UBIOPRED

The IMI Severe Asthma Call:

Unbiased Biomarkers for the Prediction Respiratory Disease Outcomes

Chris Compton MD, Novartis

On behalf of the UBIOPRED consortium

Despite current treatments, unmet needs remain in asthma

- >40 million people with asthma in the EU, >300 million globally.
- Many are well-controlled with current therapy, a proportion are poorly controlled (“severe asthmatics”) .
- Unmet needs in severe asthma
- Severe asthma is a term applied to patients who are not well controlled with existing classes of asthma treatments.
- 10% of asthma patients are not controlled by current therapy and account for up to 50% of the total costs of asthma care.
- A severe attack or exacerbation is a terrifying experience, which can lead to emergency hospitalisation and even death for 12,000 Europeans a year.
- Severe asthma is not a single disease (there are different sub-types or phenotypes with multiple co-existant mechanisms.)

U-BIOPRED: Aims to help us better understand severe asthma to improve patient care

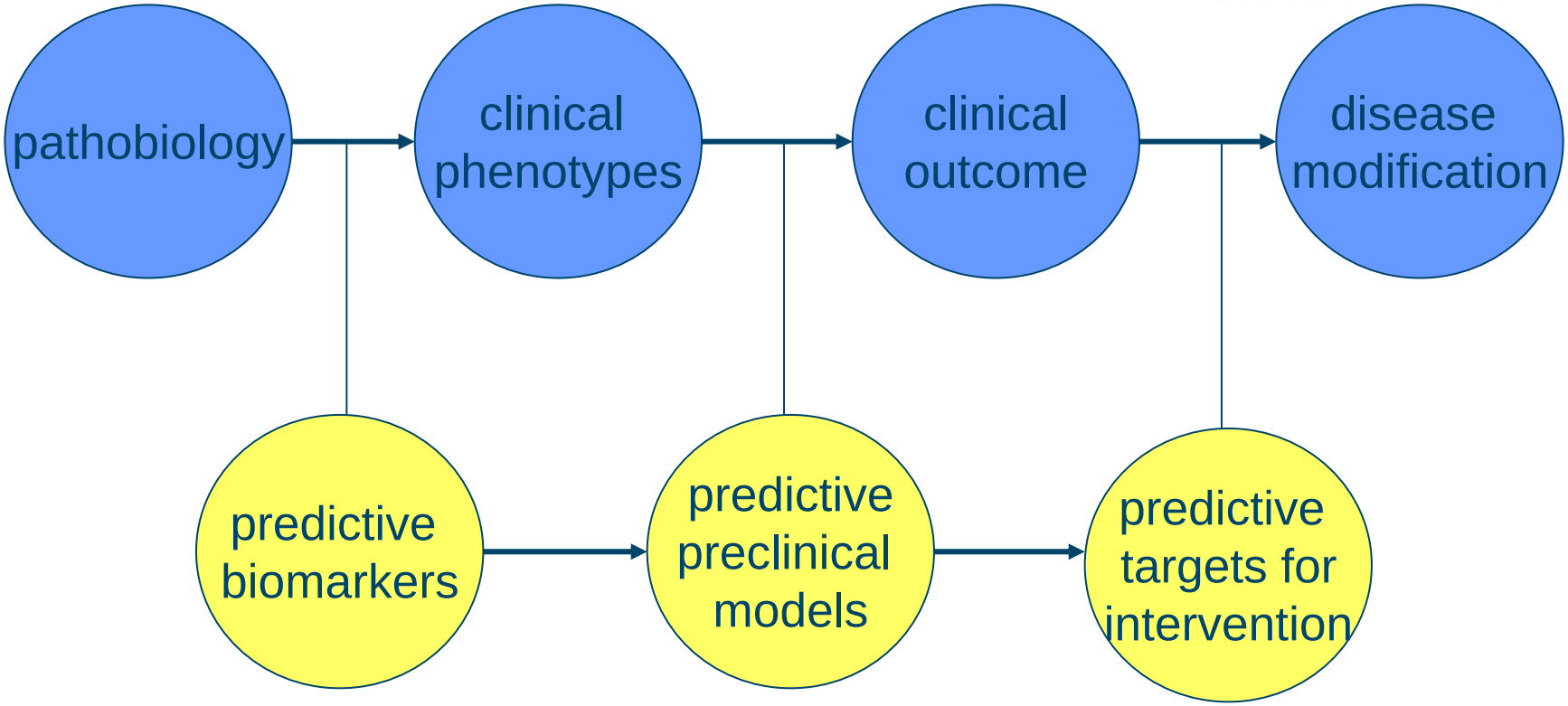
- The overall aim of U-BIOPRED is to better understand the different types of severe asthma

- This will enable us to:
  - Better consider individual characteristics of patients in their diagnosis and management
  - Make it easier to develop new and more effective medicines by overcoming the present bottlenecks to advancing new therapies.

