



Innovative Medicines Initiative

# **U-BIOPRED study: Open innovation and severe asthma**

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# Innovation vs. invention distinction



- Invention refers more directly to the creation of the idea or method itself
- Innovation [from Latin *innovare*: 'to renew or change']: the use of a better and novel idea or method

Successful innovation is usually coupled with marketing

## Example:

### Edison's bulb

- > compact fluorescent (CFL) bulb
- > light-emitting diode (LED) bulb



# Innovation in companies and academic institutions

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**Universities** specialise in **research** which may lead to **inventions** and discovery of new research methods, but they are not interested in production

Due to shareholders' expectations, **companies** are mostly interested in **innovative products/methods of commercial value** that might be marketed

Bottleneck: research <-> marketing





## 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.



# Aims

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- Identify better tools and markers to develop new therapies and diagnostics for severe asthma
- Introduce tools for predicting the effectiveness of future treatments
- Assist in producing new drugs
- Develop a personalised approach to therapy
- Include patients as partners in research



# How this will be achieved

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



# Participants & funding

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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 €



# Partners



IMI - Putting Policy into Practice  
11th October, 2012, Larnaca, Cyprus





# Partners



*IMI - Putting Policy into Practice  
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# Our aim



## Lipidomics of induced sputum – samples of lower airways excretions

material: induced sputum collected from well defined asthmatic patients and controls (n=725)

methods: high performance liquid chromatography – tandem mass spectrometry

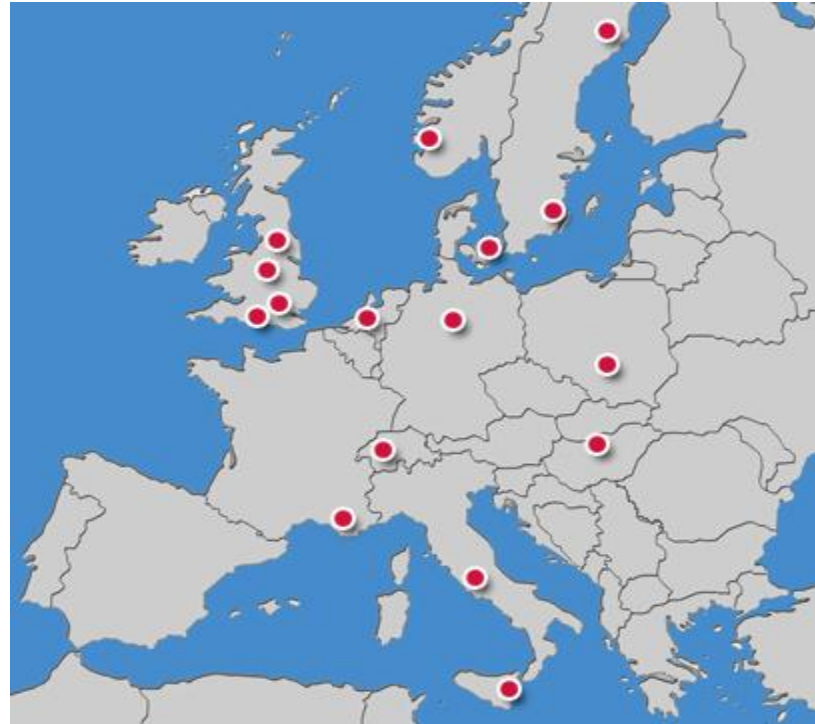
measured analytes: 10 key lipid mediators and their metabolites reflecting cyclooxygenases and lipoxygenases inflammatory pathways



# U-BIOPRED



## Patient/study subject recruitment



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## RECRUITMENT (WP3) Preliminary results as of Oct. 5th, 2012

Adult	Planned patients per protocol	Pts in CIA	Extra pts proposed in Barcelona	Total planned pts	Missing	Actual total	Increase Actual	Total outstanding (planned - actual - unusable)	unusable (SF/DO/violators)	Bronch. Visits Total - Actual	Bronch. Visits Total - actual	Exacerb. Visits Total - Actual	Exacerb. Visits Total - actual	CTscan Total - Actual	CTscan Total - actual	CTscan Total - expected (CIA)	Amend. approval status
Cohort A	400	378	11	389	11	263	10	155	18	52	3	10	0	78	1		
Cohort B	125	124	-1	123	2	33	3	93	1	3	0	0	0	10	0		10/15
Cohort C	100	100	12	112	-12	75	0	42	17	14	0	0	0	10	1		4/15
Cohort D	100	100	5	105	-5	97	0	15	12	39	3	0	0	14	0		1/15
<b>TOTAL</b>	<b>725</b>			<b>729</b>		<b>468</b>	<b>13</b>	<b>305</b>		<b>108</b>	<b>6</b>	<b>10</b>	<b>0</b>	<b>112</b>	<b>2</b>	<b>236</b>	



