



Innovative Medicines Initiative

UBIOPRED – taking on severe asthma

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U-BIOPRED



Unbiased Biomarkers for the Prediction of Respiratory Disease Outcomes

The project addresses the current inability of pre-clinical studies to predict clinical efficacy, which is a major bottleneck in drug development for severe asthma.

Examples:

Chromones (chromolyn sodium, nedocromil) – introduced in early 1970s for allergic asthma, now alternate initial controller drug

Mild efficacy, reduces risk of hospitalization by 20% in children while steroids reduce by 50%

perhaps 1 in 10 asthmatics is responder

Antileukotrienes (montelukast, pranlukast) – introduced in late 1980s for moderate-to-severe asthma, moderate efficacy. Risk for exacerbation is 60%

greater if used alone than with steroids

perhaps 1 in 4 asthmatics is responder



How this will be achieved



- Clinical data from a large cohort
- Omics technology (genomics, transcriptomics, proteomics, lipidomics)
- Animal and laboratory models
- Human challenge models
- Systems biology



Participants & funding



The consortium encompasses the representatives of all stakeholder groups by involving partners from academia (20), biopharma industry (EFPIA) (9), patients/care organisations (6), SMEs (3) and Multinational industry (1)

- **Duration:** 60 months, started 1 Oct 2009
- **Total costs:** 22 846 864 €
- **IMI contribution:** 8 977 151 €
- **EFPIA contribution:** 11 007 989 €



Coordinator: Academic Medical Centre,
University of Amsterdam, Amsterdam, The
Netherlands

EFPIA coordinator: Novartis Pharma AG



University of Southampton, Imperial College London, University of Manchester,
Nottingham University Hospital (UK)

University of Catania, University of Rome Tor Vergata, Università Cattolica del Sacro
Cuore (I)

Ctr. Nat. Recherche Scientifique , Université de la Méditerranée (F)

University Hospital, Umea, Karolinska Institutet, Haukeland University Hospital (S)

University Hospital, Copenhagen, Hvidovre Hospital (DK)

Jagiellonian Univ. Medi.College (PL), University Hospital, Inselspital (CH)

Semmelweis University (HU), Fraunhofer Institute (D), Ghent University (B)

Netherlands Asthma Foundation, European Lung Foundation , Asthma UK, European.
Fed. Of Allergy and Airways Diseases Patients' Associations, Lega Italiano Anti Fumo,
International

Primary Care Respiratory Group, Philips Research Laboratories, Synairgen Research
Ltd, Aerocrine AB, BioSci Consulting, Almirall, AstraZeneca, Boehringer Ingelheim,
Chiesi, GlaxoSmithKline, Pfizer, Roche, UCB



Our aim

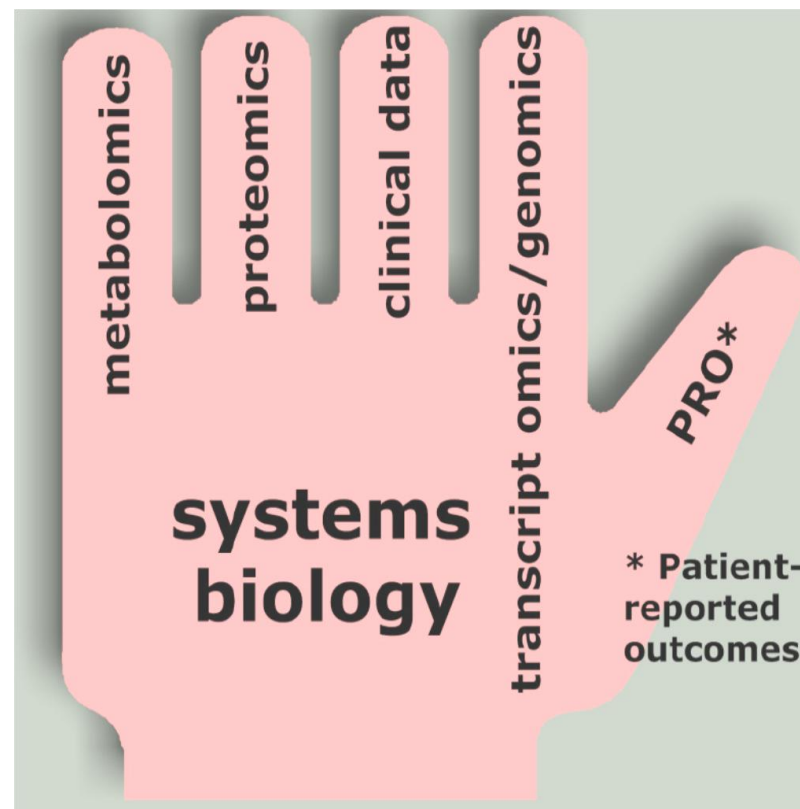


Lipidomics of induced sputum – samples of lower airways excretions

material: induced sputum collected from well defined asthmatic patients and controls (n=1000)

methods: high performance liquid chromatography – tandem mass spectrometry

measured analytes: 10 key lipid mediators and their metabolites reflecting cyclooxygenases and lipoxygenases inflammatory pathways



Our experience in the field



Sachs-Olsen C, Sanak M, Lang AM, Gielicz A, Mowinckel P, Lodrup Carlsen KC, Carlsen K-H, Szczeklik A. Eoxins: a new inflammatory pathway in childhood asthma. *J Allergy Clin Immunol* 2010; 126: 859-867.

Sanak M, Gielicz A, Nagraba K, Kaszuba M, Kumik J, Szczeklik J. Targeted eicosanoids lipidomics of exhaled breath condensate in healthy subjects. *Journal of Chromatography B*. 2010; 878: 1796-1800.

Sanak M, Gielicz A, Bochenek G, Kaszuba M, Nizankowska-Mogilnicka E, Szczeklik A. Targeted eicosanoid lipidomics of exhaled breath condensate provide a distinct pattern in the aspirin-intolerant asthma phenotype. *J Allergy Clin Immunol* 2011; 127: 1141-1147.