- Key bottlenecks to advancing new therapies are:
  - our poor understanding of the different phenotypes within the severe asthma population
  - lack of biomarkers that enable us to effectively track disease progression or the impact of a novel therapy on disease in clinical studies
  - the poor predictivity of pre-clinical data to clinical

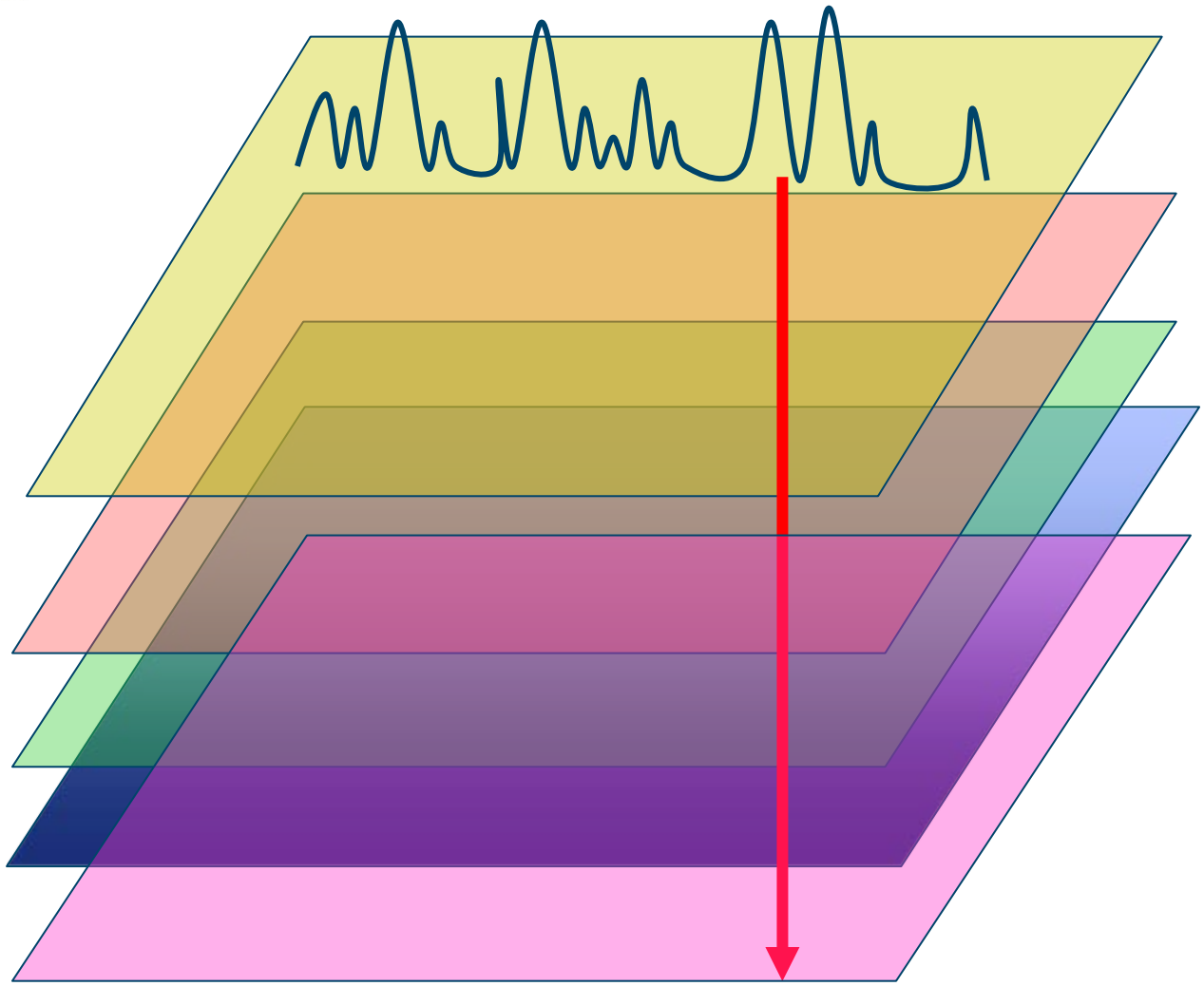
Bottlenecks to developing new medicines for severe asthma

