LYVA LABS

Microbiome Discovery to Commercialisation:

Developing the Liverpool City Region (LCR) Innovation Ecosystem

A report on understanding and addressing barriers to translating microbiome research into commercial and implementation impact.

iiCON

UK Research and Innovation

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Executive Summary

A New Frontier

This is an exciting area of new science where Liverpool City Region has a strong competitive edge. It's an opportunity that resonates with the City Region's history and culture of exploration, discovery and innovation, as well as our capacity to forge connections and foster effective partnerships and fruitful collaboration.

The human microbiome has been described as our second brain and hailed as the new genome. These seem remarkable and counterintuitive claims, but underscore the enormous. and largely uncharted potential of this increasingly important area of medical research. It is only in recent decades that we have begun to discover and understand how the myriad of microbes that comprise 90% of the cells in our body can impact on our physical health and mental well-being. Whilst the UK has been at the forefront of research into the human microbiome, it has been slow to translate its fruits into spin-outs, investment and market ready products. Lagging behind the United States and Europe there is an urgent need and a critical opportunity to harness and commercially exploit our burgeoning knowledge and understanding.

The purpose of this report is to study and plot how LIverpool City Region can explore this new frontier, and how we can utilise our unique strengths in infection biology, life sciences, data and manufacturing to play a leading role in what many see as a transformative advance in medical science.

This report is the outcome of a project led by LYVA Labs and supported by UKRI's Tackling Infectious Diseases Fund via iiCON. We have engaged more than 120 stakeholders across academia, SMEs, industry, healthcare, regulation, and policy. Through workshops, interviews, and surveys, we have begun to map the assets, capabilities, challenges, and opportunities for microbiome innovation and explored pathways to build a thriving open innovation ecosystem in Liverpool City Region.

Our analysis identifies how our City Region can achieve microbiome innovation driven growth by capitalising on its unique innovation assets and research capabilities, including the Microbiome Innovation Centre (MIC), the Centre for Genomic Research (CGR), iiCON, Unilever R&D, STFC Hartree Centre, IBM and established translational biomanufacturing capabilities.

These assets constitute a rich and fertile ecosystem, akin to an institutional microbiome, with the potential to become an integrated and accessible innovation platform, and a stimulus for a thriving research and biomanufacturing centre.

The report also explores the persistent barriers across commercialisation, data, infrastructure and regulation and how, as a region, and with the right investment, we can expand our microbiome assets, resources and capabilities to navigate and overcome these challenges.

This is an exciting area of new science where Liverpool City Region has a strong competitive edge. It's an opportunity that resonates with the City Region's history and culture of exploration, discovery and innovation, as well as our capacity to forge connections and foster effective partnerships and fruitful collaboration.

Founded on robust research and hard-headed practical analysis, this report offers a route map for the policy makers, decision-takers, investors and innovators who together can transform opportunity into reality.

Where we are today

Global and National Context

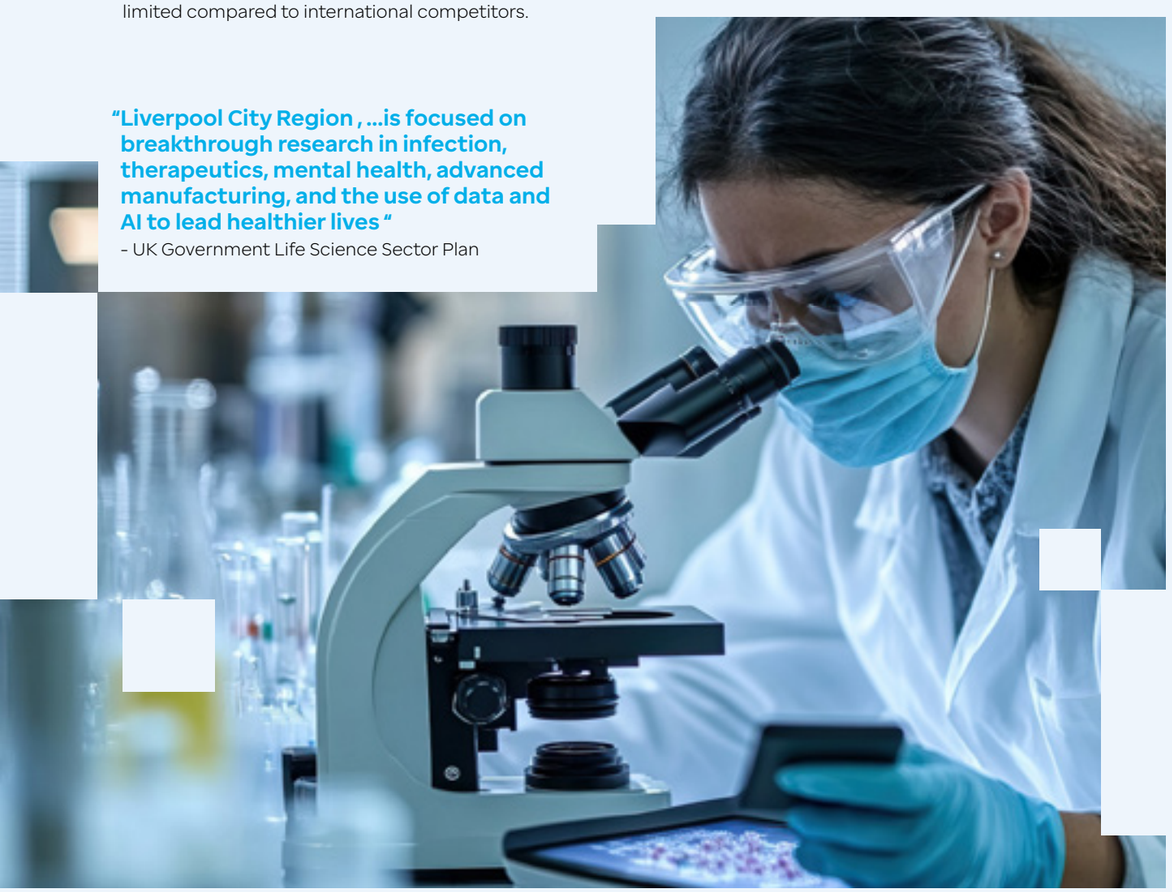
Microbiome science has moved from niche research to mainstream innovation. Recent FDA approvals for recurrent Clostridioides difficile infection underscore its clinical potential, while the global microbiome therapeutics market is projected to grow from USD 296.5m in 2023 to USD 1.37bn by 2030. Parallel growth in consumer markets, particularly microbiome skincare (forecast to reach USD 795m by 2030), illustrates the breadth of applications.

Patent activity and clinical trials are accelerating: over 8,000 microbiome-related patents have been filed globally since 2005, with the UK contributing more than 600. Around 2,000 clinical trials are underway worldwide, including Phase I studies by UK companies such as Microbiotica. Yet in the UK, translation remains fragmented, commercial pathways underdeveloped, and specialist investor interest limited compared to international competitors.

National policy increasingly recognises this gap. The Industrial Strategy, Life Sciences Sector Plan UK, UK Advanced Manufacturing Sector Plan, and Science and Technology Framework all identify engineering biology (including microbiome engineering) as a critical technology, with genomics and bioinformatics as distinct technology themes. Significant Innovate UK, BBSRC and MRC funding towards microbiome programmes further signal government intent. Microbiome is also relevant to the Biological Security Strategy and UK AMR Strategy from the standpoint of surveillance and reducing antibiotic reliance.

"Liverpool City Region , ...is focused on breakthrough research in infection, therapeutics, mental health, advanced manufacturing, and the use of data and AI to lead healthier lives "

- UK Government Life Science Sector Plan



Breaking down barriers

Pathways, infrastructure and investment

Stakeholder engagement across Liverpool City Region and the wider UK consistently highlighted a set of interlinked barriers that are restricting the translation of microbiome science into commercial and clinical outcomes. One of the most pressing challenges lies in the area of regulation and standards. The absence of clear regulatory pathways for emerging modalities such as live biotherapeutics, diagnostics, and adjunct therapies has created uncertainty on the classification of products as food, supplement, or drugs. This regulatory ambiguity, combined with high costs and protracted approval processes, is deterring investors and delaying market entry for promising innovations.

Demonstrating evidence of efficacy through clinical trials presents another major obstacle. The design and delivery of randomised controlled trials for microbiome-based products is complicated by patient heterogeneity and the inherent variability of microbiome composition. This makes it difficult to achieve statistical robustness, while the cost and complexity of these trials place them out of reach for many SMEs.

Infrastructure gaps further constrain translation. There is limited access to shared GMP facilities, bioprocessing capacity, and preclinical or clinical validation platforms. Where these assets do exist, they are often siloed or not configured to support microbiome-specific requirements. In parallel, data and analytics remain a persistent weakness. Datasets are fragmented across institutions, metadata capture is inconsistent, and standardised approaches across omics platforms are lacking. Although Trusted Research Environments offer a potential solution, their use for microbiome data is still at an early stage, and specialist bioinformatics skills are unevenly distributed.

These scientific and technical challenges are compounded by weaknesses in commercialisation pathways. Specialist investor awareness of microbiome opportunities remains limited, the UK venture capital base is less mature than in the US or parts of Europe, and entrepreneurship training for early-career researchers is patchy. This means that spin-out formation and scaling remain inconsistent, despite the strength of the underlying science. Capabilities and assets are fragmented across institutions and disciplines, with communities, although this is being addressed through the new BBSRC funded network Microbiome Innovation Network. Microbiome literacy remains low, and patient and public involvement is often bolted on late in projects rather than being embedded from the outset, limiting the scope for public confidence and uptake of products with microbiome claims.

Informatics and data science

The report investigates the informatics barriers hindering the translation of microbiome research into commercial impact, with a particular focus on the Liverpool City Region (LCR). Drawing on literature, questionnaires, case studies, and workshops, it highlights persistent challenges across experimental design, statistical power, metadata capture, and data integration. Many microbiome studies are underpowered, inconsistently designed, or lack robust metadata standards, which hampers reproducibility and downstream analysis. Researchers also struggle to access and connect with existing bioinformatics expertise, while informatics workflows remain fragmented and overly reliant on ad hoc solutions. These issues slow progress and reduce the reliability of outputs for both academic and commercial exploitation.

At the same time, the report identifies clear opportunities to strengthen the ecosystem by professionalising data management, commissioning fit-for-purpose software tools, and fostering early collaboration between experimental and informatics specialists. Large-scale projects such as C-GULL and corporate initiatives provide valuable models for best practice, while the region's assets in sequencing, multiomics, and computational infrastructure represent strong foundations for growth. Unlocking commercial potential will require systematic approaches to metadata, scalable informatics services, and more effective pathways for industry to access biobanks and datasets. Overall, the findings suggest that technology is not the fundamental barrier—the greater challenge lies in access, coordination, capacity, incentivisation, and governance to ensure that LCR's strengths translate into investable microbiome ventures.

Recommendations

Collaborate, co-ordinate and communicate!

In response to these challenges, stakeholders identified a set of priority actions to establish a thriving open innovation ecosystem for microbiome commercialisation in Liverpool City Region. A central theme is the need for stronger coordination of assets and capabilities. This includes the creation of a centralised intelligence hub to map and connect the region's infrastructure, expertise, and intellectual property, underpinned by governance structures that provide strategic direction and focus activity around areas of highest market potential.

To use a computing metaphor, the microbiome innovation ecosystem can function like a 'service mesh' — not by directly providing seamless communication itself, but by enabling it through dedicated integrators such as the proposed Intelligence Hub. In a digital system, the service mesh acts as a connective layer that lets independent services coordinate reliably without each one solving the same problems alone. In the same way, the ecosystem's integrators should make navigation of research, data, standards, regulation, commercialisation and manufacturing feel seamless for innovators, even though that coordination is being actively facilitated behind the scenes.

Collaboration across allied research agendas must also be reinforced. Stakeholders called for more cross-institutional and interdisciplinary models, such as a "research hotel" approach, that would allow teams to co-locate and share resources. Integration with the biofilm and phage communities, alongside closer ties to biobanks and resources from legacy programmes (such as the Skin Microbiome in Healthy Ageing (SMiHA) programme funded by UKRI, BBSRC and MRC), would help unlock synergies and accelerate discovery.

Harnessing the region's strength in data science is another priority. Coordinating access to High Performance Computing (HPC) and AI infrastructure, embedding bioinformatics expertise early in study design, and standardising metadata capture will all be critical steps. In parallel, the development of federated microbiome datasets within Trusted Research Environments could enable more powerful in silico research and create a platform for industry engagement.

To strengthen the commercialisation pipeline, there is a clear need to enhance investment readiness. Establishing a specialist regional investor network, dedicated accelerators and incubators for microbiome-focused ventures, and targeted entrepreneurship training for early-career researchers would all help build capacity and confidence. Complementary to this, investment in infrastructure to accelerate product translation is required. Priorities include the creation of end-user validation platforms for consumer health applications, a centre for microbiome-drug interaction studies to support precision therapies, and the expansion of bioprocessing and manufacturing capacity linked to the LCR biomanufacturing corridor. These should be complemented by a regional skills institute to ensure a pipeline of trained specialists across technical, data, and translational roles.

Ensuring effective standards and regulatory pathways is essential for translating microbiome science into real-world products. Research suggests that while regulation provides the framework for market access, industry standards often set the pace for innovation, sometimes years ahead of formal regulatory change. Nationally, a microbiome standardisation programme backed by the MHRA and WHO is establishing international reference reagents and benchmarks to improve the consistency and comparability of microbiome research. For Liverpool City Region, there is a clear opportunity for local industry and academic actors to play a greater role in shaping these global standards, enhancing both the region's visibility and its influence in the field. Locally, there is also strong support for regulatory sandpits, where companies and regulators can co-develop new approaches to assessing efficacy and safety of live biotherapeutics, phage therapies, and adjunct innovations. Recent developments such as the Regulatory Innovation Office and the NHS Innovators Passport represent opportunities to engage with the national agenda.

Finally, improving public engagement and awareness was seen as essential to build trust and drive adoption. Embedding patient and public involvement from the outset, running microbiome literacy campaigns in schools and communities, and developing accessible resources such as websites, podcasts, and public events would help to create a more informed and receptive public sphere.

Microbiome Commercialisation and Place-Based Economic Development

Unlocking potential of Liverpool City Region

Evidence from national cluster studies shows that innovation clusters are powerful engines of growth, improving productivity, resilience, and international competitiveness when supported by sustained investment and strong networks of collaboration. For LCR, microbiome science represents a distinctive strength that can be leveraged into a globally visible cluster, complementing its established reputation in infection research, data/AI, and biomanufacturing.

The Life Sciences Sector Plan highlights LCR as an important health and life science cluster, and microbiome innovation provides a natural anchor to attract further investment. A harbinger for future funding streams is the UKRI Local Innovation Partnerships Fund (LIPF) which will invest up to £500m to scale high-potential clusters across the UK, explicitly encouraging "Quadruple Helix" collaboration between government, academia, industry and civil society.

Yet the research shows that science alone is not enough. Analyses of UK innovation pathways consistently find that the UK excels at discovery science but lags in translation, hindered by fragmentation, complex support landscapes, and limited incentives for academic entrepreneurship. The same applies in LCR, where globally competitive microbiome research has yet to produce a pipeline of commercial ventures on par with the Golden triangle, US, or parts of Europe. Tackling these barriers requires not just laboratory infrastructure but stronger systems of coordination, enterprise training, and translational support.

The implication is clear: building a microbiome innovation ecosystem is not only a scientific endeavour but a translational challenge. By convening its universities, businesses, and civic actors around a coherent agenda for translation, Liverpool City Region can move from a collection of excellent assets to an integrated testbed for microbiome-driven innovation. Strengthening pathways for translation — from experimental design through data integration, trials, and regulatory readiness — will enable discoveries to move more efficiently from the lab into practice, positioning LCR as the UK's leading hub for microbiome research in both human and animal health.

Commercialisation, however, remains constrained by fragmented standards, infrastructure, skills, and investment pathways. To capture the full economic value of its translational strength, LCR must align stakeholders around a shared strategy, invest in coordinated infrastructure, and expand support for venture creation and scale-up. By doing so, the region can convert scientific breakthroughs into new businesses, skilled jobs, and inward investment, establishing itself not only as a national leader in microbiome innovation but also as a contributor to global health resilience, antimicrobial stewardship, and sustainable economic growth.

– Understanding Geographies of Innovation: Research agglomerations, knowledge networks, and implications for place-based innovation

The LCR Competitve Advantage

Liverpool City Region (LCR) offers a highly connected and comprehensive health and life science ecosystem of uniquely integrated innovation assets and capabilities for microbiome research, translation, commercialisation and manufacturing.

