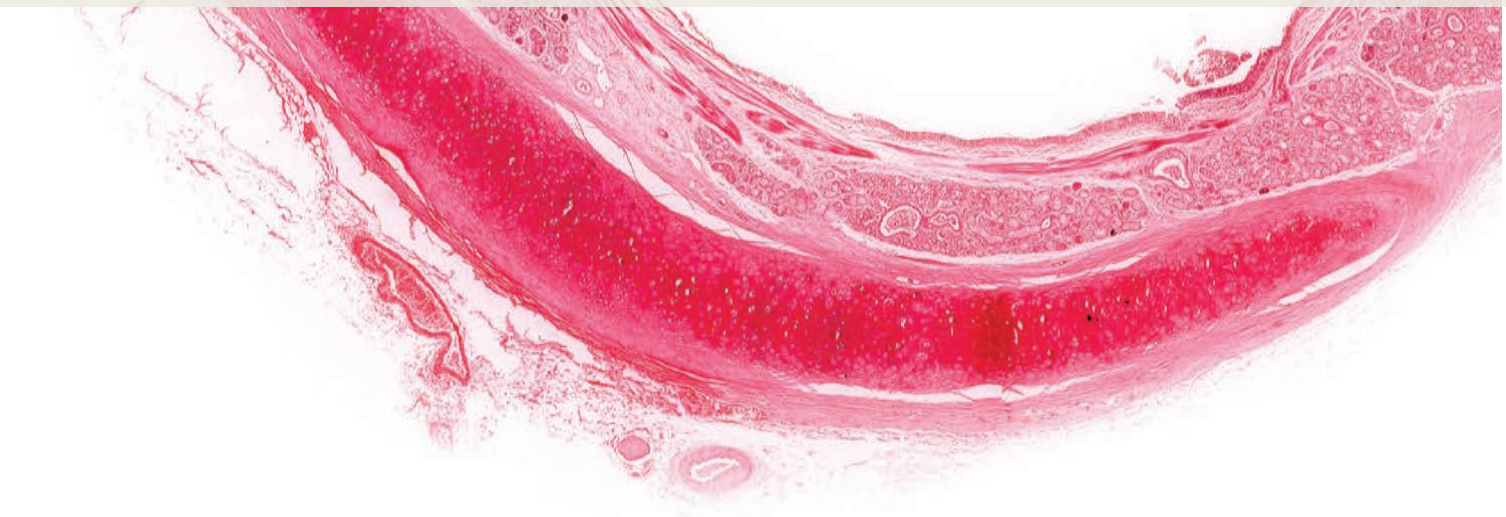
A SELECTION OF EU-FUNDED *respiratory* RESEARCH PROJECTS



ERS EUROPEAN RESPIRATORY SOCIETY
every breath counts

ELF EUROPEAN LUNG FOUNDATION

The European Respiratory Society (ERS; www.ersnet.org) is an international organisation that brings together physicians, healthcare professionals, scientists and other experts working in respiratory medicine. We are one of the leading medical organisations in the respiratory field, with a growing membership representing over 140 countries worldwide. Our mission is to promote lung health in order to alleviate suffering from disease and drive standards for respiratory medicine globally. Science, education and advocacy are at the core of everything we do.

The European Lung Foundation (ELF; www.europeanlung.org), was founded by ERS in 2000 with the aim of bringing together patients and the public with respiratory professionals to positively influence lung health. ELF works to communicate respiratory science to those outside the respiratory field. ELF also works to ensure that people with lung diseases and the general public have the opportunity to influence respiratory research and guidelines at the European level.

Aims of this booklet

This booklet aims to showcase seven research projects in which the European Respiratory Society (ERS) and/or the European Lung Foundation (ELF) have a key role. The projects, most of which are on-going, have received funding under the EU's Seventh Framework Programme for Research and Development (FP7).

There are various unmet needs in the field of respiratory medicine. These projects are dealing with different aspects in the translational process of turning observation in the laboratory, clinic and community into interventions that improve the health of individuals and the public, specifically:

- The need to develop new patient-reported outcomes that are relevant for the patient (PROactive)
- The need for better phenotyping of disease to enable validation of qualifying biomarkers (U-BIOPRED)
- Using interdisciplinary efforts to develop new, patient-specific computer models of lungs to ensure better outcomes of treatments (AirPROM)
- Bringing together key stakeholders and experts to identify gaps in asthma research and propose solutions for more rapid communication of research results (EARIP)
- Improving future public health responses by involving clinicians in preparedness planning, effective communication and information exchange, and building clinical research as part of the response (PREPARE)
- Multidisciplinary efforts spanning basic science, clinical research and epidemiological studies to combat the growing threat of drug resistance in Europe (TB PAN-NET)
- The need for targeted investments to support the careers of outstanding and experienced researchers in the field of basic research (RESPIRE2)

This booklet provides a concise summary of each project, its objectives and important project outcomes, and highlights key future research questions.

These selected research projects cover a wide range of major respiratory diseases i.e. chronic obstructive pulmonary disease (COPD); asthma, including severe and difficult-to-treat asthma; multidrug-resistant tuberculosis, and rapidly emerging infectious pathogens (e.g. influenza epidemics).

A range of different FP7 research instruments are associated with the projects highlighted in this booklet which illustrates neatly the different types of collaboration that have been facilitated through EU funding.

