



Innovate
UK

Innovate UK Global Expert Mission Report

XR and Mental Health Technologies in the US

March 2023



PUBLIC

Contents

01	Executive Summary	4
02	Acronyms	6
03	Definitions	7
04	Introduction	8
05	Market Overview	15
06	Opportunities for Future Collaboration	28
07	Potential Barriers to Collaboration	32
08	Conclusions	34
	Appendix 1: XR & Medical Tech to US GEM	36

01. Executive Summary

Immersive technology's capability to profoundly impact our mental health and wellbeing is greater than any preceding technology.

In conjunction with the increased prevalence of common mental disorders, and mental health conditions, there is an enormous opportunity for the UK to catalyse positive impact at scale while at the same time capturing and creating value internationally.

This Global Expert Mission explicitly reflects findings from the Northeast Coast of the United States, with the following stakeholder groups: universities, hospitals, psychiatric institutions, policymakers, and a not-for-profit and private corporation.

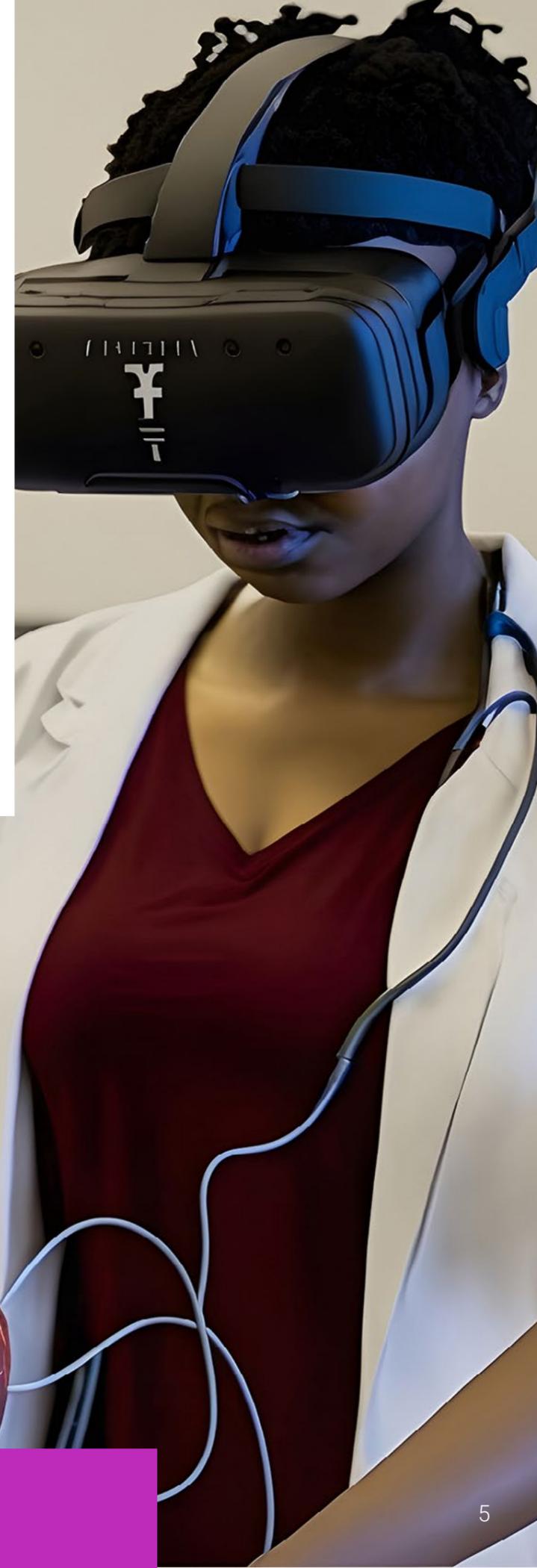
UK companies working in XR and Mental Health are well equipped to collaborate with these stakeholders, with clear funding initiatives and resources through the soon-to-launch Center for Excellence. Further, many UK start-ups working at this intersection are university spinouts that are particularly well equipped to engage with US academics on collaborative research and with US institutions for clinical trials and market integration.

Challenges specific to the US healthcare ecosystem and opportunities for new solutions include waiting times for diagnosis, costs associated with in-hospital care, at-home care solutions, wellness while waiting for care, CMD interventions, mental health awareness, education and empathy training for healthcare professionals, remote collaboration between healthcare professionals and patient diagnosis.

However, given the nascent stage of XR technology in the UK and US, there are several challenges that need to be overcome to facilitate international cooperation. These include navigating the US' national and federal regulations, insurance policies, data and privacy regulations, unclear distribution channels, ethical and accessibility frameworks, funding and (a lack of) standardisation.

This Mission has provided insights into the market and policy drivers for mental health technology and how the UK can overcome challenges related to collaboration, market access and navigating regulatory barriers.

