IMPACTT

Immunoglobulin IgY Pseudomonas A clinical trial for cystic fibrosis treatment

EC FP7 Project

Background

- IgY from egg yolk
- Safe when given orally
- >15 years in Swedish study
- Flagellin identified as the main antigen
- Antibodies block adhesion
- Should not lead to resistance

The project consortium

Participant no.	Participant organisation name	Part. short name	Country
1	Uppsala University	UU	Sweden
2	Immunsystem	IMS	Sweden
3	Mucoviszidose Institut	MI	Germany
4	Region Hovedstaden	RH	Denmark
5	Vilnius University Children Hospital	VU	Lithuania
6	Cystic Fibrosis Europe	CFE	Germany
7	Heinrich-Heine-Universitaet Duesseldorf	HHU	Germany
8	Karolinska Universitetssjukhuset	Karolinska	Sweden
9	Institut National de la Santé et de la Recherche Médicale	INSERM	France
10	Consorzio Italiano per la Ricerca in Medicina	CIRM	Italy

WP1 (pre-clinical)

Excerpt of tasks:

- Effects relating to adhesion and bacterial growth.
- Reactivity of the formulation towards different PA strains.
- Stability and shelf-life.

WP2 (clinical)

Excerpt of tasks:

- Trial initiation and management
- Data management
- Monitoring of the clinical trial
- Pharmacovigilance
- Biostatistical analysis

WP3 (clinical/pre-clinical)

Excerpt of tasks:

- Precipitins analysis.
- Microbiology testing of patient samples
- In vitro studies.

WP4 (pre-clinical)

Excerpt of tasks:

- Human pharmacokinetics studies, in CF patients.
- Bioavailability. To see if antibodies against anti-Pseudomonas IgY can be detected in patient samples.
- Human efficacy study. Control of inflammatory activity in clinical trial patients.

WP5&6 (clinical/pre-clinical)

Excerpt of tasks:

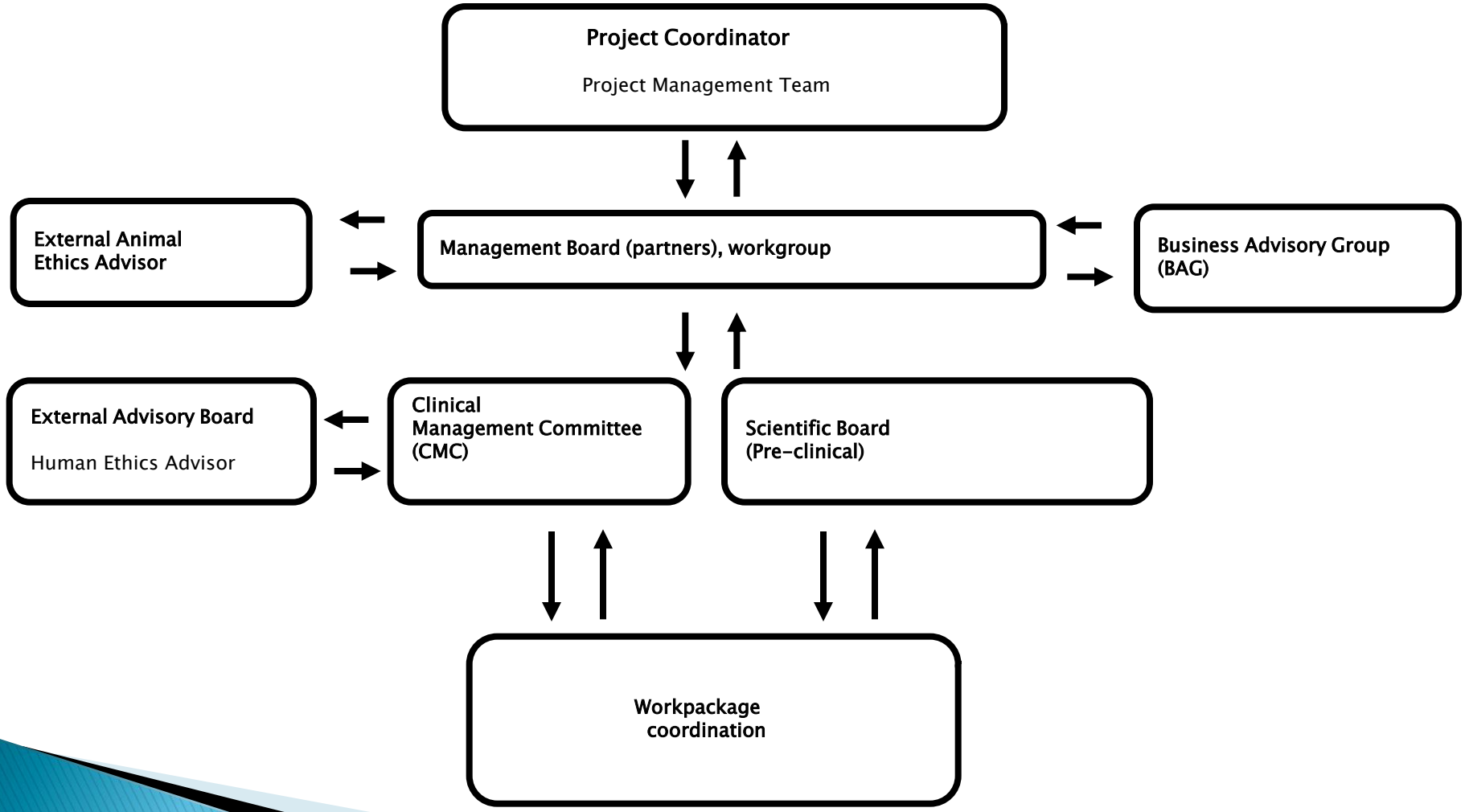
- Gastrointestinal flora. To study the effect the treatment has on the normal faecal flora in animal models.
- Gastrointestinal epithelial cells. To study the effect the treatment has on the gastrointestinal tract in animal models.
- Production of formulation.

WP7&8

Excerpt of tasks:

- Dissemination
- Patient involvement
- Management

Management organisation



IMPACTT objective

- Develop the product to a marketing authorization for the orphan drug
- Make the treatment available for all CF patients within the European Union.