

# CYSTIC FIBROSIS EUROPE

for a better & longer live  
for all CF patients in Europe





**Immunoglobulin IgY Pseudomonas  
clinical trial for Cystic fibrosis Treatment**

**[www.impactt.eu](http://www.impactt.eu)**



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



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[www.impactt.eu](http://www.impactt.eu)

#### IMPACTT consortium:

Uppsala University, Sweden

Immunsystem AB, Sweden

Mucoviszidose Institut,  
Germany

Region Hovedstaden,  
Denmark

Vilnius University, Lithuania

Cystic Fibrosis Europe,  
Germany

Heinrich-Heine-Universität,  
Germany

Karolinska University  
Hospital, Sweden

Institut National de la Santé  
et de la Recherche Médicale,  
INSERM, France

Conorzio Italiano per la  
Ricerca in Medicina, CIRM,  
Italy

IMPACTT is a research project  
supported by EU (FP7)

#### IMPACTT objective:

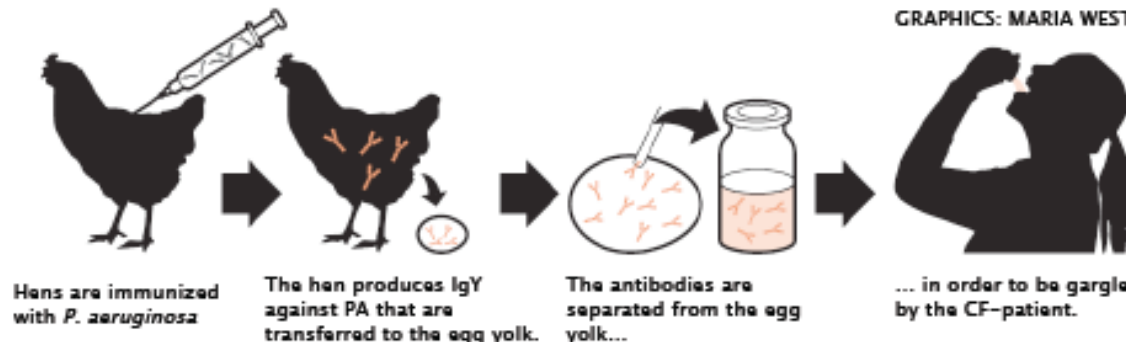
to provide an "intervention therapy for prophylaxis and treatment of *P. aeruginosa* (PA) infections in CF patients" and to make this treatment available for the CF patients. In addition IMPACTT wants to explore ways of meaningfully involving CF patients and families into clinical CF research.

#### 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 from different European countries
- ★Effects of the normal gastrointestinal flora and other potential side effects.

GRAPHICS: MARIA WESTHOLM

# **Project's external communications**

- **presentation of communication tools**
- **external contact and activities etc**
- **discussion (of new ideas, prospects)**

