



Innovative partnerships for innovative medicines

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Industry drivers for IMI



- Globally the large pharma model is becoming more challenging
 - Wealth of opportunity from genomics but huge challenges to translate this into new medicines
 - Increased regulatory pressures
 - Increased cost not matched by increases in new product launches
 - Treating diseases of old age requires new biomarkers and new endpoints
- All large pharma recognise that increased cooperation between industry, academia and other stakeholders will be required to tackle these problems

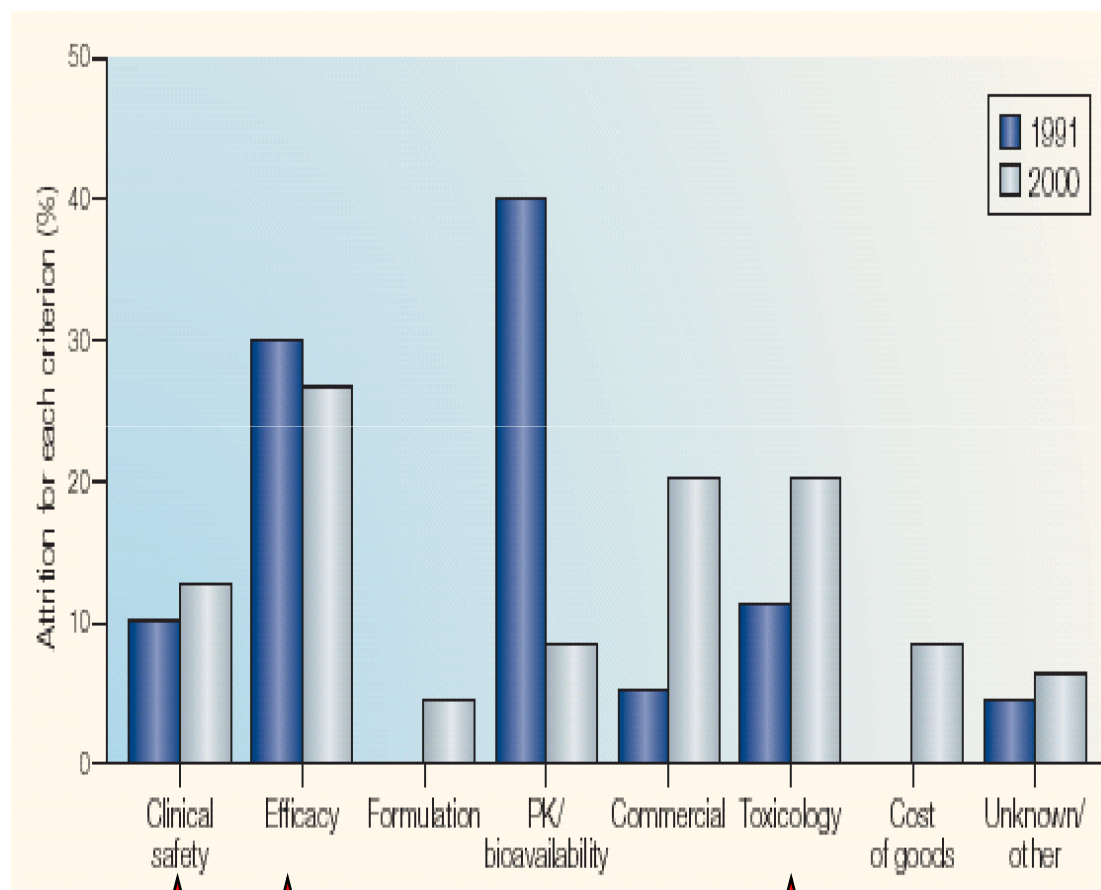
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please cna we make sure bullets are correctly formated and justified - I have done this for the first and last bullet
ajh11705; 10/09/2009



Bottlenecks in drug development



Bottlenecks in drug development:

- Lack of efficacy
- Clinical safety concerns
- Toxicological findings in pre-clinical evaluation



IMI priorities are defined by the Strategic Research Agenda



**The Innovative Medicines Initiative (IMI)
Strategic Research Agenda**

*Creating Biomedical R&D Leadership for Europe
to Benefit Patients and Society*

DATE OF PREPARATION: 15 September 2006 (Version 2.0)