Innovative Medicines Initiative



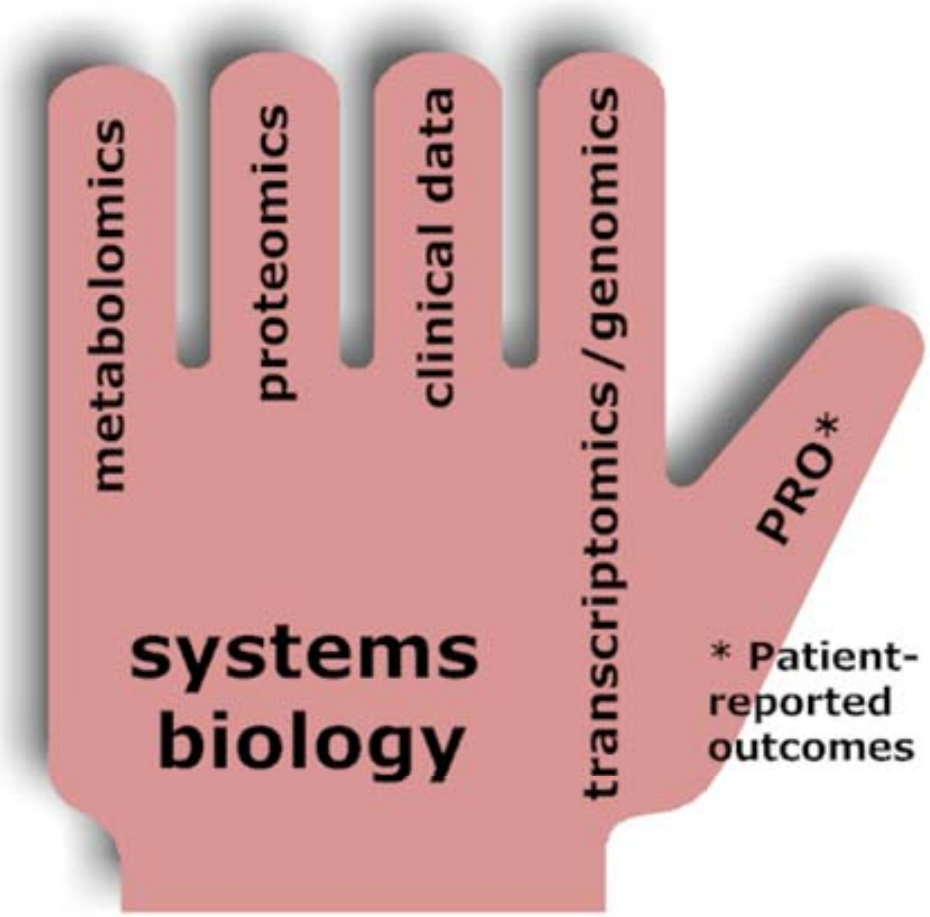
efpia

UBIOPRED, a sophisticated and novel integrated 'Systems Medicine' approach to understanding Severe Asthma

