



Innovative Medicines Initiative

PROactive

Physical Activity as a Crucial Patient Reported Outcome in COPD

Thierry.troosters [AT] med.kuleuven.be

Info [AT] proactivecopd.be



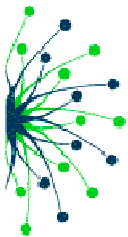
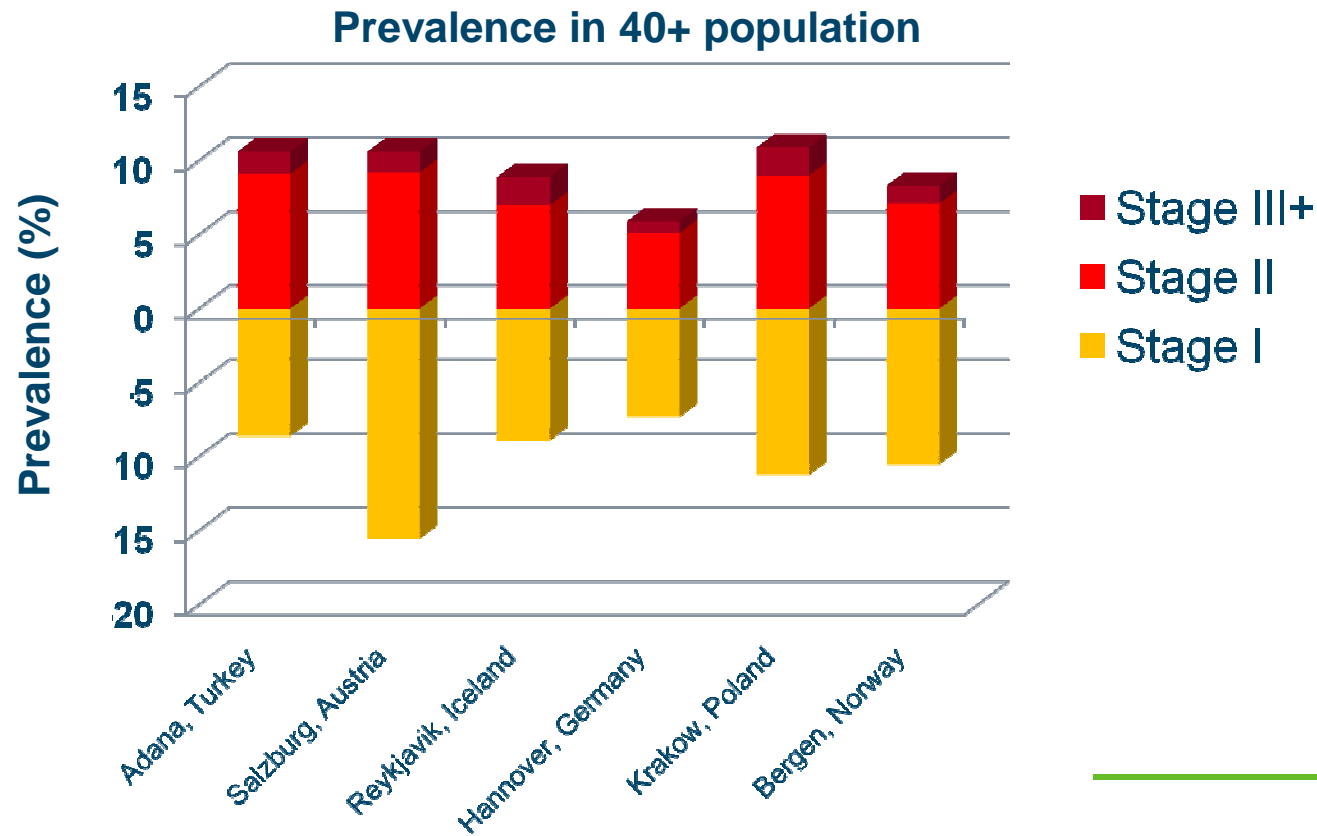
efpia

What patients need

What Europe needs



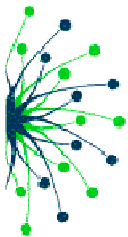
- Chronic Obstructive Pulmonary Disease is a disease with increasing prevalence



What patients need What Europe needs



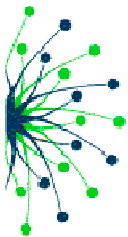
- Chronic Obstructive Pulmonary Disease is a disease with increasing prevalence
- Treatment based on **Prevention, Pharmacotherapy, Non-Pharmacological interventions** (www.goldcopd.com)



