Microbiome Analysis in Lithuania: Overview of the Global and Local Ecosystem, Strengths, Weaknesses, and Recommendations

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Introduction

Problem

Chronic diseases including diabetes, cancer, and heart disease are the world's leading causes of mortality and morbidity. They are responsible for 41 million deaths each year, or 74% of all deaths globally according to the World Health Organization.[1] In response, the United Nations' 2030 Sustainable Development Goals aim to reduce premature mortality from chronic diseases by one-third.[2] These goals emphasize the importance of prevention, treatment, and mental health promotion in combating these issues, and it is hypothesized that microbiome therapies and innovations could be possible solutions.

The human microbiome is a growing research area in the prevention and treatment of chronic diseases and other illnesses such as COVID-19. The microbiome is made up of trillions of microorganisms, including bacteria, viruses, fungi, and archaea that reside in and on our bodies, and plays a vital role for our health by supporting the immune system and preventing disease.[3] The European Innovation Council recognizes gut microbiome analysis and therapy as significant innovations with the potential to address the global challenge of chronic diseases.[4]

With the growing global emphasis on the microbiome and the rise of chronic diseases, it is essential to explore Lithuania's potential within this field. In 2022, Lithuania's expanding life sciences sector contributed 2.7% to the country's GDP, with a goal of increasing this percentage to 5% by 2030.[5] Microbiome research presents a significant opportunity to support this ambition by meeting the rising demand for innovative health solutions.

Further growth is supported by strategic initiatives such as the "New Generation Lithuania" plan, which focuses on investments in education, innovation, and personalized healthcare.[6] This plan lays a solid foundation for breakthroughs in microbiome-related health technologies, contributing to improved public health outcomes and positioning Lithuania as an emerging leader in this field.

Goal

The goal of the project is to enhance Lithuania's global competitiveness in the microbiome sector by identifying recommendations for promising scientific and industrial opportunities.

Project milestones

The project goal will be achieved by fulfilling these project milestones:

1. Overview of microbiome terminology and importance
2. Global overview and emerging trends in the microbiome sector

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[1] https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases#:~:text=Key%20facts,-%20and%20middle-income%20countries

[2] https://sdgs.un.org/2030agenda

[3] https://humanmicrobiomeaction.eu/human-microbiome/

[4] https://op.europa.eu/en/publication-detail/-/publication/7c1e9724-95ed-11ec-b4e4-01aa75ed71a1

[5] https://investlithuania.com/wp-content/uploads/Lithuanian-Life-Sciences-sector-facts-and-figures-2023.pdf

[6] https://2021.esinvesticijos.lt/2021-2026-m-planas-naujos-kartos-lietuva/apie-plana-naujos-kartos-lietuva

3. Case study analysis of successful foreign practices
4. Overview of the microbiome sector in Lithuania
5. SWOT analysis of the microbiome sector in Lithuania
6. Recommendations for Lithuania

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Microbiome Terminology and Importance

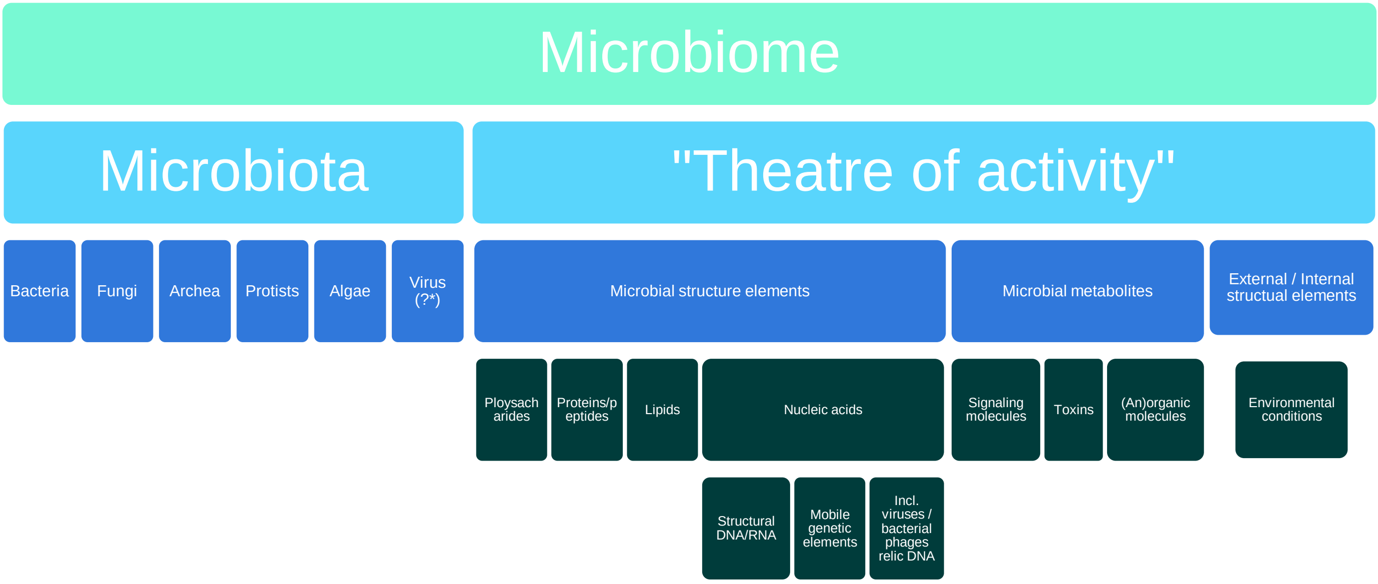
Microbiome Terminology

The microbiome refers to the collection of trillions of bacteria, viruses, yeast, fungi, and archaea, including their genetic material, and their interactions inside and on a host organism or environment.[7]

While the term 'microbiome' broadly encompasses the diverse microorganisms within a host, the distinction between the terms 'microbiota' and 'microbiome' is often misunderstood or used interchangeably. Microbiota describes the living microorganisms found in a defined environment, such as oral and gut microbiota.[8] The microbiome refers to the collective genomes of all microorganisms within a given environment. This includes not only the microbial community, known as the microbiota, but also their "theater of activity," which encompasses structural components, metabolites, signaling molecules, and surrounding environmental conditions. In this sense, the microbiome represents a broader concept than microbiota, capturing both the organisms and their dynamic interactions within their habitat.[9] Understanding these distinctions is essential, as the microbiome's influence reaches beyond individual hosts to impact entire ecosystems and the interconnected health of humans, animals, and the environment.

Figure 1

Microbiome Terminology Components



Note: prepared by the authors, based on Xia & Sun, 2023[10]

[7] https://op.europa.eu/en/publication-detail/-/publication/69446d55-1f41-11ec-bd8e-01aa75ed71a1/language-en

[8] https://doi.org/10.1038/s41392-022-00974-4

[9] https://doi.org/10.1016/b978-0-323-98338-9.00001-3

[10] https://doi.org/10.1016/b978-0-323-98338-9.00001-3

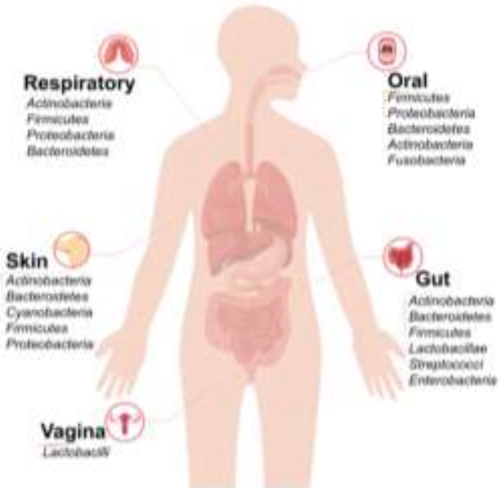
The Role of the Microbiome in Human Health

The composition and distribution of the human microbiome vary from person to person. It is influenced by genetic factors as well as environmental conditions, including diet and medication use. Bacteria make up approximately 99.9% of the human microbiome, while fungi, viruses, and phages collectively account for less than 0.1%.

Within the human body, the gut microbiome composes about 95% of the total human microbiome and is considered to be the most important one for maintaining health.[11] The second largest microbial community is the oral cavity, which includes smaller habitats, including the tongue, gums, and palate habitats. The rest of the human microbiome is made up of the skin, nose, respiratory, and vagina microbiomes, all of which have unique compositions of microbiota.[12]

Figure 2

Microbiota Composition in the Human Body



Note: source from Hou et al., 2022.[13]

The human microbiome plays a crucial role in various processes:

Microbiome and its Role in Digestion and Metabolism

Microbiota in the gut play a vital role in digestion and metabolism by breaking down complex carbohydrates and dietary fibers that the body cannot process by itself. This breakdown produces short-chain fatty acids (SCFAs), which are essential nutrients that help nourish the cells lining your gut, promoting a healthy digestive environment.

In addition to their role in digestion, gut bacteria provide enzymes necessary for synthesizing important vitamins such as B1, B9, B12, and K. Though small in quantity, these micronutrients are critical, as deficiencies in them can lead to significant health issues, including vitamin B12 deficiency, folate deficiency, and vitamin K deficiency.

Moreover, gut bacteria assist in metabolizing bile in the intestines. When the liver releases bile to aid in fat digestion, bacteria break down the bile acids, allowing them to be reabsorbed and recycled. This recycling process is vital

[11] https://op.europa.eu/en/publication-detail/-/publication/69446d55-1f41-11ec-bd8e-01aa75ed71a1/language-en

[12] https://doi.org/10.1038/s41392-022-00974-4

[13] https://www.nature.com/articles/s41392-022-00974-4

because, without it, the body wouldn't have enough bile to digest fats properly, and cholesterol could build up in the bloodstream, leading to potential health problems.[14]

Considering the vital role gut bacteria play in these processes, it's evident that preserving a balanced gut microbiome is essential. Dysbiosis refers to a disruption in the gut microbiome, defined as the imbalance of microorganisms in the body. This is characterized by the loss of beneficial microorganisms, the overgrowth of potentially harmful bacteria, and a decrease in overall microbial diversity.[15] Dysbiosis can trigger low-grade systemic inflammation, which elevates the risk of obesity and metabolic diseases.[16] Additionally, it has been associated with various chronic diseases, including gastrointestinal, inflammatory, metabolic, neurological, cardiovascular, and respiratory illnesses.[17]

The gut microbiota also impact functions in the brain and skin through the gut-brain axis and gut-skin axis, which will be explained further in detail.

Microbiome and its Role in the Immune System

Microbiota regulate the immune system and maintain balance (homeostasis) by producing cytokines and T cells, which are essential for potecting the body against pathogens. The microbiome interacts closely with the immune system and is strongly influenced by environmental factors during birth and infancy. It also plays a role in the development of certain immune system components, such as myeloid cell derivatives, suggesting that microbiota influence immune cell differentiation and the effectiveness of immune responses.[18]

Environmental factors, particularly diet and antibiotics, significantly impact the microbiome. Diet alters the microbiota and, in turn, alters T cell responses to microbes. Antibiotics decrease the level and diversity of the microbiota, reducing the efficacy of the immune response.[19]

Microbiome and its Role in Mental Health

The microbiome plays a crucial role in mental health through the gut-brain axis, which is the bi-directional communication between the brain and gut microbiome. In addition to regulating cortisol and amino acid pathways, the gut microbiota produce neurotransmitters and short-chain fatty acids (SCFAs) which promote mental health well-being. In turn, the brain affects the gut microbiota by modulating gut functions and secreting signaling molecules, which affect the health and functions of bacteria in the gut.[20]

Therefore, an imbalance in the gut microbiome directly affects the brain. The abundance or scarcity of several microbiota is linked to mental health illnesses including depression, anxiety, and bipolar disorder.[21] Neurodegenerative diseases, such as Alzheimer's and Parkinson's, are also correlated with dysbiosis. There is growing support and research to use microbiota-based treatments for these conditions.

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[14] https://my.clevelandclinic.org/health/body/25201-gut-microbiome

[15] https://doi.org/10.1093/advances/nmy078

[16] https://doi.org/10.1016/j.biopha.2022.112678

[17] https://doi.org/10.1038/s41430-021-00991-6

[18] https://doi.org/10.1615/critrevimmunol.2019033233

[19] https://doi.org/10.3390/nu11122862

[20] https://pmc.ncbi.nlm.nih.gov/articles/PMC4367209/

[21] https://doi.org/10.3390/nu15143258

Recent research has demonstrated that prebiotics and probiotics, which contain beneficial bacteria, can alter the microbiome to treat mental health disorders. These are known as psychobiotics, and evidence suggests that they potentially have positive effects on mood, cognition, and anxiety. For example, probiotics like *Lactobacillus* secrete gamma-aminobutyric acid (GABA), which leads to reduced depression-like symptoms. Therefore, incorporating probiotic-rich foods into the diet may support mental health by boosting beneficial bacteria and reducing harmful ones.[22]

Microbiome and its Role in Cancer

The microbiome is increasingly associated with its role in cancer. Certain strains of bacteria are associated with colorectal cancer, gastric cancer, lung cancer, breast cancer and serve as biomarkers for early diagnosis and prevention. An earlier diagnosis is crucial to increasing survival rate and being able to develop personalized interventions.[23]

It is essential to also consider the effects cancer treatments can have on the microbiome itself. Chemotherapy and immunotherapy in cancer treatment heavily alter the microbiome, increasing harmful bacteria and reducing beneficial bacteria, leading to cognitive impairment and neuroinflammation. This dysbosis can also lead to tumor progression.[24]

Researchers have found potential in altering microbiota to better respond to cancer treatments. One method is by using antibiotics targeted towards the carcinogenic microbiota. Although antibiotics are generally harmful towards the microbiome and are related to poor clinical outcomes for cancer patients, antibiotics targeted towards specific microbiota may assist in improving clinical outcomes and cancer prevention by killing harmful bacteria. Another method is genetically modifying bacteria in the microbiome to enhance their anti-cancer activity.[25] This strategy restores the balance of beneficial bacteria and can lead to improved clinical outcomes for cancer patients.

Microbiome and its Role in Skin Health

The skin, our largest organ, acts as a barrier against external threats. The skin microbiota assist in this protection by secreting molecules to kill pathogens.[26] However, disruptions in gut microbiome diversity can weaken this defense, affecting immune tolerance and skin health. Gut dysbiosis triggers immune responses and is linked to conditions such as acne, allergies, atopic dermatitis, psoriasis, and rosacea.

This connection between the gut and skin is called the gut-skin axis, which explains how gut microbes influence skin health through immune and metabolic processes, such as regulating the function of immune cells.

Diet plays a major role in this relationship: high-fat diets decrease microbial diversity and increase the production of lipopolysaccharides, leading to inflammation and a higher risk of allergic diseases and skin conditions. In contrast, high-fiber diets promote beneficial bacteria and reduce inflammation. Additionally, consuming prebiotics and probiotics improves anti-inflammatory responses by supporting positive microbial populations in the gut.[27]

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[22] https://doi.org/10.1007/s12031-022-02053-3

[23] https://pmc.ncbi.nlm.nih.gov/articles/PMC10376920/

[24] https://doi.org/10.3390/microorganisms12010024

[25] https://doi.org/10.1038/s41392-023-01406-7

[26]https://pmc.ncbi.nlm.nih.gov/articles/PMC7444652/#:~:text=A%20recently%20recognized%20essential%20function,antimicrobial%20peptides%20and%20other%20molecules.

