

# The Innovative Medicines Initiative (IMI)

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Where are we in March 2009

Profession: Bio-Entrepreneur 2009

Patrick Tricoli  
sanofi-aventis R&D External Innovation

Access to Innovation Europe Head  
IMI Governance Task Force



# IMI History (1)



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May 2004	Start of official discussions between the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the European Commission (EC)
June 2004	Agreement of EFPIA to take leadership of the European Technology Platform for Innovative Medicines
November 2004	Submission of pilot project InnoMed to the EC
December 2004	Publication of IMI Vision Paper
August 2005	Publication of IMI Strategic Research Agenda developed through broad consultation
October 2005	Start of pilot project InnoMed funded under Framework Program 6 (€ 18 million)
September 2006	Publication of IMI Strategic Research Agenda version 2 (including draft governance and IP Policy)

## IMI History (2)



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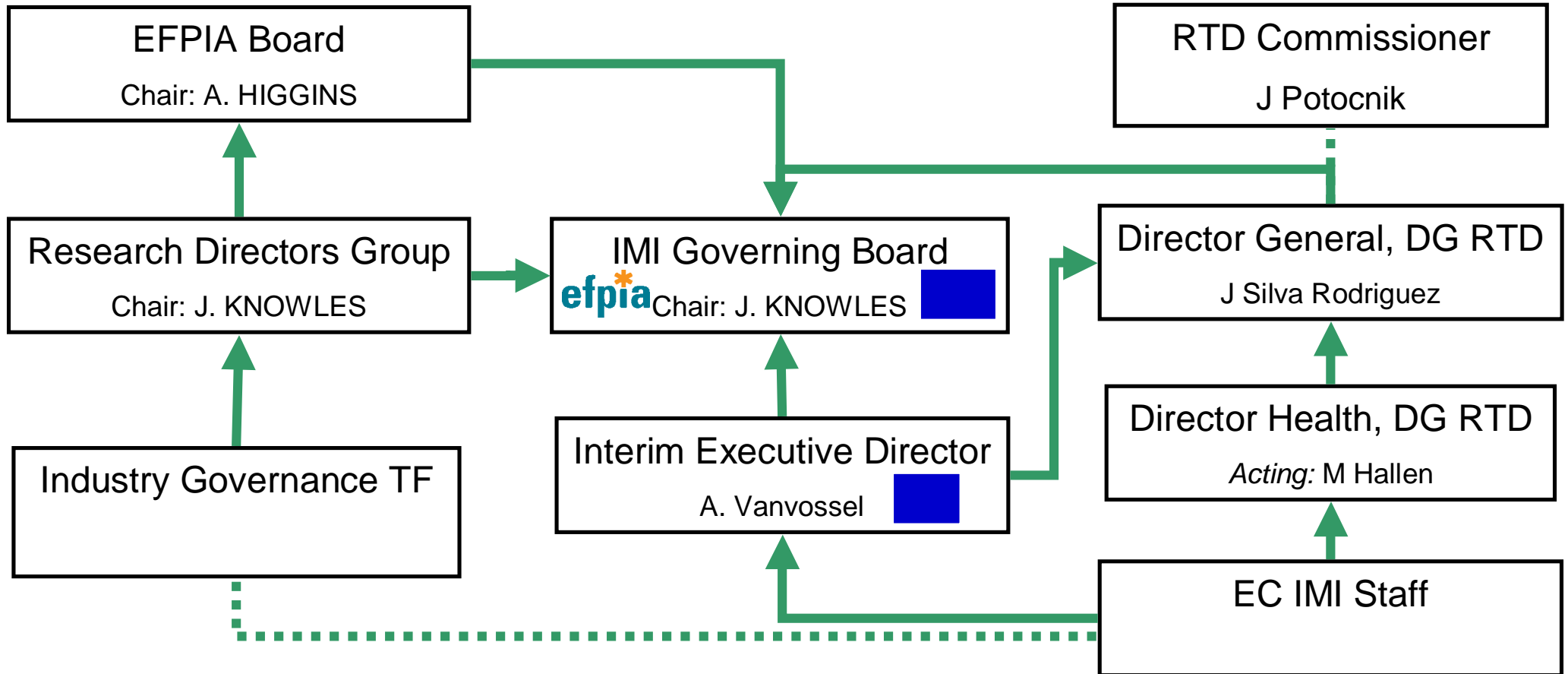
November 2006	Launch of the IMI website <a href="http://www.imi-europe.org">www.imi-europe.org</a>
February 2007	Submission of the IMI Impact Assessment
May 2007	Adoption of IMI legal package by the EC
May 2007	Submission of IMI legal package to European Competitiveness Council and European Parliament
August 2007	Adoption of IMI Intellectual Property Policy
November 2007	Adoption of IMI legal package by the European Competitiveness Council
December 2007	Adoption of the European Parliament opinion
December 2007	Approval of the establishment of IMI Joint Undertaking by the European Council