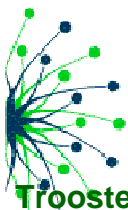
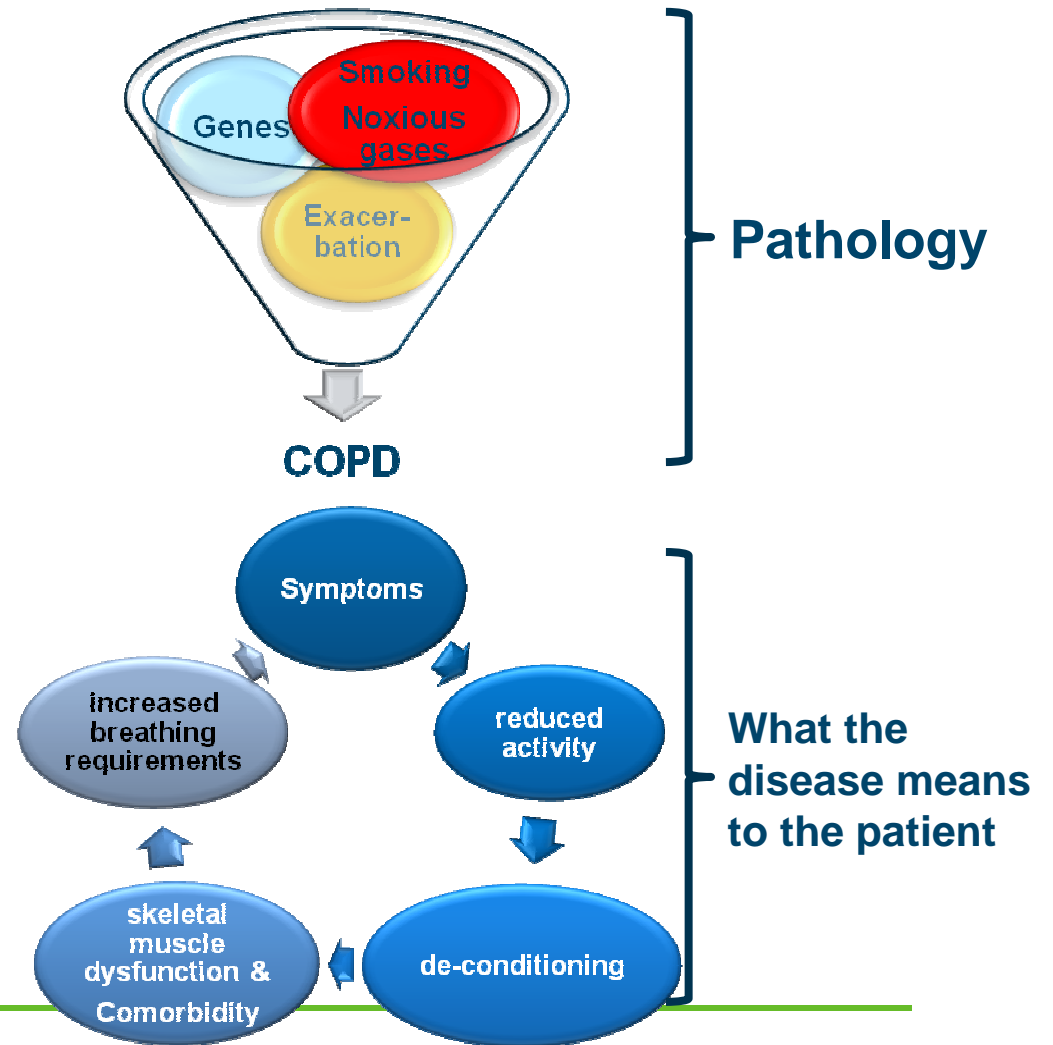
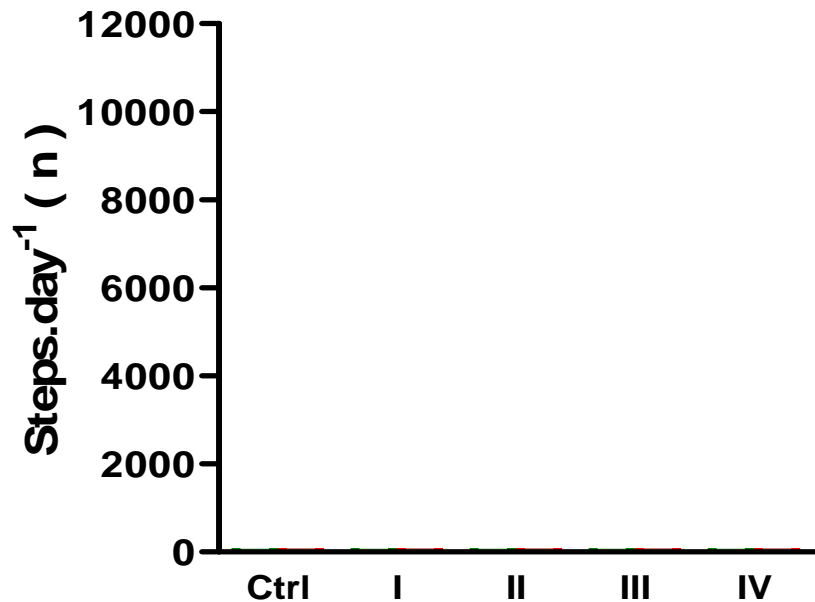
What patients need What Europe needs