This is an inspiring time for the UK to initiate a closer relationship with US stakeholders in XR and mental health, given the early stage of the industry, the blue ocean market and US stakeholder willingness to collaborate, including US regulators. For the same reason, careful attention is needed to shape these relationships, the regulatory landscape, frameworks for collaboration and accessibility guidelines to support long-term economic opportunity, impact and market stability.



02. Acronyms

AI	Artificial Intelligence
AR	Augmented Reality
B2B	Business to Business
B2C	Business to Consumer
BUMC	Boston University Medical Campus
CMD	Cognitive Mental Disorder
DBT	Department for Business and Trade
DSIT	Department for Science, Innovation and Technology
EHR	Electronic Health Record
FCDO	Foreign, Commonwealth and Development Office
FDA	Food and Drug Administration
GEM	Global Expert Mission
MR	Mixed Reality
NHS	National Health Services
NPC	Non-player character
SIN	Science and Innovation Network
UKRI	UK Research and Innovation
VR	Virtual Reality
XR	Extended Reality

03. Definitions

Clinical Mental Health

The perception of using XR for clinical application has improved in recent years. There is now a growing number of applications of XR in a clinical setting to treat Post-Traumatic Stress Disorder (PTSD), phobias, ADHD, neuropsychological assessments and social anxiety disorder.

Mental Wellbeing

Application of XR to engage people in exercise and emotional wellness, such as encouraging creativity and exercise and aiming to reduce anxiety through creating relaxing environments for mindfulness and meditation. Relaxation experiences are becoming popular among at-home users, as well as in care home settings.

Extended Reality (XR)

Immersive technology (virtual reality, augmented reality, mixed reality technologies and capabilities; plus haptics, sonics and advanced sensory interfaces; along with advanced visualisation and display technologies; plus real-time and associated production technologies) and emerging digital therapies which support the development of urgently needed new digital delivery models for mental health services.

Augmented Reality (AR)

A technology that superimposes a computer-generated image on a user's view of the real world.

Haptics

The use of technology that stimulates the senses of touch and motion, especially to reproduce in remote operation or computer simulation sensations that would be felt by a user interacting directly with physical objects.

Mixed Reality (MR)

A medium consisting of immersive computer-generated environments in which elements of a physical and virtual environment are combined.

Virtual Reality (VR)

The computer-generated simulation of a three-dimensional image or environment that can be interacted with in a seemingly real or physical way by a person using special electronic equipment, such as a virtual reality headset, gloves fitted with sensors, or a full-body haptics suit.

04. Introduction

Innovate UK, Innovate UK KTN and the Global Expert Missions

Innovate UK supports business-led innovation and is part of UK Research and Innovation (UKRI)¹. UKRI convenes, catalyses and invests in close collaboration with others to build a thriving, inclusive research and innovation system. To this end, Innovate UK helps businesses to identify the commercial potential in new technologies and turn them into new products and services that will generate economic growth and increase productivity. With a strong business focus, Innovate UK drives growth by working with companies to de-risk, enable and support innovation. Innovate UK KTN exists to connect innovators with new partners and new opportunities beyond their existing thinking – accelerating ambitious ideas into real-world solutions. Innovate UK KTN is part of the Innovate UK group.

As innovation is increasingly a global endeavour and the ambition of UK businesses to become truly international enterprises is at its highest, Innovate UK established its Global Expert Mission (GEM)² programme in 2017. Delivered by Innovate UK KTN, in partnership with the FCDO Science and Innovation Network (SIN)³, GEMs help further Innovate UK's global strategy by providing the evidence base for where it should invest and by providing opportunities for UK businesses to build partnerships and collaborations with key economies.

Built around UK business, policy and translational research, a GEM's objectives are:

1. Informing UK businesses and government

The findings and opinions of experts on the topic of the GEMs are made available to UK businesses and government departments. These inform UK businesses about potential opportunities for innovation in the country and the UK government on how it can help UK businesses make the most of those opportunities.

2. Building International Collaborations

The expert insights will help inform how Innovate UK can best help UK businesses find and exploit the opportunities for innovation partnerships. The GEM creates connections with key organisations and people that will deepen and widen the collaboration with the partner country to benefit UK business.

3. Sharing UK Capabilities

During the Mission, the delegation of experts will use the opportunity to promote and share the strength of the UK's innovation. This helps to identify synergies between the US and the UK and whether there is an appetite for joint funding opportunities.



