Unbiased BIOmarkers in PREDiction of respiratory disease outcomes

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Research Areas

Biomarker Research
Diagnostic, Genomic Biomarker

Basic Research

At a Glance

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

Abstract

The Unbiased BIOmarkers in PREDiction of respiratory disease outcomes (U-BIOPRED) consortium seeks to create and validate innovative testing methods to classify distinct types of severe asthma. Using a systems biology approach, the consortium develops ‘handprints’ of asthma types using clinical data and omics (i.e. genomics, proteomics). The project hopes to identify different sub-types (known as phenotypes) of severe asthma by using samples and medical information from hundreds of patients with severe asthma and comparing them to samples from healthy volunteers and patients with mild asthma. U-BIOPRED convenes scientists from universities, research institutes, the pharmaceutical industry, and small companies. Patients and patient organizations are involved to ensure their perspectives are incorporated. For example, these groups advise on how to recruit people with asthma, on how many visits are appropriate for a patient to make to a testing center, and on how to communicate the project to the public. U-BIOPRED is funded by the Innovative Medicines Initiative (IMI), which was set up in 2008 by the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA). The IMI funds large-scale collaborative research and is also one of the first initiatives to bring together this many pharmaceutical companies together to work as partners and not competitors.

Mission

In April 2014, U-BIOPRED recruited 1,025 study participants. Each participant underwent extensive testing and donated blood, sputum, and samples of their breath. Some participants had airway biopsies, CT scans, and intensive monitoring. These different types of data are being combined into a “handprint” of severe asthma. U-BIOPRED aims to sub-type patients with severe refractory asthma by using an innovative systems biology approach. The U-BIOPRED consortium specifically aims to:

- understand more about severe asthma
- determine how it differs from person to person, and
- uncover new information and ideas that could lead to the creation of effective new treatments.

Since the participants were recruited, over 20 papers have been published on the analysis of the data. This number will continue to rise as the data analysis continues. U-BIOPRED aims to be highly productive in delivering value and high quality science to push severe asthma research forward.

Consortium History

- 2009 – Project start date
- 2011 – U-BIOPRED recruits first adult into major asthma study (May)
- 2011 – U-BIOPRED announces the asthma art contest winner, Marije Kootstra (July)
- 2011 – U-BIOPRED project presents findings to press and patients (September)
- 2013 – U-BIOPRED hits patient recruitment target (April)
- 2013 – U-BIOPRED uses electronic nose to find differences among severe asthma patients, which was a first step towards the project’s goal of identifying distinct subtypes of severe asthma based on the extensive biological characterization of patients (October)
- 2014 – U-BIOPRED wins best practice award at BIO-IT World (May)
- 2015 – U-BIOPRED releases its first classifications of severe asthma at the ERS Congress in Amsterdam
- 2015 – The Lancet praises U-BIOPRED’s efforts in an editorial
- 2015 – U-BIOPRED successfully completes its funded period and enters a new phase supported by the ERS and the continued input of consortium partners
- 2015 – First major papers published describing the adult and pediatric cohorts
- 2016 – Inflammation, gene expression, and first clustering papers published

- 2017 – Major year for publications with over 10 papers published in leading journals – U-BIOPRED hits patient recruitment target (April)

Structure & Governance

The U-BIOPRED consortium has representatives from all stakeholder groups, including from 20 academic institutions, 10 biopharma industry partners (EFPIA), 6 patient organizations, 3 small to medium enterprises, and 1 multinational industry. U-BIOPRED has representatives from 12 European countries.

The project is coordinated by the Academic Medical Centre at the University of Amsterdam. Professor Peter Sterk is the project leader.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) coordinator is Novartis Pharma AG.

Patients have been involved in all stages of the project: as members of the Ethics Board (EB), the Safety Monitoring Board (SMB), and the Patient Involvement Platform (PIP), and as participants.

There are three advisory boards that oversee the project and tackle any issues. The boards ensure that the project meets the needs of patients while remaining ethical and safe. Topics that require input from the boards can be submitted from any of the work packages in the project.