[27] https://doi.org/10.1080/19490976.2022.2096995

Microbiome and its Role in Maternal and Infant Health

The microbiome plays a crucial role in both maternal and infant health. During pregnancy, dysbiosis of the gut microbiome can lead to adverse outcomes, including gestational diabetes, preeclampsia, and restricted fetal growth.[28]

Several factors influence the health of the infant's microbiome. For example, the mode of delivery significantly influences the microbiome composition. Babies born vaginally are exposed to their mother's vaginal and gut microbiota, which helps develop a microbiome that supports immune development. In contrast, infants born via cesarean section often develop a microbiome more similar to their mother's skin microbiome, which may negatively impact their immune system and increase the risk of allergies, asthma, and autoimmune disorders.[29][30]

Breastfeeding also plays a key role in infant health by providing beneficial bacteria, such as Bifidobacterium, which nourish the gut microbiota. This support is vital for promoting a healthy microbiome and fostering stronger immune development, ultimately laying the groundwork for the infant's long-term health.[31]

As the infant grows, their microbiome becomes more diverse with increased exposure to the environment. By the age of 3, the child's microbiome follows similar patterns to an adult's microbiome. In adolescence, the microbiome continues to increase in stability and diversity. During these stages of development, environmental factors such as diet, antibiotic use, and living space heavily influence the composition and health of the microbiome.[32]

In older age, the composition of the microbiome also undergoes major shifts. Unhealthy ageing is associated with decreased variability in the microbiome and a reduction in beneficial species, which are crucial in maintaining homeostasis.[33]

Microbiome and its Role in COVID-19

Coronovirus disease (COVID-19) susceptibility, severity, and outcomes have been linked to an altered and less diverse gut microbiome. Increased levels of *Enterococcus* and *Enterobacteriaceae* bacteria are associated with increased severity of infection, while the abundance of probiotic bacteria, such as *Bifidobacterium*, decreases as COVID-19 severity increases.[34]

Studies have also shown that patients treated with antibiotics experienced more significant disruptions to their microbiomes, as well as more severe COVID-19 outcomes. In patients with long-term illness, microbiome dysbiosis persisted for a longer period. Additionally, there is evidence that changes in the gut microbiome can lead to changes in the bloodstream, potentially increasing the risk of bloodstream infections.[35] The primary challenge is determining if the dysbiosis was due to COVID-19, or is the effect.

Several microbiome-based treatments, including dietary changes, fecal microbiota transplantation, probiotics, prebiotics, and microbiota-derived metabolites, have shown beneficial outcomes in clinical trials against COVID-19.

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[28] https://doi.org/10.3389/fcimb.2022.824925

[29] https://doi.org/10.3390/microorganisms8101587

[30] https://pmc.ncbi.nlm.nih.gov/articles/PMC8733716/

[31] https://hms.harvard.edu/news/diet-gut-microbes-immunity

[32]https://pmc.ncbi.nlm.nih.gov/articles/PMC8714606/#:~:text=During%20childhood%20years%20the%20diversity,species%20(113%2C%20114)

[33] https://doi.org/10.1038/s41575-022-00605-x

[34] https://doi.org/10.3389/fimmu.2023.1180336

[35] https://doi.org/10.1038/s41467-022-33395-6

Oral probiotics and prebiotics, in particular, have been found to boost antiviral activity, increase gut microbial diversity, and improve recovery in COVID-19 patients. Microbiome-based approaches not only hold promise for preventing or treating COVID-19 but could also enhance the efficacy of vaccines.[36]

COVID-19 has also affected infants born during the pandemic. An analysis revealed differences in microbiome diversity between infants born before and during the pandemic, and other studies demonstrated that the risk of childhood conditions such as obesity, myopia, and mental health disorders increased during this period.[37]

Environmental Microbiome

The environmental microbiome is fundamental to the stability of ecosystems, driving processes such as nutrient cycling, climate regulation, and soil fertility. [38]

Nutrient Cycling in Soil

One of the primary roles of microbial diversity in ecosystems is in nutrient cycling. Nutrient cycling in soil involves the transformation and movement of essential elements such as carbon, nitrogen, phosphorus, and sulfur. Soil microbes are pivotal in these cycles, mediating processes that convert nutrients into forms accessible to plants and other organisms.

Figure 3

Nutrient Cycling in Soil

Carbon Cycle	Nitrogen Cycle	Phosphorus Cycle	Sulfur Cycle
• Microbiota decompose organic matter into simpler compounds and release carbon dioxide through respiration • Bacteria recycle carbon and produce humus, which improves soil structure and fertility	• Soil microbes convert atmospheric nitrogen into ammonia through nitrogen fixation • Other bacteria then transform ammonia to nitrites and nitrates, which plants ingest as nutrients • Denitrifying bacteria turn nitrates back into nitrogen gas, preventing excess nitrogen buildup in the soil	• Bacteria and fungi in the soil help release phosphorus from organic and inorganic sources, making it accessible to plants • *Mycorrhizal* fungi form symbiotic relationships with plant roots, improving phosphorus and nutrient absorption	• Sulfur-oxidizing bacteria in the soil convert sulfides into sulfate, which plants then absorb to make amino acids and proteins • Sulfate-reducing bacteria then change sulfate back into sulfide

Note: source from Ruikar et al. (2024).[39]

[36] https://doi.org/10.1038/s41575-022-00698-4

[37] https://doi.org/10.1038/s41575-022-00698-4

[38] https://doi.org/10.48047/AFJBS.6.Si1.2024.198-216

[39] https://www.afjbs.com/uploads/paper/b81b1ed007342ac572735500a7c1c6b3.pdf

Climate Regulation

Microbiota play a crucial role in climate regulation through their involvement in biogeochemical cycles and greenhouse gas dynamics. Photosynthetic microorganisms help mitigate climate change by converting carbon dioxide into organic carbon, and other microorganisms contribute to global warming by producing methane or nitrous oxide, potent greenhouse gases.

Soil Health and Erosion Prevention

Soil microbes facilitate nutrient cycling and improve soil health by decomposing organic matter, leading to humus formation. Humus enhances soil texture, water retention, and aeration, supporting root growth and nutrient availability, benefiting plant health and productivity. Additionally, microbial exudates, such as polysaccharides, bind soil particles, forming stable aggregates that reduce erosion and improve soil stability.

However, human activities like intensive agriculture, deforestation, pollution, and climate change can harm them, leading to soil degradation and reduced fertility. Overuse of fertilizers and pesticides, as well as land conversion, disrupts microbial communities, reducing their ability to decompose organic matter and cycle nutrients.

To counteract these negative impacts, sustainable practices like crop rotation, organic farming, reduced tillage, and cover crops can help restore microbial diversity, promoting nutrient cycling, improve soil structure, overall health, and enhance fertility.[40]

Human-Environmental Microbiome Interactions

The One Health Concept

Human and environmental health is closely interconnected and dependent on one another. One Health is a concept that describes this relationship between the human, animal, and environmental microbiomes. Changes in the environment, such as warming temperatures, alter the soil microbiome's physical and chemical composition, leading to less nutrient-rich food, and therefore a less diverse microbiome in both humans and animals. This negatively affects human and animal health by increasing disease susceptibility.[41] In turn, human activities such as urbanization and pollution hurt the environmental microbiome by lowering soil microbial diversity. It also negatively impacts animal health, with habitat loss. This leads to an increase in soil-borne pathogens, which then negatively affect the health of animals and humans who are exposed to that soil microbiome.[42] Emphasizing the importance of the connection between human and environmental microbiomes and increasing collaboration between these sectors is crucial to improve human, animal, and environmental health.

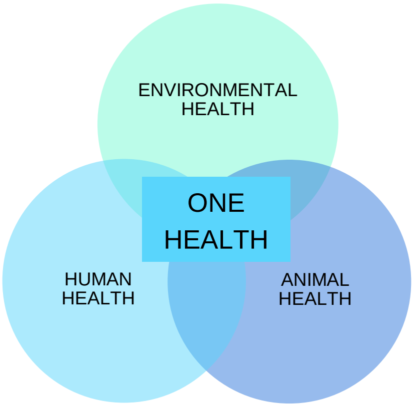
[40] https://www.afjbs.com/uploads/paper/b81b1ed007342ac572735500a7c1c6b3.pdf

[41] https://www.sciencedirect.com/science/article/pii/S2949704323000318?via%3Dihub

[42] https://doi.org/10.1038/s41579-022-00779-w

Figure 4

One Health Principle



Note: prepared by authors based on the Destoumieux-Garzón et al., 2018.[43]

The One Health Joint Plan of Action seeks to unite countries on an actionable strategy to achieve the 2030 Sustainable Development Goals (SDGs) through One Health approaches. The goals related to human health are SDG 1 (No Poverty) and SDG 3 (Good Health and Well-Being). The environmental related goals are SDG 6 (Clean Water and Sanitation), SDG 13 (Climate Action), SDG 14 (Life Below Water), and SDG 15 (Life on Land). The health of all living systems is covered by SDG 2 (Zero Hunger) and SDG 11 (Sustainable Cities and Communities), and SDG 17 (Partnerships for the Goals) is crucial for the implementation of the One Health approach. Understanding the interconnectedness of all living systems under the One Health perspective is critical to achieving the SDGs. By fostering interdisciplinary collaboration and sustainable practices, this approach lays the foundation for solutions to global health and environmental challenges.[44]

Figure 5

Sustainable Development Goals through the One Health Approach

Note: source from One Health and the United Nations Sustainable Development Cooperation Framework, 2023. [45]

[43] https://www.researchgate.net/publication/322642012_The_One_Health_Concept_10_Years_Old_and_a_Long_Road_Ahead

[44] https://doi.org/10.4060/cc5067en

[45] https://doi.org/10.4060/cc5067en

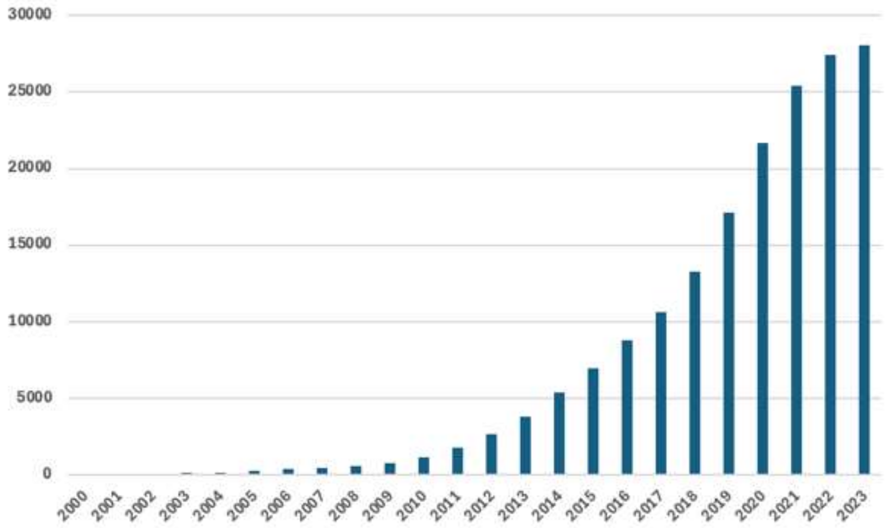
Global Overview and Emerging Trends in the Microbiome Sector

Overview of Microbiome Research and Innovations

Microbiome research has rapidly advanced over the past decade, fueled by breakthroughs in molecular biology and sequencing technologies.[46] Publication rates in this field have surged by 634.39% from 2013 to 2023, reflecting its increasing prominence across academia (**Figure 6**).

Figure 6

Publications with Search Query: Microbiome



Note**:** prepared by authors from PubMed data.[47]

Based on the number of published studies by country, the United States has remained the leader in microbiome research since 1985, with over 26,000 publications. Since 2018, China has emerged as a significant contributor, showing a consistent year-over-year increase in its number of publications. In Europe, Germany and the United Kingdom have been the most prominent contributors to microbiome research (**Figure 8**).[48]

In terms of innovation, based on the number of companies involved in research and development (R&D), as well as the volume of drug and therapy candidates and ongoing clinical trials, the United States is recognized as the global leader in microbiome research, based on 2021 data. In Asia, South Korea leads the field, while France and the United Kingdom are among the top contributors in Europe (**Figure 7**).[49]

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[46] https://doi.org/10.1016/j.soh.2024.100065

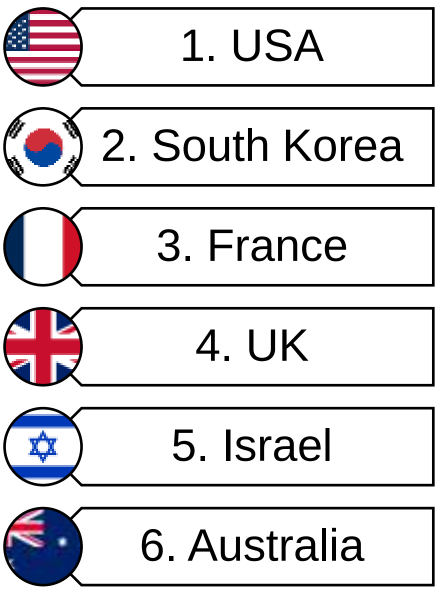
[47] https://pubmed.ncbi.nlm.nih.gov/?term=microbiome

[48] https://doi.org/10.1093/procel/pwad031

[49] https://www.gazettelabo.fr/media/files/211007_CP_APM_EtudeSectorielle2021_VF.pdf

Figure 7

Microbiome Innovation Leaders



Note: prepared by authors, data obtained from Alliance Promotion Microbiote, 2021.[50]

Figure 8

Microbiome Research Leaders

Note: prepared by authors, data obtained from Gao et al., 2023.[51]

Sector Size

According to PwC, the market for microbiome-based prescription products is still in its early stages, with varying estimates of its global value. Strategic Market Research estimated the prescription-based microbiome market at $115 million in 2021, with projections to reach $1.3 billion by 2030. While these figures are small compared to other therapeutics markets, such as oncology, they do not account for the potential of microbiome-based therapies to replace conventional treatments. Given their broad potential applications, microbiome-based prescription products are expected to evolve into a multi-billion-dollar industry by 2030.

In contrast, non-prescription microbiome products, including consumer-focused items like probiotic supplements, are more established and considerably larger in scale. This segment is projected to grow at a compound annual growth rate (CAGR) of 6.4%, reaching $85.4 billion by 2027.[52]

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[50] https://www.gazettelabo.fr/media/files/211007_CP_APM_EtudeSectorielle2021_VF.pdf

[51] https://doi.org/10.1093/procel/pwad031

[52] https://www.strategyand.pwc.com/de/en/industries/pharma-life-sciences/impact-microbiome-therapeutics.html

Sector Products

The microbiome sector encompasses a diverse range of products. There is no generalized system of classification, but several authors have designed their own frameworks for categorizing microbiome-related therapies and supplements. Manrique et al. outline three generations of products, where the first generation includes interventions, the second generation ecompasses therapies, and the third generation focuses on personalized medicine (**Figure 9**). Gulliver et al. classify microbiome-based products into nutrients, bacterial, or "microbiome mimetics" (**Figure 10**).

