

# \ Presentation of **BeYs Outsourcing Services**

Outsource your business processes to gain agility and accelerate your growth.

# Rely on an independent and sovereign partner

For over 20 years, the BeYs group has industrialized the processing of sensitive digital data, ensuring legal security for transaction stakeholders. BeYs leverages its expertise to enhance the economic efficiency of your digital systems and their ecosystems.

## Digital Trust

Identify stakeholders, facilitate and optimize transactions, combat fraud and identity theft, ensure the security, including legally, of all parties involved, develop and manage each party's digital assets, support and make the digital daily life of all our partners seamless, and help them interact within a global, efficient, and sustainable ecosystem.



## Digital Solutions for Healthcare

Support patients and their families in their daily lives, improve their medical care by offering innovative solutions in remote monitoring, medical devices, and healthcare journey management.



## Cloud

Protect data and its processing in a French sovereign and ultra-secure Cloud.



## Research & development

Accelerate innovation in the service of our solutions and their uses by combining the scalability of Big Data, the power of AI, and the traceability of Blockchain.



## Publishing Division

Translate our vision into reality by addressing, for all ecosystem stakeholders, the challenges of urbanization, architecture deployment, and mastery of technologies essential to the efficiency of software development.



## Outsourcing services

Gain productivity and flexibility by relying on qualified teams who master business processes and customer service in over 20 languages.



## Insurance/Healthcare Technologies

Offer insurance stakeholders and policyholders a range of solutions and services driven by the optimization and excellence of management, risk cost control, customer satisfaction, user experience quality, the ability to innovate and develop new value chains, leveraging state-of-the-art technology and system urbanization.



# Key figures

+4200

employees

10

countries

200 M €

2024 revenue

160 K

man-days per year  
dedicated to R&D  
in 2024

4

data processing  
centers in France,  
Luxembourg, and  
Switzerland

+22 M

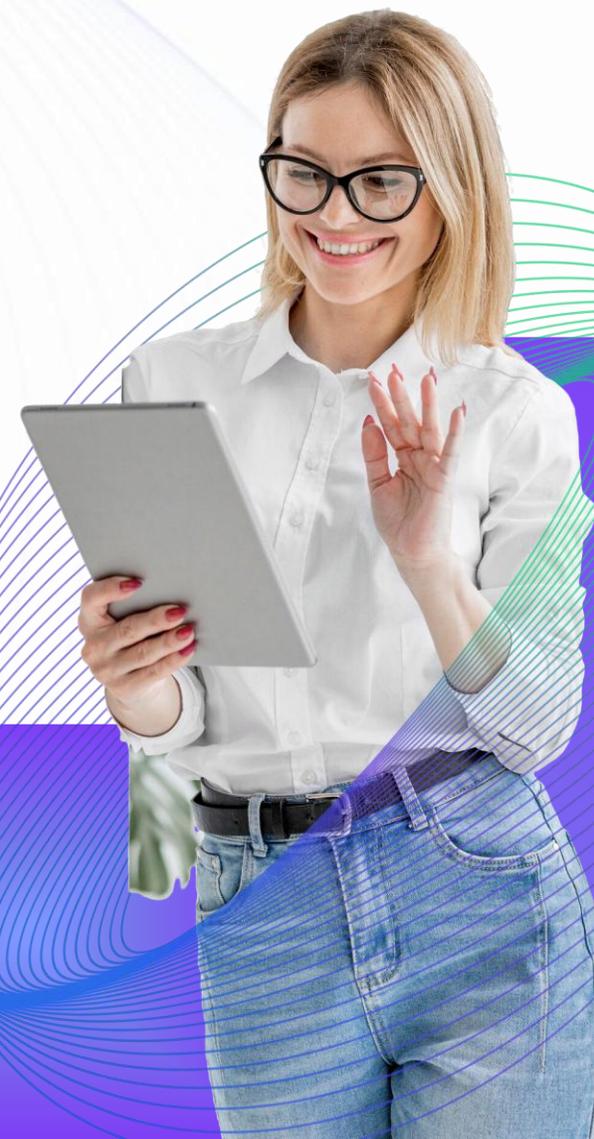
people use our services

+12 B €

In financial transactions  
managed per year

1

AI expert hub supported by  
leading laboratories: ENS and  
EPFL, and incorporating AI ethics





# ✓ Presentation of BeYs Outsourcing Services

The BPO & customer relations division of the  
BeYs Group

# Presentation be ys outsourcing services



- be ys outsourcing services has been an expert in business process outsourcing, management solutions and industrial data processing for over 20 years.
- These years of experience enable us to support our customers in optimizing processing costs, managing fluctuating activity and improving processing efficiency and quality.
- All this within the regulatory framework of respect for personal data protection and HDS-certified data hosting.

## Our key figures



## OUR COMPANIES

### INDIAN OCEAN - Madagascar

2 production sites  
**1600+** employees  
Multilingual: French/English



### EUROPE - Romania

2 production sites  
**500+** employees  
Multilingual: **20 languages**



### EUROPE - France

1 production site  
**50+** employees  
Multilingual: French/English



### NORTH AFRICA - Morocco

1 production site  
**30+** employees  
Multilingual: French/Spanish/English



## Standards & certifications



# Integrated Healthcare Solutions – B2C & B2B

## CX Management & 24/7 Customer Support

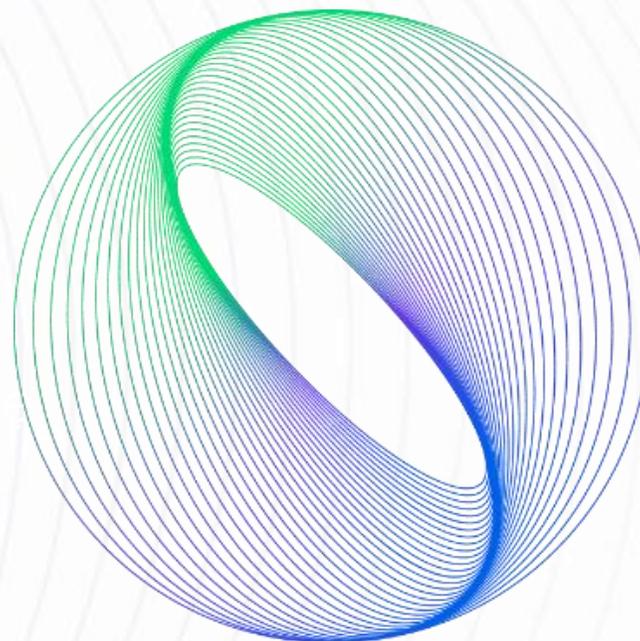
Multichannel and multilingual customer  
Surveys and polls  
Lead Generation & Outreach

## Back-office

Secure administrative data management  
Patient & partner record processing  
Quality, compliance & traceability  
Identity Management (KYC)  
Monitoring

## IT Services & Helpdesk

Helpdesk and 24/7 Monitoring  
Cybersecurity  
Backup and Business Continuity  
AI Support  
Data Annotation



## Integrated Healthcare & Insurance Solutions

End-to-end hospital billing and payer-compliant invoicing

Digital pre-admission (KYP) to streamline workflows and enhance the patient experience

Secure interoperability with healthcare providers, insurers, and Social Security systems

Medical tele-secretarial and administrative support services

Revenue cycle optimization through intelligent billing and performance analytics

Ethical receivables management to improve cash flow while maintaining patient trust

End-to-end member and policyholder management (eligibility, coverage, claims, disputes)

Secure identity management and protection of sensitive health data in full regulatory compliance

Patient-centric process optimization for a seamless, transparent care journey

### Our sectors of activity



Retail & e-commerce



Insurance & Risk Protection



Culture & Heritage



Information Technology



Gaming & Online Betting



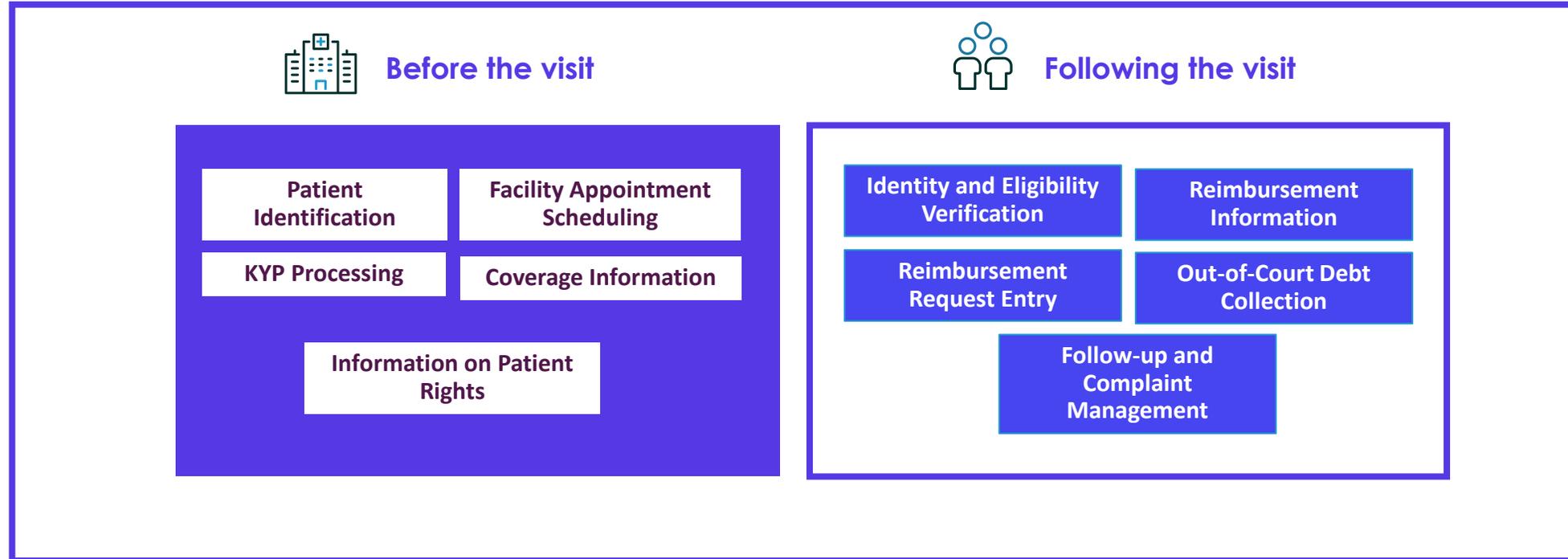
Healthcare Professionals



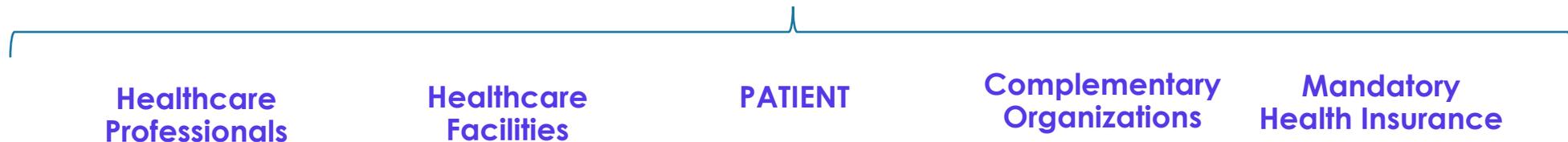
Tourism & Leisure

# Our Strategic Positioning

BYOS: Present at Key Stages of the Processing Chain



Needs Arising from Multiple Stakeholders



# The strengths of BeYs Outsourcing Services

20 years of expertise in service outsourcing



## EXPERTISE

Over **150 clients** trust us with more than **280 projects** deployed. Proven experience in both **B2C** and **B2B**



## HUMAN RESSOURCES

Turnover rate: **5,5%**  
Average tenure: **5 ans**  
40% of employees are promoted internally, **including 55% of our managers**



## DATA HOSTING

Data hosting capacity in our **HDS-certified datacenter** (France) and our **100% sovereign cloud**.



## SERVICE CONTINUITY

- **BCP - DRP**
- Remote internal business recovery
- Backup solutions (6 production sites)



## OPERATIONAL FLEXIBILITY

**Overflow:** provision of dedicated teams for bulk stock processing and/or handling incoming tasks.



## TOOLS DEVELOPMENT

Over **20 tools** developed by our internal teams for our clients and to improve internal processes.

# Our Services of Sovereign cloud & accommodation center

Enjoy a 100% sovereign cloud, with data hosted in France on servers fully managed by our teams. A guarantee of security, confidentiality, and independence from international players.

## Our sovereign cloud services

### CLLOUD Computing

- Accelerate and simplify the deployment of your application architectures and security infrastructures with our catalog of technical components deployable in just a few clicks

### Managed VPS & VM

- Meeting the needs of businesses, professionals, communities, and public organizations that wish to move towards a sustainable and secure hosting solution

## DATACENTER “LA CITADELLE”

- **High quality:** hosting, storage, backup, and maximum availability
- **Flexibility:** 5 rooms to meet different hosting needs based on the sensitivity and criticality of processing and data

## CYBER DEFENSE AND SOC CENTER

- 24/7 monitoring of vulnerabilities and threats and tracking of security events
- Early detection and alert in case of incidents
- Assistance for mitigation strategies



SOVEREIGNTY



SECURITY



SCALABILITY

NEW

BeYs Cloud strengthens its infrastructure with a **new computer room in Luxembourg**. BeYs announces the opening of a computer room in a **Luxembourgish datacenter**, a strategic choice strengthening its infrastructure in Europe. This site allows its clients to benefit from sovereign and secure hosting, in addition to the historic “La Citadelle” data center in France.

