

# hVIVO



## Company Presentation

January 2025

AIM: HVO

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Dr. Yamin 'Mo' Khan  
Chief Executive Officer



*The strategic acquisition of CRS*

# Expanding our European Footprint

**hVIVO**

  
Venn Life Sciences  
part of hVIVO

**hLAB**

 **CRS** EXPERTS.  
EARLY PHASE.

## Mission

Delivering today's healthcare by empowering tomorrow's innovation

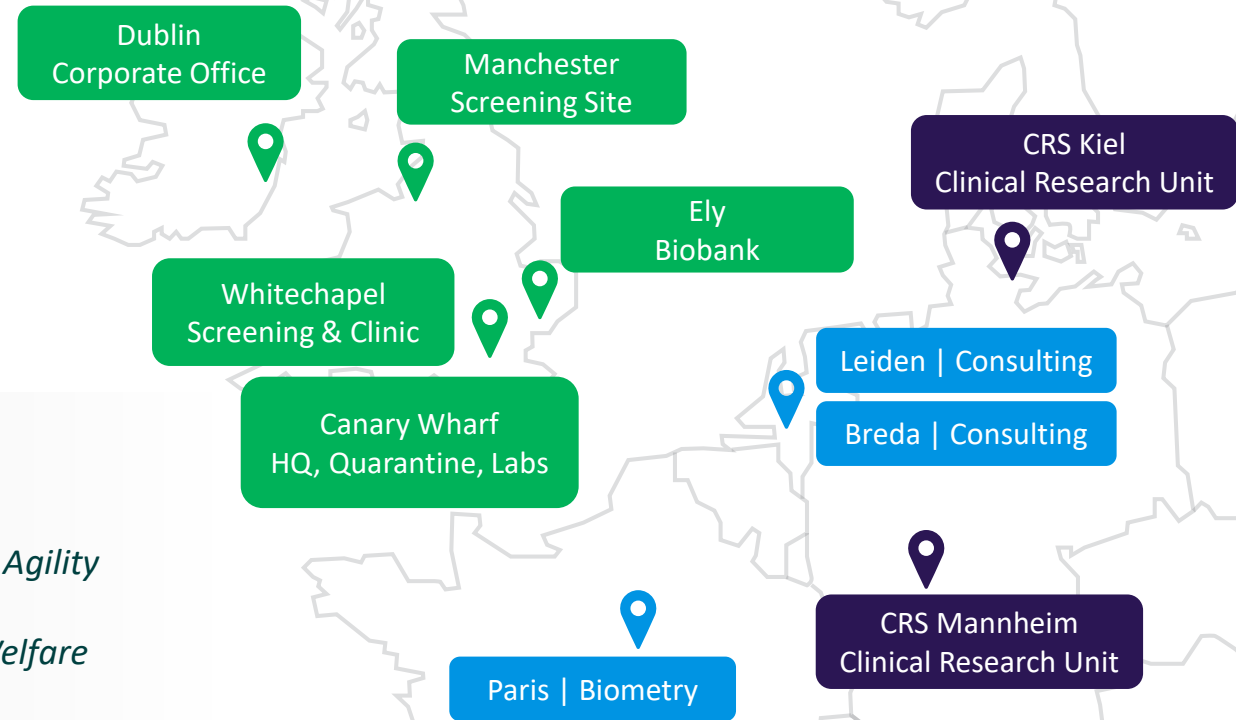
## Vision

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

## Values

- ✓ *Innovation & Agility*
- ✓ *Growth*
- ✓ *Integrity & Welfare*
- ✓ *One Team*

 hVIVO Location  Venn Location  CRS Location



# Who is CRS?



## BUSINESS OVERVIEW



Full-service early phase Contract Research Organisation (CRO) which provides solutions for early clinical development, from First-in-Human studies to Proof-of-Concept trials in patients



**Mannheim**  
94 beds, 2290m<sup>2</sup>



**Kiel**  
26 beds, 590m<sup>2</sup>



**European**  
Customer Base



**45+**  
Years of experience



**12**  
Customers in 2024



**120**  
Total Beds



**78**  
Long-term Beds



**GCP & FDA**  
Inspected



**>30**  
Drugs brought to market



**>50%**  
Repeat Business



**4**  
Top 10 global pharma clients

## LEADER IN EARLY-PHASE TRIALS

Long-term track record as early-phase specialist - high-quality, full service early-phase trials with unique patient access and reputable principal investigators

### Early-Phase Specialist

CRS is highly specialised in early phase trials I+IIa



**+1,850**

Trials Completed



**+37,000**

Subject Pool

### Trial Expertise

Reliable research in first-in-human and core indications



**>4**

Core therapeutic areas



**+100**

Specialists & experts



**9**

Years average tenure

### Dedicated Sites

One of the Largest Early Clinical Development Units in Germany

### A Trusted Partner

Broad, established client base across pharma, biotech & CROs

**Exemplary safety record – zero emergencies in 6 years – c.6,600 healthy volunteers & c.1,100 patients**

# Why CRS?



## Aligning with our M&A strategy to broaden our service offering for our clients

End-to-end early drug development service offering

Phase I capability (patients & healthy volunteers)

Increase in early-phase clinical studies (patients)

Expansion of geographies

Addition of new therapeutic expertise



Field study offering: multi-site capability

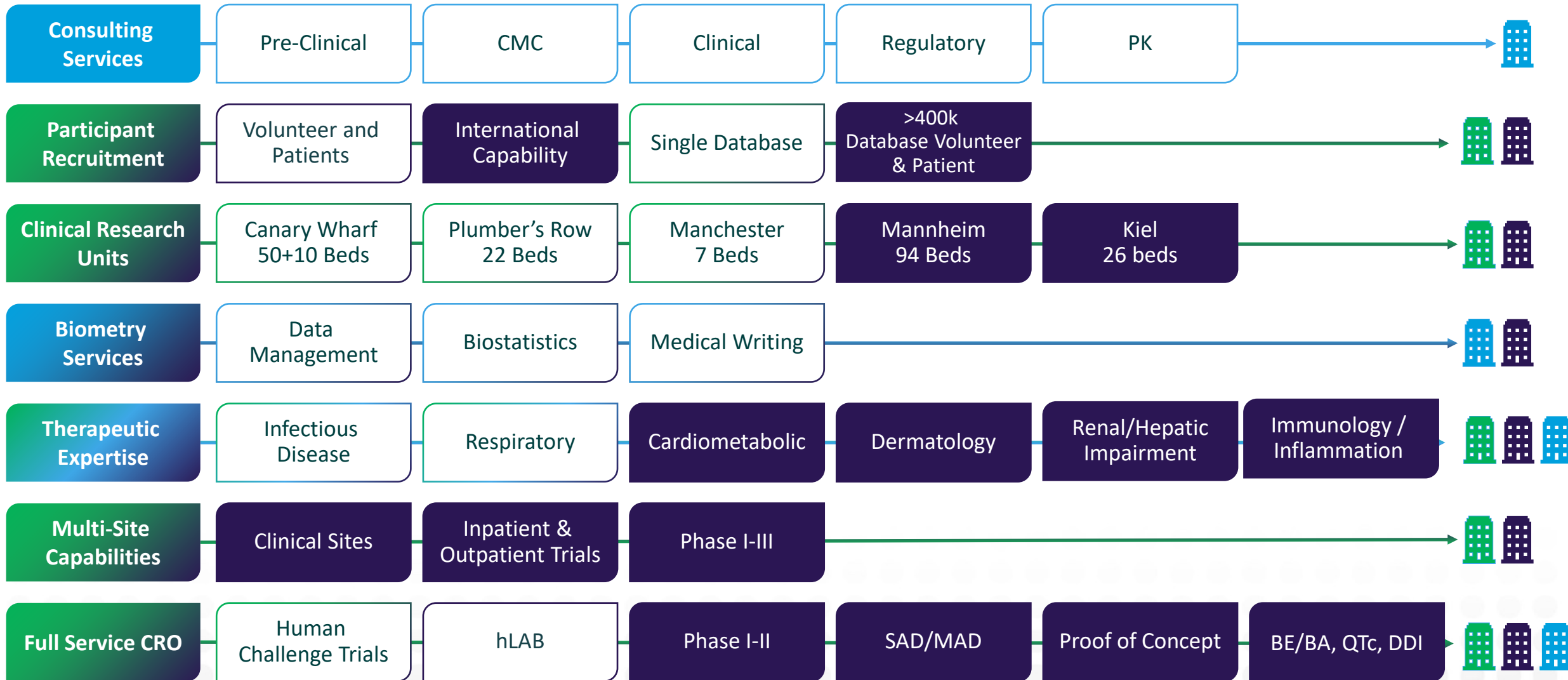
New geography for patient recruitment services