University of Liverpool hosts the **Microbiome Innovation Centre (MIC)** which delivers both the **Microbiome and Infectious Disease Innovation Hub (MaID)** and the national **Microbiome Innovation Network** alongside **NBIC.** This enables end-to-end translational support, from experimental design to lab access and significant industrial partnerships with companies such as **Unilever** and **Croda**. It is also home to the **Computational Biology Facility (CBF)**, offering advanced multi-omics analytics and data integration to strengthen discovery and translational pipelines. The University uniquely hosts Veterinary and Medical campuses, enabling microbiome research spanning animal health to human clinical translation. Advanced computational capability exists at **STFC Hartree® Centre** collaborating with **IBM** through the **HNCDI** programme, to offer cutting-edge AI and high-performance data analysis for microbiome research. The Infection Innovation Consortium- **iiCON**- is a leading global centre for infectious disease R&D, bringing together industry, academia, and the **NHS** through open-access platforms that accelerate the product journey from discovery to adoption. World-class science and innovation campuses at **Sci Tech Daresbury, Knowledge Quarter** and **The Heath** support SMEs offering bespoke business support. **LYVA Labs** delivers innovation and commercialisation support including pre-seed funding and tailored accelerators for R&D focused companies. An internationally significant industrial biomanufacturing cluster, comprises multi-national companies such as Elanco- which possesses some of the world's largest microbial fermentation capacity. Fiscal incentives and policy levers including **Innovation Zone** and **Freeport** status set LCR apart from other UK regions.

Elanco

4th largest fermenter capacity in the world

LSTM LIVERPOOL SCHOOL OF TROPICAL MEDICINE

Liverpool School of Tropical Medicine Leads the Biologics Regional Innovation and Translation Ecosystem (BRITE) with research strengths in organoid models and vector borne diseases

Sci-Tech DARESBURY

One of UK's leading Science and Innovation campuses

LIVERPOOL JOHN MOORES UNIVERSITY

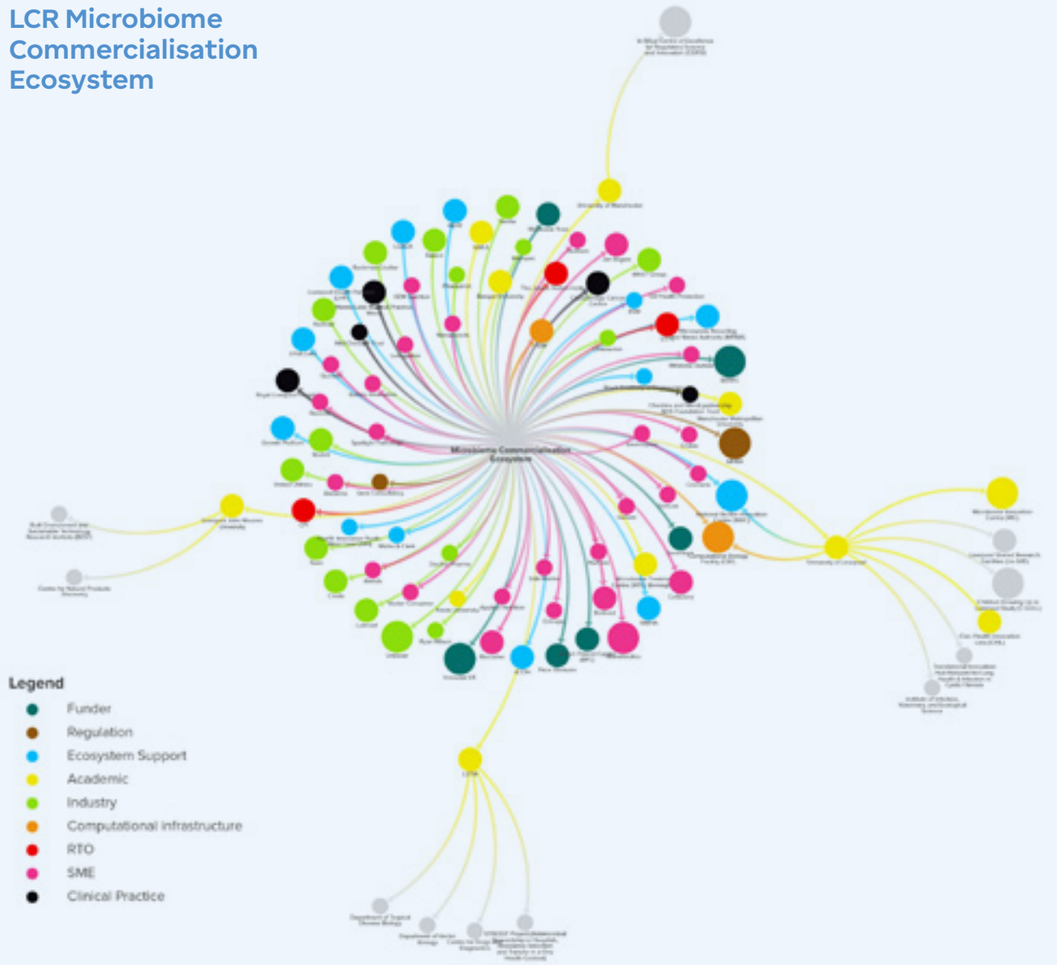
Hosts the Centre for Natural Products Discovery (CNPD)

LYVA LABS

Liverpool City region's (LCR) innovation and commercialisation vehicle

LCR Innovation prospectus

LCR Microbiome Commercialisation Ecosystem



iiCON

Infection Innovation Consortium that has brought 36 products to market

Unilever

30,000 - One of the world's largest collection of skin microbiome samples

UKRI Science and Technology Facilities Council Hartree Centre | IBM

AI and High performance Computing (HPC) capabilities

UNIVERSITY OF LIVERPOOL

Hosts the Microbiome Innovation Centre (MIC), Computational Biology Facility (CBF), & Microbiome: Accelerating Innovation and Development (MAID) hub

cpi

Technology and innovation facilities, part of the UK High Value Manufacturing Catapults (HVMC)

LCR Microbiome Ecosystem

Acknowledgements

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We would like to acknowledge all the interview, survey, and workshop participants for generously sharing their insights and experiences.

We are also grateful to our colleagues at LYVA Labs for their continued support and contributions throughout this project, particularly Lorna Green and Ivo Kerkhof for their guidance.

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About the project

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About the project

What we set out to achieve

The aim of this report is to directly influence policies and decisions, to identify and breakdown barriers and realise the unique potential of Liverpool City Region to contribute to one of the most exciting and transformative areas of modern science.

This report is the outcome of a LYVA Labs project to scope and better understand and overcome barriers for translating microbiome research and innovation into major commercial and clinical impacts. The report was funded by the Tackling Infectious Diseases fund through iiCON on behalf of UKRI. It is primarily aimed at regional policymakers and innovation agencies, government departments and funders, universities and research centres, industry partners and investors, and research and technology organisations. Our aim is to directly influence policies and decisions, to identify and breakdown barriers and realise the unique potential of Liverpool City Region to contribute to one of the most exciting and transformative areas of modern medical science.

LYVA Labs is the commercialisation and innovation agency for Liverpool City Region (LCR) with a track record running the Innovate UK funded Microbials Accelerator, alongside partners, that supported 24 UK founders in 2023 with microbiome, phage and biofilm technologies. This report aims to support the longer-term endeavour of building an open innovation ecosystem to support commercialisation to improve health outcomes and drive economic growth both regionally and nationally.

The Liverpool City Region possess an agile, highly integrated ecosystem to enable high impact, scalable innovation across sectors and disciplines. Notable examples of successful open innovation platforms are Infectious Disease Innovation Consortium (iiCON) for vaccine development; Materials Innovation Factory (MIF) for materials science; and Glass Futures for foundry industries.

“An Open Innovation Platform is a coherent set of physical, digital and knowledge assets designed to support innovation, collaboration and knowledge-sharing between different organisations; set up so that its exploitation is only loosely controlled by the platform owner”
- Prof Matt Reed, University of Liverpool

LYVA Labs Microbials Accelerator Report

The process we undertook

This report draws on both primary and secondary research.

Primary research

Between October 2024 and June 2025, we engaged a wide range of stakeholders to identify opportunities, gaps, and challenges from the standpoint of diverse perspectives and Technology Readiness Levels (TRLs). Of the 160 stakeholders approached, 128 participated, representing academia, industry, SMEs and supply chains, healthcare bodies, regulators, Research and Technology Organisations (RTOs), Technology Transfer Offices (TTOs), funders, and policymakers. Engagement methods included:

- A survey, completed by 38 respondents.
- Three workshops, attended by 100 participants in total.
- Fifty-six in-depth interviews.

In addition, a discrete piece of work on data science barriers and opportunities was commissioned and delivered by specialist bioinformatics consultants Cofactory, with key recommendations incorporated into this report.

Secondary research

We reviewed more than 30 industry, market, policy, and regulatory reports. Furthermore, the UK microbiome start up and scale up landscape was analysed using The Data City platform. A set of 10 keywords, developed with input from stakeholders, was applied within the platform's machine learning tool to generate a list of 150 small to medium enterprises (SMEs). This process was iterative, combining the machine learning outputs with manual review to ensure accuracy and completeness. We liaised with the Data City team to externally validate the results.

The keywords used were:

1. Clinical microbiology
2. Skin microbiome
3. Anaerobic digestion
4. Biofuel
5. Bioinformatics
6. Bioprocessing
7. Bioremediation
8. Biotherapeutic
9. Microbial fermentation
10. Microbiome engineering

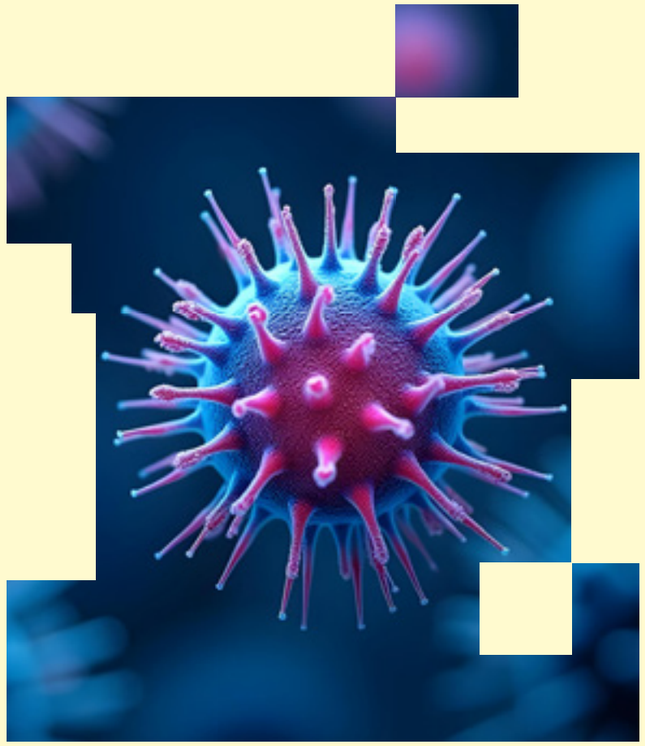
We also undertook desk-based research to map microbiome-related research activity in the Liverpool City Region, drawing on university websites, lists of publications supplied by interviewees, Innovate UK microbiome landscape tool, and the UKRI Gateway to Research (GtR) platform. To visualise this activity, project titles were clustered to identify dominant research areas using KMeans clustering, following dimensionality reduction with UMAP.

– For more detailed information about this work please email enquiries@lyvalabs.com

The relevance of the project

This report is timely due to the recent launch of the Industrial Strategy, Health and Life Science Action Plan and NHS 10 Year Plan supported with commitments for a pro-innovation regulatory and clinical trial environment. The UK has a world leading position in microbiome science and within LCR possesses some of the world's leading consumer health and wellness and pharmaceutical companies, combined with a supportive environment for life science and biotech start-ups.

At a regional level, Liverpool City Region has launched its Local Growth Plan to strengthen LCR's Life Sciences and Health Innovation powerhouse. It also delivers a Health and Life Science Innovation Zone has launched the Microbiome: Accelerating Innovation and Development Hub (MAID) led by University of Liverpool in partnership with CPI. This is additional to LYVA Labs receiving funding for its Innovate, Grow, Accelerate and Partner (IGAP), a five-year initiative that will help early-stage and scaling businesses to develop and commercialise cutting-edge health and life sciences- including microbiome-technologies. LYVA Labs is also delivering an Innovate UK Biomedical Catalyst funded Future Medicines Accelerator. Furthermore, Liverpool School of Tropical Medicine have launched their Biologics Regional Innovation and Translation Ecosystem (BRITE), a partnership with, local HEIs, industry and SMEs to establish the region as a global leader in biologics innovation and manufacturing.



The scope of the project

Reflecting the "place-based" R&D approach of current UK policy and funding bodies to support city regions and clusters, the geographical scope of this work focused primarily on the Liverpool City Region, however we did engage with stakeholders nationally to align with broader developments, avoid duplication and learn from good practice. The research and translation scope was centred on microbiome but there was recognition of important work taking place across the wider microbial sector- including phage and biofilms- which we have engaged with during the process. In line with the One Health approach, experts from human, animal and plant sectors were consulted with. Though the concentration of activity within LCR lay within human health, there was activity relating to process industries and the environment identified. Antimicrobial Resistance (AMR) contributions arose from various perspectives including infection prevention control and wastewater in environmental sector.

UKRI define research commercialisation as "the process by which new or improved technologies, products, processes and services that have arisen from research are brought to market." This can involve spin outs and SMEs created but also multi national companies via process innovation and efficiency gains. Certain stakeholders, particularly researchers and clinicians at low TRL stages, referred to "impact" beyond commercialisation such as influencing clinical practice and standards.

The structure of this report is laid out as follows. There is a discussion of the interview, survey and workshop insights framed from the perspective of 3 different personas representing broadly distinct TRL stages: **explorers** comprising of researchers and clinicians at the early TRL stages; **builders** consisting of spinouts, start ups, and SMEs operating at mid TRL stages; and **scalers** comprising of multi national companies and large scale institutions taking products to mass markets. There follows a set of regional case studies representing the different personas and how their engagement within the innovation ecosystem has supported commercialisation. Finally, the report concludes with a set of recommendations aligned with those from the Innovate UK KTN Microbiome Innovation Network Strategic Roadmap and Human Intestinal Microbiome Therapies and Diagnostics Report.

Report Limitations

This report stops short of examining international best practice and international collaborations beyond those which were mentioned during interviews, though there are notable models such as in Denmark/Sweden (MediCon Valley Alliance Microbiome Network), Ireland (APC), France (INRAE) and Netherlands (Holomicrobiome Initiative) which are worthy of close study.

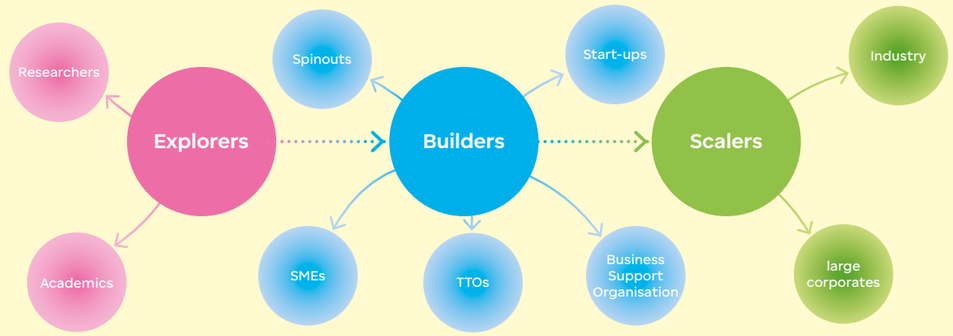
There were some clinical areas not scoped within the timeframe meriting further exploration based on LCR's strengths e.g. Oncology, Mental Health, Opthamology, Comparative Animal and Human health and water remediation. Our intention is to undertake further engagement in future in these areas to better understand opportunities and barriers.

Disclaimer

The content of this report is derived from the insights of delegates that were consulted during the interviews, workshops, and survey and should not be construed as incontrovertible facts or as reflections of LYVA Labs opinions or stances. The insights presented are based exclusively on the information and perspectives that were shared at the time. It is important to acknowledge that, while efforts have been made to accurately convey the content of the discussions, these accounts are not exhaustive and might not encompass all viewpoints or all available data. Hence, the report serves as a summary of discussions rather than an expression of LYVA Labs official position or a factual assertion.

