

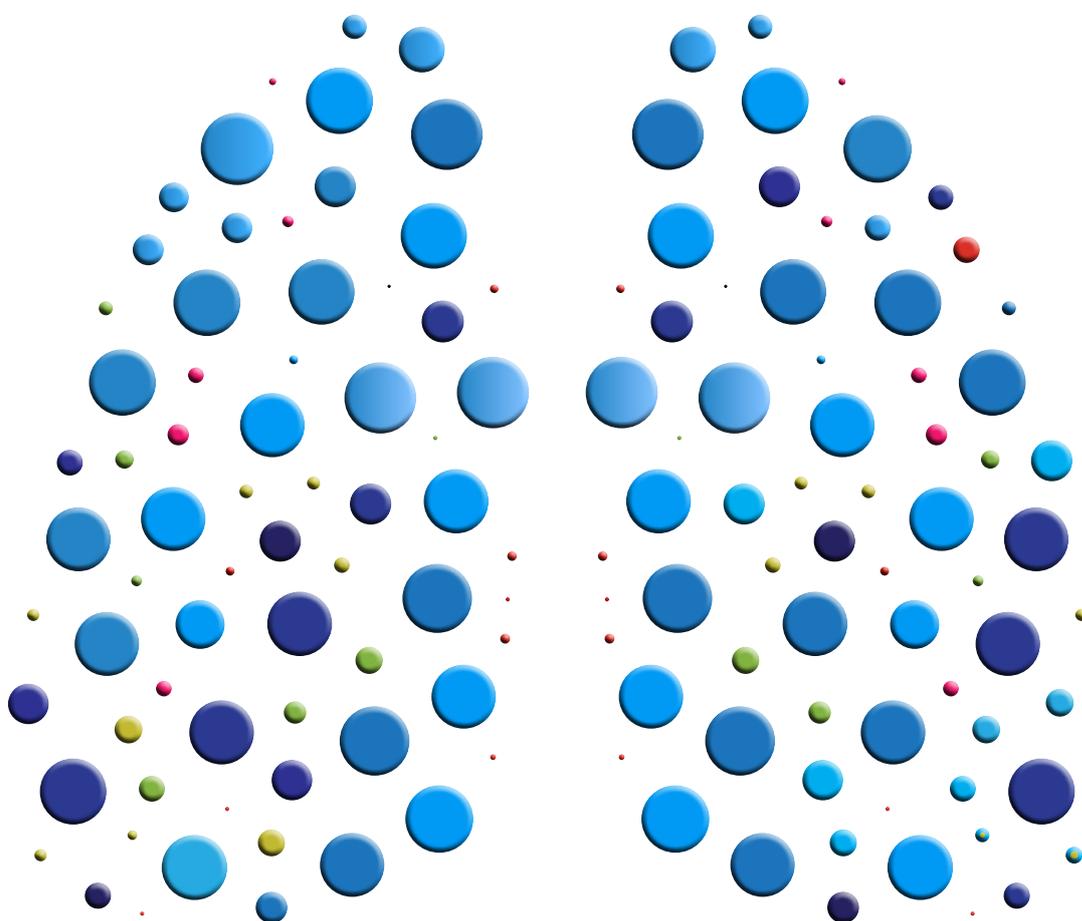
AirPROM

closing event report

31st May 2016

New tools to measure progression of lung diseases

Contribution to the future of medicine's research



Introduction

Our lungs may look similar, but they are not exactly the same. They differ in shape and capacity and properties. Where our eyes do not have the same colour, our lungs are also unique to each of us. To help to better understand the functioning of the lungs in people with asthma and chronic obstructive pulmonary disease (COPD), the European Union's Seventh Framework Programme (FP7) has funded AirPROM (2011-2016) a project to develop a detailed modelling of the human lung.

New tools to measure progression of lung diseases

AirPROM refers to Airway Disease Predicting Outcomes through Patient Specific Computational Modelling involving researchers from a wide variety of fields. Thanks to their different backgrounds, AirPROM partners have worked together to determine micro – and macro-small airway models and a macro-large airway model to see how the human lung works. Through AirPROM, healthcare professionals will use of a virtual tool to see progression on respiratory disease and be able to anticipate individual patients' response to medicine before they begin to follow treatment.