# BE Ys Outsourcing – Your Strategic Partner in Healthcare & Insurance

**Expert Operations Management** – Streamline policy, claims, and back-office processes to ensure efficiency, accuracy, and compliance.

**Enhanced Member & Patient Experience** – Deliver personalized, multilingual support across all channels, maximizing satisfaction and loyalty.

**Data-Driven Insights** – Transform analytics into actionable decisions that optimize operations and improve outcomes.

**Compliance & Quality Assurance** – Ensure regulatory adherence, risk management, and process excellence at every step.

We leverage our deep **operational expertise** to deliver **secure, trusted, and high-impact solutions** that **accelerate growth, boost efficiency, and create strategic advantage** for **healthcare and insurance organizations**.





be<sup>v</sup>ys \ Merci !

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Copyright 2025. Toute utilisation des présentations propriété de be ys doit faire l'objet  
d'une demande d'autorisation.





cea

leti



Cluster 1 Health



# *ISO-conform modular microfluidics, sensors and biomaterials for NAMs and bioprinting*

**Name: Caroline Desvergne, [caroline.desvergne@cea.fr](mailto:caroline.desvergne@cea.fr)**

**Organisation: CEA-Leti, RTO**

**Country: France**

**Contacts / website: [www.cea-leti.com](http://www.cea-leti.com)**

1/ Topic: Integrating New Approach Methodologies (NAMs) to advance biomedical research and regulatory testing - HORIZON-HLTH-2026-01-TOOL-03

**Offer to contribute as a partner with:**

- Standardized microfluidics under ISO-compliant formats
- Embedded electrochemical sensors
- Imaging solutions from 2D to 3D, all compatible inside the bioreactor
- Dynamic hydrogels as compliant matrices for organoid expansion and morphogenesis

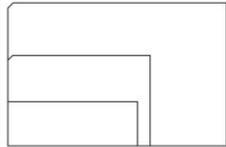
# DESIGN AND MICROFABRICATION OF MICROFLUIDIC DEVICES

ISO-conform and scalable building blocks for organoids-on-chips



**ISO 22916:2022**

## Cards

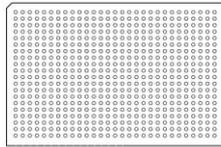


Microscope slide  
26 x 76 mm

Credit card  
54 x 84 mm

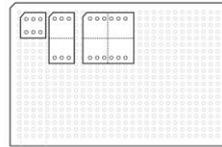
Microplate  
85 x 128 mm

## Connections



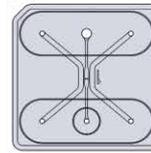
1.5 x 1.5 mm grid

## Building blocks

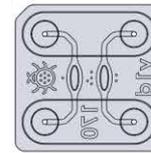


Multiples of 15 x 15 mm

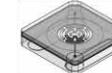
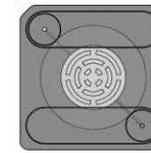
## Pancreas-on-chip



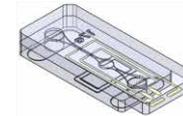
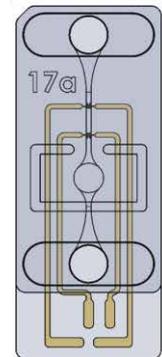
## Organ-on-chip



## Filter Building block



## Integrated impedance & oxygen Sensors\*

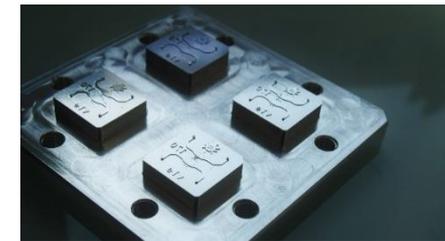


Bussoo A, et al., *Biosensors and Bioelectronics: X, Volume 11, 2022*  
 Dekker S., et al., *Sensors and Actuators B: Chemical, Volume 272, 2018*



- From rapid prototyping up to small series
- Thermoplastic (COC) devices
- Micromilling, hot-embossing, lamination

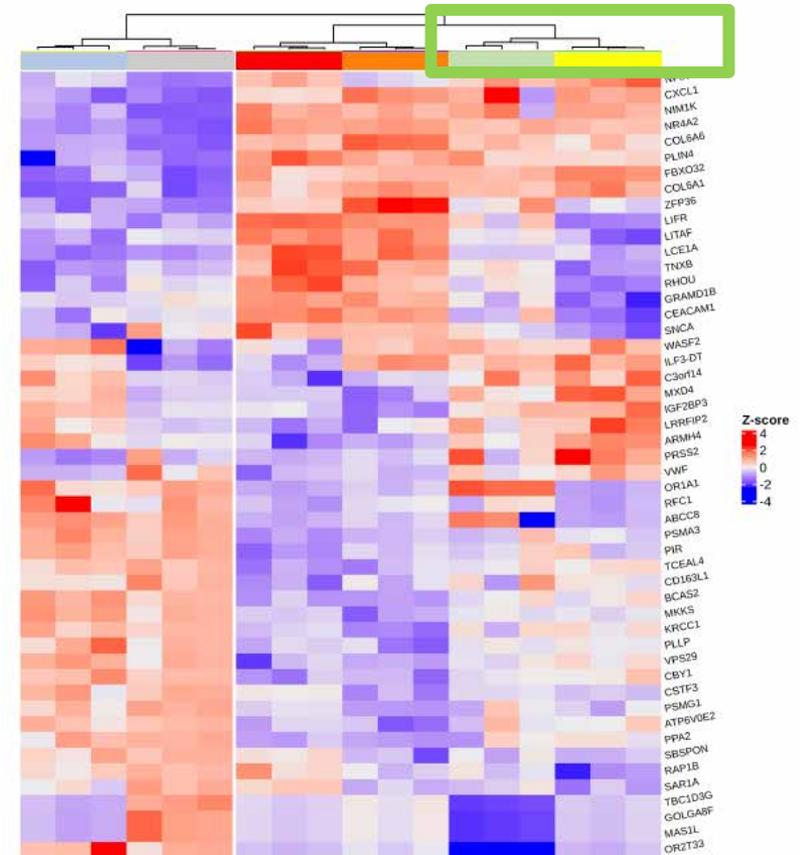
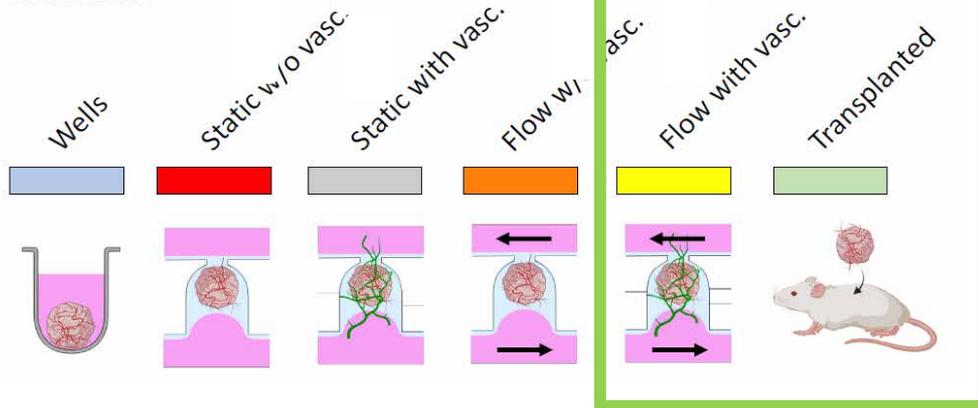
CEA-Leti is a member of ISO TC/48/WG3 & CEN TC 332/WG7  
 on Microfluidic devices)



# WORLD PREMIERE: SPECIFIC MICROFLUIDIC DESIGN FOR VASCULARIZATION-ON-CHIP

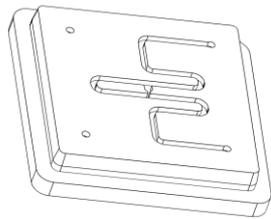
Flow + vasculature show a functional maturation (RNAseq) comparable to mice transplanted with xenografts

Conditions

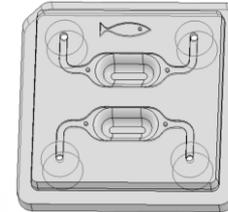


Thanks to polymer and hybrid microfluidic cartridges to maintain viability of a pancreas-on-chip and stability of an endothelial network for one month

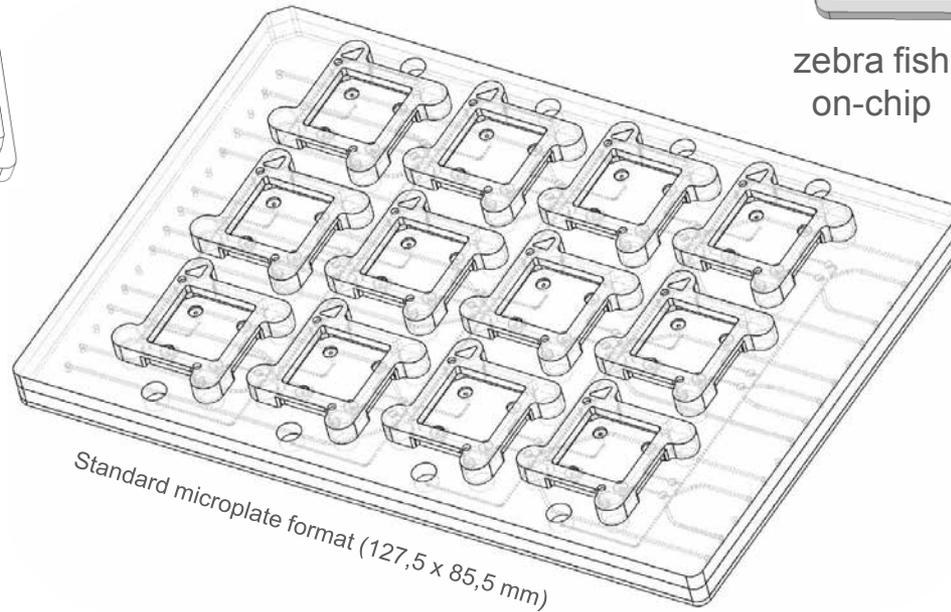
# TOXBOX: OUR STANDARDIZED MICROFLUIDIC PLATFORM FOR TOXICOLOGY



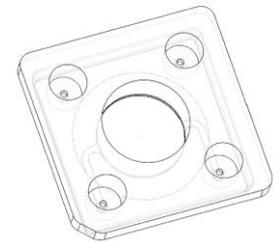
liver organoid on-chip



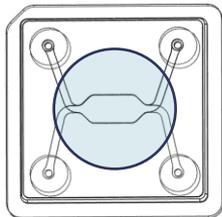
zebra fish on-chip



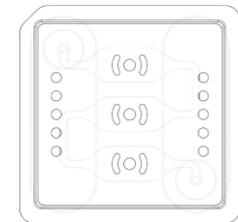
Standard microplate format (127,5 x 85,5 mm)



skin-on-chip



lung-on-chip



CEA-Leti electrochemical sensor chip



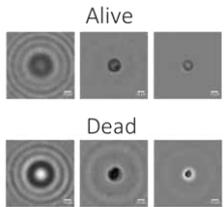
ALL-IN-ONE TOXICOLOGY PLATFORM

Jan. 2024 – Dec. 2027



# CUSTOM IMAGING SYSTEMS for OoCs: from 2D to 3D

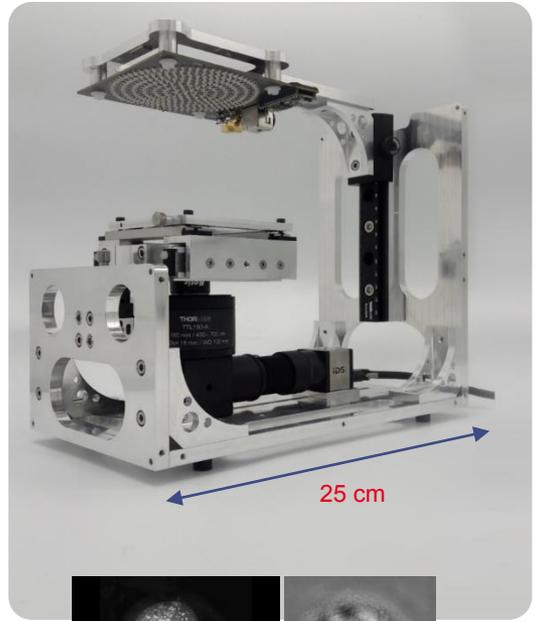
Suitable for implementation inside the bioreactor