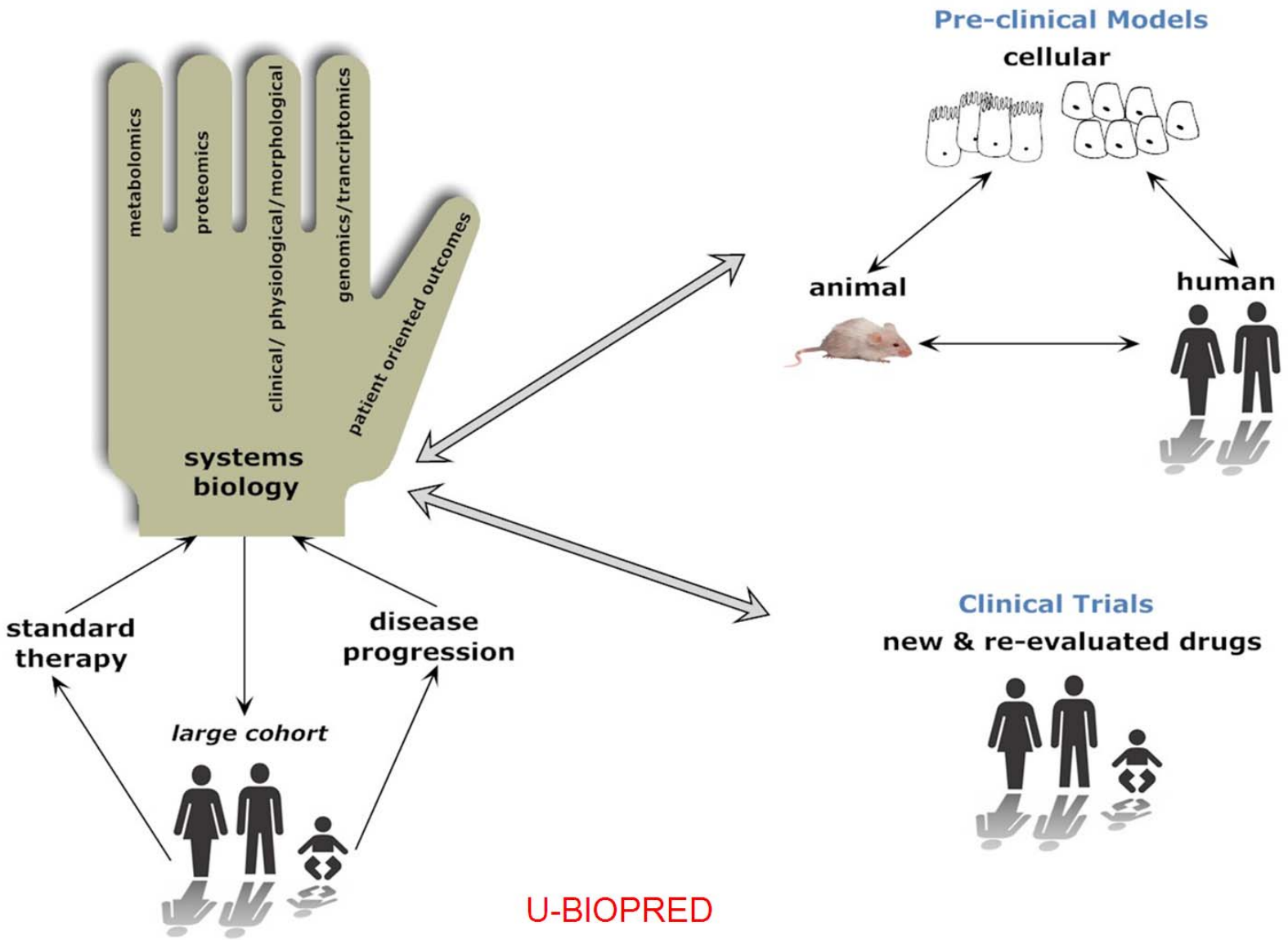


Auffray *et al*. Genome Med 2009;1:2

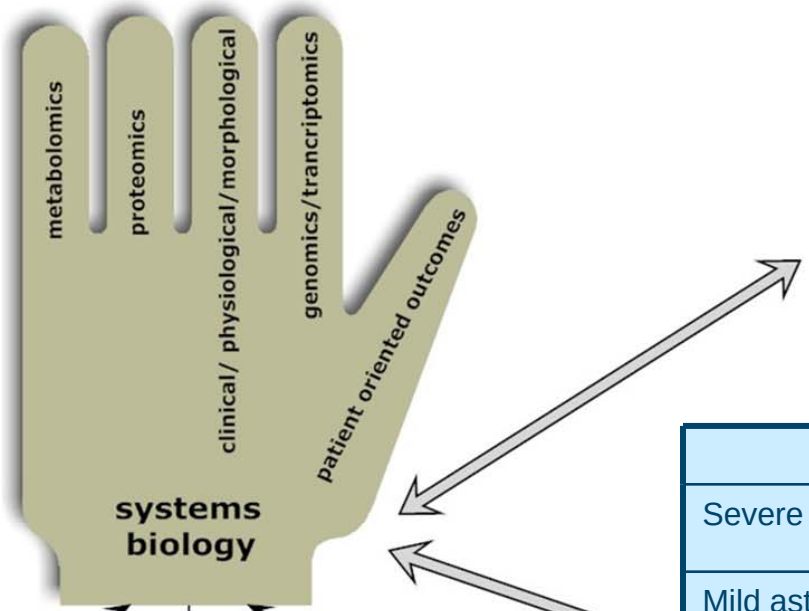
The resulting ‘handprint’ will enable us to more precisely characterise patients with different types of severe asthma

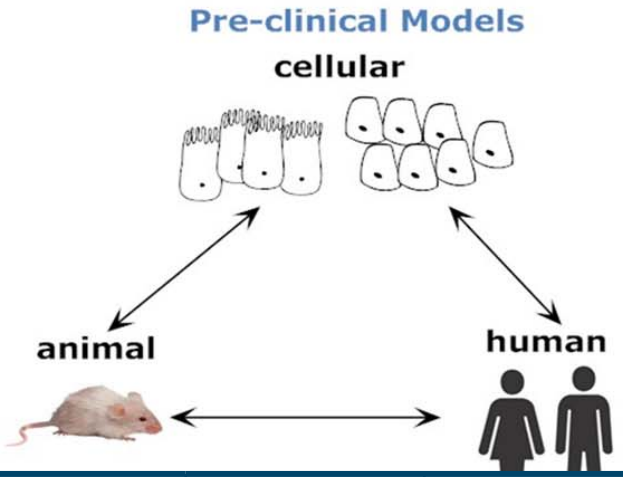


U-BIOPRED

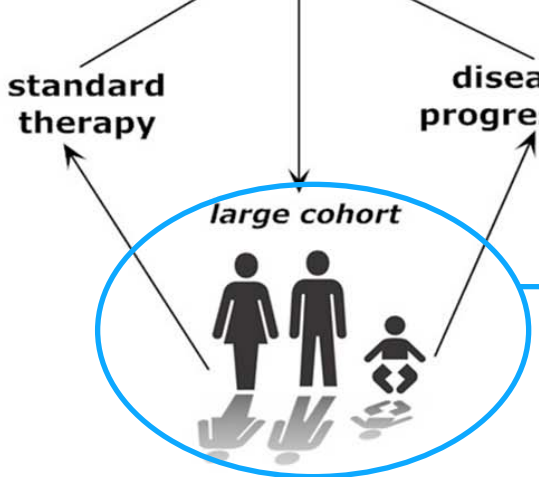

metabolomics
proteomics
clinical/ physiological/morphological
genomics/trancriptomics
patient oriented outcomes
systems biology
Pre-clinical Models
cellular
animal
human
standard therapy
disease progression
large cohort
Clinical Trials
new & re-evaluated drugs

U-BIOPRED Patient Cohort





	Adults	Children
Severe asthma	500	100
Mild asthma	75	50
COPD	100	
Healthy controls	50	
Infants with severe recurrent wheeze		100
Infants with mild recurrent wheeze		50