Cross-selling opportunities

Addition of new client base

History, quality and brand recognition

# A Newer Fuller Service CRO



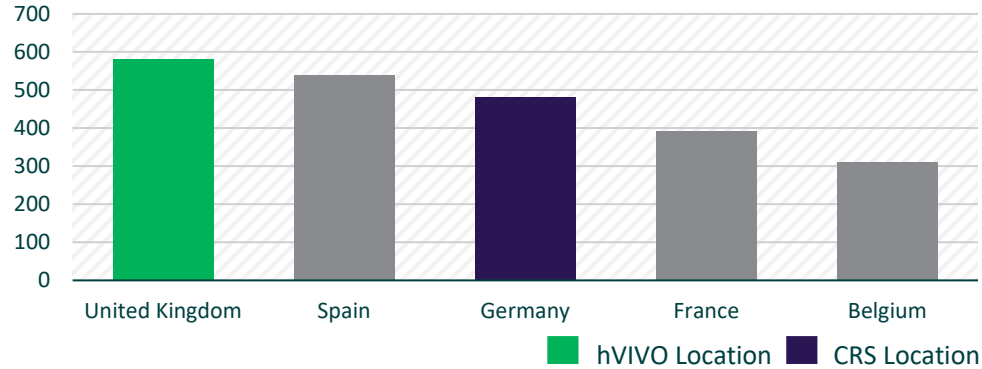
*Supported by strong back-end synergies*



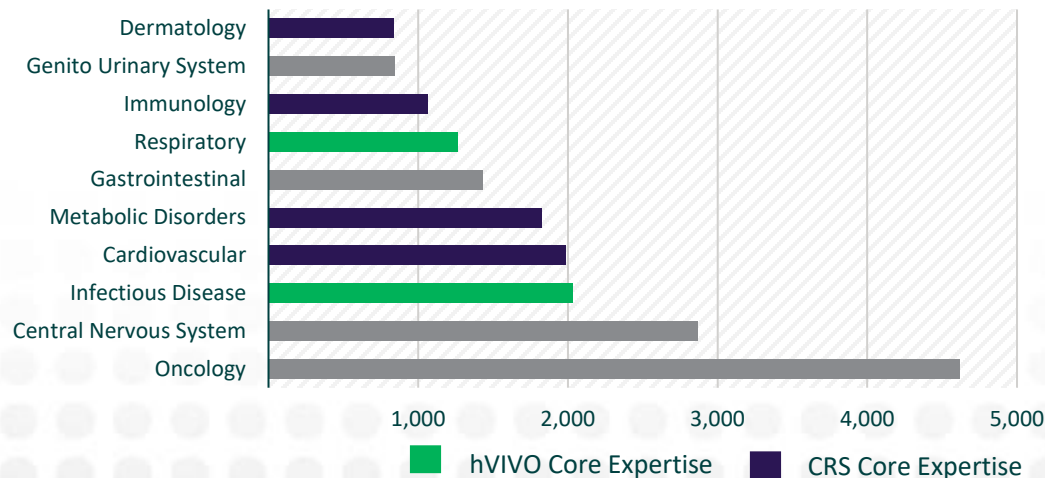
# Integrated Early Phase Solutions in Germany



## Phase I & Phase I/II Trials by Country (2021-2024)



## Global Phase I & Phase I/II Trials by Indication (2021-2024)



## Germany – A Key Location

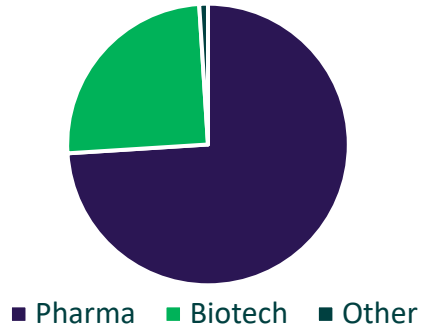
- **70 Ongoing Phase I trials in Germany**
- **Approval timeline** for clinical trials in Germany reduced from **45 days to 26 days (2024)**
  - Reduced approval times – **incentive** for sponsors, improved efficiency in project management - saving time and resources
- **A strong and growing market**
  - **>1,200** pharma & biotech companies
  - **\$6Bn** clinical trials market by 2030
- **Access to large pool of potential trial participants:**
  - Mannheim metropolitan area - **2.4m** inhabitants
  - Kiel metropolitan area - **5.4m** inhabitants
  - Active database - **37,000** participants



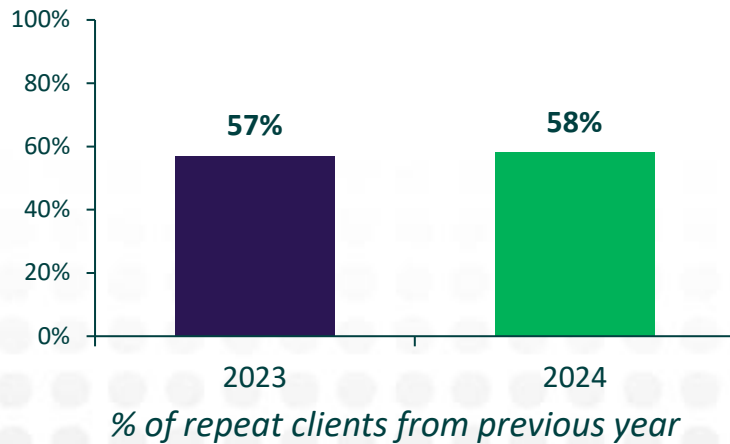
# Expanding Client-Base & Broadening Revenue Streams