# IMI Interim Period Management Structure (1)



- When approving IMI the EU Member States agreed that the Regulation establishing IMI should stipulate that the European Commission is in charge of running IMI until it can be autonomous
- The RDG and the EFPIA Board agreed to sign a letter of commitment to the IMI Regulation
- The EFPIA letter of commitment was supported by each individual CEO of the companies that sit on the RDG via individual letters of commitment from the companies

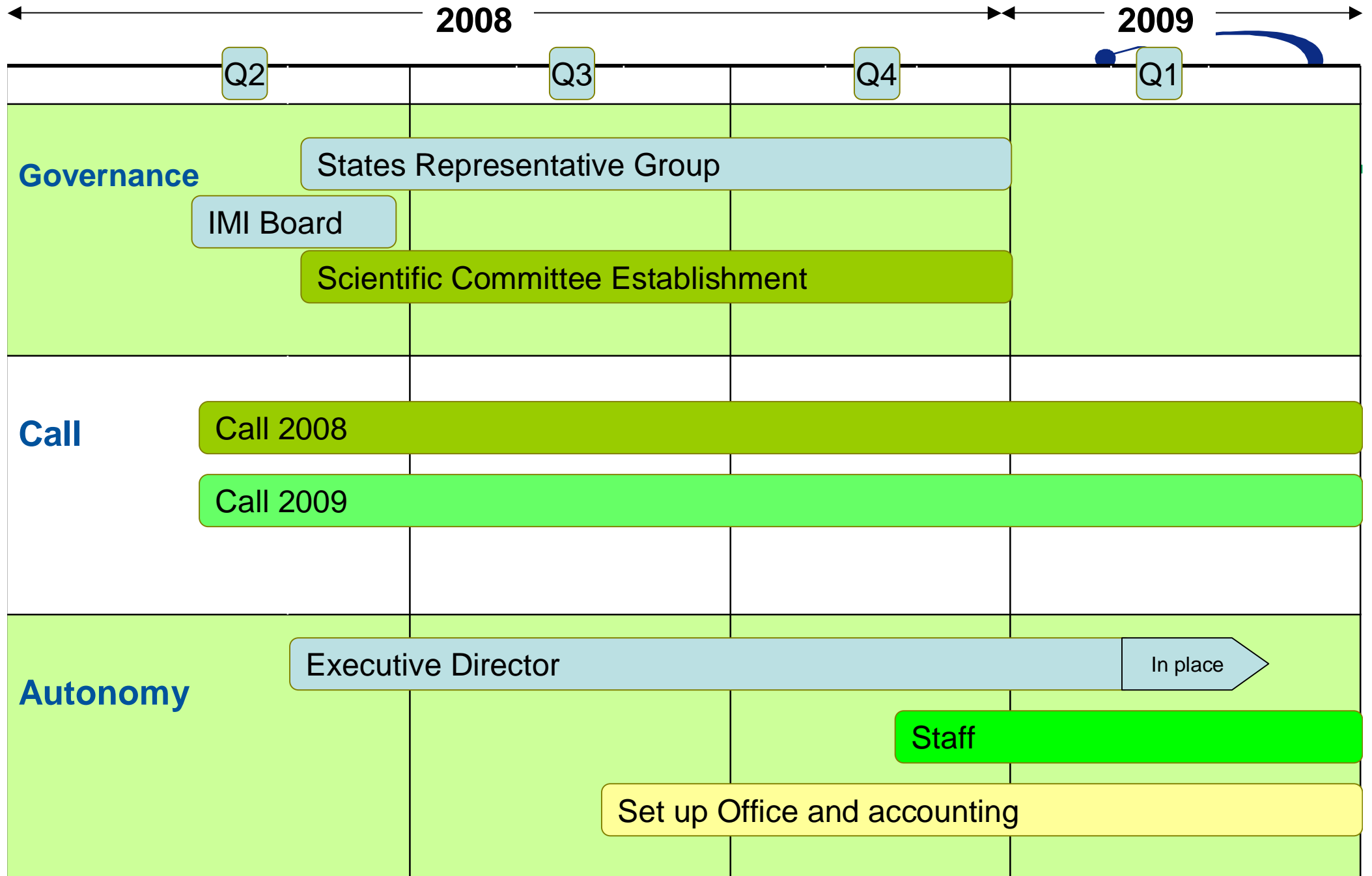
# IMI Interim Period Management Structure (2)