Committed to strengthening science

ERS aims to consistently achieve its mission by being at the forefront of basic and translational research through a range of activities:

- Showcasing the latest innovations in clinical advances at the ERS International Congress
- Helping break new ground and enable in-depth exchanges among scientists by hosting scientific conferences and research seminars
- Publishing research and state-of-the-art knowledge in ERS' scientific journals
- Participating in EU-funded research projects, and providing a platform for dissemination, education and training or selecting experts to serve on the advisory boards of research projects
- Developing pan-European multi-centre networks of principal investigators, called Clinical Research Collaborations (CRC), that offer an umbrella for a network of researchers – both inside and outside the Society – to come together to improve knowledge of respiratory science and medicine
- Investing and furthering the careers of promising early-stage and experienced researchers in the form of various highly competitive and respected fellowship programmes.

THE ENTIRE CYCLE OF CLINICAL RESEARCH IS *crucial*

Motivated to involve patients in research

Ensuring a meaningful and an integrated approach to involving patients throughout the entire cycle of clinical research is crucial. Clinical practice needs to have access to the best available evidence and the clinical research agenda should match the concerns and needs of patients and clinicians.

Involvement of those with expertise in living with a condition in research study design, on ethics boards and patient input groups can help ensure:

- Recruitment targets are met
- Patients taking part in research can have a positive and well-informed experience

- Real-world outcomes are achieved by the project
- Projects are communicated and disseminated to key stakeholders outside of the respiratory professional community
- Ethical and transparent practices and accountability are promoted
- A continued legacy of impactful patient involvement.

Patients also need to be better informed of possibilities for involvement in trials and studies as study participants. The move towards personalised medicine aspires to cure rather than suppress disease, which represents a huge shift in treatment and engagement with patients. To encourage full and active participation, patients and their families need to be fully informed at all stages. ELF's goal in EU projects is to support patients at all stages:

- To provide patients with the knowledge and skills to take up opportunities to get involved in the research process via the ELF's free online course: the European Patient Ambassador Programme (EPAP; www.EPAPonline.eu)
- To facilitate and integrate patient involvement throughout the research process for the lifetime of the project
- To communicate the aims and results of the project to patients and the public in lay language
- To promote the role of patients as project partners, and communicate successful involvement to advance the number and range of opportunities for patient involvement.

PRO active

PHYSICAL ACTIVITY AS A CRUCIAL PATIENT-REPORTED OUTCOME IN COPD

PROACTIVE

This project has received funding from the European Union (IMI JU) and in-kind support from EFPIA companies under *grant agreement no 115011*

Aim: The aim of PROactive is to develop, validate and use two tools that can measure the impact of chronic obstructive pulmonary disease (COPD) on physical activity. Prior to the project launch no instruments were available to capture this important outcome and if the tools were validated, they could help healthcare professionals judge the effectiveness of interventions to help improve levels of physical activity.

An essential factor in this project is that the tools are developed according to the guidance of the US Food and Drug Administration and the European Medicines Agency for patient-reported outcomes (PROs). The project started with information directly obtained from patients and then a concept around physical activity was developed that captures an aspect of COPD burden that is very relevant and understandable to patients.

The first tool will be a user-friendly electronic tool that will help patients to assess on a day-to-day basis their experience with physical activity in terms of the amount of exercise and the difficulties patients experience. The second tool will be used during clinical (hospital, research or doctors) visits to assess the patients' physical activity. The tools are being tested in clinical trials with more than 600 COPD patients.

Project milestones: Over the past few years several important milestones were met:

- Suitable activity monitors were selected, tested and validated for user experience. Three activity monitors were deemed suitable for use in COPD (Van Remoortel PLoS One 2012; Rabinovich Eur Respir J 2013). These monitors are now also frequently used in pharmaceutical and non-pharmaceutical trials.
- With extensive qualitative studies, a conceptual framework was constructed from a patient perspective around the physical activity experience (Dobbels Eur Respir J 2014) and a systematic review placed physical activity in the context of other relevant outcomes (Gimeno-Santos Thorax 2014).
- Items were selected that best capture physical activity along the previously developed concept of the physical activity experience (Gimeno-Santos Eur Respir J 2015). Data support that a combination of activity monitored outcomes and items best capture physical activity in two domains relevant to patients with COPD: amount of physical activity and difficulty experienced with physical activity. Two tools were developed, one for daily use and one for use during clinical visits.
- Interactions with regulators prepared the field for acceptance and use of the tools. Several studies are currently finalised to further validate the

PRO-tools and their use in multicentre studies across the globe. Among these studies one developed an innovative tele-coaching programme for patients with COPD using a smartphone interface, a step counter and semi-automated algorithms to coach patients towards a more active life style. Other studies included pharmacological interventions, pulmonary rehabilitation and combinations.

ERS/ELF involvement in the project: ERS has an important role in the project, ensuring dissemination of key project outcomes to the wider community of respiratory health professionals but also facilitating their input to validate the draft items. For instance, results stemming from PROactive have been included in an ERS postgraduate course currently under development dealing with the specific aspect of physical activity, its causes, consequences and evaluation in COPD. Moreover, the expertise of ERS in organising 'virtual' meetings is used to implement meetings with patients, scientists and other stakeholders. The ERS products (European Respiratory Journal, the International Congress) are used as a platform for communication with the scientific and clinical stakeholders. The ERS-ELF network have used the expertise developed by PROactive around physical activity in their campaigns for better respiratory health and in emphasising the growing importance of physical activity in preventing chronic respiratory diseases.

The future: The research question 'How to best capture the physical activity experience for patients with COPD' will be answered at the end of the PROactive project. This is just the beginning of our understanding of the true impact of inactivity on disease progression and the development of comorbidities. Treatment of physical inactivity is complex and needs to be embedded in contemporary and comprehensive disease management from prevention of inactivity to the reversal of an inactive life style. The more frequent use of the PROactive tools in further large clinical studies should help to determine the utility of enhancing physical activity or successful prevention of decline in physical activity in patients suffering from COPD.