The boards are:
Ethics Board
Safety Monitoring Board
Patient Input Platform

The boards are comprised of volunteers from different countries with a range of expertise. This ensures European-wide input to account for different perspectives and expectations from different countries. All members of the board participate as individuals and do not represent organizations. As patient involvement is key to the U-BIOPRED project, patient representatives are included on all boards.

The Ethics Board (EB) is an academic and patient-driven advisory group for evaluation and guidance on all ethical and scientific conduct issues. The EB acts in a collaborative way in accordance with the Declaration of Helsinki on human rights. It aims to provide ethical guidance and balanced opinion on the research carried out in U-BIOPRED.

Members:
Biomedical research (Jan-Bas Prins, The Netherlands)
Clinical care (Representative from Germany)
Legal affairs (Elisabetta Lanza, Italy)
Paediatric care (Hazel Evans, United Kingdom)
Patient representation (Martine Puhl, Co-chair, The Netherlands)
Patient representation (Lina Buzermaniene, Lithuania)
Patient representation (Val Hudson, United Kingdom)
Patient representation (Laura Bond, United Kingdom),
Patient representation and pathobiology (Pim de Boer, Chair, The Netherlands)
Research ethics (Guy Widdershoven, The Netherlands)
Research methodology and biostatistics (Representative from Germany)

Tasks:

- Developing criteria to review documents and progress from scientific, ethical, and patients' perspectives.
- Monitoring ethical and scientific conduct of studies and the project as a whole (for example to suggest solutions for delayed recruitment).
- Reviewing documents (such as study protocols, patient information, and informed consent).
- Reviewing potential conflicts of interest for U-BIOPRED partners and determining appropriate solutions.
- Providing advice on any ethical issue arising in the project.
- Providing a final report on all ethical issues arising from the project and its results.

Throughout U-BIOPRED, the Safety Monitoring Board (SMB) monitors patient safety, makes decisions on safety issues, coordinates crisis management, and evaluates the efficacy of interventions. The SMB also works collaboratively to provide safety guidance and balanced opinion. Members of the SMB include health and research professionals, patients, and patient representatives.

Members:

Clinical care (William MacNee, United Kingdom)
Clinical pharmacology (Representative from Italy)
Paediatric care and infectious diseases (Louis Bont, The Netherlands)
Patient representation (Per-Ake Wecksell, Sweden)
Patient representation and pathobiology (Pim de Boer, Chair, The Netherlands)
Patient safety advice and clinical care (Co-chair, Representative from Germany)
Research methodology and biostatistics (Representative from Germany)

Tasks:

- Developing criteria to review documents and progress from scientific, safety, and patients' perspectives.
- Monitoring the safe conduct of the studies and the project as a whole (for example, evaluating any adverse events arising during the clinical studies).
- Reviewing documents (such as study protocols, patient information, and informed consent).
- Providing advice or decisions on any patient safety issues arising in the project.
- Providing a report on all safety issues arising from the project.

The Patient Input Platform (PIP) is comprised of patients and patient representatives. These members are elected via an open job application submitted to one of the patient organizations involved in U-BIOPRED. PIP members do not represent the patient organization that nominated them.

Members include:
Amanda Roberts, UK
David Supple (Chair), UK
Dominique Hamerlijnck, The Netherlands
Jenny Negus, UK
Juli?tte Kamphuis, The Netherlands
Lehanne Sergison, UK
Luigi Visintin, Italy
Pim de Boer (Co-chair), The Netherlands
Susanne Onstein, The Netherlands

Tasks:

- Developing criteria to review documents and progress from the patients' perspectives.

- Monitoring conduct in the studies and the project as a whole from the perspective of participating patients.
- Reviewing documents (study protocols, patient information, and informed consent).
- Providing advice on any issue or question arising from the project from the patient perspective.
- Helping communicate and disseminate results of the U-BIOPRED study in plain language via various means, so that the project can be understood by the public across European countries.