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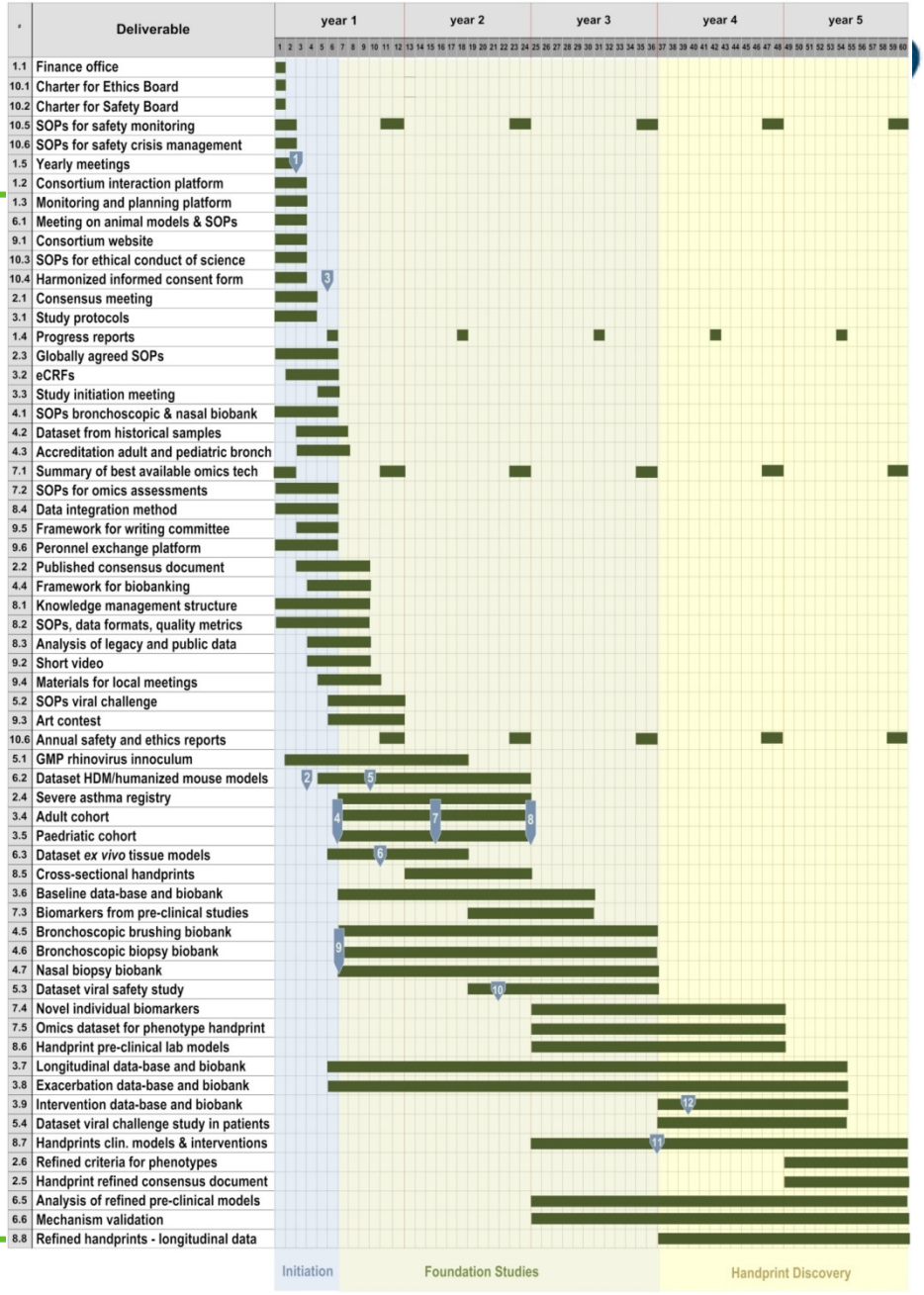
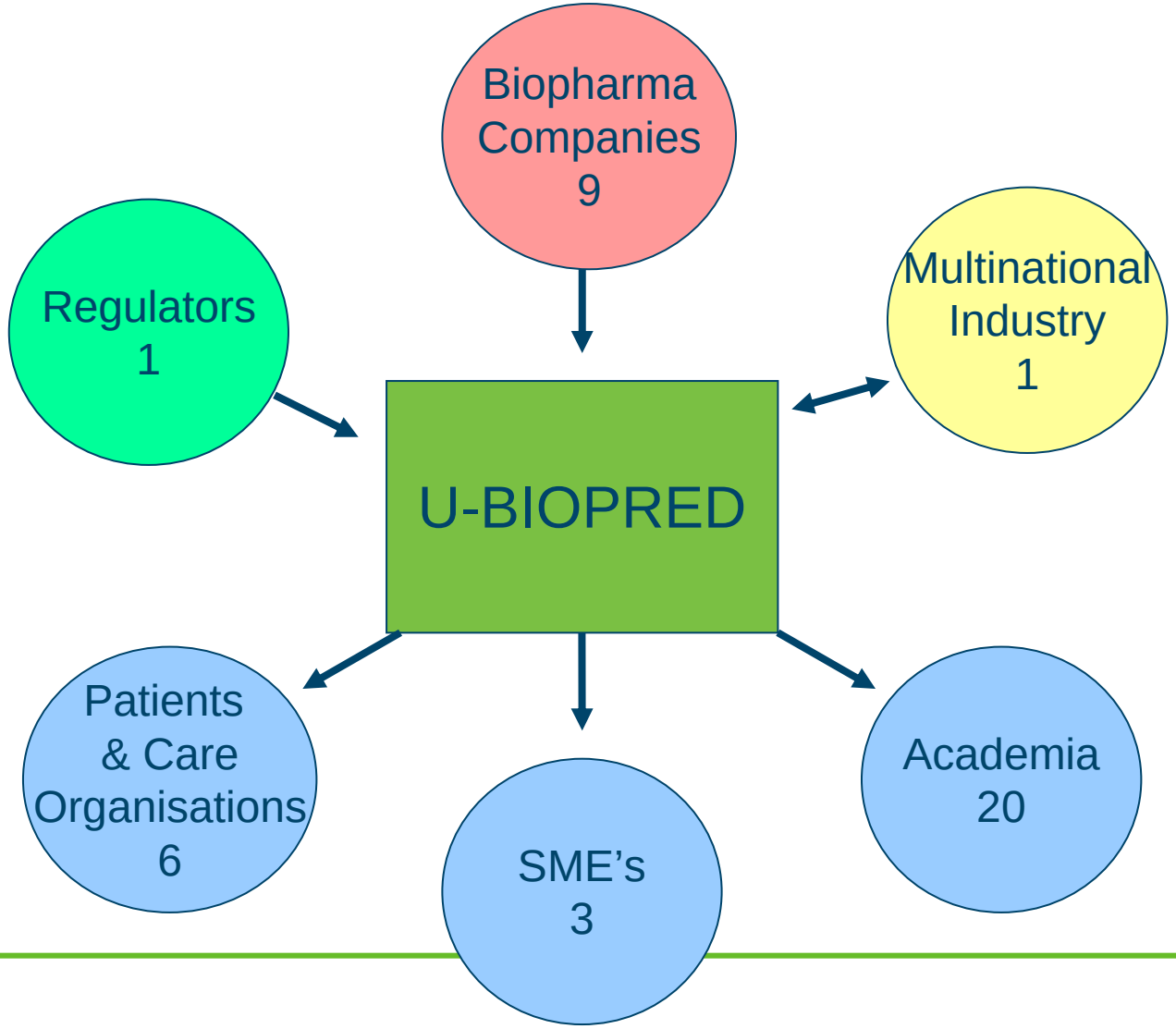
U-BIOPRED Workpackages

1. Coordination and management
2. Consensus generation
3. Cross-sectional and longitudinal cohorts
4. Bronchoscopic assessment
5. Pre-clinical human models
6. Pre-clinical laboratory models
7. Omics technologies
8. Bioinformatics and systems biology
9. Dissemination
10. Ethics

Deliverables as planned in Annex I.