- Chronic Obstructive Pulmonary Disease is a disease with increasing prevalence
- Treatment based on Prevention, Pharmacotherapy, Non-Pharmacological interventions (www.goldcopd.com)
- Problems for patients:
 - Airflow obstruction, Symptoms, Exacerbations, reduction in physical activity
 - ‘systemic consequences’



What patients need What Europe needs

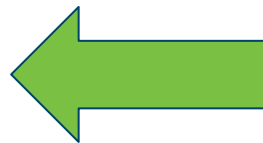


What patients need What Europe needs



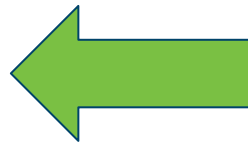
Classical outcomes

Lung function
CT-scan
(Bio-markers)



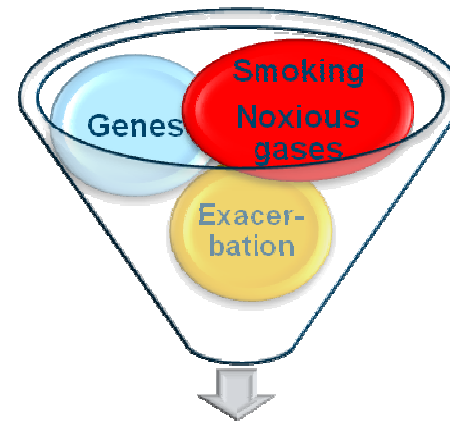
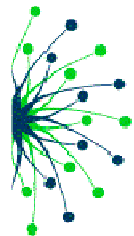
Classical outcomes

Exercise capacity

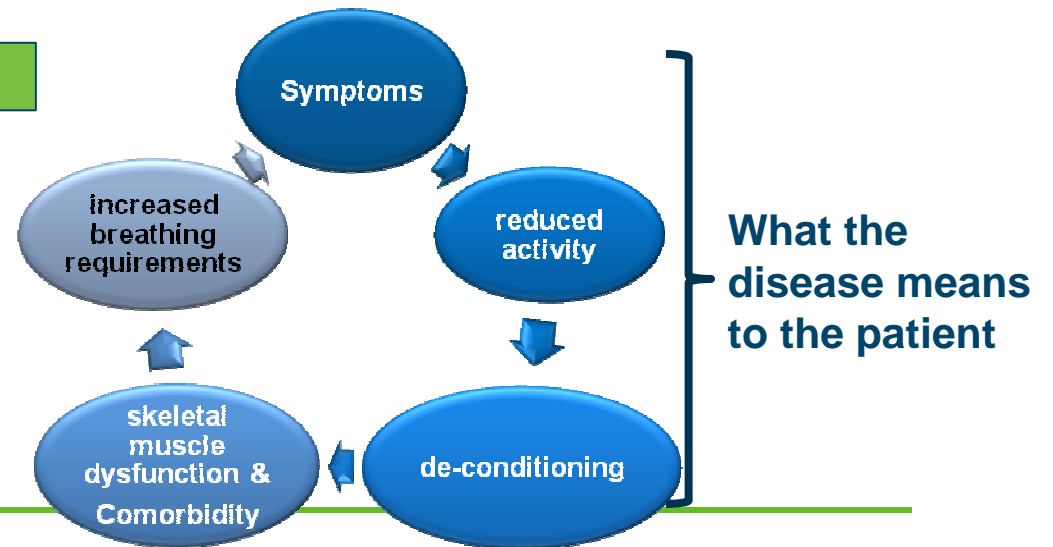


Patient Reported Outcomes

Few are available



COPD



What patients need What Europe needs



- What is the **effect** of our **interventions** on outcomes that are relevant to the patients suffering from COPD?