Local growth Plan

Personas Driving the Microbiome Innovation Pipeline



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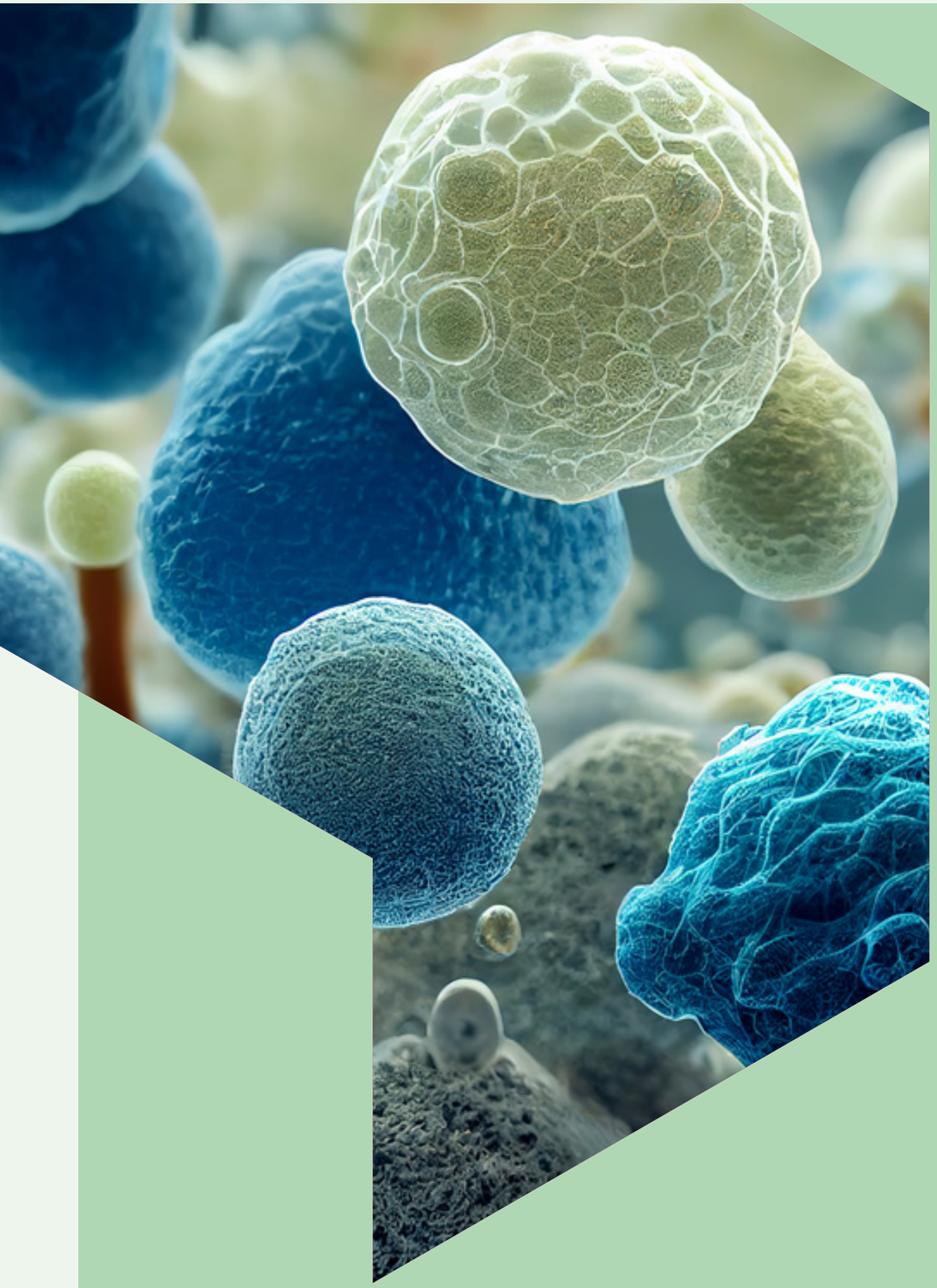
Landscape and Context



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Landscape and Context

Political

Microbiome research aligns perfectly with all the key priorities of UK innovation and economic policy and its overarching objective: to lead the future by making it.

The political landscape for microbiome innovation is strongly shaped by UK national research and innovation policy, alongside strategies in life sciences and engineering biology. Microbiome research aligns perfectly with all the key priorities of UK innovation and economic policy and its overarching objective: to lead the future by making it.

At the time of writing, the Industrial Strategy and the Health and Life Science Sector Plan and NHS 10 Year Plan have been published. DSIT have published the Science and Technology Framework though details around specific funding streams via DSIT and UKRI from the Spending Review for 2025 are still to be announced.

Funding and regional development opportunities are also politically relevant. UKRI's Local Innovation Partnerships Fund has announced £500 million to support high-potential innovation clusters across the UK. This presents one significant opportunity amongst others for LCR to position itself as a microbiome innovation cluster of national and international relevance.

The Life Sciences Sector Plan highlights Liverpool City Region as a centre of excellence in infection, therapeutics, mental health, advanced manufacturing, and health-related data and AI – areas that provide fertile ground for microbiome innovation to align with national priorities for economic growth and health improvement.

UK Research and Innovation (UKRI) is the primary funder of microbiome-related research, with its 2022–2027 strategy emphasising place-based innovation and interdisciplinary science. Complementing this, the UK Innovation Strategy ("Leading the Future by Creating It") and the UK Science and Technology Framework both signal the government's ambition to position the UK as a global science superpower. Within these frameworks, bioinformatics, genomics, and engineering biology – all highly relevant to microbiome science – are identified as key technology families of strength and opportunity.

The microbiome agenda also aligns with broader national policy priorities around health security and antimicrobial resistance (AMR). The Biological Security Strategy (2023) stresses the importance of developing innovative antimicrobial treatments, while the UK's National Action Plan for AMR highlights the potential of phage therapy and microbiome modulation. This has been reinforced by a 2023 Parliamentary enquiry into the antimicrobial potential of bacteriophage, signalling political recognition of microbial-related science as a contributor to national health security.

Economic

The global microbiome economy is rapidly expanding, with applications spanning therapeutics, diagnostics, consumer health, and manufacturing services. The **microbiome therapeutics market**, valued at USD 296.5 million in 2023, is forecast to grow more than fourfold to USD 1.37 billion by 2030, driven by rising prevalence of chronic diseases, regulatory approvals, and an expanding clinical pipeline. Within this, **live biotherapeutic products (LBPs)** are the fastest-growing category, with applications emerging in gastrointestinal disorders, oncology, and metabolic disease. The associated **CDMO market** is also expected to triple by 2030, reflecting rising demand for specialist manufacturing as microbiome therapies move into late-stage clinical development. Alongside therapeutics, the **microbiome skincare market** was by one estimation at USD 363.9 million in 2023 and is projected to double by 2030, with premium serums and creams leading growth and Asia-Pacific markets accelerating adoption.

Globally, microbiome innovation is being driven primarily by small and mid-sized enterprises, with companies such as Microbiotica in the UK, Pendulum Therapeutics in the US, and MaaT Pharma in France leading in clinical development. These SMEs are the bridge between academic discovery and commercial adoption, but they require strong translational support and growth-stage financing to scale effectively.

The UK's relative position in this global landscape is mixed. The UK lags behind the United States and parts of Europe in translating leading-edge research into globally competitive businesses. The US dominates with first-to-market approvals (Rebyota, Vowst), stronger late-stage pipelines, and higher investment flows.

On the other hand, UK is an active player in microbiome innovation, with over 640 patents granted by 2020. IUK Business Connect mapped over 150 organisations as well as over 400 research projects relating to microbiome on its online interactive tool. Based on analysis using The Data City, there are around 150 microbiome-focused SMEs, employing 1,963 people and generating over £500 million turnover. UK firms have raised more than £365 million in private capital alongside £41.9 million in Innovate UK grants, with many demonstrating international reach through exports and global partnerships. The sector is growing steadily at an estimated 10.3% annually, with women-led companies making a visible contribution to its diversity.

European biotech hubs in France, Belgium, and the Nordic countries are successfully clustering microbiome activity around Horizon funded ecosystems such as Denmark/Sweden (MediCon Valley Alliance Microbiome Network), Ireland (APC), France (INRAE). Comparatively, the UK suffers from infrastructure fragmentation across **technology readiness levels (TRLs).** World-class universities, public R&D labs, and the Catapult network provide strong but often siloed capabilities, meaning innovators must navigate a complex and geographically dispersed system to access scale-up and translational support. Lab-space shortages in leading regions also constrain expansion and increase costs. This complexity adds costs and delays for microbiome SMEs working through discovery, clinical validation, and manufacturing. By contrast, US and European clusters often offer more integrated translational infrastructure and capital.

Recent investment commitments to LCR are bolstering its Health and Life Science cluster. The **Life Sciences Investment Zone** is expected to unlock up to £800 million in public and private investment and create 8,000 jobs over the next decade, with £160 million of government support focused on advanced lab space and infrastructure. Local awards, including £10 million for AI-enabled robotic labs and the creation of a **Microbiome: Accelerating Innovation and Development Hub (MAID)** at the University of Liverpool, will reduce costs and accelerate timelines for microbiome companies within and attracted to the region.

Part of the challenge for commercialising microbiome science in the UK lies in the difficulty of translating university-based research into commercial ventures. Reviews such as the **Independent Review of the Research, Development and Innovation Organisational Landscape (Nurse Review)** and the I**ndependent Review of University Spin-outs (Tracey Review)** highlight complex and inconsistent spin-out processes, fragmented translational support, and challenges in securing founder- and investor-friendly deal terms. Government responses have committed to addressing these frictions by creating a national spin-out database, improving transparency in equity structures, and strengthening Research England's oversight. Efforts to streamline bureaucracy within HEIs are designed to reduce barriers across the innovation pipeline. These reforms matter economically because they reduce transaction costs, improve investability, and can accelerate the emergence of microbiome ventures from UK universities.

Finally, the UK still faces a shortage of patient, growth-stage capital compared to the US, exacerbating the "valley of death" for spin-outs. The Industrial Strategy pledged that the British Business Bank will be able to make direct equity investments – potentially supporting university spinouts or other firms that universities are working with. This will help crowd-in further private sector investment into these firms and reduce the risk of them moving overseas to seek finance.

References
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Social

Society faces pressing issues related to human health, food insecurity, agroecosystem degradation, loss of global biodiversity, and climate change. The UK conducts significant research into the interaction of microbes and their hosts generating valuable insights into human disease, consumer health and wellbeing, animal health and environmental sustainability as well as combating the AMR threat and aiding pandemic preparedness. Microbiome science as a discipline has emerged with the advent of multi omics and increasing interdisciplinarity between the fields of biology, chemistry, computer science and bioinformatics, and is contributing to addressing many of these societal challenges.

The human microbiome—trillions of microorganisms and their genomes residing mainly in the gut and on the skin—plays a critical role in metabolism, immune regulation, and pathogen defence. Increasingly recognised as a cornerstone of health, the microbiome is driving innovation across medicine, personal care, and sustainable agriculture. Dysbiosis, or microbiome imbalance, linked to factors such as antibiotics, poor diet, and viral infections, contributes to over 25 conditions, including infectious diseases (notably recurrent Clostridioides difficile infection), autoimmune disorders like IBD and Crohn's, neurological disorders such as Parkinson's disease and certain cancers.

Microbiome-based therapeutics, or modulators, are advancing rapidly. Recent landmark FDA approvals include effective treatments for rCDI, a US$1bn market in the US alone. In the UK, Microbiotica has notably received approvals to launch Phase 1b human clinical studies for two of its key microbiome medicines for advanced melanoma and ulcerative colitis. These developments highlight the sector's commercial and clinical potential.

The field's growth has been fuelled by initiatives such as the EU-funded MetaHIT program (2007–2012), a multinational effort that mapped the genetic potential of human microbiota and revealed their influence beyond digestion. More recently, in 2023, the Dutch government made €200 million investment into the Holomicrobiome institute.

Apart from their transformative role in human health, microbiomes are increasingly being applied to address environmental and industrial challenges. They are central to wastewater treatment, nutrient cycling, and the conversion of organic waste into high-value products such as biofuels, bioplastics, and sustainable animal feed. Leveraging microbial systems in these contexts reduces environmental impact, closes resource loops, and supports the transition to a more circular economy.

Liverpool City Region is uniquely positioned to lead in these applications. Its proven expertise in wastewater monitoring and treatment — demonstrated through wastewater-based disease surveillance led by University of Liverpool academics during the COVID-19 pandemic — offers a foundation for next-generation microbial process optimisation, enhanced by AI and hybrid modelling approaches. Together with strengths in natural product discovery at Liverpool John Moores University, and high-performance computing at the STFC Hartree Centre, the region has the capability to integrate waste streams across food, water, and industrial sectors.

With expanding applications in animal health, food, and environmental sustainability, the microbiome has moved firmly into mainstream science and public discourse, attracting strong engagement from academia, industry, philanthropy, and government stakeholders.

Technology

The technological foundations for microbiome science are advancing rapidly, reshaping the scope and pace of research. At the frontier, computational breakthroughs such as DeepMind's AlphaFold have demonstrated how artificial intelligence can accelerate biological discovery by solving long-standing structural problems. Advances in experimental model systems include organoid platforms—miniaturised, stem-cell-derived models of human tissues—which are increasingly used to study host–microbe interactions in physiologically relevant settings, complementing computational and animal models.

In microbiome research, a similar transformation is being driven by advances in **multi-omics** (genomics, metagenomics, metabolomics, metaproteomics, spatial genomics) combined with **machine learning and deep learning** approaches. These tools are enabling the integration of complex, heterogeneous datasets at scale and offering more sophisticated insights into host–microbe interactions. Within Liverpool City Region, this technical stack is in place. The University of Liverpool hosts: the **Centre for Genomic Research (CGR)** provides sequencing and computational analysis; the **Microbiome Innovation Centre (MIC)** offers expertise in microbiome biology; and the **Computational Biology Facility (CBF**) provides multi-omic analytics and integration. STFC Hartree Centre and the Hartree National Centre for Digital Innovation (HNCDI) programme with IBM offer advanced machine learning capabilities and computational tools and high performance computing infrastructure for SME and industry focused demonstrator projects.

In parallel, developments through cloud platforms, automated bioinformatics pipelines, and experimentation platforms is reducing the costs and time of microbiome research. Such infrastructure make it possible to run high-throughput, reproducible workflows for sequencing, functional analysis, and strain characterisation. Microbiome research in particular benefits from these capabilities given the inherent diversity and complexity of microbial communities. However, they remain environments where expert oversight is required; the technology is not yet mature enough to be deployed as fully automated, user-friendly support tools.

Data environments represent another critical technological layer. Frameworks such as **FAIR data principles** and the **Five Safes** model establish standards for how microbiome and health datasets should be structured and accessed, but they do not themselves provide usable platforms. Usable solutions require robust metadata capture, standardised ontologies, and secure, interoperable systems. At the national level, **Health Data Research UK (HDR UK)** is addressing these challenges through initiatives such as the Health Data Research Gateway, Safe People and Cohort Discovery tools. Locally, Liverpool City Region (LCR) via the Civic Health Innovation Lab (CHIL) led by the University of Liverpool is developing a **Trusted Research Environment (TRE)** to enable secure clinical research and computational analysis, with standardised bioinformatics tools to support microbiome science.

Regulation

Both the Industrial Strategy and the Health and Life Sciences Sector Plan make strong commitments to "smart regulation" and streamlined adoption pathways, recognising engineering biology as a national priority technology. This signals a long-term political commitment to ensuring that regulation enables, rather than hinders, innovation.

The regulatory environment for scientific innovation in the UK has been undergoing reform, with an explicit shift towards a more "pro-innovation" approach across the life sciences. The Pro-innovation Regulation of Technologies Review: Life Sciences, led by Dame Angela McLean, sets out a series of cross-cutting measures to strengthen the regulatory system. These include improving data-sharing across regulatory bodies, and publishing clearer, faster and more predictable approval timelines. In addition, sector-specific reforms have been identified for medicines, medtech and diagnostics, and engineering biology – all of which are directly relevant to microbiome therapeutics and diagnostics. The establishment of the Regulatory Innovation Office (RIO) within the Department for Science, Innovation and Technology (DSIT) creates for the first time, a coordinating role across government, helping to identify and resolve regulatory barriers, support cross-sectoral learning, and back regulatory experimentation. Together, these reforms create the conditions for faster, more efficient routes-to-market for microbiome-based products if developers engage with regulators early in the process.

As designated Government critical technologies, Engineering biology and AI in health are among the focus areas of RIO, which presents opportunities for the microbiome sector in the future. This complements broader governance changes in Engineering Biology, where the Regulatory Horizons Council has recommended moving towards a product-focused regulatory model based on the properties of the end product rather than the production method. The Engineering Biology Regulators Network (EBRN) – bringing together regulators such as MHRA, FSA, HSE and the Environment Agency – has been created to ensure consistency, share expertise, and align regulation with innovation. For microbiome innovators, this shift offers opportunities to develop proportionate evidence frameworks that demonstrate safety and efficacy in ways that align with regulator expectations.

