



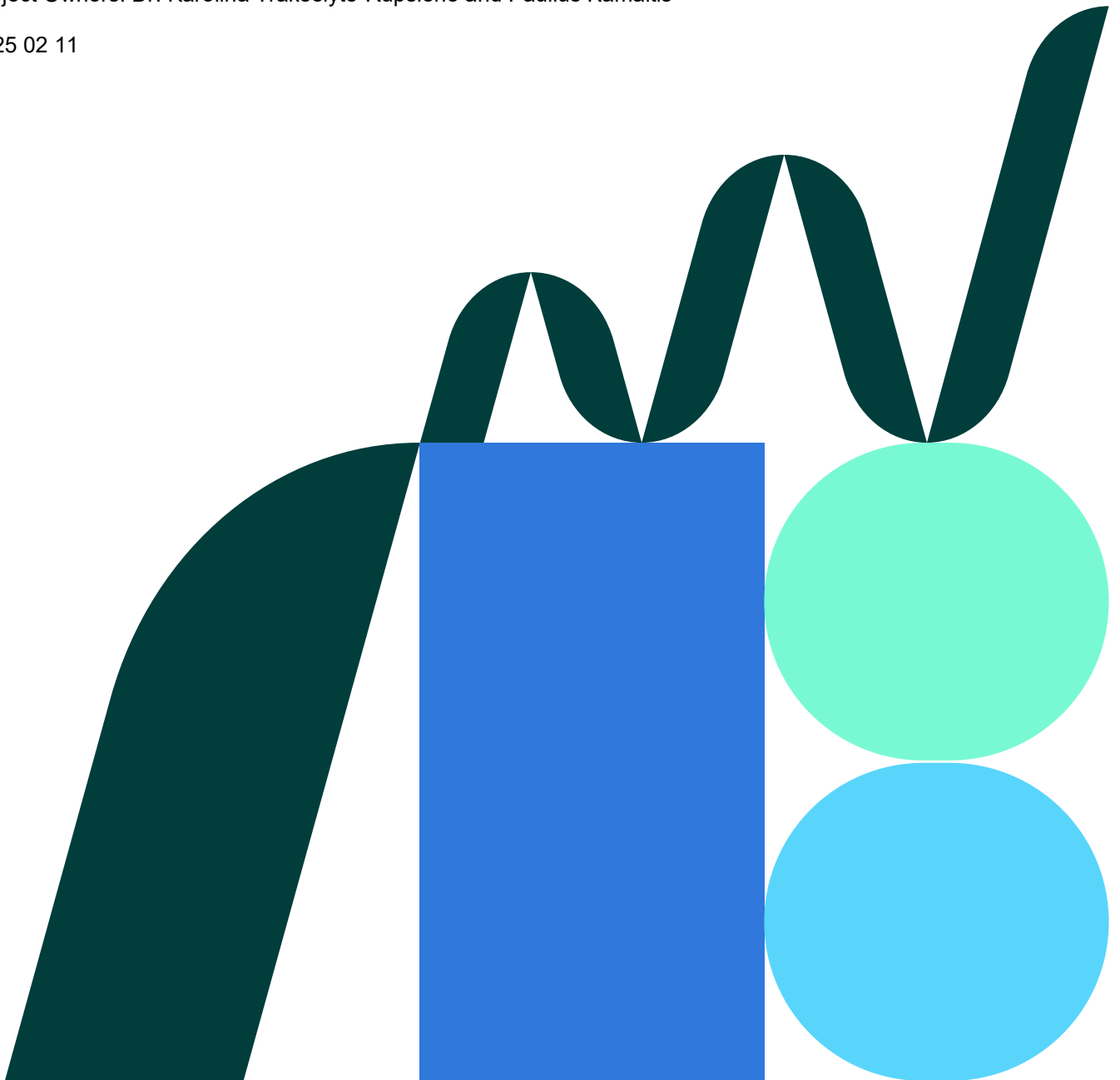
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# Microbiome Analysis in Lithuania: Overview of the Global and Local Ecosystem, Strengths, Weaknesses, and Recommendations

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# 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 4<sup>th</sup> globally in both microbiome academic research<sup>1</sup> and innovation<sup>2</sup>. 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**<sup>3</sup> 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.<sup>4</sup> They are leading the world's largest microbiome standardization program, including the development of the first **WHO International Reference Reagents** for the microbiome.<sup>5</sup> This program is crucial for advancing microbiome research by standardizing methodologies.