¹ <https://www.ukri.org>

² <https://iuk.ktn-uk.org/programme/global-expert-missions/>

³ <https://www.gov.uk/world/organisations/uk-science-and-innovation-network>



4.1 Mission Overview

The increased prevalence of common mental disorders (CMD) is a major challenge for public health, with the NHS spending £14.3 billion on mental health services in 2020/21⁴. With one in four people likely to experience CMD each year in the UK, it is estimated that only one in eight will receive treatment.⁵ This has been further exacerbated by the COVID-19 pandemic, where introductions to social restrictions and the resulting financial uncertainty have led to a 38% increase in the prevalence of CMD in the UK. The mental toll from the pandemic has worryingly affected the younger population, with recent data suggesting 41% of previously healthy 18-24-year-olds had a mental health condition in April 2020, a significant increase from the 19% reported in 2018-2019.⁶ Mental health is a rising problem in the UK, which has a detrimental impact on the UK economy and the population's wellbeing. There is an urgent need to establish innovative programmes to address this crisis. These programmes are currently being delivered through the UK's flagship Mindset programme.

⁴ Mental health statistics in England, Parliamentary briefings

⁵ McManus S, Bebbington P, Jenkins R, Brugha T. (eds.) (2016). Mental health and wellbeing in England: Adult psychiatric morbidity survey 2014

⁶ The Resolution Foundation "Double trouble: Exploring the labour market and mental health impact of Covid-19 on young people."



4.2 Mindset Programme

The vision for the Mindset programme is to achieve a post-COVID transformation of UK Mental Health provision in the face of an accumulating crisis. The programme aims to achieve change by developing and scaling up emerging digital therapies. It will do this by catalysing collaboration between healthcare providers and creative sectors, growing an innovative sector with global potential, and providing urgently needed digital delivery models for mental health services in the UK. In addition to providing funding to develop the technologies, the programme will create a collaborative ecosystem to support companies in bringing their innovations to market.

4.3 Mission Scope and Objectives

With 95% of global R&D and innovation occurring outside of the UK, it is vital for the UK to engage internationally with strategic countries to grow and scale innovative UK businesses. The GEM plays a key role in providing a deep-dive into the research opportunities and industry advances in the US in Mental Health Technology and builds strategic partnerships with key stakeholders. This Mission's primary focus is on the application of XR used in Clinical Mental Health and Mental wellbeing.

Five key objectives were identified to enhance the UK's XR and mental health sector:

1. Investigate the current landscape in XR technologies applied to mental health in the US.
2. Identify key research outputs in the public and private sectors
3. Identify innovation opportunities for UK businesses
4. Identify US demonstrators, test-bed and government departments responsible for pre-commercial deployment and support
5. Understand the UK's comparative position to the US in XR R&D outputs, commercialisation, policy and regulations

05. Market Overview

5.1 The Growing Value of XR in Healthcare in the UK

Digital services are at the core of NHS England's Five Year Forward View for Mental Health. The strategy sets out a long-term view to delivering digital technologies to address CMD.⁷ The NHS strategy aligns with the UK Government Levelling up wellbeing mission to improve mental health wellbeing in the UK.⁸ The UK Government has committed to developing a new cross-government 10-year plan for mental health and wellbeing⁹ immersive technology plays a leading role in revolutionising and achieving the objectives in the strategy.

The Growing Value of XR in Healthcare in the UK Report,¹⁰ published in May 2021 and sponsored by a cross-section of healthcare organisations and institutions, is a response to this interest and recognition of the need for accurate intelligence and market data to inform strategic priorities in the public and private sectors. With 1 in 17 households having a VR headset at home,¹¹ and this number is predicted to increase in the future; there is an opportunity for the creative and healthcare industries to capitalise on this trend. There is a clear benefit to, and an opportunity for, the UK to utilise XR technologies to create and deliver world-leading mental healthcare. Therapies delivered remotely through XR have several potential benefits, such as being cheaper than traditional delivery routes, significantly reducing wait times, as well as improving patient engagement.

⁷ NHS England: The Five-Year Forward View for Mental Health

⁸ Levelling up the United Kingdom

⁹ Call for evidence for new 10-year plan to improve mental health

¹⁰ The Growing Value of XR in Healthcare in the UK

¹¹ Eccles, Louise. 2021. 'Virtual Reality: Pandemic Leads to Rise in Headset Sales to Escape Lockdown'. The Sunday Times, 17 January 2021.

5.2 XR Healthcare Market in the US

Globally, the market for XR in healthcare could reach \$7B by 2026.¹² According to the Extended Reality Association (XRA), healthcare leaders are increasingly turning to technology to help solve their biggest challenges - 75% of business leaders in the healthcare industry, with decision-making power, indicating they are optimistic about XR technology and its potential for the healthcare industry.¹³ In the US, The National Institute for Mental Health (NIMH) is one of a few federal bodies exploring the use of digital technology to address CMD. The NIMH has four priority areas, suicide prevention, genomic psychiatry, mental health disparities and global mental health, and plays a key role in supporting early-stage studies in mental health intervention technologies. Between 2009 – 2015 the NIMH awarded 404 grants totalling \$445M to develop mental health intervention technologies.¹⁴

According to the National Council for Mental Wellbeing’s 2022 survey, 42% of US adults reported needing mental health care over the past 12 months, and a staggering 43% of those did not receive care, citing numerous barriers to access.¹⁵ XR, therefore, presents a huge opportunity to expand and improve care. Overall, the US is a global leader in digital health technologies and has seen the most investment in developing mental health technologies. The US leads in private and public investment (figure 1) with a geographic focus on Silicon Valley, New York and Boston.