# Current priorities for IMI



- 
- IMI Governance:
    - Get the agreed elements of the governance structure in place
  - IMI autonomy:
    - Progress IMI from its interim period to autonomy (hire staff, establish accounting system)
  - IMI Call 2008:
    - To get quality IMI research projects started as soon as possible with a minimum of bureaucracy.



2008

2009

Q2

Q3

Q4

Q1

**Governance**

States Representative Group

IMI Board

Scientific Committee Establishment

**Call**

Call 2008

Call 2009

**Autonomy**

Executive Director

In place

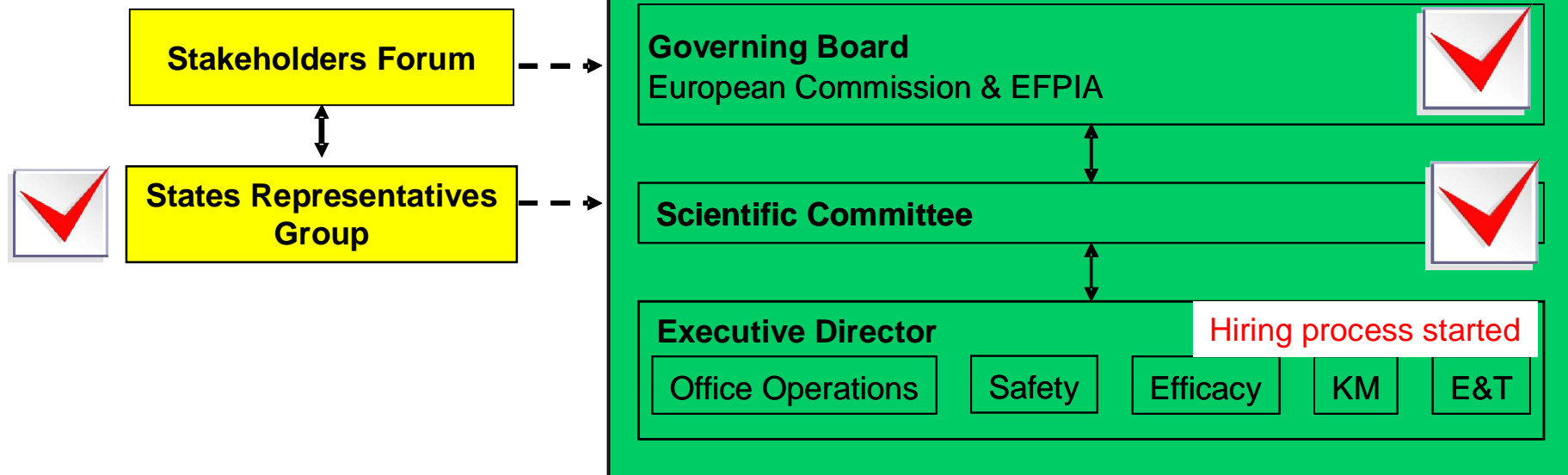
Staff

Set up Office and accounting

# Establishing necessary governance



## IMI Joint Undertaking





# Members of the IMI Governing Board



- Brian Ager, EFPIA Director General
- Andreas Busch, EFPIA Presidency, RDG member, Bayer HealthCare
- Jackie Hunter, RDG Member, GSK
- Carlo Incerti, EBE President, Genzyme
- Jonathan Knowles, RDG Chair, Roche (chair)
- Franco Biscontin, DG Research, Director "Resources"
- Daniel Jacob, DG Research, Deputy Director general in charge of the political framework and simplification (deputy chair)
- Georgette Lalis, DG Enterprise, Director Consumer goods (including legislation)
- Andrzej Jan Rys, DG SANCO, Director Public health and risk assessment
- Zoran Stancic, DG Research, Deputy Director general in charge of scientific advances

# Members of the IMI Scientific Committee



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Avendano, Cristina	Director of the Spanish regulatory agency
Baker, Mary Geraldine	President of the European Federation of Neurological Associations
Bell, John	President of the Academy of Medical Sciences, UK
Crommelin, Daan	Scientific Director of the Dutch Top Institute Pharma
Dulak, Josef	Vice dean for international cooperation at the Jagiellonian University
Gaviraghi, Giovanni	CEO Siena Biotech
Geislinger, Gerd	Board member of ZAFES
Hojgaard, Liselotte	Head of Department of Clinical Physiology and Nuclear medicine & PET and Cyclotron Unit at Copenhagen University Hospital
Jones, Trevor	Consultant
Maggi, Adriana	Director of the Centre of Excellence on Neurodegenerative Diseases of the University of Milano
Noe, Christian	Dean of the Faculty of Life Sciences, Vienna
Sanz, Ferran	Vice-rector for Scientific Policy, University Pompeu Fabra
Sokoloff, Pierre	Head of Exploratory R&D-Neurology and Psychiatry at Pierre Fabre
Vas, Adam	Senior Research Adviser of Gedeon Richter, Budapest
Xenarios, Ioannis	Director of the Swiss Institute of Bioinformatics