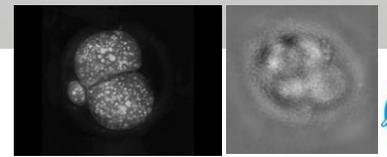
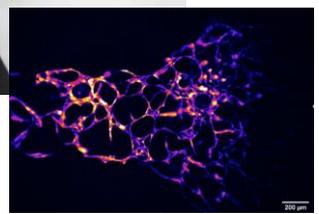
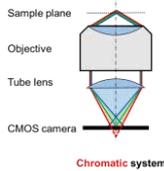
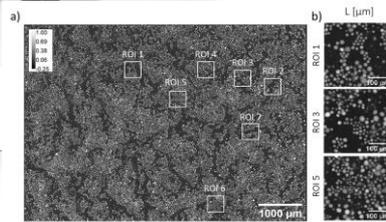
## 2D- Phase & fluorescence



## 3D- Phase & fluorescence



## 2D- Phase



"Alternation of inverse problem approach and deep learning for lens-free microscopy image reconstruction", L. Hervé et al., Nature Scientific report, (2020) 10:20207 | <https://doi.org/10.1038/s41598-020-76411-9>



"Phase and fluorescence imaging with a surprisingly simple microscope based on chromatic aberration", O. Mandula et al., Vol. 28, No. 2 / 20 January 2020 / Optics Express 2079, <https://doi.org/10.1364/OE.28.002079>



"3D time-lapse imaging of a mouse embryo using intensity diffraction tomography embedded inside a deep learning framework", Pierré, W., et al., Applied Optics Vol. 61, Issue 12, pp. 3337-3348 (2022) | <https://doi.org/10.1364/AO.453910>



REVEAL

Neuronal microscopy for cell behavioural examination and manipulation

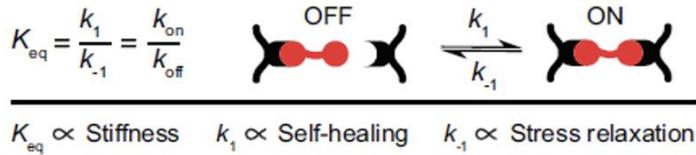
H2020 2021-2025

2/HORIZON-HLTH-2027-03-TOOL-02: Advancing bio-printing of living cells for regenerative medicine

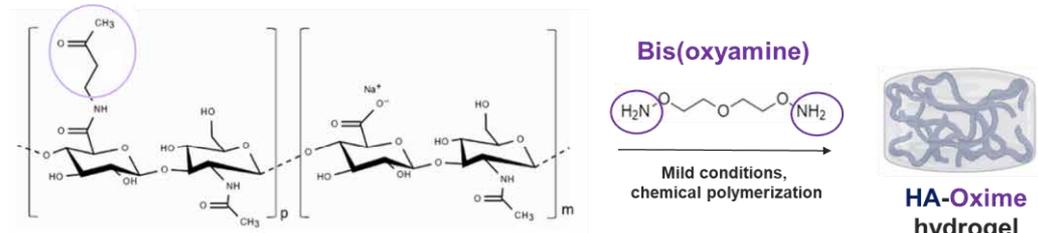
Offer to contribute as a partner with:

- Dynamic hyaluronan (HA)-based hydrogels for bioprinting

# Development of dynamic hyaluronan (HA)-based hydrogels for bioprinting (also for organoid expansion and morphogenesis for NAMs)

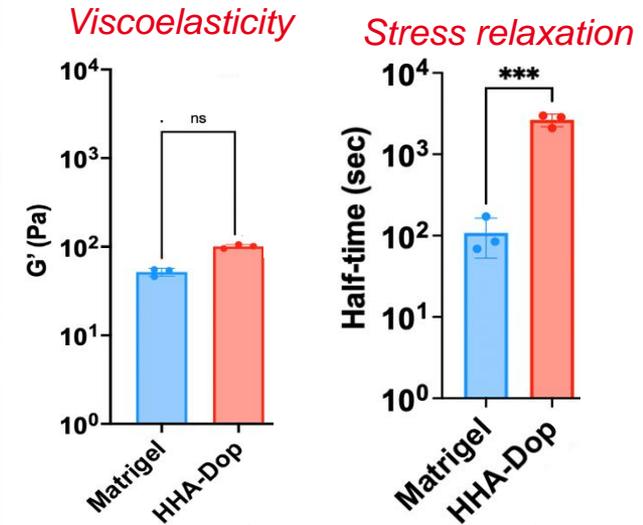
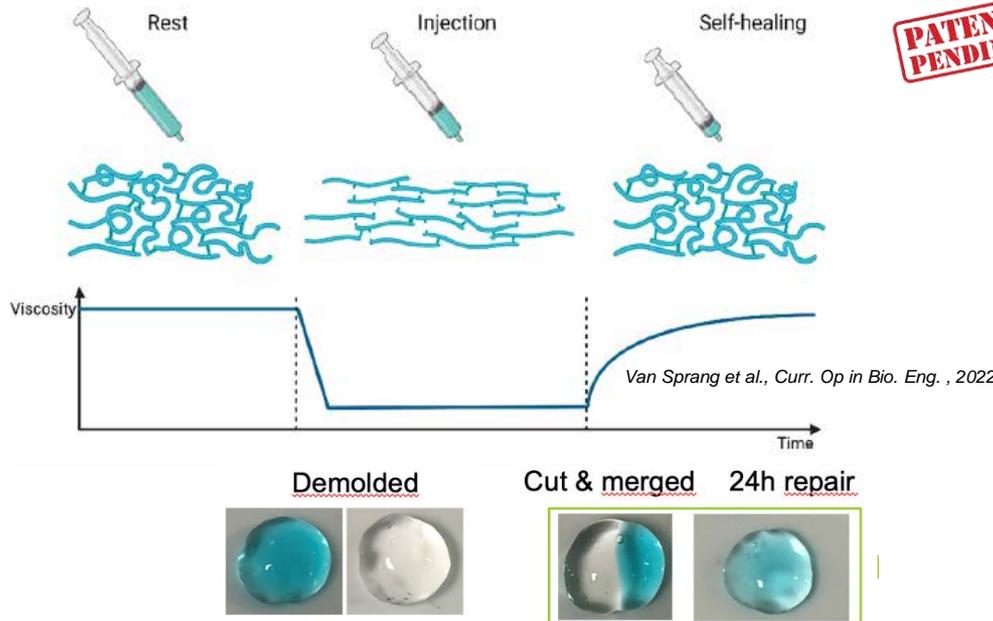


Morgan et al., *Advanced Health Mat.*, 2022



Sacchi et al., *in preparation*

**PATENT PENDING**



Please contact me in case you need more information

Thank you!

[caroline.desvergne@cea.fr](mailto:caroline.desvergne@cea.fr)

# Aethernova

## Context Aware XR-AI

Next-generation neurodevelopmental assessment

We are building a dual-use XR-AI diagnostic platform for data-driven neurodiversity and mental health assessment, delivered through a 30-minute immersive gameplay assessment and advanced analysis that reduces bias, enables earlier intervention, strengthens integrated support, and cuts co-morbidities and downstream costs for healthcare systems and the wider economy.



# Market Opportunity

20% global population are neurodivergent

\$47B+

TAM

Global market for neurodevelopmental and mental health assessment

\$12.8B

SAM

UK, US, EU, Singapore, GULF

\$150M

SOM

## □ Proof of Demand (UK)

**'Clinical Partners'** – one of the UK's largest private autism & ADHD assessment providers – has scaled to **£25M+ in annual revenue** in the **UK** alone, with a largely manual, clinician-time-limited model and long waitlists.

If a single, service-heavy provider can reach this scale in one country, a scalable XR-AI platform like Aethernova addressing the global markets represents a far larger opportunity.

## Go-to-market Strategy

### Near term (0–18 months)

- GULF & Singapore: Faster procurement, fewer regulatory bottlenecks; community pilots via government innovation units; convert into tenders

### Longer term (18–36+ months)

- Partner with technology-enabled care organisations and payers that need scalable measurement + clinician-guided workflows; validate outcomes and health economics to support reimbursement pathways.

# Why Now

Several converging factors highlight the critical timing for Aethernova's innovative approach

-  **Transdiagnostic Science Validated**

The scientific basis has been affirmed, as evidenced by "World Psychiatry, 2024".

-  **XR Hardware Deployable at Scale**

Extended Reality (XR) hardware is now clinically deployable at scale, making advanced assessment accessible.

-  **Global Health Systems Seeking Innovation**

Global health systems are actively seeking new and effective AI innovations.

-  **Payer payment rails are shifting to outcomes-based, tech-enabled care**

US Medicare is piloting outcome-aligned payments for technology-supported care — validating the direction of travel for reimbursing measurable outcomes (not activity billing).

-  **Maturity of Multimodal AI**

The advanced maturity of multimodal AI unlocks new and powerful diagnostic potential.

-  **Urgent Global Demand and Service Gaps**

There is an urgent global demand for neurodevelopmental assessments, coupled with massive existing service delivery gaps.

# Founder Story

My son = Mini Me

AuDHD, he waited 1 year each to be assessed for autism ADHD. but missed-diagnosed for ADHD.

He waited another year to be seen by education specialist In Grammar school. dismissed to be assessed due to lack of budget in Primary school

He is super intelligent but hate school

He suffers gut issues

Challenges with spelling and writing, but incredibly creative.

He suffered bullies and misunderstanding from peers and teachers, or some family members.

He has sensitive nervous system, and needs regulation support.

Mental health challenges in early childhood, suicidal intent, learn to prioritising the self.





# Founder

## Aphrodite Yao – CEO & Product Lead

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### Experience & Expertise

#### 8+ Years Start-up Experience

Architect of Aethernova's XR-AI diagnostic platform.

#### Strategic IP Development

Designed IP strategy bypassing ADOS-2 licensing barriers.

#### Partnership Builder

Skilled at building clinical and research partnerships.

#### Bridging Disciplines

Connects scientific, clinical, technical, and commercial domains for scalable, ethical tech.

### Why I'm the One to Do This

#### → Driven by Mission

Lived experience of bias/misdiagnosis; son's missed support due to ADHD/autism overlap.

#### → Cross-Disciplinary Edge

Gaming/R&D/Product/Commercial background + extensive clinician interviews & literature review informed our transdiagnostic, multimodal XR-AI approach.

#### → Human-Centred Science

Features per-person baselines, adaptive thresholds, clinician-in-the-loop design, cultural-linguistic localisation, and modality flexibility.

#### → Privacy & Sovereignty

Prioritizes on-device inference, federated learning, and local data storage to ensure privacy.

#### → Global Network for Diverse Datasets

Actively building multi-site, multi-ethnic cohorts across UK/EU/MENA/US to prevent majority-data overfitting.

# The Problem of Current Clinical Assessment

Neurodevelopmental assessment is outdated, expensive, and inequitable:

## Time-Intensive

14+ hours of clinician time per child

## Long Waitlists

2+ year waitlists across UK, EU, and Canada

## Expensive (Long clinical hours + Paperwork)

£1,050+ average cost per assessment (co-occurring conditions common)

## Fragmented

80%+ of children have multiple conditions, yet are assessed separately

## Biased

Cultural/gender bias: tools misdiagnose or exclude 100+ immigrant communities in UK

## Licensing Bottleneck

ADOS-2 training = £2,000/clinician, plus per-use material fees

Millions of children miss the early window for support — the system is collapsing under demand.