The PROactive tools are 'products' that need to be protected in terms of proper use, translation and application in clinical trials. During the project several

relatively large cohorts of well-phenotyped patients were studied in six clinical sites. Follow up of these patients using the PROactive tool can provide unique insight into disease progression in a highly heterogeneous cohort of patients. Such efforts will require funds beyond the PROactive project.

The project has provided a blueprint for the development of a 'hybrid' PRO tool. This will be of interest in other disease areas in and beyond respiratory disease.

To serve these goals, the PROactive project aims to continue as a consortium beyond the termination of the project with the aim to continue doing research with partners interested in physical activity as a key outcome for COPD.

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PROJECT PI	**Coordinator** Dr Mario Scuri Chiesi Pharmaceuticals Parma, Italy M.Scuri@chiesi.com **Scientific coordinator** Prof Thierry Troosters Department of Rehabilitation Science University Hospital Gasthuisberg, Blegium Thierry.troosters@kuleuven.be
DURATION	6 years (1 September, 2009 – 31 August, 2015)
FUNDING	€15m (€8.5m EU funding and the rest in kind by EFPIA partners)
PROJECT PARTNERS	Chiesi Katholieke Universiteit Leuven Glaxo Smith Kline University of Edinburgh Thorax Research Foundation, Athens Royal Brompton and Harefield NHS Foundation Trust Universität Zürich, Zürich University Medical Center Groningen Centre for Research in Environmental Epidemiology Netherlands Asthma Foundation, Leusden British Lung Foundation Choice Healthcare Solutions European Respiratory Society, Lausanne Almirall Novartis AstraZeneca UCB Boehringer Ingelheim

UNBIASED BIOMARKERS FOR THE PREDICTION OF RESPIRATORY DISEASE OUTCOMES

U-BIOPRED

This project has received funding from the European Union (IMI JU) and in-kind support from EFPIA companies under *grant agreement no 115010*

U-BIOPRED

UNBIASED BIOMARKERS FOR THE PREDICTION OF RESPIRATORY DISEASE OUTCOMES (U-BIOPRED)

Aim: The U-BIOPRED project aims to speed up the development of better treatments for patients with severe asthma. Several knowledge gaps exist that make it hard to predict how well a new experimental medicine will work in patients. One of the major difficulties is the discovery that there are many different forms of severe asthma, caused by different mechanisms of disease. Patients with different types of asthma may react differently to new or existing treatments.

The aim of U-BIOPRED is to identify these different types of severe asthma, by using comprehensive clinical characterisation plus biological fingerprints of the disease. Combining these fingerprints will deliver integrative handprints of severe asthma, allowing tailored development and application of therapies.

Project milestones: As the project draws to a close in 2016, the following milestones have been achieved:

- Completion of the clinical adult and paediatric studies using over 100,000 cross-sectional and longitudinal samples
- Completion of baseline and bronchoscopy sample analysis using large-scale systems to analyse many factors in one go (known as omics technology)
- Completion of the longitudinal follow-up studies that included daily monitoring and analysis of exacerbations
- Completion of the pre-clinical studies using animal models
- Development of the first fingerprint for adult and paediatric patients and the first accessible handprint
- Development of an Asthma Disease Map, capturing the various biological networks underlying severe asthma
- Papers published and submitted on the clinical cohorts, methodological validations, and first omics fingerprint.

ERS/ELF involvement in the project: ELF is a member of the groups in the project working on dissemination, ethics and monitoring. For the final two years of the project, ELF has also been coordinating the project's advisory group consisting of patients, known as the Patient Input Platform (PIP). ELF brings value to the project, and so expedites advocacy on behalf of patients, by:

- managing the project's public website
- communicating key findings and developments to diverse patient, public and professional audiences, including the media and study participants
- promoting and facilitating appropriate and impactful patient involvement throughout the cycle of the project through the PIP and patient members of the project's ethics and safety monitoring boards.

From the outset, U-BIOPRED included patient organisations, and the PIP, not just as advisers but also as participating partners in the project. Accordingly, U-BIOPRED has strived to increase patient involvement in research beyond tokenism. ELF, and the strong support for patient involvement demonstrated by ERS members within the project and by IMI, has helped make U-BIOPRED a model for successful and impactful patient involvement within large-scale multi-centre and multi-stakeholder projects.

The future: The novelty of the U-BIOPRED approach and the first results from the project, have already led to new spin-off projects. After setting up its innovative multi-scale analysis, a new IMI project (eTRIKS) was developed by the collaborators within WP8, which is establishing and standardising the required Knowledge Management platform.

The project has also incorporated new research questions on the relationship of disease phenotypes with the respiratory microbiome and practical research questions aimed to define a minimal set of clinically assessable biomarkers that will serve to phenotype patients in day-to-day patient care. These latter questions were provided with IMI grants.

U-BIOPRED has given rise to several research questions and new projects driven by EFPIA partners. These efforts will benefit patients in daily practice:

- The U-BIOPRED handprints will be used for stratification of patients for novel and costly biological therapies. Studies from EFPIA partners within U-BIOPRED are underway for this.
- Several requests have already been made to use the U-BIOPRED GMP (Good Manufacturing Practice) rhinovirus 16 challenge model for testing new treatments for asthma exacerbations.
- Some of the academic partners will test the temporal behaviour of biomarkers validated by U-BIOPRED, based on the hypothesis that biomarker fluctuations provide a powerful clinical signal by themselves. EU Marie Curie/ERS Respire2 have provided a grant for this.

Severe asthma represents the pioneering and validating work in the project, but U-BIOPRED purposely includes other chronic diseases such as chronic obstructive pulmonary disease (COPD), interstitial lung diseases (ILD), and other complex inflammatory conditions. Expansion of the U-BIOPRED concept into COPD, ILD and other chronic respiratory diseases will be sought through new grant public and/or private grant opportunities. Notably, co-morbidities will be an explicit part of that.