The consortium



U-BIOPRED

acad*

pat org*

SME*

U-BIOPRED academic centers (1)

United Kingdom	Southampton	Djukanovic, Davies, Holgate
	London	Adcock, Barnes, Chung, Bush, Johnston
	Manchester	Woodcock, Singh, Langley, Fowler
	Nottingham	Knox
La France	Marseille	Chanez
	Paris-VilleJuif	Auffray
Italia	Roma	D'Amico
	Roma	Montuschi
	Catania	Polosa

U-BIOPRED academic centers (2)

Nederland	Amsterdam	Sterk, Bel
België	Gent	Lambrecht, Hammad
Deutschland	Hannover	Krug, Braun, Hohlfield
Norge	Bergen	Bakke
Sverige	Stockholm	Dahlen
	Umeå	Sandström, Ådelroth
Danmark	Copenhagen	Vestbo
	Copenhagen	Bisgaard
Polska	Krakow	Szczeklik, Sanak
Magyar	Budapest	Horvath, Lazar
Schweiz	Bern	Frey

U-BIOPRED
patient and care organisations/charities

ELF European Lung Foundation	**Lausanne (CH)**	Powell, Carlsen
EFA Eur Fed Allergy Asthma Airw Patients Associations	**Brussels (B)**	Palkonen
Asthma UK	**London (UK)**	Versnel
AF Nederlands Astma Fonds	**Leusden (NL)**	De Boer, Rutgers
LIAF Lega Italiano Anti Fumo	**Catania (I)**	Polosa
IPCRG Int. Primary Care Respir Gr.	**Aberdeen (UK)**	Haughney

U-BIOPRED Industry

Philips Research	Eindhoven (NL)	Vink, van Kesteren

U-BIOPRED SME's

BioSci	Lanaken (B)	Wagers
Synairgen	Southampton (UK)	Monk
Aerocrine	Stockholm (S)	Alving

U-BIOPRED
Pharmaceutical industries (EFPIA)

Almirall	WP 1,2,3,6,9	Jorge Beleta
AstraZeneca	WP 1,2,3,5,6,8	Lars Larsson, Maria Gerhardsson
Boehringer Ingelheim	WP 1,2,3,10	Katja Nething
Chiesi	WP 1,2,3,5,6,10	Tim Higenbottam
GlaxoSmithKline	WP 1,2,3,4,6,7	David Myles, Ana Sousa
Novartis	WP 1,2,3,7	Chris Compton
Pfizer	WP 1,3,5,6	Lyn Purkins
Roche	WP 1,7,8	Rob England
UCB	WP 1,2,3,6,7,8	Neil Gozzard

Expected outcome

- U-BIOPRED aims to:
  - create adult/paediatric cohorts and biobanks (from over 1000 individuals)
  - create novel phenotype “handprints” by combining molecular, histological, clinical and patient-reported data
  - validate such “handprints” in relation to exacerbations and disease progression
  - refine the “handprints” by using preclinical and human exacerbation models
  - refine the diagnostic criteria and phenotypes
  - reach an international consensus on diagnostic criteria
  - establish a platform for exchange, education and dissemination