# Multi-System Challenges in Neurodivergence

## Body → Internal Systems

 Nervous System

Sensory overload, motor differences

 Sleep & Fatigue

Chronic disruption, circadian issues

 Balance & Movement

Postural and coordination difficulties

 Gut-Brain Axis

GI symptoms, microbiome differences

 Immune System

Inflammation, allergies, dysregulation

 Metabolic Health

Insulin resistance, metabolic links

## Body → Behaviour & Outcomes

 Speech & Communication

Delayed/atypical speech, apraxia

 Reading & Learning

Dyslexia, high cognitive effort

 Sensory & Pain

Hypersensitivity or reduced sensitivity

 Trauma & PTSD

4–10× higher PTSD risk

 Mental Health

High anxiety, depression, suicidality

 Life Outcomes

70–85% unemployment

**Early, integrated intervention is essential to prevent trauma, mental illness, and lifelong exclusion.**

# The Solution

Aethernova's XR-AI platform delivers fast, inclusive, transdiagnostic assessment



## Fast Assessment

30-minute assessment capturing autism, ADHD, and co-occurring conditions in one session



## Community Deployment

Deployable in the community — schools, nurseries, local clinics



## Culturally Adaptive

Dynamic scenarios tailored to 100+ cultural backgrounds



## Multimodal Data

Cognitive, physiological, affective, and contextual signals not accessible via traditional tools



## AI-Driven Insights

Outputs tailored to clinicians, psychologists, educators, and caregivers



## Human-Centred Profiles

Reframes from "what's wrong" to "what is" - observes, adapts, and learns, asking questions instead of forcing certainty



## Gamified Clinical Tests

Designed to bypass ADOS-2 licensing restrictions through gamified and innovative clinical assessments



## Significant Cost Saving

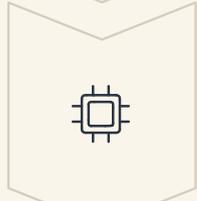
Identified £2.69M annual savings for a single NHS Trust, scalable across 150+ Trusts in the UK

# How It Works (System at a Glance)



## Sensing

XR headset (OpenXR) captures eye-tracking, motion, speech/prosody, and physiology (HRV/EDA)



## On-device inference

Privacy-first models run locally for low latency and low-connectivity settings



## Secure store & governance

Encrypted, standards-based (FHIR/SMART on FHIR), audit-ready



## Clinician dashboard

Explainable AI patient analysis and profile; longitudinal tracking and export to EMR



## Human-in-the-loop

Remote clinician review finalises reports



## Outcomes-ready reporting

Structured exports to support payer/provider outcome reporting and audits

# Full-stack Vertical with end-to-end care pathway.



# Traction

Strong clinical, technical, and regulatory foundation already in place

## UK Partners

- Clinical R&D collaboration with **Health Innovation South East Scotland (HISES)** to make sure work-flow integration
- Prototype testing secured with **HSC Northern Ireland Trust**
- **Queen Mary University of London** (HCI & Robotics Fellowship)
- **UCLPartners** (Clinical Co-design, Clinical Testing)
- **Ulster University** (Quantum-sensor communication R&D)

## Defence & US pipeline:

- TechBridge interest for PTSD triage pilots

## International Partners

**Horizon Europe Proposal (€8M) consortium (1st Phase Submitted):**

- AIJU (Spain) ✓
- ZEUS & EILD (Greece) ✓
- University College Cork (Ireland) ✓
- Lithuanian University of Health Sciences ✓
- Autism Lithuanian Association ✓
- Autism Europe (Belgium, *90 members, 5M ppl*) ✓
- Maastricht University (Netherlands) ✓
- Vrije Universiteit Brussel (Coordinator) ✓
- Global Health Research Center of Central Asia (Kazakhstan) ✓
- İstinye University (Turkey) ✓
- CTIC Technology Centre (Spain) ✓
- Rīga Stradiņš University (Latvia) ✓

# Team Member & Advisors



## Dhruv Shah - Lead Engineer

Dhruv leads XR and AI technical development. He has hands-on experience building immersive XR prototypes and implementing the data capture and signal processing needed to translate short tasks into structured outputs. He works across the full technical stack—XR interaction design, instrumentation (for example, gaze/voice/motion where available), data pipelines, model experimentation, and deployment-ready engineering—while collaborating closely with product and domain stakeholders to ensure the system is usable, measurable, and aligned with real-world workflows. He iterates quickly, documents decisions, and builds with privacy and auditability in mind.



## Brandis Moylan - Team (Regulation & Business)

Medical-device regulatory professional with 14+ years across regulatory operations and affairs, experienced in submissions coordination, document control, inspection readiness and cross-functional collaboration with R&D and Quality; MBA candidate at UC Davis. Based in Northern California.



## Jun (Luke) Huan, PhD - Tech Advisor

AI/ML leader spanning academia, big tech, and government funding. Led agentic-AI and foundation-model initiatives at AWS; previously Distinguished Scientist at Baidu and Program Director (IIS) at the US NSF. Former endowed professor associated with \$60M+ in federal research funding; co-PI on NIH centre grants. PhD in Computer Science (UNC-Chapel Hill).

# Business Model for Clinical Assessment Toolings

## Platform Licensing + Usage-Based AI

1

Annual License — £180,000 per NHS Trust/Hospital

- Includes XR hardware, software, and clinician training
- Unlimited clinician access and support

2

Per-Assessment Fee — £400

- Combined ADHD/Autism
- AI-driven analysis and report generation
- Continuous model improvement and updates

3

Premium Add-ons (Year 2+)

- Value-based contracts (US): per-member/per-month monitoring + outcomes-linked bonus (where applicable).
- Personalised intervention recommendations: £50 per assessment
- Research database access: £100,000/year

---

## Unit Economics

Cost per assessment: £155 (including clinician's time/cost)

Current NHS cost: £1,200 for children combined ADHD/Autism

→ 67–85% cost reduction with faster, broader diagnostic insights

# Dual-use Application: PTSD Assessment (NavalX Interest)



## Problem

Self-report bias + long interviews (e.g., CAPS-5) delay care/readiness



## Approach

30 minute XR task battery elicits stress/attention signatures; explainable fusion of eye-tracking, voice, motion, HRV/EDA; complements PCL-5/CAPS-5



## Path to fielding

OTA/CRADA pilot; IL-appropriate hosting; device-agnostic deployment (Meta/Pico/enterprise)



## Why this matters

Objective, repeatable triage for Navy/USMC EMH and first responders; dual-use revenue funds core ND roadmap

# Competition

## Traditional Tools (e.g. ADOS-2, ADI-R):

- ❌ Diagnose one condition at a time
- ❌ 8–14 hours of clinician time
- ❌ Inaccurate across cultures, genders, & age ranges
- ❌ Expensive training and licensing
- ❌ No physiological or contextual data

## Digital Health Startups:

Examples: Cognoa, Qbtech, Autism AI, Tali Health

- ❌ Limited to screening — not diagnostic-grade
- ❌ Single-condition focus (e.g. autism or ADHD only)
- ❌ No transdiagnostic capability
- ❌ Poor cultural or linguistic adaptability
- ❌ Struggle to scale beyond niche or tech-savvy settings

## Big Pharma & Neurotech:

Examples: Roche (Cogstate), Novartis, Akili Interactive, Eli Lilly

- ❌ Built for research or clinical trials — not frontline assessment
- ❌ Require intensive training/supervision
- ❌ Complex, costly systems that don't scale to schools or communities
- ❌ Still rely on single-disorder models

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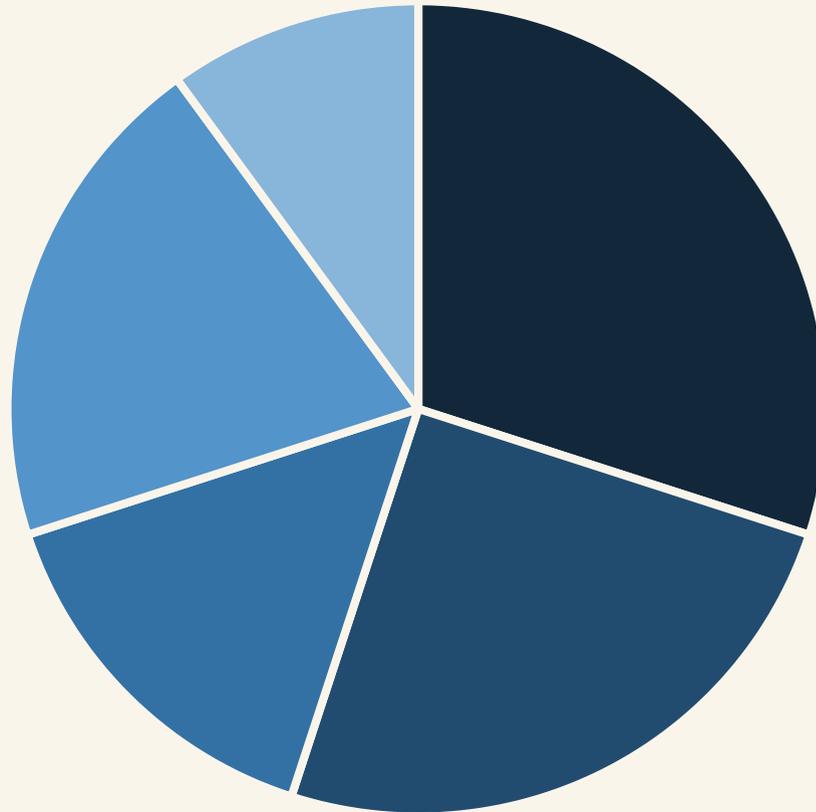
## Our Moat

- ✅ Transdiagnostic by design — captures co-occurring conditions in one adaptive assessment
- ✅ Scientifically validated — aligned with latest research findings framework
- ✅ Technically advanced — XR + AI + multimodal physiological monitoring
- ✅ Culturally adaptive — only platform tailored to multi cultural contexts
- ✅ IP-protected architecture — bypasses ADOS licensing barriers
- ✅ Clinically integrated — co-designed with clinicians for real-world deployment

# The Ask

Raising: \$5M (3-year runway)

Use of Funds:



■ Platform Development   ■ Clinical Validation   ■ Regulatory Approvals   ■ Team Expansion   ■ Patent Portfolio

- \$1.5M – Platform development (OpenXR integration, AI models, data infrastructure)
- \$1.25M – Clinical validation (500 children, 5 culturally diverse sites)
- \$0.75M – Regulatory approvals (UK MDR, FDA pathway)
- \$1.0M – Team expansion (8 key hires across engineering, clinical ops, regulatory and partnerships)
- \$0.5M – Patent portfolio (IP filings, legal strategy, international coverage)

# Vision — 5+ Years



## Global Deployment

The standard of care for neurodevelopmental assessment, embedded in health, education and employment systems worldwide



## Lifelong Personalised Supports

From one-off diagnosis to lifelong, data-driven support for individuals, families, schools, educators and care providers.



## Deep science & frontier tech

Assessment data powering phenotype–genotype discovery and new, complementary tools (e.g. quantum-sensor communication).



INFO DAYS 2026  
**BROKERAGE  
EVENT**  
CLUSTER | HEALTH

THE EU RESEARCH & INNOVATION PROGRAMME 2021 - 2027

# STANDARD-BIO: AI-Enabled New Approach Methodologies for Standardised Biomechanical Testing in Health Technologies

**Olga Barrera**

**Oxford Brookes University, UK**

**Luxembourg Health & Sport Sciences Research Institute**

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[obarrera.asbl@lunex.lu](mailto:obarrera.asbl@lunex.lu)

# The problem-Current Limitations in Biomechanical Testing

## STANDARD-BIO:

AI-Enabled New Approach Methodologies for Standardised Biomechanical Testing in Health Technologies



Lack of harmonised, predictive testing standards at tissue to analysis of body motions



Complex soft tissues & tissue-implant interfaces poorly characterised



Lab-to-lab variation limits reproducibility



Slows regulatory approval and clinical translation



# *The solution - STANDARD-BIO*

- **AI-enabled New Approach Methodologies (NAMs)**
- **Integrates experimental testing + physics-based & data-driven modelling**
- **Covers soft & hard tissues, musculoskeletal systems, and human-machine interfaces**
- **Produces standardised, regulator-ready frameworks**

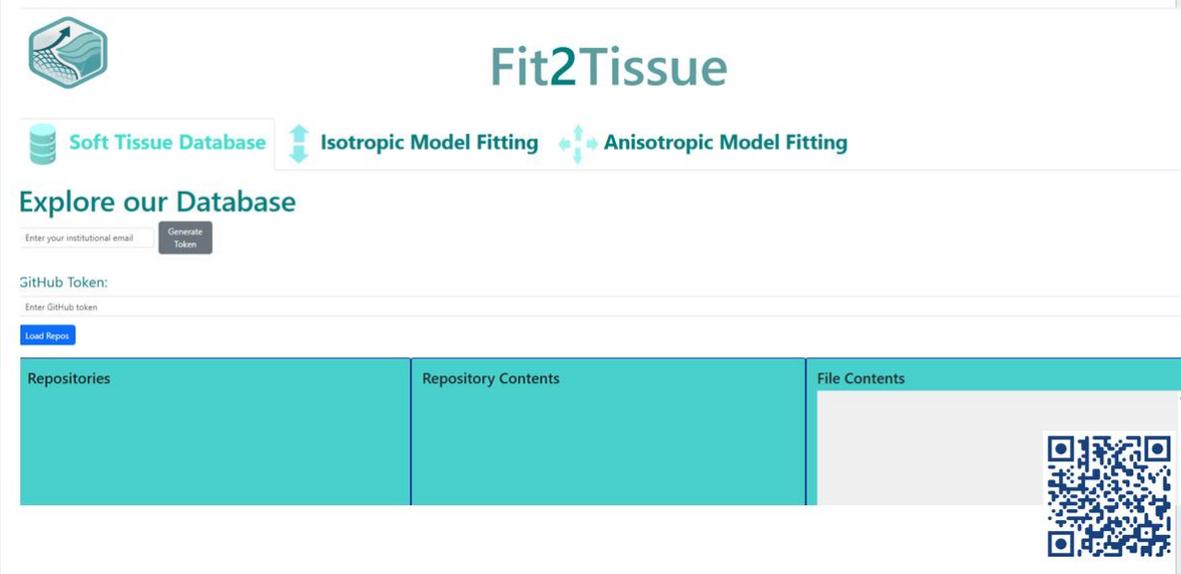
# *Why it matters*

- **Supports innovation in tissue repair, implants, and assistive devices**
- **Accelerates translation from lab to clinic**
- **Improves interoperability of biomechanical data**
- **Strengthens Europe's leadership in health technology and regulatory science**

# Project Coordination & Expertise

- Experts in soft-tissue biomechanics, AI-enabled modelling, musculoskeletal analysis
- Strong track record of international and interdisciplinary collaboration
- Integration of experimental, digital, and regulatory methodologies
- Fully aligned with Horizon Europe Cluster 1 TOOL priorities