There has been growing interest in regulatory sandboxes as a way to test new approaches in practice. The Engineering Biology Sandbox Fund is supporting regulator-led pilots, including a food standards sandbox for cell-cultivated products designed to reduce approval costs and accelerate market entry.

The Industrial Strategy and Life Sciences Sector Plan reference new access pathways to accelerate the adoption of innovative health products into the NHS. For medicines, the Innovative Licensing and Access Pathway (ILAP) provides earlier and more integrated engagement with MHRA, NICE and NHS England, and offers an "Innovation Passport" to support faster approval. These routes present opportunities for microbiome-based innovations, for instance live biotherapeutics to reach patients more rapidly.

03

Barriers to Translation and Commercialisation

03
Barriers to Translation and Commercialisation

Every journey requires a route map, and it's only by identifying the challenges and barriers, that we can navigate a course towards our destination.

From October 2024 to June 2025, we consulted with a diverse range of stakeholders with the purpose of identifying opportunities but also gaps and challenges from diverse perspectives and Technology Readiness Levels (TRLs). Every journey requires a route map, and it's only by identifying the challenges and barriers, that we can navigate a course towards our destination. We wanted to hear directly from the players whose knowledge, experience and expertise would be integral to the fulfilment of the City Region's potential in this sphere.

The insights in this section represent extensive stakeholder engagement and consultation through workshops, survey, and interviews to understand in detail the barriers in translating microbiome research and innovation to products-to-market and clinical impact. Table 1 summarises the main themes that emerged from these interactions. A detailed description of each of the thematic areas then follows.

Table 1 - Summary of thematic barriers

Thematic Area	Summary of Key Barriers
Commercialisation and Funding Barriers	Immature science, undefined products, and risk-averse investors hinder funding access. Gaps in commercial skills and unclear market demand make it hard for innovations to become investable and reach consumers.
Data Science, Advanced Analytics, and Expertise Gaps	Many projects suffer from poor design and lack bioinformatics support. High costs, analytical complexity, and a shortage of interdisciplinary data scientists limit the value extracted from microbiome datasets.
Physical Infrastructure and Ecosystem Fragmentation	Limited access to lab, manufacturing, and HPC facilities slows scaling. A disparate ecosystem and disconnected infrastructure make collaboration, data reuse, and innovation pipelines difficult to build and sustain.
Regulatory and Standardisation Challenges	Regulatory uncertainty, lack of standard methods, and limited data reproducibility make approval processes slow and unclear, discouraging investment and complicating translation of microbiome products.

1. Commercialisation and Funding Barriers

1.1 Immaturity of Research and Product Definition

Much of the microbiome science is considered too early-stage for licensing or commercial uptake, lacking data readiness and validated use cases, particularly in therapeutic areas. There is a gap in effectively presenting academic outputs in a format that is directly applicable for commercial stakeholders, requiring support for academics to frame research findings as more investable propositions. The lack of a clear, defined product significantly limits investment readiness, making it difficult to translate complex microbiome-derived materials into patentable or protectable assets that attract industry interest. Here, companies like Microbiotica have found success by demonstrating a therapeutic pipeline and presenting consistent (safety, clinical effect) and promising pre-clinical results underscoring the value of clear product definition and robust early-stage data for attracting investment.

"There is an urgent need to create an environment that leads to more translational opportunity, such as more spin-outs and start-up companies and industry-academia collaborations and strategic partnerships"

UK KTN, Microbiome Strategic Roadmap

1.2 Investor Hesitancy and Funding Access

A general risk-aversion among investors is prevalent due to the inherent complexity, regulatory uncertainty, and long development timelines associated with microbiome innovations. Accessing grants, VC funding, and SME-specific funding is a significant difficulty, especially for early innovation stages. As per the survey, the majority of businesses relied on self-funding and private investment to commercialise microbiome products. Large funding applications often require strong commercial partnerships, which can be a barrier for academics and smaller entities. Academic (Explorers) survey respondents also mentioned facing challenges like "Lack of early interaction with industry partners" and difficulties with universities and companies "meet[ing]/swap[ping] information easily". This hinders the formation of necessary commercial partnerships. Spin-out processes have been under scrutiny for being slow, inconsistent, and unattractive to founders and investors. While progress is being made, there is an opportunity to learn from best practice at institutions like Imperial College, which has adopted a light-touch, low-equity, no-royalty approach that enables more companies to form quickly. In Liverpool, these challenges are compounded by socioeconomic barriers to risk-taking: unlike peers in the Golden Triangle, many students and postdocs lack the financial cushion to absorb the risks of founding a company, limiting the spin-out pipeline despite world-class science.

1.3 Skills Gaps in Commercialisation

There is a recognised difficulty in finding individuals who can navigate both scientific and commercial domains, leading to a shortage of translational business developers with microbiome expertise. This includes a lack of enterprise/commercialisation skills among researchers and limited awareness of IP. For instance, a researcher working on plant microbiomes, noted that her team has "a lot of data but need help translating it into a commercial offering" and "lacks experience in the business/enterprise side". Academics need training in innovation, commercialisation, and business engagement, and there's a need to embed enterprise thinking within microbiome science programmes and career pathways. While most clinicians interviewed did not understand the commercial aspects of translating their work (e.g., had not considered whether their samples could be used in biobanks), however the few who had interacted with SMEs in the past found the experience fulfilling and has provided them with a better understanding of the commercial constraints to product development.

1.4 Market Understanding and Consumer Adoption

There is a lack of clarity regarding market needs for emerging microbiome-based products. Challenges exist in demonstrating the economic value of microbiome interventions. Consumer awareness and acceptance of microbiome benefits are also seen as barriers to market adoption. This leads to uncertainty around adoption, as Explorers and Builders worry about clinical validation while Scalers worry about whether consumers will actually buy and trust the product.

"Microbiome exploitation has been driven more by marketing and consumer communication than it has by science..., "microbiome friendly" became a ubiquitous claim, and people put a stamp on their product and say it's microbiome friendly"

Innovation Intermediary

"This is one sector where adoption readiness levels would matter at least as much as technology readiness levels"

Innovation Academic

2. Data Science, Advanced Analytics, and Specialised Expertise Gaps

2.1 Inconsistent Bioinformatics Support and Experimental Design

Access to bioinformatics expertise is often inconsistent. There is a recognised need for earlier integration of data scientists into experimental design phases to improve statistical power and data utility. Many projects are underpowered or based on unclear hypotheses, and longitudinal study designs, while valuable, are harder to fund. This is often an 'unknown unknowns' problem where researchers who do not know where to source Informatics support, or even that they need Informatics support, also tend not to know how to ask for it. There's a common issue of clinicians delivering the "wrong data" to bioinformaticians because of poor initial experimental design. For instance, one of the clinicians interviewed, who is a self-taught bioinformatician, noted that his "clinician peers [are] unlikely to even know where to look for microbiome sequencing and informatics support". The problem isn't always finding the right experiment, but asking the right questions, which is facilitated by early collaboration with data scientists.

2.2 Challenges in Multiomics and Advanced Analytics

While the potential of multiomics approaches (measuring DNA, RNA, proteins, metabolites) is recognised, practical application is limited by cost, lack of integrated platforms, and analysis challenges. The ultimate goal for many researchers is to identify the causal basis of dysbiosis, the mechanistic reason a microbiome changes from one state to another. This is a significant analytical challenge, as snapshot datasets often lack the information needed to assign cause, consequence or correlation. Advanced analytical approaches like Digital Twins and AI are considered "moonshots" and are currently at an early Technology Readiness Level (TRL), needing much more development before they truly benefit translation. There is a perception that "AI will provide a solution," but this often feels much more like an article of faith than a detailed strategy as very little technical insight was offered into the precise form this AI might take. Respondents alluded to "ChatGPT-style LLM-type models" or "Deep Learning being used to define universal microbiome embeddings". There's a risk of "biologically guileless" Machine Learning, where data is processed without sufficient biological understanding, leading to errors.

"..they [AI/LLMs] can be and are sometimes utilised incorrectly, and AI models built on trash data will output trash conclusions"

Bioinformatician

2.3 Difficulty with Data Analysis and Meta-Analyses

Many microbiome studies face challenges with data analysis and interpretation, particularly in moving beyond simple pattern identification to uncovering mechanistic drivers. Related projects are rarely integrated to conduct meta-analyses, leading to lost value from expensive data not being fully mined. Technical issues, such as strong batch effects from variations in sampling and sequencing, confound straightforward cross-project comparisons. There is also a tendency for some researchers to fail to appreciate or overcomplicate the solution of dataset stratification by metadata, which can convert global analyses into more tractable sub-problems and reveal strong signals within specific subgroups.

Clinical stakeholders highlighted challenges presented by isolated clinical systems, with no linkage between them to enable cross-analysis of microbiome data at scale. For instance, GP records, acute care and pharmacy records were not connected. While there is significant potential in analysing linked Electronic Health Record (EHR) data, achieving this integration remains difficult. Solutions such as the NHS Secure Data Environment (SDE) were proposed to help address this barrier.

2.4 Shortage of Life Science-Grounded Data Scientists

There is a critical need for Data Scientists who are thoroughly grounded in Life Sciences, meaning they possess an extensive understanding of biology. The trend of turning biology into numbers and applying machine learning without biological context is not endorsed by those working in microbiome data science. Papers led by pure Data Scientists, without life sciences training were seen to contain "egregious biological errors" and failing to leverage obvious biological insights to simplify data mining problems. Recruiting and retaining such interdisciplinary talent is a significant challenge for academic and commercial informatics providers due to high demand and competition for talent. Specially designed non-principal investigator (PI) career pathways, such as Senior Experimental Officers, were seen to have helped to some extent to retain the skills of this workforce within the region.

"In 2020 BBSRC ran a workshop to understand the current and future capabilities needed for microbiome research. It identified gaps in quantitative skills, big data, machine learning, single cell work and experimental design. It positioned them as opportunities for improving doctoral training and upskilled early-career scientists."

IUKBC Report Human Intestinal Microbiome Therapies and Diagnostics the Science, Opportunities and Challenges 2022

3. Physical Infrastructure and Ecosystem Fragmentation

3.1 Lack of Manufacturing and Lab Facilities

A major bottleneck is the absence of a GMP large-scale microbiome manufacturing facility in the UK, hindering companies attempting to scale from discovery to clinical-grade production. There is also insufficient access to facilities for data analysis, sequencing, and secure sample storage. More generally, a lack of incubator space, scale-up facilities, and suitable premises limits the transition of pilot projects to scalable interventions, particularly within the NHS and academic settings. Government-supported infrastructure is identified as a missing link, with international examples such as Denmark/Sweden (MediCon Valley Alliance Microbiome Network), Ireland (APC), Finland (VTT), Netherlands (TNO), Belgium (VIB), and France (INRAE) identified as of where public investment has filled critical translational gaps effectively.

3.2 Disconnected Ecosystem and Navigation Barriers

Stakeholders reported finding it difficult to navigate the various high-quality but disconnected resources across the region. There is a recognised need for a more coordinated ecosystem with better signposting and shared access models. Builders noted they struggled with weak industry links (funding, ideation, product development) and lack of structured support for SMEs to connect with large manufacturers. They mentioned often feeling isolated without strong bridges to academia and government support mechanisms. This fragmentation means that innovators often struggle to identify and connect with the right partners for design, data science, manufacturing, or licensing. Barriers in having a single point of access to university expertise and subsiding Full Economic Costs (FEC) in accessing facilities were consistently brought up in the workshops. The MAID programme by MIC is seeking to address these barriers. Achieving regional collaboration, for example between Liverpool and Manchester, presents political, cultural and institutional barriers, though there are areas where the cities are exploring closer collaboration which presents opportunities for the future.

3.3 Challenges in Biobanking Practices

Biobanking practices were flagged as needing reform. Scientists often store only what is immediately useful to their own research, resulting in the loss of valuable biological materials that could support broader translational goals. There was a call for standardised extraction methods and government-coordinated infrastructure to improve biobanking. While many biobanks exist regionally, their commercial potential is often untapped due to a disconnect between potential customers and university and hospital provision, highlighting a need for dedicated business development to market and sell access. At the time of writing this report, Liverpool Health Partners (LHP) are leading an initiative to create an LCR life-course bioresource offer. There are also national developments between National Biofilm Innovation Centre (NBIC) and CABI to explore a UK microbiome biobank.

3.4 Access to High-Performance Computing (HPC)

While the UK has made significant investments in high-performance computing (HPC) infrastructure, stakeholders highlighted that access pathways can be complex to navigate, particularly for external or academic users. This can create additional administrative and optimisation demands for informatics experts, who are already managing the intricacies of biological and data science workflows. It was noted that simplifying supported access would help ensure that advanced computational capacity is fully leveraged for microbiome research, enabling experts to concentrate on maximising the scientific and translational value of the data.

4. Regulatory and Standardisation Challenges

4.1 Regulatory Complexity and Uncertainty

Regulation is consistently identified as a critical barrier, particularly for novel modalities like AI-driven diagnostics or bacteriophage therapies, requiring new, adaptive regulatory approaches. There can be uncertainty around product classification (e.g., as foods, supplements, or medicines), which determines the required regulatory pathway. This complexity contributes to investor risk-aversion by lengthening development timelines. Navigating these processes can be costly requiring experienced consultants to create a Common Technical Document, due to a perceived lack of clarity in regulator expectations. Furthermore, a lack of communication between innovators and regulators acts as a barrier, although regulators are increasingly seeking early engagement with innovators. Regulatory bodies, such as the MHRA, tend to prioritise products already "in their hands" rather than proactively engaging with future innovations. There have been positive developments within the microbial regulatory innovation space with UK's first official guidance to support the safe development and use of phage therapies launched in June 2025.

"MHRA deals with so many drugs that they have to prioritise what is in their hands, not what is going to reach them at some point, maybe in the future"

Regulatory expert

4.2 Evidence Requirements and Clinical Trial Design

Demonstrating efficacy in randomised controlled trials (RCTs) remains difficult for microbiome treatments, even after passing Phase 1 safety trials. Unlike small molecules, these treatments are generally regarded as safe and almost always succeed at this stage, a characteristic that should, in principle, be favourably considered by regulatory bodies. However, bodies like NICE apply a heavy burden of evidence and long review times, which are seen as major bottlenecks. There was consensus that clinical trials for microbiome interventions need to be designed differently from those for typical chemical drugs, when assessing for safety and efficacy. The survey also identified "Limited datasets" and concerns about "Causality in microbiome studies", emphasising the struggle to establish cause-and-effect relationships from the collected data. Many trials suffer from poor design, unclear endpoints, and a lack of stratification, often being underpowered and not adequately accounting for the complexity and variability of microbiome data. This makes any associated risk unacceptable, as studies may be too small to yield useful insights.

"...clinical trials (microbiome) need to be considered in a different way, we keep designing clinical trials the same way we'll design a trial for paracetamol."

Regulatory expert

4.3 Lack of Methodological Standardisation and Reproducibility

A fundamental challenge reported was the pervasive lack of standardisation in emerging technology areas, such as microbiome-based diagnostics and interventions, directly hampering regulatory clarity and investor confidence. Existing microbiome data was characterised as "absolute chaos" and "not to be trusted" due to significant bias at every stage – sampling, storage, DNA extraction, sequencing, and bioinformatics. This bias means information cannot be reliably combined from different datasets. Reproducibility of mechanistic findings and causal understanding remains a significant challenge, highlighted as a top concern for Builders. Even within a single study, variability can arise from operators, instruments, or environmental factors, making consistency challenging and regulatory approval difficult. Data produced by academics is often repeated by industry due to this lack of standardisation, thereby duplicating effort.

4.4 Metadata and Reference Database Quality

Inconsistent and poor-quality metadata remains a critical bottleneck in microbiome research. There is a lack of consensus and user-friendly tools for metadata capture, with existing standards like FAIR (Findable, Accessible, Interoperable, and Reusable) and ALCOA (Attributable, Legible, Contemporaneous, Original, and Accurate) not widely implemented. An illustration of interpretation inconsistency was shared by a stakeholder, where a subject's ethnicity was recorded as "Austrian," which is a nationality, not an ethnicity. The core issue is often poor metadata tooling rather than a lack of standards. Problems with underlying reference databases, including over/under-representation of certain bacteria, bias towards bacteria over fungi and viruses, incomplete taxonomies, and geographical biases, were reported to directly impact the accuracy and completeness of microbiome sample compositions. For example, this means if a strain is present in a sample but not in the database, it cannot be assigned.

The Personas

Liverpool City Region's competitive edge is based on its existing Innovation Ecosystem - a flourishing life science and bio-tech sector comprising leading edge academic and research institutions, pioneering startups and a cluster of global manufacturing businesses. These players represent the three key "personas" that are the dynamic to make the City Region a thriving and globally significant centre for innovation and commercial exploitation at a new frontier of science.