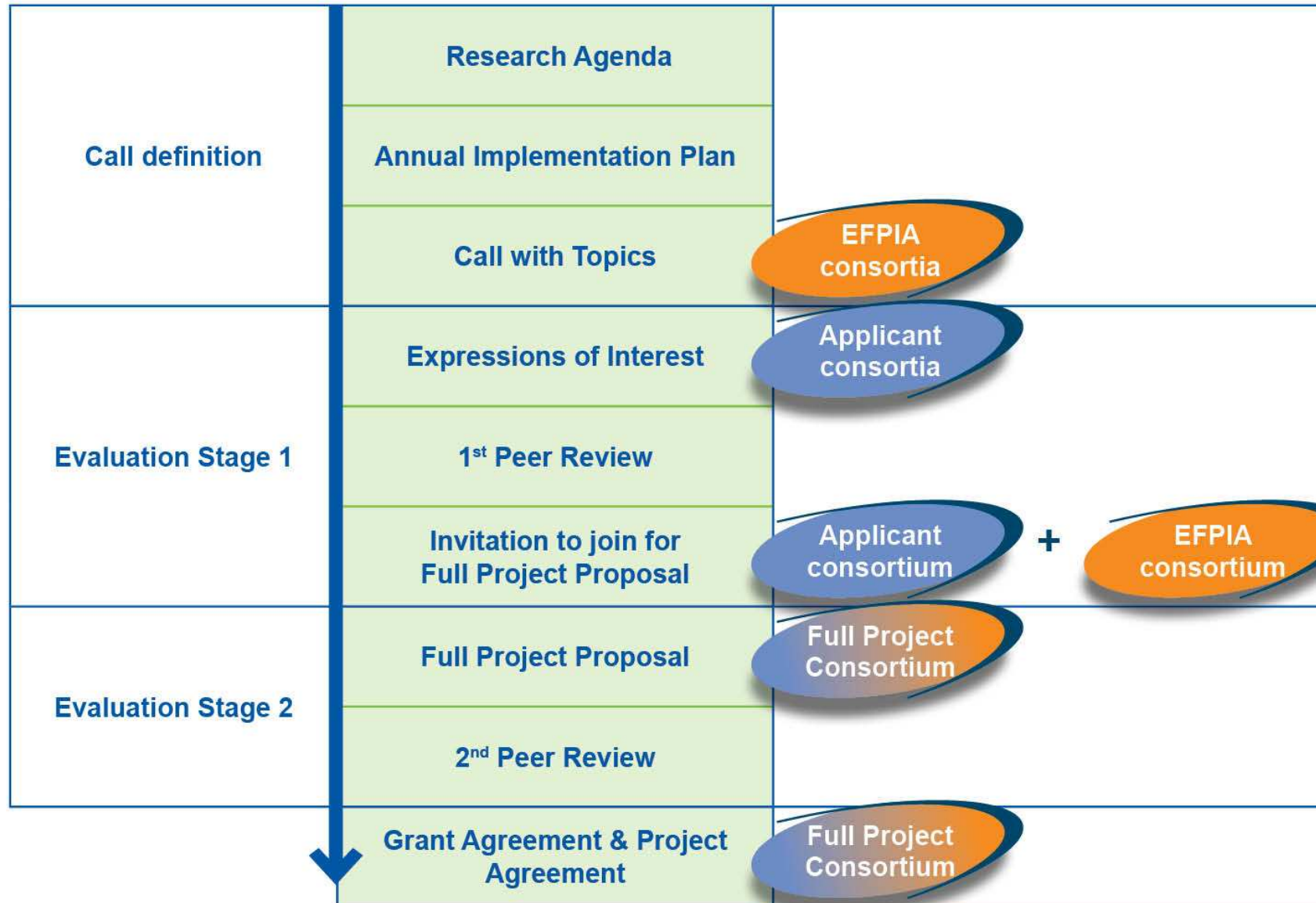
http://www.efpia.org/4_pos/SRA.pdf

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- Research bottlenecks in drug development and a plan to guide their implementation are described in the IMI Strategic Research Agenda
- Published in 2006 and due for review by IMI scientific committee in 2010
- EFPIA Research Directors Group (RDG) selects priority areas for each call from the Strategic Research Agenda



IMI Call process





2009 Call has been announced



Three oncology topics

- Target validation to improve drug efficacy
 - Improved models of disease
 - Integrated bioinformatics of multivariate data in order to generate testable hypotheses (systems biology)
- Molecular biomarkers for accelerating cancer therapy development and accelerating patient care
 - Characterisation of circulating and disseminating tumour cells and circulating tumour cell DNA and RNA
 - Collection and characterisation of cancer stem cells
 - Identification of markers of tumour heterogeneity and marker predictive of therapeutic response
- Imaging biomarkers
 - Markers of tumour proliferation, starvation and death
 - Markers of the invasive phenotype



2009 call (continued)



Infectious diseases

- Identification of rapid point of care diagnostic tests for bacterial diagnosis. Includes:-
 - Differentiation of bacterial and fungal infections from viral
 - Differentiation of gram positive from gram negative bacterial species and diagnosis of markers of resistance

Inflammation

- Aberrant adaptive immunity
 - RA, lupus and IBD
- Translational research in chronic immune-mediated disease (IMD)
 - Improved animal models with increased predictive validity in IMD
 - Bio-banking and translational biomarkers



