Innovative Medicines Initiative

The Innovative Medicines Initiative: Building new models of collaborative research across Europe

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IMI, Belgium

www.imi.europa.eu

Public Private Partnerships Boost Alzheimer's Disease Drug Discovery.
IMI Official Satellite Symposium of the AD/PD 2011 Conference,
9th March 2011, Barcelona Spain

What is IMI ?

Innovative Medicines Initiative

An European Public-Private Partnership
Focused on
Needs Common to
Pharmaceutical Industry and Patients

The Innovative Medicines Initiative: the Largest PPP in Life Sciences R&D

Innovative Medicines Initiative

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European Federation of Pharmaceutical Industries and Associations

€1 billion*

Innovative Medicines Initiative

€1 billion

* Research performed by EFPIA member companies

= *in kind* contribution

IMI Research funding for

Academia, SMEs, patients organisations, Regulatory Authorities, etc.

IMI Research Projects

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EFPIA Member Companies

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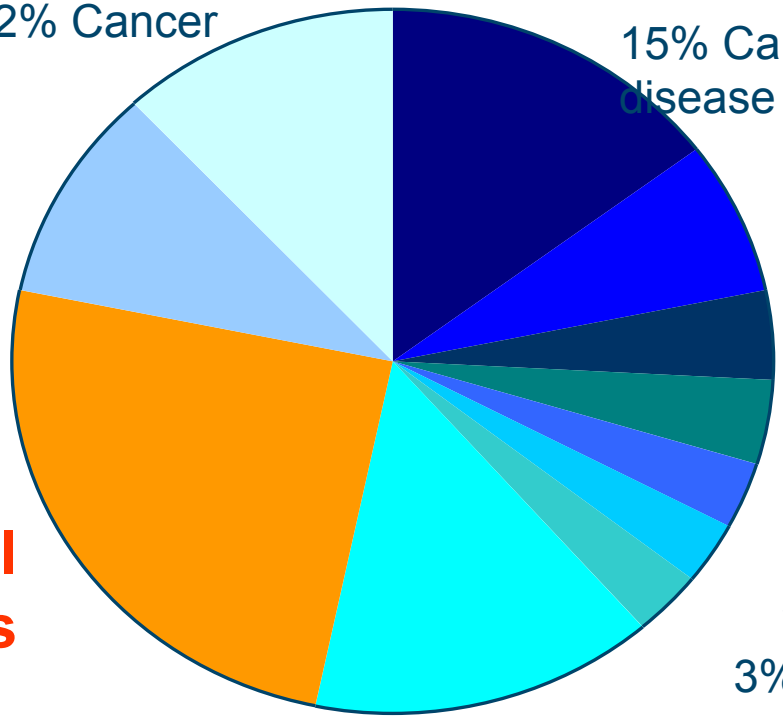
Participating companies (September 2010):

Almirall
Bristol-Myers Squibb — Together we can prevail.
Johnson & Johnson
NOVARTIS
sanofi aventis — L'essentiel c'est la santé.
AMGEN
Chiesi
Lilly
novo nordisk
SERVIER
AstraZeneca
A lot to discover ESTEVE
Lundbeck
ORION
sigma-tau
Bayer
genzyme
MERCK SERONO
Pfizer
Boehringer Ingelheim
gsk GlaxoSmithKline
MERCK SHARP & DOHME
Roche
ucb

IMI Objectives

- Making the pharmaceutical R&D process faster and more effective, rather than directly delivering new drugs
- Accelerating the development of safer and more effective medicines for patients in Europe
- Improving the environment for pharmaceutical R&D in Europe
- Boosting the biopharmaceutical sector in Europe

…Burden of Mental Disorders is huge..



Serious mental illness costs ~ 320Billion/year

~100B Direct Costs

~ 200B Indirect Costs

…and Unmet Need is Still Very High..

Efforts to discover and develop new drugs for brain disorders, particularly those that might revolutionize disease treatment, have been relatively unsuccessful, some of the reasons being…