UNBIASED BIOMARKERS FOR THE PREDICTION OF RESPIRATORY DISEASE OUTCOMES (U-BIOPRED)

WEBSITE	www.ubiopred.eu
TWITTER	@ubiopred
PROJECT PI	**Coordinator and Managing Entity:** Prof Peter Sterk | p.j.sterk@amc.nl Academic Medical Centre | Amsterdam, The Netherlands **Industry lead:** Dr Veit Erpenbeck | veit.erpenbeck@novartis.com Novartis | Basel, Switzerland
DURATION	6 years (1 October, 2009 – 30 September, 2015)
FUNDING	€27m (€12.5m in EU funding and the rest in-kind by EFPIA partners)
PROJECT PARTNERS	Novartis Pharma AG University of Southampton, Southampton, UK Academic Medical Centre, University of Amsterdam, Amsterdam, The Netherlands Imperial College London, London, UK University of Catania, Catania, Italy University of Rome 'Tor Vergata', Rome, Italy Hvidore Hospital, Hvidore, Denmark Jagiellonian Univ. Medi.College, Krakow, Poland University Hospital, Inselspital, Bern, Switzerland Semmelweis University, Budapest, Hungary University of Manchester, Manchester, UK Université d'Aix-Marseille, Marseille, France Fraunhofer Institute, Hannover, Germany University Hospital, Umea, Sweden Ghent University, Ghent, Belgium Ctr. Nat. Recherche Scientifique, Villejuif, France Università Cattolica del Sacro Cuore, Rome, Italy University Hospital, Copenhagen, Denmark Karolinska Institutet, Stockholm, Sweden Nottingham University Hospital, Nottingham, UK University of Bergen, Bergen, Norway Netherlands Asthma Foundation, Leusden, NL European Lung Foundation, Sheffield, UK Asthma UK, London, UK European. Fed. of Allergy and Airways Diseases Patients' Associations, Brussels, Belgium Lega Italiano Anti Fumo, Catania, Italy International Primary Care Respiratory Group, Aberdeen, Scotland Philips Research Laboratories, Eindhoven, NL Synairgen Research Ltd, Southampton, UK Aerocrine AB, Stockholm, Sweden BioSci Consulting, Maasmechelen, Belgium Almirall AstraZeneca Boehringer Ingelheim Chiesi GlaxoSmithKline Roche UCB Janssen Biologics BV Amgen NV Merck Sharp & Dome Corp

AIRWAY DISEASE PREDICTING OUTCOMES THROUGH PATIENT-SPECIFIC COMPUTATIONAL MODELLING

AIRPROM

This project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under *grant agreement no 270194*

AIRWAY DISEASE PREDICTING OUTCOMES THROUGH PATIENT-SPECIFIC COMPUTATIONAL MODELLING (AIRPROM)

Aim: The overall aim of the AirPROM project is to develop more personalised treatments to help improve the lives of people with asthma and chronic obstructive pulmonary disease (COPD). To achieve this aim, the project is producing computer and physical models of the whole airway system for people with asthma and COPD. The models will be able to quantify disease, predict response to treatment and understand disease progression. Developing accurate models will bridge the gap in patient management by providing better monitoring of the disease and a method to match the right treatment to each patient.

Project milestones: In the 4-years to date, AirPROM has produced innovative and exciting airway models to help scientists to predict disease progression and find the best treatment for each patient. Key milestones include:

- Collaborated with the world's largest severe asthma genetics study to link genetic information to clinical aspects of the disease.
- Completed a pivotal clinical trial of an anti-eosinophilic therapy in asthma and undertook a study of a new thermoplasty therapy.
- Developed computational models that:
  - link airway shape and size with lung function tests
  - describe airway flow throughout the airway tree
  - predict the interactions between cells in the airway wall

ERS/ELF involvement in the project: Both ERS and ELF are involved in the dissemination of the project. This involves communicating key findings and developments to all stakeholders.

ELF is responsible for managing the project's public website and ensuring that information about the project is easy to understand for a wide audience. ERS

is tasked with educating respiratory health professionals with the project's educational outcomes.

Meetings and scientific sessions will take place during the ERS International Congress to bring together airway disease specialists and industry representatives to discuss the project outcomes. ERS distributes project updates to its members in different formats including videos, newsletters and posters.

The future: AirPROM-related research has led to a number of interesting clinical findings; however, the key research questions revolve around further development of the computer models generated in the project. The application of these models within clinical trials is then the next step – and one which has already been taken in one trial so far. It is certain that each model will evolve and be updated as further clinical experience is gained.

AirPROM has been working on a plan to ensure its sustainability. The plan includes the creation of a more powerful modelling tool as a marketable product that project members can take forward into their own commercialisation projects. Computational models offer a unique perspective on clinical trial data and have enormous potential to assist in the treatment of patients. The AirPROM outputs aim to utilise this opportunity.

Legacy goals for AirPROM include:

- AirPROM models will contribute towards developing further patient-specific models, which will enable predictions for treatment responses based on patient data.
- Presenting and disseminating AirPROM findings through the publication of papers, with the aim of further scientific development.
- To utilise the valuable network of organisations with different areas of expertise that form part of the AirPROM project. One or more networks will be created in order to keep the clinical, dissemination, computational and modelling partners involved in work to further develop predictive patient-specific models.