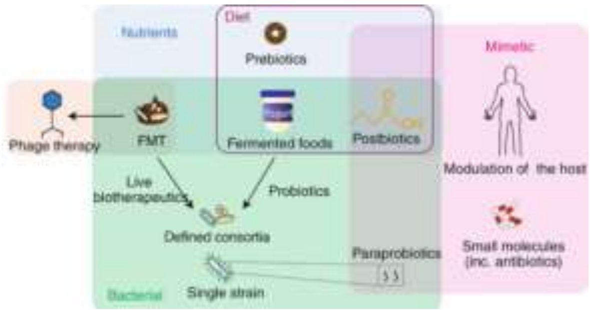
Figure 9

Three Generations of Products (Manrique et al.)

Note : source from Manrique et al., 2024.[53]

Figure 10

Microbiome-Based Product Classification (Gulliver et al.)



Note : source from Gulliver et al., 2022.[54]

The authors of this analysis categorized microbiome-based products into therapeutics, dietary supplements, and food-based approaches. Therapeutics focus on medical interventions, such as fecal microbiota transplantation (FMT) and live biotherapeutic products. Dietary supplements are designed to enhance gut health and are generally not approved to treat disease. Food-based interventions include dietary strategies and functional foods that influence microbiome composition and diversity.

This framework offers a comprehensive view of the sector:

Figure 11

Microbiome Sector Products

Microbiome Sector		
Therapeutics	**Dietary Supplements**	**Food**
• Microbiome-derived metabolite therapy • Fecal microbiota transplantation • Live biotherapeutic products → Genetically modifiied bacteria → Phage therapy	• Probiotics • Prebiotics • Synbiotics • Postbiotics • Psychobiotics	• Diet intervention • Functional foods

Note: prepared by authors

[53] https://doi.org/10.20517/mrr.2023.80

[54] https://www.researchgate.net/publication/360835425_Review_article_the_future_of_microbiome-based_therapeutics

Therapeutics

Microbiome-based therapies are increasingly being researched, as they combat antibiotic resistance and have higher specificity than modern medicines. Therapies targeting the microbiome include microbiome-derived metabolite therapy, fecal microbiota transplantation (FMT), and live biotherapeutic products (LBPs).[55]

Microbiome-Derived Metabolite Therapy

Microbial metabolites play a vital role in linking diet, the gut microbiome, and host health. Two key classes—short-chain fatty acids (SCFAs) and tryptophan (Trp) metabolites—are known to influence inflammation, immunity, and metabolism. Many diseases are linked to an imbalance in the gut microbiome and a decrease in microbial metabolite production, making the provision of these metabolites a multi-targeted treatment approach. While numerous preclinical studies highlight the therapeutic potential of SCFAs and Trp metabolites, they often require high doses and frequent administration to achieve systemic effects, limiting their clinical use. To overcome these challenges, several pharmaceutical strategies have been developed to enable targeted, delayed, or sustained delivery of microbial metabolites. These strategies, such as enteric encapsulation, esterification with dietary fiber, prodrugs, and nanoformulations, are setting the stage for the next generation of microbiome-based therapeutic approaches. [56]

Fecal Microbiota Transplantation

Fecal microbiota transplantation (FMT) is an emerging therapy that involves transferring fecal matter from a healthy donor to a recipient to restore gut microbiota. FMT confers health benefits by increasing microbial diversity and altering metabolite production. The donor stool replenishes the recipient's disrupted gut microbiome, reintroducing beneficial strains and improving resistance against pathogenic bacteria.[57]

Currently, FMT is primary used to treat recurrent *Clostridioides difficile* infection (CDI), an infectious disease of the colon that is difficult to treat with antibiotics. Researchers are also investigating its potential for treating inflammatory bowel disease, irritable bowel syndrome, metabolic disorders, and other conditions.[58]

Although FMT has demonstrated beneficial outcomes, there are still several risks that underscore the need for further investigation before widespread approval. The primary safety concern is the possible spread of infectious pathogens, especially for immunocompromised patients.[59] Another challenge is standardization, since FMT‘s effectiveness depends on the health of the donor and stool processing methods. New FMT strategies to improve standardization include developing non-invasive techniques such as oral medication alternatives and identiying specific bacterial strains responsible for therapeutic effects.[60]

FMT‘s regulatory framework varies across countries. The United States Food and Drug Administration (FDA) classifies FMT as an investigational therapy. It is not approved for the treatment of Crohn's disease or irritable bowel

[55] https://doi.org/10.1093/gastro/goab046

[56] https://www.sciencedirect.com/science/article/abs/pii/S0163725824000251

[57] https://doi.org/10.1093/cid/ciad639

[58] https://doi.org/10.3748/wjg.v28.i23.2546

[59] https://doi.org/10.2147/idr.s419243

[60] https://doi.org/10.20517/mrr.2023.80

syndrome, or other conditions. However, the FDA permits FMT to treat CDI in patients who do not respond to standard therapies, without requiring an Investigational New Drug (IND) application.[61]

In the European Union, regulation of FMT remains decentralized, with each EU member state having the responsibility to set their own rules. This leads to some countries classifying FMT as a medical product, while others regulate it as a tissue transplant. The European Consensus Conference established guidelines addressing regulatory and laboratory requirements for FMT, but these are not legally binding.[62] To address inconsistencies, the European Academic Faecal Microbiota Transplantation (EURFMT) network was established to promote harmonization across Europe.[63]

Live Biotherapeutic Products

Live biotherapeutic products (LBPs) are newer treatments. They are similar to prebiotics and probiotics, as they are biological products that contain live organisms, but their intent is to prevent, treat, and cure diseases.[64] Similarly, the FDA's definition of live biotherapeutic products is composed of three factors: 1) contains live organisms; 2) is applicable to the prevention, treatment, or cure of a disease or condition of human beings; and 3) is not a vaccine.[65] This definition is very broad and encompasses LBPs containing a single species of bacteria or spores to an entire diverse microbial community. The methods of delivery could also include enema or oral delivery.

Types of live biotherapeutic products include genetically modified bacteria and phage therapy:

- **Genetically Modified Bacteria:** Genetically modified bacteria refer to specific bacterial strains that are modified to treat various diseases, including gastrointestinal diseases, cancer, diabetes, obesity, and hypertension. Bacteria can also be modified to degrade antibiotics in the gut, which mitigates the adverse effects of antibiotics and is beneficial for the balance of the microbiome.[66] A significant advantage of using genetically modified bacteria in the microbiome is their potential to offer therapeutic functions with minimal side effects. This makes them a promising candidate for replacing medications like antibiotics, which can cause dysbiosis. However, current regulations make it difficult to develop these treatments, as clinical trials often mandate the use of non-genetically modified bacteria for safety and regulatory reasons.[67]

- **Phage Therapy:** Phage therapy is an innovative approach that uses called bacteriophages, viruses that precisely identify and destroy harmful bacteria. These phages can be naturally ocurring or genetically engineered to enhance their precision, ensuring they selectively attack pathogenic bacteria while protecting beneficial strains.[68] Unlike antibiotics, which can indiscriminately harm both beneficial and harmful bacteria,

[61] https://doi.org/10.14309/ajg.0000000000002167

[62] https://gut.bmj.com/content/gutjnl/66/4/569.full.pdf

[63] https://www.microbiotajournal.com/wp-content/uploads/sites/7/2 023/11/e954.pdf

[64] https://assets.kpmg.com/content/dam/kpmgsites/ch/pdf/kpmg-ch-whitepaper-microbiome.pdf.coredownload.inline.pdf

[65] https://www.fda.gov/files/vaccines,%20blood%20%26%20biologics/published/Early-Clinical-Trials-With-Live-Biotherapeutic-Products--Chemistry--Manufacturing--and-Control-Information--Guidance-for-Industry.pdf

[66]https://pmc.ncbi.nlm.nih.gov/articles/PMC9606703/#:~:text=Microbial%20genetic%20engineering%20uses%20genetic,the%20bacteria%20with%20new%20phenotypes

[67] https://pmc.ncbi.nlm.nih.gov/articles/PMC10367592/

[68] https://www.pharmabiotic.org/microbiome-based-medicinal-products/#:~:text=Non-living%20biotherapeutic%20products%20(as,will%20have%20to%20be%20defined

phages are very specific and do not affect human cells. This specificity makes phage therapy a promising alternative to antibiotics. There are several challenges with the adoption of phage therapy. Regulation and policy issues complicate clinical approval, as phages are considered biological agents and not pharmaceuticals. High production costs and the need for personalized treatments also limit accessibilty. Additionally, more clinical studies are needed to verify the therapeutic effects of phage therapy, as there are possibilities that extensive use of phages might lead to resistance.[69]

Currently, there are three live biotherapeutic products worldwide that have been granted regulatory approval. Two LBPs have been approved by the FDA: Rebyota™ and VOWST™ produced by Ferring Pharmaceuticals Inc. and Seres and Nestle, respectively. Biomictra™, produced by BiomeBank, was approved by the Australian Therapeutic Goods Administration (TGA) in 2022, and was the world's first donor-derived microbiome drug to receive regulatory approval.[70] All three of these therapies are intended to be taken for recurrent *C. difficile* infection (CDI).[71] Biomictra and Rebyota contain fecal microbiota as the active ingredient and are rectally administered, whereas VOWST is comprised of fecal microbiota spores and is orally administered.

The FDA and TGA regulate live biotherapeutic products as biological drugs and biological medicines, respectively. Similarly, in the EU, the European Medicines Agency (EMA) regulates live biotherapeutic products (LBPs) as medicinal products. In 2018, the European Pharmacopoeia Commission set quality requirements for LBPs, outlining standards for manufacturing, strain selection, and stability assessments to ensure their safety and efficacy. However, the EMA has not yet approved any LBP products to date.

Difference Between FMT and LBPs

Due to the similarities in sourcing and method of administration, FMT and LBPs can be easily mistaken for each other. The key differences between FMT and LBPs are the mode of manufacturing and the method of obtaining them. Both undergo rigorous testing to verify that there are no pathogens. The manufacturing of LBPs includes an additional process after deep-freezing. In addition, production of LBPs must follow Good Manufacturing Policy

(GMP) guidelines and undergo rigorous clinical trials to prove they are safe and effective.[72] FMT, on the other hand, is not standardized and shows variability with collection procedures, storage, and donor screening.

Another key differentiation is the modification of the donor sample. For fecal microbiota transplantation, the donor sample is typically not modified before transplanting to the recipient, whereas live biotherapeutic products undergo several methods of processing before being administered. This can include selecting for certain strains of bacteria or enhancing metabolic properties of microbiota. Therefore, although the current FDA and TGA-approved therapies are based on fecal microbiota, they are regulated as live biotherapeutic products, due to their manufacturing, regulatory oversight, and clinical testing.

Dietary Supplements

According to the European Food Safety Authority (EFSA), food supplements are defined as concentrated sources of nutrients (such as vitamins and minerals) or other substances with a nutritional or physiological effect, which are

[69] https://pmc.ncbi.nlm.nih.gov/articles/PMC9550173/

[70] https://www.biomebank.com/news/biomebank-announces-world-first-regulatory-approval-for-donor-derived-microbiome-drug/

[71] https://www.nixonpeabody.com/insights/alerts/2023/05/15/fda-approves-microbiome-based-therapies

[72] https://www.pharmacytimes.com/view/clinical-overview-fecal-microbiota-transplantation-vs-live-biotherapeutic-products-for-management-of-recurrent-c-difficile-infection

marketed in "dose" form. These may include, but are not limited to, pills, tablets, capsules, or liquids in measured doses. Food supplements may contain a wide variety of ingredients, including vitamins, minerals, amino acids, essential fatty acids, dietary fiber, as well as various plant and herbal extracts.

Within the European Union (EU), food supplements are regulated as foods. Harmonized legislation governs the use of vitamins, minerals, and their respective sources in the production of food supplements. For substances other than vitamins and minerals, the European Commission has established specific regulations aimed at safeguarding consumer health. This includes maintaining a list of substances known or suspected to pose adverse health risks, thereby controlling their use in food supplements.[73]

The following sections review dietary supplements related to the microbiome sector:

Probiotics

The International Scientific Association for Probiotics and Prebiotics (ISAPP) defines probiotics as "live microorganisms that, when administered in adequate amounts, confer a health benefit to the host".[74] Probiotics can be found in yogurt, other fermented foods, dietary supplements, and even beauty products.[75] As dietary supplements, they are available in various forms, including capsules, powders, and liquids, often containing mixed cultures of live microorganisms.[76]

The most commonly used probiotic bacteria are *Lactobacillus* and *Bifidobacterium*, which are naturally found in the human gastrointestinal tract and various dairy products. Other EFSA-approved species include *Streptococcus*, *Bacillus*, and the yeast *Saccharomyces*. EFSA regularly updates a list of QPS (qualified presumption of safety) recommended microorganisms for safety assessments every six months.[77] However, certain fungi, bacteriophages, and bacterial taxa, such as *E. coli*, are excluded from QPS assessments due to potential risks and require specific evaluation.[78]

Probiotics play essential roles in human health by maintaining gut balance, supporting the immune system, and protecting against certain pathogens. Numerous studies have explored their general health benefits and their role in various diseases.[79]

However, any health claims related to probiotics must be authorized by the European Commission following an evaluation by the European Food Safety Authority (EFSA). Despite a wealth of scientific literature supporting the health benefits of probiotics, EFSA has rejected all health claims for probiotics submitted so far, except for the effect

[73] https://www.efsa.europa.eu/en/topics/topic/food-supplements

[74] https://doi.org/10.20517/mrr.2023.80

[75] https://www.nccih.nih.gov/health/probiotics-usefulness-and-safety

[76] https://ods.od.nih.gov/factsheets/Probiotics-HealthProfessional/

[77] https://www.efsa.europa.eu/en/topics/topic/qualified-presumption-safety-qps

[78] https://doi.org/10.20517/mrr.2023.80

[79] https://doi.org/10.20517/mrr.2023.80

of standard yogurt cultures on lactose digestion.[80] The FDA has also not approved any probiotics for treatment or prevention of disease.[81]

On the commercial side, according to Statista, North America currently leads the global market for probiotic supplements, followed closely by Europe.[82] By 2027, the global market for probiotic supplements is projected to reach 3.28 billion,[83] with a significant portion of this market focused on supporting gastrointestinal health. [84]

Prebiotics

Prebiotics are substances that are selectively used by host microorganisms and provide health benefits through microbiota-mediated mechanisms. This includes the substance itself, its physiological effects, and the mechanisms by which these effects occur. Prebiotics can be naturally occurring or synthetically produced. Common examples of naturally occurring prebiotics include inulin, oligosaccharides, dietary fibers, and resistant starches, and synthetic prebiotics include lactulose and pyrodextrins (and sometimes oligosaccharides or resistant starches when processed.

Prebiotics are crucial for human health, serving as an energy source for certain gut bacteria. These bacteria metabolize prebiotics and produce byproducts that influence other microbial species in the gut. This process, known as substrate cross-feeding, can significantly affect the composition of the gut microbiome.

