

Microbiotica

www.microbiotica.com



Translating precision in microbiome science into predictive biomarkers and more effective drugs

With the world's leading culture collection and reference genome database, and advanced bioinformatics and machine learning systems, UK-based Microbiotica can identify and isolate the full complement of gut bacteria linked to patient phenotype, attracting global interest and partnering deals from big pharma.

The microbiome is a multi-therapeutic opportunity that will revolutionize medicine. We now know gut bacteria control disease and drug response throughout the body, and have evidence that modulating microbiota drives positive health outcomes. Yet, there remain technical barriers to predictable translation in this emerging field. Microbiotica is addressing the barriers and helping drive a new era of rigorous, data-driven microbiome R&D.

Microbiotica is built on transformational advances of over a decade of research in Trevor Lawley's Wellcome Sanger Institute laboratory that addressed key barriers, including the design of defined bacterial therapeutics, mass isolation of gut bacteria, and comprehensive and precise analysis of gut bacteria to accurately link patient phenotype to the intestinal microbiome for the first time.

Leading microbiome capabilities

Microbiotica has scaled, industrialised and extended the technology originally developed at the Wellcome Sanger Institute. The company has developed the ability to isolate the full complement of gut bacteria from patients, built the world's leading Culture Collection and Reference Genome Database, and set up advanced bioinformatics and machine learning systems. The capability is unrivalled in characterising patient microbiota fully and precisely, and linking them to patient phenotypes for discovery of bacteria that represent biomarkers and Live Bacterial Therapeutics (LBTs) (Fig. 1). This is demonstrated both by benchmarking compared to leading service providers, which shows a marked difference in the ability to identify bacteria and their abundance, and by the company's identification of the first bacterial signature in immuno-oncology drug response predictive across clinical datasets, where others have disagreed on the bacteria involved.

Armed with industry-leading technology to enable the most comprehensive and precise microbiome profiling, Microbiotica is working to discover bacterial biomarkers of drug response and best-in-class LBTs in inflammatory bowel disease (IBD) and immuno-oncology (I-O), its current areas of therapeutic focus.

Microbiotica's status as a global microbiome leader is illustrated by the calibre of its collaborators. Genentech, an organization renowned for its scientific standards, chose Microbiotica for its foray into the microbiome based on its conviction that a new level of rigour was required in microbiome patient profiling. Genentech contacted

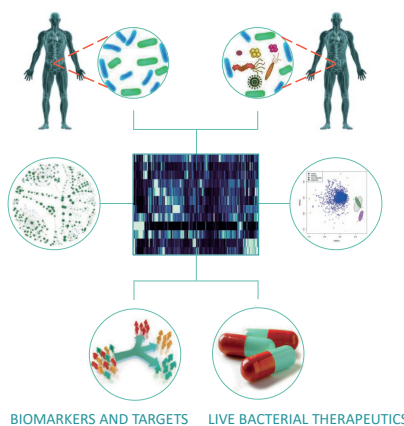


Fig. 1 | Microbiotica's unrivalled human microbiome discovery platform.

Large-scale precision microbiome profiling

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

Microbiome signature for drug response

Platform identifies microbiome signatures linked to different patient outcomes from large-scale studies coupled with machine learning

Biomarker, target and LBT discovery

Bacterial signatures stratify patients for personalised drug treatment and identify candidates for Live Bacterial Therapeutics (LBT) and for conventional target discovery

Microbiotica weeks after its founding and entered into a \$534 million deal within 18 months.

Microbiotica followed up the agreement with Genentech with a second validity deal with Cancer Research UK (CRUK) that gave it access to key large-scale clinical data to feed its programs, and to tackle the widely studied link between the microbiome and response to checkpoint inhibitors.

Using the data and its unique ability to characterize the microbiome, Microbiotica became the first group to identify a single microbiome biomarker signature predictive of checkpoint inhibitor drug response in melanoma and lung cancer across multiple clinical studies. The signature, which is 91% predictive of responses in melanoma, could serve as a companion diagnostic for identifying likely responders, and is the basis for one of Microbiotica's lead candidates.

Translating science into breakthrough medicines

Microbiotica identified the subset of bacteria that cancer patients must have to respond to checkpoint inhibitors and created a LBT to deliver them. The candidate, which is due to enter the clinic in 2022, could bring the powerful responses seen in a minority of people to the broader population.

Microbiotica is advancing the I-O asset in parallel to an ulcerative colitis candidate. By working with the University of Adelaide, in Australia, to study patients who went into remission after undergoing fecal microbiota transplantation (FMT), Microbiotica identified bacteria that were responsible for the efficacy of the intervention. Delivering just the defined bacteria could more reliably and

safely achieve the cures that are possible with FMT. The drug is set to enter the clinic in 2022.

With two candidates on the cusp of human testing, Microbiotica is scaling up its operation. A funding round is planned for 2021, by when Microbiotica will have moved into a new purpose-built facility. The 50-strong team, led by Crescendo Biologics co-founder and GSK veteran Mike Romanos, along with Lawley, is growing, and will build and advance the IBD and I-O pipelines.

The breadth of the microbiome opportunity, which spans autoimmune, CNS and metabolic diseases, provides many therapeutic areas for Microbiotica to apply its industrial isolation and culture capabilities. The company plans to expand its internal pipeline into some of those therapeutic areas but, to realise the full potential of its technology, it is also open to partnering. The partnerships will enable other companies to benefit from Microbiotica's expertise in the discovery of LBTs, microbiome signatures for drug-response stratification and novel targets.

In bringing that expertise to internal and partnered programs, Microbiotica will be the focal point of a new, data-driven era of microbiome R&D, and develop defined LBTs that realise the full therapeutic potential of the nascent field.

CONTACT

Mike Romanos, Cofounder and CEO
Microbiotica
Cambridge, UK
Tel: +44 1223 786061
Email: info@microbiotica.com