….Most brain disorders are heterogeneous and multi-factorial

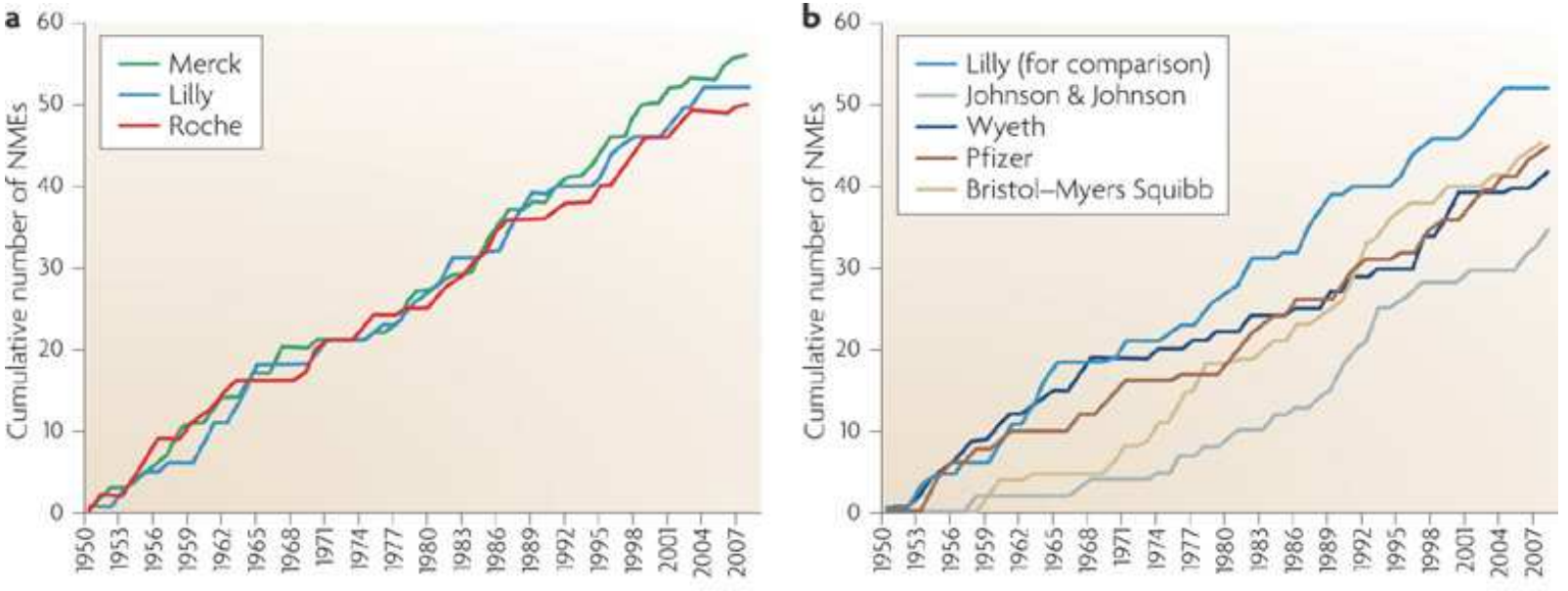
…..Target validation is challenging

….Complexity of symptoms is not simply the sum of its parts

……Diagnosis is based on subjective criteria

……Animal models are inadequate

…Current R&D Models Show no Significant Impact on R&D Innovation



Munos B., Nature Reviews Drug Discovery 8, 959-968 (December 2009)

1+1=1

The Health-care Ecosystem is changing….

- Health care reform and health IT, are driving the system to include many companies not traditionally involved in the health care business.

- Patients from been traditionally relatively passive participants in health delivery are been empowered by technological progress to become educated super-consumers with a much more active role in management of their health care.

The New Environment of “Big Pharma”

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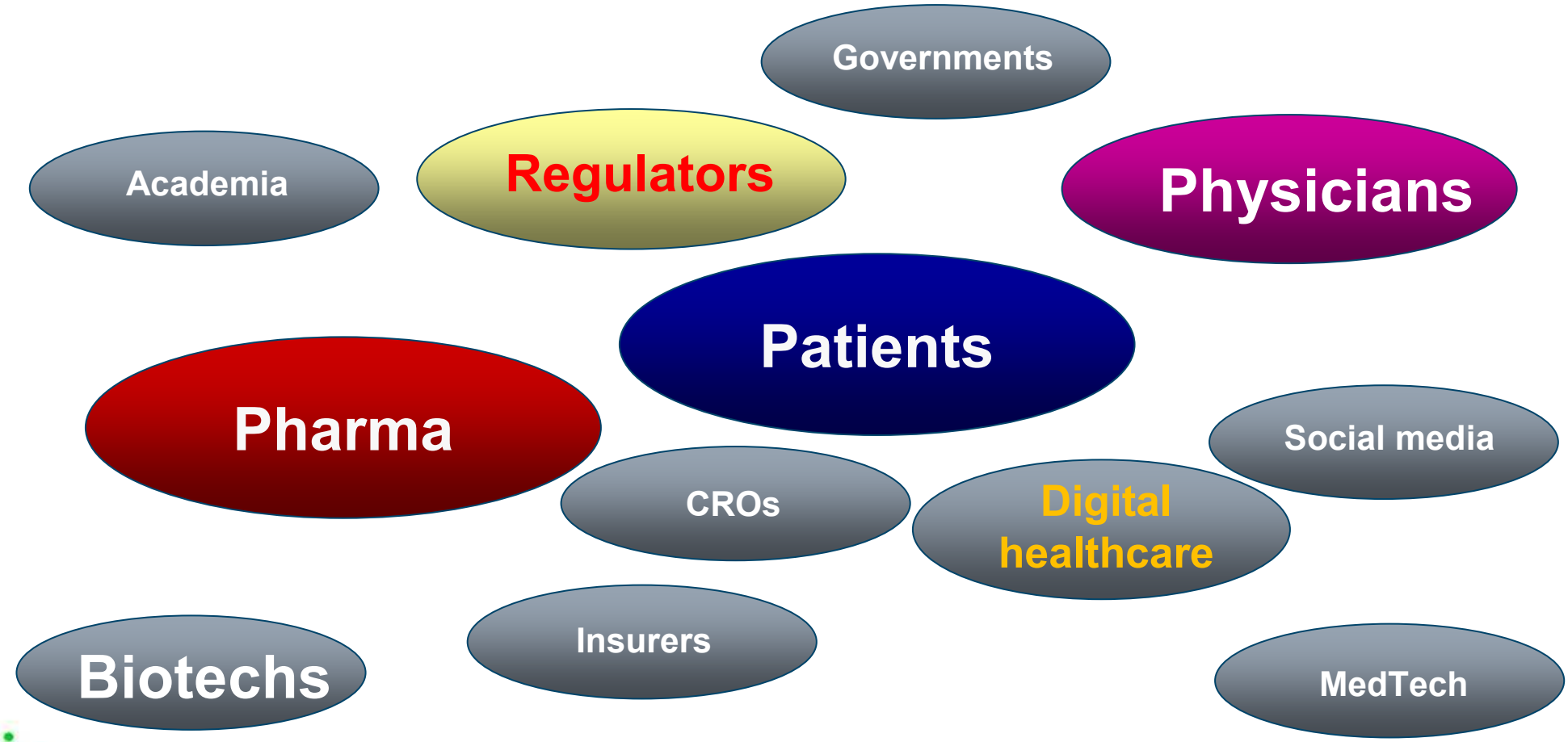