Prebiotics have shown therapeutic potential for various conditions by modulating the gut microbiome. In inflammatory bowel disease (IBD), they can improve gut microbiome composition and reduce inflammation. Research into the gut-brain axis also suggests that plant-derived prebiotics, such as inulin and resistant starch, may help manage Parkinson's disease by promoting beneficial gut bacteria and reducing neuroinflammation. Additionally, prebiotics have been linked to improved management of diabetes and obesity.[85]

Synbiotics

The term "synbiotic" refers to nutritional supplements that combine probiotics (live bacteria) and prebiotics (the food components they rely on) to create a synergistic effect.[86] Initially, synbiotics were developed to enhance the functionality of probiotics by pairing them with prebiotics.[87]

The primary reason for using synbiotics is that a probiotic, without its prebiotic 'food source', struggles to survive in the digestive system. Without this necessary food, probiotics become more intolerant of oxygen, low pH, and temperature. Additionally, without a specific food source, probiotics must compete with other bacteria, which can take over.

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80 https://foodsupplementseurope.org/wp-content/themes/fse-theme/documents/publications-and-guidelines/FSE-Probiotic_Report-April2021.pdf

81 https://doi.org/10.1016/j.jff.2021.104718

82 https://www.statista.com/statistics/1198117/forecast-of-the-global-probiotic-supplements-market/

83 https://www.statista.com/statistics/1197251/forecast-of-the-global-probiotic-supplements-market/

84 https://www.statista.com/statistics/1198131/forecast-of-the-global-probiotic-supplements-market/

85 https://doi.org/10.20517/mrr.2023.80

86 https://doi.org/10.15740/has/fsrj/7.2/327-334

87 https://doi.org/10.20517/mrr.2023.80

The health benefits associated with synbiotic consumption include:

1) Increased levels of *lactobacilli* and *bifidobacteria* and a balanced gut microbiota

2) Improvement of liver function in cirrhotic patients

3) Enhanced immunomodulatory effects

4) Prevention of bacterial translocation and reduced incidence of nosocomial infections in surgical patients.[88]

Postbiotics

According to the definition proposed by Salminen et al., postbiotics refer to a “preparation of inanimate microorganisms and/or their components that confers a health benefit to the host”.[89] Postbiotics are primarily derived from *Lactobacillus*, *Bifidobacterium*, and yeasts like *Saccharomyces cerevisiae* through fermentation processes. The resulting metabolites or polysaccharides often possess antioxidant, anti-inflammatory, and immunomodulatory properties. Short-chain fatty acids (SCFAs), which are produced by bacterial fermentation of dietary fiber, are a key example of postbiotics.

Novel postbiotics, such as inactivated bacterial cells, can be approved as novel foods. For example, pasteurized *Akkermansia muciniphila* has shown promise in reducing obesity, improving diabetes, and enhancing cardiovascular health. It has also been linked to improvements in insulin resistance and glucose metabolism.

Compared to probiotics, postbiotics offer several advantages. They pose a reduced risk of bacterial translocation and infections, making them safer—especially for vulnerable populations. Postbiotics also have a longer shelf life and are more effective in topical formulations, which is beneficial for the cosmetic industry.

While many probiotics report health benefits, their effectiveness is often limited due to the complexity of the gut microbiota and varying strain efficacy. Many probiotics fail to establish stable colonization in the gut after treatment ends. To overcome these challenges, significant efforts are being made to develop more effective therapies, such as live biotherapeutic products (LBPs) and fecal microbiota transplants (FMT), both of which have demonstrated benefits and are recognized as medical products.[90]

Psychobiotics

Psychobiotics are a class of probiotics that provide mental health benefits by modulating the gut-brain axis. They stimulate the production of neurotransmitters such as seratonin and gamma-aminobutyric acid (GABA) and promote anti-inflammatory cytokines, which support mental health.[91] They also enhance microbial diversity and increase the production of metabolites, including short chain fatty acids (SCFAs). These metabolites play a critical role in regulating brain function and have shown promise in alleviating symptoms of central nervous system (CNS) disorders such as depression, insomnia, Parkinson’s disease, and multiple sclerosis.[92]

Microbiome-based treatments are becoming increasingly favorable, and the market for psychobiotics is currently experiencing significant growth since they offer alternative solutions to address antidepressant resistance.

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[88] https://pmc.ncbi.nlm.nih.gov/articles/PMC4648921/#CR77

[89] https://doi.org/10.1038/s41575-021-00440-6

[90] https://doi.org/10.20517/mrr.2023.80

[91] https://doi.org/10.1007/s00284-020-02289-5

[92] https://doi.org/10.3390/medicina60040601

Food

Diet is one of the most influential factors in shaping the composition and function of the microbiome.[93] Given its significance, this topic will be explored in more detail in the following section.

Dietary Interventions

A microbiome dietary intervention refers to dietary changes designed to modulate the gut microbiota to improve human health. Various diets—such as the Mediterranean diet, high-fiber diets (rich in fruits, vegetables, and whole grains), ketogenic diets, and gluten-free diets—have been linked to specific gut microbiome compositions.

These dietary interventions can reduce inflammation, improve insulin sensitivity, promote weight loss, enhance cognitive function, and boost immunity. They may also help manage chronic diseases such as inflammatory bowel disease (IBD), irritable bowel syndrome (IBS), Crohn's disease (CD), and Type 2 diabetes, and even improve the effectiveness of cancer treatments like immunotherapy and chemotherapy.

However, the effectiveness of these interventions depends on an individual's baseline physiological state and gut microbiome composition. While many studies suggest that diets can influence microbiome composition, the specific factors that predict microbiome responses remain unclear. Future research should focus on identifying diet-responsive microbiota profiles and accounting for recent dietary patterns to enhance the success of these interventions.[94]

Functional Foods

Incorporating more functional foods into one’s diet can help diversify and enrich the gut microbiome. A functional food can be a natural food or a food that contains one or more specific ingredients, which positively impact the health and well-being of the consumer. These components can be added, removed, or naturally enhanced or modified in the food to deliver health benefits.[95]

One important category of functional foods is fermented foods, which are especially rich in probiotics. These foods are created through the activity of live microbial cultures, which can help diversify and support the gut microbiome. However, not all fermented foods contain live cultures by the time they are consumed. For example, sourdough bread and many commercial pickles lack live cultures after processing, while certain yogurts contain beneficial probiotics like *Lactobacillus bulgaricus* and *Streptococcus thermophilus*. Other fermented foods that may contain live cultures include kimchi, kombucha, sauerkraut, miso, pickles (if unpasteurized), and raw apple cider vinegar. It's important to note that not all these foods are proven probiotics.

Additionally, some unfermented foods, such as certain milks, juices, and nutrition bars, may have added microorganisms. However, whether these foods offer true probiotic benefits depends on factors such as microorganism levels, survival through digestion, and the specific strains involved.[96]

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[93] https://doi.org/10.1016/j.bpg.2023.101828

[94] https://doi.org/10.20517/mrr.2023.80

[95] https://doi.org/10.1016/B978-0-12-384947-2.00340-8

[96] https://ods.od.nih.gov/factsheets/Probiotics-HealthProfessional/

Future Trends

Technologies in the microbiome sector are advancing rapidly, with promising developments in personalized medicine, non-live microbiome-derived drugs, targeted phage therapy, and CRISPR-based gene editing.

Personalized Medicine

The microbiome is increasingly significant in personalized medicine, especially in oncology. The microbiome can serve as a diagnostic tool by aiding in the early detection of disease and the development of targeted therapies for several conditions, including inflammatory bowel disease and colorectal cancer.[97]

Non-Live Microbiome-Derived Drugs

Non-living biotherapeutic products are an emerging class of drugs containing dead or inactivated microorganisms and are intended to treat or prevent disease.[98] An advantage of these products compared to live biotherapeutic products is their stability.

CRISPR in Microbiome Modulation

CRISPR is a powerful technology that offers transformative possibilities for editing bacterial genomes to optimize the microbiome. CRISPR stands for "clustered regularly interspaced short palindromic repeats", and it is a gene editing tool that is able to target and cut specific DNA sequences. This allows scientists to change the genetic code in any organism.[99] In microbiome research, CRISPR is being tested to selectively eliminate harmful bacterial strains in patients while retaining beneficial ones. A recent breakthrough demonstrated the application of CRISPR technology to target certain strains of *E. Coli* in the gut, preserving the strains that contribute to health.[100] CRISPR is also being used to develop synthetic probiotics. Researchers are able to modify beneficial bacteria to create strains that perform enhanced functions or produce specific metabolites.[101]

The Use of AI in Microbiome Research

Recent advancements in artificial intelligence (AI) and machine learning have revolutionized microbiome research by enabling the analysis of complex datasets. These tools are instrumental in uncovering relationships between genes and disease outcomes. By identifying microbiome-based biomarkers, AI facilitates the development of targeted therapeutics tailored to an individual's unique microbiome composition. It is also used to determine the physical and chemical interactions between components of the microbiome.[102] AI in microbiome research holds immense potential for accelerating discoveries and translating them into real-world solutions.

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[97] https://doi.org/10.1016/j.mayocp.2017.10.004

[98] https://www.microbiometimes.com/non-living-microbiome-therapeutics-european-organisation-strives-to-bring-regulatory-challenges-for-these-drug-products-into-focus/

[99] https://www.synthego.com/learn/crispr#:~:text=CRISPR%20stands%20for%20Clustered%20Regularly,directed%20by%20a%20customizable%20guide

[100] https://www.dtu.dk/english/newsarchive/2023/05/scientists-create-the-first-crispr-based-drug-candidate-targeting-the-microbiome

[101] https://doi.org/10.35248/2329-8901.23.11.322

[102] https://www.nature.com/articles/s43705-022-00182-9

Case Study Analysis of Best Foreign Practices

This analysis explores the innovation frameworks of leading countries— the United Kingdom, Germany, France, and the USA— to identify best practices and strategies driving microbiome research and innovation. These insights could serve as valuable lessons to strengthen Lithuania's microbiome sector and foster its development.

The United Kingdom

With world-class academic institutions, diverse funding strategies, rapidly advancing technologies, and an overall increased focus on the microbiome sector, the United Kingdom ranks 4th globally in both microbiome academic research[103] and innovation[104]. By adopting similar approaches, Lithuania can position itself as a competitive player in this field.

The *UK Microbiome Strategic Roadmap*

The United Kingdom government supports microbiome research through targeted policies and strategic initiatives. Innovate UK published the **UK Microbiome Strategic Roadmap**[105] in 2021, which outlines the vision of the UK becoming a world leader in microbiome research. It identifies the nation's strengths and weaknesses in this field and provides recommendations emphasizing:

- The One Health approach, connecting human, animal, and environmental microbiomes and forming collaboration networks in these areas.
- Maintaining its strong capabilities with microbiome sequencing technologies.
- Developing "Next Generation" biobanking.
- Leveraging capabilities in diagnostics to develop treatments.
- Prioritizing microbiome-centric funding.
- Encouraging cross-disciplinary training and collaboration.
- Addressing gaps in infrastructure.

Innovate UK's Strategic Roadmap aims to standardize research methodologies and drive advancements in microbiome research and technologies. The **Medicines and Healthcare Products Regulatory Agency (MHRA)** is the UK's primary regulatory body, responsible for ensuring that all microbiome-based therapies meet all standards of safety, quality, and efficacy.[106] They are leading the world's largest microbiome standardization program, including the development of the first **WHO International Reference Reagents** for the microbiome.[107] This program is crucial for advancing microbiome research by standardizing methodologies.

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[103] https://doi.org/10.1093/procel/pwad031

[104] https://www.gazettelabo.fr/media/files/211007_CP_APM_EtudeSectorielle2021_VF.pdf

[105] https://iuk-business-connect.org.uk/news/ktns-microbiome-innovation-network-launches-the-microbiome-strategy-roadmap/

[106] https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about

[107] https://nibsc.org/science_and_research/idd/microbiome.aspx

The roadmap also emphasizes fostering partnerships between academia, healthcare, and industry. Current examples include:

- **Cancer Research UK (CRUK)** and the **National Health Service (NHS)** conduct large-scale clinical trials to investigate the role of the microbiome in cancer treatment and prevention.
- The **NHS Genomic Medicine Service**, the **Wellcome Sanger Institute**, and the **National Genomic Laboratory Network** provide quality genomic testing technologies, integrating microbiome findings into precision medicine approaches.[108][109]
- The **Bioindustry Association** connects researchers and industry to accelerate therapeutic development.[110]

Additionally, Innovate UK developed the **Microbiome Innovation Network Landscape Map**, a comprehensive database of microbiome institutions and companies designed to foster cross-sector connections. This interactive tool provides easy access to investigate projects, businesses, and institutions across the UK, fostering connections and collaboration between researchers and institutions. The tool allows the user to sort by sector and size, with the "Microbiome Services" sector including companies such as NCIMB Unlimited or Eagle Genomics, or the "Human Therapeutic Products" sector, which includes 4D Pharma, Microbiotica, and VeMico Ltd.[111]

Together, the Strategic Roadmap and Microbiome Innovation Network Landscape Map highlight leading institutions in this field, including **Imperial College London**, **King's College London**, and **University of Oxford**. These universities have dedicated microbiome research centers and networks.[112] Leading non-university institutions, such as the **UK Biobank** and **Norwich Research Park Biorepository**, also play a key role. They offer large-scale health data and sample storage, which are essential for microbiome research.[113] These biobanks are crucial in microbiome research by providing long-term data to investigate disease prevention and treatment methods. Additionally, there are also specialized centers like the **Quadram Institute** that focus on microbiome health and disease.[114]

Funding

UK Research and Innovation (UKRI) has allocated a £210 million budget for precision medicine initiatives, including whole genome sequencing, which benefits microbiome research.[115]

- The **Biotechnology and Biological Sciences Research Council (BBSRC)** supports microbiome research with grants of up to £2 million.[116] Additionally, it funds microbiome research centers such as the Quadram Institute.

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[108] https://iuk-business-connect.org.uk/wp-content/uploads/2023/02/0489_KTN_HIMDD_Final2_AW_Updated-230228.pdf

[109] https://www.sanger.ac.uk/about/strategy-and-funding/

[110] https://www.bioindustry.org/

[111] https://iuk-business-connect.org.uk/programme/microbiome-landscape/

[112] https://iuk-business-connect.org.uk/wp-content/uploads/2023/02/0489_KTN_HIMDD_Final2_AW_Updated-230228.pdf

[113] https://biorepository.org.uk/about-biorepository/

[114] https://quadram.ac.uk/about/

[115] https://www.ukri.org/what-we-do/browse-our-areas-of-investment-and-support/data-to-early-diagnosis-and-precision-medicine/

[116] https://www.ukri.org/what-we-do/browse-our-areas-of-investment-and-support/integrative-microbiome-research/

- The **Industrial Strategy Challenge Fund (ISCF)** supports innovation in clean growth, the ageing society, the future of mobility, and artificial intelligence.[117] These themes often intersect with microbiome innovation, particularly in fields such as environmental sustainability and precision healthcare.