## CRS Client Mix



## CRS Multi-Year Repeat Business



**12**  
*clients served in 2024*

**4 of the top 10**  
*global biopharma as clients*

**5**  
*+£1 million accounts in 2024*

**c.15 Years**  
*Average tenure of key clients*

## CRS – More, Higher Revenue, Multi-Site Patient Studies

### Studies 2018-2023



### Studies 2023-2024

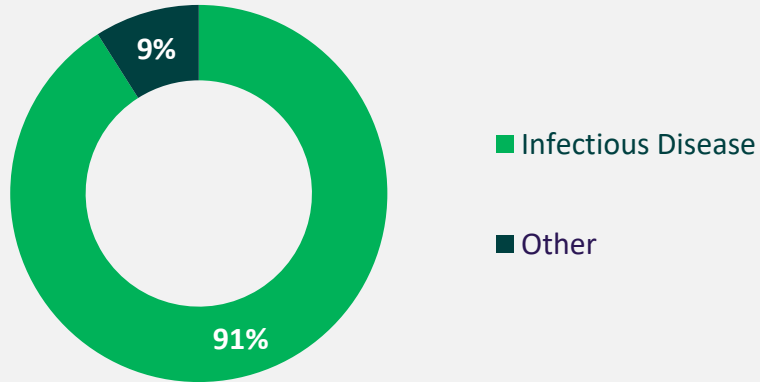


**9% first-in-human trials last 3 years**

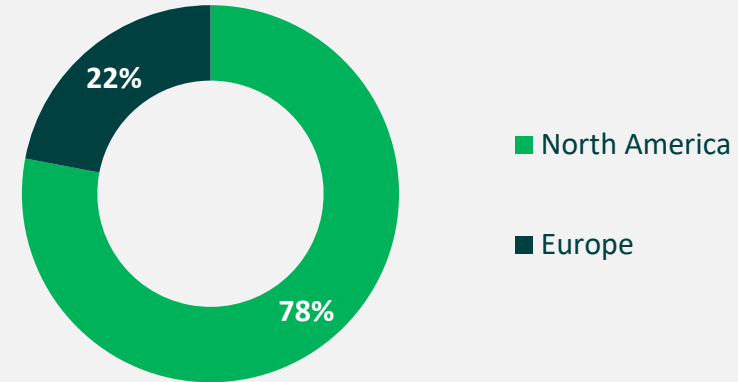
# Diversification of Clients & Therapeutic Areas



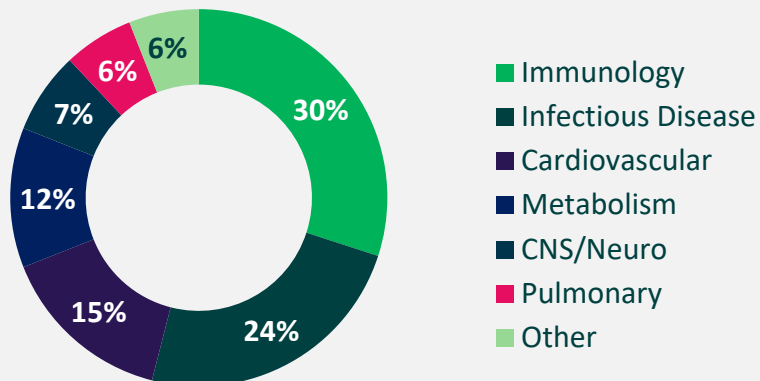
## Revenue by Disease Area - hVIVO



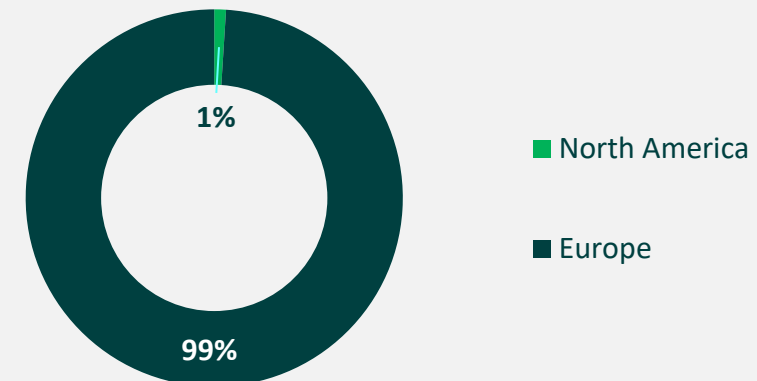
## Revenue by Client Geography - hVIVO



## Revenue by Disease Area - CRS



## Revenue by Client Geography - CRS





Stephen Pinkerton

Chief Financial Officer



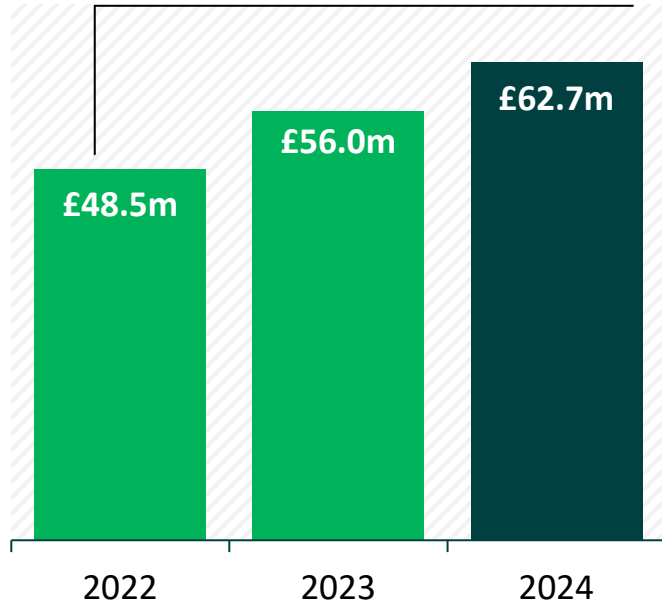
*A record year & first acquisition*

# hVIVO 2024 - Record Metrics

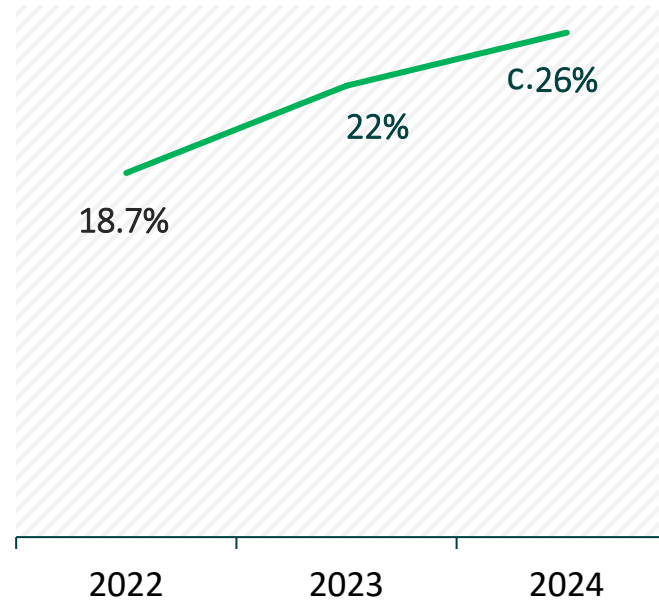


## Revenue

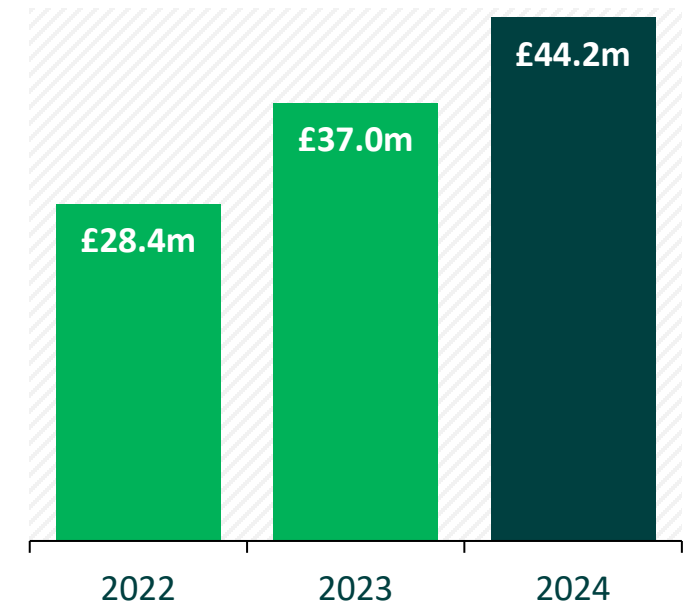
Revenue CAGR of 13.7%



## EBITDA Margin



## Cash



- 11.9% revenue growth
- Record number of inoculations
- New service field trial of 817 participants