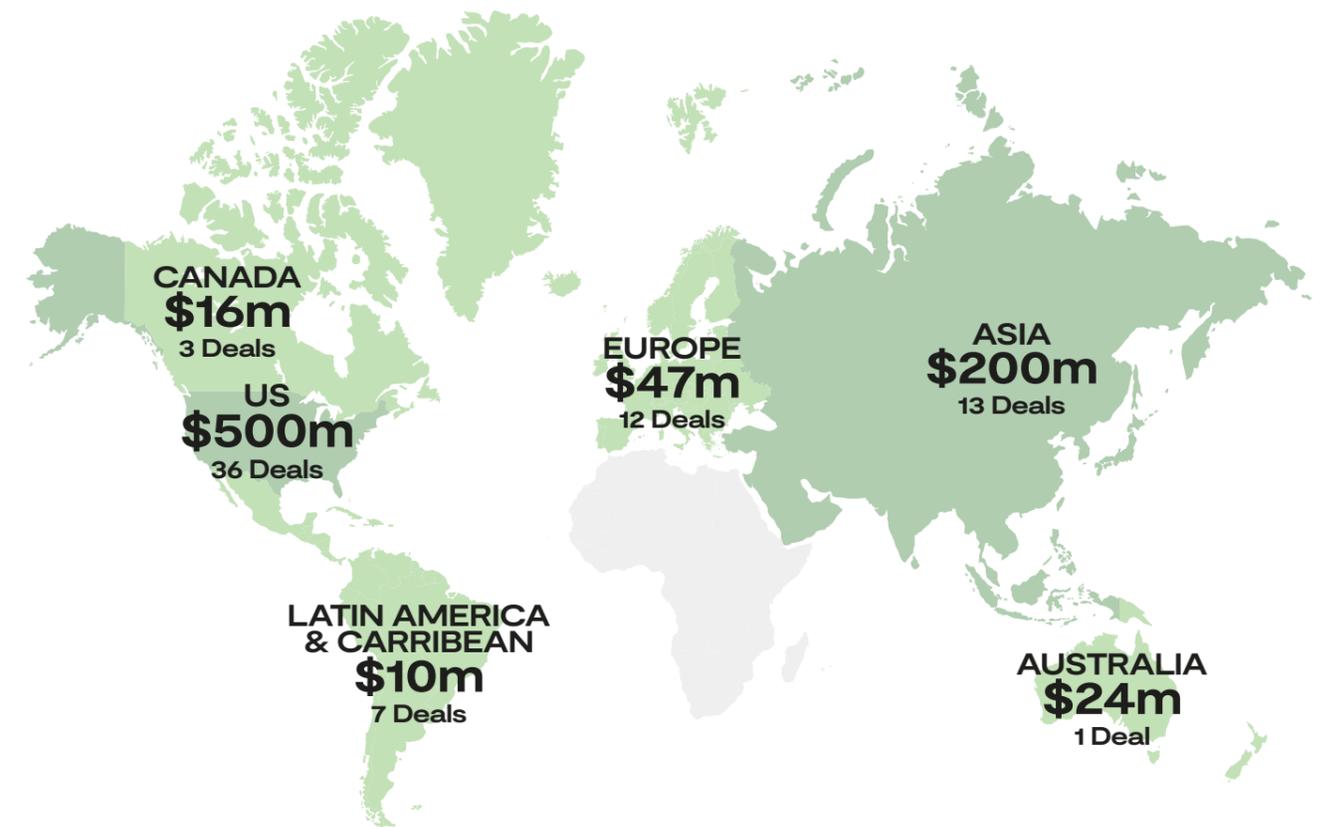


Figure 1. Number of funding and deals globally in mental health technology.
Source: State of Digital Health, Global Q3 2022, CB Insights.

¹² AR/VR in Healthcare Market To Reach USD 7.05 Billion By 2026 | Reports And Data

¹³ New Reality in Immersive Technology (XR): Insights and Industry Trends, September 2020.

¹⁴ NIMH: Technology and the Future of Mental Health Treatment

¹⁵ <https://www.thenationalcouncil.org/news/more-than-4-in-10-us-adults-who-needed-substance-use-and-mental-health-care-did-not-get-treatment/>

5.3 Innovation Landscape

The **Small Business Innovation Research (SBIR)** and **Small Business Technology Transfer (STTR)** programmes are highly competitive programs that encourage domestic small businesses to engage in Federal Research/Research and Development (R/R&D) with the potential for commercialisation. The Mission of the SBIR/STTR programs is to support scientific excellence and technological innovation through the investment of Federal research funds in critical American priorities to build a strong national economy. Additional information on the programmes can be found [here](#).