[117] https://committees.parliament.uk/work/1006/the-industrial-strategy-challenge-fund/

Germany

Germany leads Europe in microbiome research, showcasing its advanced capabilities in this rapidly growing field.[118] This achievement underscores the significant benefits of investing in and fostering microbiome research—an inspiring example for Lithuania as it seeks to develop its own potential in this area.

Excellence Strategy (ExStra)

German universities are known for their high-quality research, with selected institutions receiving strong support from the federal and state governments. To boost the international competitiveness of research at these universities, the **Excellence Strategy (ExStra)** was introduced as a permanent funding program.

The main goal of the Excellence Strategy is to support world-class research in key areas, strengthen German universities, and advance the country's higher education system. To achieve this, the strategy has two main funding lines: the ***Clusters of Excellence*** and the ***Universities of Excellence***.

- ***The Clusters of Excellence*** funding line offers project-based support for internationally competitive research areas at German universities. The annual budget for this funding line is EUR 385 million, which will increase to EUR 529 million starting in 2026. This funding line is managed by the Deutsche Forschungsgemeinschaft (DFG), the German Research Foundation. These clusters foster top-level research by offering extensive cooperation opportunities and state-of-the-art research infrastructures, creating ideal conditions for groundbreaking work.

- ***The Universities of Excellence*** funding line supports institutional strategies aimed at strengthening universities, including their research, teaching, infrastructure, knowledge and technology transfer, governance, personnel development, and internationalization. The annual budget for this funding line is EUR 148 million. The funding helps universities or consortia enhance their institutional profile and global standing in research, building on the success of their Clusters of Excellence. This funding line is managed by the Wissenschaftsrat (WR), the German Science and Humanities Council. [119]

The German Research Foundation

The **German Research Foundation - Deutsche Forschungsgemeinschaft (DFG)** - is Germany's leading research organization, supporting high-quality research across disciplines with an annual budget of over €3.9 billion, primarily funded by the German federal government and individual states. It provides competitive funding, shapes research policies, and fosters dialogue between academia, society, and politics.[120]

To advance scientific discovery, the DFG launches initiatives in emerging fields, such as microbiome research. For example, in March 2024, the organization established the Priority Program **"Illuminating Gene Functions in the Human Gut Microbiome" (SPP 2474).** Its goal is to deepen understanding of the gut microbiome's functions and their influence on human health. [121]

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[118] https://doi.org/10.1093/procel/pwad031

[119] https://www.exzellenzstrategie.de/en/what-is-exstra/

[120] https://www.dfg.de/en/about-us/about-the-dfg/what-is-the-dfg

[121] https://www.dfg.de/en/news/news-topics/announcements-proposals/2024/ifr-24-60

Institutions

Germany is renowned for its advanced research environment. The **Max Planck Society** is one of Germany's most prestigious and successful research organizations. Its Institutes and Department of Microbiome Science have a strong focus on microbiome research.[122] With 31 Nobel Laureates among its alumni, the Max Planck Society is globally recognized for its groundbreaking contributions to science.[123] Additionally, it ranks as the third most prestigious institution globally in the Nature Index for 2023.[124]

Another key player in Germany's microbiome research landscape is the **Helmholtz Centre for Infection Research**, part of the Helmholtz Association.[125] This institute addresses global challenges related to health, the environment, and technology, consistently ranking among the top research organizations worldwide. In the 2023 Nature Index, the Helmholtz Association secured the eleventh position globally. [126]

Equally significant is the **Leibniz Institute for Natural Product Research**, particularly its Department of Microbiome Dynamics.[127] The Leibniz Association, which comprises 96 independent research institutions, is dedicated to pushing the boundaries of scientific exploration. [128]

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122 https://www.bio.mpg.de/48843/microbiome-science-ruth-ley

123 https://www.mpg.de/nobel-prize

124 https://www.helmholtz.de/en/about-us/who-we-are/facts-and-figures/scientific-performance/

125 https://www.helmholtz-munich.de/en/comi

126 https://www.helmholtz.de/en/about-us/who-we-are/facts-and-figures/scientific-performance/

127 https://www.leibniz-hki.de/en/microbiome-dynamics.html

128 https://www.leibniz-gemeinschaft.de/en/about-us/about-the-leibniz-association

France

France is recognized as the leader in microbiome innovations across Europe.[129] This notable achievement serves as a powerful example for Lithuania, demonstrating the significant potential of investing in and nurturing innovation within the rapidly advancing field of microbiome science.

MetaGenoPolis

MetaGenoPolis (MGP) is a groundbreaking public-private initiative established by INRAE (the French National Institute for Agricultural Research) and is supported by the French Initiative for Future Investments.[130] Since 2010, MGP has earned international recognition for its expertise in gut microbiome analysis and its transformative applications in health and nutrition.[131] With a €24.7 million budget spanning 2012–2025, MGP is at the forefront of developing microbiome-based therapeutics.[132]

Collaborating with industrial partners such as Adisseo, Dupont, Bridor, Sanofi, and Roquette, as well as start-ups such as Enterome, Novobiome, and MaaT Pharma, [133] academia, and clinical partners, MGP designs and executes projects tailored to specific needs. To explore the connections between the microbiome, nutrition, and health, MGP employs advanced technological platforms and benefits from ethical oversight provided by the Catholic University of Lyon (UCLy).[134]

MGP's three innovative platforms offer comprehensive microbiome analysis services, including *tailored recommendations for sample collection, biobanking, DNA extraction, library preparation, shotgun sequencing, quantitative and functional metagenomics, bioinformatics, statistical analysis, and data interpretation*.

This integrated approach bridges research with actionable outcomes, driving the development of new products, diagnostics, and prognostics to enhance human health and well-being.[135]

By 2022, MGP had achieved significant milestones:

- 140 scientific publications (15 among the most globally cited),
- 36 patents, 10 licenses, and leadership in over 230 research projects.
- Collaborations with public and private partners generated €42 million in funding, firmly establishing MGP as a leader in microbiome research and its translation into impactful health solutions. [136]

Looking ahead, MGP aims to deepen industrial collaborations and foster the creation of start-ups to accelerate the pace of innovation in microbiome science, health, and nutrition.[137]

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[129] https://www.gazettelabo.fr/media/files/211007_CP_APM_EtudeSectorielle2021_VF.pdf

[130] https://one.oecd.org/document/DSTI/STP/BNCT(2016)20/FINAL/en/pdf

[131] https://www.inrae-transfert.fr/en/focus-on/104-2-demonstrateurs

[132] https://one.oecd.org/document/DSTI/STP/BNCT(2016)20/FINAL/en/pdf

[133] https://mgps.eu/about/who-we-are/

[134] https://www.inrae-transfert.fr/en/focus-on/104-2-demonstrateurs

[135] https://mgps.eu/about/our-mission/

[136] https://www.inrae.fr/en/reports/gut-microbiota-our-new-health-ally/metagenopolis-unique-place-dedicated-knowledge-microbiota

[137] https://www.inrae-transfert.fr/en/focus-on/104-2-demonstrateurs

Le French Gut

A highlight of MGP’s work is its leadership of **Le French Gut**, a key initiative within the global ***Million Microbiome of Humans Project (MMHP).***

- MMHP aims to sequence and analyze one million microbial samples in 3-5 years to create a microbiome map of the human body and build the world's largest open-access microbiome database. The primary focus will be on the gastrointestinal tract and oral cavity, with additional body sites included. The project is a collaboration among institutions in Sweden, China, Denmark, France, and Latvia. Using MGI's DNA sequencing technology, it will generate microbial maps and establish an open-access database to advance the field globally.[138]

In partnership with AP-HP (French university hospital center), this ambitious project aims to collect 100,000 fecal samples and associated health data from individuals across France by 2027. The initiative seeks to better understand gut microbiota diversity and its links to diseases such as diabetes, obesity, inflammatory bowel disease (IBD), and Alzheimer’s, enabling personalized medicine and targeted prevention strategies.[139]

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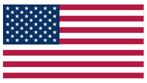
[138] https://db.cngb.org/mmhp/white.paper.pdf

[139] https://lefrenchgut.fr/the-french-gut-project/

USA



The United States is a global leader in microbiome research[140] and innovation[141], with early initiatives playing a key role in its current position. Looking at this example, Lithuania could draw valuable lessons from these successes.

Human Microbiome Project (HMP)

The **Human Microbiome Project (HMP)** was supported by the National Institutes of Health (NIH) Common Fund from 2007 through 2016.[142] The project was developed to advance research on the microbial communities residing in and on the human body. Before the HMP, the understanding of these microbes' influence on human development, physiology, immunity, and nutrition was limited. The HMP aimed to fill this gap by creating and sharing resources to enable the comprehensive characterization of human-associated microbiota and their functions.

The HMP achieved significant milestones, including:

- Sequencing approximately 3,000 reference bacterial genomes from the human body.
- Profiling the microbiome of over 300 healthy individuals.
- Creating the world's largest metagenome sequence dataset from a single human cohort.
- Developing the only complete dataset of bacterial, fungal, viral, and protist community composition from a single cohort.
- Producing integrated datasets of metagenomic, transcriptomic, proteomic, and metabolomic profiles from both microbiome and host in multiple human cohorts.
- Developing software and online tools to support microbiome research.
- Conducting iHMP studies on conditions like preterm birth, inflammatory bowel disease, and prediabetes, deepening the understanding of host-microbiome interactions.

By 2017, HMP-funded researchers had published over 650 scientific papers, collectively cited more than 70,000 times, showcasing the project's profound influence on microbiome research. The datasets, tools, and methods developed under the HMP are now globally accessible, fostering ongoing research into the microbiome's role in improving human health. [143]

Institutions

Many institutions and universities in the United States provide dedicated microbiome groups. These include The Pennsylvania State University's **One Health Microbiome Center**, which combines researchers of diverse expertise to collaborate on human, animal, and environmental health. It is one of the largest centers in the field.[144] Another initiative is the University of California Davis' **Microbiome Special Research Program**, which connects researchers and provides training opportunities. They also compiled a list of microbiome-focused research centers across the world.[145]

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[140] https://doi.org/10.1093/procel/pwad031

[141] https://www.gazettelabo.fr/media/files/211007_CP_APM_EtudeSectorielle2021_VF.pdf

[142] https://hmpdacc.org/hmp/

[143] https://www.nih.gov/news-events/news-releases/nih-human-microbiome-project-defines-normal-bacterial-makeup-body

[144] https://www.huck.psu.edu/institutes-and-centers/microbiome-center/about/mission

[145] https://microbiome.ucdavis.edu/resources/microbiome-centers-and-organizations

The **Microbiome Center** in Chicago is another institution focusing on collaboration, combining three different centers: the University of Chicago, the Marine Biological Laboratory, and Argonne National Laboratory.[146]

Other noteworthy institutions include the AGA Center for Gut Microbiome Research and Education, Janssen Human Microbiome Institute, and the Cedars-Sinai Microbiome Institute.[147][148][149]

FDA

The **Food and Drug Administration (FDA)** plays a crucial role in protecting public health in the U.S. by ensuring the safety, efficacy, and security of drugs, biological products, medical devices, food, cosmetics, and radiation-emitting products. The FDA also provides science-based health information to help the public make informed decisions.[150]

The main goal of the FDA's Advancing Regulatory Science at FDA: Focus Areas of Regulatory Science (FARS) report is to highlight the impact of the FDA's regulatory science research. The FDA regularly reviews and updates these focus areas to address evolving needs. In the 2022 report, the FDA revisited the focus areas from 2021, incorporating updates and examples that reflect the latest advancements in regulatory science.

One of the key focus area in the report was the microbiome.[151] A major milestone in this area was the FDA's approval of Rebyota™, a rectally administered fecal microbiota product, in late 2022 [152] [153] The FDA later approved VOWST™, the first orally administered fecal microbiota product.[154] Both Rebyota and VOWST are produced by Ferring Pharmaceuticals Inc. and Seres and Nestlé, respectively. Beyond these companies, there is a growing number of companies in the U.S. working on microbiome-based therapies, including Finch Therapeutics, Siolta Therapeutics, Axial Biotherapeutics, and others.

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[146] https://microbiome.uchicago.edu/node/791

[147] https://gastro.org/aga-leadership/centers/aga-center-for-gut-microbiome-research-education/

[148] https://www.janssen.com/article-type/human-microbiome-institute

[149] https://www.cedars-sinai.edu/health-sciences-university/research/departments-institutes/medicine/human-microbiome.html

[150] https://www.fda.gov/about-fda/what-we-do

[151] https://www.fda.gov/science-research/advancing-regulatory-science/focus-areas-regulatory-science-report

[152] https://www.fda.gov/news-events/press-announcements/fda-approves-first-orally-administered-fecal-microbiota-product-prevention-recurrence-clostridioides

[153] https://www.nixonpeabody.com/insights/alerts/2023/05/15/fda-approves-microbiome-based-therapies

[154] https://www.fda.gov/news-events/press-announcements/fda-approves-first-orally-administered-fecal-microbiota-product-prevention-recurrence-clostridioides

Overview of the Microbiome Sector in Lithuania

Lithuania's Global Position in Biotechnology

Lithuania has firmly established itself as a global leader in biotechnology, with its strategic positioning in various international rankings. As a member of numerous prestigious organizations, Lithuania continues to build on its legacy of innovation and development. [155]

Key global accomplishments include:

- **Ranked in the Top 35** in the Global Innovation Index (GII) for two consecutive years.[156]
- **1st globally** in unicorn value relative to its economy size.
- **1st globally** for the proportion of women with higher education in the workforce.[157]
- **22nd globally** in 2024 IMD Digital Competitiveness Ranking.[158]
- **16th globally** in the 2024 StartupBlink Ecosystem Index, with Vilnius ranked as the best EU city for cybersecurity.[159]

Lithuania's strong presence in biotechnology is underpinned by a 50-year legacy in precision medicine, biomanufacturing, and AI-driven healthcare innovations. Its network of science valleys and leading educational institutions foster a thriving ecosystem, making Lithuania an attractive hub for biotech investments.[160]

- **3rd in OECD** for biotechnology R&D spending intensity (as a percentage of value added).
- **92%** of pharmaceutical and healthcare products are exported to over 100 countries. [161]
- One of the highest STEM graduate rates in Europe. [162]

Successful Areas in Biotechnology

Precision Medicine: Advancing Healthcare with Cutting-Edge Technologies

- Lithuania is globally recognized for its leadership in cell and gene therapies, collaborating with top institutions like EMBL and earning accolades such as the Kavli Prize for CRISPR-Cas9 advancements. A strong R&D environment drives next-generation therapeutics.

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[155] https://investlithuania.com/wp-content/uploads/Lithuanian-Life-Sciences-sector-facts-and-figures-2023.pdf

[156] https://www.wipo.int/web-publications/global-innovation-index-2024/en/gii-2024-results.html

[157] https://lithuania.lt/governance-in-lithuania/lithuania-among-the-top-35-strongest-countries-in-the-global-innovation-index-for-the-second-year-running/

[158] https://www.imd.org/centers/wcc/world-competitiveness-center/rankings/world-digital-competitiveness-ranking/

[159] https://lithuania.lt/governance-in-lithuania/vilnius-leads-the-eu-in-cybersecurity-according-to-global-startup-index/

[160] https://investlithuania.com/biotechnology/

[161] https://lithuania.lt/governance-in-lithuania/lithuanias-life-sciences-sector-maintains-momentum/

[162] https://www.cedefop.europa.eu/en/data-insights/17-how-many-ivet-students-graduate-stem-subjects

- The AI sector supports healthcare innovations with skilled ICT talent and a centralized health data infrastructure. Lithuania's one-stop-shop data agency simplifies access to health data, while its two-decade-old electronic health records system aligns with the European Health Data Space (EHDS).