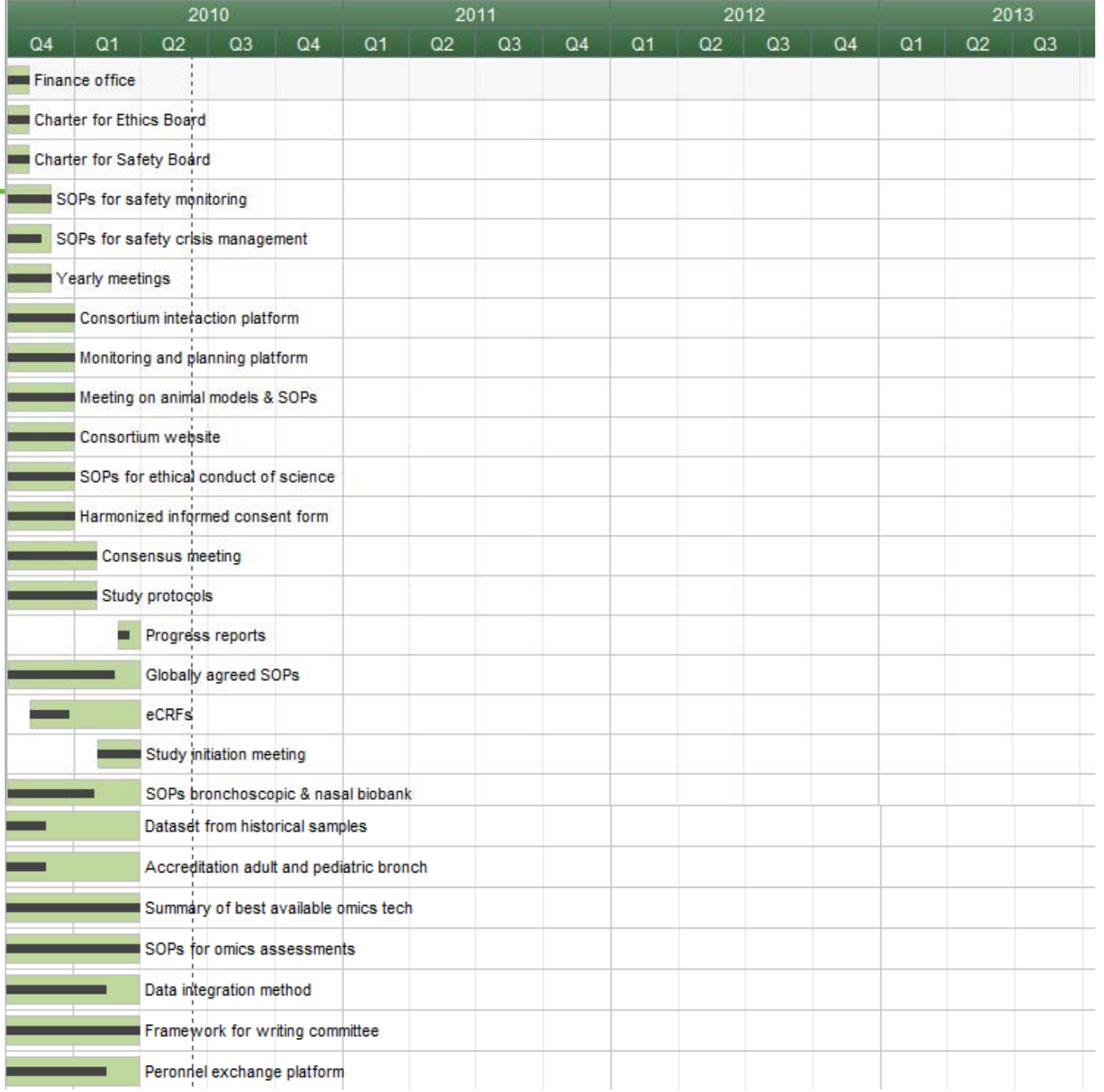
- This will allow us to:
  - Better consider individual characteristics of patients in their diagnosis and management
  - Make it easier to develop new and more effective medicines by overcoming the present bottlenecks to advancing new therapies.

Results/achievements so far

- Highly level of collaboration between partners
- International consensus meeting June 2008 to agree diagnostic criteria and inform protocol
- Project officially started October 2009
- Significant progress across all work packages and on-track according to project plan
- Protocol finalised with view to study start Oct 2010
- Website launched http://www.ubiopred.european-lung-foundation.org/

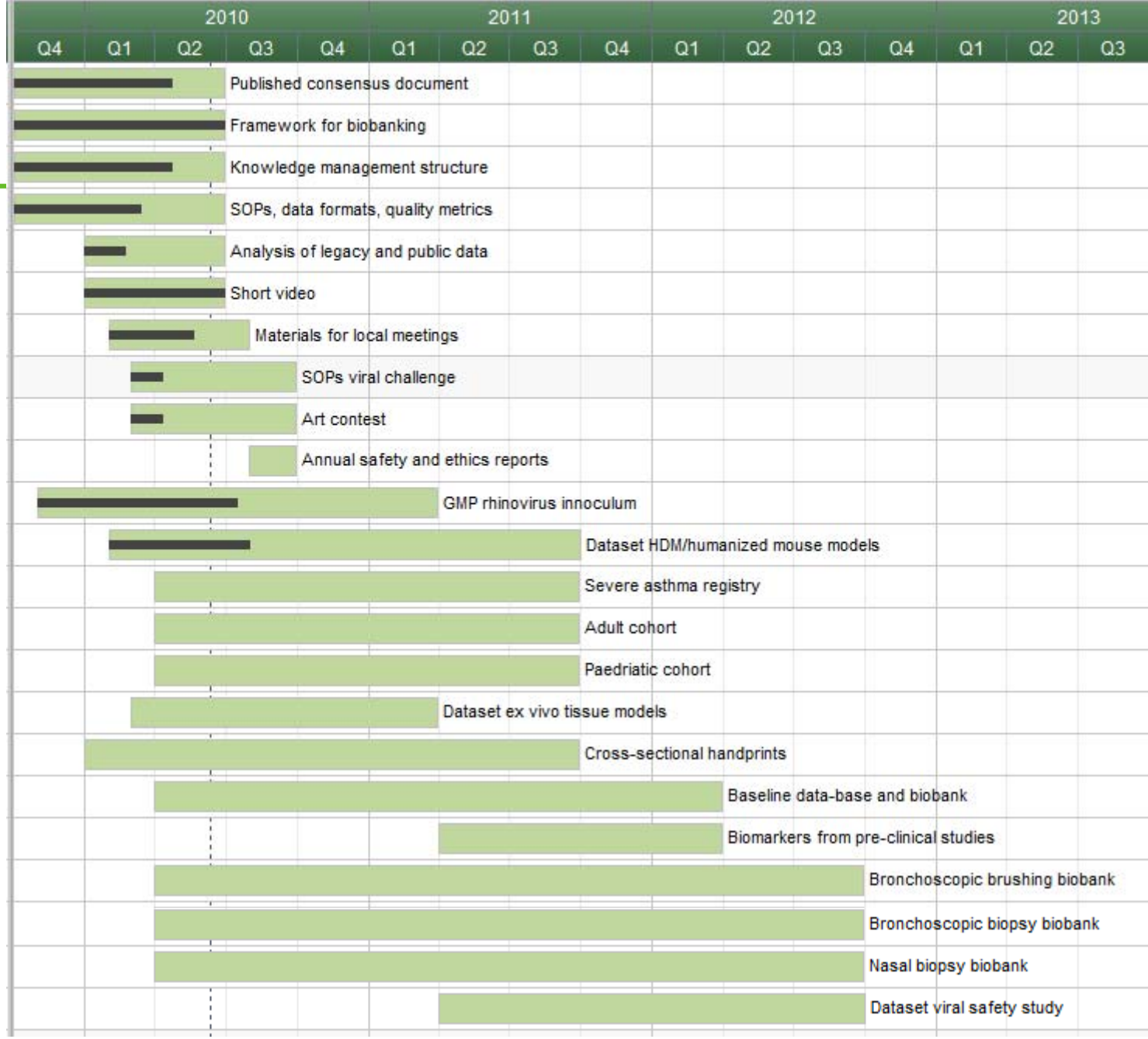
Progress on initiation phase deliverables

