



# Chiesi and IMI

## A Partnership Case Study

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# The Chiesi - IMI Partnership

## IMI1 – Call 1, 2, 3

### U-BIOPRED

Unbiased **B**IOmarkers for the **P**REDiction of Respiratory Disease Outcomes

Start date **2009**

End date **2015**

#### Contributions (Mil €)

IMI Funding 10,0

EFPIA in-kind 14,5

Other 2,4

**Total Cost 26.9**

### PRO-active

Physical Activity as a Crucial **P**atient **R**eported Outcome in COPD

Start date **2009**

End date **2016**

#### Contributions (Mil €)

IMI Funding 6,8

EFPIA in-kind 7,2

Other 1,6

**Total Cost 15,6**

### EUPATI

European Patient Academy

Start date **2012**

End date **2017**

#### Contributions (Mil €)

IMI Funding 5,2

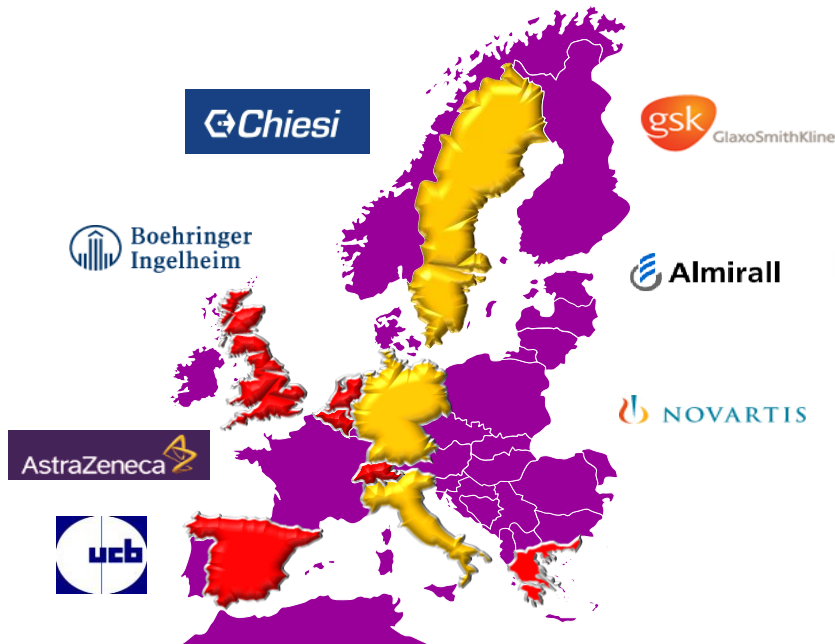
EFPIA in-kind 5,7

Other N/A

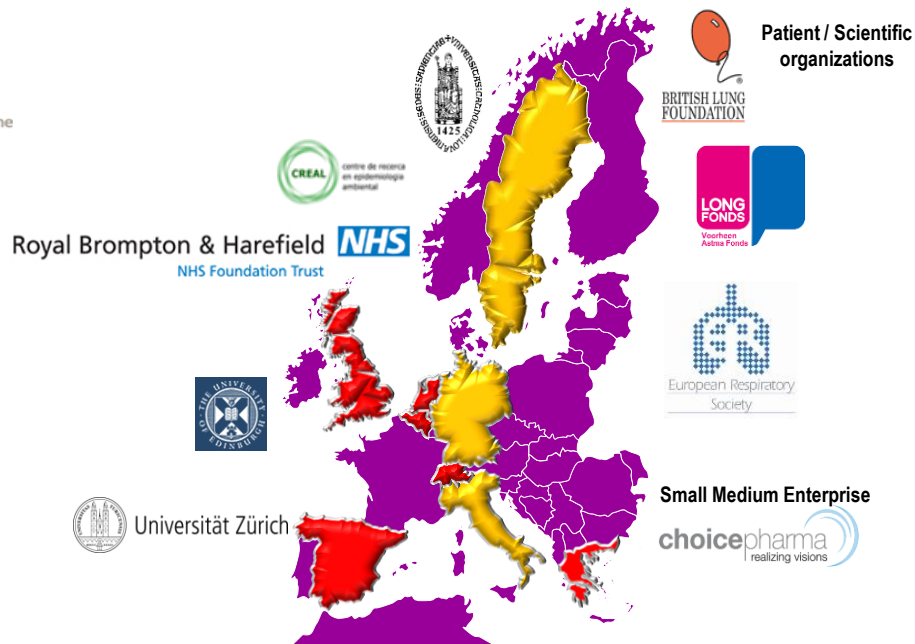
**Total Cost 10,9**

# IMI PROactive – The Consortium

## EFPIA Members



## Academic Partners



# IMI PROactive – Objectives

To **develop** and **validate** a new “Patient Reported