Key Concepts

Innovative Medicines Initiative

- Open Innovation

- Pre-competitive research

Open Industry-Academia Networks are Key to Achieve Innovative Medicines

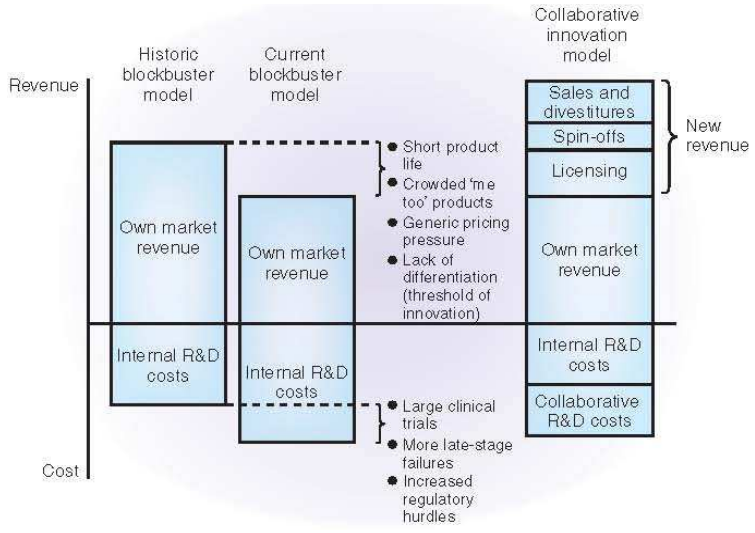
COMMENTARY

Open innovation networks between academia and industry: an imperative for breakthrough therapies

Teri Melese, Salima M Lin, Julia L Chang & Neal H Cohen

The demand to bring transformative therapeutics to patients and the escalating costs of doing so are driving the life science industry to seek collaborations with academia to stimulate innovation. Despite the opportunities afforded by working together, companies and universities lack a systematic approach for capturing the full potential of such relationships. Detailed here are a few suggested strategies to help these collaborations succeed.

The term 'open innovation' was coined by Henry Chesbrough to describe "how useful knowledge and technology was becoming increasingly widespread," such that newly developing technologies and products benefited from integrating knowledge and expertise from multiple sources[1]. He also made the case that the economics of innovation is a key driver for companies to open their innovation process[1,2]. Pharmaceutical and large biotechnology companies, as an example, increased their research and development (R&D) spend



VOLUME 15 | NUMBER 5 | MAY 2009 NATURE MEDICINE

Precompetitive Research to Boost Innovation in Biomedicine

nature publishing group

NEWS & VIEWS

MACROSCOPY

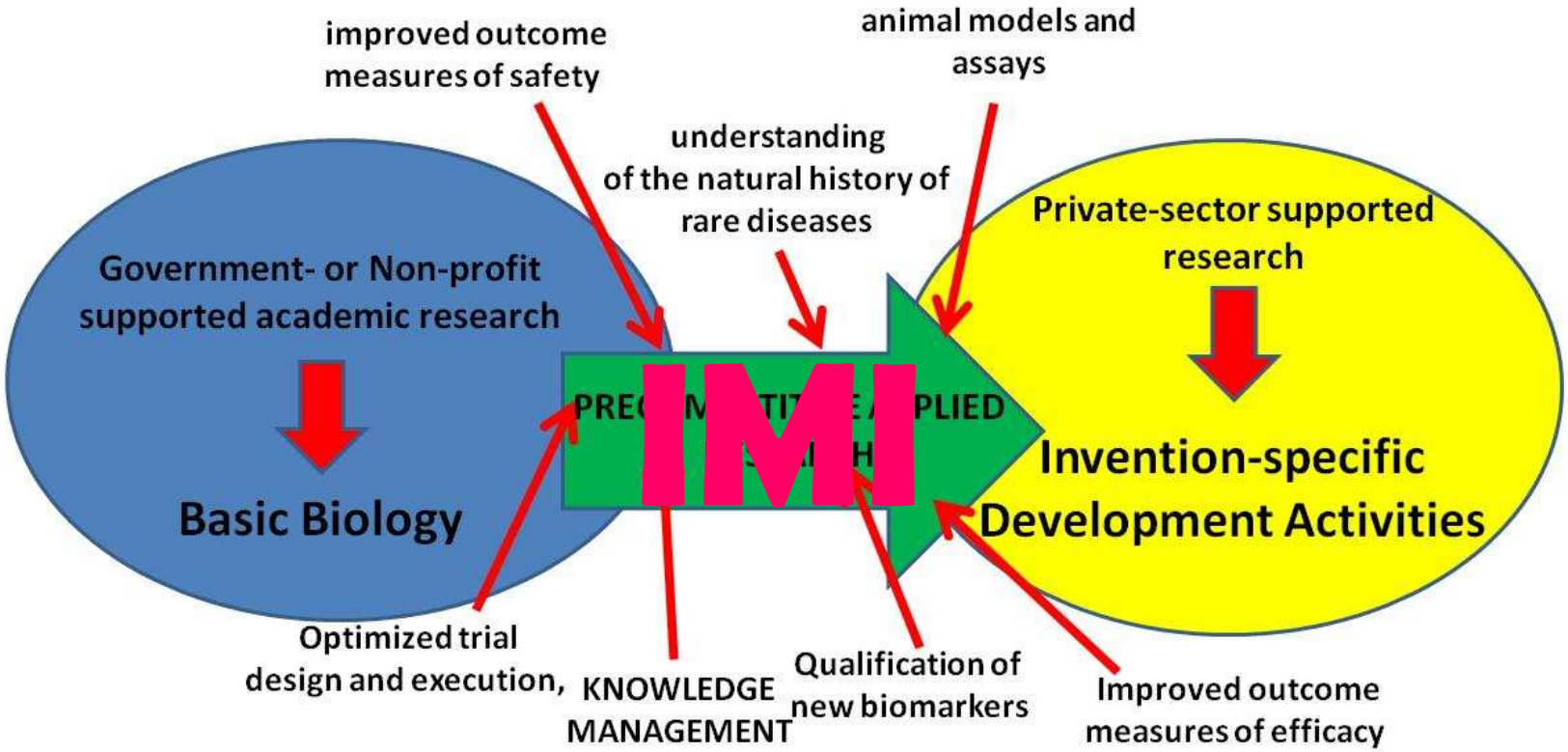
Precompetitive Research: A New Prescription for Drug Development?

