Interview transcript

Why every healthcare company should have a microbiome strategy

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NB: Hi Tomas and thanks for doing this interview. Over the last years, the microbiome has become a very hot topic. To start with, please tell us what the Microbiome is.

TdW: A microbiota is a community of microbes that lives in a certain habitat. Just as we know it from the soil or the oceans, most places on earth have their specific microbiota that are an integral part of the ecosystem. In this interview, we are referring to the gut microbiome.

Formerly referred to as “gut flora”, the “gut microbiota” was largely understudied and only attributed basic digestive functions. This was mainly due to the difficulties in cultivating this multitude of bacteria and other microbes. Advances in sequencing technology in the early 2000s have accelerated our understanding of this integrative part of our body through a genomic characterization of our microbiota. This pool of genes that constitutes 100-times more genes than the human genome is referred to as the “microbiome”.

Extensive studies of the crucial role of the microbiome in health, identified its role in multiple chronic and untreatable diseases, adding the next piece to the puzzle of human health.

NB: And why is the microbiome so important for our health?

TdW: Our microbiome is “external” to our body but an integral part of human physiology. In the good and in the bad. In healthy humans, the microbiome contributes to the renewal of the intestinal mucosa, supports the extraction of energy from our diet, regulates our endocrine system, and plays a key role in educating and regulating our immune system.

A microbiome composition that has a detrimental effect on its host, is referred to as dysbiotic.
It is not only very difficult to draw the red line between health and disease, but it even seems to be very contextual if a microbiome is beneficial or detrimental.

The key differentiator of the microbiome from the rest of our physiology is that our microbiome is acquired. This opens tremendous opportunities to treat diseases that are linked to the microbiome by changing our microbiome towards a health-supporting composition or activity. These treatments could modify our extended physiology and change the patient's disease instead of treating symptoms.

Currently, the strongest clinical evidence is based on the use of healthy human stool to replace diseased microbiomes. The positive results using this approach in recurrent infections kickstarted a race to translate these findings into a new modality, live biotherapeutic products (LBP's), i.e. the use of bacteria that are not probiotics but therapeutics. The first successes in Phase III clinical development of microbiome therapeutics have been reported in 2020.

NB: For which therapeutic areas is it particularly relevant and why?

TdW: Due to its close link to the immune and endocrine systems, the microbiome has a very broad field of relevance, ranging from inflammatory diseases like colitis, and rheumatic diseases to metabolic diseases like obesity and Diabetes. The increasing understanding that cancer therapy outcome depends on microbiome composition is rightfully being explored for therapeutic applications. Even less intuitive indications linked to the central nervous system like Alzheimer's, autism, and multiple sclerosis show a high potential to be improved by microbiome therapy.

This in no way means that the microbiome is the solution to all diseases but rather reflects the central role of the microbiome in human physiology. In short, the microbiome is at the crossroad of the immune system, the endocrine system, and digestion and therefore plays a prominent role in a broad range of diseases.

The first generation of microbiome therapeutics addressed recurrent *C. difficile* infections, an indication with strong evidence that the re-establishment of a healthy microbiome can prevent the repeated blooming of this infectious bacteria.

The second generation of programs is now addressing more complex indications such as colitis, where the microbiome can regulate the development of inflammation in the gut epithelium, or immuno-oncology, where the microbiome is a predictor for the success of the therapy.

NB: What is differentiating PharmaBiome from the other companies in that space?

TdW: PharmaBiome was founded out of the insight that the key to successful microbiome treatment is control over the microbiome composition and as a consequence microbiome activity. This can only be achieved by understanding what defines microbiome composition in every single individual.

Our unique value proposition is based on 3 pillars:

1. A unique microbiome reference database based on biological measurements, allowing a highly differentiated understanding of dysbiosis in a disease.
2. A unique co-cultivating approach that allows a fast translation of these insights into a mechanisms-based therapeutic.
3. A proprietary and scalable process to produce the resulting products at scale in a cost-efficient and robust manner.

NB: and finally, to answer the question in the interview title, why does every Pharma-company need a Microbiome strategy?

TdW: Just like the immune system, the microbiome will be part of every serious patient anamnesis and a factor to consider in patient stratification and treatment.

Some indications will benefit from stand-alone live biotherapeutic products, but even more often, LBP's will improve existing treatment strategies based on microbiome analysis or adjuvant treatment.

That is why every Pharma company should understand how the microbiome affects their indications and treatments and what strategy is best for them to address this challenge. The list of big pharma investing and entering the microbiome field is growing quickly.

We see the strength of PharmaBiome in our deep understanding of this new modality that can strongly support pharmaceutical companies in their drug development process.