The AirPROM results were presented at the European Parliament on the 31st of May 2016 (World No Tobacco Day): this event was organised by the European Federation of Allergies and Airways Patients' Diseases Associations (EFA) in collaboration with the European Respiratory Society (ERS) and the European Lung Foundation (ELF). Thanks to their complementary backgrounds, AirPROM researchers have put together several modeling techniques to help predict lung

diseases. This means that through AirPROM future technology, healthcare professionals will be able to use a virtual tool to assess progression of respiratory diseases and to predict individual patients' response to medications even before treatment.

During the event, members of the AirPROM consortium informed the public, patients and policy makers of the AirPROM project outcomes and their integration in clinical practice beyond the project lifespan; people with asthma and COPD outlined their hopes for the impact of AIRPROM in their daily life. This was followed by a discussion by a panel of experts in the field and policy makers, including the leadership of the Innovative Medicines Initiative and the European Parliament. The discussion explored how computer modelling can enable a personalised medicine approach. Participants tried to identify potential actions at the political level to promote and facilitate this approach, and which could benefit European healthcare systems as well as patients' quality of life.



Plenary session: Beyond the AirPROM Project – AirPROM contribution to the future of medicine’s research and ultimate delivery of healthcare and prevention

“Over the last 5 years, AirPROM has worked to produce models that are capable of managing patients with difficult-to-treat respiratory diseases and developed knowledge that can allow the development of new and more effective treatments” said hosting MEP David Borrelli, member of the European Parliament Interest Group on Allergy and Asthma. He welcomed the participants, stating that this event is exactly how the results of EU funded projects should be brought back and communicated to the policy makers.



We are close to tailored care and treatment of respiratory disease

Personalised medicine is a medical model that separates patients into different groups — with medical decisions, practices, interventions and/or products being tailored to the individual patient according to their predicted response or risk of disease. AirPROM has brought personalised and precision medicine at higher levels by working on techniques related to inflammation and gene expression. These techniques can be

used to better understand how diseases develop. Thanks to the participation of thousands of patients, AirPROM researchers have been able to discover biomarkers that identify individuals with an increased risk of developing respiratory diseases.

“Thanks to results like those from AirPROM, our approach to managing the common airway diseases such as asthma and chronic obstructive pulmonary disease (COPD) will change in the future. The tools used for self-management will improve to empower patients and enable them to be more involved in clinical trials, with the aims of making safer drugs and more effective technology. This represents an important step towards precision medicine”, said Prof. Fan Chung, from Imperial College London.

Nevertheless, there are still challenges to overcome. Understanding of disease progression in asthma and COPD is still limited as these conditions are affected by multiple genes and biomarkers. Disease classification is outdated and potential offered by big data analysis is still limited. Infrastructures must be improved and funding opportunities increased. Governance and ethical issues will need to be addressed when implementing new treatments and approaches.

AirPROM achievements and future diagnosis and care of lung disease

AirPROM has taken on some of these challenges to come up with a personalised treatment approach. The results achieved so far are outstanding. AirPROM has validated models to predict airways diseases progression and response to treatment: it has been the first study to demonstrate the efficacy of anti-DP2 antibody when airways are inflamed. It also developed the first computational model of thermoplasty, a treatment suitable for some adults with severe asthma.

AirPROM data have been collected in a knowledge portal and integrated in the electronic European Genome-Phenome Archive, which will allow scientists to study the genetic basis of different diseases and to produce patient-specific tools.

Imaging technologies provide greater understanding of the lungs in an individual patient than a standard questionnaire assessment of lung disease, and having the airways structure available will provide with a

more accurate idea of how lung diseases can influence the life of the patients.

In practice, by taking low dose of high-resolution computed tomography scans at inspiration, breathing in and expiration, breathing out AirPROM research team has been able to produce, visualise and measure the volume of lungs and lung lobes, blood vessels, airway (walls) and so on. These macro scale organ models enables the study of lungs reactions to treatments and whether these responses are linked to morphological deformations.