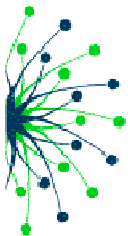
Criteria for a modern **P**atient **R**eported **O**utcome:

Responsive to
clinically relevant
treatment effects

Meaningful to
clinicians

Understandable to
patients

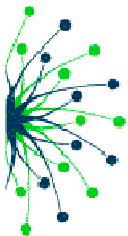
Acceptable to
Regulatory Authorities



What we will do about it



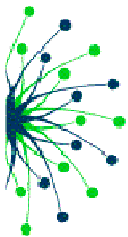
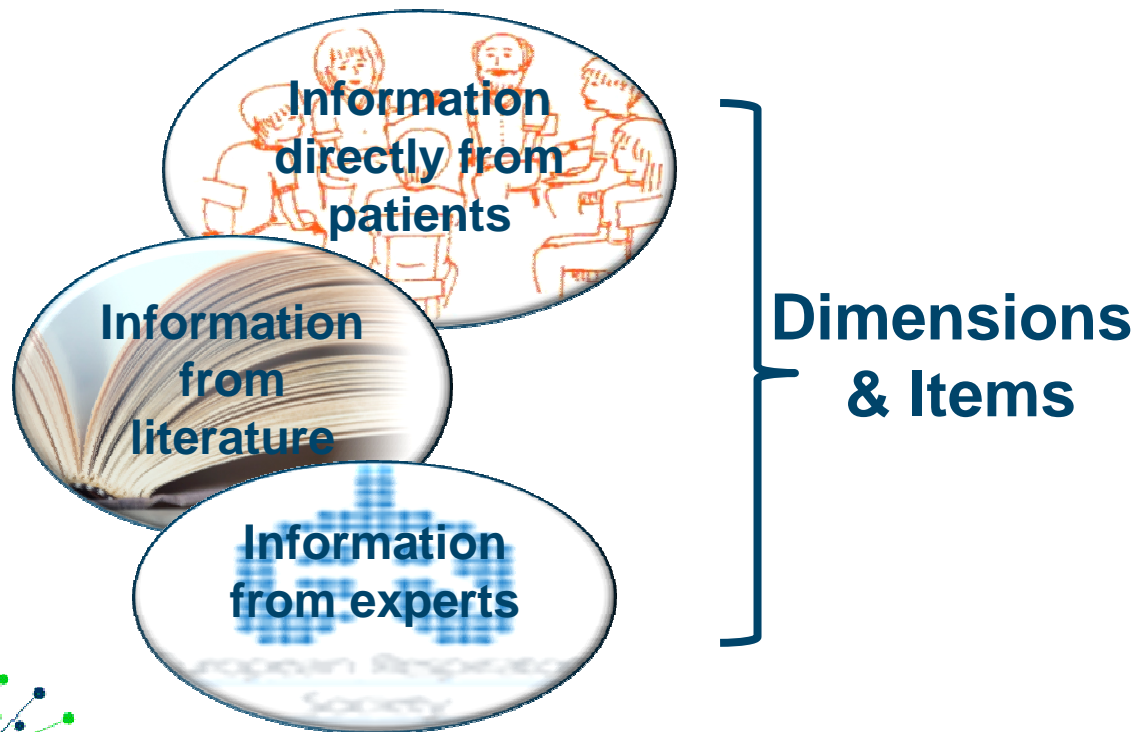
- PROactive will **develop** Patient Reported Outcome tools that capture the impact of COPD and our treatments on **physical activity**
- **Step 1: What are according to the patients relevant aspects of physical activity?**
 - What can I do
 - How many symptoms do I experience
 - Difference on ‘a bad day’
 - Problems by not being able to cary out expected tasks



What we will do about it



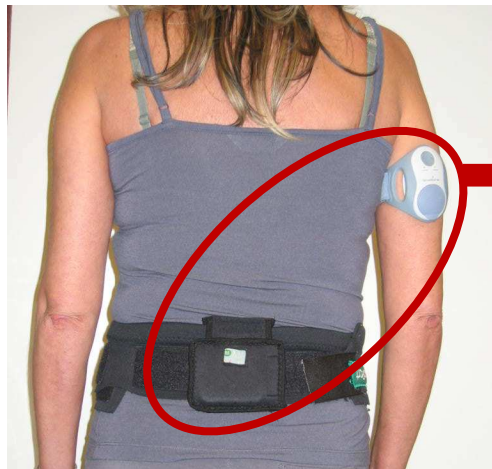
- **Step 1: What are according to the patients relevant aspects of physical activity?**