# IMI Call 2008 – outcome of Stage 1



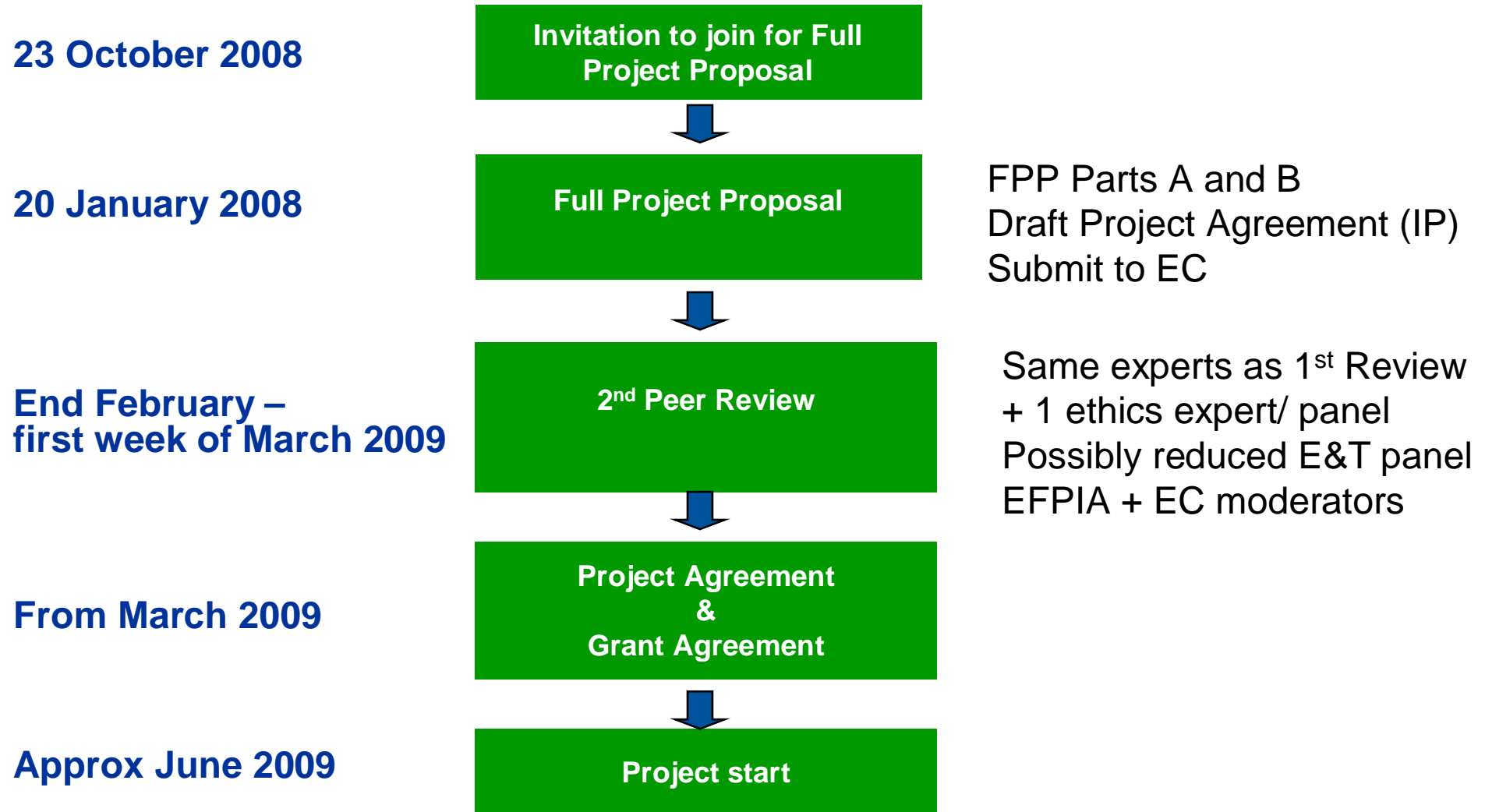
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- 134 Expressions of Interests eligible and evaluated
  - Almost 1300 participating teams
  - At least one Expression of Interest received for each Topic
  - After 1<sup>st</sup> stage evaluations, first ranked applicant consortia chosen as partners by EFPIA consortia for all 18 topics
  - Consortia not among top 3 informed by EC at end of November

# IMI Call 2008 – Stage 2



- Stage 2 launched by the European Commission (EC) on October 23rd
- Decision by EC to take charge of the submission and evaluation process for Stage 2 and to move the deadline for the submission of the Full Project Proposal
- Interim Executive Director Alain Vanvossel sent invitations to EFPIA coordinators with available IMI documentation:
  - Full Project Proposal (FPP):
    - Administration Forms (FPP part A)
    - Template for project description (FPP part B)
  - Evaluation Form Stage 2

# IMI Call 2008 - Stage 2 overview



# Current 2008 call status



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- IMI JU has, by the deadline of 20 Jan, received 18 eligible full project proposals in response to the second stage of the first IMI JU call .
  - A first general screening indicates a total cost of the projects of around 340 M€ , with a total of about 157 M€ "in kind" contribution from EFPIA partners involved, and about 131 M€ requested to the IMI JU.
  - As such, the submission to the second stage can be considered successfull