Outcome” (PRO) that captures relevant dimensions of physical activity (PA) in COPD Patients that are sensitive to change with interventions including pharmacotherapy



**Activity Monitor**



**Validated questionnaire capturing different dimensions of daily activities**

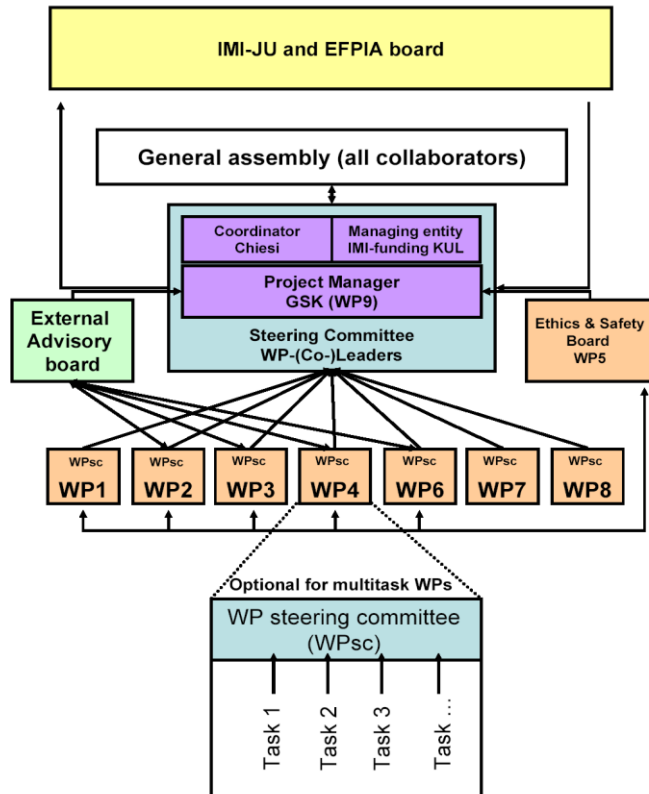
- ✓ Symptoms
- ✓ Overall condition etc.

**Novel Hybrid Tool to improve Physicians and researchers armamentarium of relevant markers of disease progression as well as therapeutic efficacy**



- ✓ Five large clinical studies with a total of 1330 patients recruited
- ✓ Validation of activity monitor through field testing of six different devices

# IMI PROactive - Governance



## Chiesi Contribution and Role

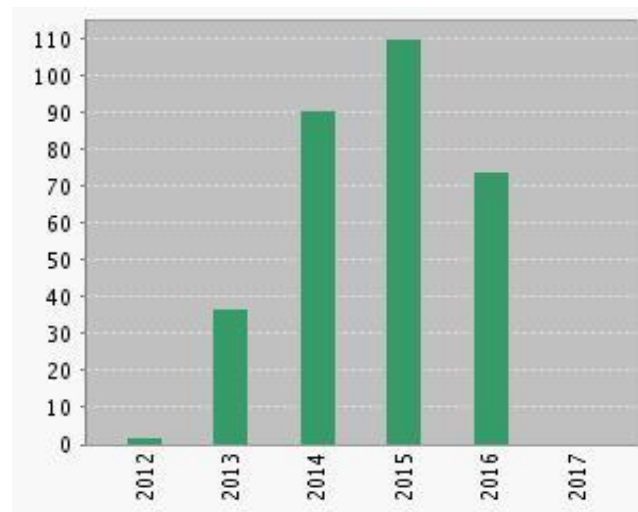
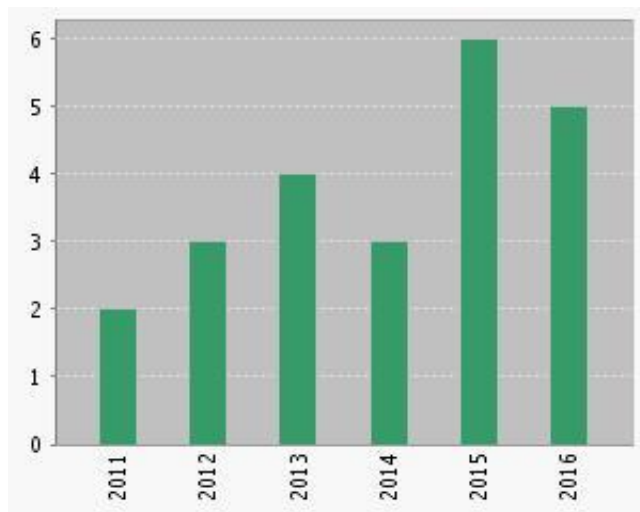
- Project coordination:
  - ✓ Caternina Brindicci (2009-2011)
  - ✓ Mario Scuri (2011-2016)
- Financial and administrative project managers:
  - ✓ Roberta Montacchini, Chiesi
  - ✓ Jaspreet Singh, Chiesi
  - ✓ Silvia Tosini, Chiesi