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## Preliminary results of the Polish Team

Poland (07)											
Cohort A	11	3	14	17	17	0	-3			EC meeting 28 Sept	Recruited 3 pts more than target. Local CRA supported site to prepare docs for the amendment. Submission will be performed on week 38. Recruitment: Investigators are willing to recruit more patients but because of holidays it will be possible at the end of September or even in October. Difficult to specify how many patients can be included more.
Cohort B	4	-3	1	1	1	0	0				
Cohort C	4	1	5	5	5	0	0				
Cohort D	5	0	5	5	5	0	0				
			25	28	28	0	-3				



25th September, 2012, Gdańsk, Poland



efpia

# Our experience in the field

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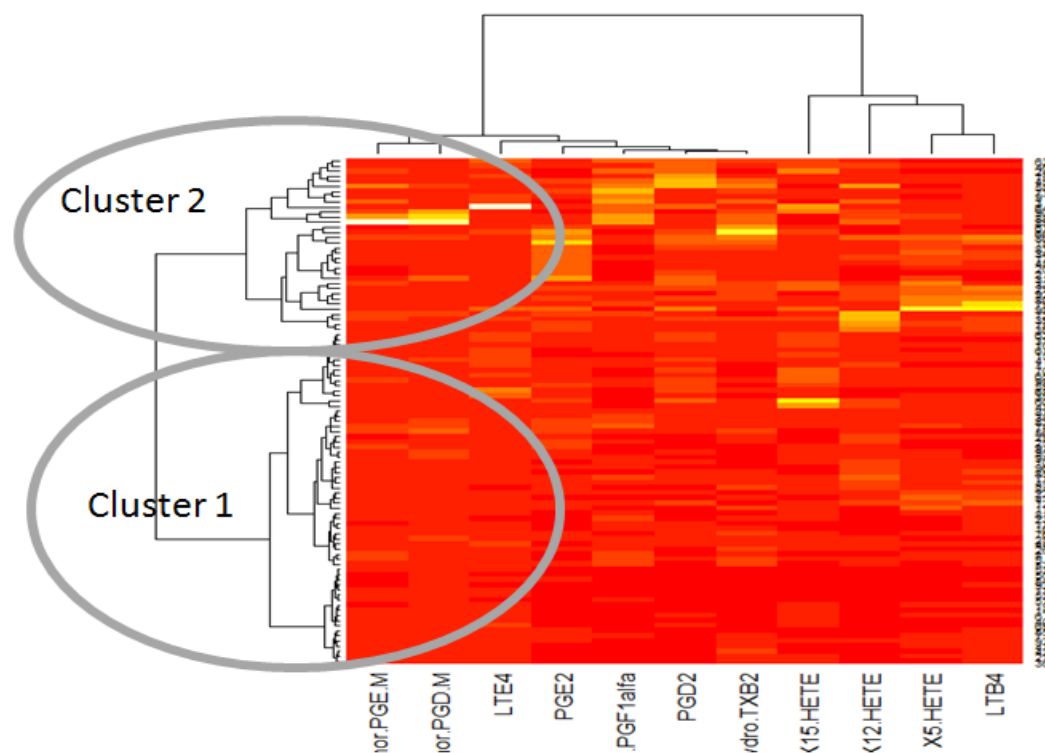
Sachs-Olsen C, Sanak M, Lang AM, Gielicz A, Mowinckel P, Lodrup Carlsen KC, Carlsen K-H, Szczeklik A. Eoxins: a new inflammatory pathway in childhood asthma. *J Allergy Clin Immunol* 2010; 126: 859-867.

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.



## Preliminary results of the Polish Team (WP7) – mediators/ hierarchical clustering



# U-BIOPRED

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## Challenges faced during other projects

- Funding for R&D
- European projects: require that project results are widely available free of charge
- Paradox: patents required as project indicators but products/results may not be commercialised





# U-BIOPRED

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## Challenges faced during U-BIOPRED

- Withdrawal of partner from consortium
- Unknown research framework
- Partner cooperation (formal and scientific)
- Recruitment of subjects (loss of data / enrolled subjects)
- Co-financing



# U-BIOPRED



## Advantages

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- + IMI consortium is an optimum research framework (innovation is possible!)
- + We are already close to our aim 1: Identify better tools and markers to develop new therapies and diagnostics for severe asthma
- + Involvement in new state-of-the-art research
- + Funding for R&D
- + Local capacity/team building
- + Prestige / „good CV line” for future innovative projects



## Thank you

Questions?

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