To nurture and fulfill that potential we need to understand the distinctive roles, concerns and support needs of "Explorers" (Researchers and Academics), "Builders" (Start-ups, SME's and Support Agencies) and "Scalers" (Large-scale manufacturers and corporates).

The objective is to facilitate supportive interaction between the "personas" focused on a shared vision, a seamless relational framework and a deep collaborative ethos.

Persona specific challenges

Category	Explorers (Researchers, Academics, and Clinicans)	Builders (Spinouts, Start-ups, SMEs, TTOs, Business Support Organisations)	Scalers (Industry and large corporates)
Commonalities	• Funding access is difficult for all personas. • Perceived unclear regulations and lack of common standards. • Translating research to market is a shared struggle. • Data quality, standardisation, and reproducibility issues persist. • Causality and host-microbiome interactions are often unclear. • Lack of infrastructure and facilities impacts all. • Collaboration and communication gaps are widespread. • Skills gaps in commercialisation and business development remain.		
Key Differences	• Causality in studies. • Funding for basic research is often limited. • IP protection versus publication creates tension. • Lack of commercialisation skills and early industry engagement. • University IP bureaucracy hinder translation.	• Reproducibility at scale is the biggest challenge. • Accessing early-stage VC and SME funding is difficult. • Long and complex, regulations are a major barrier. • Struggle translating research into tangible products. • Lack of incubator space and scale-up facilities. • Need clear clinical adoption pathways.	• Manufacturing and scale-up are significant barriers. • Concerned with microbiome-host interactions and manufacturability. • Lack of strategic government support is an issue. • Academia's REF publication focus misaligns with product goals. • Shortage of skilled technical workforce for scaling. • Challenges proving economic value and consumer trust.
Top Concerns	• Disassociating biological complexity in studies. • Ensuring statistical rigour in measurement. • Managing sensitive data and anonymisation. • Internal academic adoption of ideas. • Uncertainty in innovation pathways to pursue.	• Navigating complex legal contracts and paperwork. • Unclear innovation support structures from agencies. • Building and retaining specialised teams is a talent challenge. • Technological limits hinder scaling solutions.	• Navigating post-Brexit regulations is complex. • Legal contracts and IP complexities are a concern. • High full economic costs of research collaborations. • Application testing and formulation validation is key. • Ensuring reliable endpoint research for products.
Needs & Support	• Enhanced funding and access to resources. • Support to translate research to market. • Earlier and stronger industry engagement and networks. • Training in commercialisation skills and mentoring. • Clearer policy advice for innovation support. • More interdisciplinary teams and career pathways. • Reduced bureaucracy for smoother collaborations. • Academic reward for translational work.	• Easier grants and venture capital access. • Faster, clearer regulatory pathways. • Better access to scale-up facilities and expertise. • Stronger SME-industry networks and partnerships. • NHS adoption and co-development support. • Clearer innovation agency support, knowledge exchange and communication. • Specialised talent recruitment and retention assistance. • Support for international scaling and growth.	• Investment to scale infrastructure and equipment. • Clearer routes to human efficacy testing. • Stronger academic collaboration and champion support. • Policy changes to speed innovation and derisk ventures. • Government funding for de-risking and scaling innovation. • Access to skilled technical workforce and capability building for scaling. • Support proving economic value and consumer trust. • Assistance with reliable endpoint research.
Challenge Evolution	Scientific Rigor & Validation	Reproducibility & Regulation	Market Readiness, Production & Adoption

04

Case Studies

04
Case Studies

Ambitions must be more than dreams for the future. They must have roots and be founded on where we are now and what we are already doing.

The potential of Liverpool City Region to become a major UK and global centre in one of the most exciting and transformative areas of science, requires both vision and a robust strategic approach. This report provides the framework, the route map and a set of recommendations to transform potential into reality. Our optimism is founded on the region's track record of collaborative working and its deep-rooted capacity to invent and innovate. Ambitions must be more than dreams for the future. They must have roots, and be founded on where we are now, and what we are already doing. These case studies demonstrate the unique value and diversity of assets already established within the City Region and best practice from beyond the region. They outline the scope and potential that can now be nurtured to realise our ambitions and become a world class open innovation ecosystem centre for microbiome research and commercialisation.

01

Advancing Beauty and Personal Care Innovation through Microbiome Science: Unilever's Research and Ecosystem Partnerships

Sector:

- Consumer Health & Personal Care
- Microbiome Science

Theme:

- Skin & Oral Microbiome
- Ecology & Commensals
- AI & Data-Driven Insights

Organisation(s):

- Unilever (Industry)
- University of Liverpool (Academic Partner)

Unilever, a global leader in consumer health and personal care, has historic close ties in the Liverpool City Region, continuing to have a R&D base at Port Sunlight, Wirral. It is a major contributor to microbiome science, with research spanning skin, oral, home care, and beauty & wellbeing categories. It manages one of the world's largest collections of skin microbiome samples—over 30,000—collected through clinical and consumer studies across geographies. Since initiating its microbiome research in 2003, Unilever has embedded microbiome science into product development and innovation pipelines with a clear commercial and consumer health focus.

A defining feature of Unilever's microbiome R&D strategy has been its long-standing partnership with the University of Liverpool. Over 18 years, this collaboration between academic excellence and industrial R&D has flourished. It builds on Unilever's pivotal regional innovation leadership role and open innovation approach encompassing flagship, collaborative infrastructure- Materials Innovation Factory (MIF), a joint facility with the University of Liverpool, focussed on innovation in formulation and material science. Partnering with the Microbiome Innovation Centre (MIC), Unilever delivers academic-industry knowledge exchange initiatives such as Knowledge Transfer Partnerships (KTPs), postdoctoral research placements, and contract research projects. The broader Liverpool City Region innovation ecosystem also offers supplementary innovation capabilities such as High-Performance Computing (HPC) which Unilever utilised to apply explainable AI to understand skin microbiome composition and its phenotypic links. This was achieved through a STFC Hartree Centre partnership with IBM as part of the Hartree National Centre for Digital Innovation (HNCDI) programme.

The Unilever research team have published fundamental and translational microbiome research covering topics such as skin ageing, host–microbe interactions, infant and adult microbiome differences, and microbiome responses to beauty and personal care products covering skin, scalp, axilla and oral microbiomes.

Unilever's research is strongly rooted in the ecology of commensal microbiomes and their role in maintaining health and wellbeing. Their latest groundbreaking discovery, published in collaboration with MIC and the Brain & Behaviour Lab at the University of Liverpool, revealed a link between the skin microbiome and mental wellbeing, specifically highlighting how the presence of certain microbial genera like Cutibacterium may correlate with improved mood and psychological states. This finding highlights the potential of the skin microbiome as a critical part of the skin-brain axis, paving the way for microbiome-targeted skincare innovations. Other research projects cover molecular and population-level approaches to understand areas such as odour modulation, psychobiological interactions, and skin health. The ecological framing of microbiome research—beyond single-pathogen approaches—reflects a holistic orientation within the company's research and development.

The internal Unilever research team lead on hypothesis development, study design and data interpretation but will collaborate with ecosystem partners on sequencing and bioinformatics to complement their in-house capabilities. This model ensures agility, enabling them to dip into the ecosystem to access specific assets and capabilities, while upholding scientific rigour, regulatory compliance and efficient implementation of innovation across its global operations.

The longevity and continuation of the partnerships support mutual capability development and process improvements over the long term. For example, research data is managed under consent frameworks that permit future reuse with the University of Liverpool, and Unilever maintains metadata-rich sample records, including demographics and biological context, enabling deeper insights across studies. Unilever's research portfolio has resulted in more than 100 patents and multiple microbiome product applications. Unilever's Dove brand is an excellent example of how it has applied research carried out with MIC to develop microbiome-friendly personal care products for the benefit of consumers.

The relationship between Unilever, University of Liverpool and LCR Innovation Ecosystem illustrates good practice in industrial-academic collaboration, open innovation, and the commercial use of microbiome research and data for evidence-based product development.

02

Leveraging AI for Microbiome Research:
STFC Hartree Centre's Role in Complex Disease Understanding

The STFC Hartree Centre, located within the Sci-Tech Daresbury campus in the Liverpool City Region, plays a pivotal role in applying artificial intelligence (AI) and high-performance computing (HPC) to address some of the most complex data challenges in health research, including microbiome studies.

Sector:

- Data Science & Health Research
- NHS

Theme:

- AI & Bioinformatics
- Health Data Analytics
- Precision and personalised medicine

Organisation(s):

- STFC Hartree Centre (Research & Technology Organisation), IBM (Industry), REPROCELL (Industry)

Through the Hartree National Centre for Digital Innovation (HNCDI) programme, REPROCELL, a global leader in stem cell technologies and precision medicine, worked with the STFC Hartree Centre and IBM to create Pharmacology-AI, a novel application designed to provide insights that support precision medicine and optimise clinical trial design initially focused on inflammatory bowel diseases.

For every successful drug, nine others fail during clinical trials. Many promising drugs never reach the market because current trial designs are broad, resulting in failures when only a subset of patients respond positively. Factors such as genetics, microbiome composition, environment, and behaviour can all influence patient response. By incorporating microbiome data into trial design, REPROCELL aims to identify patient subgroups most likely to respond well to specific drug candidates.

The Hartree Centre team leveraged IBM's AutoXI4Omics tool, integrating omics and patient clinical datasets, to train predictive models of IBD therapeutic drug response. They then built a bespoke AI platform with custom software to manage, further analyse, and present these insights in a format accessible to researchers and industry users.

Pharmacology-AI can recognise clinical trial patient identifiers, including microbiome signatures and characterise the potential response of an individual to a drug candidate. These insights can streamline trial development, increase the likelihood of success and therefore deliver many more drugs to market, helping translate microbiome science into life-saving therapeutic applications, and the platform is being applied to a range of related life sciences projects ongoing at Hartree centre. This technology presents potential to benefit the pharmaceutical and healthcare industries by reducing costs associated with failed drug trials, enabling approaches to personalised medicine and diagnostics, and advancing the development of more innovative digital technologies in the future.

This collaboration highlights the importance of integrating domain expertise, advanced data science infrastructure, and explainable AI techniques to generate actionable biological insights. The Hartree Centre's ability to scale data processing, ensure data integrity, and apply cutting-edge analytical tools significantly accelerated the project's timeline and demonstrated the value of embedding computational capabilities into microbiome research.

"This is a strong example of how cutting-edge research can be transformed into practical tools that accelerate discovery and deliver real societal benefits, such as enabling more effective, targeted treatments. Our collaboration with IBM through the Hartree National Centre for Digital Innovation demonstrates the power of working together to bring digital technologies to solve real-world challenges in sectors like healthcare."

Kate Royse
Director, STFC Hartree Centre

References
AI meets human tissue to fast-track precision medicine development
AutoXAI4Omics: an automated explainable AI tool for omics and tabular data | Briefings in Bioinformatics | Oxford Academic

03

Building a Regional FMT Capability:
University of Birmingham Microbiome Treatment Centre

The University of Birmingham's Microbiome Treatment Centre has emerged as a national exemplar in the development and clinical deployment of Faecal Microbiota Transplantation (FMT) and the first MHRA approved service in the UK. Headed by Professor Tariq Iqbal—a leading Gastroenterologist and former Chair of the UK Gut Microbiome for Health Expert Panel—the Centre brings together clinical expertise, academic rigour, and regulatory engagement to deliver a pioneering model for microbiome-based therapies within the NHS.

Sector:

- Health & Microbiome-Based Therapeutics
- NHS

Theme:

- Faecal Microbiota Transplantation (FMT)
- Clinical Translation
- Regulatory Engagement

Organisation(s):

- University of Birmingham Microbiome Treatment Centre (Academic & Clinical)

Initially launched in 2013 through a Public Health England initiative, the FMT service at Birmingham addressed recurrent Clostridioides difficile infections (CDI) by establishing a clinical pathway and robust hospital-based delivery model. When FMT was formally recognised as a medicinal product in 2015, the Centre was able to comply with Good Manufacturing Practice (GMP) standards. This involved implementing comprehensive donor screening, manufacturing protocols, ethical oversight, batch validation, and quality control systems.

Today, the Birmingham FMT programme operates under GMP licensing and supplies clinical material to over 180 NHS Trusts across the UK. The service has treated more than 1000 patients and integrates seamlessly with NHS clinical pathways. Its infrastructure includes advanced donor screening methods, real-time PCR testing, cryopreservation, and a secure distribution network using blood bike services and dry-ice logistics.

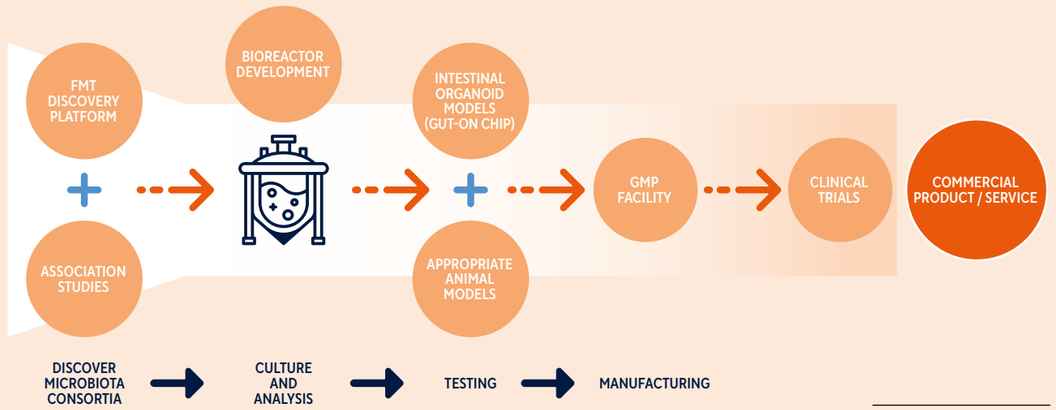
A defining feature of the Centre's approach has been its emphasis on cooperation between academic, clinical, and commercial stakeholders. The model demonstrates how close collaboration with regulators can advance innovation.

The Gut Microbiome for Health Expert Panel played a facilitative role in standard setting which informed national governance frameworks via NICE, allowing regulatory compliance to evolve alongside scientific progress.

This service model has shown significant patient outcomes, translational and sustainable impact. It is self-sustaining and supported future research in gastro-intestinal disease through clinical trials such as STOP-Colitis and FARGO which explore the immune response and microbial diversity associated with FMT in two forms of IBD.

The Microbiome Treatment Centre's FMT programme exemplifies how regional innovation ecosystems can deliver regulated, high-quality microbiome therapies to support the health needs of the population. MTC has built a sustainable operational strategy encompassing an NHS-embedded service delivery, centralised and standardised manufacturing production, early regulatory engagement, and the development of multi-stakeholder partnerships. Its success offers a replicable framework for similar initiatives across the UK, underlining the value of strategic alignment between science, policy, and service delivery in realising the potential of microbiome research to meet NHS goals.

Proposed Roadmap to Novel Biotherapeutics



By Professor Tariq Iqbal

04

Personalised Microbial Therapies for Gut Health:
GutSee Health's AI and Multi-Omics Approach

Sector:

— Health & Microbiome-Based Therapeutics

Theme:

— Gut Disorders
— Precision Microbiome Therapies
— AI & Multi-Omics

Organisation(s):

— GutSee Health (Start-up SME)

Founded by Dr Joanna Wiecek and Dr Ketaki Mhatre, GutSee Health is developing a cutting-edge, multi-omics, precision-based approach to treating gut disorders by combining AI-driven microbiome analysis with synthetic biology tools to develop personalised microbial therapies. Unlike current general approaches such as probiotics or fecal transplants, GutSee Health's platform tailors interventions to each individual's microbiome profile, identified through advanced machine learning models trained on data from healthy and diseased individuals. This example illustrates the Innovate UK KTN Microbiome Innovation Network's Strategic Roadmap recommendation for the need to create an environment that leads to more translational opportunity by mobilising seed funding, national and local advisory and networking support organisations with incubator hubs working alongside microbiome centres of excellence.

GutSee Health followed the Hatchery startup incubator programme at University College London which supported them with due diligence, hiring legalities, and business support and received funding from Zinc VC and Female Founder Incubator at Alderley Park.

Following a series of meetings with LYVA Labs, GutSee Health were attracted by the joined up offer of the LCR Microbiome Innovation Ecosystem comprising: specialist lab facilities at Sci-Tech Daresbury and STFC; the nationally recognised microbiome research excellence and multi-omics, bioinformatics capabilities of University of Liverpool's Microbiome Innovation Centre; and the place-based incentives offered via LCR H&LS Innovation Zone project "Microbiome and Infectious Disease Hub" and LYVA Labs' Innovate, Grow, Accelerate and Partner programme. The region also offers diverse specialisation of NHS trusts for clinical trials and an internationally significant health and life science cluster, with strong industry collaboration between SMEs and Multi national corporations.