- Facility funding
- Recruitment & clinic efficiencies
- New models & technology

- Overlapping facility costs
- Flow through of facility fee
- Strong cash generation continues

## CRS Trading History (unaudited)

- Revenue FY24 €19.9m (FY23 €18.6m)
- Adjusted EBITDA FY24 -ve€1.8m (FY23-ve€1.6m )
- Contracted orderbook - €11.1m (31 Dec 2024)
- No debt
- Net liabilities <€0.5m

## CRS Acquisition

- Cash consideration of €10.0m
- Fully funded by hVIVO's existing cash resources
- Paying c.0.5 X Revenue
- Restructuring & transaction costs c.€2.5m
- Acquiring annualised revenue of €19.9m
- 2025 adjusted EBITDA loss broadly in line with FY24
- Earnings accretive in 2026

## Realisation of Synergies

- Biometry services
- Medical Writing services
- PK analysis
- Clinical Operational planning
- Project Management
- Business Development
- Quality Assurance
- Back-end services

## Deployment of hVIVO's Systems to CRS to Deliver Efficiencies

- CRM system
- Recruitment System
- Clinical eSource
- eTMF
- LIMS

## High Performance Culture

- Open & collaborative culture
- Culture of innovation
- Transparency in operations & business performance
- Project tracking & deadline orientated
- Introduction of KPI & monitoring
- Rewarding all employees for success



Dr. Yamin 'Mo' Khan  
Chief Executive Officer



*Optimise, scale, diversify*

# Our Core Business: Human Challenge Trials



## 2024 Key Highlights

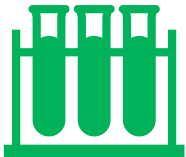
- New 50-bed CL-3 quarantine unit opened
- Record inoculations across 7 virus strains
- Expedited delivery of projects with 3 active quarantine sites in H1 24
- World's first Flu B human challenge trial successfully completed
- New H1N1, H3N2, RSV A, RSV B models now available
- Omicron characterisation study contracted
- hMPV challenge agent manufactured & successful pilot characterisation trial completed
- MSA signed with mid-sized pharma client for HCT services
- 5 scientific papers published
- 8 conference presentations

## Key Growth Drivers

- + Larger study sizes
- 📊 Broader portfolio of models
- 🌐 Bivalent / multivalent
- 💧 Mucosal
- 🦠 RSV antivirals
- 🦠 hMPV
- ✓ CL-3 capability
- 🔬 Bacterial laboratory
- 📌 Transmission studies
- 👁️ Market awareness
- 👥 Broader client base - cross selling opportunities



## hVIVO's Largest HCT to date with ILiAD Biotechnologies



### Pivotal Phase 3

- ILiAD's *B. pertussis* vaccine candidate
- Large scale pivotal challenge trial
- Post-FDA discussions
- Trial expected to commence H225



### Unmet Medical Need

- 16 million affected (2008)\*
- 195,000 global deaths (2008)\*
- Current vaccines have failed to control pertussis epidemic



### Study Aim

Generate efficacy data to support a marketing authorisation application



### Bacterial Challenge

- Expanding HCT portfolio to include bacterial challenge
- Capacity for bacterial lab at Canary Wharf

# Field Studies: Strong Success & Strategic Growth



## Largest Field Study to Date

**Multinational trial**  
Sites in US & UK,  
hVIVO selected as the  
sole UK site

**FluCamp**  
Successfully enrolled  
817 volunteers in  
just over 6 weeks



*I'm in awe of your dedication, efficiency, and attention to detail. You've not only set a new record but have done so while maintaining the highest standards of data quality. That's no small feat, and it speaks volumes about the calibre of your team.*

*Your hard work has given our study a tremendous boost, and I can't thank you enough for your commitment. You should all be incredibly proud of what you've accomplished.*