## Our Database App



Fit2Tissue

Soft Tissue Database | Isotropic Model Fitting | Anisotropic Model Fitting

Explore our Database

Enter your institutional email | Generate Token

GitHub Token: | Enter GitHub token | Load Repos

Repositories | Repository Contents | File Contents

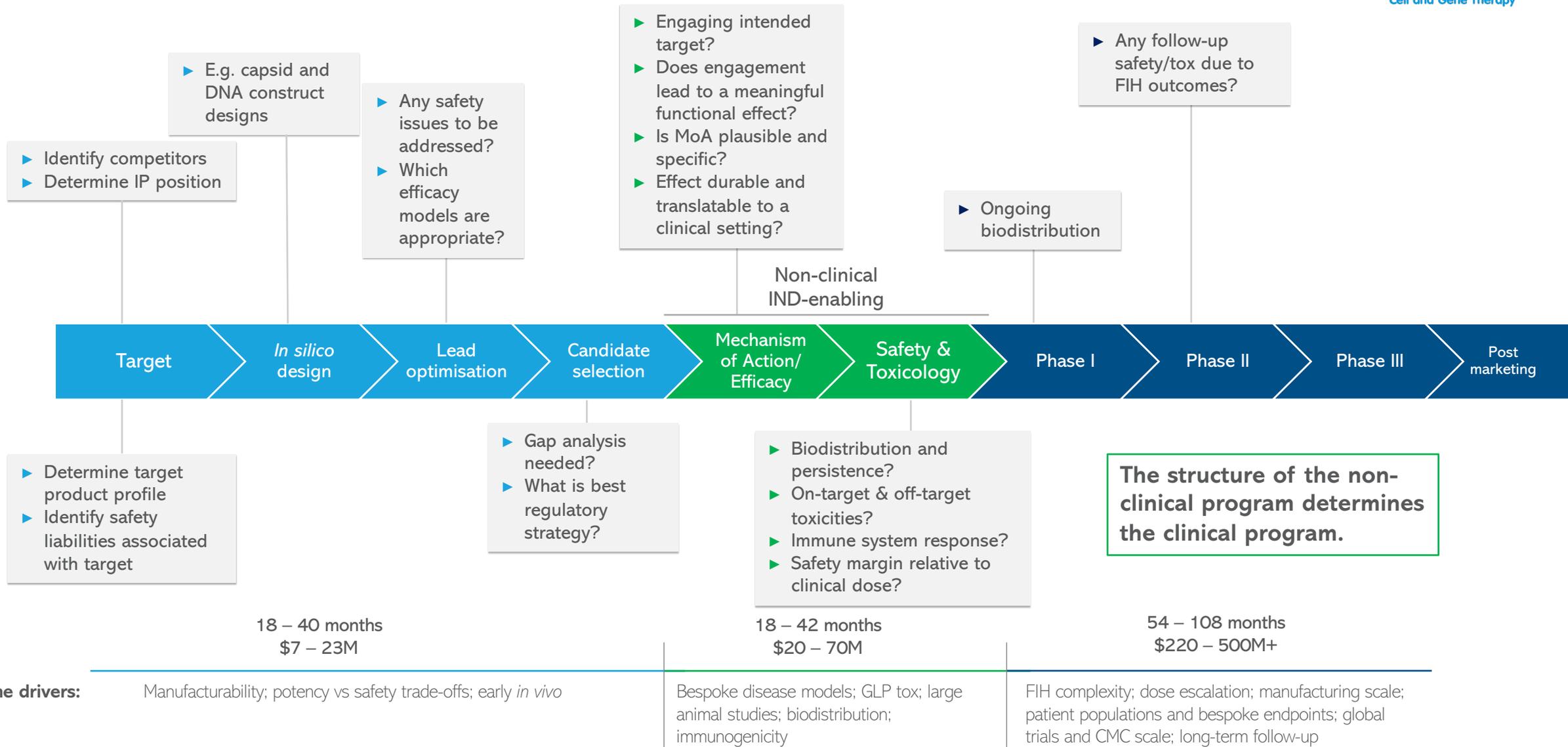
QR Code

- ❑ **Challenges in Biomechanics**
  - Complex data types (mechanical testing, imaging, motion analysis)
  - Lack of standardisation in sample prep, test methods, and metadata
  - Nearly 50% of datasets (2015–2022) lack necessary annotations for replication
- ❑ **Mechanical Testing Methods**
  - Include uniaxial, compression, biaxial tests with varying speeds and setups
  - Sensitive to preservation, geometry, and testing devices
- ❑ **Computational Modelling Hurdles**
  - Diverse hyper-elastic models with non-unified strain energy formulations.
  - Parameter fitting depends on inverse modelling tools and their configuration.

# New Approach Methodologies (NAMs) Strategy

*Accelerating regulatory approval through creation of robust, reproducible,  
and human-relevant non-clinical tools*

# The drug development pipeline (ATMP)



# Industry, regulators, and society are converging on NAMs adoption

FDA/CDER considers non-clinical tests to be NAMs when they are conducted in *vitro*, *ex vivo*, *in silico* (computational), or *in chemico* (chemical-based); improve the predictivity of clinical outcomes; shift studies to phylogenetically lower animals; or otherwise help replace, reduce, and refine animal use (i.e., the 3Rs) in non-clinical drug development programs.

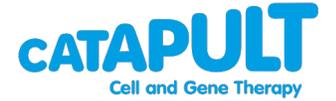
Press release

## Animal testing to be phased out faster as UK unveils roadmap for alternative methods

New plan backs researchers to seize on new and developing opportunities to phase out animal tests with specific commitments for the coming years.

From: [Department for Science, Innovation and Technology](#), [Department for Environment, Food & Rural Affairs](#), [Home Office](#) and [Lord Vallance](#)

Published 11 November 2025



Incorporating NAMs into medicines development: Insights from regulators, industry and academia



16 September 2025

FDA NEWS RELEASE

## FDA Announces Plan to Phase Out Animal Testing Requirement for Monoclonal Antibodies and Other Drugs

For Immediate Release: April 10, 2025

Published November 27, 2025



Scientists at Roche and Hubrecht Institute review progress in the field and exciting future opportunities to apply human models in industry settings.

*More than 85 percent of US adults support discontinuing animal testing, while more than 90 percent of drugs successful in animal trials fail to gain FDA approval.*

McKinsey  
& Company

## Despite sector-wide enthusiasm, the NAMs landscape is fragmented.

### Technical



#### High innovation, low convergence

- Variable biology and protocols
- Limited standardisation of assays, endpoints, & QC
- Data formats not designed for aggregation or modelling
- Few multi-site or cross-platform benchmarks

► Models optimised for **biological insight** over multi-site reproducibility.

### Regulatory



#### Regulators are open but constrained:

- Current models are not robust or reproducible
- Lack of validated endpoint panels
- No cross-platform comparability and benchmarking
- Data structures not designed for regulator-first review

► **Gap between innovation and decision-grade evidence.**

### Commercial



#### Incentive misalignment & unclear ROI to developers

- High upfront costs for industry to develop and validate NAMs
- Unclear ROI vs traditional animal studies to developers
- Fragmented vendor & platform landscape
- SMEs disproportionately impacted by risk & cost
- Data sharing limited by competitive dynamic

► NAM adoption is inconsistent, bespoke, and sponsor-specific.

Regulators **face uncertainty** when reviewing NAM-derived data; developers default back to animal studies as a precaution; NAM adoption remains inconsistent and sponsor-specific; and ATMP-specific needs risk being under-represented as the space moves forward.

# Catapult is uniquely positioned to co-accelerate NAMs and non-clinical ATMP development

## New therapeutics

- A strong flow of novel ATMPs being applied to a broader spectrum of diseases, with ever increasing clinical efficacy.

## Lower cost of goods

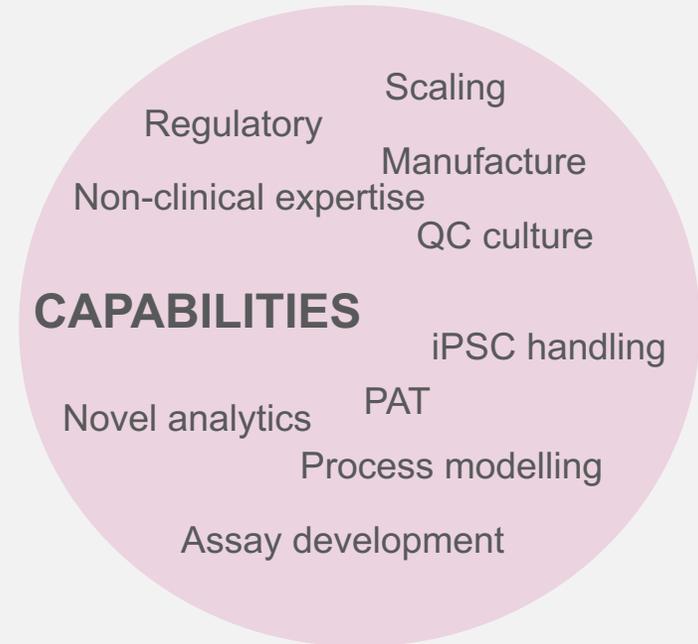
- A substantive shift in manufacturing technologies that enables a dramatic reduction in the cost of manufacture for ATMPs.

## Strong supply

- A substantial and robust manufacturing sector capable of meeting the demands of a rapidly expanding uptake.

## High uptake

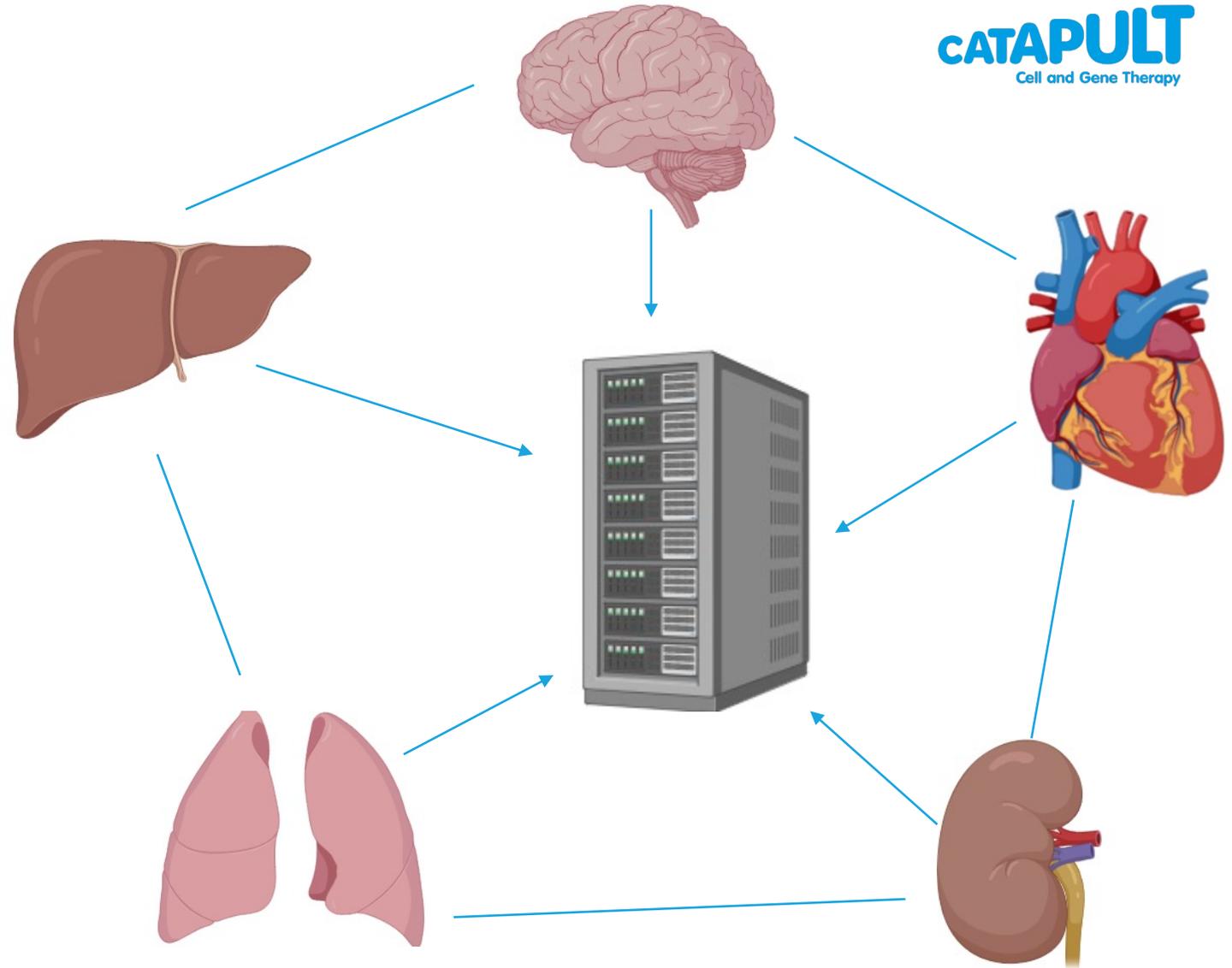
- Efficient adoption systems, continued demand from society and a new approach to investing in innovation through health system demand and reimbursement



Through our capabilities, network, and sector position, we are uniquely positioned to address the challenges facing contemporary NAMs development.