J Woodcock[1]

Center for Drug Evaluation and Research, US Food and Drug Administration, Silver Spring, Maryland, USA.

Clinical pharmacology & Therapeutics | VOLUME 87 NUMBER 5 | MAY 2010

IMI Supports Precompetitive Research



IMI is an Industry driven initiative

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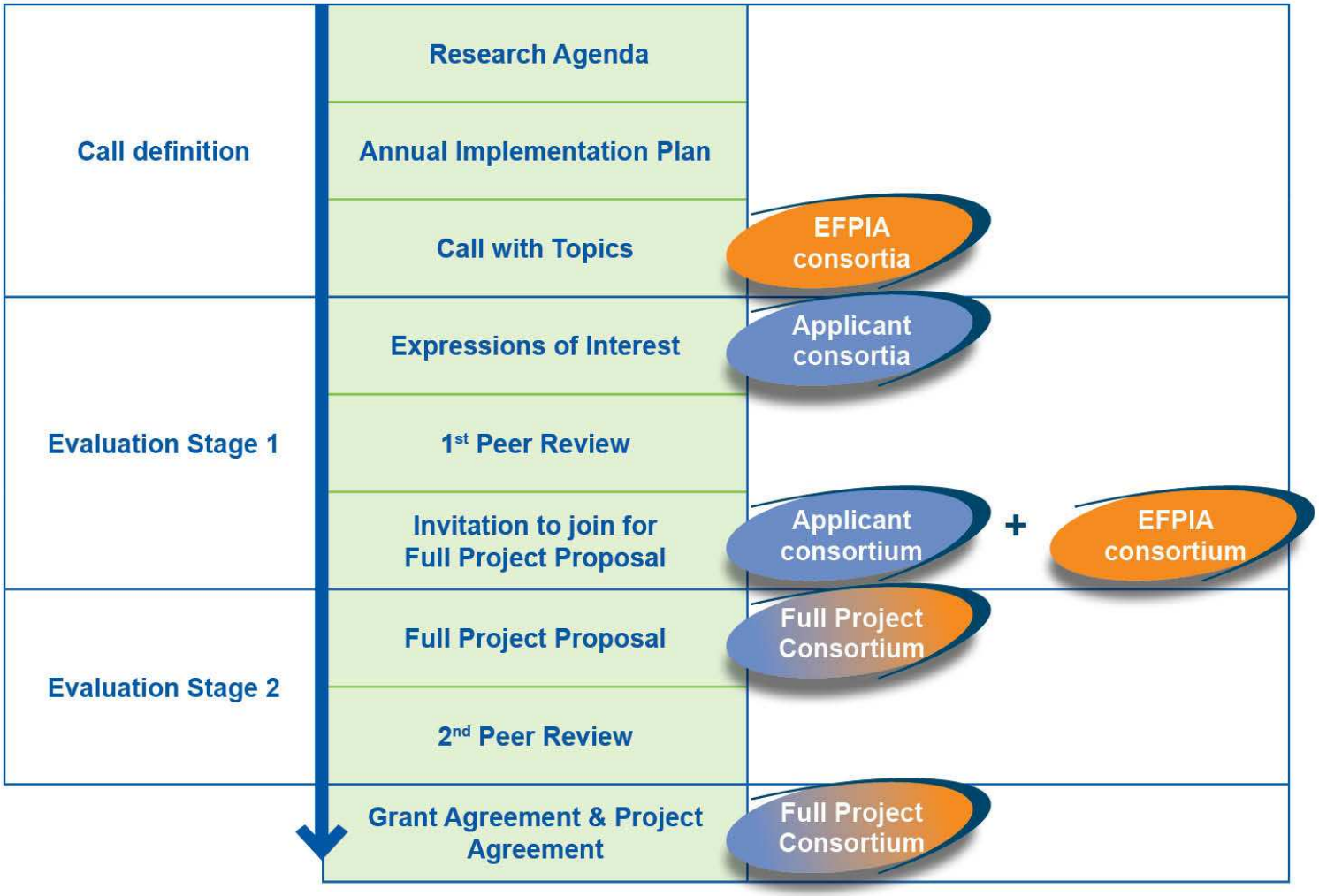
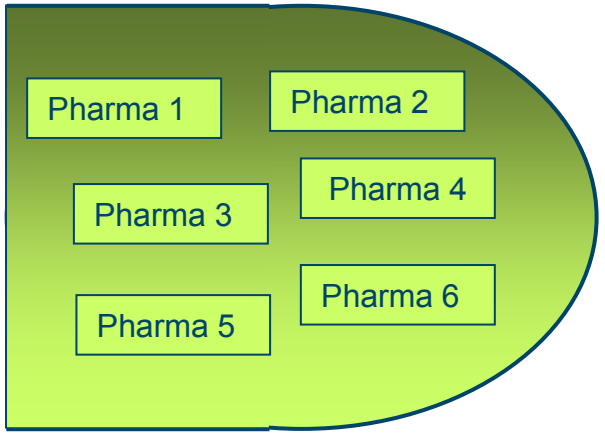
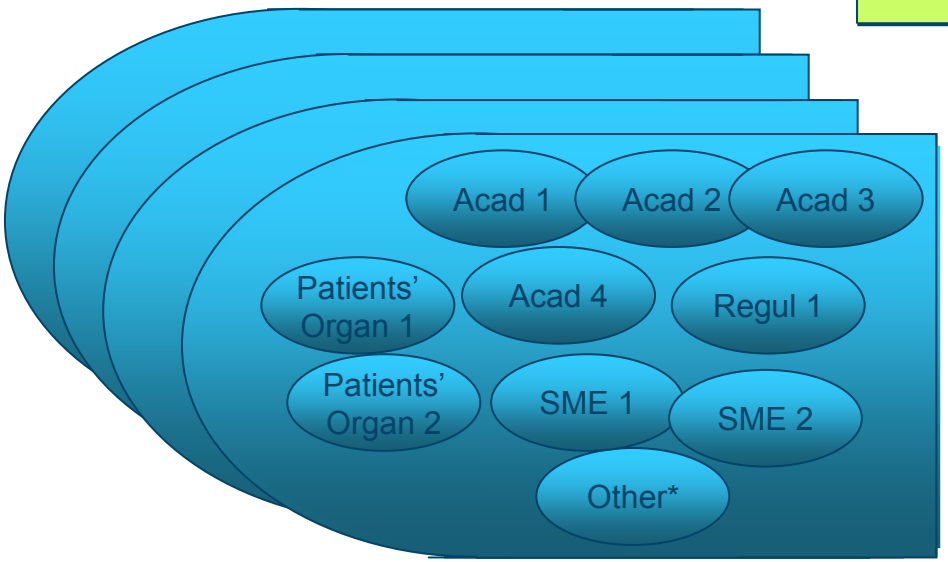


