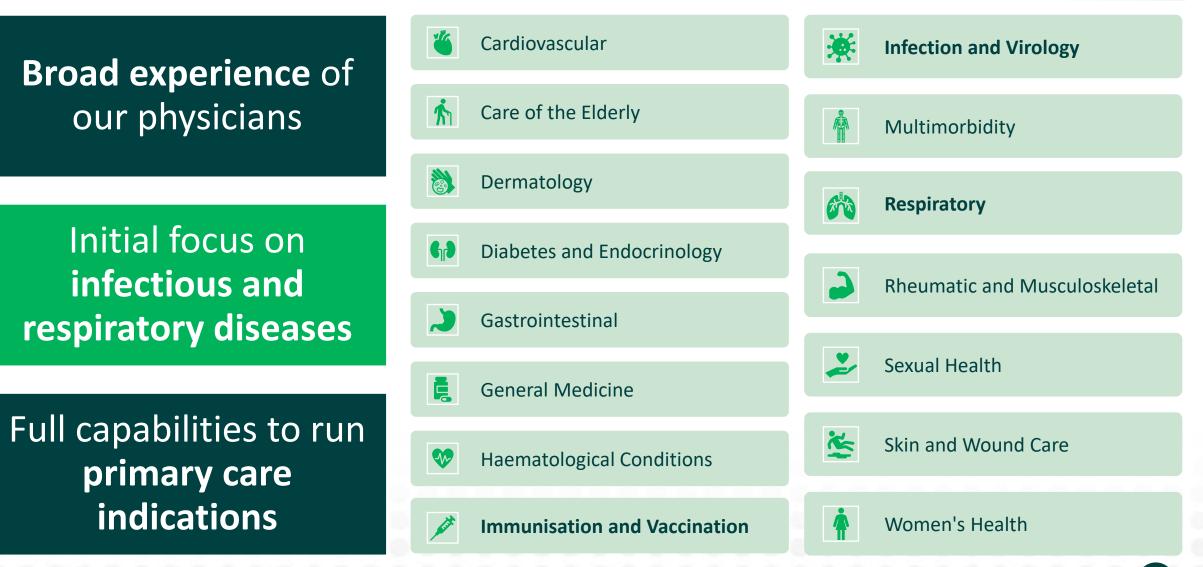


Clinical Site Services

Addressing the need of specialised services in infectious and respiratory diseases

# New Patient Studies – Primary Care Indications





# Case Study: Phase 2b Field Study





#### FluCamp

Enrolling up to 1,000 volunteers in 8 weeks



Flexible Resourcing Model





### Expansion of Out-Patient Unit to Facilitate Future Field Studies

#### Increasing Vaccination Capacity from 100 to 200 volunteers per week







#### **Different Collaboration Scenarios**

**Full-Scope** Phase II studies Acting as a Site in large Phase II-III studies Stand-alone Recruitment Services (subject referral)

# Venn Life Sciences Service Offering



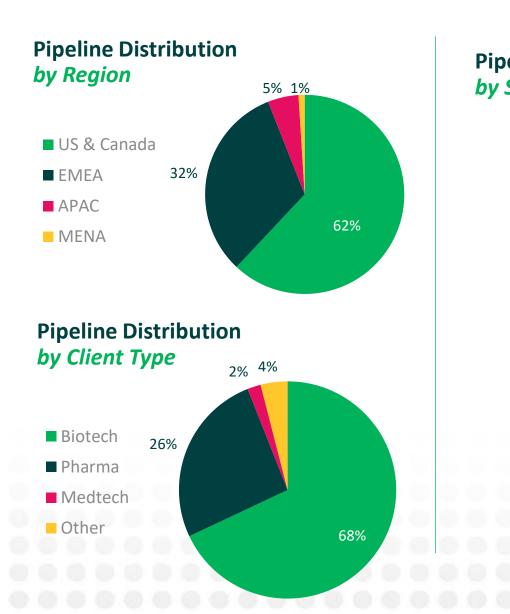
				part of hVIVO		
Discovery/Lead Optimization	Drug Development	NDA, BLA,	MAA	Lifecycle Management		
Gap Analysis, Due diligence						
	Quality (Chemistry, Manufacturing, and Controls)		V	ariations/ Changes		
	Quality development (CMC): process development, analytical development, process development, analytical development, process development, and characterization, specification setting, stability studies, formulation, CDMO sel and management			Process changes provements		
(Q)TPP, DDP	Nonclinical					
	Nonclinical development: proof of concept, ADME, toxicology,Toxicokinetics, safety pharmacology etc					
	Biomarker Safe starting dosePhase IPhase IIPh	nase III	Pos	st-Marketing Studies		
	Clinical development: clinical trial design, PK/PD, M&S, project management (Phase I), medical writing (clinical operations only for phase 1)					
<b>Regulatory Affairs</b>	s CTA, IND CTA, IND CTA	A, IND	Mar	keting Authorization		
	Scientific Advice meetings	CTD				

