

PARTNERS

IMPACTT began as a collaboration between ten partners from seven European countries (Sweden, Germany, Denmark, Belgium, France, Italy, and Lithuania). Ireland joined the Clinical Study in 2013 and we hope the IMPACTT clinical study will be able to welcome other countries such as Czech Republic, in the near future.

Partner 1: Coordinator: Uppsala University, Sweden (UU)

Partner 2: Immunsystem I.M.S AB, Sweden (Immunsystem)

Partner 3: Mukoviszidose Institut gemeinnützige Gesellschaft für Forschung und Therapieentwicklung mbH (MI)

Partner 4: Region Hovedstaden, Denmark (RH)

Partner 5: Valstybinis Moksliniu Tyrimu Institutas Inovatyvios Medicinos Centras, Lithuania (VU)

Partner 6: Cystic Fibrosis Europe, (CFE)

Partner 7: Heinrich-Heine-Universitaet Duesseldorf (UDUS)

Partner 8: Stockholms Laens Landsting, Sweden (KI)

Partner 9: Institut National de la Santé et de la Recherche Médicale, France (INSERM; 2011-2012)

Partner 10: Consorzio Italiano per la Ricerca in Medicina, Italy (CIRM)

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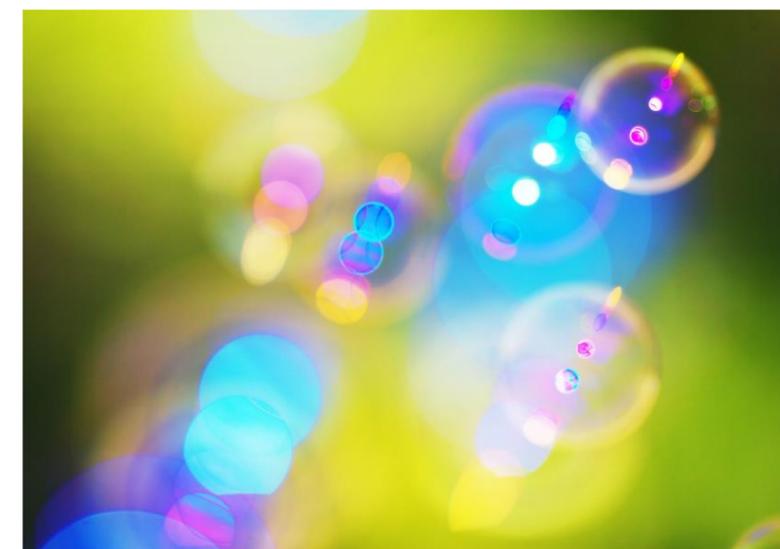
www.impactt.eu

Clinical Trial - IMPACTT

This clinical trial aims to demonstrate the critical preventive and therapeutic effects of a pioneering intervention therapy against the chronic infection of *Pseudomonas aeruginosa* in Cystic Fibrosis (CF) patients. The overall goal is to prevent *Pseudomonas aeruginosa* infection in CF patient lungs.

IMPACTT mobilizes a pan-European critical mass of experts from academia, patient organizations, clinical trials managers, clinicians and industry.

A novel approach to prevent lung infections in CF patients



Immunoglobulin IgY pseudomonas A clinical trial for cystic fibrosis treatment.

The Clinical Study

"As parents of a CF child we think this study is extremely important! We really hope they will find solutions to prevent pseudomonas more effectively, so we could prevent chronic infection and loss of lung function. By participating in such clinical trials you can really contribute in research and help to find solutions for pseudomonas. Wouldn't life be great if a simple treatment was found: one pill and 'bye pseudomonas'..."

Mother of a child with CF

The IMPACTT clinical phase III trial

Full name: 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.

The clinical study has been registered in the international clinical trial registry clinicaltrials.gov. For more information, please contact Dr. Jutta Bend, via Email jbend@muko.info or phone: +49 228 98780-47.

This study is still recruiting patients.