Thanks to imaging, healthcare professionals will be able to look at each patient individually and understand how they respond to treatment. According to Wim Vos from FLUIDDA NV, "since the lung is able to stabilize its functioning despite regional health issues, looking at the lung health directly via images gives us more insight in the disease processes and treatment responses."



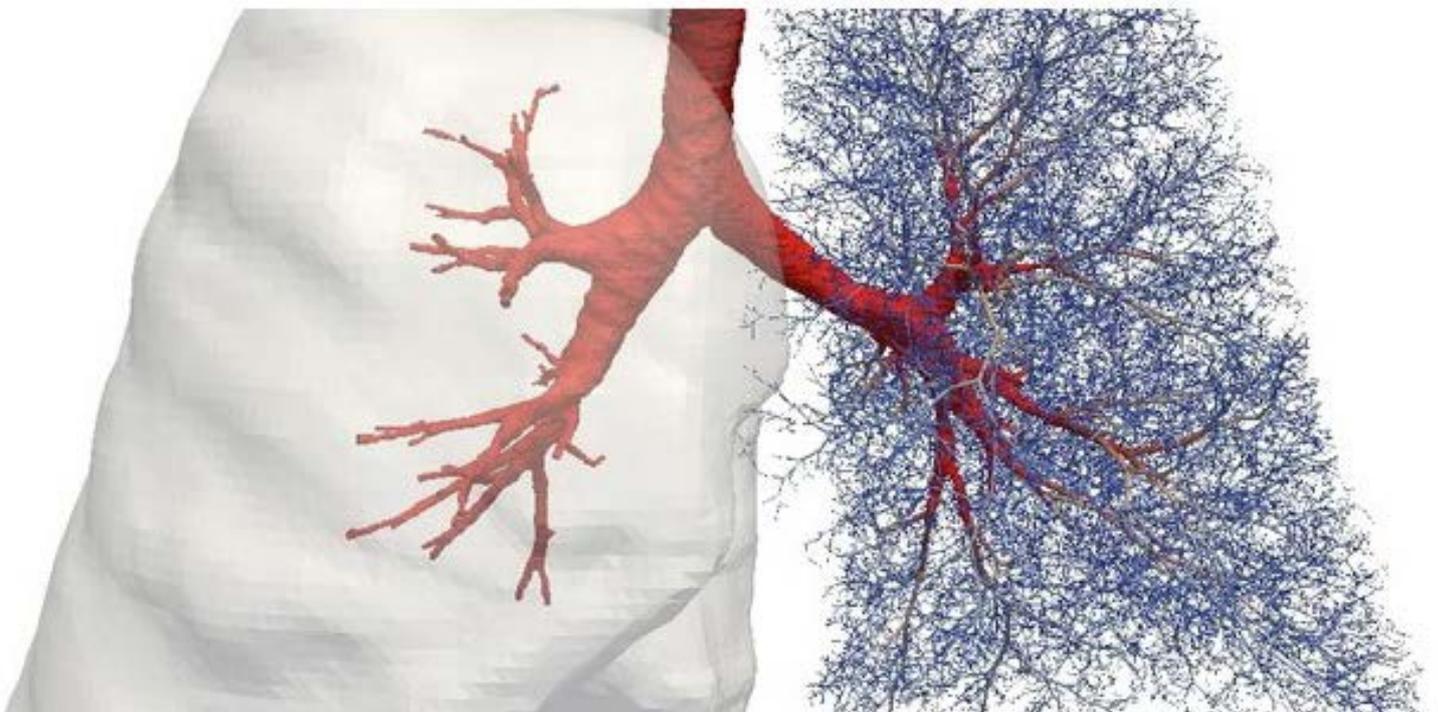
AIRPROM benefits for the patients

Severe asthma often prevents patients from walking and talking without experiencing symptoms such as breathlessness and coughing. Asthma can also cause poor sleep, tiredness, exhaustion, and no sense of smell. Managing side effects and adverse effects of medications is also challenging. Asthma can be triggered by cigarette smoke, air conditioning or air fresheners preventing patients from having a normal life.

This is the reason why patients are at the center of AirPROM, to ensure the project was improving and tailoring treatments better to individual patient's needs. Thanks to the participation of patients, AirPROM scientists could develop lung models that can help them study disease without the need to conduct consuming tests or examinations on patients.