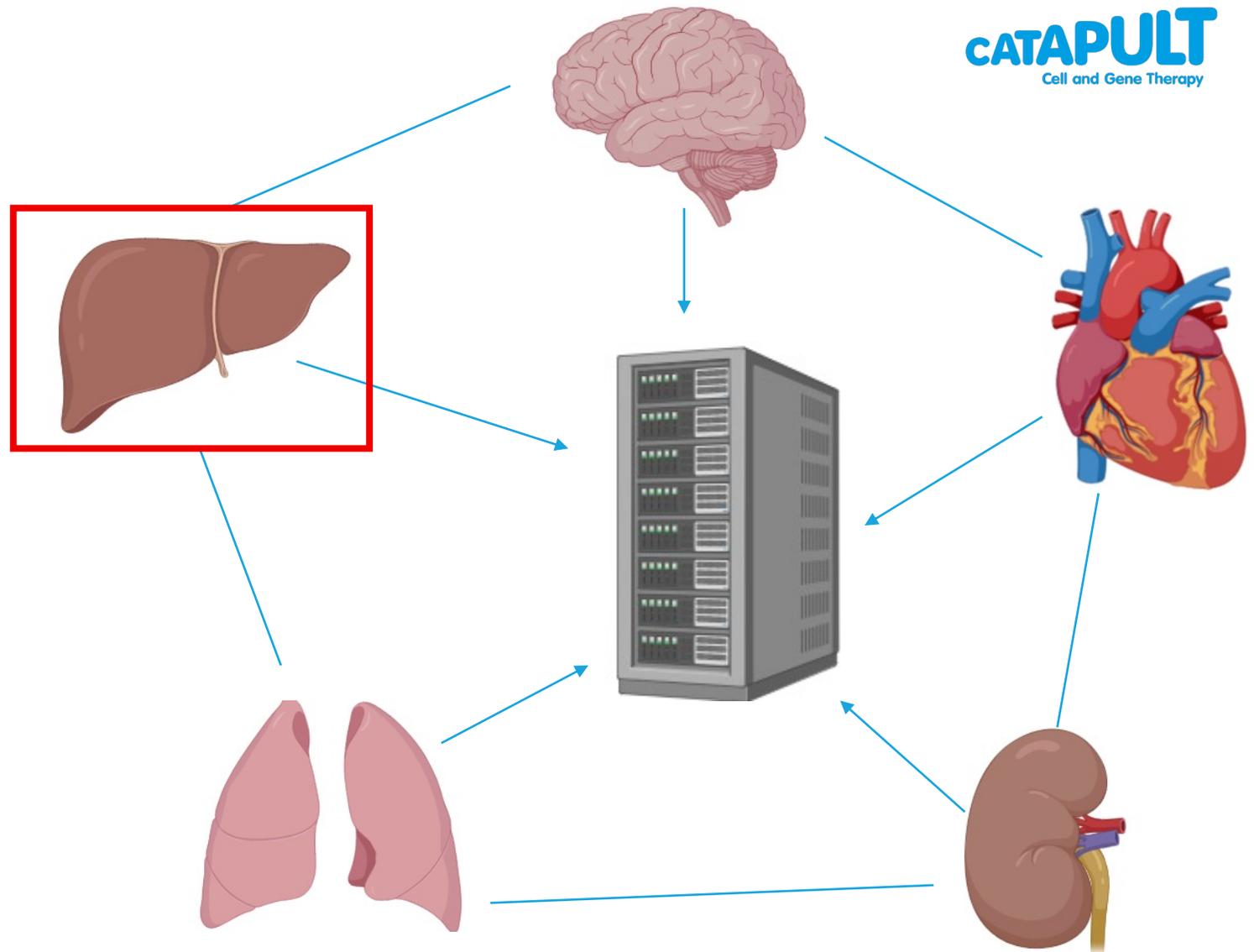
# Multi-organ human-relevant predictive toxicology

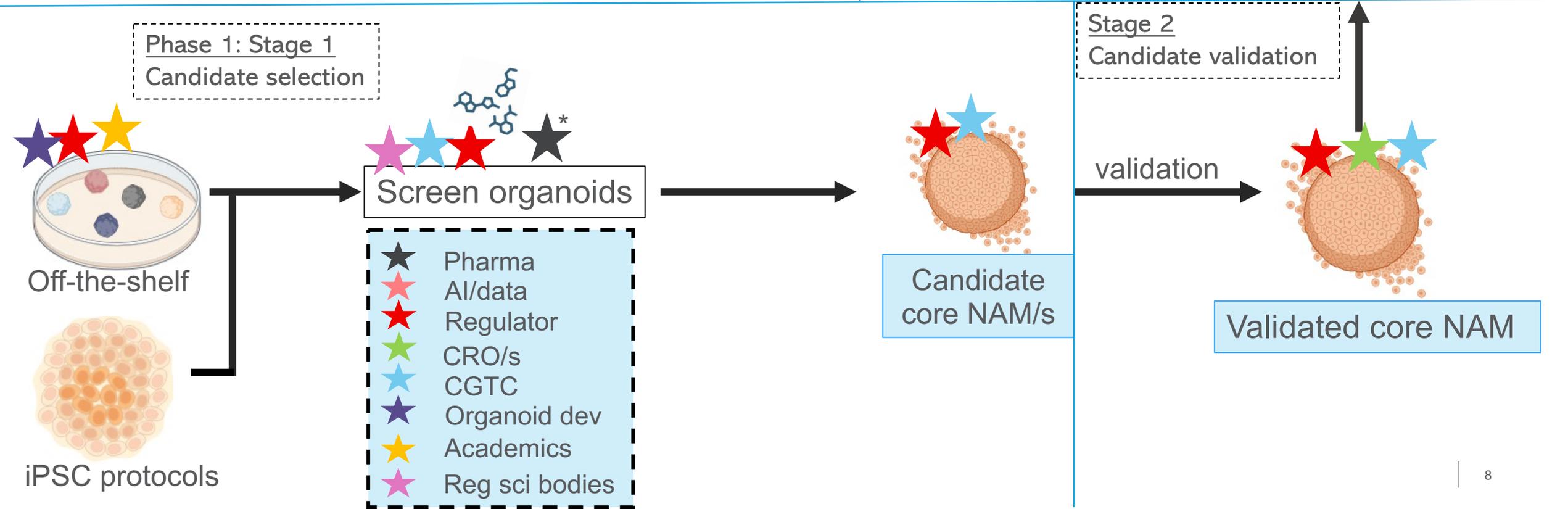
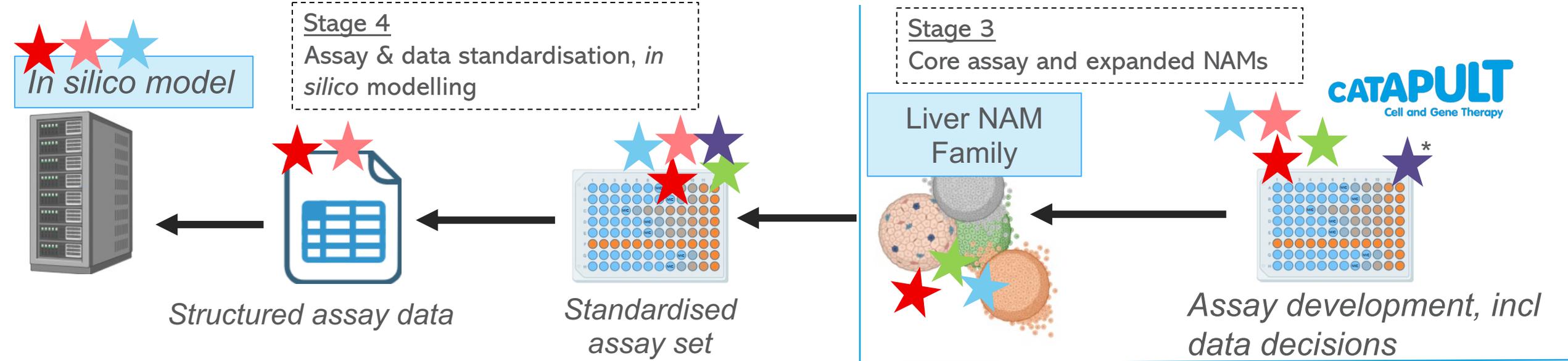
- Establish a regulator-aligned NAMs framework spanning the 5 major toxicological organs
- Each model generates standardised, **decision-grade data** that feeds into a shared *in silico* interpretive layer
- Allow NAM-derived data to be combined, contextualised, and interpreted in a way that is scalable and suitable for regulatory decision-making, **with in-built consideration for complex modalities like ATMPs**



# Phase I: liver as the foundation

- Primary site of toxicity
  - Most frequent dose-limiting organ across all modalities
- High regulatory relevance
- Strong translational challenge
  - Inter-species differences in liver biology, metabolism, and immune sensing limit predictive value of animal models
- Maturity of enabling space
  - Liver organoids and MPS are among the most advanced, providing realistic starting point





# CATAPULT

Cell and Gene Therapy

Contact us:  
[Keith.McLuckie@ct.catapult.org.uk](mailto:Keith.McLuckie@ct.catapult.org.uk)  
[Fiona.Nugent@ct.catapult.org.uk](mailto:Fiona.Nugent@ct.catapult.org.uk)

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Cell and Gene Therapy Catapult is committed to ensuring high standards of research integrity and research best practice in the activities we carry out. We subscribe to the principles described in the UK concordat to support research integrity.

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# AI-Enabled Health Technologies and Digital Innovation Platforms (University of Huddersfield)

**Name: Chioma Ugwudi**

**Organisation: University of Huddersfield**

**Country: United Kingdom**

**Contacts / website : [business@hud.ac.uk](mailto:business@hud.ac.uk)**

# Topic of Interest & Proposal Objective

## Topic of Interest

Health Technologies, Data & Innovation Platforms - with a focus on AI-enabled diagnostics, smart sensing, digital platforms, and precision engineering for health applications.

## Proposal idea/ Objective of Proposal

To co-develop next-generation digital health technologies that integrate advanced sensing, data analytics, and intelligent platforms to improve diagnosis, monitoring, and personalised intervention. We aim to contribute expertise in AI, modelling, precision engineering, and digital system integration to strengthen European health innovation ecosystems.

## Expertise of the University of Huddersfield

The University has internationally recognised strengths in AI, data science, medical engineering, digital platforms, and sensor technologies. Our Centre for Precision Technologies recently secured €377k from Horizon Europe for a major collaborative project involving 17 European partners, applying advanced modelling, simulation, and digital verification to complex systems. We also host leading groups in biomechanics, rehabilitation technologies, industrial analytics, and digital health adoption, providing a full pipeline from engineering innovation to real-world clinical evaluation.

## Existing Partnerships & Partner needs

We have collaborated extensively with UK and NHS partners, and applied research centres.

For this call, we seek partners in:

- Clinical validation and trials
- Health data governance and interoperability
- Digital therapeutics
- Large-scale platform deployment
- Behavioural and public health evaluation
- EU industries

# Previous projects

Huddersfield's Horizon Europe portfolio includes the FLASH project, developing a flexible laser-based manufacturing system using precision metrology and digital simulation. This demonstrates our capability to deliver high-impact, multi-partner, technology-driven European projects. We also have a strong track record in Innovate UK, KTPs, and interdisciplinary digital health collaborations.



# PeptiMatrix™

Next generation peptide hydrogels



Cluster 1 Health



Developing and using new tools, technologies  
and digital solutions for a healthy society

## Developing New Approach Methodologies to advance biomedical research



Stem Cell  
Glycobiology  
Group

### Dr Viola Erdelyi, PhD MRSB



- HORIZON-HLTH-2026-01-TOOL-03: Integrating New Approach Methodologies (NAMs) to advance biomedical research and regulatory testing
- HORIZON-HLTH-2026-01-TOOL-06: Support to European Research Area (ERA) action on accelerating New Approach Methodologies (NAMs) to advance biomedical research and testing of medicinal products and medical devices



**Telephone**

+44 (0) 7599 442 871



**Address**

Biodiscovery Institute, Nottingham, UK



**Website**

[peptimatrix.com](http://peptimatrix.com)



**>90%**

Attrition rate of new drugs at clinical trial.

**\$985M**

Median cost of bringing each new drug to market<sup>1</sup>.

**115M**

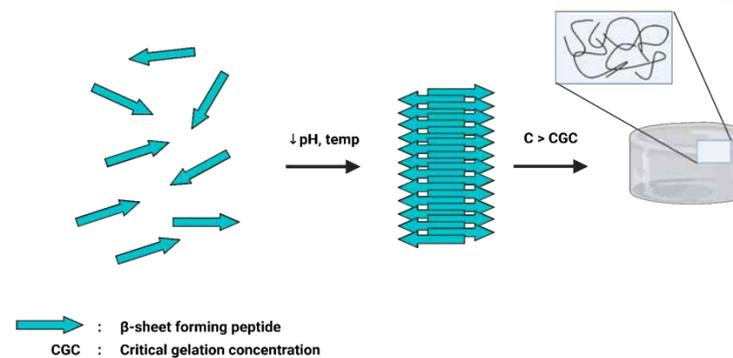
Animals sacrificed annually for research<sup>2</sup>.

