

Microba

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MICROBA™

For the best microbiome therapies, understand your bugs

Australia's Microba is leveraging its world-leading microbiome tools and data science for rigorous hypothesis-driven live-biotherapeutics development.

The microbiome impacts most aspects of human health; however, the first generation of donor-derived microbiome therapeutics have traveled a challenging path to regulatory approval and struggled to deliver sufficient efficacy outside of infectious disease. This is, in part, because companies jumped into development based on weak associational data and simplistic understandings of how specific bacteria impact disease.

Better microbiome therapies will depend on precision microbiome science—that is the idea driving Microba, which was founded in 2017 to develop a human-first data-driven platform for microbiome analytics and therapeutics. After recognizing the potential to advance health with new solutions developed from the human microbiome, Gene Tyson and Phil Hugenholtz co-founded Microba based on research from their academic laboratories at the University of Queensland, Australia.

"We saw huge potential to improve on technology gaps in the burgeoning field," said Tyson, who sits on Microba's board and is now the director of the Queensland University of Technology (QUT) Centre for Microbiome Research (CMR). "The microbiome industry was taking root, especially consumer testing and therapeutic development in the US. But it was clear we had a superior platform to identify microbial species that were important in the context of health and disease."

The Microba Community Profiler

The company's core technology for metagenomic microbiome analysis is the Microba Community Profiler (MCP), validated last year in a *Frontiers in Microbiology* paper that demonstrated the platform's advantages over existing approaches. It has also developed the Microba Genome Database, the world's largest and most advanced microbiome data bank, containing 1.2 million microbial genomes. Together, these technologies let Microba build knowledge and insights to develop the next generation of therapeutic products based on precise measurements of the microbiome (Fig. 1).

"Between our database and our highly accurate and precise bioinformatics pipelines, we can see signals that other companies can't, giving us a huge advantage," said Tyson. The analytics platform supports microbiome testing products in consumer, healthcare provider and research spaces, as well as Microba's internal therapeutics pipeline and partnerships.

"What first excited me about Microba was the ability to characterize the gut microbiome in a much more precise way, defining which bacteria are in your gut, how many of them and what they're

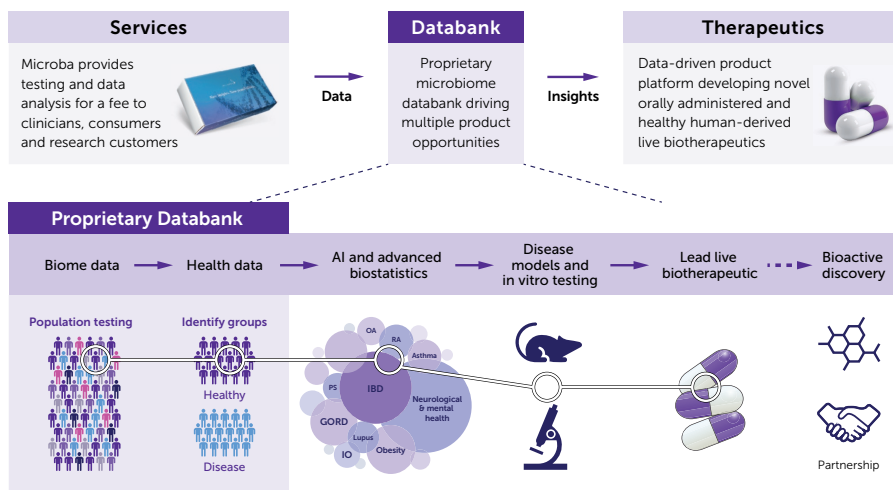


Fig. 1 | The Microba advantage. The depth and accuracy of the microbiome analysis gives a specific competitive advantage to create powerful insights. AI, artificial intelligence.

doing," said Ian Frazer, a professor at the University of Queensland and a Microba board director. "But understanding the microbiome was just the first step. To create novel therapeutic products for a wide variety of health conditions, it requires harnessing this knowledge in a concrete way."

Microba has developed genome-directed isolation strategies and, more recently, a high-throughput cultivation platform. Before these tools were deployed, only about 30% of gut-resident organisms had been cultured. Through these additional capabilities, the company is developing a pipeline of live biotherapeutic candidates, with research and development (R&D) capacity to rigorously test hypothesis-driven approaches.

"Many companies in the microbiome space approach drug development in the traditional pharma mold, screening a huge library of candidates in search of a hit," Frazer said. "We can instead take the 'designer drug' approach, understanding which among the millions of microbes are relevant to disease, and which are just along for the ride."

Therapeutic areas of focus

Much of Microba's therapeutics work focuses on the interface between the gut microbiome and the immune system. For its lead program, Microba used the MCP to develop a model of inflammatory bowel disease, identifying bacteria commonly present in healthy individuals that were significantly reduced in individuals with ulcerative colitis. It then tested these therapeutic candidates in a series of animal models

to confirm their impact on disease relevance. These studies enabled selection of MAP 315, a single bacterial strain that the company is currently advancing through current good manufacturing practice (cGMP) manufacture to support a clinical trial in 2023.

The pipeline also includes a program in autoimmune disease, through Microba's partnership with Ginkgo Bioworks, to identify lead candidates for lupus, psoriatic arthritis and certain autoimmune liver diseases.

The company is also developing microbiome-derived therapeutics to pair with immune checkpoint inhibitors (ICIs), a class of cancer immunotherapies that have shown remarkable efficacy—but typically in only a small percentage of patients. A handful of ICIs marketed by large pharmaceutical companies are already in clinical testing in combination with microbiome modulators, but the rationale is not clear in all cases. "Big pharma clearly sees the promise, but the space has seen a number of false starts in the last few years. Anyone looking to partner had better come to the table with some very compelling evidence of efficacy," said Frazer. "That plays right into Microba's strengths."

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