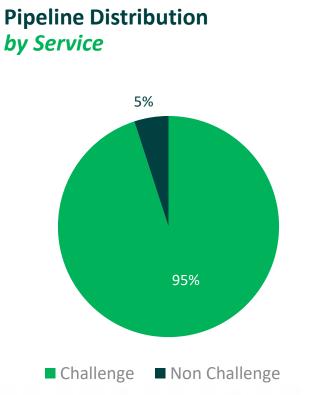
Scientific Advice meetings Pre-IND meeting, EOP1 meeting

CTD authoring

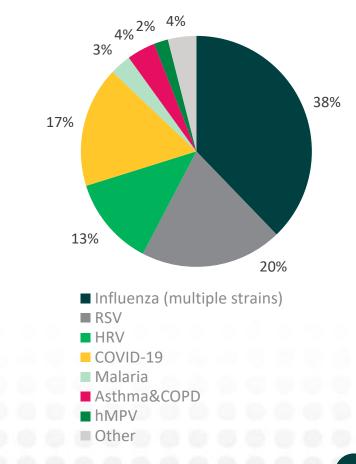
# Diverse and Growing Sales Pipeline







Pipeline Distribution by Model





# Dr Yamin 'Mo' Khan & Stephen Pinkerton

A THERE BELLA

**Chief Executive Officer** 

**Chief Financial Officer** 

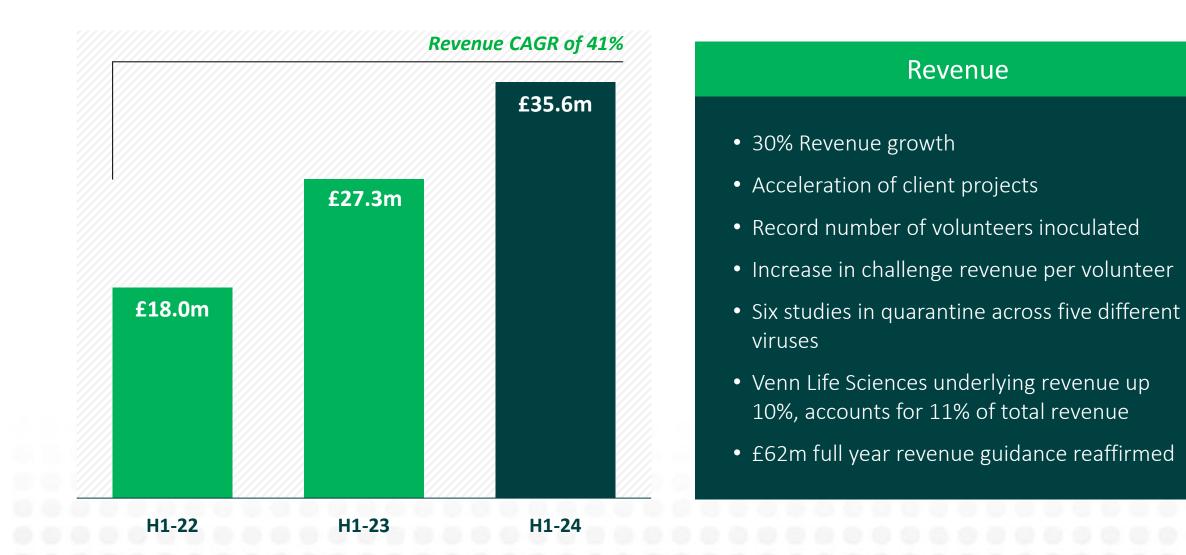




Trading Update Q&A

## Record Revenue Growth





# An Increasingly Profitable Business

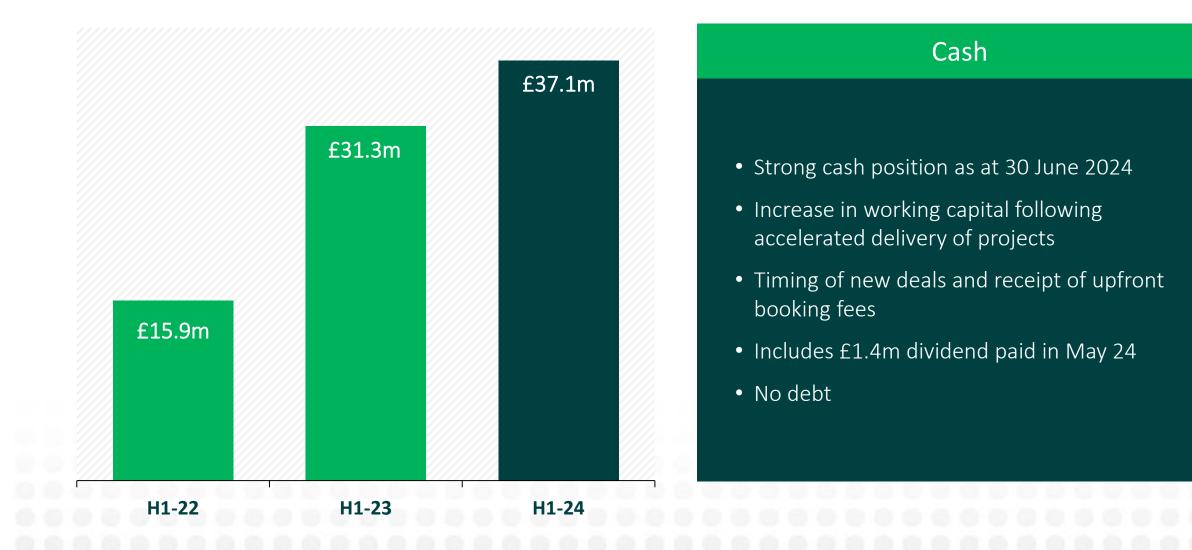


#### EBITDA Margin

- Significant volume of work leads to margin uplift in H1 24
- Good utilisation of the overlapping facilities
- Significant Flucamp synergies delivering lower volunteer acquisition costs