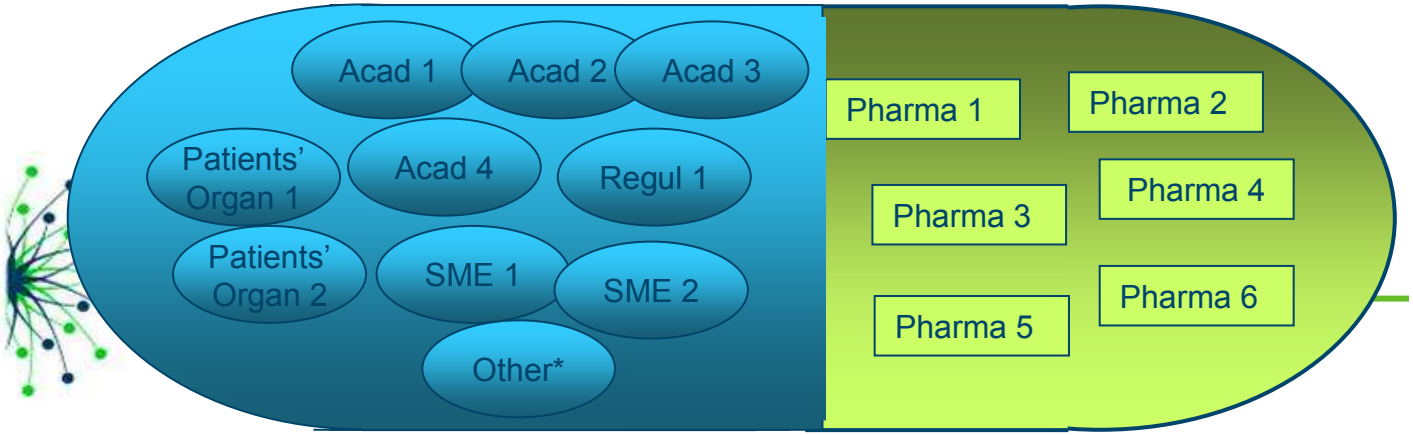
Building a IMI Consortium



Step 1:
A set of EFPIA companies define a topic on which they commit to collaborate



Step 2:
Consortia eligible for EU funding compete through expressions of interest which are ranked by independent experts



Step 3:
The top-ranked EU-fundable consortium join the EFPIA companies to form the final consortium which develops the full proposal, subject to peer-review before final approval

EMA supports IMI activities

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European Medicines Agency

London, 23 September 2009
Doc. Ref. EMEA/585460/2009

The European Medicines Agency's participation in Innovative Medicines Initiative (IMI) Research projects