# 2008 call participation



19/01/2009

## Overview of company participation

	Almirall	Amgen	AstraZeneca	Bayer	BI	Chiesi	Eli Lilly	Esteve	Genzyme	GSK	J&J	Lundbeck	Merck	Merck Serono	Novartis	Novo Nordisk	Orion	Pfizer	Pierre Fabre	Roche	Sanofi Aventis	ScheringPlough	Servier	Sigma-Tau	Solvay	UCB	Wyeth	Companies per topic
1. Immunogenicity			X	X	X				⓪			⓪	⓪	X	X	X		X		X						X		9
2. Carcinogenesis				X	X							X			X	⓪		⓪							X	X		6
3. Expert systems			X	X	X			X		X	N	X			X			X		X						X	N	12
4. Non-clinical safety				X	X									X	X		X			X	X		X		⓪	X		9
5. Translational safety	X	X	X	N	X		X			X	⓪			⓪	X			X		X					⓪			10
6. Pharmacovigilance		X	X	X	⓪		⓪		X	X		X		X	X	X		X		X	X			⓪				12
7. Islet cell research		⓪	X		X		X						⓪		X	X				X	X		X		X			9
8. Surrogate markers			N		X		X									⓪			⓪	X			⓪		X			5
9. Pain			X		X		X	X		X			⓪				X	X	X		X					X	X	11
10. Psychiatry			X				X			X	X	X			X		X	X	X	X			X		X		X	13
11. Neurodegeneration			X		X		X			X	X	X		X	X			⓪	X	X			X		⓪	X		12
12. Severe asthma	X		X		X	X				X			⓪		X			X		X						X		9
13. COPD	X		X		X	X				X			⓪		X			X								X		8
14. E&T: Euro Med. Res.	X	⓪	X	X	X	⓪	⓪	X	X	X	X	X	⓪	X	X	X	X	X	⓪	X	X		⓪	⓪		X		18
15. E&T: Safety Sci.	X	⓪	X	X	X	⓪	X	⓪	⓪	X	X	X	⓪	X	X	X	X	X	⓪	X	X		⓪	⓪		X		17
16. E&T: Pharma Med.	X	X	X	X	X	⓪	⓪	X	⓪	X	X	⓪	⓪	X	X	X	X	X	⓪	X	X		⓪	⓪		X		17
17. E&T: Int. Med.	X	⓪	X	X	X	⓪	X	⓪	X	X	X	X	⓪	X	X	X	X	X	⓪	X	X		⓪	⓪		X		18
18. E&T: Pharmacovig.	X	X	X	X	X	⓪	X	⓪	⓪	X	X	X	⓪	⓪	X	X	X	⓪	⓪	X	X		⓪	⓪		X		15
Participation per company	8	4	16	11	16	2	9	4	3	13	8	9	0	8	16	8	8	12	3	15	9		4	0	4	13	3	

Key: N = New participant after call publication (April 24, 2008); ⓪ = Confirmed withdrawal after call publication

# Next steps



- RDG IMI Priorities for 2009:
- IMI Call 2008: To get quality IMI research projects started as soon as possible with a minimum of bureaucracy
- IMI Call 2009: To launch a successful second IMI Call
  - Current key action: IMI Call 2008 lessons learned exercise involving the European Commission and Call 2008 coordinators
- IMI autonomy: Progress IMI from its interim period to autonomy
  - Current key action: Hiring staff for IMI, Staff policy plan, budget
- Current Status:
- February 02 – March 4: Peer Review of Full Project Proposals including panel meetings
  - EFPIA Coordinators can obviously not be part of this peer review, therefore less Industry input, however, no additional industry experts in Stage 2 were allowed by the European Commission
- March 20: Board approval of final projects.
- March 21-June, 2009: Finalising project agreement, negotiating and signing of Grant Agreements, thereafter possible project start up
- IMI autonomy:
- End of January: Selection of short list candidates for IMI Executive Director



# Selected topics from the RDG for 2009 call



- 1. Imaging biomarkers for anticancer drug development
- 2. New tools for target validation to improve drug efficacy in oncology
- 3. Molecular biomarkers: accelerating cancer therapy development and refining patient care
- 4. Identification and development of rapid point of care diagnostic tests for bacterial diagnosis to facilitate conduct of clinical trials and clinical practice
- 5. Drug/disease modelling: library & framework
- 6. Open pharmacological space
- 7. Electronic Health Records (EHR) data re-use for supporting medical research
- 8. Understanding aberrant adaptive immunity mechanisms in human chronic immune-mediated diseases
- 9. Translational research in chronic immune-mediated disease: bridging between animal models and humans