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# IMPACTT: Immunoglobulin IgY Pseudomonas A clinical trial for cystic fibrosis treatment



## IMPACTT

Is a research project supported by the European Commission under FP7.

## IMPACTT objective:

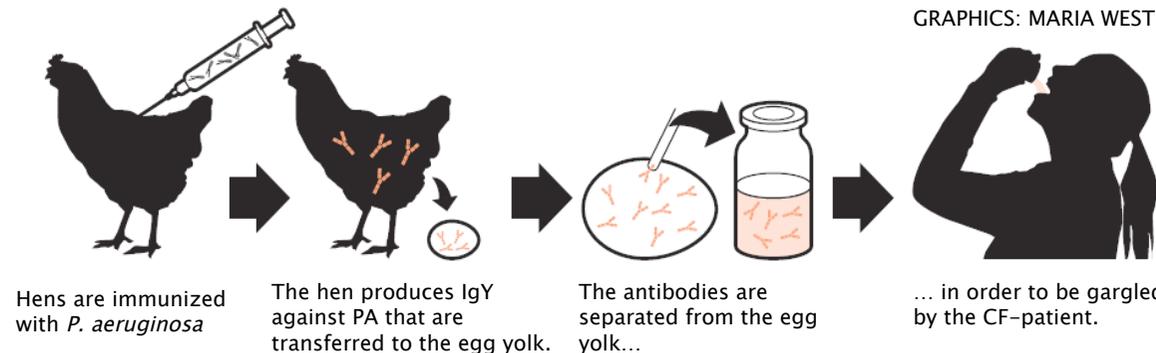
To provide an "intervention therapy for prophylaxis and treatment of *P. aeruginosa* (PA) infections in CF patients" and to make this treatment available for the CF patients. In addition IMPACTT wants to explore ways of meaningfully involving CF patients and families into clinical CF research.

## Study design

Randomized double-blind placebo-controlled clinical study combined with preclinical studies.

## Anti-Pseudomonas IgY

Anti-Pseudomonas IgY is prepared by vaccinating hens with PA bacteria. The hens produce antibodies against PA that are transferred to the egg yolk in high concentration. Anti-Pseudomonas IgY is extracted from the egg yolk. The formulation only contains egg proteins without any other additives.



## Clinical study

★The aim is to reduce/delay the onset of new PA positive cultures.

★180 patients will be enrolled from countries in EU.

★Patients that have had PA positive culture(s), but are not chronically colonized will be included.

★Daily treatment with Anti-pseudomonas IgY or placebo gargle until PA pos. culture (=primary endpoint), but not longer than two years.

## Preclinical studies

★Duration of the antibodies in the oral cavity.

★Reactivity with antibodies towards *Pseudomonas* strains from different European countries, and their effect on biofilm formation.

★Effects of the normal gastrointestinal flora and other potential side effects.

GRAPHICS: MARIA WESTHOLM