Biomanufacturing: A Hub for Innovation

- Global companies like Thermo Fisher Scientific and Teva drive Lithuania's biomanufacturing sector. The upcoming €7 billion Bio City campus will feature cutting-edge facilities for cell and gene manufacturing and 3D bioprinting, making it Europe's largest biotech hub.

Agrotech and Novel Food: Leading Sustainable Food Production

- Lithuania pioneers alternative proteins, vertical farming, and functional food, promoting eco-friendly supply chains and addressing global food security challenges through sustainable practices.

Industrial Biotechnology: Transforming Manufacturing

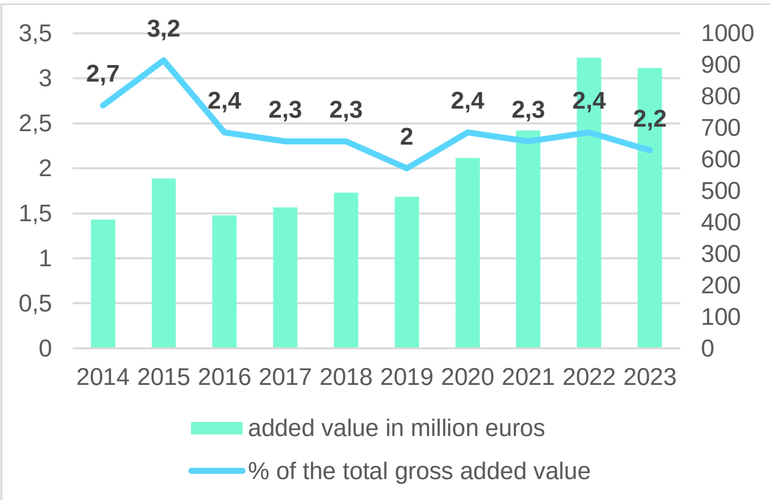
- Lithuania excels in synthetic biology, producing biomaterials like enzymes and amino acids for industries such as chemicals, FMCG, and cosmetics. Advanced fermentation technologies and raw material diversity, leveraged by companies like Roquette, drive sustainable business growth.[163]

Life Science Sector Growth

The added value of the life sciences sector has more than doubled since 2014 (**Figure 12**), from 408.4 million euros to 889.9 million euros. The growth rate experienced a slowdown in 2023, with the life sciences sector contributing 2.2% to the GDP

Figure 12

Added Value of the Life Sciences Sector in Lithuania



Note: prepared by the authors, data obtained from State Data Agency.[164]

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[163] https://investlithuania.com/biotechnology/

[164] https://inovacijuagentura.lt/site/binaries/content/assets/analitika/tyrimai/smart-makro-dalis-2024_12_27_final-1.pdf

This slowdown in the life sciences sector is attributed to a reallocation of investments and focus toward strategic geopolitical and technological priorities, which are perceived as yielding quicker returns or being critically important in the context of national security and economic competitiveness.[165]

Necessity for Sustainable Health Solutions in Lithuania

Based on the potential health benefits of the microbiome and Lithuania's leadership in biotechnology, further exploration into the microbiome sector could serve as a potential solution for preventing various diseases in Lithuania.

- **Life Expectancy:** The COVID-19 pandemic caused a sharp decline in life expectancy in Lithuania (down by 2.3 years from 2019 to 2021). Recovery efforts increased life expectancy to 76 years by 2022, still nearly five years below the EU average.
- **Mortality Rates:** Lithuania has among the highest levels of preventable and treatable mortality in the EU, highlighting weaknesses in both public health initiatives and healthcare delivery systems.
- **Health Status:** In 2022, only 48% of Lithuanian adults reported good health—the lowest rate in the EU. A stark income-related gap persists: 72% of high-income individuals reported good health, compared to just 25% of low-income groups.
- **Leading Causes of Death:** Circulatory diseases and cancer dominate, with coronary heart disease and lung cancer most common. External causes, including accidents and suicides, are notable contributors.
- **Mental Health:** Depression, particularly among women and low-income groups, persists as a major issue despite progress in reducing suicide rates.
- **Risk Factors:** Behavioral and environmental risks such as poor diet, tobacco use, and alcohol consumption account for nearly half of deaths, with dietary risks alone contributing to 25% far above the EU average of 17%. [166]

Overall, Lithuania holds significant R&D potential in the life sciences and microbiome sector for the reasons outlined above. Furthermore, health assessments of the Lithuanian population indicate mulitple areas that require improvement. Advancing microbiome research and innovations could lead to groundbreaking discoveries, potentially addressing pressing health challenges. To drive meaningful change and foster innovation in this field, financial initiatives and dedicated funding programs are essential to initiate progress.

[165] https://inovacijuagentura.lt/site/binaries/content/assets/analitika/tyrimai/smart-makro-dalis-2024_12_27_final-1.pdf

[166] https://www.oecd.org/en/publications/lithuania-country-health-profile-2023_5ed683c8-en.html

Overview of European Union and Lithuanian Initiatives and Funding Programs

EU Financing Initiatives

Horizon Europe

Horizon Europe, with a budget of EUR 93.5 billion for 2021-2027, supports research and innovation to achieve the UN's Sustainable Development Goals and enhance the EU's competitiveness.[167] It is structured around three pillars: Excellence Science, Global Challenges, and Industrial Competitiveness.[168,169]

Horizon Europe includes five missions under the Global Challenges pillar: Adaptation to Climate Change, Cancer, Restore Our Oceans and Waters, Climate-Neutral and Smart Cities, and Soil Deal for Europe. All five are beneficially impacted by microbiome research, due to the One Health principle, which emphasizes the interconnectedness of human, animal, and environmental microbiomes. The mission closely related to the human microbiome is the Cancer mission, which aims to improve diagnosis, treatment, and quality of life.[170] Although this mission does not directly emphasize microbiome research, the microbiome role in disease prevention and treatment indicates that studies in this area would contribute greatly to the Cancer mission.

The importance of the microbiome is mentioned more specifically in the "Microbiome World" pathway, funded by Horizon Europe, which supports projects like MASTER, HealthFerm, DOMINO, WHEATBIOME, and TRIBIOME. These projects investigate microbiome roles in sustainable food systems, diets, and health biomarkers, underscoring the importance of financing microbiome studies for advancing public health and sustainability.[171]

European Innovation Council (EIC)

The European Innovation Council (EIC) under Horizon Europe funds innovative companies through schemes like EIC Pathfinder, EIC Transition, EIC Accelerator and a new 2025 initiative, STEP Scale-Up.[172] The EIC Fund, part of the EIC Accelerator, invests in European startups across health, energy, green, digital, and deep-tech sectors. Perseus Biomics, a company specializing in microbiome genetic analysis, is one such selected company.[173]

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167 https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe_en#proposal

168 https://www.consilium.europa.eu/en/policies/horizon-europe/

169 https://lmt.lrv.lt/en/research-funding/horizon-europe/horizon-europe-programme/

170 https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe_en#proposal

171 https://op.europa.eu/en/publication-detail/-/publication/abbb2634-9001-11ee-8aa6-01aa75ed71a1/language-en

172 https://eic.ec.europa.eu/about-european-innovation-council_en

173 https://eic.ec.europa.eu/eic-fund/eic-fund-portfolio/perseus-biomics_en

Although the EIC Work Program for 2025 doesn't explicitly mention microbiome-based solutions, several challenges under EIC Pathfinder and EIC Accelerator present opportunities for microbiome-related projects.[174]

EU4Health Program

The EU4Health Program, launched in response to the COVID-19 pandemic, focuses on improving health in the EU, protecting against cross-border health threats, enhancing the availability of medicinal products, and strengthening health systems and the healthcare workforce. [175]

In the 2024 EU4Health work program, key areas related to the microbiome include personalized cancer medicine and antimicrobial resistance. The latter indirectly involves microbiome research, especially regarding "other health technologies as alternatives to antibiotics." [176] Personalized cancer medicine may involve microbiome research in identifying biomarkers and creating tailored treatment plans.

National Financing Initiatives

Smart Specialization

The EU Cohesion Policy (2021–2027) aims to create a smarter, greener, and more connected Europe.[177] In line with this, Lithuania approved its Smart Specialization Strategy (S3) to boost R&D, innovation, and global competitiveness. **The focus is on three key Research, Development, and Innovation (R&D&I) priorities:**

- Health technologies, biotechnologies, and safe food
    - Molecular medicine and biopharmaceuticals
    - Advanced health technologies
    - Medical engineering for early diagnosis/treatment
    - Safe food and sustainable agrobiological resources.
- New production processes, materials, and energy efficiency
- ICT for an inclusive, creative society.[178] [179]

Although not explicitly highlighted in the smart specialization strategy, a focus on microbiome research offers significant potential to drive R&D, foster innovation, and boost global competitiveness.

[174] https://eic.ec.europa.eu/document/download/5e1eb75f-e437-477f-9ee9-ef54ff6387fd_en?filename=EIC%20Work%20Programme%202025.pdf

[175] https://commission.europa.eu/strategy-and-policy/eu-budget/performance-and-reporting/programme-performance-statements/eu4health-performance_en#contribution-to-horizontal-priorities

[176] https://health.ec.europa.eu/document/download/4fb8f72b-eac7-484f-9bab-03c945f59032_en?filename=c2024_7871_annex_en.pdf

[177] https://inovacijuagentura.lt/site/binaries/content/assets/analitika/tyrimai/lietuvos-moksliniu-tyrimu-ir-eksperimentines-pletros-bei-inovaciju-sumaniosios-specializacijos-ataskaita-2023-m..pdf

[178] https://www.e-tar.lt/portal/en/legalAct/9f349d40221011edb4cae1b158f98ea5

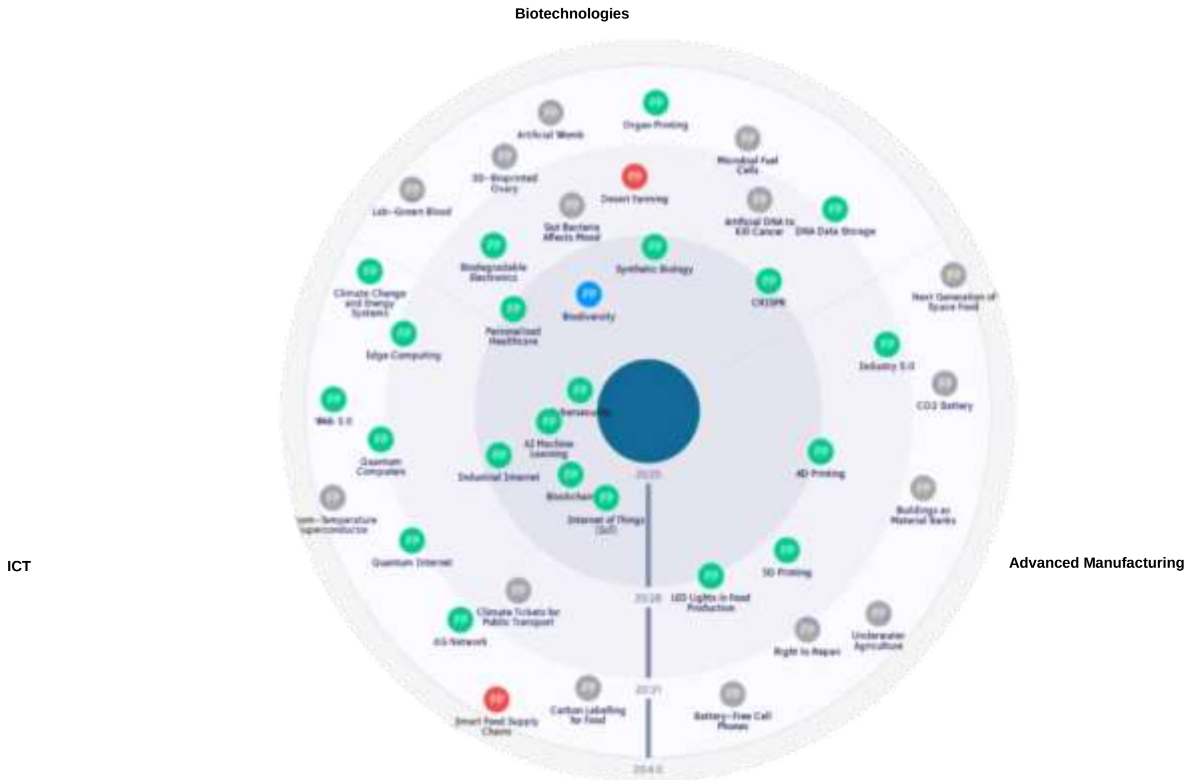
[179] https://eimin.lrv.lt/en/sector-activities/innovation/smart-specialization/

Future of smart specialization strategy

Lithuania will soon begin planning its 2028–2034 Smart Specialization Strategy (S3), presenting an opportunity to refine focus areas. While technology foresight is not yet formally adopted in Lithuania, it has helped define priorities in other countries.[180] By leveraging this approach, Lithuania can better identify key focus areas for the new S3.

Figure 13

Foresight Radar for Smart Specialization



Note: prepared by the authors, based on the source from Futures Platform, 2025

An AI model was tested in this analysis to generate a foresight model for S3 focus areas. This AI foresight tool generated trend cards for each S3 category as follows:

The trends are categorized as follows:

- Green – high-impact emerging trends
- Blue – declining trends with most change potential realized
- Red – low-probability but significant 'wild card' events
- Grey – weak signals with uncertain future relevance.

In the biotechnology area of this model, trends correlating with the microbiome sector include:

- Synthetic biology (Timestamp: 2027)
- Personalized healthcare (Timestamp: 2027)

[180] https://data.kurklt.lt/wp-content/uploads/2024/11/Smart-Specialisation-Strategy-in-Lithuania_Current-Situation-Analysis.pdf

- CRISPR (Timestamp: 2028)
- Gut bacteria's effect on mood (Timestamp: 2029)

These trends suggest potential avenues for refining and detailing Lithuania's upcoming biotechnology focus areas. Increasing attention to microbiome-related advancements could play a pivotal role in driving innovation and competitiveness within the sector.

