PROactive

Research Areas

At a Glance

- Status: Active Consortium
- Year Launched: 2009
- Initiating Organization: Innovative Medicines Initiative
- Initiator Type: Government
- Location: Europe

Abstract

The PROactive project aims to develop validation and use of patient-reported outcome (PRO) tools to investigate dimensions of physical activity that are judged as being essential by patients living with Chronic Obstructive Pulmonary Disease (COPD). The aim of the 60-month long consortium is to develop new tools that will enable patients, their doctors, and clinical researchers to accurately assess the improvement or deterioration of COPD.

Mission

The PROactive consortium is part of the European Commission’s Innovative Medicines Initiative (IMI) with aims to develop validation and use of patient-reported outcome tools to investigate dimensions of physical activity that are judged as being essential by patients living with Chronic Obstructive Pulmonary Disease. The PROactive consortium will develop patient-reported outcome tools that detect small but clinically relevant changes in physical activity and their related symptoms, and, as such, it will offer results more relevant to patients and doctors. A user-friendly electronic tool will help patients to assess on a day-to-day basis the activities in which they engage and the symptoms associated to these activities. The second tool will be used during hospital visits to assess the patients’ physical
activity and experience of the disease. To verify the usefulness of the tools, they will be tested in clinical trials with more than 600 COPD patients. The European Medicines Agency and the U.S. Food and Drug Administration will be closely involved in the developments.

**Consortium History**

2009 – Project start date
2011 – IMI lung disease projects present finding to press and patients (September)
2013 – PROactive and COPDMAP sign Memorandum of Understanding to join forces on COPD work (July)

**Structure & Governance**

Project Coordinators:
Mario Scuri
Dr. Caterina Brindicci

Managing entity of IMI beneficiaries & coordinator of scientific activities:
Thierry Troosters

Within the PROactive project, there are two advisory boards that pro-actively oversee the progress of the project and tackle any issues that may arise. The boards ensure that the project is ethical and safe and that it meets the needs of patients.

The two advisory boards are:

**Financing**

This project is funded by the Innovative Medicines Initiative, a public-private partnership between the European Union (EU) and the European Federation of Pharmaceutical Industries and Associations (EFPIA), resources of which are composed of financial contribution from the EU Seventh Framework Programme and EFPIA companies’ in-kind contributions. Large Pharmaceutical companies
participating in IMI projects do not receive IMI funding.

The IMI Intellectual Property (IP) Policy governs the IP regime of all projects funded by the IMI JU. To assist with specific IP queries, IMI has set up a dedicated IP Helpdesk, which can be contacted by e-mailing IMI-IP-Helpdesk@imi.europa.eu. The IMI IP policy can be accessed at the following address: http://www.imi.europa.eu/sites/default/files/uploads/documents/imi-ipr-policy01august2007_en.pdf

Patent Engagement

PROactive held events for patients and the public. IMI Executive Director Michel Goldman opened the event with a presentation on how Europe is responding to the needs of respiratory patients. Other talks explained how patients and scientists are working together in the U-BIOPRED and PROactive projects and Marc Decramer, president of the European Respiratory Society, discussed the roadmap for respiratory research in the years ahead. The event was part of the 2011 European Respiratory Society Annual Congress in Amsterdam in September.

The IMI project PROactive is also developing new ways of gauging the impacts of chronic obstructive pulmonary disease on patients’ daily lives. While current activity tests tell doctors what patients can manage in theory, they do not reveal what patients are actually doing on a day-to-day basis or how patients feel about their activity levels. Through interviews with patients, PROactive has found that patients consider three aspects of physical activity to be important to overall quality of life: the amount of physical activity (e.g., how far someone can walk), the symptoms triggered by the activity (e.g., shortness of breath or fatigue), and the way the patient copes with these symptoms (e.g., stopping to rest every few minutes). Based on the findings, the PROactive team has developed some questions that capture the impacts of COPD on patients’ quality of life. As of September 2011, the team planned to create a tool that combines these questions with input from activity monitors (small external devices that measure activity levels and are worn by the patient) to accurately assess physical activity levels from the patients’ point of view. The tool could be used by physicians and researchers alike to test the efficacy of treatments, for example. The tool could also be adapted for other chronic conditions that affect physical activity.

The results of the research performed by the PROactive consortium will be of immediate importance to the 10 percent of elderly European citizens suffering from COPD. It will provide a means of assessing the impact of either medication or rehabilitation by asking the patient how it has affected their everyday
physical activity. This, in turn, will allow clinicians and pharmaceutical companies to reflect the outcomes and results of these interventions and treatments in the patients' own language (the “patient-reported” part).

Homepage  http://www.proactivecopd.com/
Other website  http://www.imi.europa.eu/content/pro-active

Data Sharing

According to IMI’s intellectual property policy, the participants undertake to disseminate the data as soon as reasonably practicable but not later than one year after the termination or expiry of the project. The Project Agreement shall include a description of the material that must be disseminated in accordance with the IP Policy and referenced in the Grant Agreement. If the participants do not disseminate within such time periods without good reason, the Executive Office has the right to disseminate such results in a manner consistent with the Grant Agreement.

Points of Contact

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Sponsors & Partners

Chiesi Farmaceutici S.p.A, Parma, Italy  
(Project Coordinator)  
GlaxoSmithKline Research and Development LTD, Brentford, UK  
Pfizer Limited, Sandwich, UK  
Almirall, S.A., Barcelona, Spain
Novartis Pharma AG, Basel, Switzerland
AstraZeneca AB, Södertälje, Sweden
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Astma Fonds Longstichting, Leusden, Netherlands
British Lung Foundation, London, UK
European Respiratory Society, Lausanne, Switzerland
Choice Pharma, Hitching, UK

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