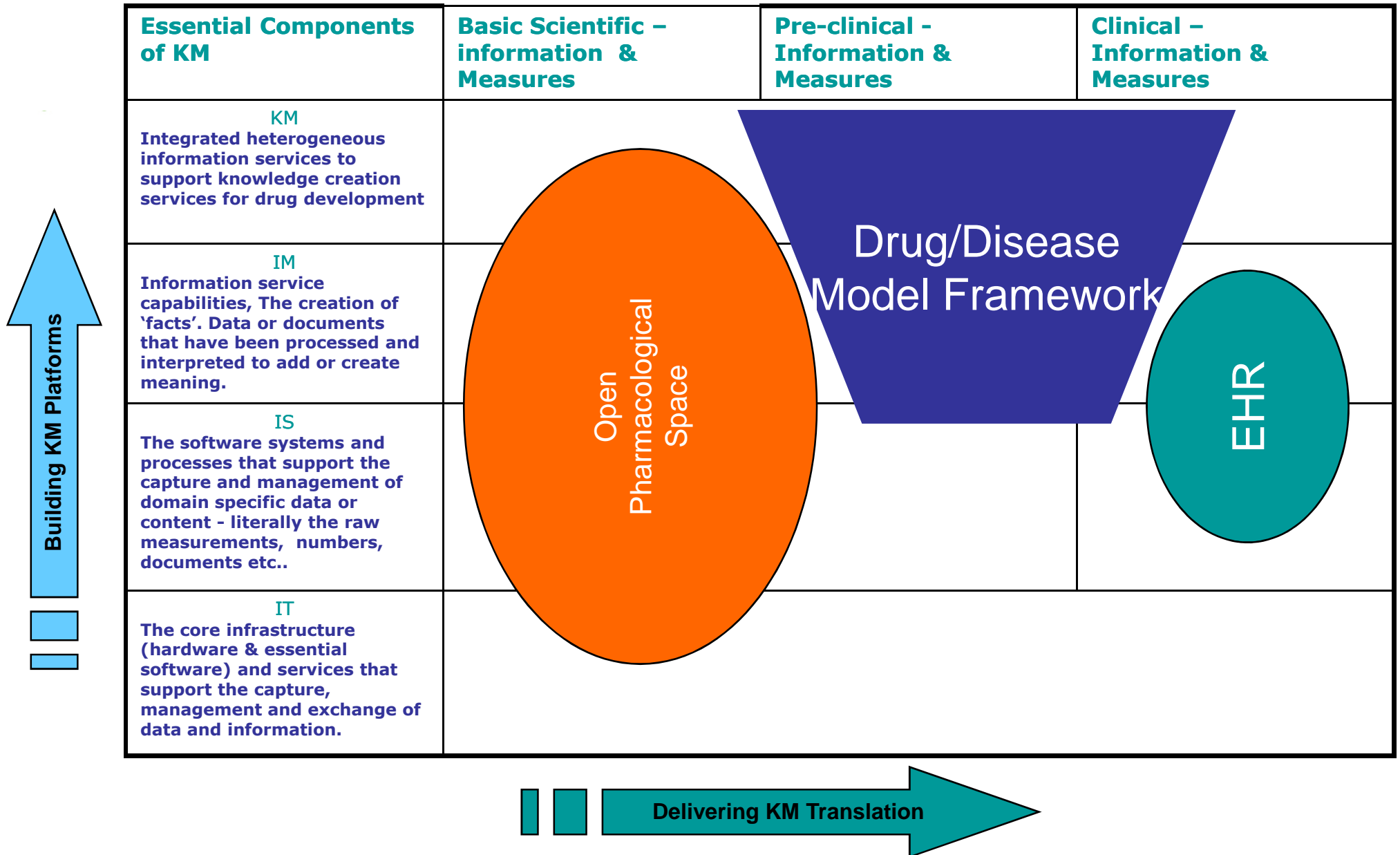
2009 call (continued)



Three knowledge management topics

- Drug/disease modelling including
 - Model library
 - Interoperability framework
 - Standard model mark-up language
 - Standard model description and coding language
- Open pharmacological space
 - Development of a robust infrastructure to link chemical and biological resources in drug discovery
- Electronic health records including
 - Framework and guidelines for emerging EHR projects across Europe
 - Pilot projects
 - HER business model to share EHR data for research purposes and more efficiently connect patients to research

IMI KM Framework – How the KM Calls Fit....





Challenges going forward



- Maintaining communication between all the stakeholders with clear expectations
- Devoting enough time and attention to projects by all participants
- Maintaining effective project management to deliver on milestones and objectives – need early successes
- Ensuring high level of company commitment to subsequent calls
- Ensuring increased involvement of SMEs and patient groups



What has worked well



- Industry can come to consensus on priorities to be addressed
- Bottlenecks can be articulated in specific call topics
- Large consortia **can** be formed around key bottlenecks
- Trust between participants has developed
- Industry in kind contribution can be valued
- IPR and legal issues can be overcome
- Lots of energy, commitment and time from all participants