National Progress Plan and Lithuanian Life Sciences Roadmap

Lithuania's National Progress Plan 2021–2030 aims to enhance global competitiveness through science, technology, and innovation.[181] The vision for Lithuania is that its life sciences sector will become a leader in the development of world-class products. The Lithuanian Life Sciences Sector Roadmap sets a target for the life sciences sector to contribute 5% to GDP by 2030. The future of the life sciences sector is intrinsically linked to transformative technological advancements and groundbreaking innovations. A recent study featured in the life sciences roadmap by the European Innovation Council highlights 100 pivotal emerging technologies and breakthrough innovations essential for Europe's progress. Among these, the microbiome is identified as a key example of a future technological trend in the life sciences.[182]

2021-2027 Investment Program of European Union Funds

The 2021–2027 EU Funds Investment Program allocates nearly €8 billion to Lithuania, focusing on areas like energy, mobility, social inclusion, and climate change. While the microbiome sector isn't a key focus, it fits within the €650 million science and innovation budget for R&D and the €531 million healthcare budget for preventive care and workforce expansion.[183]

New Generation Lithuania

"New Generation Lithuania" is a national strategy leveraging the EU's Recovery and Resilience Facility to address COVID-19 impacts. €268 million will strengthen healthcare by improving collaboration, infectious disease surveillance, and personalized care services. Another €1.05 billion will enhance higher education, science-business partnerships, and innovation. Microbiome research supports these efforts, fostering healthcare resilience and scientific progress. €6.3 million has also been allocated to sequence the genome of a representative Lithuanian population sample.[184]

Innovation Agency (IA)

Innovation Agency Lithuania fosters economic growth by supporting startups and businesses. As a partner in the Horizon Europe "PRECISEU" project, it helps advance personalized medicine and reduce inequality in the EU by facilitating the adoption of advanced technological innovations. The project connects European ecosystems to

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181 https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/c1259440f7dd11eab72ddb4a109da1b5?jfwid=32wf90sn

182 https://eimin.lrv.lt/uploads/eimin/documents/files/Gyvybe%CC%87s%20mokslu%CC%A8%20sektoriaus%20kelrodis(1).pdf

183 https://esinvesticijos.lt/apie-programas/2021-2027-m-es-fondu-investiciju-programa/apie-2021-2027-m-es-fondu-investiciju-programa

184 https://finmin.lrv.lt/en/news/the-government-approved-the-integrated-plan-new-generation-lithuania/

expand healthcare innovations, focusing on advanced therapy medicinal products and health data.[185] Under the Smart Specialization initiative, IA runs projects like Inostartas, Inobranda, and Inopažanga (InoStart, InoBrand, and InoProgress). However, microbiome research is not a specific focus, so participants compete in broader focus areas.

Research Council of Lithuania

The Research Council of Lithuania funds national R&D and supports knowledge exchange between universities and institutes. It allocates grants, manages funding programs, supports EU research participation, and fosters international collaboration. Its mission is to strengthen Lithuania's R&D system for broad societal benefits.[186] While it funds microbiome studies, the support falls under broader research categories rather than a dedicated focus.[187] The Research Council of Lithuania developed a funding call in 2019 for the implementation of "Spin-Off Companies" that develops products based on research results. With a total funding allocation of up to 5 million euros, this initiative aims to encourage the translation of scientific research into marketable products.[188]

Microbiome Research and Innovation Ecosystem in Lithuania

To provide a clearer view of Lithuania's life sciences landscape, including the microbiome sector, this map highlights key players and their roles within the ecosystem (**Figure 14**). It features universities, research institutes, hospitals, government agencies, and industry partners that drive innovation, collaboration, and practical applications in the field.

At the center of the map, a circle showcases institutions actively involved in microbiome-related activities while also contributing to the broader life sciences sector. Institutions outside the circle represent those engaged in various other areas of life sciences. Additionally, the map highlights companies operating specifically within the microbiome sector.

- SMEs (including startups) and large enterprises.
- Academic community: Universities, research institutions, and university clinics. In Lithuania, microbiome research is conducted by Vilnius University, Kaunas University of Technology, and the Lithuanian University of Health Sciences. Additionally, research is carried out by associated institutes such as the National Cancer Institute, the Center for Innovative Medicine and Lithuanian Research Centre for Agriculture and Forestry. Vilnius University Hospital Santaros Clinics and Lithuanian University of Health Sciences Kaunas Clinics also conduct research in this field.
- Agencies promoting innovation, entrepreneurship, and foreign direct investment (FDI): The Innovation Agency and the Lithuanian Research Council.
- Regulatory institutions: The State Food and Veterinary Service and the State Medicines Control Agency – the State Food and Veterinary Service regulates food safety in Lithuania and follows the European Food Safety Authority (EFSA) guidelines. For medicinal products, Lithuania follows the European Medicines Agency (EMA) regulations as well as national guidelines set by the State Medicines Control Agency.

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[185] https://inovacijuagentura.lt/kcis/apie-mus/projektai/igyvendinami-projektai/preciseu.html?lang=lt

[186] https://lmt.lrv.lt/en/research-funding/

[187] https://www.vu.lt/en/scientific-report-2021/faculties/life-sciences-center

[188] https://lmt.lrv.lt/lt/kvietimai/kvietimas-teikti-paraiskas-atzaliniu-imoniu-moksliniu-tyrimu-ir-eksperimentines-pletros-mtep-projektams-igyvendinti/

Figure 14

Microbiome and Life Science Sector Ecosystem Map

Note: prepared by authors, based on the source from EIMIN, 2023

Below is an overview of key research institutions involved in microbiome studies, as well as the business ecosystem in Lithuania.

Key Research Institutions

Key Lithuanian institutions working on microbiome projects include:

- Vilnius University Life Sciences Center
- Lithuanian University of Health Sciences (LSMU)
- Food Institute of Kaunas University of Technology
- Department of Food Science and Technology at KTU

Lithuanian researchers have received notable certifications in recent years:

- Dr. Aurelijus Burokas received the Somerfeld-Ziskind Research Award for his research on the microbiota gut-brain axis in 2019.[189]

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[189] https://sobp.org/somerfeld-ziskind-research-award/

- Dr. Jurgita Skiecevičienė and Dr. Greta Varkalaitė won the UNESCO Women in Science competition in 2019 and 2024, respectively.
- The 2021 Lithuanian Science Prizes in the field of biomedicine and agricultural sciences was awarded to Jurgita Skiecevičienė, Laimis Virginijus Jonaitis, Gediminas Kiudelis, and Juozas Kupčinskas for their project “Tumor and inflammatory diseases of the digestive system: new molecular biomarkers, clinical-epidemiological aspects, modern methods of treatment”.[190]
- In 2023, Dr. Juozas Kupčinskas was elected General Secretary of the European Helicobacter and Microbiota Study Group.[191]
- The research team from LSMU, who have been working on microbiome research over the last 10 years, have published multiple research papers in top journals including Nature, Nature Genetics, Lancet Gastroenterology Hepatology, New England Journal of Medicine, Gut, Gastroenterology, Gut Microbes, and many others. Most recently, the GUT journal in 2024 announced Solveiga Samulėnaitė, a PhD student at Vilnius University Life Sciences Center, as the winner of the Best Paper of 2024 award for the article “Gut microbiota signatures of vulnerability to food addiction in mice and humans.[192]

These achievements underscore Lithuania’s growing influence and contribution in the global microbiome research community.

Ongoing Research Projects

The **LSMU** research group focusing on the microbiome, led by Dr. Juozas Kupčinskas and Dr. Jurgita Skiecevičienė, is actively contributing to groundbreaking studies on the gut microbiome and gastrointestinal diseases. Recently, they secured funding for seven projects under Horizon Europe and EU4Health, amounting to more than 3.7 million euros. These projects include:

- **MiGut-Health,** co-coordinated by Dr. Jurgita Skiecevičienė. The goal of the study is to identify the changes in the microbiome in inflammatory bowel diseases, and how diet and lifestyle factors affect the disease course.[193] Within this project, LSMU is focusing on organoids derived from patients with inflammatory bowel diseases to study potential metabolite therapies.
- **Personalized Disease Prediction and Prevention in Chronic Inflammatory Disorders (PerPrev-CID)** is a result of MiGut-Health and was initiated in 2024. The consortium, made up of 9 countries and 15 international partners, plans to create new standards for preventative and treatment strategies for rheumatoid arthritis and inflammatory bowel disease by investigating biomarkers, implementing nutritional changes, and developing digital health technologies.[194] LSMU’s contribution to this project involves providing an organoid model and researching microbiota.
- **Artifically Intelligent Diagnostic Assistant (AIDA)** is a project to aid clinicians in diagnosis and monitoring of gastric inflammation and cancer by using an AI assistant.[195] LSMU‘s research in the microbiome will be integrated into the creation of this AI system.

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[190] https://archyvas.lsmu.lt/en/front/news-and-events/winners-of-the-lithuanian-science-prizes-allocate-significant-support-to-ukraine.html

[191] https://lsmu.lt/en/lithuanian-researchers-achieving-breakthrough-in-gut-microbiome-research/

[192] https://www.lrytas.lt/sveikata/ligos-ir-gydymas/2024/07/12/news/kodel-zmones-yra-linke-persivalgyti-tyrimas-atskleide-netiketa-priezasti-32881225

[193] https://www.migut-health.eu/research/objectives

[194] https://www.perprev-cid.eu/

[195]https://www.aidaeuproject.org/

- **The TOwards GAstric Cancer Screening Implementation in the European Union (TOGAS)** project's goal is to develop new approaches for screening and detection of gastric cancer. Latvia University leads this project, and 13 other countries are collaborators for this 3 year long initiative.[196]
- **ONCODIR: Evidence-based Participatory Decision Making for Cancer Prevention through implementation** and **ONCOSCREEN** are programs focusing on colorectal cancer risk factors and prevention. Similar to AIDA, ONCODIR will create an artificial intelligence (AI) platform to enhance personalized approaches to treatment.[197] LSMU's role in these two projects involves researching biomarkers and testing mobile applications for the AI platform.
- **LyophilizeD fecal micrObiome traNsfer for primAry closTridioides difficilE infection (DONATE)** is a study testing the efficacy of a new compound, called Lyo-FMT, that is intended to treat primary *Clostridiodes difficile* infection (CDI). This new compound is easy to administer and does not require freezing, and the hope is that this convenient therapy might be a potential new option for CDI treatment.[198] This project was awarded €1,722,220 for 2023-2026.

Researchers at the **Vilnius University Life Sciences Center**, including Dr. Aurelijus Burokas, Dr. Eric Banan-Mwine Daliri, and Eglė Lastauskienė, are also leading innovative projects focusing on the gut-brain axis, functional foods, and expanding microbiome research into other areas in the body.

Key areas of study include:

- **Gut-brain axis:** Investigating microbiota changes linked to chronic stress, anxiety, Alzheimer's, addiction behaviors, and other cognitive changes through mouse models.
    - **Kefir-fermented HERBs in Alzheimer's Disease and its associated gut dysbiosis (HERB4AD)** is led by VU and aims to develop nonpharmacological therapeutics that could potentially delay cognitive deterioration, restore gut microbiota and restore earlier cognitive function. This work is a collaboration between VU and the Lithuanian Research Center for Agriculture and Forestry.
- **Obesity:** Exploring microbiota patterns associated with obesity.
- **Menopause:** Studying the vaginal microbiome to identify biomarkers for menopause.[199]
- **Functional foods:** Enhancing the nutritional and antioxidant properties of foods.
- **Fermented foods:** Examining the benefits of fermented foods for hypertension, diabetes, and probiotic properties.
- **Prebiotics, probiotics, and psychobiotics:** Researching their effects on the gut-brain axis, obesity, hypertension, cholesterol, and ageing.[200]
    - **Unravelling the role of probiotic candidates isolated from solid-state fermented psychoactive leaves in the microbiota-gut-brain axis** is a project aimed at isolating, screening, and identifying potential psychobiotics from solid-state fermented C. sativa and tobacco leaves and determining their mechanism of action.

The **Kaunas University of Technology (KTU) Food Institute (FI)** conducts cutting-edge research in functional foods, food safety, and biotechnological innovations, enhancing the bioavailability and bioactivity of health-promoting compounds. The Institute integrates microbiome research into food systems, bridging food and health sciences from policy to industry and farm-level implementation. KTU FI actively collaborates with international networks, including **Healthy Diet for a Healthy Life (HDHL), Standing Committee on Agricultural Research (SCAR) Food Systems Strategic Working Group,** and **the Bioeast Network.**

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[196] https://health.ec.europa.eu/document/download/0dc222dd-b41a-40a8-a374-ffea2eb3a9f7_en?filename=ncd_cancer_eu4h-prj_togas_factsheet_en.pdf

[197] https://www.oncodir.eu/about/

[198] https://open-research-europe.ec.europa.eu/articles/4-61/v1

[199] https://scholar.google.com/citations?user=-njGfCIAAAAJ&hl=lt

[200] https://scholar.google.co.kr/citations?user=hluwc9AAAAAJ&hl=en

Under the leadership of Dr. Alvija Šalaševičienė, Dr. Antanas Šarkinas, Dr. Irena Mačionienė, Dr. Lina Vaičiulytė, Dr. Natalja Makštutienė, and Dr. Darius Černauskas, the Institute's research is structured around three core pillars: circular economy, functional food systems, biotechnologies for food and health. Key research and innovation areas are:

- **Functional foods and drinks** – Developing bioactive food microbiota-based fermented foods, and alternative protein innovations.
- **Bio-preservatives and food safety through microbiota** – Utilizing KTU FI's 65-year-old national probiotic bacterial strain collection for biopreservation, antimicrobial solutions, and food safety advancements.
- **Food safety and microbiological risk modelling** - Using microbiome-based predictive models to assess food safety risks in dairy, meat, and fish industries.

Ongoing projects are **Horizon Europe HDHL Food4Health (2025-2028), Horizon Europe CleverFOOD (2024-2026),** and **TECHNOGEST (2022-2025)**, and future research will focus on exploring host-microbiome interactions in functional foods, developing microbiome-based dietary recommenda tions, and advancing metagenomics and metabolomics research.[201][202][203] Additionally, the Institute aims to strengthen European collaborations in food biotechnology.

The **Kaunas University of Technology (KTU) Faculty of Chemical Technology**, **Department of Food Science and Technology**, is leading innovative projects focusing on fermented and functional food, and uses one of the most representative *in vitro* technologies, the SHIME (Simulator of the Human Intestinal Microbial Ecosystem) model, to simulate the complex physiological, chemical and microbiological properties of the digestive tract. For the biomaterial functionality studies, the researchers use state-of-the-art molecular techniques using the available next generation sequencing tools ION5 Sequencing and QuantStudio Absolute Q Digital-PCR-System.

The Department of Food Science and Technology research group focusing on the microbiome led by Dr. Aušra Šipailienė is actively participating in the INFOGUT (2024–2028) project. This international network focuses on *in vitro* colon models, simulating gut microbiota interactions to advance research in digestive health. The project is part of the COST (European Cooperation in Science and Technology) initiative.

The Research and Design of Food Structures working group at the Department of Food Science and Technology led by Dr. Daiva Leskauskaitė focuses on encapsulation of biologically active compounds to control their release in the gastrointestinal tract of consumers. This includes development of probiotic microcapsules with stability and viability during the technological process and storage and development of special purpose products through structural design. An ongoing national project under Dr. Leskauskaitė is "Development of an innovative cannabinoid-enriched prebiotic from fibrous hemp products and its' benefits for the human microbiota evaluation".[204]

Several non-university institutions that have conducted studies in the microbiome include the Nature Research Center and the Center for Innovative Medicine.

In general, microbiome research in Lithuania is rapidly expanding. Researchers are involved in collaborating internationally in various EU projects, expanding investigation into different microbiomes of the body, and discovering new capabilities for disease prevention and treatment.