The **National Institute of Health (NIH)** typically funds biomedical research at a later stage. The institute is the largest public funder of biomedical research in the world, investing more than \$32 billion a year

The **National Science Foundation (NSF)** funds research and education in most fields of science and engineering.

The **National Institute for Mental Health (NIMH)** is the lead federal agency for research on mental disorders. The NIMH has four priority areas; suicide prevention, genomic psychiatry, mental health disparities and global mental health, and it plays a key role in supporting early-stage studies in mental health intervention technologies. Between 2009 – 2015 the NIMH awarded 404 grants totalling \$445M to develop mental health intervention technologies.¹⁶

Games for Change is a non-profit connected to a broad ecosystem of government grants, VCs, and impact investors, including philanthropists who fund research and projects in areas of health such as Parkinson's and bipolar disorder. Many of these funds go towards research on brain science.

The **Digital Therapeutics Alliance** is an organisation developing frameworks to streamline the process of bringing safe and effective digital therapeutics into clinical use. This includes working with regulators to pass legislation through Congress.

The **XRA** promotes the responsible development and thoughtful advancement of virtual, augmented and mixed reality. XRA is leading the way for the responsible development and adoption of XR by convening stakeholders, developing best practices and research, and advocating on behalf of our members and the greater XR industry. The XR Association represents the broader XR ecosystem, including headset manufacturers, technology platforms, component and peripheral companies, internet infrastructure companies, enterprise solution providers, and corporate end-users.

The **Mental Health Coalition** is a mental health organisation with 30 mental health stakeholders in the US, a central body for collaboration.

The **Veterans Association (VA)** is an organisation that provides legal assistance, housing, employment opportunities, business ownership, discharge upgrades, medical aid, family outreach, and support for other pressing issues that stand as debilitating factors preventing veterans and their families from receiving "quality care" in mainstream society.



¹⁶ Technology and the Future of Mental Health Treatment

The **Boston Children's Hospital** has research funding available for projects with a clinical partner and internal accelerators which support a product's go-to-market strategy. Previous XR products developed include an AR application that places medical devices in a patient's home prior to delivery.

Applied VR and **BehaVR** are examples of US companies that received funding in the VR and health industry and can be used as reference cases for UK companies. In 2020, **Applied VR raised a \$36M Series B**, bringing its total funding to \$71M, to expand its research, infrastructure and distribution platform, enabling patients and providers to take advantage of VR for therapeutics. AppliedVR's flagship product for chronic pain recently became the first virtual reality (VR) prescription therapeutic to receive FDA Breakthrough Device Designation for treatment-resistant fibromyalgia and chronic intractable lower back pain. The round included investments from F-Prime Capital, JAZZ Venture Partners, Sway Ventures, and SVB Ventures.

Best Buy also bought Current Health, a UK-based company, for the opportunity they see in the market for at-home healthcare tech, indicating US market interest from mass retailers in acquiring health and wellbeing companies focused on digital solutions.

Manage XR is used to manage and update XR devices remotely at scale. Although it's not a funding body, the company was mentioned several times during the GEM and can support distribution and deployment at scale.





5.4 US Stakeholders

Boston University Medical Campus (BUMC)

Boston University Medical Campus (BUMC), located in the historic South End of Boston and includes **Boston Medical Center**, the primary teaching affiliate of the Chobanian & Avedisian SOM, and the Solomon Carter Fuller Mental Health Center, a state mental health facility. The visit focused on the use of virtual reality, NPCs and avatars to augment educational simulations, develop empathy between patients and caregivers, and streamline workflow procedures such as connecting geographically distributed patients, doctors and social workers.

McLean Institute for Technology & Psychiatry (ITP)

The McLean Institute for Technology in Psychiatry (ITP) was founded in 2016 to advance psychiatric research and practice through innovations in digital health technology and informatics. The UK delegation met with the Program Director and Scientific Director who are leading the immersive technology research in ITP. The delegation learned about ITP's research activity and strategy for XR with a focus on using VR to assess and treat patients with mental health conditions.

Massachusetts General Hospital Psychiatry Unit (MGHPU)

The Department of Psychiatry Center for Digital Mental Health was launched to explore scaling technology solutions to prevent, assess, and treat mental illness and promote mental health, with cognitive behavioural therapy as a core area of focus. They also advocate with policymakers to get digital tool solutions reimbursed as treatments. The delegation met with the Program Director, Clinical Psychologist and Chief of Psychology at MGHPU. The visit offered insights into the organisation's R&D strategy and potential opportunities for collaborative work. The MGHPU team shared case studies of previous work, including the use of VR experience and smartphone apps to support patients with body dysmorphia.

