

Federico Bianchi

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at Cerbios-Pharma



Federico Bianchi holds a Master's Degree in Pharmaceutical Chemistry and Technology (CTF) and a second Master's in Pharmaceutical Marketing and Project Management. He has accumulated over 15 years of experience in the pharmaceutical industry, with specialized expertise in the sales of finished products and international licensing. Currently, he oversees Sales & Marketing activities at Cerbios-Pharma for its portfolio of probiotic based finished products.

Cerbios-Pharma SA has developed a new dietary supplement in which the probiotic strain *Enterococcus lactis* SF68® is formulated with other innovative functional ingredients, whose synergistic activity helps control the symptoms of cardiometabolic disease. Can you tell us about the process that led from the probiotic to the supplement?

FB - Cerbios-Pharma has a long-standing history in the field of probiotics. The cornerstone of this new formulation is our proprietary SF68® strain, recently reclassified as *Enterococcus Lactis*, which was first isolated in 1968. By the early 1970s, it was registered as a pharmaceutical product for classic probiotic indications: the treatment of diarrhea, traveler's diarrhea, and antibiotic-associated dysbiosis. It remains a market leader for these uses in Switzerland and Austria today.

Our direction evolved as scientific evidence grew, clearly linking the microbiota not only to gut health but also to the function of other body systems, such as the skin, nervous and immune systems, and the genitourinary tract. Recognizing that dysbiosis is often associated with various disorders, including acne, metabolic and cardiovascular conditions, diabetes, obesity, and IBS, we committed to investigating the efficacy of our SF68® strain in these new therapeutic areas.

This research demonstrated the strain's exceptional efficacy across several metabolic functions. Consequently, our strategy was to enhance its potential by formulating it with other natural, functional ingredients, aiming for a synergistic effect. One of the most significant outcomes of this approach is SF68 SLIPIDO®, developed to manage dyslipidemia and overweight, conditions that have reached epidemic proportions in the Western world.

Prior research had already indicated SF68®'s ability to regulate plasma cholesterol. Cerbios substantiated this through a series of preclinical studies in obese mice, which confirmed significant positive outcomes for the SF68 SLIPIDO formulation, particularly regarding weight control, cholesterol management, and the reduction of basal inflammation and intestinal permeability.

These promising results formed **the scientific foundation for a subsequent clinical investigation in humans, conducted at the University of Florence. The findings from this study are presented below by Professor Francesco Sofi.**

Professor Sofi, within which disease framework is this product positioned, and what specific condition was it designed to address?

FS - This product is positioned within the context of intermediate cardiovascular risk in a clinically healthy population. It targets individuals who do not have an evident clinical disease but present an intermediate-risk profile according to cardiology Scientific Societies. Key risk factors include a high body mass index indicating overweight, abdominal obesity, elevated plasma lipids, specifically total cholesterol, LDL cholesterol, and triglycerides, as well as glucose intolerance, predictive of diabetes development. Currently, these conditions often fall outside the standard pharmacological treatment guidelines, as they do not fully meet the intervention criteria. Effectively improving this composite risk profile is crucial for mitigating the underlying pro-inflammatory state, thereby substantially reducing the potential onset of cardiovascular and metabolic diseases.

What were the main results of this clinical trial?

FS - In the clinical trial (active vs. placebo) these clinically healthy subjects were enrolled, and a series of specific *endpoints* were established to measure changes in key parameters from baseline and versus placebo.

Regarding anthropometric measures, SF68 SLIPIDO® demonstrated a statistically significant reduction in fat mass and waist circumference compared to both baseline and the placebo group, without substantial lifestyle modifications by the participants (as per protocol).

In terms of lipid metabolism, total plasma cholesterol decreased in the active group (-5%) while it increased in the placebo group. Furthermore, the HDL/LDL ratio improved markedly, showing a 25% increase in the active arm compared to a 16% decrease in the placebo arm, clearly demonstrating the product's efficacy in optimizing the plasma lipid profile.

We also observed a reduction in values for parameters related to oxidative stress, which are typically elevated in overweight/obese individuals. Additionally, SF68 SLIPIDO® confirmed *in vivo* the improvement in intestinal permeability previously seen in preclinical studies, alongside a favorable reduction in pro-inflammatory markers.

Finally, microbiota analysis (via the *Evenness index*) confirmed a beneficial balancing of bacterial populations, consistent with a shift toward a healthier microbial ecosystem.

How does this new supplement fit into the market and what sets it apart from other products already available?

FB - SF68 SLIPIDO® is designed for a specific and growing demographic: clinically healthy individuals but with an elevated cardiovascular risk profile due to overweight, suboptimal plasma lipid levels, and a state of low-grade basal inflammation. It is intended for those who are not yet candidates for standard pharmacological interventions, such as statins or GLP-1 agonists, or for individuals who are unable or unwilling to use such drugs due to concerns like over-treatment or side effects, but who wish to proactively and gradually optimize their key metabolic parameters.

The product's distinctiveness stems from its multi-targeted formulation. It combines the proprietary probiotic SF68® with other functional ingredients, phytosterols and 5-MTHF (the biologically active form of folic acid), to act synergistically through complementary mechanisms of action. This composition not only drives efficacy but also supports two authorized EFSA claims related to the maintenance of normal blood cholesterol and homocysteine levels, enabling clear and compliant communication to consumers, pharmacists, and physicians.

Crucially, SF68 SLIPIDO® is supported by a robust scientific dossier, including preclinical data and a dedicated human clinical trial, a level of substantiation not common for a dietary supplement. This positions it as a premium and scientifically credible alternative in a market where most of the products for cardiovascular health rely on Fermented Red Rice containing Monacolin K. This compound, chemically identical to a statin, is under regulatory scrutiny by EFSA over safety concerns, leading to dosage restrictions and prescribing limitations.

FB - In conclusion, **with the development of SF68 SLIPIDO®, Cerbios-Pharma aims to offer a non-pharmaceutical solution to improve the general metabolic condition and keep under control the cardiovascular risk of clinically healthy subjects but with altered parameters, preventing progression to a situation that would require pharmacological intervention.**

Francesco Sofi

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Francesco Sofi, MD, PhD, is Associate Professor of Food Sciences at the University of Florence and Director of the Clinical Nutrition Unit at Careggi University Hospital. He leads the Master's in Food Sciences and chairs the national council for Human Nutrition programs (LM-61). Author of 280+ publications, he teaches across medicine and health degrees and serves on Tuscany's regional ethics committee.