WELCOME !

Michel Goldman, MD, PhD

Executive Director

IMI Stakeholder Forum, Brussels, 30 May 2012

The Quest for Innovative Medicines

Major need to develop novel pharmaceuticals

with the proven ability to yield treatments not previously

available or providing clinically significant improvements,

with large health gains, at an acceptable cost.

e.g. brain disorders, diabetes, cancer,
inflammatory diseases, antimicrobial resistance

Innovative Medicines Initiative:

Joining Forces in the Healthcare Sector

Core objectives

- To overcome research bottlenecks in drug development through collaborative approaches
- To increase investments in the biopharmaceutical sector and provide socio-economic benefits across Europe
- To contribute to the health of European citizens

Key Bottlenecks in Pharma R&D

- Disease heterogeneity
- Lack of predictive biomarkers for drug efficacy/ safety
- Insufficient pharmacovigilance tools
- Unadapted clinical designs
- Lack of incentive for industry

Key Concepts

- “Non-competitive” collaborative research for EFPIA companies
- Competitive calls to select partners of EFPIA companies (IMI beneficiaries)
- Open collaboration in public-private consortia (data sharing, wide dissemination of results)

THERAPEUTICS DISCOVERY

The Precompetitive Space: Time to Move the Yardsticks

Thea Norman,[1] Aled Edwards,[2] Chas Bountra,[3] Stephen Friend[4]*

Industry, government, patient advocacy groups, public funders, and academic thought leaders met in Toronto, Canada, to set into motion an initiative that addresses some of the scientific and organizational challenges of modern therapeutics discovery. What emerged from the meeting was a public-private partnership that seeks to establish proof of clinical mechanism (POCM) for selected "pioneer" disease targets using lead compounds—all accomplished in the precompetitive space. The group will reconvene in April 2011 to create a business plan that specifies the generation of two positive POCM results per year.

2011 may become known as the year in which "out-of-the-box thinking" transformed into "out-of-the-box doing" in the realm of therapeutics discovery—that is, if the bold conclusions that emerged from the February 2011 Summit in Toronto, Canada, archipelago, of experts funded by industry, public funding agencies, and private foundations and would engage patients, clinicians, and scientists from academia, industry, and regulatory agencies as active co-participants. The name ARCH2POCM has their limits; but with a precompetitive drug discovery effort in place, it should be possible to rapidly disseminate negative POCM information in order to protect patient safety and minimize the costly redundancy of having multiple pharmaceutical companies pursuing the same disease targets in isolation of one another.

From this mutual starting point, Summit participants agreed that bold ideas, not pilot programs, are needed to meet the challenges that today's pharmaceutical industry faces. And everyone concurred that ARCH2POCM must be structured such that all resulting data are made publicly available with no intellectual property (IP) generated through the POCM stage; such an open-access model would unleash truly translational, mechanism-based research and would foster rapid clinical validation of pioneer targets in a manner that (i) maximizes patient safety and (ii) rapidly informs the drug-development industry about those targets for which POCM has been successfully