GutSee Health has successfully applied to join LYVA Labs' incubator programme for support with commercialisation strategy, industry connections and regulatory support, alongside an initial investment of £25K. The programme will be helping the team to develop their investment case to secure follow-on funding for the next stages of their commercial and development plans. Additionally, LYVA Labs have added value by connecting GutSee Health with leading academics and clinicians in the field of gastroenterology at the University of Liverpool, with specialisation in advanced metabolomic, microbiome, and mycobiome analyses to better understand and diagnose gastrointestinal disorders and the use of volatile organic compounds (VOCs) for disease diagnosis.

"GutSee Health is excited to be part of the Liverpool City Region. One of the key drivers behind our decision to relocate part of GutSee Health's operations here was the strength of the local ecosystem … We also plan to make use of the excellent microbiology and molecular biology facilities of the University of Liverpool to support our upcoming preclinical work. … Working with the Hartree Centre will be instrumental in helping us optimise these pipelines (AI Discovery platform) – enabling our transition from R&D-grade to industrial-grade systems ready for commercialisation. … LYVA Labs has provided invaluable guidance across regulatory strategy, product development, and commercialisation. Their financial support has helped us accelerate lab work and begin planning preclinical testing this year.

We see Liverpool as a strategic hub that will help accelerate both our scientific and commercial ambitions, and we're looking forward to growing as part of this thriving ecosystem."

Joanna Wiecek
CEO & Co-Founder at GutSee Health

05

Understanding and Predicting Bovine Lameness through the Microbiome: Research from the University of Liverpool

Sector:

— Animal Health & Veterinary Microbiomes

Theme:

— Bovine Lameness
— Predictive Diagnostics
— Microbiome-Based Epidemiology

Organisation(s):

— University of Liverpool – Institute of Infection, Veterinary and Ecological Sciences

Digital dermatitis (DD) is one of the most prevalent and costly infectious causes of lameness in dairy cattle globally. Despite decades of research, its aetiopathogenesis (cause and development) remains poorly understood. Professor Georgios Oikonomou, a clinician and academic at the University of Liverpool's Institute of Infection, Veterinary and Ecological Sciences, is addressing this knowledge gap through a pioneering programme that uses microbiome science to track and predict disease progression in dairy herds. His research focuses on bovine microbiome impacts on disease resistance and productivity in dairy cattle. He also focuses upon the impact of good husbandry practices, feeds and animal breeding on maintenance of a healthy microbiome.

At the heart of this research is a longitudinal microbiome study that investigates the foot skin microbiota of dairy heifers before, during, and after the onset of digital dermatitis lesions and builds upon the group's previous work (Bay, Gillespie et al., 2022). The study utilised 16S rRNA and shotgun metagenomic sequencing on serially collected skin swabs from animals in a commercial dairy herd, with microbial DNA extraction and analysis conducted at the University's Centre for Genomic Research. Samples were tracked over six months and categorised into three groups: animals that never developed DD lesions, those that developed and recovered, and those that developed persistent lesions. This fine-grained approach has enabled Oikonomou's team to detect changes in the microbial community composition up to two months before the visible appearance of DD lesions, including increased abundance of DD-associated pathogens such as Mycoplasma and Dichelobacter.

This work has major implications for the early detection, diagnosis, and even prevention of lameness in ruminants. The identification of early microbial biomarkers in foot skin suggests new avenues for predictive diagnostics and targeted interventions, with the potential to significantly reduce antibiotic use and improve animal welfare. The research is also advancing broader capabilities in animal microbiome research and data integration, supported by advanced sequencing and bioinformatics expertise at the University of Liverpool.

Professor Oikonomou's wider work spans veterinary clinical practice, genetics, and microbiome-based epidemiology. He is also involved in collaborative efforts to develop practical applications from microbiome research, including integration with animal health surveillance systems. His work exemplifies how veterinary medicine can harness microbiome insights to address persistent challenges in livestock production. This research is situated within the broader Liverpool City Region ecosystem that possesses global leadership in health and life sciences, including the University of Liverpool Veterinary School and it's Leahurst campus that uniquely houses two working farms, which is increasingly driving innovation in veterinary fields through research translation. The region's growing biomanufacturing cluster further supports this pipeline, with global manufacturer Elanco Animal Health anchoring some of the world's largest fermentation capability. Together, these assets position Liverpool as a national leader in microbiome research with translational potential in agri-tech and veterinary health.

References

The bovine foot skin microbiota is associated with host genotype and the development of infectious digital dermatitis lesions - PubMed

06

Harnessing the Breast Milk Microbiome:
BoobyBiome's Precision Synbiotics for Infant Health

Sector:

— Health & Microbiome-Based Therapeutics

Theme:

— Infant Gut Health
— Precision Probiotics
— Synbiotic Scale-Up

Organisation(s):

— BoobyBiome (Start-up SME), CPI (Research and Technology Organisation)

BoobyBiome is a pioneering female-led biotech translating insights from the breast milk microbiome into precision synbiotic therapeutics designed to enhance infant gut health. Drawing on the natural diversity of breast milk bacteria, the company's discovery platform applies metagenomics, gut modelling, and functional microbiology to isolate and optimise beneficial strains capable of supporting immune and metabolic development during the critical early months of life.

Their lead product targets microbiota restoration in infants, aiming to support immune training and long-term health outcomes. With increasing concerns about C-section births, early antibiotic exposure, and reduced breastfeeding rates disrupting infant microbiota colonisation, BoobyBiome is addressing a clear unmet need through a natural, biologically informed solution.

Support from the Innovate UK Microbials Accelerator programme was pivotal to BoobyBiome's early success. The programme not only accelerated commercial development but also helped shape regulatory strategy and investor readiness. Partners such as Bionow, iiCON, LYVA Labs, and Health Innovation North West Coast offered cross-cutting support—from regulatory mapping and market case building to grant application refinement. A KPMG-authored regulatory roadmap provided through the programme is now a key tool in investor discussions.

As part of their development and scale-up journey, BoobyBiome also collaborated closely with the Centre for Process Innovation (CPI), which provided critical support in advancing the company's commercial readiness through demonstrating the manufacturing feasibility of BoobyBiome's top bacterial candidates. As one of the few facilities in the UK with capabilities to support with microbiome product development, scale up and pilot scale manufacturing, CPI offered technical expertise in upstream process development, developed analytical methods for product characterisation and viability assessment of probiotic strains, and conducted a feasibility study on co-culturing multiple species of bacteria at scale. . This enabled BoobyBiome to work towards a scalable manufacturing process for their synbiotic. CPI's work with BoobyBiome played a central role in making the supplement commercially viable and de-risking the route to manufacture—an essential step for early-stage biotech entering a regulated health market.

In parallel, the company has used its public engagement opportunities to raise awareness about infant microbiome health. BoobyBiome's founder, Dr Lydia Mapstone, has spoken widely on the topic, advocating for greater investment in early-life microbial therapeutics and highlighting the value of building a translational science-business interface in the UK.

Following a successful feasibility phase, BoobyBiome secured a £1.6 million Biomedical Catalyst award to support rigorous clinical testing and scale-up of their lead product. This funding will enable clinical validation, further process development, and regulatory alignment—marking a critical inflection point in their path to market.

BoobyBiome's journey reflects the maturing microbiome innovation landscape in the UK, showcasing how cutting-edge academic science, targeted ecosystem support, and integrated manufacturing capability can converge to fast-track novel health solutions. Their progress also underscores the role of regionally anchored partnerships in enabling microbiome start-ups to access the tools, infrastructure, and networks necessary for commercial success.

05

Recommendations

05
Recommendations

The purpose of this report is to affect and influence policy and practice. The unique potential that exists within Liverpool City Region will only be realised if we fully understand the opportunities and challenges and devise the practical actions necessary to secure our objectives. The value of our research rests ultimately on the application of its recommendations.

Recommendation: 01

Improved co-ordination of ecosystem assets and capabilities towards microbiome cluster development

Recommendations

- **Centralise Intelligence of Assets and Capabilities**
  A Central Intelligence Hub would act as a business-forming engine: actively scouting opportunities, shaping investable propositions, and connecting researchers with capital, commercial partners, and product development expertise. Crucially, the Hub should serve as a bridge into established product development teams within large companies, ensuring that promising discoveries can flow directly into pipelines with the resources, regulatory experience, and global reach needed to reach the market.

  The hub activities could include building upon regional mapping exercises to coalesce a single, up to date register of current microbiome capabilities and infrastructure to support strategic planning and collaboration.

  Map existing intellectual property in microbiome related technologies to identify white space, avoid duplication, and inform investment strategy.

  Mapping to include publications, patent activity, UK public-funded projects for these innovation-related initiatives, location of publicly accessible infrastructure.

- **Strategic, evidence-led and pan LCR approach to supporting innovation-led growth**
  Establish an entity for strategic joint working at corporate level to execute growth of microbiome ecosystem including governance and decision-making structure.

  Devise an LCR Microbiome strategy owned by stakeholders with agreed: purpose, vision, values, ambition, outcomes, enablers, success measures.

  Use place-based innovation frameworks and data tools to identify cross cutting economic development opportunities synergizing between H&LS and HPC/AI capabilities.

- **Develop Market Opportunities and Focused Application Areas**
  Reach agreement on high-potential application areas for innovation specialisation in LCR (e.g., gut health, skin care, femtech, respiratory, neurodegenerative disease, oncology, animal health).

  Co-ordinate business development opportunities for LCR Microbiome Innovation Ecosystem (e.g. attendance at relevant conferences and grant funding applications).

Key stakeholders

- LCR CA H&LS Cluster Board & LYVA Labs
- Invest Liverpool/H&LS Cluster Board/ Liv Shared Services
- University of Liverpool, Unilever, Croda
- iiCON

IUK Microbiome Strategic Roadmap (MSR) Recommendations

MSR2: Create Microbiome Research & Innovation Collaboration Networks / Virtual Microbiome Institutes

Microbiome KTN Roadmap

Recommendation: 02

Reinforce collaboration across allied research agendas through single point of access

Recommendations

- **Foster greater Interdisciplinary working through a research and innovation hub**
  Alignment within institutions e.g UoL Research Frontiers on Infection Resilience and AI for Life.

  Co-operation between institutions: UoL, LJMU, LSTM, Edge Hill and LCR NHS Trust personalised, precision and regenerative medicine agenda across research and clinical training activities.

  Collaboration across disciplines: Human and Veterinary clinicians on comparative Human and Animal Health Therapeutics. Explore opportunities for "one medicine" approaches between human and animal medicine research as the barriers to research and therapy developments are lower in animals. This is an accepted strategy by drug developers in the field.

  Collaboration across clinical areas: such as Gut-Brain axis; Brain-Skin axis.

  Taking a mission led approach to focus on broad societal goals to widen the scale and resources e.g. AMR, Children's Health, Cancer Care, Mental Health, Oral Hygiene and Animal Health.

- **Strengthening Inter-Regional and Boundary Spanning Collaboration with Biofilm & Phage communities**
  The microbiome cluster exists at the intersection of a broader microbial sector comprising biofilm and phage industry-spanning intermediaries. Enabling increased collaboration, knowledge sharing and good practice between the National Biofilms Innovation Centre and phage research and innovation communities to explore access to infrastructure and knowledge relevant to microbiome biofilm interactions; and phage therapeutic and diagnostic synergies with the microbiome sector.

- **Integrate with Bioresource Infrastructure**
  Single point of access to improve access to samples and longitudinal data through partnerships with regional or national biobanks.

- **Knowledge transfer from relevant current and legacy UKRI funded programmes e.g. UK Gut Immune Brain Axis Network (GIBA), Skin in Microbiome Healthy Ageing (SiMHA)**
  Transfer knowledge and capabilities developed under the SiMHA programme to support current and future microbiome initiatives in the region particularly relating to human health.

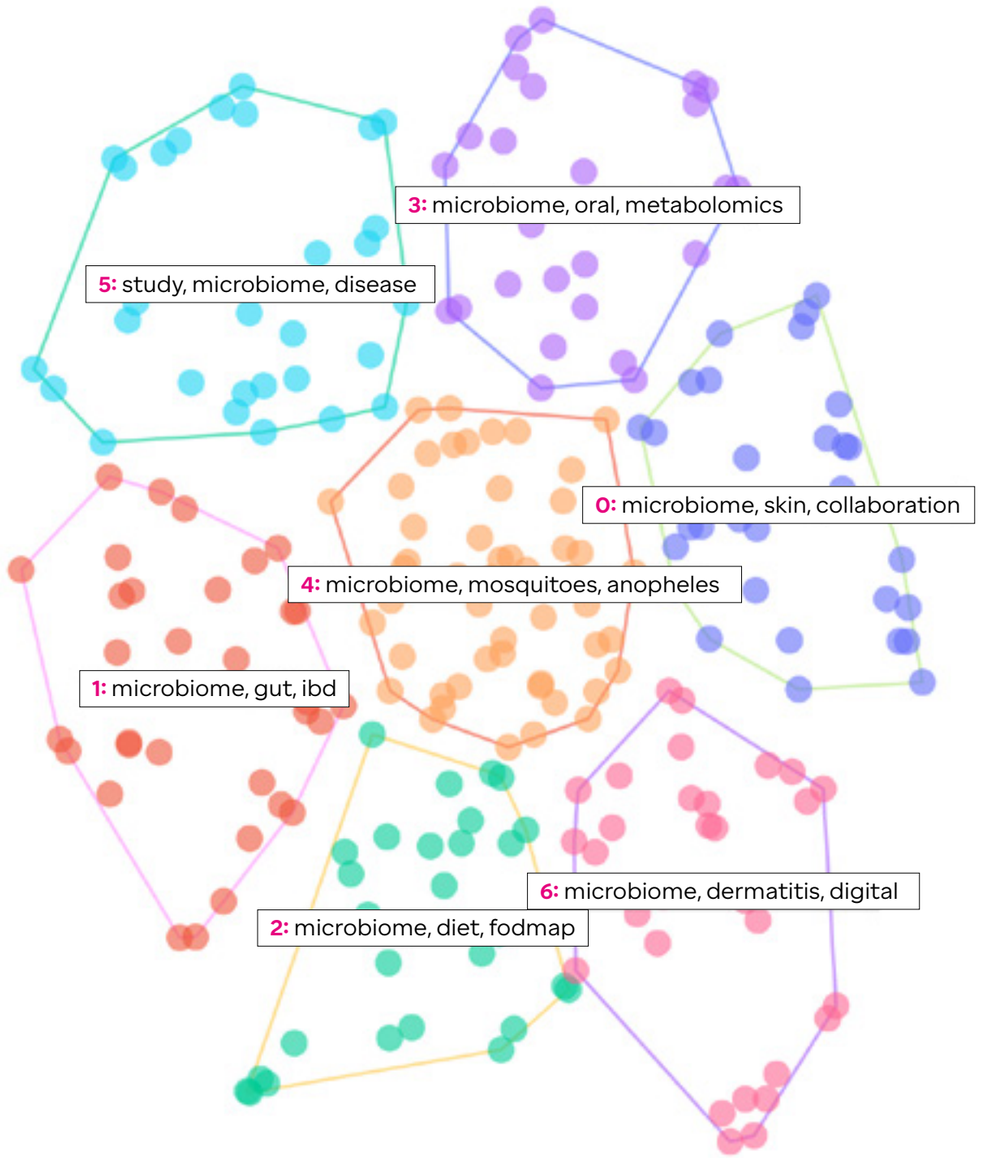
Key stakeholders

- MIC
- UoL, LJMU, LSTM, Edge Hill, LUHG/LAASP
- NBIC/Open Innovation Hub for Anti Microbial Surfaces/LHP
- LHP/UoL Liv Shared Services
- SMiHA/Unilever/ Gut Immune Brain Axis Network, Microbiome-Net
- iiCON

IUK Microbiome Strategic Roadmap (MSR) Recommendations

MSR2: Create Microbiome Research & Innovation Collaboration Networks / Virtual Microbiome Institutes

Thematic Clusters of Microbiome Research Across LCR



Recommendation: 03

Capitalise on data science capabilities to strengthen scientific rigour and advance clinical trials and regulatory pathways

Recommendations

- **Coordinated Ecosystem approach to HPC/AI/Data Storage Infrastructure**
  Leverage the LCR ecosystem as a tech stack for "in silico" expertise as a service consisting of: automated multi omic bioinformatic pipelines, explainable AI workflows for bench and clinical data applied to human health and drug discovery problems.

  Enhance connectivity between academic centres, HPC facilities, and industry through shared business development resource. This will lower the barriers to access through targeted seminars and training sessions to showcase infrastructure and services nationally and internationally.