WEBSITE	www.airprom.eu
TWITTER	@airprom
PROJECT PI	Professor Chris Brightling Institute for Lung Health Leicester, UK ceb17@le.ac.uk
DURATION	5 years (1 March, 2011 – 29 February, 2016)

AIRWAY DISEASE PREDICTING OUTCOMES THROUGH PATIENT-SPECIFIC COMPUTATIONAL MODELLING (AIRPROM)

FUNDING	€11.7m
PROJECT PARTNERS	University of Leicester, United Kingdom Helmholtz Zentrum München Deutsches Forschungszentrum für Gesundheit und Umwelt (GmbH), Germany Academisch Medisch Centrum at the Universiteit van Amsterdam, Netherlands Imperial College London, United Kingdom Queen's University of Belfast, United Kingdom The Chancellor, Masters and Scholars of The University of Oxford, United Kingdom The University of Nottingham, United Kingdom The University of Sheffield, United Kingdom Institut Mines-Télécom, France The University of Warwick, United Kingdom Fundació Privada Parc Científic de Barcelona, Spain Materialise NV, Belgium ANSYS UK Ltd., United Kingdom Instytut Chemii Bioorganicznej, Polskiej Akademii Nauk, Poland FLUIDDA NV, Belgium Biomax Informatics AG, Germany European Respiratory Society, Switzerland BioSci Consulting, Belgium University of Southampton, United Kingdom Università degli Studi di Catania, Italy Semmelweis Egyetem, Hungary The University of Manchester, United Kingdom Université d'Aix-Marseille, France Umeå universitet, Sweden Karolinska Institutet, Sweden Objet Geometries Gmbh, Germany Università degli Studi di Ferrara, Italy European Federation of Asthma & Allergy Associations IDEELL FORENING, Belgium Instytutu Gruźlicy i Chorób Płuc, Poland Västra Götalands läns landsting, Sweden Országos Korányi Tbc és Pulmonológiai Intézet, Hungary Commissariat à l'énergie atomique et aux énergies alternatives, France University Hospitals Coventry and Warwickshire NHS Trust, United Kingdom European Lung Foundation, United Kingdom

EUROPEAN ASTHMA RESEARCH AND INNOVATION PARTNERSHIP

EARIP

This project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under *grant agreement no 602077*

EUROPEAN ASTHMA RESEARCH AND INNOVATION PARTNERSHIP (EARIP)

Aim: The EARIP project is identifying gaps in asthma knowledge with the aim of reducing asthma deaths in Europe by 25% within ten years and by 50% within 20 years. The partnership, made up of 12 European-based organisations, also aims to halve hospital admission rates, speed up the discovery of new treatments and improve self-management.

The EARIP project will do this by identifying key gaps in asthma knowledge; it will then address these using a pioneering approach to research, development and innovation across Europe. Through rapid dissemination of project results, EARIP will ensure that outcomes from knowledge-based asthma research will quickly result in an improved quality of life for people with asthma.

EARIP is a coordinated and integrated approach to asthma research, development and innovation across Europe. The project activities range from basic cell science research to assessing and improving European healthcare systems. Supported by the European Commission, and run over a three-year period, EARIP brings together asthma experts from across Europe to define what is needed to reduce asthma deaths and hospitalisations in all EU member states.

Project milestones: The project has just passed its mid-way point with some key milestones already achieved and more to follow:

- A systematic review of the literature on new diagnostic and patient management tools has been completed and is due for publication. This will be followed by two reports identifying research priorities for diagnostic and patient management tools and systems.
- A 'State of Play' document looking at asthma research in Europe has been completed.

- A report of effective mechanisms to identify biological targets and define the role of existing targets will be produced and published.
- A systematic review on biomarkers for the stratification of asthma will be produced and published.
- A literature review is due to be published on effective European models of system change including recommendations for effective models for system change.

ERS/ELF involvement in the project: ELF is leading the work to produce an Asthma Roadmap entitled 'Development of a Research Agenda.' The Roadmap will identify research gaps, and then prioritise research needs, in line with Horizon 2020's Health sub-programmes and jointly coordinated activities supported by national research programmes.

ELF are developing this in dialogue with industrial partners, academics, patient groups, technology companies and health system representatives to agree strategic actions required for better asthma research. This work will involve:

- Developing a European 'state of play' document in relation to asthma research
- Identifying key stakeholders to contribute to an online survey looking at asthma research
- Selecting key stakeholders to take part in a pan-European prioritisation workshop
- Establishing consensus on outstanding asthma research priorities at this workshop.

Looking to the future: Through the coordination of asthma research at a pan-European level, EARIP is bringing together world-leading asthma researchers to achieve a common goal. The project will define and prioritise exactly what research is needed and provide specific calls to action regarding areas for funding. It is estimated that 30 million people in Europe are currently living with asthma, and around 15,000 people die each year from asthma attacks in the region. Between now and 2020, if no major breakthroughs in research and the management of asthma are made, about 120,000 people in Europe will die as a result of asthma attacks, and 4 million will be hospitalised. Having defined and prioritised exactly what research is needed, we are then in a much stronger position to lobby for the money necessary to deliver the changes that will reduce asthma deaths and hospitalisations and our challenge is to secure this funding.