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201 https://www.healthydietforhealthylife.eu/hdhl-food4health

202 https://maistas.ktu.edu/events/3884/

203 https://en.ktu.edu/projects/combination-of-wet-extrusion-and-fermentation-processes-for-the-improvement-of-protein-quality-and-digestibility-of-matrices-based-on-plant-byproducts-technogest/

204 https://ktu.edu/projects/inovatyvaus-kanabinoidais-praturtinto-prebiotiko-sukurimas-is-salutiniu-pluostiniu-kanapiu-perdirbimo-produktu-ir-jo-naudos-zmogaus-mikrobiotai-ivertinimas/

Collaboration Networks

In Lithuania there is a strong collaboration network between researchers at all universities working on the microbiome. In addition to collaborating on projects with each other, investigators work with Vilnius University Hospital Santaros Klinikos and the Hospital of Lithuanian University of Health Sciences Kaunas Clinics to implement clinical trials. Notably, Dr. Vaidotas Urbonas, who works at Vilnius University Hospital and the Vilnius University Faculty of Medicine, specializes in pediatric gastroenetrology and is a key collaborator in microbiome projects. The Ministry of Health is also a collaborator in several projects, including the Horizon Europe project ONCODIR.

Lithuanian researchers frequently collaborate with international pharmaceutical companies and researchers to conduct clinical trials. These include participation in Horizon Europe and EU4Health projects, several of which were mentioned above. These collaborations strengthen Lithuania's visibility in the microbiome field and enable Lithuanian researchers to collaborate with universities internationally to share knowledge and work on best research practices.

A notable international collaboration partner is Kiel University in Germany, which hosted medical doctors from the Hospital of Lithuanian University of Health Sciences Kaunas Clinics hospital for fellowships. These doctors then brought new microbiome transplantation skills back to Lithuania.[205] Kiel University also collaborates with Lithuanian researchers in a few EU projects, including Mi-Gut Health and PerPrev-CID.

Infrastructure

Center for Innovative Medicine

The Center for Innovative Medicine in Lithuania is a State Research Institute that hosts laboratory services for scientific research and experimental development. These services include a disease biomarkers research laboratory and immunotechnology research laboratory.[206] A current project at this institution is related to the microbiome, titled "Towards personalized management of autoimmune epithelitis: a study on the links between microbiota, immune response and clinical expression".[207]

National Cancer Institute

The National Cancer Institute's (NCI) purpose is to improve quality of life by focusing research on precision medicine, particularly on early diagnosis and prevention strategies and treatment selection. They collaborate with partners in Lithuania and internationally on research projects, including "The Cancer Tissue Genome Atlas" and the "Cost Action Initiative". These ongoing projects involve members from around the world from different disciplines to improve health outcomes.[208] NCI also has a clinic to treat patients, in which multidisciplinary teams focus on individualized cancer treatment.[209]

It hosts a biobank, which has more than 10,000 tissue, blood, and urine samples from cancer patients as well as healthy donors. This library provides key data to support clinical research both in Lithuania and abroad.[210]

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205 https://lsmu.lt/en/lithuanian-researchers-achieving-breakthrough-in-gut-microbiome-research/

206 https://www.imcentras.lt/services/

207 https://www.imcentras.lt/key-projects/

208 https://www.nvi.lt/biobank-projects/

209 https://www.nvi.lt/clinic/

210 https://www.nvi.lt/biobank/

Medical Science Center

Vilnius University opened the Medical Science Center near the end of 2024. This complex hosts laboratories and research facilities spanning the topics of genetics, biomarker research, neuroscience, and dentistry and took EUR 66 million to fund, the largest investment in medical science infrastructure in Lithuania. The primary goal is to translate research into practical applications by bringing together researchers of different disciplines into one center to collaborate with practitioners. Researchers use the new facilities of the center to explore organoid model cultivation and novel AI technologies, both of which will allow scientists to better understand disease pathology and progression.[211]

The Medical Science Center launched the Biobank of Lithuanian Population and Rare Disorders, which stores specimens of both healthy people and individuals with rare diseases. These specimens will be available for research and commercial purposes in Lithuania and internationally. With this development, researchers will be better able to investigate the microbiome to develop prevention and treatment strategies, including personalized medicine.[212]

Human Biological Resources Center

The Human Biological Resources Center is a collaboration between LSMU and Lithuanian University of Health Sciences Hospital Kaunas Clinics, along with National Cancer Institute, Vilnius University, Vilnius Univesrity Hospital Santaros Klinikos, and the Center for Innovative Medicine. The ultimate goal of the biobank is to develop new treatments and diagnosis methods by allowing researchers to conduct research using their data to search for biomarkers. It was funded by the European Regional Development Fund and hosts solid tissue, liquid tissue, special live tissue, and a health information database, allowing more clinical studies to take place.[213]

Microbiome Research Institute

In the near future, the Lithuanian University of Health Sciences (LSMU), together with the Lithuanian University of Health Sciences Hospital Kaunas Clinics and its international partner, Kiel University, plan to establish a microbiome research institute. This initiative will provide Lithuania with a dedicated and strategic focus in this rapidly evolving field. [214]

Microbiome Industry in Lithuania

The Lithuanian biotechnology and life science sector boasts a dynamic and thriving business ecosystem, marked by a significant number of innovative advancements.

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211 https://www.vu.lt/en/news-events/news/from-organoid-cultivation-to-digital-solutions-for-fighting-cancer-the-new-medical-science-centre-boasts-remarkable-innovations

212 https://www.mf.vu.lt/en/institutes/the-biobank-of-lithuanian-population-and-rare-disorders#about

213 https://lsmu.lt/en/two-strategically-important-medical-facilities-opened-in-kaunas-new-opportunities-for-disease-diagnosis-and-treatment/

214 https://lmt.lrv.lt/public/canonical/1731063365/3713/Kandidatai%20kurti%20kompetencijos%20centrus.pdf

Food Sector: A Growing Strength

Lithuania's microbiome-related food sector is experiencing rapid growth, driven by an increasing number of companies developing functional foods that support microbiome health. Innovations such as probiotic-enhanced drinks, fortified snack bars, and other microbiome-friendly products are gaining traction in the market. As public interest in gut health and wellness continues to rise, Lithuania is well-positioned to become a key player in the functional food sector.

Emerging Opportunities in Therapeutics and Biotechnology

Lithuania hosts a thriving biotechnology sector, with companies specializing in gene editing, genome sequencing, and biopharmaceutical research. Several companies are actively exploring microbiome-based innovations, including psychobiotics, which have the potential to transform mental health treatments. The increasing focus on microbiome science presents significant opportunities for further investment and expansion in microbiome-targeted therapeutics.

In terms of therapeutics, fecal microbiota transplantation is available in Lithuania through clinical trials. In 2019, 18 total FMT procedures were performed in Lithuania for recurent *C. difficile* infection, and since then, multiple clinical trials have been done to test the safety and effectivess of FMT, including a study on its long-term efficacy in Lithuania.[215][216] Additionally, ongoing research is exploring the applications of FMT beyond *C. difficile*, such as inflammatory bowel disorders.

With a strong foundation in biotechnology and a rapidly evolving functional food sector, Lithuania is poised for growth in microbiome research and innovation. Lithuania's strong foundation in biotechnology ad rapidly evolving functional food sector creates an ideal environment for new ventures, partnerships, and investments aimed at unlocking the full potential of microbiome-based health solutions.

[215] https://www.sciencedirect.com/science/article/pii/S2666776221001587

[216] https://pubmed.ncbi.nlm.nih.gov/34752587/

SWOT Analysis of the Lithuanian Microbiome Sector

To evaluate the current state of the microbiome sector in Lithuania and identify opportunities for growth, we have conducted a SWOT analysis. This analysis provides an overview of the sector's strengths, weaknesses, opportunities, and threats, offering insights into its competitive position, challenges, and potential pathways for future development.

Below is the SWOT analysis of Lithuania's microbiome sector:

Strengths	Weaknesses
Technological Advancements: • Access to cutting-edge technologies like CRISPR, which enable advanced microbiome research.	**Knowledge and Talent Development:** • Limited public knowledge about the microbiome field and its significance. • Lack of exchange programs for postgraduate students to go abroad and expand networks. • Current study programs are not well-adapted for the development of specialized fields such as bioinformatics, limiting the training of experts essential for life science sector.
Universities and Collaborations: • Leading universities with high-competency specialists drive research in Lithuania • Many international collaborations with leading universities and pharmaceutical and biotechnology companies. • New centers, such as the Medical Science Center, support interdisciplinary collaboration and research.	**Funding and Investment:** • Calls and grants do not specifically mention microbiome topics. • Government funding does not meet the sector's needs to provide sufficient support for large-scale or long-term projects crucial to the expansion and development of the microbiome sector, impacting product commercialization.

Support and Funding: • Availability of national and EU funding that indirectly supports microbiome research projects. • Funding programs by governmental institutions help develop favorable conditions for start-ups to create and grow.	**Infrastructure and Resources:** • High cost of clinical trials and DNA sequencing in local institutions, making outsourcing to other countries more feasible. • There are few incentives to modernize or renew research infrastructure, and untapped opportunities to utilize existing facilities.
	Regulations and Bureaucracy: • Regulatory pathways and framework should be improved for food supplements and microbiome-based therapies and drugs in both the EU and Lithuania to make it easier for products to go to market. • Public procurement policies are not favorable for supporting clinical trials and scientific research. • Local documentation requirements impose additional constraints on business development.
	Industry-Academia Collaboration: • Difficulty initiating clinical trials due to the limited presence of pharmaceutical companies in Lithuania. • Weak collaboration between industry and academia due to high costs, different priorities, and time constraints. • Few companies invest in research-backed, scientifically tested products.

Opportunities	Threats
Specialization: • Lithuania has an opportunity to carve out a unique identity in the emerging microbiome field due to its relative newness in this area. • By specializing in specific technologies such as CRISPR, tissue engineering, and microfluidics, Lithuania can attract foreign investors and stand out globally.	**Talent Drain:** • Skilled professionals in all fields are migrating abroad for better opportunities leading to brain drain.
Market Position and Ecosystem: • The rising global microbiome sector aligns well with Lithuania's Life Sciences Roadmap goal to reach 5% by 2030. • With limited competition in the microbiome field within Lithuania, there is a unique opportunity for the country to establish itself as a regional leader in microbiome research and applications. • Favorable conditions for new biotech companies to enter the microbiome market, fostering innovation, creating jobs, and attracting international investment.	**Regulatory Challenges:** • Lack of clear and supportive regulations hinders the start and growth of product development in the microbiome sector. • Slow approval processes by the European Medicines Agency (EMA) for drugs and the European Food Safety Authority (EFSA) for functional foods delay market introductions.
Partnerships: • Strong international partnerships with leading universities and pharmaceutical companies provide an opportunity to enhance knowledge exchange, drive innovation, and elevate Lithuania’s global presence in microbiome research.	**Global Competition:** • As the microbiome sector grows, Lithuania may face increasing competition from other countries with more established programs and resources.
	Public Awareness: • Limited awareness and support for the microbiome sector may hinder investment and collaboration.

Recommendations

Based on the analysis of global and Lithuanian microbiome research and product development trends, we recommend the following steps to strengthen and expand Lithuania's contributions to this growing field:

International Collaboration and Talent Attraction:

1. **Address Brain Drain:** The Lithuanian government and its institutions should offer competitive salaries and career opportunities to attract and retain international specialists. Additionally, clear career pathways should be established, ensuring long-term professional development opportunities.

2. **Attract Pharmaceutical Companies to Lithuania:** Government institutions should actively promote Lithuania as a strategic hub for world-renowned pharmaceutical companies. This would address challenges in high DNA sequencing costs, initiation of clinical trials, and the shortage of investments and infrastructure for broader R&D expansion, all of which stem from the limited presence of these companies.

Public Engagement and Awareness:

1. **Launch Public Awareness Campaigns:** To address the lack of awareness about the importance of the microbiome sector, nationwide initiatives should be launched to educate the public on its significance for health and well-being. This can be accomplished by partnering with influencers, healthcare professionals, and businesses to organize events, webinars, and workshops.

2. **Promote Healthy Food Catering Initiatives in Schools and Daycares:** Given the importance of food and diet to the microbiome, healthy eating habits should be promoted by providing organic, microbiome-friendly food in educational institutions to support better health outcomes from an early age.

National Strategy and Policy Framework:

1. **Revise National Strategies:** Revise key documents, like the *Smart Specialization Strategy (S3)* and the *Life Sciences Roadmap*, to highlight microbiome research and align with global trends, fostering growth and competitiveness.

2. **Provide Suitable Public Procurement Policies for Scientific Research:** Current public procurement policies are not conducive to supporting clinical trials and scientific research. These policies should be updated to better support scientific advancement.

3. **Promote Long-Term Projects:** Extend the duration of current projects by prioritizing long-term grants for microbiome research, particularly for high-risk, high-reward projects with breakthrough potential. Short-term projects often fail to allow full exploration of a topic, whereas a long-term focus on specific research areas will better support progress toward commercialization. Additionally, since microbiome changes can take months or even years to influence health outcomes, lengthening project timelines is essential for obtaining meaningful scientific results.

4. **Encourage Initiatives for Translating Research Into Product:** Few companies invest in research-backed, scientifically tested products. Continuing initiatives that support companies in bringing clinically tested products to market would significantly enhance innovation and the ability to commercialize R&D results.

5. **Initiate Microbiome Product Regulations:** Advocate for and establish improved regulatory pathways for food supplements and microbiome-based therapies and drugs, starting at the EU level and then extending to national regulations.

6. **Encourage Infrastructure Efficient Usage and Development:** There are currently few incentives to modernize or upgrade research infrastructure in Lithuania. However, significant opportunities remain to better utilize existing facilities, which could enhance efficiency, strengthen collaboration within the research ecosystem, and improve the translation of academic research into market-ready products.

Research and Innovation Development:

1. **Develop Unique Signature Products:** Lithuania can position itself as a global leader in the microbiome sector by creating innovative products in specialized fields, leveraging its expertise in *CRISPR, microfluidics,* and *tissue engineering.* These advancements can gain international recognition, strengthening Lithuania's competitive edge.

2. **Include the Microbiome Field in Current Funding Calls**: Although microbiome research is currently covered under the broader category of life sciences, explicitly mentioning it in funding calls and programs would help address existing financing gaps. This adjustment would sustain ongoing projects and attract new researchers by providing targeted financial resources.

3. **Encourage Postgraduate Exchange Program Initiatives:** Encourage postgraduate exchange programs that promote international student exchanges, research partnerships, and collaboration, strengthening global ties and fostering expertise among Lithuania's future researchers.

4. **Develop Specialized Training Programs:** Develop targeted programs in universities to address the shortage of skilled professionals, such as investing in bioinformatics, biostatistics, and microbial science programs. The creation of the new bioinformatics program can serve as a model. This new program equips students with essential skills for emerging research in microbiome research and personalized medicine. Additionally, establishing interdisciplinary training programs combining microbiology with data science and medicine, with a focus on both human and environmental health perspectives, would strengthen Lithuania's research capabilities and attract global partnerships.