

# HFMA Bulletin

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## Huge advances in understanding the human microbiome

The human microbiome is one of the current hot topics in clinical research. What was historically viewed as being on the periphery of mainstream scientific research is now very much in the vanguard. There are over 24,000 peer-reviewed scientific publications relating to the microbiome. Barely a week goes by without another area of health or disease being linked to these complex communities of microorganisms that live in (and on) our bodies.

The majority of the published research relates to the gastrointestinal microbiome, but increasingly the evidence points towards significant health implications from other microbial ecologies, with the skin, the lungs and the oral microbiomes all featuring heavily in recently published research. And, as our analytic capabilities improve, so our understanding of these dazzlingly complex systems increases – and crucially we advance our ability to manipulate these microbial communities to improve health outcomes.

ADM Protexin has been investing in high quality clinical and pre-clinical research for many years. Historically, the majority of microbiome research focused on gastrointestinal diagnoses. Our research portfolio includes multiple trials looking at the prevention of acute gastroenteritis and non-alcoholic fatty liver disease and includes the largest clinical trial conducted to date on the use of probiotics in the management of irritable bowel syndrome.

In recent years, ADM Protexin has sought to diversify its research portfolio and led on research linking the gut microbiome with neurological and psychiatric diagnoses, an area of research known as the gut-brain axis. Last year we published the first successful randomized, placebo-controlled trial using a probiotic to manage migraine symptoms. The results of this particular trial were ground-

breaking and for the first time showed how the gut microbiome can impact migraine frequency and intensity and reduce the use of pharmacological migraine treatments. We are just about to start a second migraine trial, building on the success of the first.

More recently, we collaborated with researchers at the University of Edinburgh to show how one of our probiotic strains can have a profound impact on the development of the protein that causes Parkinson's disease –  $\alpha$ -synuclein. This particular probiotic strain was shown to inhibit the aggregation and even remove pre-formed aggregates of  $\alpha$ -synuclein. The probiotic bacterium was shown to impart its protective effect through the alteration of multiple protective pathways in the host, including biofilm formation, nitric oxide secretion and lipid metabolism. This represents an incredible advance in microbiome research and Parkinson's research.

Yet despite all these successes, from a regulatory perspective the communication to the end consumer of these novel and exciting research findings and health benefits associated with microbiome interventions is not possible. In fact, even use of the term 'probiotic' is considered an implied health claim under the scope of the Nutrition and Health Claims Regulation enacted by EFSA in 2006. And so we wind up in the bizarre situation of having novel, ground-breaking, peer-reviewed research that cannot be communicated to consumers. What is of interest, though, is the interpretation of EFSA's opinion, which varies across the EU, and in some countries the word 'probiotic' – Italy being the most obvious example – is used liberally.

Microbiome research has advanced enormously in recent years, and the prospect of future successes is high – it would be shame to allow scientific innovation to be stifled by a disproportionate regulatory environment.

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