## 2025 & Beyond

CRS strengthening our field study offering

5

Sites

2

Countries

200

Total Beds

400k

Trial Participant  
Database

4

New disease area  
expertise

# Delivering - hLAB Standalone Services



## hLAB's Largest Field Study to Date

Multinational trial  
Phase 2 field study

£3.6 million  
Project value to date

US-based biotech



61 sites

Influenza  
Drug  
Candidate



5,000 Vols

~60,000  
Antibody assays  
on serum samples

~450  
PCR assays on  
respiratory swab  
samples

Genotyping &  
Phenotyping  
analysis

## State-of-the-Art Facility

New Facility Supporting Standalone Work



3X

Usable lab space

CL-3

Lab on-site

85k

Yearly samples

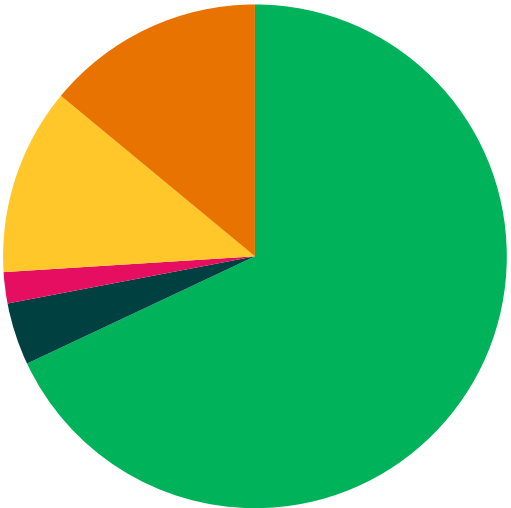
5

Contracts signed  
2024

99%+

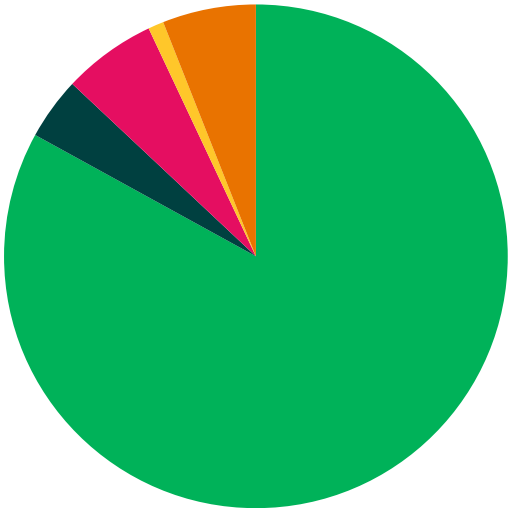
Study proposals  
in 12 months

## £67m Net Contracted Orderbook\*



- Challenge
- Site Services
- hLAB
- Venn Life
- CRS

## Pipeline Distribution by Service



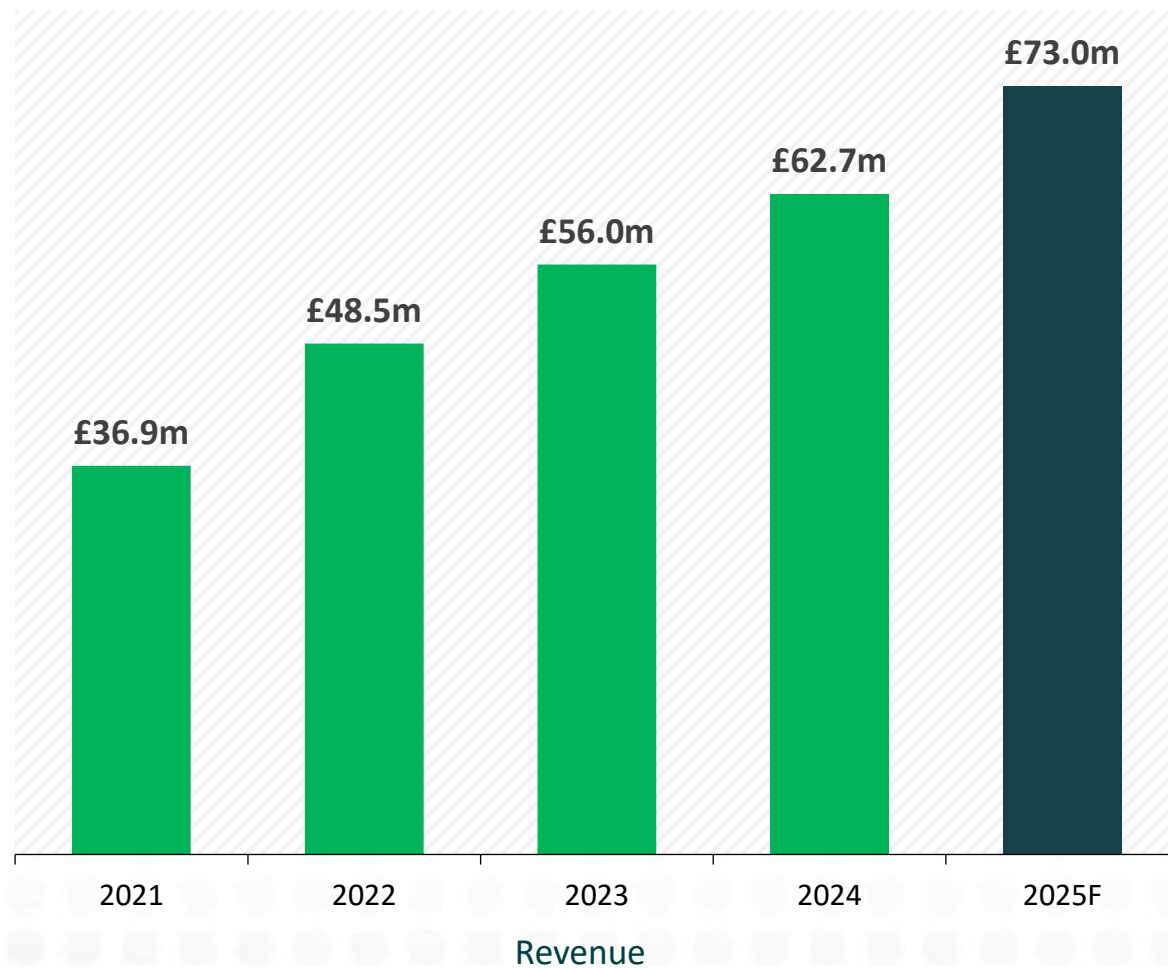
- Challenge
- Site Services
- hLAB
- Venn Life
- CRS

## Sales Pipeline *Record high - value & volume*

- c.£15m of c.£40m short-medium term potential opportunities contracted
- c.£25m remain active opportunities
- New opportunities added
- Strong interest in HCT following portfolio expansion
- Good client interest in hMPV
- Continued growth in new revenue streams expected
- Increase in CRS pipeline expected

\*Does not include recently announced pivotal Phase 3 HCT for ILiAD Biotechnologies, expected to be the Group's largest HCT to date

# Combined Company – Future Outlook



- 2025 revenue guidance of £73m (H2 weighting)
- 2025 adj EBITDA guidance mid-high teens\*, reflecting integration of CRS into the Group
- CRS brings new services, geographies
- Earnings accretive 2026
- A cash generative business
- Larger contract sizes across the board expected
- Continued momentum of hLAB & field studies
- Exploring further small bolt-on acquisitions
- On track to deliver £100m revenue by 2028

\*excluding any one-off costs

A photograph of two scientists in a laboratory setting, wearing full personal protective equipment (PPE) including hoods, face shields, and gloves. They are focused on a small vial held by one of them. The image is overlaid with a semi-transparent teal filter.

*h*VIVO

Questions



hVIVO

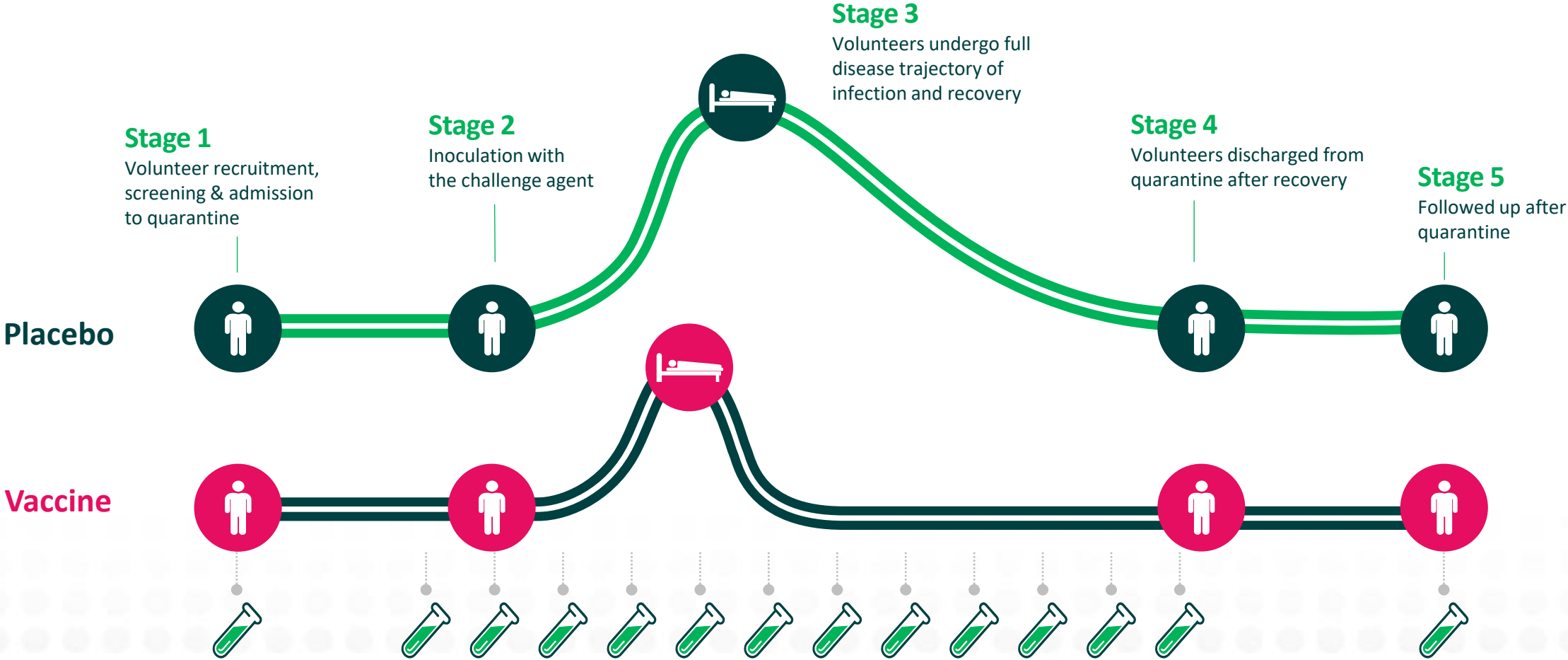
FluCamp<sup>®</sup>  
Clinical Trials Recruitment

Appendix

# What is a Human Challenge Trial?



A clinical trial where healthy volunteers are exposed to a pathogen to test the effectiveness of vaccine and treatments



...in a faster and more efficient setting.