"Being an active patient advocate at national and EU level has enabled me to learn more about asthma, provided opportunities for me to raise awareness about chronic respiratory diseases and even to contribute to research studies", Breda Flood, severe asthma patient advocate.

"Had tools like 'AIRPROM model' been available for my doctor 20 years ago, I would have been able to know and see what was happening in my lungs, and have more personalized treatment much earlier."



Panel Discussion: How can computer modelling enable a personalised medicine approach which will help healthcare professionals and patients? What can be done at political level for promoting and facilitating this approach?

AirPROM results and their application in daily consultations

There are different types of asthma and COPD. AirPROM researchers have been able to improve the understanding of severe asthma thanks to the synergies created by the consortium with other EU projects like U-BIOPRED (Unbiased BIOMarkers in PREDiction of respiratory disease outcomes). Thanks to the results of several successful studies in animals, and the ongoing clinical studies with patients, there will be new data available that will enable healthcare professionals to make predictions about the progression of a disease. "This was impossible to achieve before AirPROM", said Ian Adcock, ERS Assembly Head of Airway Diseases and one of the principle investigators in U-BIOPRED.

Imaging in clinical trials can speed up the drug research and development process and lead to better tailor each individual treatment for specific sub-groups of difficult-to-control asthma. Once treatments are available, imaging can be used in clinical practice to match these highly targeted treatments with patients who can benefit from them the most.

However, there is still a way to go before these techniques are ready to use in clinical practice. Some of the challenges are currently being addressed by other research projects, such as myAirCoach. MyAirCoach will provide real-time health information for healthcare professionals and patients with asthma, including information on behavioural aspects and environmental factors affecting them. Knowledge created by MyAirCoach links new technologies, patients and healthcare professionals.

Thanks to these projects, patients will be able to benefit from new technology faster. Patients bring a unique perspective to large collaborative research projects and they are keen to be actively involved in them. Juliëtte Kamphuis, a severe asthma patient advocate from the Netherlands, would like to be more involved in research to access the technology faster, as lives of patients like her are particularly hard due to limited treatment options for severe asthma.