EUROPEAN ASTHMA RESEARCH AND INNOVATION PARTNERSHIP (EARIP)

WEBSITE	www.earip.eu
PROJECT PI	Dr Samantha Walker Asthma UK, London, UK earip@asthma.org.uk
DURATION	3 years (September, 2013 – August, 2016)
FUNDING	€0.5 m
PROJECT PARTNERS	Asthma UK, UK Imperial College London, UK Karolinska Institutet, Sweden European Federation of Allergy & Airways Diseases Patients' Associations (EFA), Belgium European Lung Foundation, UK National and Kapodistrian University of Athens, Greece University of Southampton, UK Swiss Institute of Allergy and Asthma Research, Switzerland University of Lodz, Poland Novartis, Switzerland GlaxoSmithKline, UK Arrixaca Biohealth Research Institute of Murcia (IMIB), Spain

PLATFORM FOR EUROPEAN PREPAREDNESS AGAINST RE-(EMERGING) EPIDEMICS

PREPARE

This project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under *grant agreement no 602525*

PLATFORM FOR EUROPEAN PREPAREDNESS AGAINST RE-(EMERGING) EPIDEMICS (PREPARE)

Aim: Using lessons learned from the H1N1 pandemic, the PREPARE project aims to establish a clinical research framework, which is prepared to rapidly respond to any severe infectious disease outbreak. The framework will enable harmonised large-scale clinical research studies on infectious diseases, providing real-time evidence for the clinical management of patients and for informing future public health responses.

PREPARE will transform Europe's research response to future severe epidemics or pandemics by:

- implementing 'inter-epidemic' research programmes
- conducting patient-orientated studies into the pathogenesis of infectious diseases
- developing novel near-patient diagnostics
- developing and testing of pre-emptive solutions to ethical, administrative, regulatory, logistical and clinical bottlenecks
- investing in education and training of the members of the clinical network and external opinion leaders, funders and policy makers

Project milestones: Although PREPARE only officially started in February 2014, the following has already been achieved:

- A report on barriers to research in Europe and solutions
- A systematic review of European clinical guidelines for syndromes with epidemic potential is in progress
- The ALIC4E trial of antivirals in influenza has received ethical approval and is due to start in October, 2015
- Protocols for trials on the epidemiology and clinical management of arbovirus infection, undifferentiated fever in children and pathogenesis of acute respiratory infection are in development
- An adaptive trial of 3 interventions: antibiotics, steroid and ventilator strategy in severe respiratory infection, using the intensive care networks of European Society of Intensive Care Medicine (ESICM), Network of excellence Community Acquired Pneumonia (CAPNETZ) and Combatting Bacterial Resistance in Europe (COMBACTE) is in development
- A laboratory-based questionnaire has been created for development of standard operating procedures for collection, storage and processing of specimens, including a survey of preparedness for managing Ebola specimens published in the *Journal of Clinical Virology*. A PREPARE outbreak mode strategy has been developed and applied for Middle East respiratory syndrome-coronavirus (MERS-CoV).

ERS involvement in the project: ERS works as part of the Clinical Research Education And Training in Europe (CREATE) platform, coordinated by Professor Anita Simonds. The role of CREATE is to develop an online, open-access education and training curriculum for the hospital and primary care practitioners, nurses, microbiologists and public health colleagues included in the PREPARE clinical studies. It will also include training modules for a wide range of specialists including cross-disciplinary modules.

In conjunction with ERS, the PREPARE Virtual Learning Centre (VLC) has been constructed to disseminate knowledge and educational resources and are now collaborating with partner societies European Society of Clinical Microbiology and Infectious Diseases (ESCMID), European Society of Intensive Care Medicine (ESICM), European Scientific Working group on Influenza (ESWI) and World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians (WONCA)) to build content for the VLC. Activities are also planned (postgraduate courses, workshops and videos) for the coming years which will feed directly into curriculum development.

The future: The trials are likely to lead to successful intervention strategies for future epidemics and the clinical and laboratory networks developed should facilitate early trials and implementation of results. The educational section of the project will cascade educational and training resources to staff and researchers at all levels.

PLATFORM FOR EUROPEAN PREPAREDNESS AGAINST RE-(EMERGING) EPIDEMICS (PREPARE)

WEBSITE	www.prepare-europe.eu
PROJECT PI	Professor Herman Goossens The Laboratory of Medical Microbiology University of Antwerpen, Belgium herman.goossens@uza.be
DURATION	5 years (February, 2014 – February, 2019)
FUNDING	€24m
PROJECT PARTNERS	AMC, Academic Medical Centre, University of Amsterdam Berry consultants Biocartis Biomax Informatics AG BioMérieux SA CAPNETZ Stiftung, Network of excellence Community Acquired Pneumonia EMC, Erasmus Medical Centre ERS, European Respiratory Society ESCMID, European Society of Clinical Microbiology and Infectious Diseases ESICM, European Society of Intensive Care Medicine ESWI, European Scientific Working Group on Influenza HLA and Medecine Imperial College London Institut Pasteur Janssen Diagnostics NIUD-UCD PENTA, Paediatric European Network for Treatment of AIDS foundation for the treatment and care of children with HIV RBHT, Royal Brompton & Harefield SERGAS, Servicio Galego de Saude UA, University of Antwerp UK-Bonn, Universieatsklinikum Bonn UMCU, University Medical Centre Utrecht UoC, University of Cardiff UoS, University of Split UOXF, University of Oxford UWA, University of Western Australia WONCA EUROPE, World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians

PAN-EUROPEAN NETWORK FOR THE STUDY AND CLINICAL MANAGEMENT OF DRUG RESISTANT TUBERCULOSIS

TB PAN-NET

This project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under *grant agreement no 223681*

Aim: Drug-resistant tuberculosis (TB) strains are jeopardising TB control worldwide. Although there are reductions in both the incidence of TB cases and mortality, the spread of multidrug-resistant tuberculosis (MDR-TB) is threatening this progress and delaying the ultimate goal of TB elimination.

While progress is being made towards global TB control targets, with reductions in both the incidence of new TB cases and in mortality rates, the spread of MDR-TB is threatening current progress, especially in some countries. 15 of the 22 countries considered in the "MDR-TB high burden" group belong to the World Health Organization (WHO) European region with alarming prevalence of 14% for new TB cases identified and a staggering 47.7% among previously treated cases.