The European Medicines Agency's position regarding participation in IMI consortia:
The agency fully supports the overall goals of IMI, recognising its benefits for public health. We may therefore be willing and able to participate in select projects, contingent upon a number of considerations. These include:

- *Considerations of resources:* Participation in an IMI project may be labour intensive and we need to be conscious of its internal resource constraints.
- *Potential for conflicts of interest (CoI):* Since IMI projects will be designed to, *inter alia*, develop methodologies to be applied to drug development (e.g. biomarkers, novel approaches to analysis of clinical trials, etc), it is probable that some of these novel methodologies will, at a later stage, become part of a marketing authorisation dossier or a scientific advice procedure for e.g. biomarker qualification that will be assessed by the European Medicines Agency's Scientific Committees and Working Parties. This may create a situation of potential CoI.
- *Relevance of our contribution to the consortium:* We recognise that participation of (a) regulatory agency(ies) is critical for some but not all IMI call topics and consortia.

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The NEW ENGLAND JOURNAL of MEDICINE

N ENGL J MED 362: 865-869, March 11, 2010

Perspective

MARCH 11, 2010

The Missing Voice of Patients in Drug-Safety Reporting

Ethan Basch, M.D.

A patient wants to know about symptoms she may have from a prescription drug she is taking. Consulting the label's "Adverse Reactions" section, she finds a wealth of data. Little does she realize that

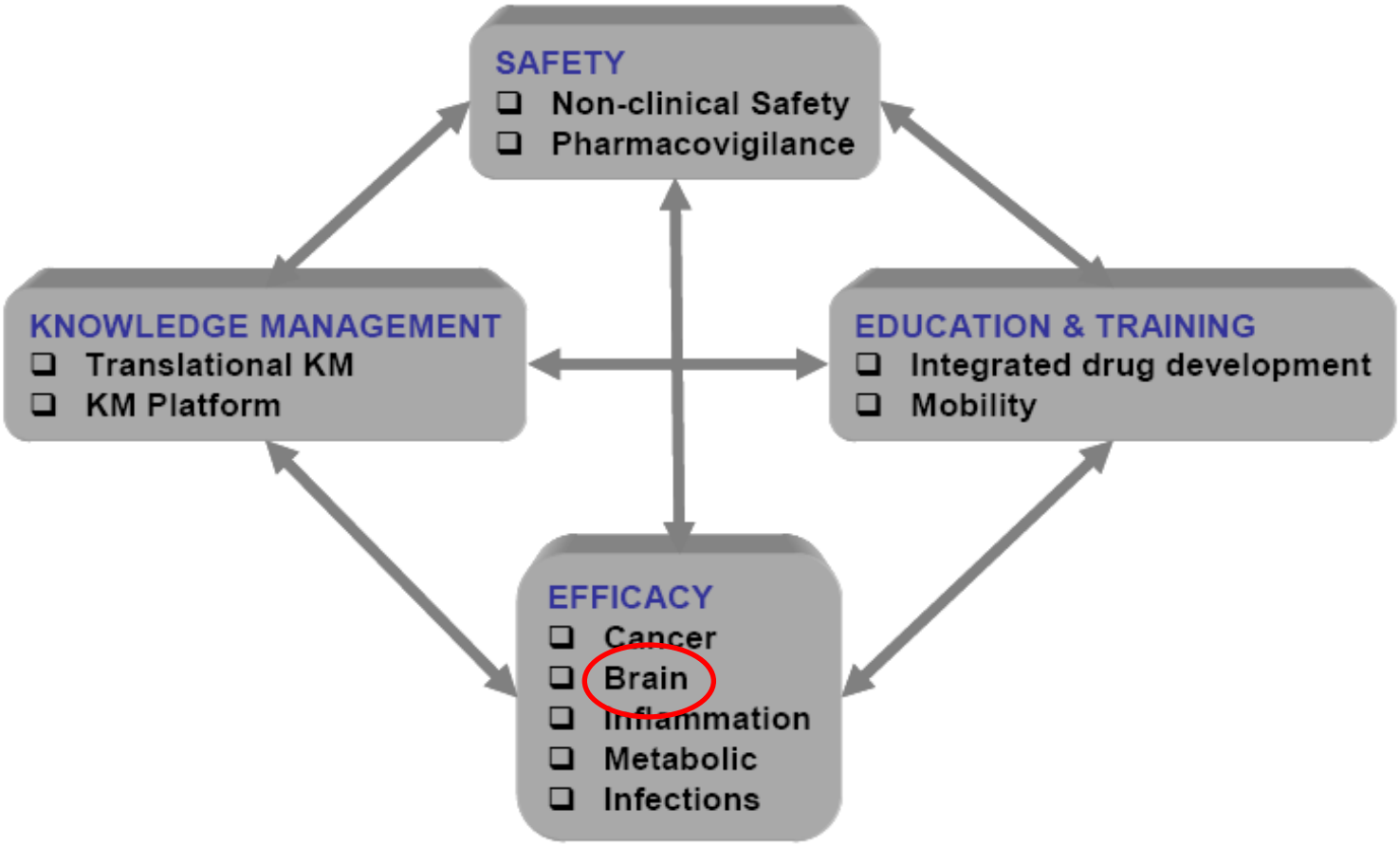
drug-development cycle if reporting by patients were standard practice.

