

## NUTRITION HORIZON

# EU Funded FibeBiotics Project Starts Clinical Trials to Reach 13.5 Immunity Health Claim

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**Summary:** This is the first large EU project where researchers work together with the industry and aim to develop end-products that might be able to pass EFSA claim evaluation and do this by using the EFSA guidelines in the area of gut and immune function.

25 Oct 2012 --- The EU FibeBiotics project studies the effect of non-digestible polysaccharides (NPS) on the gut and immune system of humans. The project started January 2012 and will last for 4.5 years, receiving an EU support of €6M.

FibeBiotics is enlisting four European universities, five research institutes, and eight companies – among them suppliers of the key ingredients used in the clinical studies – in a team effort to standardize analytical methods, set up in vitro assays to support product development, study the mechanism of action, validated biomarkers and conduct clinical trials on non-digestible polysaccharides.

This is the first large EU project where researchers work together with the industry and aim to develop end-products that might be able to pass EFSA claim evaluation and do this by using the EFSA guidelines in the area of gut and immune function. FibeBiotics beat out 30 other projects on bioactive compounds and functional products that were petitioned to the EU.

The project now announced two events that indicate the progress of the consortium.

The first announcement is the start of the first human pilot trial. The trial design is a randomized double blind placebo controlled trial with 6 arms in which 240 (40 in each arm) elderly subjects (>50 years) will receive a food intervention of 5 weeks. The five NPS included in this study are: Wellmune yeast beta-glucan, OatWell oat beta-glucan, NAXUS wheat arabinoxylan, beta-glucan of Shiitake mushroom and a powder containing exopolysaccharides produced by *Lactobacillus mucosae*. After a wash out period and 2 weeks of intervention the subjects will receive a standard flu vaccination. Subsequently, 1 and 3 weeks after the vaccination blood and faeces will be sampled to analyse the effect of the intervention. These analyses focus on the analysis of many biomarkers including those indicative for the innate immune system, the adaptive immune system, the effect on gut microbiota and metabolites generated by the gut microbiota as a response to the intervention.

“The first months of the project were already very intense. NPS compounds needed to be isolated, needed to be packed according to the double blind placebo controlled design, the ethical protocol had to be written, pilots for biomarkers analysis performed etc. But thanks to the collaborative action of the dedicated partners we managed everything in time” the coordinator Jurriaan Mes of Food & Biobased Research of Wageningen UR explained.

The clinical trial is organised by one of the FibeBiotics partners Clinical Research Centre (CRC) in Kiel. Christiane Laue, CEO of CRC, explains: “This pilot study should learn us what NPS compounds are interested to include in follow-up studies, directly learn what number of persons should be included in a pivotal trial to reach significant effects and what biomarkers are most interested to include in such a large study”.

The second important milestone of the FibeBiotics project is the First Industrial Platform meeting that was held in Ghent, October 4th. 22 members of the Industrial Platform (including some of the largest Food & Beverage companies in Europe) were present and learned about the goals and approaches of the FibeBiotics project. The members were enthusiastic on the approach and very eager to be involved in future steps. The Industrial Platform members also visited the facilities of one of the FibeBiotics partners, ProDigest.

“It was a great opportunity for us to invite these FibeBiotics Industrial Platform members at our new facility and show in real life how research with the Simulator of Human Intestinal Microbial Ecosystem (SHIME) is performed.’ Sam Possemiers illuminated.