MIT Nano Immersion Lab

MIT's \$300M campus facilities have three core pillars; the nano-fabrication facility, immersion labs, and metrology. The immersion lab includes 360 cameras, motion capture, wireless physiological monitoring, accelerometers, and laser ultrasound, dedicated to advancing research in immersive technologies. A core area of focus for the Immersion Lab is accelerating immersive technology from the lab to market. The team toured the state-of-the-art motion capture studio to learn how AR and VR can be used to train athletes and help patients recover from trauma such as strokes. The Immersion Lab collaborates with hospitals in the region, has a partnership with the clinical research centre (CRC), and works with Tufts Medical Center implementing gait analysis technology from MIT into their practice.

Boston Children's Hospital

Ranked one of the best and biggest paediatrics hospital in the world, the hospital has been working in the VR space for 15 years. The hospital has launched a number of initiatives to investigate and scale the use of VR for mental health treatment and is currently being used to help children in several ways including recovery and education.

Novobeing

A leading company in the US that is developing a digital health platform to help users improve their mental health and wellbeing with guided live support groups, mindfulness meditations, and transformational VR experiences. The company focuses on stress reduction, anxiety and depression and is in the early stages of creating VR solutions for PTSD and trauma.

Med XR Accelerator

A spin-out from the MIT media lab that brings together clinicians, scientists, developers, designers, and other experts in an intensive educational experience. Their goals are to incubate, accelerate and grow interdisciplinary teams and prototypes into successful research projects and teams. The accelerator is particularly interested in the discovery of healthcare solutions and to help connect start-ups and technology companies with healthcare experts.

Games for Change

Games for Change which formerly focused on 2D gaming have recently extended their mandate to include XR games and narrative-driven XR experiences. Recently they produced Goliath, a 25-minute VR experience about a man who spent years isolated in psychiatric institutions but finds a connection in multiplayer games. The experience creates empathy for those with mental health issues such as paranoid schizophrenia. The organisation has partnered with **Active Minds**, which works with youth and young adults to bring Goliath to new audiences.

Hunter College

The GEM team visited Hunter College to understand the development and use of avatars in VR. Discussion included eye tracking, and facial scanning and user privacy. In relation to healthcare, eye gaze is used to establish trust with patients, and AI is being explored for voice chat to support data collection before a patient speaks to a doctor, interventions with mental health conditions, and self-compassion in VR experiences.





Weill Cornell Medicine / New York State Psychiatric Institute

The Weill Cornell Medicine and New York State Psychiatric Institute acts as a test-bed for the development of solutions across a range of clinical areas and patient groups with mechanistic studies as well as applied trials. The school is at the forefront of XR training for medical students, with 200 iPads in use for AR with excellent institutional support. The GEM team met with senior stakeholders to discuss case studies, current and future projects and opportunities for collaboration. One use case shared with the team highlighted the combination of VR exposure therapy and drugs for trauma and interventions.

XR Collaboratory

The GEM team met with h **XR Collaboratory**, a Cornell Tech accelerator focused on education and research in augmented and virtual reality through course offerings, projects, and cross-campus collaborations. The XR Collaboratory is primarily interested in 3D user interfaces and interaction design for head-mounted displays. They build high-fidelity prototypes with students through projects and coursework and collaborate with Cornell faculty on exploratory XR-related research across disciplines such as computer vision, computer graphics, human-computer interaction, healthcare, education, architecture and gaming.

NYC Media Labs

The Media Lab was formed in partnership with the city of New York to unite universities across NYC and shape collaborations with private companies. The model previously relied on commercial membership for access to the lab. Today the business model relies on private companies paying to have projects completed at the Media Lab's facilities. The GEM team visited the facility to understand the role of the centre in promoting and developing XR in the NYC area, the importance of diversity and inclusive design and how the NYC Media Lab can work with UK businesses to co-develop solutions.

XR Association

The organisation represents the immersive technology landscape in the US to promote the growth of the XR industry. This includes the use of VR, AR and mixed reality across multiple sectors, including healthcare. The organisation works closely with the government, researchers and the public to provide XR education and awareness.

Google

A multinational technology company focussing on online advertising, cloud computing and artificial intelligence. The company is interested in the use of immersive technology within the healthcare context and broadly across multiple sectors.

The European-American Business Organisation (EABO)

The organisation specialises in transatlantic business development opportunities and focuses on matching European businesses with American organisations.

The Streaming Museum

Launched in 2008, brings together artists and the public through creative digital technologies. In the context of mental healthcare, there is an opportunity to work with artists and publishers to create experiences for mental wellbeing.