What we will do about it

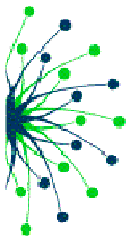


- **Step 1: What are according to the patients relevant aspects of physical activity?**
- **Step 2: Integrate this in a new tool, using modern patient friendly technology.**



Activity monitor

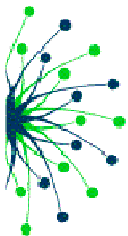
E-PRO tool for other dimensions



What we will do about it



- **Step 1: What are according to the patients relevant aspects of physical activity?**
- **Step 2: Integrate this in a new tool, using modern patient friendly technology.**
- **Step 3: Validate the new PRO's in the European population, taking into account culturally sensitive aspects.**



Innovative approach



- Start from the patient's perspective, as current regulatory guidance advocates
- Integrate objective assessment and Patient report to cover a domain as difficult as Physical Activity

Symptoms / PA

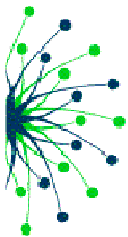
Time (days)



Expected outcome



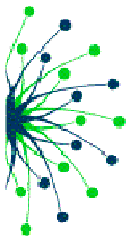
- **Patient Reported Outcome** tools integrating monitors and questionnaires for daily use and clinical visits in COPD
- A blue print for other chronic diseases where PA is equally important.



Expected benefit to patients



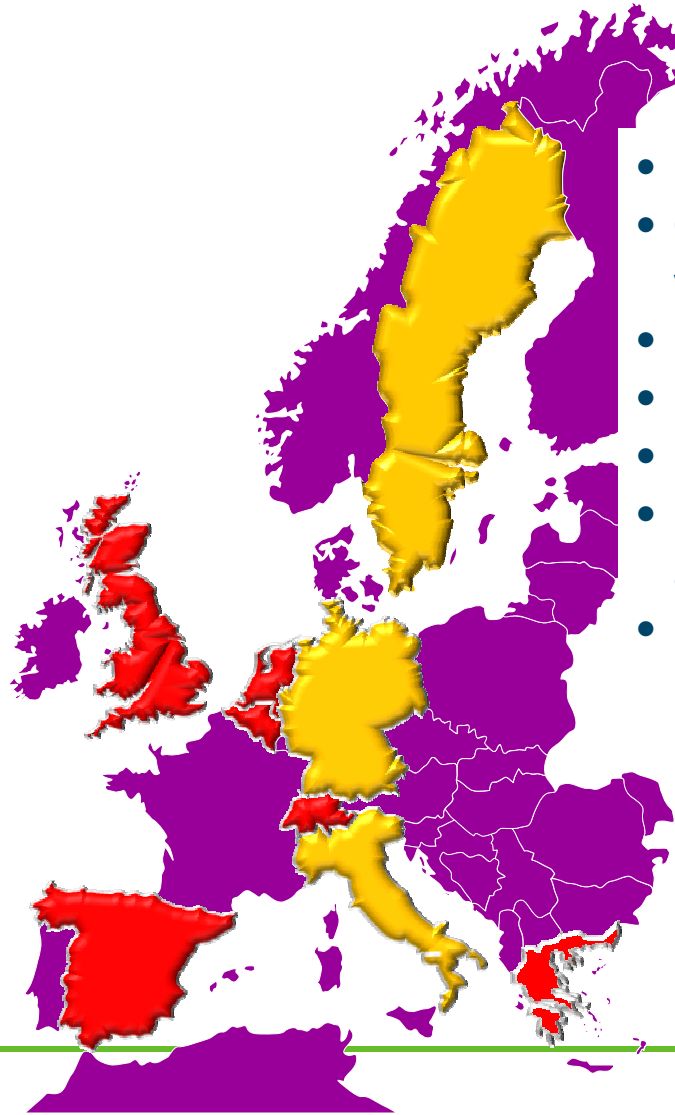
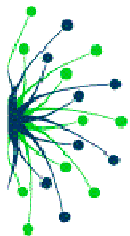
- Tools available to monitor the progression and improvement in an extremely relevant domain.
- A new and integrated outcome may open a window of opportunities for the acceptance of new therapies or combinations.
- These combinations may integrate pharmacological and non-pharmacological interventions.