The EU-funded TB PAN-NET brought together a unique research collaboration of scientists from 29 institutions in 18 countries to address the multiple challenges of MDR-TB in Europe.

Project milestones: TB PAN-NET was comprised of a large collaborative network that had access to the latest technology which enabled successful research on several translational topics. This included analysis of the mechanisms leading to drug resistance, improving the diagnosis for MDR-TB, offering training to countries to perform clinical and diagnostic trials and examining the clinical and social risk factors such as immune-depression, immigration and poverty.

TB PAN-NET worked on the development of novel tools for early diagnosis of TB and MDR-TB. By implementing the capacity to perform next generation and whole genome sequencing of MDR-TB, the consortium identified a comprehensive list of mutations predictive of drug resistance that has been made available to diagnostic test developers. The data supported the use of sequencing as a "gold standard" for identification of resistance to rifampicin and other TB drugs such as pyrazinamide. On the biomarkers side, researchers discovered that serum miRNAs could serve as promising biomarkers for the diagnosis of different TB stages, as well as for monitoring disease progression. In addition, new quantitative molecular assays were developed for monitoring early-treatment response and the preliminary evaluation of personalised regimens.

To evaluate multi-drug resistance and bacterial fitness, scientists studied the transcriptional regulatory network of M. tuberculosis strains and classified, for the first time, mutations that cause resistance to specific drugs.

Considerable effort went into training and capacity building in tuberculosis-endemic countries to perform clinical and diagnostic trials. Equally important

was the training of European clinicians on the international standards and requirements of clinical management and control of resistant tuberculosis. WHO is now collaborating with ERS on a TB elimination project in Latin America, in collaboration with the Asociación Latinoamerican del Thorax (ALAT).

The consortium also combined basic science with clinical and epidemiological studies to understand the emergence and transmission patterns of drug-resistant tuberculosis. A large web-based database has been set up and made available on the project website to help health policymakers in disease management, transmission control and treatment.

ERS/ELF involvement in the project: Training and dissemination were key components of the project and ERS was the main scientific dissemination and educational partner in TB PAN-NET.

ERS developed and maintained the TB PAN-NET project website, produced quarterly project newsletters and maintained the project members' collaboration platform.

Attracting hundreds of participants, MDR-TB management training was organised by ERS and delivered to clinicians and stakeholders at the ERS International Congresses. The educational programmes were designed to reach out to a large number of individuals.

Training events were also used for participants to network and share cases. The training enabled clinicians/health professionals in the different countries to identify gaps and exchange experiences on the day-to-day challenges they face.

ELF supported the project by developing a factsheet on tuberculosis targeting the wider public.

The future: TB PAN-NET clearly represents a successful example of a pan-European research network in terms of goals achieved and objectives met. Although TB PAN-NET formally ended in June 2014, it still is continuing its mission to promote multidisciplinary approaches to tackling TB by bringing together basic science with clinical and epidemiological studies.

TB elimination in Europe cannot be achieved without much intensified research. There are several key findings from TB PAN-NET that require further research:

- Culture-free exhaustive drug susceptibility testing (DST)
- MDR strain transmission
- The role of small ribonucleic acids (RNA) in pathobiology
- The role of microRNAs as potential biomarkers for TB diagnostics

PAN-EUROPEAN NETWORK FOR THE STUDY AND CLINICAL MANAGEMENT OF DRUG RESISTANT TUBERCULOSIS (TB PAN-NET)

WEBSITE	www.tbpannet.org
PROJECT PI	Dr Daniela M Cirillo, Head of Unit, Emerging Bacterial Pathogens Unit, Università Vita-Salute San Raffaele Milan, Italy cirillo.daniela@hsr.it
DURATION	5 years (January, 2009 – June, 2014)
FUNDING	€10.9m
PROJECT PARTNERS	Università Vita-Salute San Raffaele (USR), Italy HPA-MRU, Queen Mary and Westfield College, University of London, , United Kingdom Forschungszentrum Borstel (FZB), Leibniz-Zentrum für Medizin und Biowissenschaften, Germany Fondazione Salvatore Maugeri (FSM), Italy Azienda Ospedaliera San Gerardo di Monzam, Italy European Respiratory Society (ERS), Switzerland Foundation for Innovative New Diagnostics (FIND), Switzerland Swedish Institute for Infectious Diseases Control (SMI), Sweden Statens Serum Institut (SSI), Denmark Croatian National Institute of Public Health (CNIPH), Croatia Università degli Studi di Sienam (UNISI), Italy Hain Lifescience GmbH, Germany Infectology Center of Latvia (LIC), Latvia Montessori Guido Company, Italy Tartu University Hospital (TUH), Estonia National Tuberculosis and Infectious Diseases University Hospital (NRL), Lithuania, Lithuania Vilnius University Institute of Biotechnology (VU-IBT), Lithuania Norwegian Institute of Public Health (NIPH), Norway National Reference Laboratory for Mycobacteria, University Clinic of Respiratory and Allergic Diseases Golnik, , Slovenia Institute of Tropical Medicine (ITM), Belgium Pneumophtisiology Hospital Brasov, SPF Brasov, Romania Pneumophtisiology Institute Nasta (I-M.NASTA), Romania Institut Pasteur de Lille (IPL), France National Institute for Health and Welfare (THL), Finland Scientific Institute of Public Health (IPH), Institut Pasteur, Belgium National Tuberculosis and Lung Disease Research Institute, NRL, Poland University of Medicine and Dentistry of New Jersey (UMDNJ) USA Riga Eastern Clinical University Hospital (REUH), Latvia Fondazione Centro San Raffaele (FCSR), Italy

RESPIRE2

RESPIRATORY SCIENCE PROMOTED BY INTERNATIONAL RESEARCH EXCHANGES 2

RESPIRE 2

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RESPIRE2

RESPIRATORY SCIENCE PROMOTED BY INTERNATIONAL RESEARCH EXCHANGES 2 (RESPIRE 2)

Aim: RESPIRE 2 is an ERS and European Union (EU) co-funded post-doc fellowship programme. RESPIRE 2 enables promising researchers from any field to carry out advanced research projects (24 months) of scientific excellence in the area of respiratory medicine and science.