Current 3D *in vitro* models often rely on the use of animal-derived materials to represent the matrix.

These types of materials suffer from:

- An ill-defined composition
- Batch-to-batch variability
- Lack of relevance to human conditions

Models built on these materials then often fail to predict patient outcomes at clinical trial.



Backed by **10 years** of research at the University of Nottingham.

01

## ANIMAL-FREE

All **PeptiMatrix™** products are fully synthetic and chemically defined, with no animal products used in their manufacture.

02

## REPRODUCIBLE

**PeptiMatrix™** hydrogels have limited batch variability, and we also employ a strict batch testing protocol.

03

## CUSTOMISABLE

**PeptiMatrix™** can also be customised, both in terms of stiffness and composition, to mimic different tissue types.

04

## VALIDATED

Each formulation of **PeptiMatrix™** has been validated across multiple relevant cell types, to ensure relevant data.

05

## READY-TO-USE

Simply combine with your cells and matrix additions of choice and plate out. No complex prep required.

06

## VERSATILE

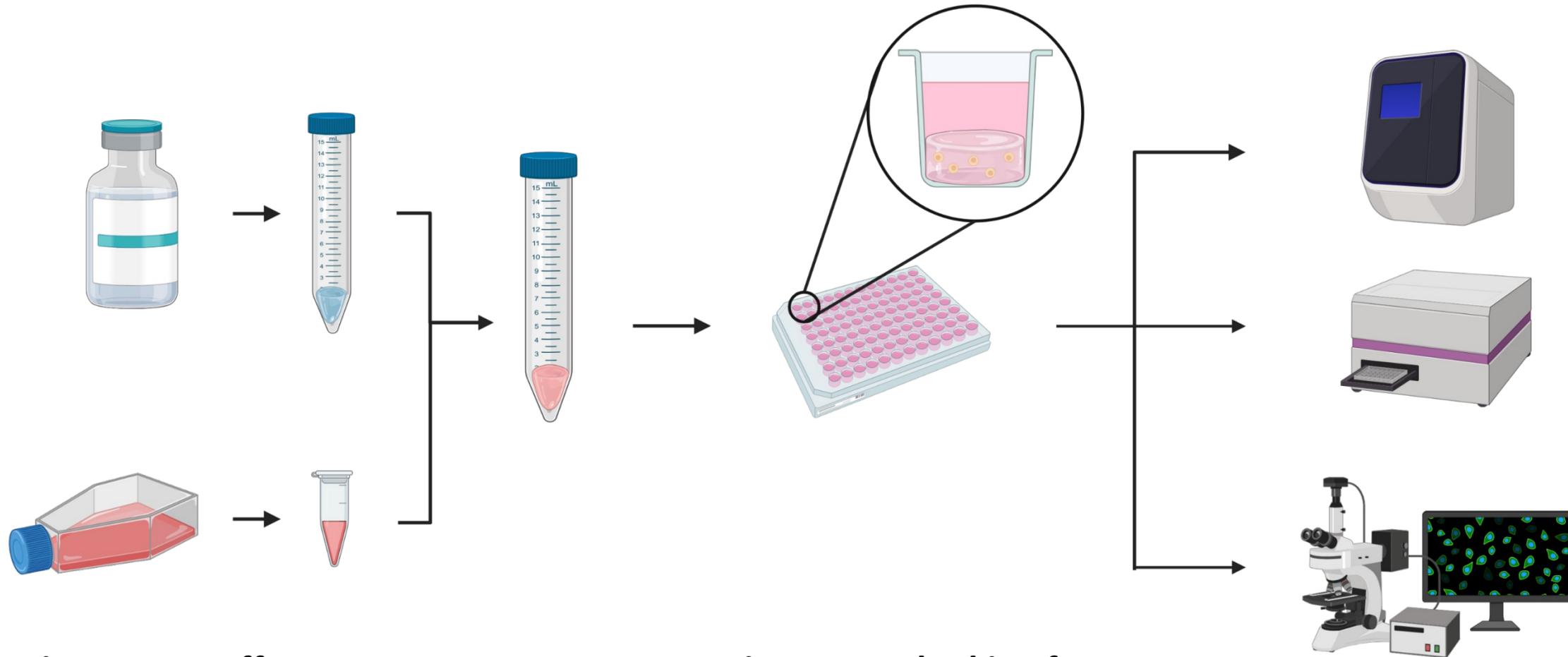
Tested for compatibility with a range of standard end-point assays, with optimised protocols available for your convenience.

**1. Aliquot gel** – ready-to-use format for easy handling.

**2. Prepare cell suspension** – with or without additional matrix supplementation (e.g., recombinant laminin)

**3. Mix and plate out** – combine cells with the cell and seed directly into your plate

Scan to watch the video demo:



**Expertise we can offer:**

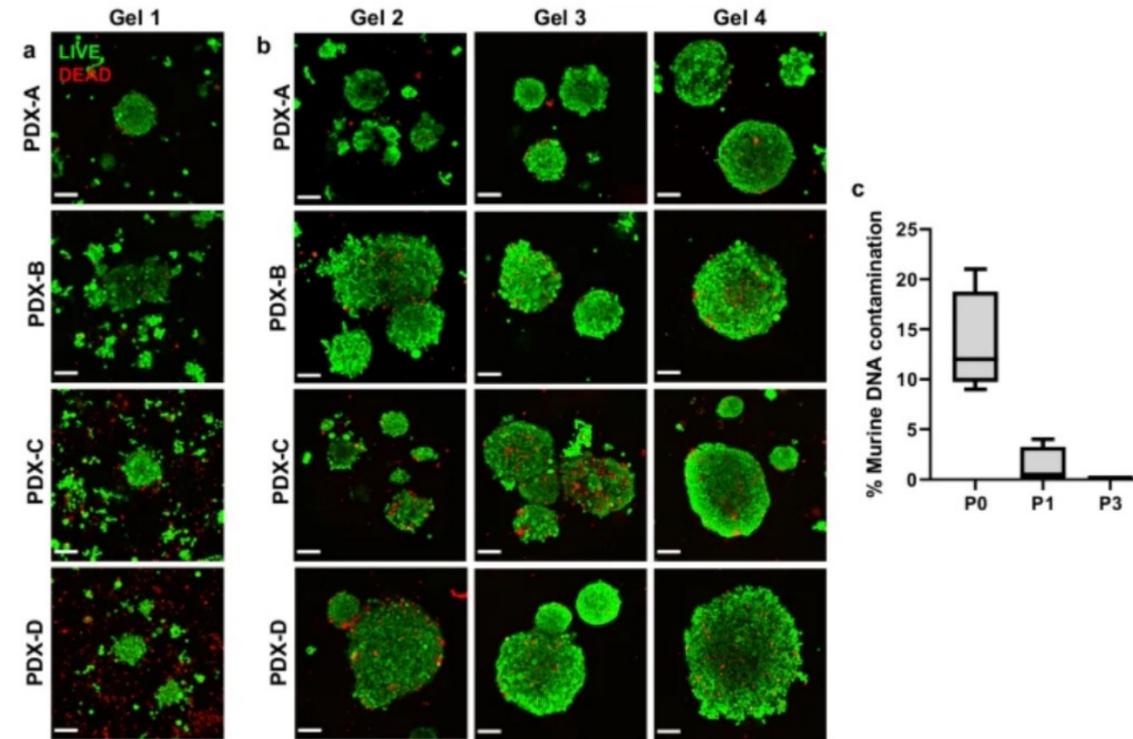
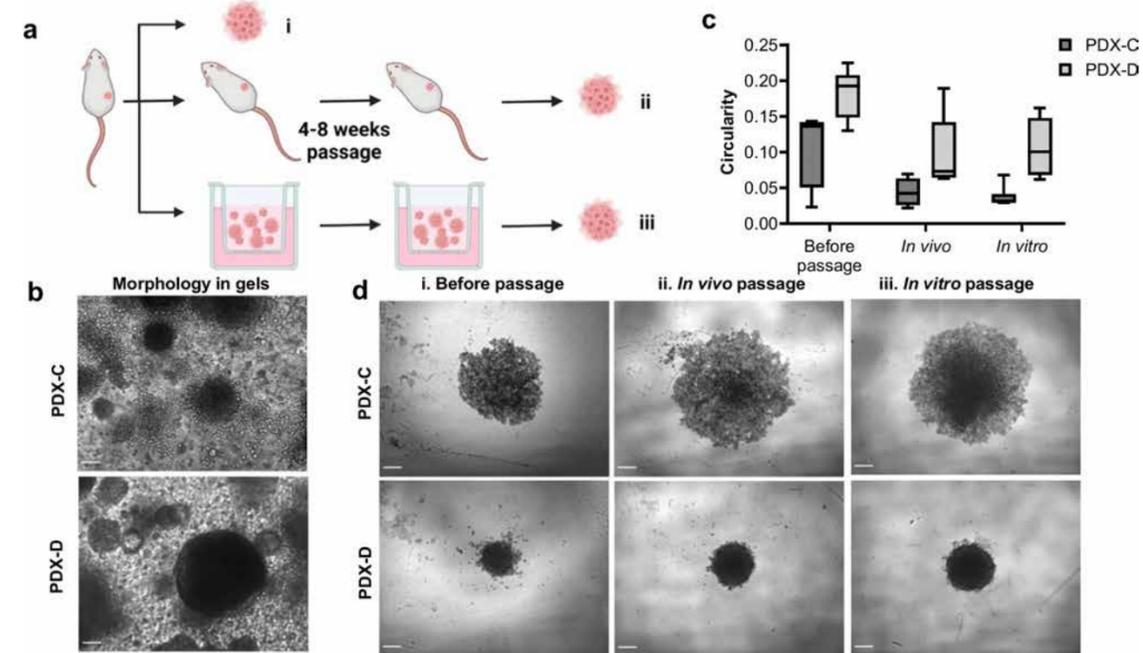
- 3D cell models
- Animal-free cell models/studies
- Extensive cell culture
- Hydrogels and biomaterials

**Expertise we are looking for:**

- Primary cells/PDX models
- New approaches to standard 3D models
- Regenerative medicine focused work