Added value of the consortium



EFPIA members



- Expertise in PRO development
- Ongoing clinical trials allowing validation
- Expertise integrating technology
- Multicenter studies
- Powerful Project management
- Network of clinical experts across EU and the world
- Established contact with regulators

Added value of the consortium



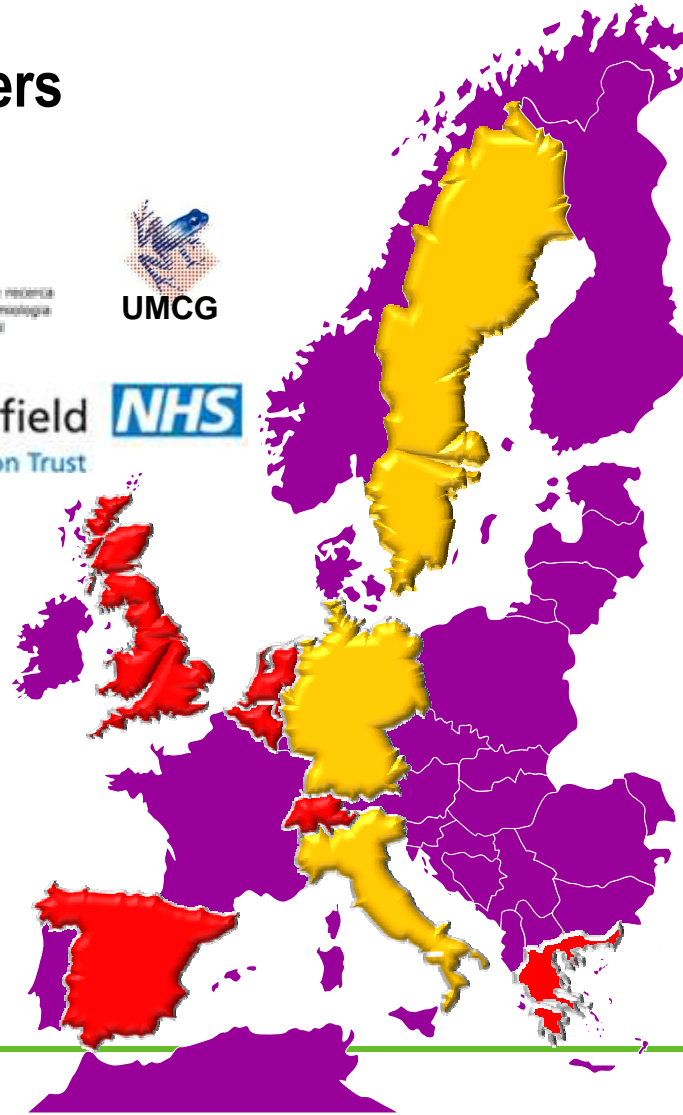
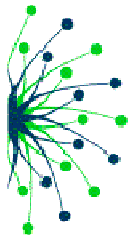
Academic partners



Royal Brompton & Harefield NHS Foundation Trust



Universität Zürich



Patient / Scientific organizations



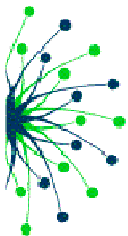
Small Medium Enterprise



Results/achievements so far



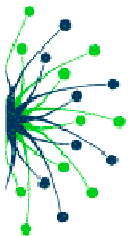
- **Literature reviews on 5 topics:**
 - What is the relation between PA and other outcomes
 - What questionnaires and items are available
 - What activity monitors are available
 - Qualitative studies in COPD: is PA important
 - What dimensions are relevant



Results/achievements so far



- **Literature reviews on 5 topics**
- **In 3 centers individual patient interviews and Focus groups are completed**
- **In 4 centers 7 activity monitors are validated**



Time and money

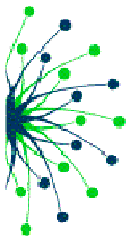


Financing

- IMI funding: **6.767.597** of a cost of **8.584.809 €**
- EFPIA contribution, mainly in kind: **8.163.949 €**
- Total project cost: **16.748.758 €**

Timing:

- Starting date: September 2009
- Duration: 5 years



Further information



Info [AT] proactivecopd.com

C.Brindicci [AT] chiesigroup.com (coordinator)

Thierry.troosters [AT] med.kuleuven.be (Scientific leader)

www.proactivecopd.com

www.imi.europa.eu