The RESPIRE 2 programme will select 12 post-doc researchers for a 2-year-fellowship duration. Successful fellows will benefit from the RESPIRE 2 grant (€64,600 per fellow per year) as well as enjoy excellent working conditions at pre-selected RESPIRE 2 Host Centres. The programme targets experienced researchers from any discipline (with a PhD or at least 4-year full-time research experience), even those not traditionally associated with respiratory research. Applicants are required to have at least 1 first author publication in an international peer-reviewed journal at the time of application.

The fellowships are open to candidates of all nationalities from anywhere in the world but the research needs to be undertaken within an ERS pre-selected RESPIRE 2 Host Centre based in Europe, see www.erscongress2013.org/respire.

RESPIRE 2 builds upon the previous success of its forerunner, RESPIRE 1, which specifically started expanding on the capacity of basic scientists in the respiratory research arena. The main improvement and innovations introduced in RESPIRE 2 are:

- Increasing the length of the fellowships from 1 year to 2 years to provide adequate time for studies to yield publications
- Emphasising career development by pre-selecting eligible host institutions that comply with a number of criteria to guarantee significantly improved working conditions for fellows including career development training, mentoring, and social security (pension medical insurance, etc).
- Specifically improving employment conditions including increased living allowance, funds for travel, relocation, and career development

Project milestones:

RESPIRE 2 is succeeding in creating and maintaining scientific networks, retaining promising researchers in Europe. There is a crucial need to expand the resources available for research and treatment of lung disease. By awarding the RESPIRE 2 fellowship to 12 researchers over a five-year period, ERS is preparing the future leaders in the respiratory field.

The scale of the RESPIRE 2 programme will serve to boost the fellows' career and their further integration in research in many ways including through an increased living allowance, but also funds for travel, relocation and career development.

The following are the main milestones that will be achieved through the programme:

- RESPIRE 2 fellows have the opportunity to tailor their educational/training programme using courses offered by both ERS and the host institutions
- Host institutes are required to support the fellow's research costs and will need to submit a plan to demonstrate this
- ERS mentoring scheme offers the fellows an external/independent source of support and advice during the fellowship, complementing the support received from the host institution.
- Participation at the dedicated "ERS Fellow's Get-Together" session at the ERS International Congress further enhances their contact network and gives fellows the opportunity to exchange experiences
- Host institutions typically have longstanding interactions with international key opinion leaders in their field and a strong industrial network
- Host supervisors encourage fellows to attend congresses and join in such collaborative networks
- Host supervisors, with the assistance of on-site HR department, coach the fellows

During and at the end of the programme, ERS will be able to measure the impact of the fellowships by assessing the number of publications from each fellow in renowned journals.

ERS/ELF involvement in the project: RESPIRE 2 is the flagship fellowship programme offered by ERS and it represents a strategic commitment of the Society to expand significantly its investment in experienced researchers coming from any scientific field. It is the mission of ERS to promote the best science in respiratory medicine and the RESPIRE 2 fellowship is a strong example of how the Society is leading the field in supporting strong scientific networks and retaining expertise in respiratory medicine in Europe.

As the single beneficiary of the grant, ERS is responsible for the entire management and implementation of the programme, including widely publicising calls and supervising and coordinating all steps of the fellowship programme from the start to the fellowship termination (e.g. periodic payments, career development support through ERS mentoring scheme, review of interim and final reports).

ERS coordinates the upfront screening of host institutions that need to meet a number of selection criteria to become an ERS-eligible RESPIRE2 host centre committed to improving the career of their fellows, providing them with best possible research conditions and career development support.

RESPIRE2

RESPIRATORY SCIENCE PROMOTED BY INTERNATIONAL RESEARCH EXCHANGES 2 (RESPIRE 2)

The evaluation committee of ERS selects the fellows based on scientific merits and transparent criteria. ERS ensures that all applications undergo an impartial and rigorous peer-review and selection procedure by recognised international experts, free from conflicts of interest.

The future: There are several ways the RESPIRE 2 fellowships will have lasting impact in the future. By selecting host institutions based on excellent working conditions, the programme will identify a gold standard for host institutions, thereby laying the groundwork for future expansion of fellowship projects. This will ensure that finding suitable host institutions will no longer be a barrier to expansion of fellowship projects.

Additionally, the programme is also non-specific in its design and the same process can be used as a template to support a broad array of future fellowships in different scientific areas.

Finally, by monitoring the fellow's career beyond the duration of the fellowship programme, ERS will use key indicators of success to continually develop and enhance their post-doctoral fellowship programmes so that they will have maximum benefit to the fellow, host and home institutions.

As part of ERS's strategic plan to promote scientific research, the Society is planning to apply to the H2020 Marie Skłodowska-Curie Actions - Co-funding of Regional, National and International Programmes (COFUND) to obtain funding for a new "RESPIRE3" fellowship programme. This represents an important opportunity to expand on existing achievements.

WEBSITE	ww.ersnet.org/ers-funding/fellowships.html
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DURATION	5 years (1 July, 2013 – 1 July, 2018)
FUNDING	Total funding : €1.83m ERS contribution 60%: €1.1m EU contribution 40%: €730 000

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