Black bars indicate % complete

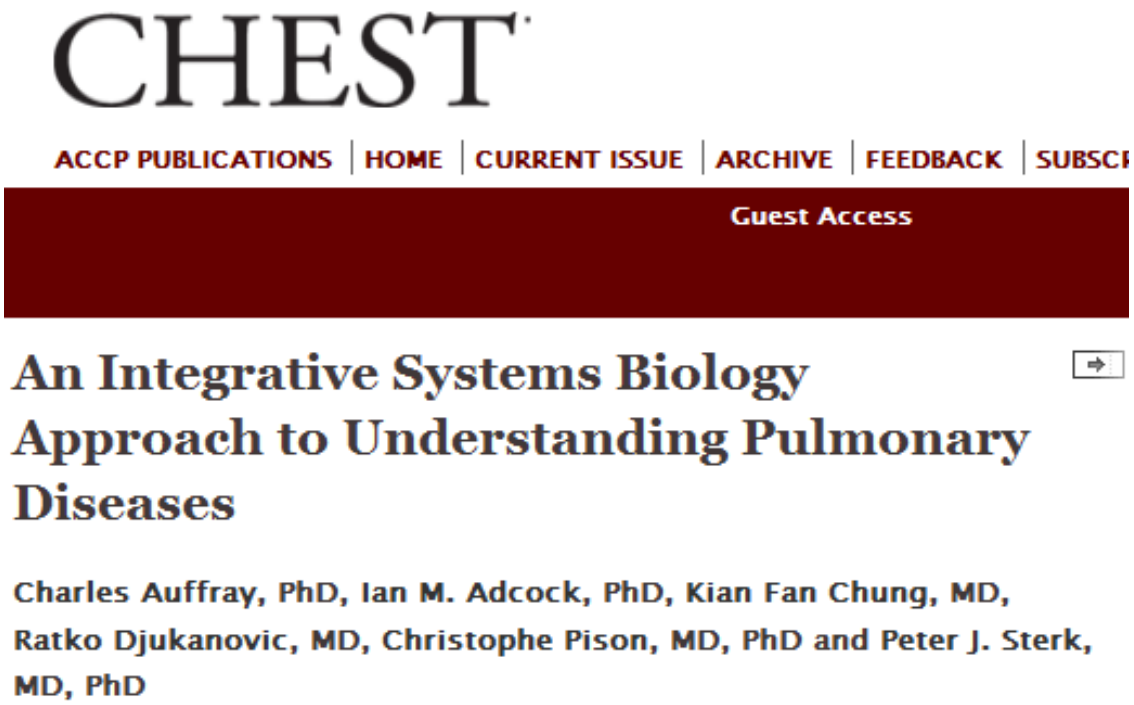


Progress on Initiation phase deliverables

* Black bars indicate % complete



Manuscripts



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An Integrative Systems Biology Approach to Understanding Pulmonary Diseases

Charles Auffray, PhD, Ian M. Adcock, PhD, Kian Fan Chung, MD, Ratko Djukanovic, MD, Christophe Pison, MD, PhD and Peter J. Sterk, MD, PhD

Manuscripts

Diagnosis and Definition of Severe Asthma: an international consensus statement from the U-BIOPRED consortium

Elisabeth H. Bel[2], Ana Sousa[3], Louise Fleming[4], Andy Bush[5], K. Fan Chung[6], Jennifer Versnel[7], Ariane H. Wagener[2], Scott S. Wagers[8], Peter J. Sterk[2], Chris H. Compton[9]

on behalf of the members of the Unbiased Biomarkers for the Prediction of Respiratory Disease Outcome (U-BIOPRED)[1] Consortium, Consensus Generation*

[1] European Union (EU) Innovative Medicines Initiative (IMI) program 'Understanding Severe Asthma. Consortium Unbiased Biomarkers for the Prediction of Respiratory Disease Outcomes (U-BIOPRED); www.ubiopred.eu

Time and money

Financing

- IMI funding: 8.976.474 Euro
- EFPIA contribution, mainly in kind: 10.374.199 Euro
- Other: 1.334.568 Euro
- **Total project cost: 20.685.241 Euro**

Timing:

- Starting date: 01 October 2019
- Duration: 60 months

Further information

- Coordinator: Peter Sterk
  Academic Medical Centre, Amsterdam p.j.sterk [AT] amc.nl

- EFPIA lead: Chris Compton
  Novartis Pharma, UK chris.compton [AT] novartis.com

http://www.ubiopred.european-lung-foundation.org/