Before a drug has received marketing approval from the Food and Drug Administration (FDA),

IMI Projects overview Call 1 &2

	Call 1	Call 2	Total
Projects	15	8	23
EFPIA Companies	21	21	23
Academic teams	195	103	298
SME teams	24	23	47
Patients' organisat.	9	2	11
Total Budget (M€)	281	172	453

IMI Four Strategic Pillars



First call (2008) funded projects

15 Projects

Total budget: 281 M€

3 Neuroscience Projects

Total budget nearly 60 M€

Acronym	*EFPIA Coordinator*	*Budget (M€)*
SAFE-T	Novartis Pharma	35.9
PROTECT	European Medicines Agency	29.8
SUMMIT	Boehringer Ingelheim	28.4
PHARMA-COG	GSK	27.7
IMIDIA	Sanofi-Aventis	25.4
NEWMEDS	Lundbeck	24.0
U-BIOPRED	Novartis Pharma	20.6
EUROPAIN	AstraZeneca	18.2
PROactive	Chiesi Farmaceutici	16.7
MARCAR	Novartis Pharma	13.3
E-TOX	Novartis Pharma	12.9
EMTRAIN	AstraZeneca	7.7
EU2P	F. Hoffman-La Roche	7.2
Pharma Train	Eur. Federation of Courses	6.6
SafeSciMET	F. Hoffman-La Roche	6.3

3rd Call Topics

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- Early prediction of drug-induced liver injury
- Risk minimization of antibodies to biopharmaceuticals
- Immunosafety of vaccines
- **Translational research on autism spectrum disorders**
- Personalized medicine in type II diabetes
- New strategies to treat tuberculosis
- Patient awareness on pharmaceutical innovation

The Path to Innovative Medicines

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nature medicine

Mechanism matters

The path of drug development is fraught with hurdles. Gaining a clear understanding of how a drug works before it enters clinical trials is the intelligent route to drug discovery and could increase the likelihood for drug success.

Drug development is a risky business. According to the US Food and Drug Administration (FDA), only eight percent of drugs that enter clinical trials are eventually approved. For a drug to gain FDA approval, it must be safe and show some efficacy. Because the FDA does not require any understanding of the mechanism by which a drug acts, it could be tempting to move into clinical trials without this knowledge. However, this may set the stage for failure. An investigational

It is true that we use many highly prescribed drugs without a clear idea of how they work—which targets they hit, what processes they alter and which of these actions are required for therapeutic efficacy. For instance, lithium, used to treat bipolar disorder, modulates many molecular targets, but which—or how many—of these are required for its beneficial effects is uncertain. Nevertheless, understanding a drug's mechanism could guide drug development and help to prevent late-stage failures such as Dimebon's.

nature medicine volume 16 | number 4 | April 2010: 347

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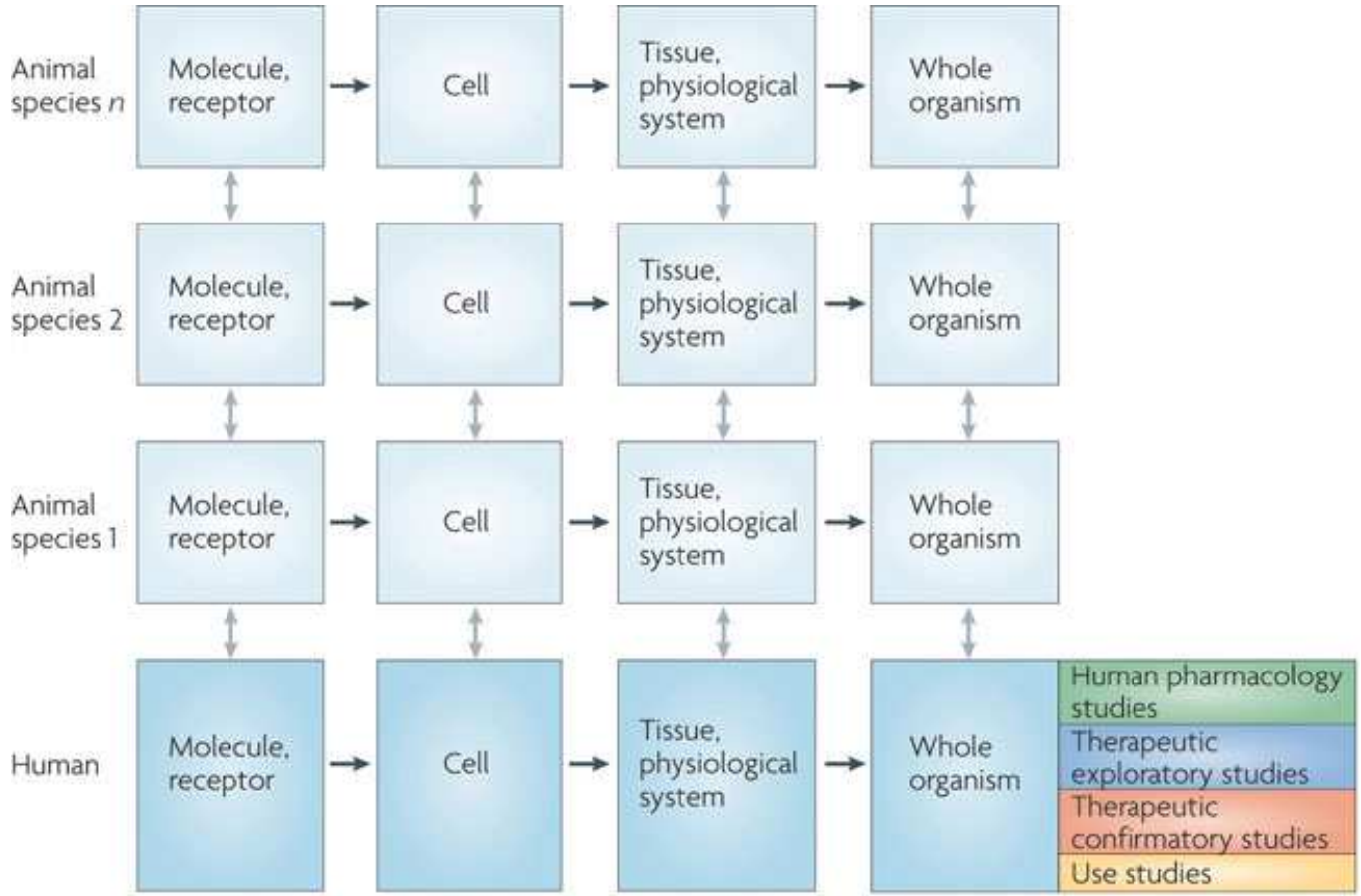
The Translational Process of Drug R&D



