PROactive

Physical Activity as a Crucial Patient Reported Outcome in COPD

Thierry.troosters [AT] med.kuleuven.be
Info [AT] proactivecopd.be
What patients need
What Europe needs

• Chronic Obstructive Pulmonary Disease is a disease with increasing prevalence

Buist et al Lancet 2007
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

Pathology

Steps.day\(^{-1}\) (n)

What the disease means to the patient

Troosters Respir Medicine 2010
Watz AJRCCM 2008
What patients need
What Europe needs

Classical outcomes
- Lung function
- CT-scan
- (Bio-markers)

Patient Reported Outcomes
- Few are available

Classical outcomes
- Exercise capacity

Pathology
- COPD
- Symptoms
  - increased breathing requirements
  - de-conditioning
- reduced activity
- skeletal muscle dysfunction & Comorbidity

What the disease means to the patient
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 **Patient Reported Outcome**:

- **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 carry out expected tasks
What we will do about it

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

  - Information directly from patients
  - Information from literature
  - Information from experts

Dimensions & Items
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
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
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