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.<sup>6,7</sup>
- The **Bioindustry Association** connects researchers and industry to accelerate therapeutic development.<sup>8</sup>

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<sup>1</sup> <https://doi.org/10.1093/procel/pwad031>

<sup>2</sup> [https://www.gazettelabo.fr/media/files/211007\\_CP\\_APM\\_EtudeSectorielle2021\\_VF.pdf](https://www.gazettelabo.fr/media/files/211007_CP_APM_EtudeSectorielle2021_VF.pdf)

<sup>3</sup> <https://iuk-business-connect.org.uk/news/ktns-microbiome-innovation-network-launches-the-microbiome-strategy-roadmap/>

<sup>4</sup> <https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about>

<sup>5</sup> [https://nibsc.org/science\\_and\\_research/idd/microbiome.aspx](https://nibsc.org/science_and_research/idd/microbiome.aspx)

<sup>6</sup> [https://iuk-business-connect.org.uk/wp-content/uploads/2023/02/0489\\_KTN\\_HIMDD\\_Final2\\_AW\\_Updated-230228.pdf](https://iuk-business-connect.org.uk/wp-content/uploads/2023/02/0489_KTN_HIMDD_Final2_AW_Updated-230228.pdf)

<sup>7</sup> <https://www.sanger.ac.uk/about/strategy-and-funding/>

<sup>8</sup> <https://www.bioindustry.org/>

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.<sup>9</sup>

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.<sup>10</sup> 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.<sup>11</sup> 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.<sup>12</sup>

## Funding

**UK Research and Innovation (UKRI)** has allocated a £210 million budget for precision medicine initiatives, including whole genome sequencing, which benefits microbiome research.<sup>13</sup>

- The **Biotechnology and Biological Sciences Research Council (BBSRC)** supports microbiome research with grants of up to £2 million.<sup>14</sup> Additionally, it funds microbiome research centers such as the Quadram Institute.
- The **Industrial Strategy Challenge Fund (ISCF)** supports innovation in clean growth, the ageing society, the future of mobility, and artificial intelligence.<sup>15</sup> These themes often intersect with microbiome innovation, particularly in fields such as environmental sustainability and precision healthcare.

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<sup>9</sup> <https://iuk-business-connect.org.uk/programme/microbiome-landscape/>

<sup>10</sup> [https://iuk-business-connect.org.uk/wp-content/uploads/2023/02/0489\\_KTN\\_HIMDD\\_Final2\\_AW\\_Updated-230228.pdf](https://iuk-business-connect.org.uk/wp-content/uploads/2023/02/0489_KTN_HIMDD_Final2_AW_Updated-230228.pdf)

<sup>11</sup> <https://biorepository.org.uk/about-biorepository/>

<sup>12</sup> <https://quadram.ac.uk/about/>

<sup>13</sup> <https://www.ukri.org/what-we-do/browse-our-areas-of-investment-and-support/data-to-early-diagnosis-and-precision-medicine/>

<sup>14</sup> <https://www.ukri.org/what-we-do/browse-our-areas-of-investment-and-support/integrative-microbiome-research/>

<sup>15</sup> <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.<sup>16</sup> 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.<sup>17</sup>

### 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.<sup>18</sup>

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.<sup>19</sup>

### 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.<sup>20</sup> With 31 Nobel Laureates among its alumni, the Max Planck Society is globally recognized for its groundbreaking contributions to science.<sup>21</sup> Additionally, it ranks as the third most prestigious institution globally in the Nature Index for 2023.<sup>22</sup>

Another key player in Germany's microbiome research landscape is the **Helmholtz Centre for Infection Research**, part of the Helmholtz Association.<sup>23</sup> This institute addresses global challenges related to health, the

<sup>16</sup> <https://doi.org/10.1093/procel/pwad031>

<sup>17</sup> <https://www.exzellenzstrategie.de/en/what-is-exstra/>

<sup>18</sup> <https://www.dfg.de/en/about-us/about-the-dfg/what-is-the-dfg>

<sup>19</sup> <https://www.dfg.de/en/news/news-topics/announcements-proposals/2024/ifr-24-60>

<sup>20</sup> <https://www.bio.mpg.de/48843/microbiome-science-ruth-ley>

<sup>21</sup> <https://www.mpg.de/nobel-prize>

<sup>22</sup> <https://www.helmholtz.de/en/about-us/who-we-are/facts-and-figures/scientific-performance/>

<sup>23</sup> <https://www.helmholtz-munich.de/en/comi>

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environment, and technology, consistently ranking among the top research organizations worldwide. In the 2023 Nature Index, the Helmholtz Association secured the eleventh position globally.<sup>24</sup>

Equally significant is the **Leibniz Institute for Natural Product Research**, particularly its Department of Microbiome Dynamics.<sup>25</sup> The Leibniz Association, which comprises 96 independent research institutions, is dedicated to pushing the boundaries of scientific exploration.<sup>26</sup>

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<sup>24</sup> <https://www.helmholtz.de/en/about-us/who-we-are/facts-and-figures/scientific-performance/>

<sup>25</sup> <https://www.leibniz-hki.de/en/microbiome-dynamics.html>

<sup>26</sup> <https://www.leibniz-gemeinschaft.de/en/about-us/about-the-leibniz-association>