*A. F. Cohen, Nature Reviews Drug Discovery **9**, 856-865 (2010)*

Biomarkers are Critical for the R&D of Innovative Drugs

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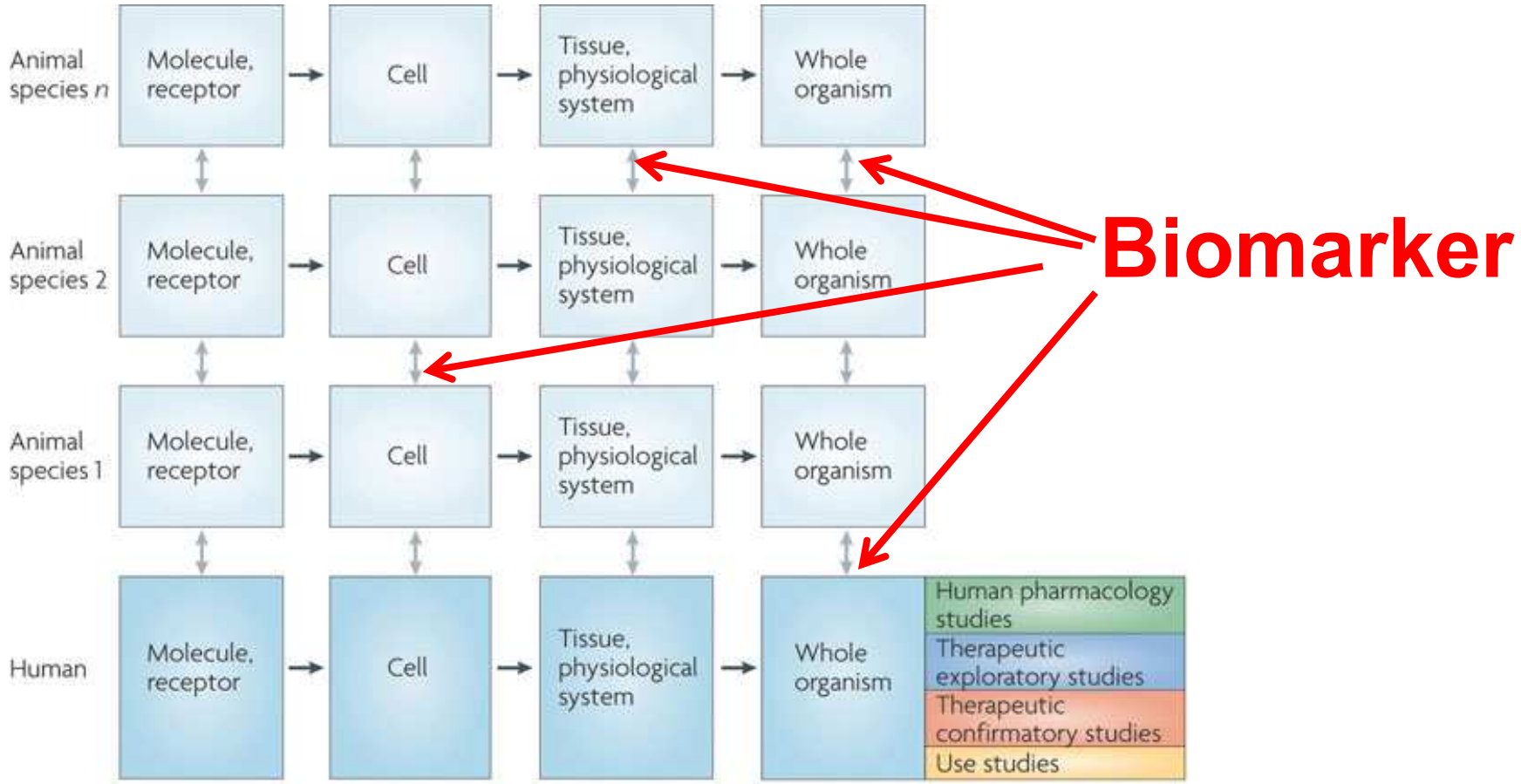
No drug candidate should enter the clinic without a species-independent biomarker as the central element of translational medicine

The Translational Process of Drug R&D



*A. F. Cohen, Nature Reviews Drug Discovery **9**, 856-865 (2010)*

Pharma-Cog

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Prediction of Cognitive Properties of New Drug Candidates for Neurodegenerative Diseases in Early Clinical Development

PharmaCog

Advancing science and treatment of Alzheimer's Disease

http://www.alzheimer-europe.org/FR/Research/PharmaCog

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Thank you for your attention!

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