Opening Clinical Trial Data

PERSPECTIVE OPEN ACCESS

Featured in *PLoS Hub for Clinical Trials*

Open Clinical Trial Data for All? A View from Regulators

Article | Metrics | Related Content | Comments: 1

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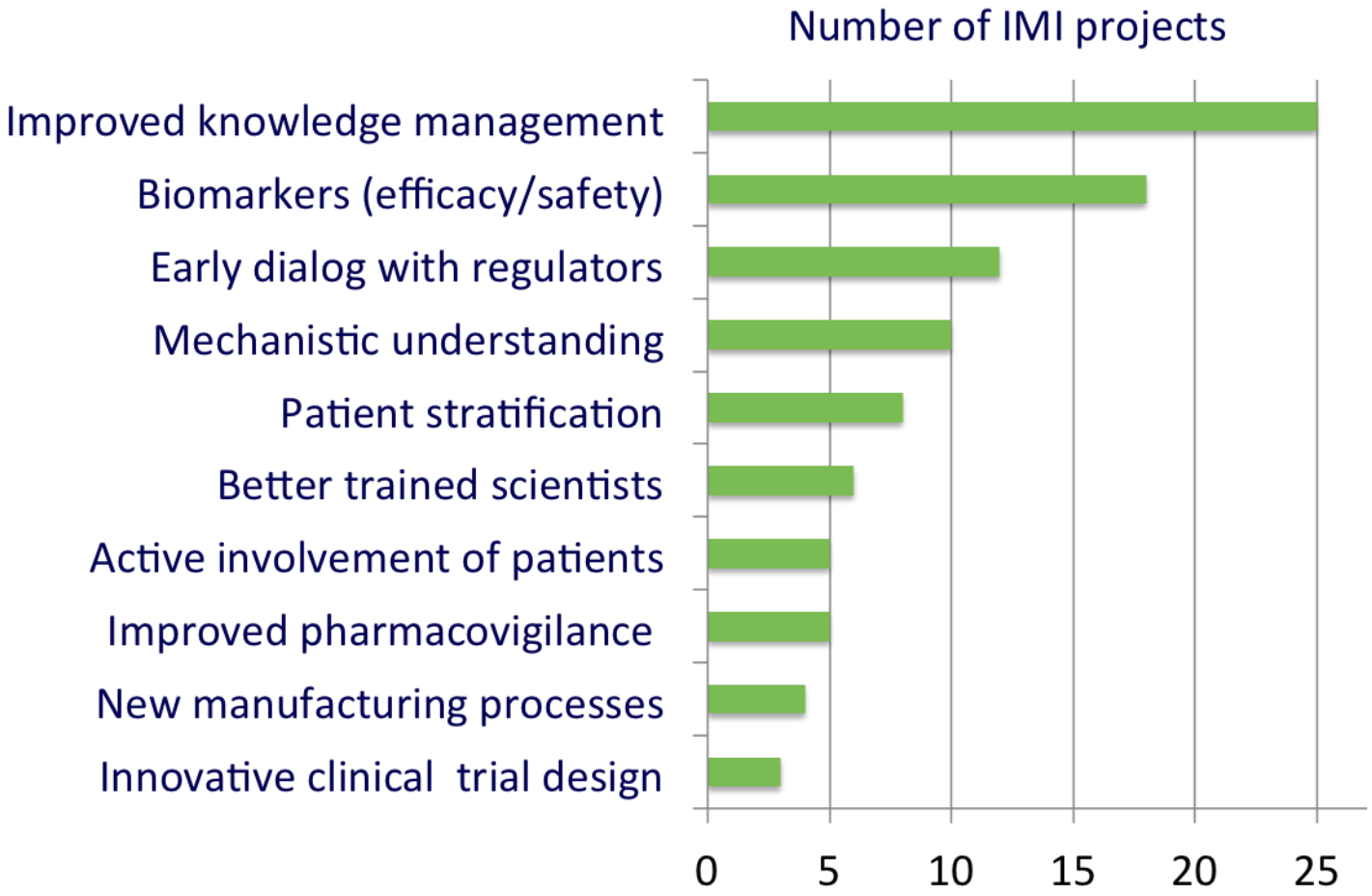
Expected output of current IMI projects



Overview of current IMI projects

	Call 1	Call 2	Call 3	Call 4	TOTAL
No of projects	15	8	7	7	37
No of EFPIA teams	160	66	54	0	280
No of academic teams	194	105	101	108	508
No of SME teams	26	22	14	30	92
No of patients' organisations	10	1	6	0	17
No of regulatory agencies	7	0	2	1	10
No of other partners	3	0	3	4	10
IMI JU contribution (€ millions)	109,6	80,7	111,8	97,9	400,0
EFPIA in-kind contribution (€ millions)	132,6	65,9	68,9	107,5	374,9

A Typical IMI Consortium

Private Investment *'n kind*

EU Public Funding *cash*

Why apply ?

- Looking for additional funding
- Interested in patient-centric research
- Interested in collaborating with large pharmaceutical companies

THANK YOU !

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