**4. Assay for cell viability or behaviour** – compatible with a variety of typical end-points

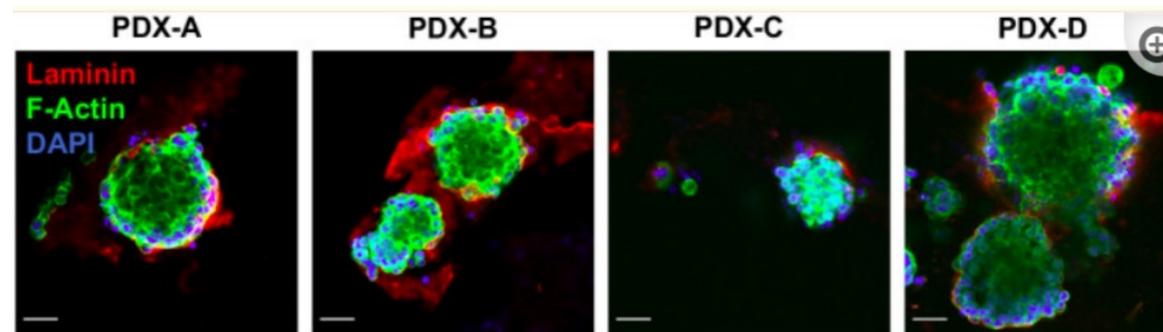
## BEYOND XENOGRAFTS: LONG-TERM PDX EXPANSION IN PEPTIDE GELS



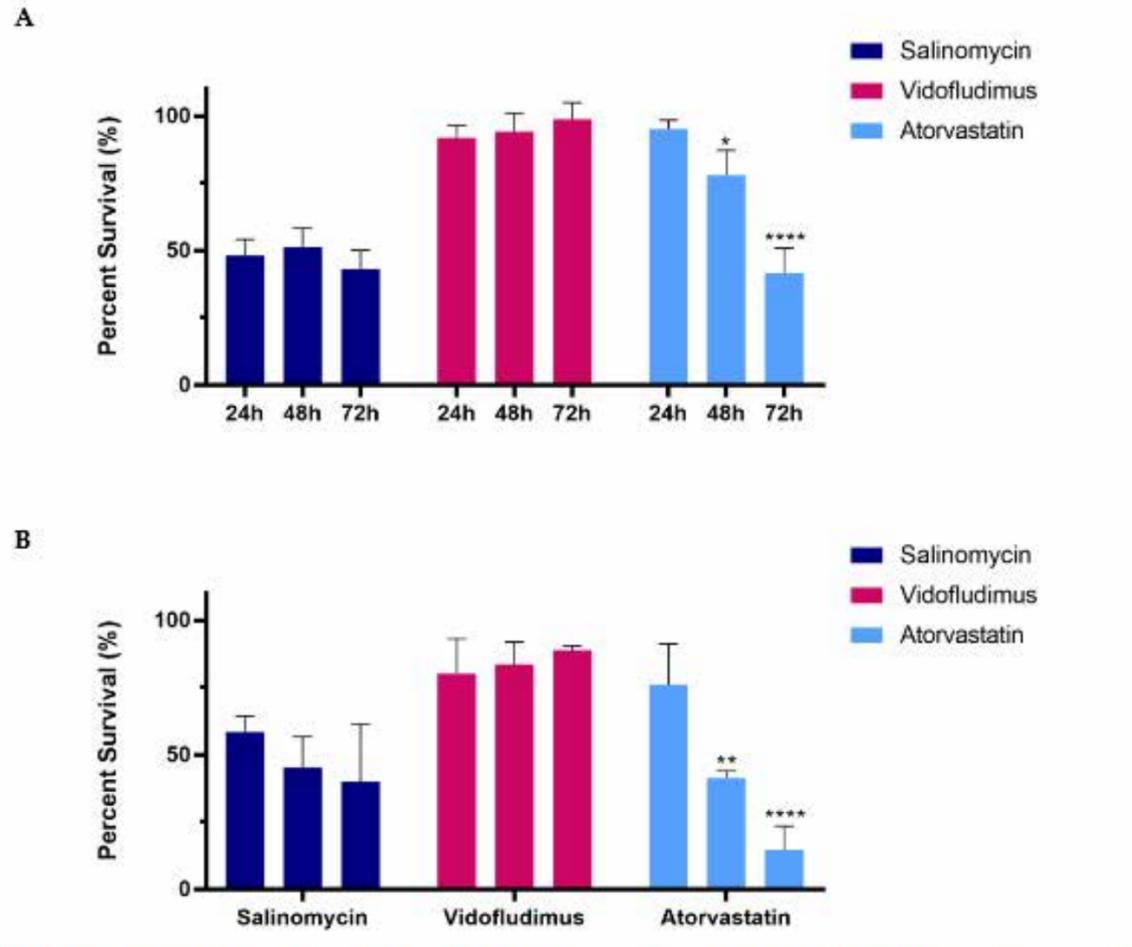
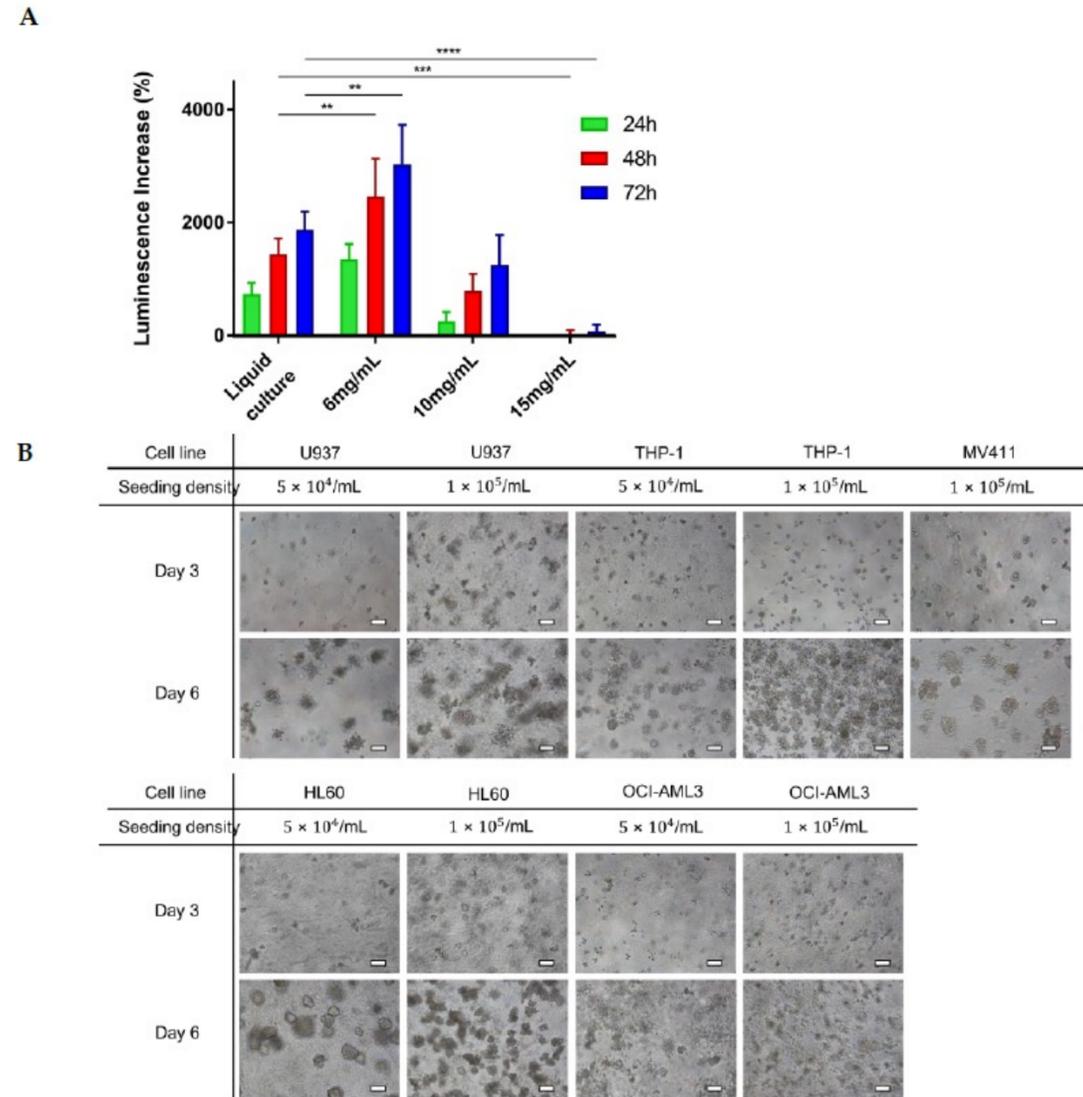
Breast Cancer



Breast cancer PDX cells can be maintained and passaged entirely in peptide gels, **eliminating the need for mouse propagation**. They retain spheroid-forming behaviour through multiple passages, show reduced murine DNA contamination from passage three, and produce their own extracellular matrix within the gel.



## DESIGNED FOR SCALE: COMPATIBLE WITH HIGH-THROUGHPUT WORKFLOWS



Leukaemia models



After optimizing culture conditions, the hydrogels create an ideal platform for **3D drug screening**.

Here we tested the effectiveness of candidate **FDA repurposed drugs** for the treatment of AML.

# THANK YOU

If you are interested in learning more, you can visit our website or feel free to contact me directly:

 [viola@peptimatrix.com](mailto:viola@peptimatrix.com)

 +44 (0) 7599 442 871

LEARN **MORE:**



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## Address

Biodiscovery Institute, Nottingham, NG7 2RD



## Website

[peptimatrix.com](http://peptimatrix.com)

# Chair Management in Innovative Health – EDHEC

**UNLEASH  
TOMORROW**

# Ranked programmes among the best in the world

**TOP 10**

**Business School in Europe**

Financial Times, 2025

**4<sup>th</sup>**

**Master in Management worldwide**

Financial Times 2024

**6<sup>th</sup>**

**Master in Finance**

Worldwide  
Financial Times, 2024

**4<sup>th</sup>**

**GMBA on ESG criteria**

Worldwide  
Financial Times, 2024

**2<sup>nd</sup>**

**BBA in France**

Challenges 2026

## Management in Innovative Health Chair (MIH)



**The Management in Innovative Health Chair (MIH)** is a multidisciplinary research and teaching chair hosted by EDHEC, dedicated to understanding and accelerating innovation in healthcare systems.

The Chair focuses on:

- Digital health and AI-driven transformation of care pathways
- Patient empowerment, behavioral change, and trust in innovation
- Value-based healthcare, outcomes, and real-world evidence
- Innovation ecosystems, public-private partnerships, regulation, ethics and AI compliance

The **MIH Chair operates at the intersection** of management sciences, health economics, marketing, data science, and public policy, with strong engagement from hospitals, pharma, medtech, startups, and regulators.

The **MIH Chair is particularly experienced in bridging technical innovation with real-world adoption**, a critical success factor in many EU-funded projects. **Contribution to 3 Consortia for European Grant Applications**

# Expertise Relevant for European Projects

## Behavioral & Societal Dimensions

- Design and evaluation of behavioral interventions (prevention, adherence, digital usage)
- Analysis of trust, acceptance, risk perception, and ethical concerns related to AI and digital health
- Patient, citizen, and professional engagement

## Innovation, Adoption & Impact

- Market access, diffusion of innovation, and scale-up strategies
- Business models for digital health, AI, and medical technologies,
- Socio-economic impact assessment and exploitation pathways

## Data, AI & Governance

- Human-centric and trustworthy AI adoption frameworks
- Use of real-world data (RWD) and real-world evidence (RWE) from a managerial and behavioral perspective
- Governance, transparency, and alignment with EU regulations (AI Act, data governance, ethics)

## Communication, Dissemination

- Design of high-impact dissemination and communication strategies
- Stakeholder mapping and multi-actor engagement
- Development of training, capacity-building, and upskilling programs (professionals, managers, students)

## What EDHEC Brings to a Consortium

**EDHEC is a strong complementary partner, especially when projects require:**

- Non-clinical but essential expertise on adoption, behavior, trust, and value
- Translation of technological innovation into societal, organizational, and economic impact
- Structuring exploitation, dissemination, and sustainability beyond the project lifecycle

Chair is committed to **supporting impact-driven European research**, contributing robust scientific expertise while ensuring that innovation effectively reaches patients, professionals, and society.



## What EDHEC Brings to a Consortium



**Loick Menvielle – PhD**  
Director Chair Management  
in Innovative Health  
loick.menvielle@edhec.edu

### Vision and Values within the Chair:

"While ethical concerns arise, it is critical to center the conversation on how these technologies are adopted and made use of by primary stakeholders, particularly patients, whose experiences and outcomes stand to be most impacted."

**innovative-health@edhec.edu**



**Simone Whale – MBA**  
Project Manager - Chair  
Management in Innovative Health  
simone.whale@edhec.edu



**UNLEASH  
TOMORROW**





# Health Technologies, Data & Innovation Platforms

**Zuhair Imran**

**Paris School of Business, Paris, France**

**[i.zuhair@gmail.com](mailto:i.zuhair@gmail.com) / [z.imran@psbedu.paris](mailto:z.imran@psbedu.paris)**

**<https://www.linkedin.com/in/zuhairimran/>**

# **Health Technologies, Data & Innovation Platforms**

Within the broad stream I would like to focus on:

- How a digital health, data-driven solutions, and platform-based approaches can strengthen health systems across UK & France, improve patient outcomes, and accelerate research-to-impact pathways.

**Health Innovation Hub: Technology & Digital Capacity Center**

# Core Idea

Establish a cross-border Health Innovation Hub that function both as real-life testing environments for health technologies and as capacity-building for clinicians, researchers, health managers, and innovators.

These Hubs will enable the co-creation, testing, validation, and adoption of digital health and data-driven solutions, while simultaneously building skills and competencies in digital health, AI, and data governance across UK & France health systems.

The project positions learning, innovation, and implementation as a single integrated process.

## **This hub will encompass a wide range of tools and solutions (but not limited to)**

- Artificial Intelligence and machine learning for diagnostics and decision support
- Biotechnology and precision medicine tools
- Health information systems (EHRs, clinical decision systems)
- Digital health applications (telemedicine, mobile health)
- Medical devices and connected wearables

## **These technologies aim to improve**

- Prevention and early diagnosis
- Quality and efficiency of care
- Patient engagement and outcomes

# The Role of Health Data

## Capture health data

- Clinical data (EHRs, imaging, lab results)
- Genomic and biomolecular data
- Public and population health data
- Patient-generated data (wearables, apps)
- Real-world evidence (RWE)

## Key Challenges

- Data silos and fragmentation
- Lack standardization
- Data quality and bias
- Privacy, ethics, and governance

## **My expertise**

### **My expertise lies at the intersection of:**

- Health innovation and digital transformation
- Data-driven platforms and innovation ecosystems
- Stakeholder coordination across academia, industry, and public institutions
- I have worked extensively on health, innovation, education, and capacity-building projects, supporting complex, multi-actor initiatives that require structured collaboration, governance, and alignment between technical, societal, and policy dimensions. This allows me to contribute particularly to platform design, coordination, dissemination, and impact-driven implementation, complementing more technical or clinical expertise within consortia.

## **Partners & Outcomes**

### **Ideal Consortium Partners**

#### **Health & Innovation Actors**

- Hospitals and primary care providers
- Patient organizations and civil society
- Startups and SMEs in digital health and AI
- Local and regional authorities

#### **Education & Skills Actors**

- Universities and training providers
- Professional bodies and health associations
- EdTech and digital learning platforms
- Policy institutions and innovation agencies

#### **Expected outcomes**

- Faster and more effective translation of health technologies into practice
- Increased digital and data literacy across health systems
- Improved trust, usability, and acceptance of health technologies
- Stronger and more resilient European health innovation ecosystems

**THANK YOU!**