Financing

This project is funded by the Innovative Medicines Initiative (IMI), a public-private partnership between the European Union (EU) and the European Federation of Pharmaceutical Industries and Associations (EFPIA), the resources of which are 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 initial project period of 5 years was extended to 6 years and heightened interest in the project led to an investment increase during the project period.

Contributions	€
IMI Funding	9 935 501
EFPIA in kind	14 574 652
Other	2 414 714
Total	26 924 867

Intellectual Property

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 that can be reached through email at IMI-IP-Helpdesk@imi.europa.eu. The IMI IP policy can be accessed here: http://www.imi.europa.eu/sites/default/files/uploads/documents/imi-ipr-policy01august2007_en.pdf

Patent Engagement

Patients have been involved at all stages of the project: as members of the Ethics and Safety Monitoring Boards, in the Patient Involvement Platform (PIP), and as participants. U-BIOPRED has also included patient representatives on the Scientific Board and in the clinical work package management team.

Data Sharing

According to IMI's intellectual property policy, participants disseminate data as soon as practicable, but not later than one (1) year after the termination or expiry of the project. The Project Agreement includes a description of the material that must be disseminated in accordance with the IP Policy and is referenced in the Grant Agreement. If participants do not disseminate within the specified time periods without good reason, the Executive Office has the right to disseminate such results in accordance with the Grant Agreement. U-BIOPRED has completed its funding period, but the work continues apace. A number of collaborations and validation initiatives with external partners have already been approved and resulted in the sharing of data. Data sharing is managed via an application procedure with approval granted by the U-BIOPRED Scientific Board.

Impact/Accomplishment

The researchers will generate a "handprint" – a combination of biological characteristics (biomarkers) – which indicates what type of asthma a patient is suffering from. The scientists will test if a patients' asthma handprint can predict how the disease progresses in that patient. Moreover, they will divide patients into sub-groups according to their handprints, and examine if patients in the same sub-groups react in similar ways to treatments. Such findings would accelerate the development of treatments and help predict the efficacy of candidate drugs. A better understanding of differences in drug-response will enable more targeted treatment for patients with severe asthma.

Links/Social Media Feed

Homepage	http://www.europeanlung.org/en/projects-and-research/projects/u-biopred/home
Other website	http://www.imi.europa.eu/projects-results/project-factsheets/u-biopred
Twitter	https://twitter.com/UBIOPRED
LinkedIn	https://www.linkedin.com/groups/UBIOPRED-4710653?home=&gid=4710653&trk=anet_ug_hm

Points of Contact

For collaboration queries:
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Sponsors & Partners

Novartis Pharma AG, Basel, Switzerland
Laboratorios Almirall S.A., Barcelona, Spain
AstraZeneca AB, Södertälje, Sweden
Boehringer Ingelheim International GmbH, Ingelheim, Germany

Chiesi Farmaceutici S.p.A, Parma, Italy
GlaxoSmithKline Research and Development LTD, Brentford, UK
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UCB Pharma SA, Brussels, Belgium
Janssen Biologics, a J&J company
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Academisch Medisch Centrum bij de Universiteit van Amsterdam, Amsterdam, Netherlands
The University of Southampton, Southampton, UK
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Universiteit Gent, Gent, Belgium
Centre National de la Recherche Scientifique, Paris, France
Universita’ Cattolica Del Sacro Cuore, Milan, Italy
Københavns Universitet (University of Copenhagen), Copenhagen, Denmark

Karolinska Institutet, Stockholm, Sweden
University of Nottingham, Nottingham, UK
Universitetet i Bergen, Bergen, Norway
Astma Fonds Longstichting, Leusden, the Netherlands
European Lung Foundation, Lausanne, Switzerland
Asthma UK, London, UK (patient organization)
European Federation of Asthma and Allergy Associations, Brussels, Belgium
Lega Italiana Anti Fumo – ONLUS, Catania, Italy
International Primary Care Respiratory Group, Aberdeen, UK
Synairgen Research Limited, Southampton, UK
Aerocrine AB, Solna, Sweden
BioSci Consulting, Maasmechelen, Belgium
Philips Electronics Nederland B.V., Eindhoven, the Netherlands

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