06. Opportunities for future Collaboration

Bridge commercial barriers by working closely with US incubator and accelerator programmes

The US' northeast innovation corridor, including Boston and New York, harbours numerous incubators and accelerator programmes to promote and support early-stage companies. They play a vital role in connecting various stakeholders, including universities, businesses and, more importantly, end-users, to support the journey from discovery and development to commercialisation. The GEM team engaged with representatives from these organisations to understand their role in the mental health technologies ecosystem locally and globally.

The Innovation and Digital Health Accelerator based in Boston Children's Hospital works closely with innovative companies to bring ideas to clinical practice. The Accelerator assesses and develops high-priority market competitive solutions with scalable impact.



CASE STUDY

One of their portfolio companies is **REACT Neuro**. Launched out of Harvard Medical School by a leading Massachusetts General Hospital neurologist, REACT Neuro focuses on objectively quantifying brain health through science-backed digital exams. These exams are short, easy-to-administer assessments given through a custom VR headset. The system aggregates findings from various senses and quantifies changes into actionable insights for physicians. The team is developing a system that aims to accurately predict the presence of brain diseases (e.g. Alzheimer's) before symptoms appear.



Closer engagement with US healthcare providers and research institute

Research Institutes play a vital role in early stage, low TRL development through to adoption and commercialisation. Innovations found in institutes such as the ITP are crucial in promoting and adopting XR technology in healthcare settings. The centre has prioritised developing and adopting immersive technology to facilitate patient wellbeing. For example, the ITP has employed virtual exposure response prevention therapy and, in geriatric care, reminiscence therapy to stimulate mental activity.

The centre acts as a test-bed for new solutions and is keen to engage in R&D collaborations. Along with universities, there is a wealth of innovation and creativity in this sector, which is pushing the boundaries of mental health technologies. Areas of interest include creating life-like avatars and NPC for better engagement with users, prototyping and developing XR for scalable applications in healthcare and consumer use and promoting international collaborations through knowledge exchange programmes.

The Veterans Health Administration is the most extensive integrated health system in the US. The VHA resembles the UK's NHS and is an excellent opportunity to trial and implement XR technology at scale.

Policy and regulatory alignment to facilitate international cooperation

With the XR market in mental health still in its infancy, there is an urgent need to introduce policies that would facilitate the adoption of immersive technologies in mental health care. Comparable to the Telecommunications Act of 1996, which enabled the internet to proliferate, a similar mandate is required to ensure the US and UK are early adopters as we approach a paradigm shift in mental health technologies. However, with the fragmented market and XR still in the early stage of mass adoption, particularly in mental healthcare applications, organisations and advocacy groups must prioritise awareness and benefits of XR interventions to promote mass adoption and scale out. With many regulators viewing XR as a gaming tool, there is an opportunity for the UK and US to strengthen and streamline communications of XR in verticals such as healthcare, manufacturing, and training.

The UK and US must lead the way in data security and privacy

There is a shared concern on data security and privacy in the use of XR between the UK and the US and an area identified as an opportunity to lead. These concerns are yet to be defined for 2D media, and therefore, there is an urgency to address this before XR can be introduced widely to the mental healthcare sector. This discussion is currently taking place at the national level in the US and includes The Health Information Privacy Act (HIPA) for patient protection and security.

Policy similarities in the UK and US XR space include the classification of hardware and software. The Digital Therapeutics Act outlines what insurance covers, although it does not specifically cover XR. The first step towards getting regulatory approval is data-driven evidence.

Accessibility and Inclusivity is key for XR interventions for mental healthcare

The NYU Media lab is working towards digital accessibility and inclusive designs that are being developed from a deep understanding of the XR ecosystem and user experiences. Particularly in underserved communities, challenges and risks may discourage AR/VR use. For example, creators must consider space availability when designing a game/video. In addition, stereotypes based on race and gender must be addressed to avoid discrimination.



07. Potential Barriers to Collaboration

Standardised data privacy and storage regulation is key

Data processing and storage in the US depends entirely on individual organisations, with many following data privacy laws set by the state and federal governments. In many cases, this can be different for each organisation, presenting a challenge to standardise responsible use and storage of data collection concerning XR and mental health use cases. Weill Cornell Medicine highlighted the importance of data privacy and security as the medical field is inherently data-driven, and therefore, access, storage and use of patient data are critical to the success of XR-related healthcare. In a broader context, there is often uncertainty around the management of devices and, therefore, which party is accountable. While IT is usually responsible for device management, the services are used by healthcare professionals, and therefore, a clear set of guidelines and the role of each party is required to ensure responsible use and sharing of confidential data.

Digital therapeutics such as VR is not covered by health insurance providers

Insurance companies do not directly cover VR healthcare solutions and therefore depend on healthcare professionals prescribing VR solutions to patients. With poor awareness of VR to treat mental health issues in the US and a shortage of digital therapeutics, VR solutions are very rarely prescribed. To overcome this challenge, start-ups are increasingly positioning themselves as digital clinics to lean on existing structures and insurance policies to cover digital health, including VR interventions.

