Title: Microbiome standards for translating research into new diagnostics and therapeutic strategies

Unmet Needs:

The Microbiome has become a hot topic over the last decade (Doré et al., 2013; The Gut Microbiome, Nature Outlook; Cullen et al., 2020). Researchers are working on understanding how the microbiome influences our lives and health and how we can manipulate the microbiome to prevent and fight diseases (Harkins et al., 2019). The microbiome manipulation has been in focus for many companies and new start-up companies. Identifying and building strategies to translate human microbiome health/disease associations into therapeutics is one aspect how we could harvest the power of the microbiome.

On the other hand, we should consider the importance of the microbiome on drug metabolism. Since a couple of years ago, it was believed that the response of a patient to medication is mainly driven by genetics and physiological factors. Increased evidence suggests a role of the gut microbiota in patients’ response to medication. Recent studies provide mechanistic insight into the role of gut microbiota metabolism in drug bioavailability, efficacy and toxicity and suggest that the gut microbiome, in addition to human genetics and environmental variables, contributes to inter-personal variation in human drug responses (Doestzada et al., 2018; Sharma et al., 2019). Although the influence of the microbiome on the drug efficiency is known, pharma companies are behind in implementing the microbiome-mediated metabolism as part of the pipeline development of new drugs. One reason could be the lack of systemic, global and standardized map for the microbiome-derived metabolism, which hinders our ability to predict and eventually interfere with the microbiome effect on drug pharmacokinetics and/or pharmacodynamics.

The microbiome research has quickly developed over the years being fueled by the improvement and development of newer technologies including the sequencing technologies and it incorporates different methodological approaches. The tools and methods used to make measurements of the microbiome vary widely and results produced by different laboratories are often not comparable. Therefore, now more than ever standards and validated protocols are crucial for translating the scientific findings into diagnostics and therapeutic strategies.

Proposal/Value Proposition:

1. To create a common framework of methodological standards for accurate data generation. This common framework should include validated methods and protocols, software, and computing infrastructure to help translate the microbiome research into diagnostics and therapeutic strategies.

2. To establish a complete database for the microbiome-derived metabolism. The generated data could be used as the foundation for developing various machine learning algorithms that could help in predicting the influence of the microbiome and identify key enzymes which contribute to the drug metabolism in the gastrointestinal tract.

What would be the benefits?

Implementing standards and creating a common methodological framework across industry and academia would lead to generating comparable data across laboratories and enable faster and accurate translation of the microbiome research into new diagnostics and therapeutics.
Mapping the microbiome-derived metabolism and creating a common database will help in developing safer and better solutions to identify and treat diseases, especially for the development of new therapeutic drugs with reduced side effects. Furthermore, this will bring the entire microbiome-focused research and industry to quicker develop new products aimed at manipulating the microbiome for increased health benefits.