Title	***11.*** ***Probiotics in Cystic Fibrosis***
Project Coordinator	C. Braggion, MD (c.braggion@meyer.it)
Internal Collaborators	Maria Chiara Cavicchi, MD (co-investigator), Roberta Pasotto, biologist (study coordinator), nurses, lab technician
Study design	A multi-center, randomized, double-blind, placebo-controlled parallel group study (Eudract no. 2009-011289-27)
Grant by	Cystic Fibrosis Foundation
Background and aims	There is evidence that a healthy intestinal microflora reduces the risk of allergy and other immune disorders, driving the development of immune response toward an effective protection against intestinal and extraintestinal infections, including respiratory infections. Children with cystic fibrosis (CF) are at risk to have a disturbed intestinal microflora, as a consequence of the abnormal intestinal microenvironment due to the impaired cystic fibrosis transmembrane regulator (CFTR), the heavy load of antibiotics, the pancreatic enzyme supplementation and the acid suppression treatment. This trial proposes to test the hypothesis that: 1) intestinal microenvironment is modified in CF likely as a consequence of CFTR mutations; 2) intestinal inflammation is frequent and probably due to a modified intestinal microflora; 3) intestinal inflammation can contribute to extraintestinal infections, including respiratory infections; 4) probiotics modify intestinal microflora and so reduce intestinal and extraintestinal infections in CF patients.
Inclusion criteria	Male or female pediatric patients with CF (2-16 years), if able to perform spirometry with a FEV1 value > 50% of predicted value; patients must be clinically stable (no evidence of pulmonary exacerbation within 2 weeks of screening).
Exclusion criteria	Pancreatic sufficiency, female patients who are pregnant or lactating and female patients of child bearing potential who are using a oral form of contraception; steroid therapy within 1 month; oral or intravenous antibiotics within 2 weeks; azitromicina therapy; use of probiotics; airway infection by *Burkholderia cepacia* spp..
Methods	This is a 36 months, multi-center, randomized, double-blind, placebo-controlled parallel group study.
Expected results and anticipated output	To confirm efficacy of the use of probiotics in improvement of intestinal condition and in reduction of pulmonary exacerbations.
Start of recruitment	For our Centre at August 2011.
End of experimental plan	For our Centre at December 2013.
Pubblication on medical Journal	About thirty patients in each site will be included.