Title	***18.*** ***A long term prospective observational study of the safety and tolerability of Bramitob® administered twice daily over three 28-day on/28-day off cycles to patients with cystic fibrosis having severily compromised lung function (non interventional study protocol – CCD-01538AA1-04)***
Project Coordinator	C. Braggion, MD (c.braggion@meyer.it), PI and partner of CTN
Internal Collaborators	Anna Silvia Neri, MD Michela Francalanci, Biologist, study coordinator
Study design	Multicenter, multinational, postmarketing, parallel group, prospective, observational study in patients with cystic fibrosis and chronic *Pseudomonas aeruginosa*
Grant by	Chiesi Farmaceutici S.p.A.
Background and aims	*Pseudomonas aeruginosa* (PA) is the primary pathogen associated with infection and pulmonary exacerbation in CF, contributing to significant morbidity and mortality. Chronic suppressive therapy of chronic PA infection with inhaled tobramycin has become the mainstay of the CF treatment regimen. Tobramycin solution for inhalation (TOBI, Novartis) has been marketed in the USA since 1997; another inhaled tobramycin solution (Bramitob, Chiesi) was approved by the US FDA as an alternative treatment option for CF but FDA approval was accompanied by a post-marketing requirement to evaluate the risk of upper airway and bronchial hypersensitivity in patients having a forced expiratory volume in one second (FEV1) ≥25% and <40% predicted. The aim of the study is to assess safety, tolerability and efficacy in approximately 30 Bramitob-exposed patients and 30 TOBI-exposed patients who meet all inclusion/exclusion criteria.
Inclusion criteria	Patients already receiving Bramitob or TOBI and to continue receiving the same medication for at least three on/off treatments cycles; age ≥6 years; stable FEV1 ≥25% and <40%; no exacerbations in the 6 weeks prior to study participation.
Exclusion criteria	Candidate for transplantation
Methods	All eligible patients will be treated and followed according to the site's standard practice during three complete cycles of treatment with Bramitob or TOBI. The observation duration will be of at least 24 weeks. Airway hypersensitivity symptoms, physical exam, FEV1, weight and body mass index, number of pulmonary exacerbations will be collected during the study.
Expected results and anticipated output	Safety and efficacy data will be compared in patients inhaling either formulations of tobramycin.
Start of recruitment	January 2016
End of experimental plan	October 2016
Pubblication on medical Journal	