**(presentation mainly by WP7 leaders)**

# **DESSIMATION –COMMUNICATION- INFORMATION**

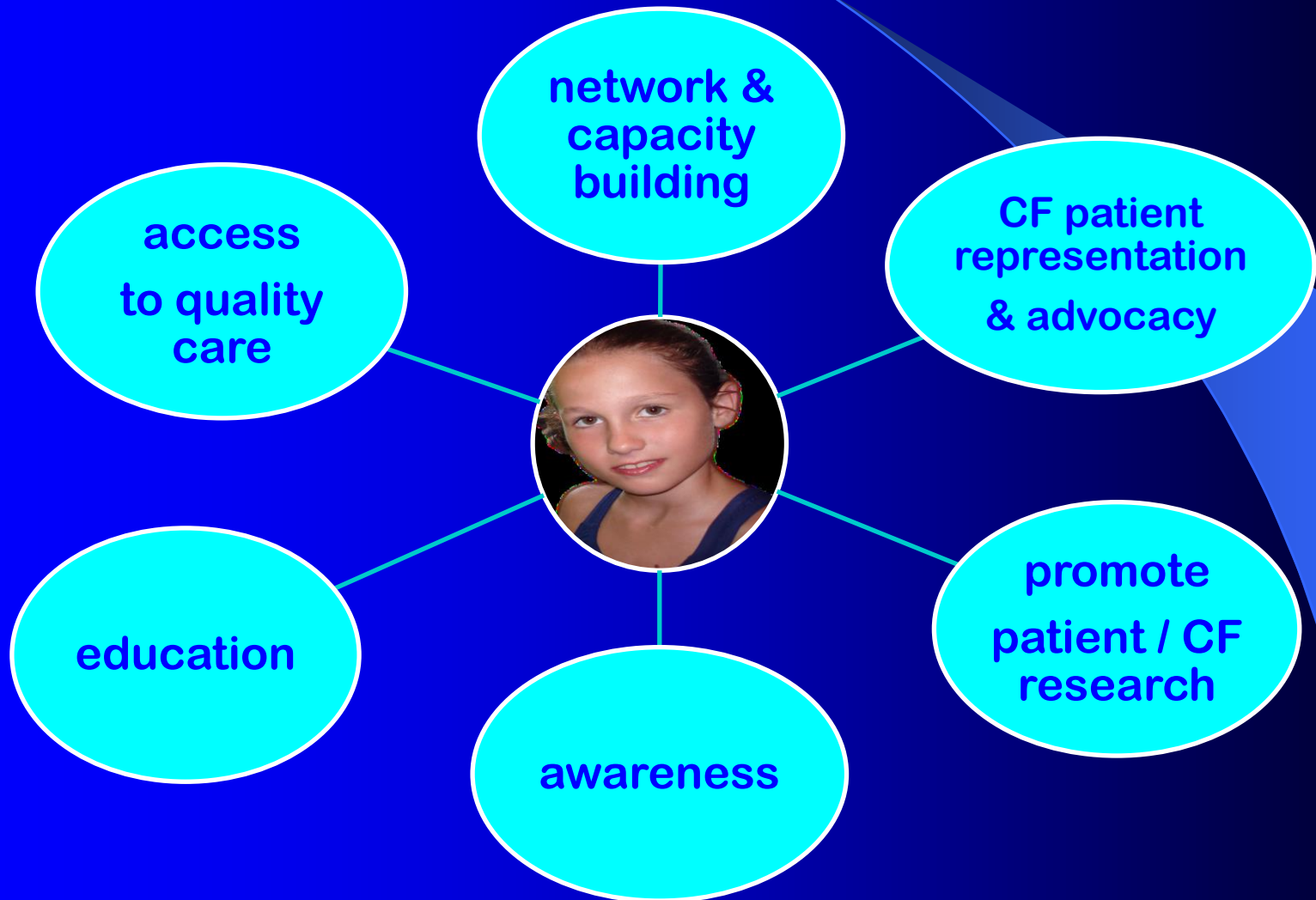
## **Why?**

- 1. Inform about Impactt**
- 2. Help all participants to understand and participate in the trial**
- 3. Understand and develop tools related to motivating patients to participate in studies**



# STRATEGIES

for a better & longer live for CF patients in Europe



# CFE: 39 member countries

Albania, Armenia, Austria, Belgium,  
Bosnia, Bulgaria, Croatia, Czech Republic,  
Denmark, Estonia, France, Germany,  
Georgia, Greece, Hungary, (Iceland),  
Ireland, Israel, Italy, Latvia, Lithuania,  
Luxembourg, FYR Macedonia, Moldova,  
Netherlands, Norway, Portugal, Poland,  
Romania, Russia, Serbia, Slovakia,  
Slovenia, Spain, Sweden, Switzerland,  
Turkey, United Kingdom and Ukraine





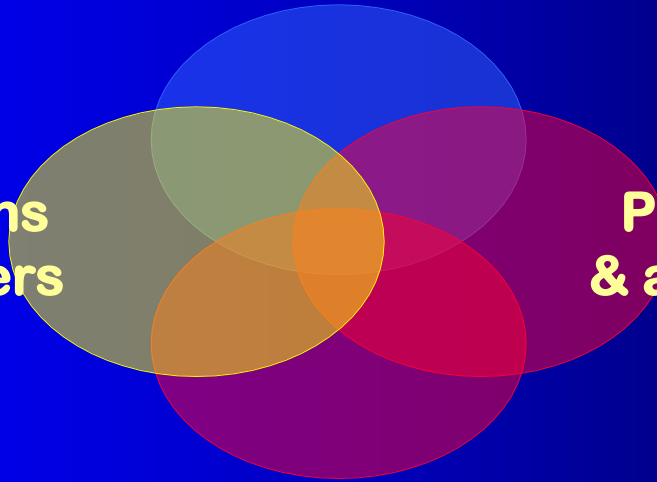
# Improved access to care for CF: a shared responsibility



**Researchers**



**Clinicians  
caretakers**



**Politicians  
& authorities**



**CF associations**







# ULTIMATE GOAL...