Name of product

Anti-Pseudomonas IgY (avian polyclonal IgY antibody against *Pseudomonas aeruginosa*) - **The therapy is based on the avian polyclonal Anti-Pseudomonas IgY formulation.**

Coordinating investigator

Prof. Dr. med. Antje Schuster, Pediatrician and CF expert from Children's Hospital, University of Düsseldorf (Germany)

Study centres

By 2012, the clinical study involved CF (cystic fibrosis) centers in Germany, Belgium, Italy, and Sweden. Thanks to a Swedish National Grant the project received in 2012, other countries could join. Ireland joined the Clinical Study in 2013 and we hope the IMPACTT project will be able to welcome more countries, such as the Czech Republic, in the near future.

Background

"I am a patient who was born in the fifties of the last century. In those days there was no therapy at all. Today there are new CF drugs under development which will make a big difference in quality of life and life expectancy. IgY has the potentiality to delay or even prevent pseudomonas infection. Thus that burden might be kept away from patients' lives for a longer time than it is possible today. That is such an exciting prospect! I want to thank all who strive to make IgY a success."

Anni Brunckhorst, CF adult

Why is it so important to prevent Pseudomonas infection?

Today a pseudomonas aeruginosa (PA) infection is treated by repeated courses of antibiotics. Antibiotics long-term use can:

- have side effects
- build up antibiotic resistance
- lead to super infections by other bacteria (is super infections correct English?)

The IMPACTT project aims at exploring a new way to prevent lung infection by those pseudomonas bacteria. Clinical trial I and II indicate that Anti-PA IgY:

- reduces the need of antibiotics
- postpones the onset of chronic infections
- keeps antibiotics more effective when needed

The IgY solution in our clinical trial - with minimal side effects!

The EMA/COMP report states the following important facts about Anti-PA IgY:

- **There exists no comparable medicine to Avian polyclonal IgY against PA** (Anti-PA IgY) for the treatment of PA infections in CF
- Anti-PA IgY has shown that it has a plausible effect on PA infections in CF Anti-pseudomonas IgY is **very safe and adverse events are very unlikely to occur**
- **Anti-PA IgY has potential to prevent infections in CF patients** and thereby to reduce the need for antibiotics

Swedish patients have been treated with the IgY formulation for more than 15 years without any signs of adverse events related to the treatment.

Concept

"If we find a way to prevent infection with *Pseudomonas aeruginosa*, this will be a huge step forward in CF management. We hope that IMPACTT will help us to reach that goal."

Prof. Schuster, IMPACTT Coordinating investigator

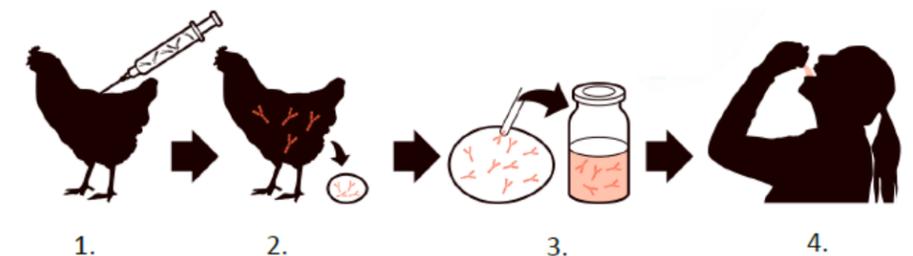
IgY - a new remedy to prevent Pseudomonas infection?

The IgY solution is an antibody against *Pseudomonas aeruginosa* bacteria which is produced from egg yolk. Hens are vaccinated with alleviated *Pseudomonas aeruginosa* bacteria after which the hens produce antibodies against PA that are transferred to the egg yolk in high concentration.

By a special procedure -the antibody (avian Anti-Pseudomonas IgY) is washed out of the eggs and a medical formulation is obtained.

The formulation only contains a water extract from egg yolk without any other additives!

IgY - a gargling solution!



1. Hens are immunized with *P. aeruginosa* (PA)
2. The hen produces IgY against PA that are transferred to the egg yolk.
3. The antibodies are separated from the egg yolk ...
4. ... in order to be gargled by the CF patient

How and when should patients gargle?

Patients should gargle the solution every evening, after brushing their teeth. The dose (70ml) can be divided into 2–4 portions.