Title	***14. Prospective randomized, placebo-controlled, double blind, multicenter study (phase III) to evaluate clinical efficacy and safety of avian polyclonal anti-Pseudomonas antibodies (IgY) in prevention of recurrence of Pseudomonas aeruginosa infection in cystic fibrosis patients***
Project Coordinator	C. Braggion, MD (c.braggion@meyer.it), Principal Investigator (Partner of CTN)
Internal Collaborators	M.C. Cavicchi, MD, Sub-investigator M. Francalanci, biologist, study coordinator
Study design	Phase III, randomized, placebo-controlled, double blind, multicentric study (Eudract no. 2011-000801-39). Study of the Clinical Trial Network of the European Cystic Fibrosis Society.
Grant by	Mukoviszidose Institute gGmbH
Background and aims	Sooner or later nearly all patients with CF acquire infections with *Pseudomonas aeruginosa (PA)*, which nearly always turns into a chronic colonization and infection and at this time eradication of *PA* is hardly possible. Chronic infection of *PA* leads to progressive pulmonary damage in CF patients and is the principal cause of irreversible loss of lung function. Active vaccinations are aimed at reducing infection with Pseudomonas aeruginosa. They have been developed, but did not prove to reduce the risk of getting a chronic infection in patients with cystic fibrosis. The purpose of this study is to find out if treatment with specific egg yolk antibodies (IgY) against *P. aeruginosa* can prevent recurrence of colonization with *P. aeruginosa* in CF patients and diminish the use of antibiotics.
Inclusion criteria	Male or female patients with CF ≥ 5 years of age, able to gargle and with a FEV_1 value between 50% and 130% of predicted value; patients who have one to several sputum or throat cough swab or endolaryngeal suction cultures positive for *PA* within the last three years and for whom *PA* has been successfully eradicated; Sputum culture neg. for *PA* and other gram-neg bacteria on study entry.
Exclusion criteria	Microbiologic evidence of chronic infection with *PA*; positive sputum culture for other gram-negative bacteria or Mycobacteria and/or Aspergillus fumigatus, associated with clinical symptoms that may necessitate specific treatment; history of allergy/hypersensitivity to hens' egg proteins.
Methods	This is a 24-months, multi-dose, multi-center, randomized, double-blind, placebo-controlled parallel group study. Both the investigational drug and the placebo preparation are solutions (70ml), which are gargled for 2 minutes every night after tooth brushing and thereafter swallowed.
Expected results and anticipated output	The primary objective is to find out, if continuous long-term treatment can prolong the time to recurrence of a sputum culture positive for *PA*. The objective to prevent infections with *PA* is also to diminish the need of antibiotics.
Start of recruitment	09/05/2013
End of experimental plan	After 24 months of treatment with study drug
Pubblication on medical Journal	