- **Augment Experimental Design across LCR R&D with Bioinformatics**
  Embed Bioinformatics Early: Mandate involvement of informatics expertise in study design, especially for clinical trials (e.g., Statistical Analysis Plans).

  Standardise Metadata Tools: adoption of user-friendly software for metadata capture and harmonisation across projects. Promote best practices in study design using bioinformatics tools to enhance data quality, reproducibility, and translational potential.

  Leverage existing and secure funding to support more Large-Scale longitudinal and epidemiological studies to generate high-quality, reusable datasets (e.g., C-GULL model).

- **LCR wide, open access approach to health data sharing relevant to microbiome R&D**
  Federated system of microbiome datasets including research, clinical trial, population study datasets within NHS primary and secondary care and social care hosted within a Trusted Research Environment.

  Ensure academic and clinical studies account for pharma-kinetic, genetic and dietary factors and representative of large patient populations to generate sufficiently reliable data to meet robust safety and efficacy standards.

Key stakeholders

- MIC, CBF, Growth Platform, STFC Hartree Centre
- UoL, LJMU, LSTM, Edge Hill
- CDC, CHIL, STFC Hartree Centre/ HNCDI, Growth Platform, CBF
- LUHG, LHP, HIN, HDR Elixir-UK
- iiCON

IUK Microbiome Strategic Roadmap (MSR) Recommendations

MSR9: Promote a Supportive Regulatory Environment

Recommendation: 04

Enhance commercialisation and investment readiness support

Recommendations

Establish a biotech/microbiome-focused investor forum to connect innovators with funding, particularly early-stage funds for pre-start-up proof of concept work and pre-seed to Series A/B investment for SMEs.

Advisory and networking support, and customised support for scaling by accessing international markets.

Appoint Entrepreneurs in Residence capable of navigating both the biological and computing disciplines to broker opportunities to codevelop technologies with multinational corporations.

- **Develop bespoke Incubator, Accelerator Programmes and Innovation Hubs for Microbiome Startups**
  Deliver a tailored accelerator that provides IPR and regulatory training, mentorship, lab access, and commercial support for emerging microbiome ventures tailored to the needs of local business clusters and localised research activities building on Innovate UK Microbials Accelerator (2023) and Future Medicines (2025)

- **Raise commercialisation awareness and capability**
  Commercialisation skills programme/module for early-stage career researchers and pathway to iCURE, doctoral training programmes incorporating innovation, IP commercialisation, and entrepreneurship training opportunities into their programmes following models such as Nucleate. Entrepreneurs in residence can support this work.

Key stakeholders

- UoL TTO, iiCON Seed Fund, LYVA Labs, NPIF2, Northern Gritstone, BPC, BioNow, RSM, UKI2S, Innovate UK
- H&LS Cluster Board, Growth Platform
- LYVA Labs, iiCON, UoL, CPI & Professional Services Community
- LYVA Labs /MIC/CPI/MDC/CGT
- LYVA Labs, TTOs, Entrepreneurs in Residence
- iiCON

IUK Microbiome Strategic Roadmap (MSR) Recommendations

MSR3: Microbiome Entrepreneurship, Seed Funding, Regulatory and Intellectual Property Rights Support

Recommendation: 05

Develop infrastructure to accelerate product translation and market adoption

Recommendations

- **Develop "Customer/End User Benefit" Platforms**
  Establish industry-led platforms that can validate the business potential of the most promising research, improve uptake and differentiation for personal care, therapeutics, diagnostics, nutrition, animal and environmental sectors. For instance, in skincare, tools that help microbiome innovators articulate consumer-relevant product attributes (e.g. texture, usability, aesthetic)

- **Microbiome and Drug Interaction Centre**
  Examine role of microbiome in drug efficacy and side effects of major drug therapies as potential to translate into new precision medicines and associated diagnostic opportunities grows, including the development of new therapies combining intestinal microbiota transfer (IMT), live biotherapeutic products (LBPs), or other therapeutic modalities as adjunct precision therapies for a range of existing and new drug classes.

- **Manufacturing Infrastructure**
  Initiate feasibility for adapting existing LCR assets into pilot scale bioprocessing plant serving innovation in microbiome (including LBPs) and broader engineering biology related industries. This can magnify the effects and encourage interactions between pharma, chemical and process industries.

  Explore a more ambitious bioprocess innovation centre within LCR biomanufacturing corridor to address UK's commercial manufacturing gap for live biotherapeutics and related modalities, engaging with Northern Arc partners and catapult. This supports the LCR Local Growth Plan ambition.

- **Skills Institute**
  Similar to Advanced Therapies Skills Training Network with focus on technical and soft skills for the future.

Key stakeholders

– MIC/LJMU with industry

– MIC, UoL Faculties e.g. Centre for Drug Safety Science, CERSI, LSTM, LJMU; LCRCA, Industry, NHS

– LCRCA, Croda, LSTM, OLS, DSIT, BBSRC

– STFC, UoM, CPI

– iiCON

IUK Microbiome Strategic Roadmap (MSR) Recommendations

MSR10: Improve Microbiome Education, Skills and Talent Pipeline

Human Intestinal Microbiome Therapies and Diagnostics Report Recommendations

Human Intestinal Microbiome Therapies and Diagnostics Report Recommendations

Recommendation: 06

Regulatory engagement to overcome complexity and advance standards

Recommendations

- Leverage MHRA Accelerated Approval Pathways working with NHS/ NICE/MHRA pathway to bring promising microbiome therapies and diagnostics to market faster with structured support.

- Establish referral routes to utilise the Innovative Development Access Pathway (IDAP) for diagnostics and devices; and the Innovative Licensing and Access Pathway (ILAP) for therapeutics, drugs.

- Use ILAP to streamline the journey from research to patient access, particularly for novel microbiome-based interventions.

- Work with regulatory and standards bodies to develop specific regulatory sandpits for intestinal microbiota transfer (IMT), LBPs or other therapeutic modalities as adjunct precision therapies for a range of existing and new drug classes.

- a 'one-stop shop' regulatory approach to queries via the MHRA Innovation Office, providing scientific advice, guidance on conducting clinical trials, applying for market authorisation and manufacturing licenses similar to approach taken with 'Advanced therapy medicinal products: regulation and licensing'.

- Engage with policy teams of Regulatory Innovation Office (RIO), NHS Innovators Passport and UKRI

Key stakeholders

– MIC/CPI with regulatory partners: MHRA, NBSIC, NICE, Health Research Authority, Veterinary Medicines Directorate, Defra, Environment Agency

– New "virtual institute" standards network for microbiome research and biobanking; CERSIs

– MIC/CPI with RIO, NHS

– iiCON

IUK Microbiome Strategic Roadmap (MSR) Recommendations

MSR9: Promote a Supportive Regulatory Environment

Recommendation: 07

Improve public engagement and awareness of the microbiome

Recommendations

- **Support Patient and Public Involvement (PPI)**
  Embed PPI frameworks into microbiome projects to ensure alignment with public needs and expectations.

  Set up scientific, patient and public involvement advisory group.

- **Increase Microbiome Literacy and Showcase LCR Cluster**
  Launch awareness campaigns and educational resources to improve public understanding and build trust in microbiome innovations via the media, schools or civic institutions to help to create broad support for the microbiome initiative.

  Organizing events such as seminars, conferences or a "microbiome festival".

  Inviting leading researchers, environmental experts or even health and wellbeing influencers to create broad interest in the topic.

  Maintaining an educational website with YouTube videos, TED talks, interviews, book reviews and recommendations.

  Pursue ethical and equitable approaches to research that champion respectful and transparent consent procedures (including expectations for data use, sharing and privacy, and benefit sharing), and that enable data diversity, equitable evidence, and fair distribution of the benefits of resulting products.

Key stakeholders

– MIC, Civil Society Partners

– UoL- Festival of Science; LCR CA Innovation Investment Fortnight

– UKRI

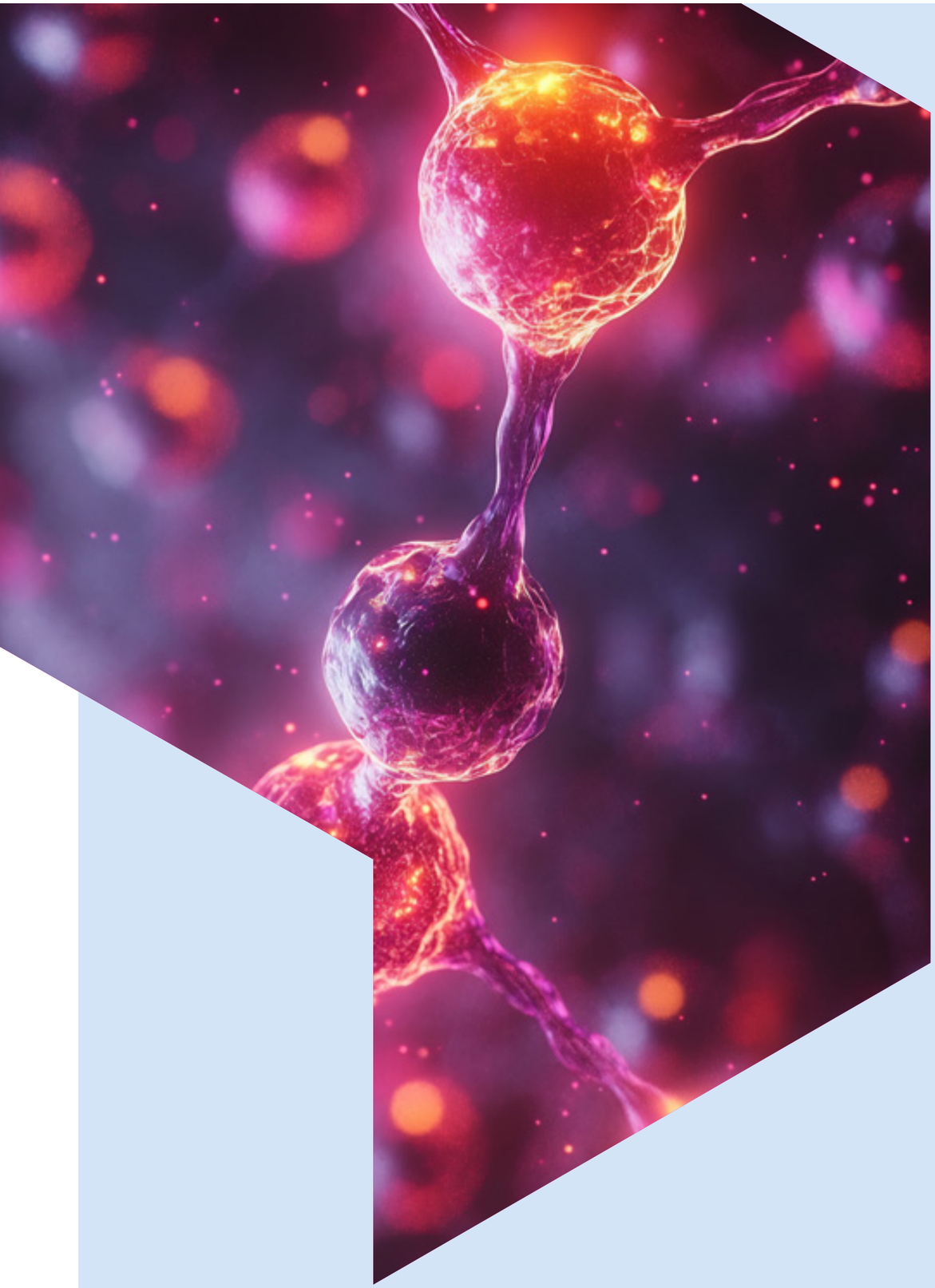
– UoL, LSTM, iiCON, UKRI

IUK Microbiome Strategic Roadmap (MSR) Recommendations

MSR10: Improve Microbiome Education, Skills and Talent Pipeline

06

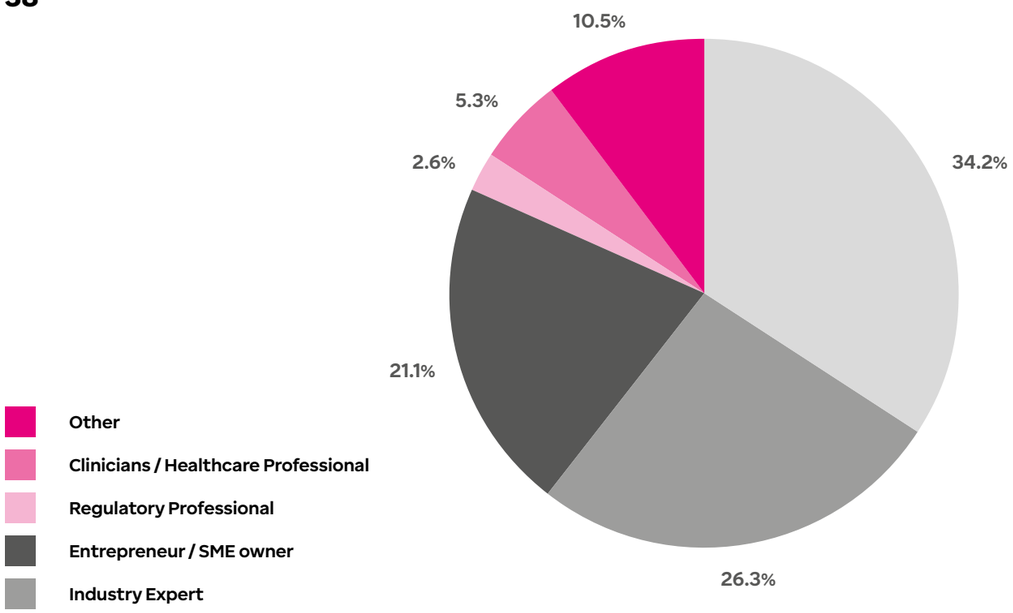
Appendices



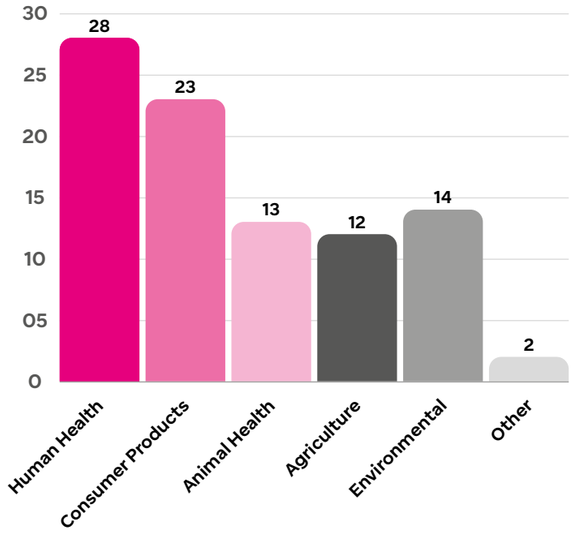
06
Appendices

Survey results & statistics

Total responses
38



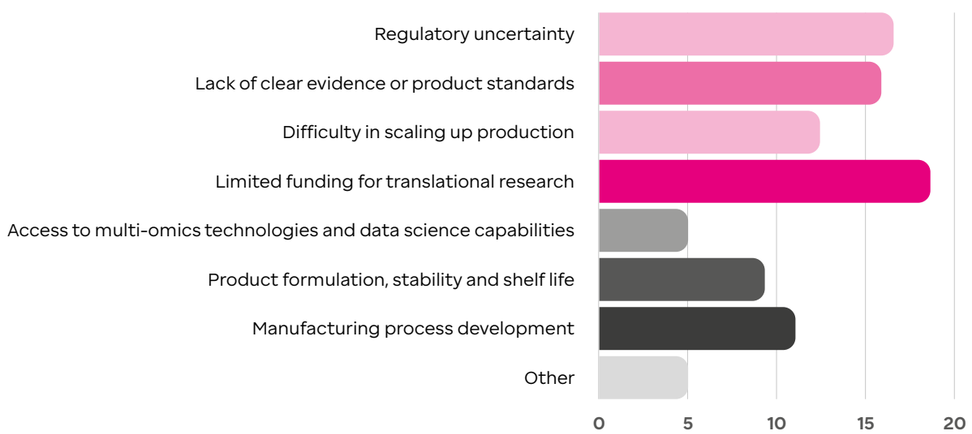
Explorers - Academics and researchers	Builders - Entrepreneurs, SMEs, Clinicians and Regulators	Scalers - Industry Experts (Big Industry, Manufacturers)
15	12	11