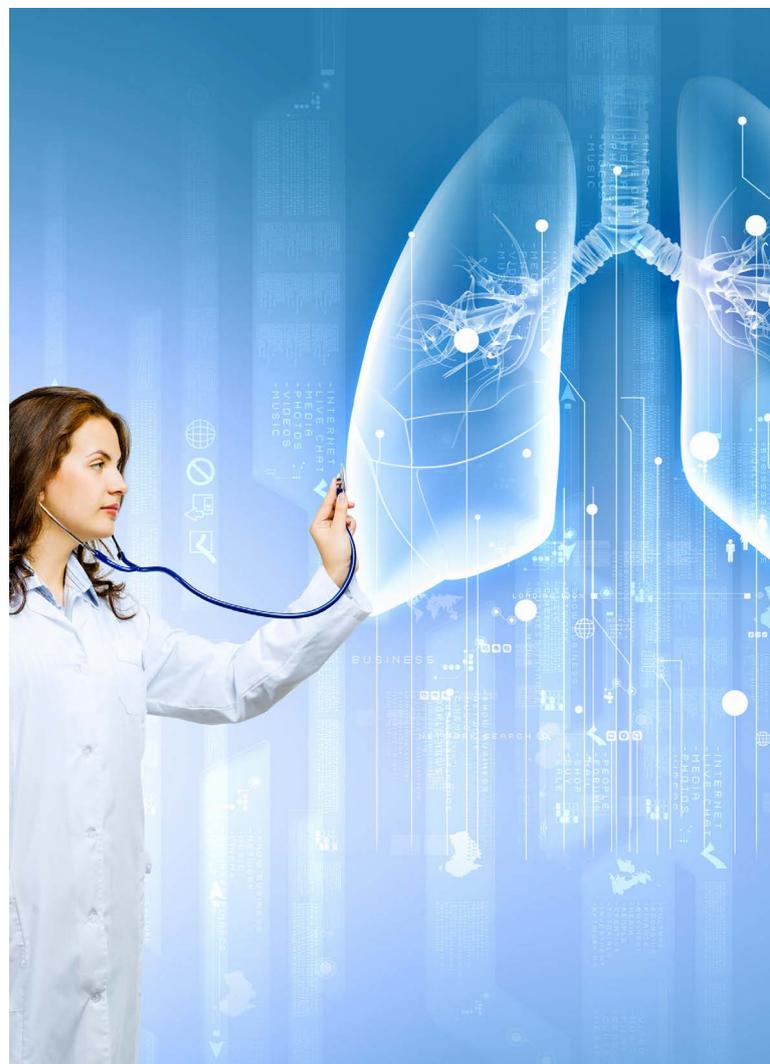
Scaling up innovation: main challenges

The tools used by AirPROM aim to be minimally invasive for the patient, whilst being the simplest and most accurate testing tools to produce the most accurate and appealing treatment options for patients. Yet to bring this possibility into everyday practice, healthcare systems in Europe need to plan investment and strategies to fully take up this innovation. Patients are aware of the challenges. Amanda Roberts, a patient advocate from the United Kingdom, remarked that asks “it is difficult to predict at the beginning of the project how any achievement might affect current challenges”, especially when technology seems to be moving so quickly.

The introduction of new medical techniques and approaches into practice requires healthcare system change and importantly, innovation need to support the sustainability of health systems, while addressing needs of patients by helping them to be more effective. According to Pierre Meulien, Executive Director of the public-private partnership Innovative Medicine Initiative (IMI), “the current economic constraints make difficult to exploit innovation in an efficient manner; however, much of the technology is already there so we need to address obstacles so that citizens can benefit from the great science in a timely and affordable way. We need to act swiftly because from a scientific point of view the train has already left the station!”. Most of IMI projects bring different components for innovation upscaling but there is a missing link between the projects and how our healthcare could benefit in a sustainable and forward looking way.

What can the EU do to accelerate access to AirPROM technologies?

Policy makers at national and at EU levels have a relevant role in promoting and facilitating the introduction of innovative approaches that can change the clinical practice in a positive way with new tools to help matching treatments with the right patients and developing new ones for those with difficult asthma or COPD. MEP Sirpa Pietikainen (EPP/Finland) proposed to develop a “European Code of Conduct of Guidance for respiratory diseases, outlining what good diagnosis, treatment, follow up, and rehabilitation should entail that can be promoted and shared as best practice”. Ms Pietikainen called all the participants to bring their insights to the European Parliament Interest Group on Allergy and Asthma, as the group’s EU policy knowledge can help improving the asthma and COPD treatment and management process.



Conclusions and next steps

The AirPROM project has developed models that will reshape the approach of treating people with asthma and COPD. Other models are still under development. Although the EU funding has ended, the consortium intends to keep working to continue the studies.

The ultimate aims of AirPROM are:

- to decrease treatment costs by reducing the time spent on clinical trial stages for drug implementation
- to develop better treatments for patients
- to use newly developed patient screening tools to ensure that each patient receives the right treatment

It is therefore necessary to invest in the research and development of new treatments and better screening tools to reduce the cost of treatment of severe asthma.

Further research and studies need to be conducted to fully understand the complexities of asthma or COPD and to introduce project results in clinical practice “but we are confident that the commitment of all partners, together with the support of other research consortia, will ensure the legacy of AirPROM and will finally result in new, innovative and less expensive treatment for asthma and COPD patients”, Neil Fitch, from BioSci Consulting who project managed AirPROM.

Thank you!

Acknowledgements

We would like to present our sincere thanks to the European Union institutions that have believed and funded a project like AirPROM. Our deepest recognition goes to all people and the 34 organisations that have participated in AirPROM, especially to all the patients whose precious voluntary involvement has guided researchers and validated clinical. We would like to express our sincere thanks to all the representative that took part in the closing event summarized in this report, namely clinicians from the European Academy of Allergy and Clinical Immunology and the Georgian society, patient representatives from Italian Federasma e Allergie, the Spanish Federation of Respiratory Diseases' Associations, the Dutch Long Foundation, Asthma Society of Ireland and the European Patients' Forum, and from the European Lung Foundation.

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