# Benefits of Human Challenge Trials



## Scientific

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



## Clinical Development

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



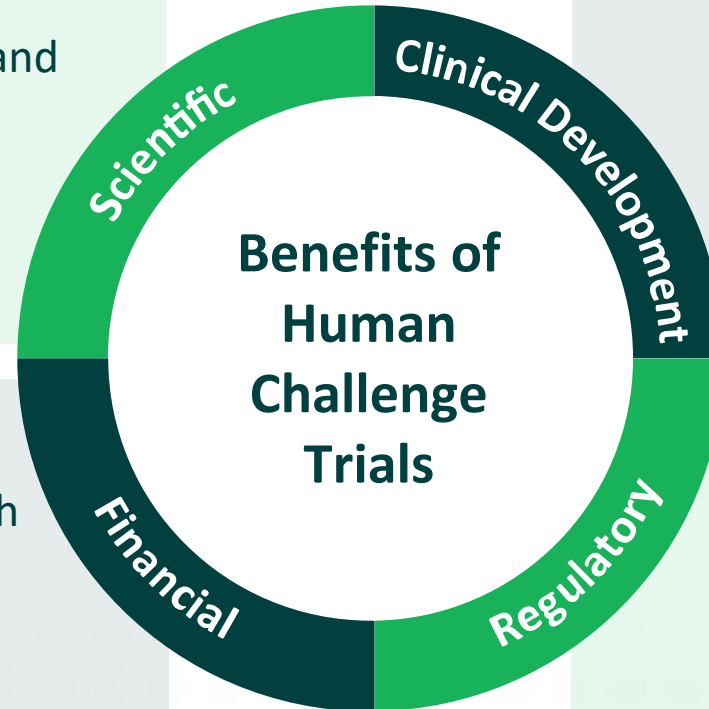
## Financial

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



## Regulatory

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



# hVIVO's Expanding Challenge Agent Portfolio



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

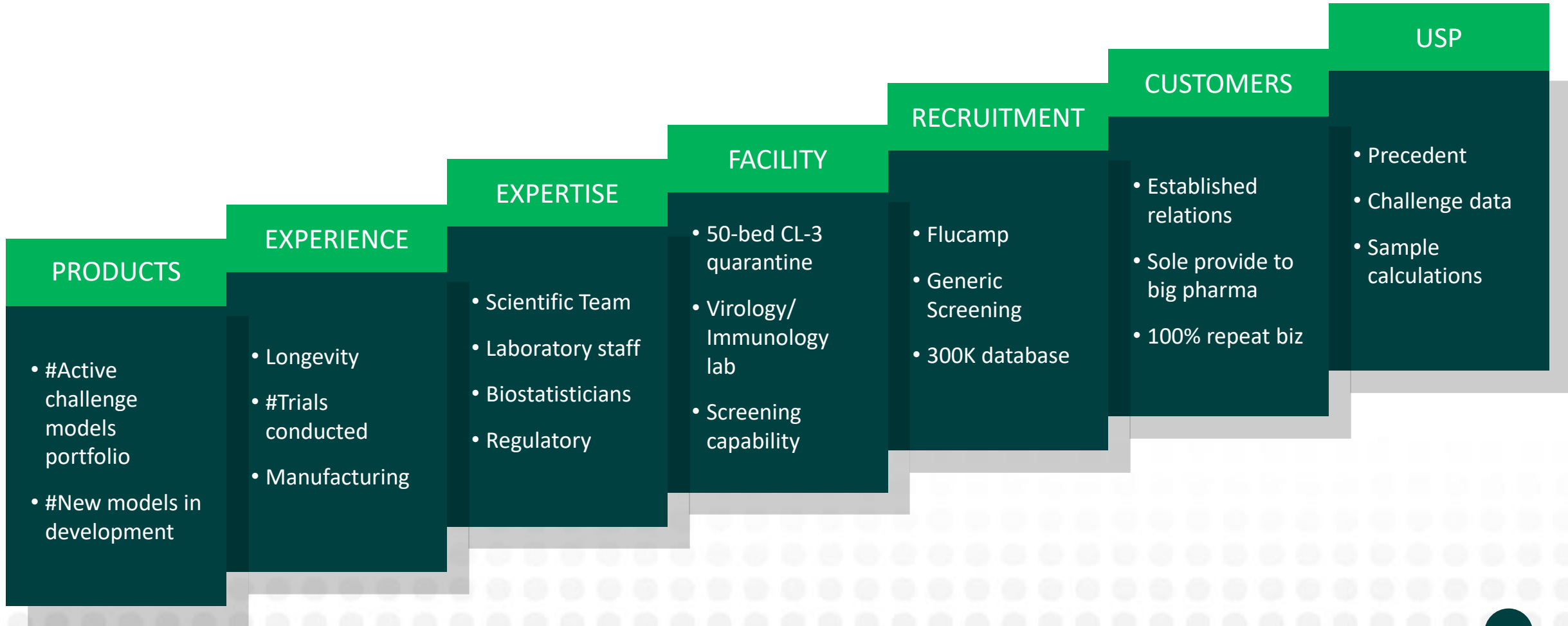
	Influenza	RSV	HRV	Malaria	Asthma	SARS-CoV-2	hMPV	Dengue
Virus Strain	H3N2 Perth	Memphis 37b	HRV 14B	Plasmodium falciparum	HRV 14B/16A	Pre-Alpha	A2 strain	Dengue*
	H3N2 Wisconsin	New RSV B	HRV 16A			Delta		
	H5N1 attenuated	New RSV A				Omicron		
	H1N1 France							
	Flu B Victoria lineage							
	H3N2 England							