## France



France is recognized as the leader in microbiome innovations across Europe.<sup>27</sup> 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.<sup>28</sup> Since 2010, MGP has earned international recognition for its expertise in gut microbiome analysis and its transformative applications in health and nutrition.<sup>29</sup> With a €24.7 million budget spanning 2012–2025, MGP is at the forefront of developing microbiome-based therapeutics.<sup>30</sup>

Collaborating with industrial partners such as Adisseo, Dupont, Bridor, Sanofi, and Roquette, as well as start-ups such as Enterome, Novobiome, and MaaT Pharma,<sup>31</sup> 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).<sup>32</sup>

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.<sup>33</sup>

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.<sup>34</sup>

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.<sup>35</sup>

### 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.<sup>36</sup>

<sup>27</sup> [https://www.gazettelabo.fr/media/files/211007\\_CP\\_APM\\_EtudeSectorielle2021\\_VF.pdf](https://www.gazettelabo.fr/media/files/211007_CP_APM_EtudeSectorielle2021_VF.pdf)

<sup>28</sup> [https://one.oecd.org/document/DSTI/STP/BNCT\(2016\)20/FINAL/en/pdf](https://one.oecd.org/document/DSTI/STP/BNCT(2016)20/FINAL/en/pdf)

<sup>29</sup> <https://www.inrae-transfert.fr/en/focus-on/104-2-demonstrateurs>

<sup>30</sup> [https://one.oecd.org/document/DSTI/STP/BNCT\(2016\)20/FINAL/en/pdf](https://one.oecd.org/document/DSTI/STP/BNCT(2016)20/FINAL/en/pdf)

<sup>31</sup> <https://mgps.eu/about/who-we-are/>

<sup>32</sup> <https://www.inrae-transfert.fr/en/focus-on/104-2-demonstrateurs>

<sup>33</sup> <https://mgps.eu/about/our-mission/>

<sup>34</sup> <https://www.inrae.fr/en/reports/gut-microbiota-our-new-health-ally/metagenopolis-unique-place-dedicated-knowledge-microbiota>

<sup>35</sup> <https://www.inrae-transfert.fr/en/focus-on/104-2-demonstrateurs>

<sup>36</sup> <https://db.cngb.org/mmhp/white.paper.pdf>

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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.<sup>37</sup>

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<sup>37</sup> <https://lefrenchgut.fr/the-french-gut-project/>

USA



The United States is a global leader in microbiome research<sup>38</sup> and innovation<sup>39</sup>, 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.<sup>40</sup> 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.<sup>41</sup>

### 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.<sup>42</sup> 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.<sup>43</sup>

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.<sup>44</sup>

Other noteworthy institutions include the AGA Center for Gut Microbiome Research and Education, Janssen Human Microbiome Institute, and the Cedars-Sinai Microbiome Institute.<sup>45,46,47</sup>

<sup>38</sup> <https://doi.org/10.1093/procel/pwad031>

<sup>39</sup> [https://www.gazettelabo.fr/media/files/211007\\_CP\\_APM\\_EtudeSectorielle2021\\_VF.pdf](https://www.gazettelabo.fr/media/files/211007_CP_APM_EtudeSectorielle2021_VF.pdf)

<sup>40</sup> <https://hmpdacc.org/hmp/>

<sup>41</sup> <https://www.nih.gov/news-events/news-releases/nih-human-microbiome-project-defines-normal-bacterial-makeup-body>

<sup>42</sup> <https://www.huck.psu.edu/institutes-and-centers/microbiome-center/about/mission>

<sup>43</sup> <https://microbiome.ucdavis.edu/resources/microbiome-centers-and-organizations>

<sup>44</sup> <https://microbiome.uchicago.edu/node/791>

<sup>45</sup> <https://gastro.org/aga-leadership/centers/aga-center-for-gut-microbiome-research-education/>

<sup>46</sup> <https://www.janssen.com/article-type/human-microbiome-institute>

<sup>47</sup> <https://www.cedars-sinai.edu/health-sciences-university/research/departments-institutes/medicine/human-microbiome.html>



## 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.<sup>48</sup>

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.<sup>49</sup> A major milestone in this area was the FDA's approval of Rebyota™, a rectally administered fecal microbiota product, in late 2022.<sup>50 51</sup> The FDA later approved VOWST™, the first orally administered fecal microbiota product.<sup>52</sup> 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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<sup>48</sup> <https://www.fda.gov/about-fda/what-we-do>

<sup>49</sup> <https://www.fda.gov/science-research/advancing-regulatory-science/focus-areas-regulatory-science-report>

<sup>50</sup> <https://www.fda.gov/news-events/press-announcements/fda-approves-first-orally-administered-fecal-microbiota-product-prevention-recurrence-clostridioides>

<sup>51</sup> <https://www.nixonpeabody.com/insights/alerts/2023/05/15/fda-approves-microbiome-based-therapies>

<sup>52</sup> <https://www.fda.gov/news-events/press-announcements/fda-approves-first-orally-administered-fecal-microbiota-product-prevention-recurrence-clostridioides>