

Microbiotica
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Microbiotica—unlocking the microbiome as a multi-therapeutic modality

Microbiotica's platform makes it a leader in precision clinical discovery of novel microbiome-based therapeutics and biomarkers. With the platform validated at scale, and a pipeline of programs, the company is open to collaborations in both therapeutic and biomarker discovery.

Microbiotica was founded in 2016 in Cambridge, UK, to translate pioneering research from the Wellcome Sanger Institute into novel, microbiome-based precision medicines. It has developed the leading platform for identifying and isolating gut bacteria linked to clinical phenotype and using the resulting bacterial signatures to design microbiome-based therapeutics and biomarkers (Fig. 1). Using this clinic-first approach, Microbiotica is developing a pipeline of next-generation microbiome-based products that includes a live bacterial therapeutic (LBT) to extend immune checkpoint inhibitor (ICI) response in cancer, an LBT to treat ulcerative colitis (UC), and the first universal, actionable microbiome signature predictive of response to ICIs. Following its recent £50 million financing, both LBT programs are progressing into phase 1b clinical trials and new discovery programs are progressing into development.

"Over the past two decades, the influence of the microbiome on health, disease and drug response has been well established, but harnessing this knowledge to develop medicines or biomarkers that can be used as complementary or companion diagnostics for drugs has proven more challenging than anticipated," said Mike Romanos, co-founder and CEO of Microbiotica. "At Microbiotica we are addressing the hurdles to translation by starting with clinic-based, precise determination of microbial signatures, using our uniquely accurate platform to identify microbes and mechanisms."

Given the versatility of its platform in many potential applications, Microbiotica is open to partnerships in multiple modes: developing new LBTs in different disease areas; identifying novel biomarkers/companion diagnostics of drug action in pharmaceutical clinical trials; and identifying novel therapeutic targets. The company has fully scaled and validated its precision clinical microbiome profiling in major collaborations with Genentech, Cancer Research UK, Cambridge University and the University of Adelaide.

Decoding the microbiome in human biology

A fundamental challenge to the translation of microbiome research into practical applications has been to fully characterize and isolate gut microbes linked to human phenotype. The issues have been as follows: incomplete or inaccurate classification of the microbiome in a patient; variability across individuals requiring statistical analysis of patient

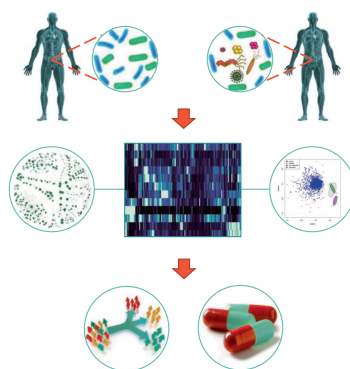


Fig. 1 | Microbiotica's industry-leading human microbiome discovery platform.

cohorts; identifying a bacterial signature correlating with phenotype from a complex dataset; and isolating the exact bacteria identified for further experimentation or drug development.

Microbiotica has tackled these challenges through its leading microbiology, bioinformatics and machine-learning capabilities. These are underpinned by the capability to comprehensively isolate bacteria from patient gut microbiomes (*Personalized Bacterial Banks*), providing the exact strains for LBT or biomarker development. This technology rapidly grows the *Microbiotica Culture Collection* coupled to the *Microbiotica Reference Genome Database*—a 'global microbiome blueprint', a leading collection of bacterial genomes from isolated cultures that is key to high-precision bacterial identification. Microbiotica's databases provide the depth and breadth needed to rapidly de-risk and advance ongoing as well as future development programs. To this are added class-leading bioinformatic and machine-learning capabilities that identify phenotype-specific bacterial signatures and mechanistic insights that serve as the foundation for therapeutic and biomarker development.

A growing pipeline of precision medicines

The company's lead immuno-oncology program is MB097, an LBT consisting of nine bacteria from all three major phyla of bacterial gut commensals that includes a previously undescribed species. In a mouse tumor model, MB097 has been shown to synergize anti-PD1 therapy, and in vitro studies have both deconvoluted the mechanism and validated immune system activation and tumor killing



Best in class microbiome profiling

Bacterial composition determined in large patient groups with unparalleled comprehensiveness and precision



Identifying signature linked to phenotype

Leading bioinformatic tools identify microbiome signatures linked to different patient outcomes missed by other groups



Biomarker, target and therapeutic candidates

Microbiome signatures stratify patients for personalized drug treatment and identify Live Bacterial Therapeutics and drug targets for testing in defined patient groups

in human cells. In 2023, MB097 will be entering a phase 1b clinical study in patients with melanoma.

In UC, the company's lead program is MB310, an LBT consisting of 10 bacteria identified as key players for remission in a large fecal matter transplant (FMT) study conducted in Australia with patients with UC. Microbiotica's researchers reverse-engineered MB310 by using the company's platform to isolate and bank all the bacteria from the FMT donors and track the engraftment of donor bacteria in the patients. The therapeutic effect of MB310 was confirmed in a mouse model of IBD, and human cell assays identified multiple therapeutic actions including robust gut epithelial barrier healing and suppression of inflammation-associated innate and adaptive immunity. MB310 will also be entering a phase 1b clinical study in patients with mild-to-moderate UC in 2023.

"With our two lead programs entering the clinic in the near future, and several other programs in exploratory or preclinical stages, we are looking forward to soon having clinical proof-of-concept for our unique approach," said Romanos. "Microbiome-based therapies provide a unique way to manage disease, but we are only now starting to realize this potential by harnessing the technical advances that allow for the development of true precision medicines."

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