# IMI PROactive - Achievements

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- Successful development along FDA-EMA guidance of a Patient Reported Outcome tool introducing an innovative HYBRID concept
- Developed simultaneously in four EU languages /cultures /patient populations (50+ culturally sensitive translations available for global use in research)
- Physical activity on the agenda ('take the active option' theme of Amsterdam 2015 ERS conference, awareness to HCP and industry, EU workshop by ERS)
  - ✓ New interventions developed for patients (tele-coaching)
  - ✓ Complex design studies conducted with success by EFPIA

# IMI PROactive - Top Project Outputs



## Science Metric

Publications

23

Sum of the Times Cited

314

Average Citations per Item

13,65

# IMI PROactive - Impact on R&D and Product Lifecycle

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- PROactive introduced a new and patient centered outcome measure to assess the effectiveness of interventions on a crucial dimension of patients lives
- PROactive introduced a new and hybrid concept, using wearables integrated into a patient centered outcome
- PROactive will allow possible labeling claims, important to bring products to the market and gain reimbursement
- Visibility as a company at the forefront of COPD research



# Value of IMI Collaboration

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- Exchange of research culture between pharmaceutical companies and academics
- Filling of a predefined need (concrete, difficult but achievable goal)
- High visibility project both in industry and academia
- An opportunity to build sustainable research networks

# Final Considerations

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- A clear understanding of the value of the collaboration between partners with different agendas and *modus operandi* is absolutely necessary
- Willingness to commit human and financial resources is the result of a culture that strives for true innovation
- In this regard IMI-like partnership provided a collaborative environment and a model of cooperation that was conducive to achieve shared goals between Industry and Academy
- Regular interactions are powerful in the development phase of PRO tools. A European consortium including all stake holders is a door opener towards regulators.

# Thanks!

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## IMI PROactive Consortium



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# Back-up

# Project Objectives

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U-BIOPRED (Unbiased BIOmarkers in PREdiction of respiratory disease outcomes) is a research project using information and samples from adults and children to learn more about different types of asthma to ensure better diagnosis and treatment for each person.

EUPATI is a pan-European project implemented as a public-private partnership by a collaborative multi-stakeholder consortium from the pharmaceutical industry, academia, not-for-profit, and patient organisations. The Academy was started, developed and implemented as a flagship project of the Innovative Medicines Initiative (<http://www.imi.europa.eu/>), and continues to be led by the [European Patients' Forum](#). EUPATI has already trained [96 patient experts](#) on medicines development, clinical trials, medicines regulations, health technology assessment. Additionally, EUPATI offers and maintains the [Toolbox on Medicine Development](#), and coordinates a [network of national platforms for patient advocates](#).

# IMI PROactive - Impact on Industry R&D process

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- Increased awareness by industry of PA as a relevant clinical outcome
- A new outcome measure
  - ready for use in the competitive space
  - providing new ways of assessing the clinical benefits of novel treatments and to differentiate between treatments.
- Enhanced knowledge on the use of wearable technology used for clinical trial purposes
- Visibility as a company at the forefront of COPD research