 New to hVIVO in the past 2 years

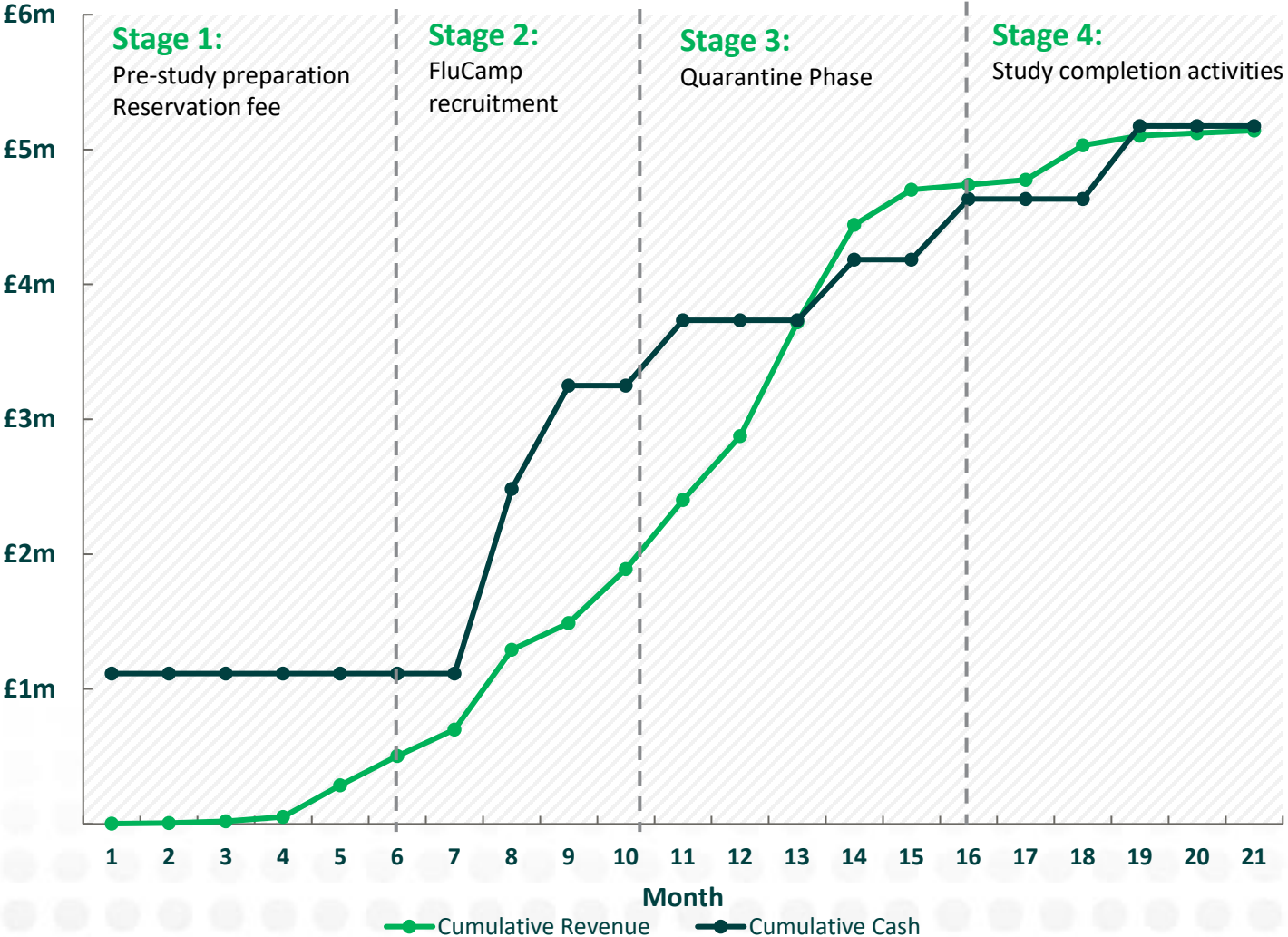
\* In development

In planning for the future: Bacterial challenge, Norovirus

# HCT Services: Significant Barriers to Entry

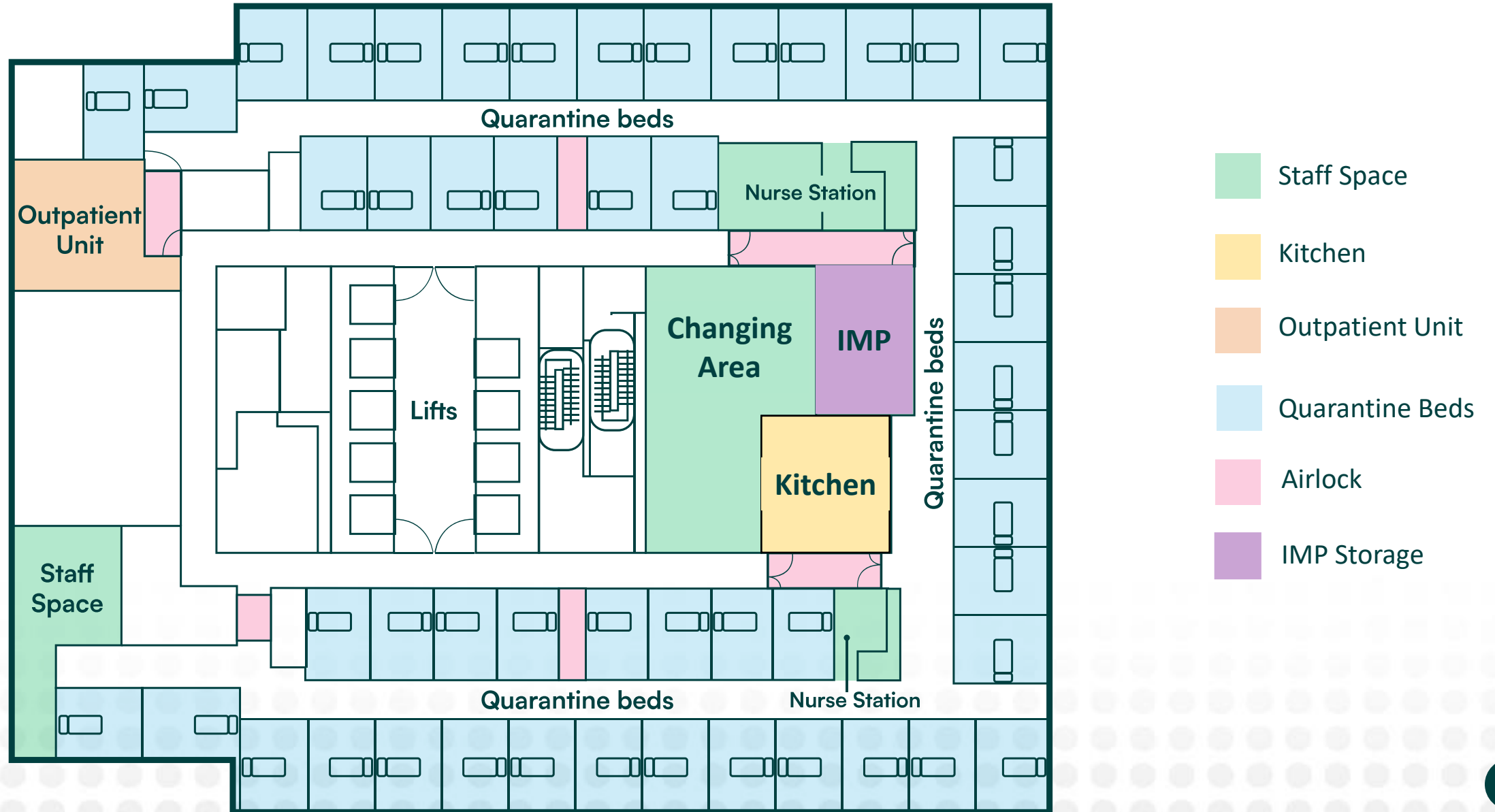


# Challenge Trial Revenue Recognition Profile

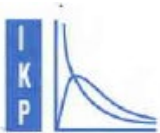


- hVIVO receives an upfront, non-refundable booking of c.10-20% of total study value to reserve quarantine space
- This mitigates against the risk of cancellation or client delay
- Majority of revenue recognition relates to the recruitment and quarantine phase of the study

# The World's Largest Human Challenge Unit



# CRS: Long History & Recognised Quality



1977

**Prof. Dr. Lücker GmbH**

Institut für klinische Pharmakologie  
Bobenheim



1992

**Pharm PlanNet**

Contract Research



2006

**CRS Clinical Research Services**

Kiel, Mannheim, Mönchengladbach  
Member of LTS group  
Established as a merger of 3 Phase One CROs



2013

**CRS Clinical Research Services**

Berlin, Wuppertal  
Strategic Partnership - Take over of BAYER RESEARCH



2017

**Management buy-out**

Acquisition of LTS shares by APLEONEX



2025

**Acquired by hvivo**

01

**FDA Inspected & Passed**

1991 | 1996 | 2002 | 2008 | 2009  
2010 | 2011 | 2014 | 2024

02

**GCP Inspected & Passed**

2003 | 2018 (system audit by local & federal authorities)