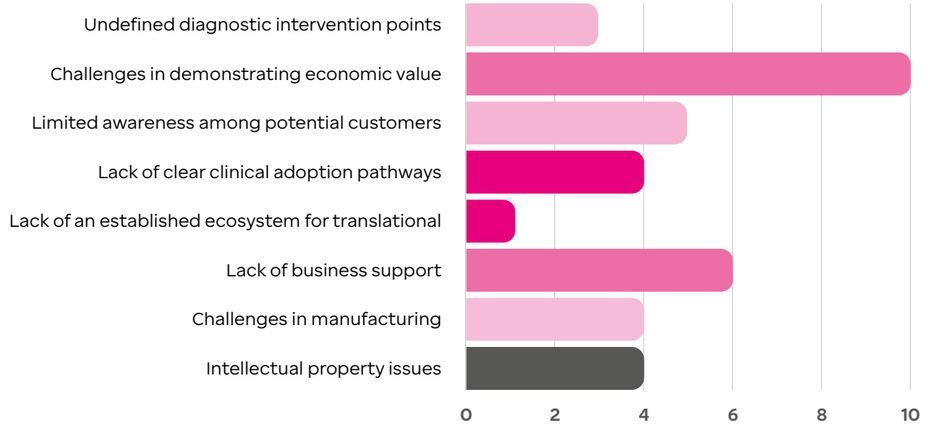
Top 3 challenges in microbiome research and development

1_ Challenge in demonstrating causality in microbiome studies.
2_ Limited undertsanding of microbiome-host interactions.
3_ Reproducibility issues in microbiome research

Barriers to Microbiome Product Translation

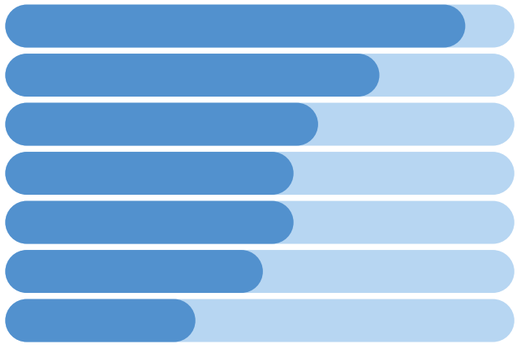


Hardest Barriers to Overcome



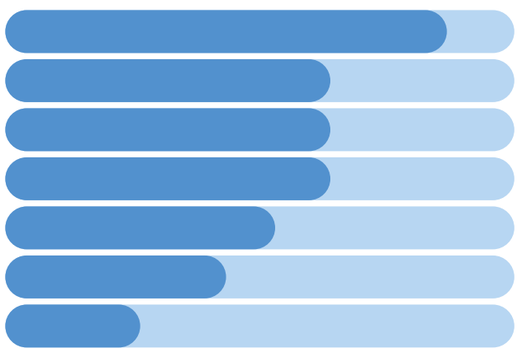
Ranking of factors for overcoming commercialisation barriers

1_ Large scale clinical trials
2_ Manufacturing facilities
3_ Data Science and AI Capabilities
4_ Access to multi-omics technologies
5_ Enterprise support
6_ Skills development programs
7_ Biobanking infrastructure

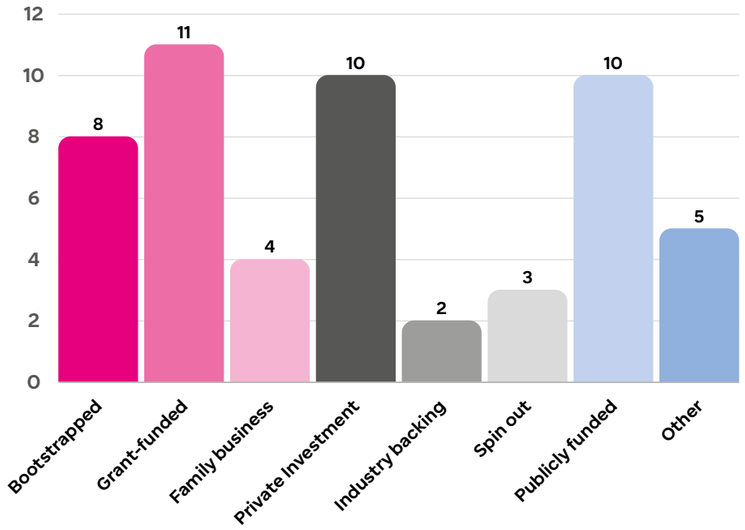


Ranking of factors for developing successful microbiome-based products

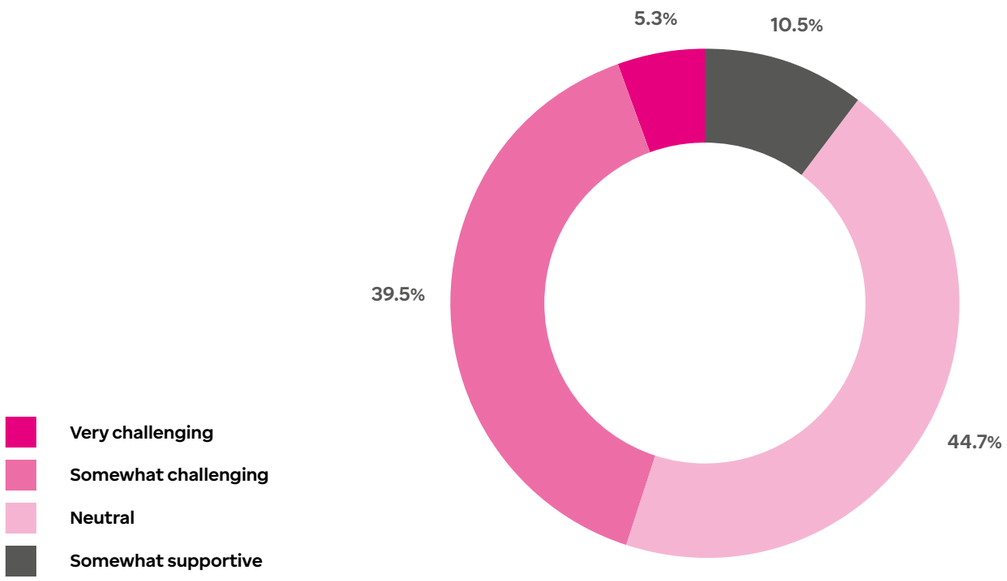
1_ Scientific rigor and validation
2_ Clear communication of product benefits
3_ Stakeholder collaboration
4_ Public and consumer acceptance
5_ Accessibility and affordability of products
6_ Access to complex microbiological models
7_ Access to multi-omics data science services



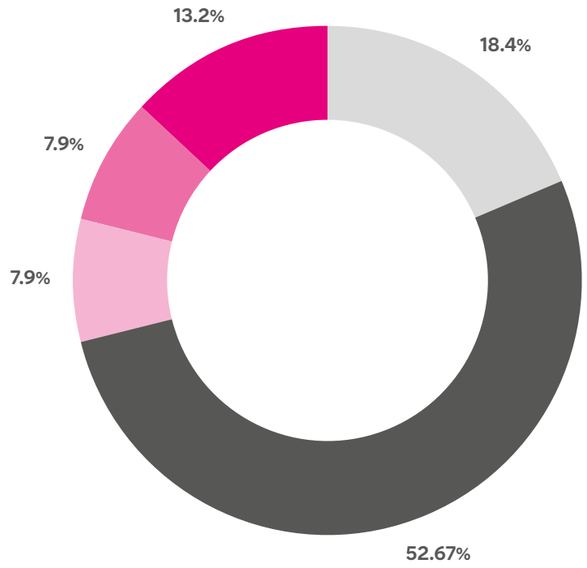
Initial funding sources for businesses – Survey respondents

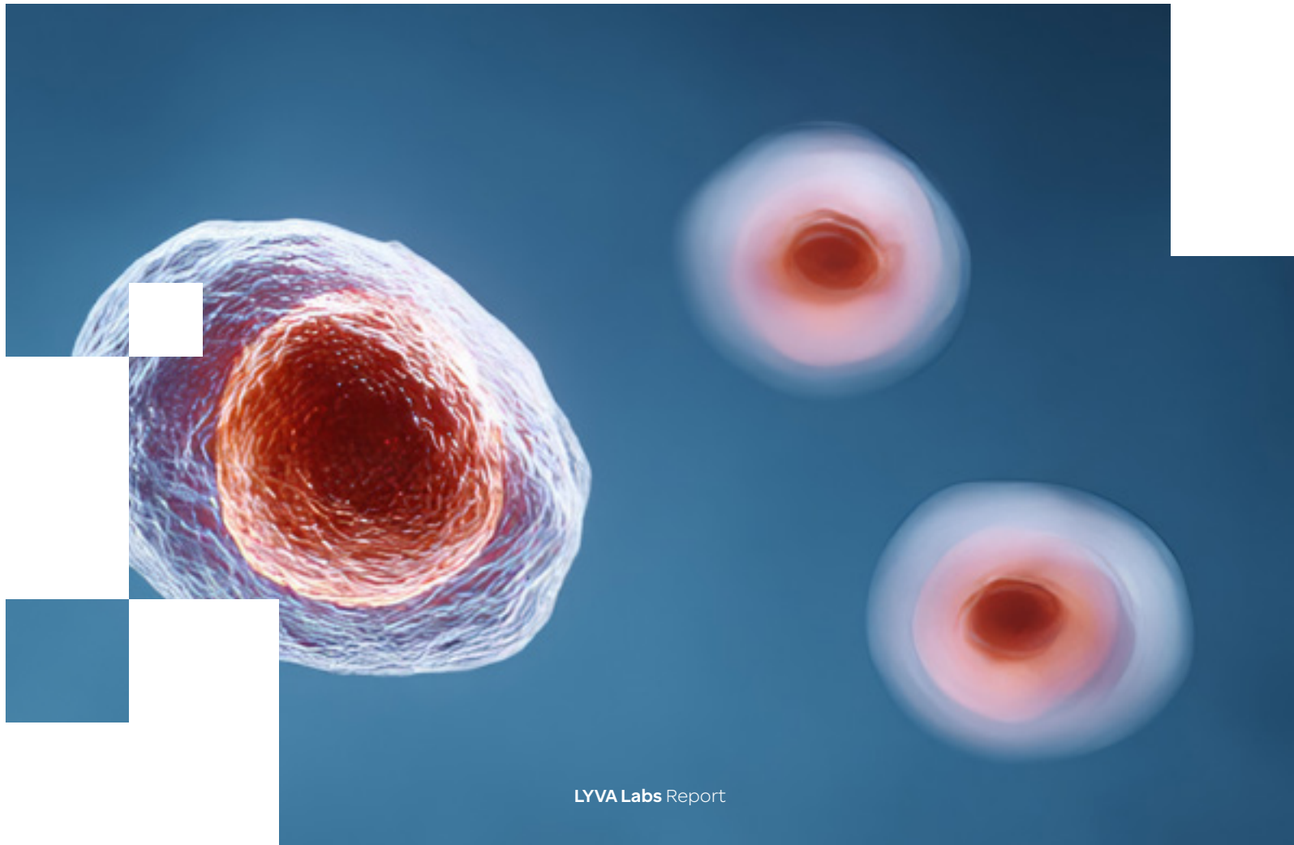


Stakeholder view on the microbiome innovation regulatory landscape



Stakeholder view on the microbiome innovation regulatory landscape





Stakeholders Consulted

S. No.	Organisation
1	Liverpool Health Partners (LHP)
2	Liverpool City Region Combined Authority (LCRCA)
3	IBM
4	STFC
5	Microbiome Innovation Centre (MIC)
6	LSTM
7	5D Health Protection
8	CPI
9	Unilever
10	University of Liverpool
11	Growth Platform
12	Elanco
13	Croda
14	Lubrizol
15	RSM
16	NIHR
17	Computational Biology Facility (CBF)
18	Clatterbridge Cancer Centre
19	MAST Group
20	Marks & Clerk
21	Quodria
22	Crobio
23	Nutricia
24	National Biofilm Innovation Centre (NBIC)
25	Liverpool John Moores University
26	United Utilities
27	Vector Consumer
28	Merseyside Recycling and Waste Authority (MRWA)
29	Marine Lake Medical Practice, Wirral
30	Enki Marine
31	Chamerion
32	Microbiome Treatment Centre (MTC) Birmingham
33	Royal Liverpool Hospital
34	In-vivo CEiRSI Manchester
35	Civic Health Innovation Labs (CHIL)
36	Pharmaron
37	iiCON
38	Health Innovation North-West Coast (HIN)
39	Gutsee
40	Reckitt
41	Lumophore
42	MHRA
43	Cheshire and Wirral partnership NHS Foundation Trust
44	Biocortex
45	British Patient Capital (BPC)
46	Seventures
47	Suez
48	Manchester Metropolitan University
49	Royal Academy of Engineering
50	Qara Consultancy
51	Entropix
52	Butters Innovation
53	Nanobiosols
54	Wundrbiotics
55	QMUL
56	The James Hutton Institute
57	Bionema
58	Beckman
59	AGA bio
60	Bangor University
61	Amity University
62	BioGrad
63	Cromerix
64	Skin Microbiome in Healthy Ageing (SMiHA) Network
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67	Pace Ventures
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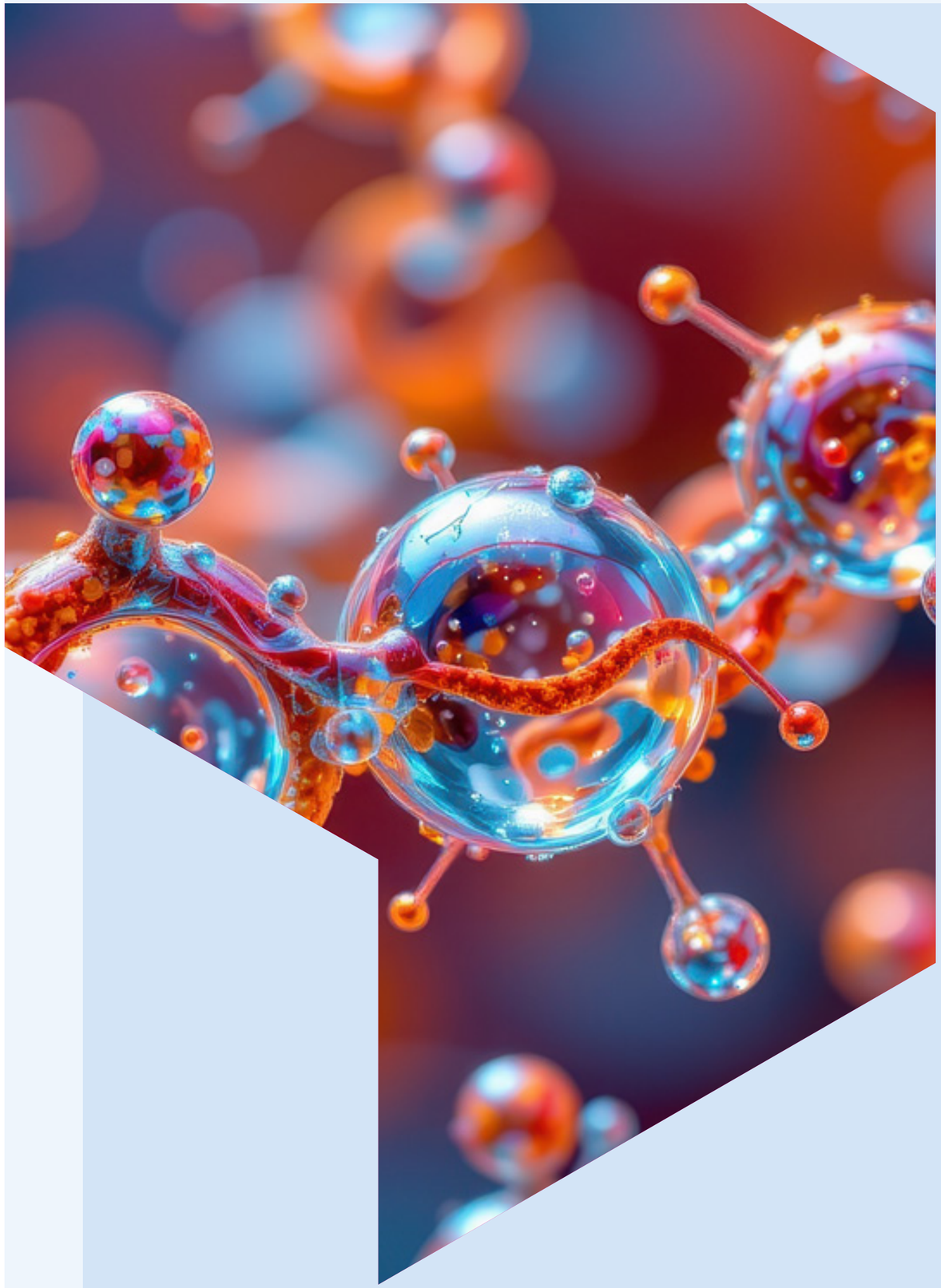

LYVA Labs
This report was written by Farhad Ahmed and Anaz Abbas. We welcome enquiries from organisations and individuals interested in exploring this report and the discrete data science report further.

October 2025.

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