Know your target audience to ensure penetration and adoption in the US market

The adoption of XR technology in the consumer and enterprise markets is much lower than anticipated due to awareness, costs and integration challenges in existing organisational structures and systems. Unlike other electronic devices, it is not clear how XR fits into everyday life. The nascent ecosystem also brings the challenge of pricing solutions for B2B and B2C use. For example, hospitals in Boston work with a large majority of underprivileged individuals who do not have the resources to acquire and maintain a headset. This presents a considerable barrier to entry and influences how XR-related content is distributed. There is an added challenge of getting regulatory approvals for XR interventions. While this has been made more accessible through the Access to Prescription Digital Therapeutics Act of 2022, introduced to the Senate in October 2022, businesses need to engage broadly with policymakers, patients, providers and payers.

ENGAGING THE 4 P'S

When considering the US market, UK organisations need to engage with policymakers, patients, providers and payers to ensure their products and services are aligned with each stakeholder. It is important to consider that each stakeholder will have different incentives and priorities, which are equally important when launching XR products for healthcare in the US.

UK businesses must understand the following perspectives regarding reimbursements and requirements:

Policymakers – Digital therapeutics (DTx) regulated by the FDA most commonly operate under Software as a Medical Device (SaMD). There are three pathways for approval **510(k)**, **De Novo** and **Breakthrough**.

Payers – Device manufacturers need to determine if coverage and appropriate codes exist. Reimbursement landscape assessment should be completed before engaging in the regulatory process.

Providers – UK organisations need to understand market access considerations and demonstrate value add to hospitals.

Patient – The value of the technology the patient perceives compared to traditional healthcare.



11. Conclusions

The Global Expert Mission established a solid foundation for economic development and collaboration between UK and US stakeholders in the XR and mental health ecosystem. Participants expressed the value of face-to-face meetings to establish trust at the early stages of the relationship, which needs to be nurtured at the individual level to stimulate momentum towards next steps. An essential outcome of the GEM was connecting UK experts to promote collaborations within the UK.

Findings from the Northeast Coast of the United States demonstrate that the UK is ahead in some areas when it comes to addressing the practical needs of healthcare services. Results emerging from university spinouts in the UK (especially with how it's funded) mean it is embedded in the real world and the healthcare sector. Academic groups in the states need to have a clearer link with innovators to turn ideas into market applications.

The opportunities for trials and interventions are clearly defined in the UK compared to the US, and therefore easier to develop and test products in the UK. In contrast, US stakeholders face a fragmented market with complex regulations and policies and highly isolated verticals in XR and healthcare. This means barriers to entry for go-to-market and shaping cross-disciplinary collaborations are much greater. However, both UK and US markets face similar challenges, including deployment, ethics concerns, regulatory challenges, data privacy and storage and market fragmentation, which should be addressed and aligned as much as possible. Investment is one of many solutions, as integration and awareness funding are also required to sustain and support the development of the ecosystem.

UK businesses will particularly need support and access to resources to navigate regulations in the US, which are different at the state and federal levels. This will inform how businesses approach the US market, especially FDA regulations and requirements, which are nascent and complex to navigate in this emerging industry.

Educating healthcare professionals and patient outreach are also critical steps towards the cultural acceptance of XR for mental health interventions. Additionally, it's recommended that IT is involved in the early stages of relationship building with potential partners as they understand an entity's infrastructure, hardware and data management processes.

Several collaboration opportunities have been highlighted, and Innovate UK will explore these and work closely with UK businesses and governments to build international collaborations and promote UK capabilities.



Appendix 1: UK Participants

XR Therapeutics

Rescape

NIHR MindTech MedTech Co-operative

Hatsumi

Cineon Training Limited

Viz Box Ltd



Appendix 2: US Participants

McLean Hospital Institute of Technology and Psychiatry (ITP)

Boston University Medical Campus (BUMC)

Boston Children's Hospital

Massachusetts General Hospital Psychiatry Unit

MIT Nano Immersion Lab

RocketVR

Med VR Medical (XR Bootcamp and Accelerator)

University of Massachusetts Medical School

Games for Change (G4C)

Hunter College, City University of New York

Weill Cornell Medicine / New York State Psychiatric Institute

XR Collaboratory

NYC Media Labs / RLabs

XR Association

Streaming Museum

The European-American Business Organisation (EABO)

Google



**Innovate
UK**

Syed Ahmed

Programme Lead – Global Expert Missions
Innovate UK KTN
syed.ahmed@iuk.ktn-uk.org

Julia Glenn

Design Innovation Lead
Healthy Ageing Challenge Fund and Mindset XR Programme
UK Research and Innovation
julia.glenn@iuk.ukri.org

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