03

**ANVISA Inspected & Passed**

- ▶ 200+ audits by clients since 2006
- ▶ 2012 | 2016



# CRS Experience (5 Years)



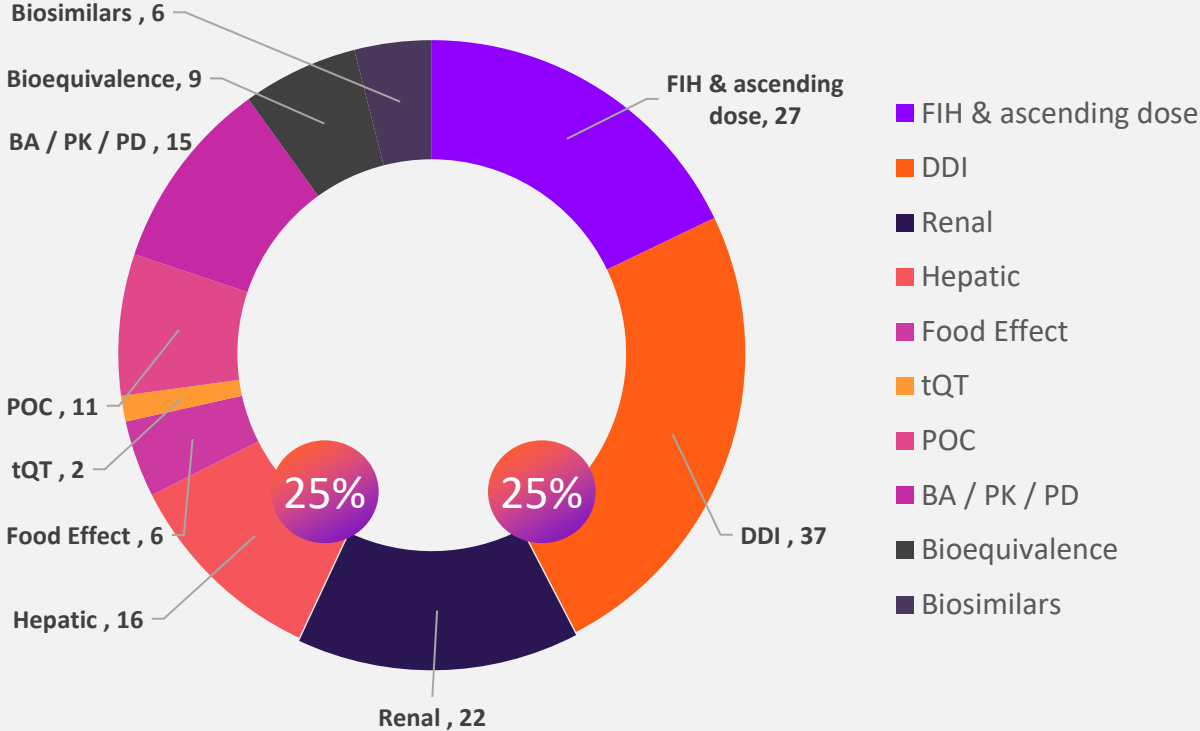
## First-in-Human

Top 5 CRO in Europe for FIH SAD/MAD, #1 in the DACH region.

## Clinical Pharmacology during Later Clinical Development

Largest European CRO for impairment studies with renal and hepatic patients and strong reputation for subsequent DDI studies (6-10 studies per year) or other pharmacokinetic studies (FE, tQT, special populations)

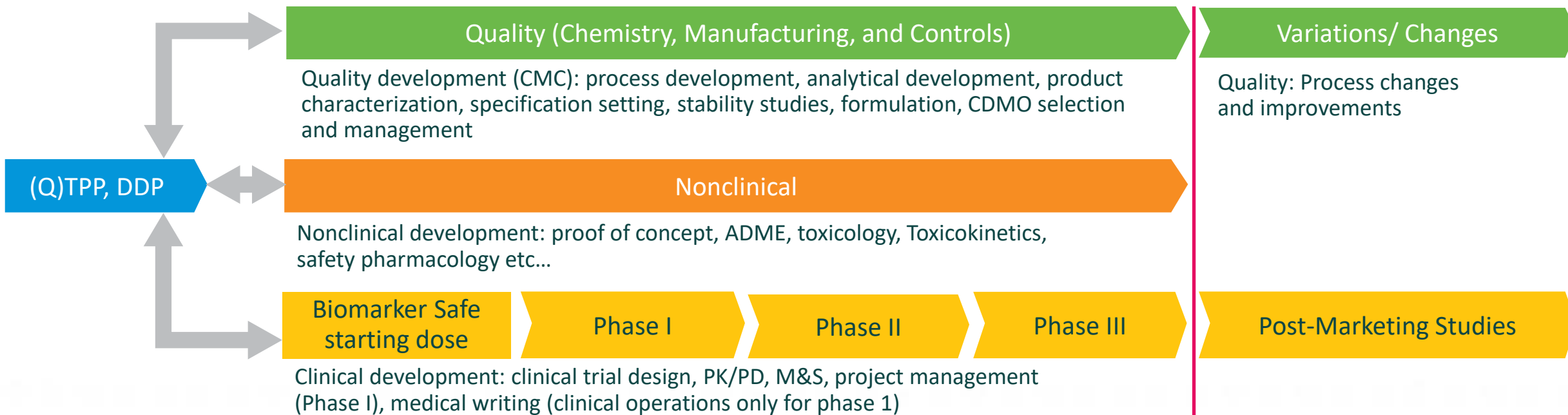
Studies performed – Healthy Volunteers (2018 - YTD 2024)



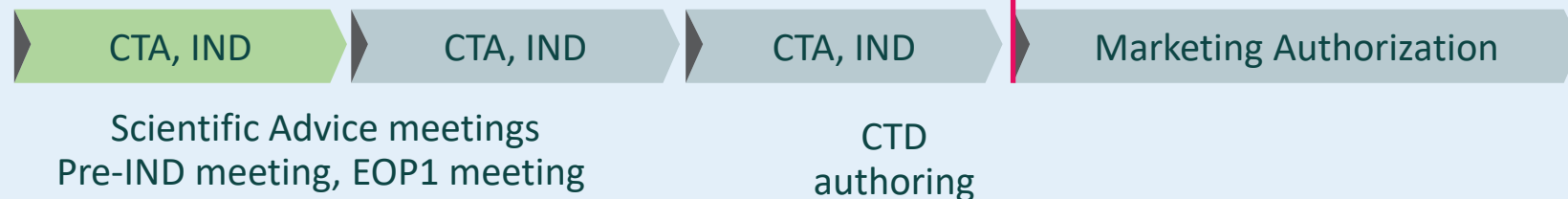
# Venn Life Sciences Service Offering



Gap Analysis, Due diligence



**Regulatory Affairs**





# Focus on ESG

- Sustainability is integral to our corporate ethos and operational framework
- As a CRO we are aware of our pivotal role to expedite the development of vital medicines through our comprehensive clinical development consulting and trial services

## Our ESG Values



1  
Advancing Health & Research



2  
Commitment to Staff



3  
Commitment to Volunteers & Patients



4  
Social & Community Investment



5  
Operating Sustainably



6  
Commitment to Ethical & Compliant Business Practices

# Sustainability Highlights



ESG Group reports to Audit & Risk Committee



ISO 14001 implemented 2024



Energy & carbon reporting, waste reduction, sustainable food practices



Expanding services to help tackle infectious disease



Community engagement & charitable donations policies



Staff well-being and development – flexible working, training & development programme



Move to Canary Wharf supports hVIVO's commitment to ESG

# hVIVO's State-of-the-Art Facilities



Canary Wharf Quarantine Unit



hLAB Virology & Immunology Laboratories



Plumbers' Row Screening Facility



Manchester Screening Centre



Biobank



Watch the walk-through tour of Canary Wharf [here](#)



*h*VIVO

Stay in touch



AIM: HVO