- Includes manufacturing costs for replacement viruses & facility move costs
- Full year EBITDA margin at the upper end of market expectations

## Cash Generative Business









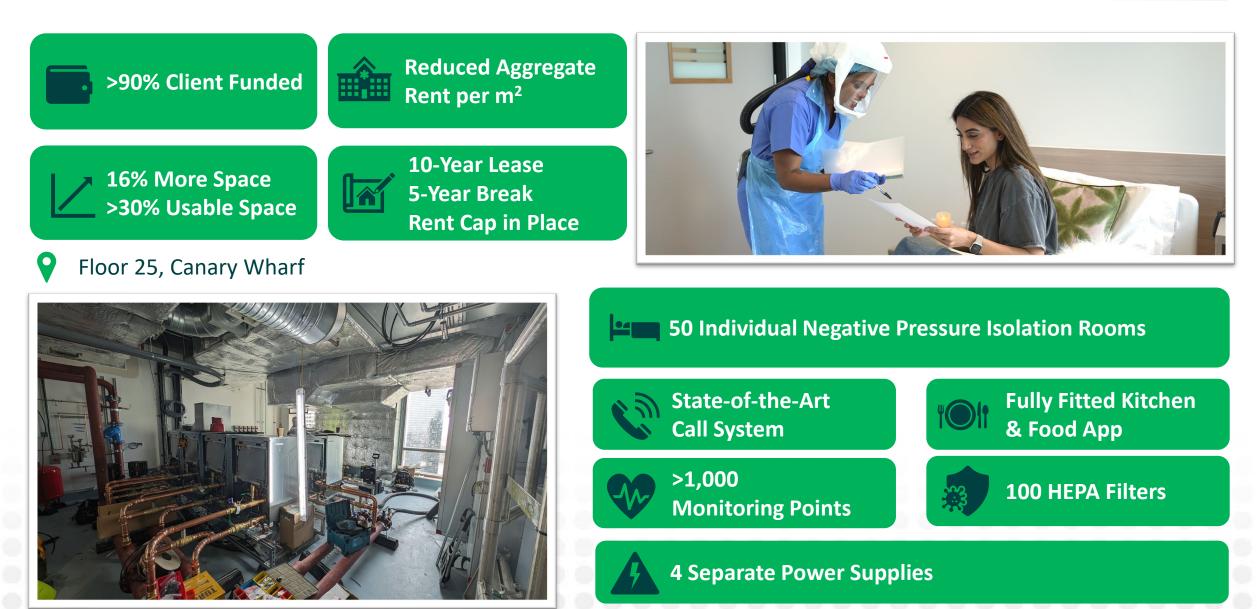


Chief Executive Officer

#### Closing Comments

## The World's Largest Human Challenge Trial Unit





# hlab







CAP-Certified Virology & Immunology Labs



Scope for Bacterial Lab



BLS-3 Lab

3x more usable space



Pneumatic chute system



### Mission

Delivering today's healthcare by empowering tomorrow's innovation.

## Vision

To transform global healthcare by revolutionising the drug development process through scientific ingenuity.







# Stay in touch

