Innovative Medicines Initiative

Reshaping biopharmaceutical research in Europe

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Agenda

- Urgency to reshape pharmaceutical R&D in Europe
- The challenges facing the R&D-based pharmaceutical sector
- How is industry responding to these challenges?
- The value of IMI and why the pharmaceutical sector is engaging strongly
- A few challenges for IMI
- Moving forward

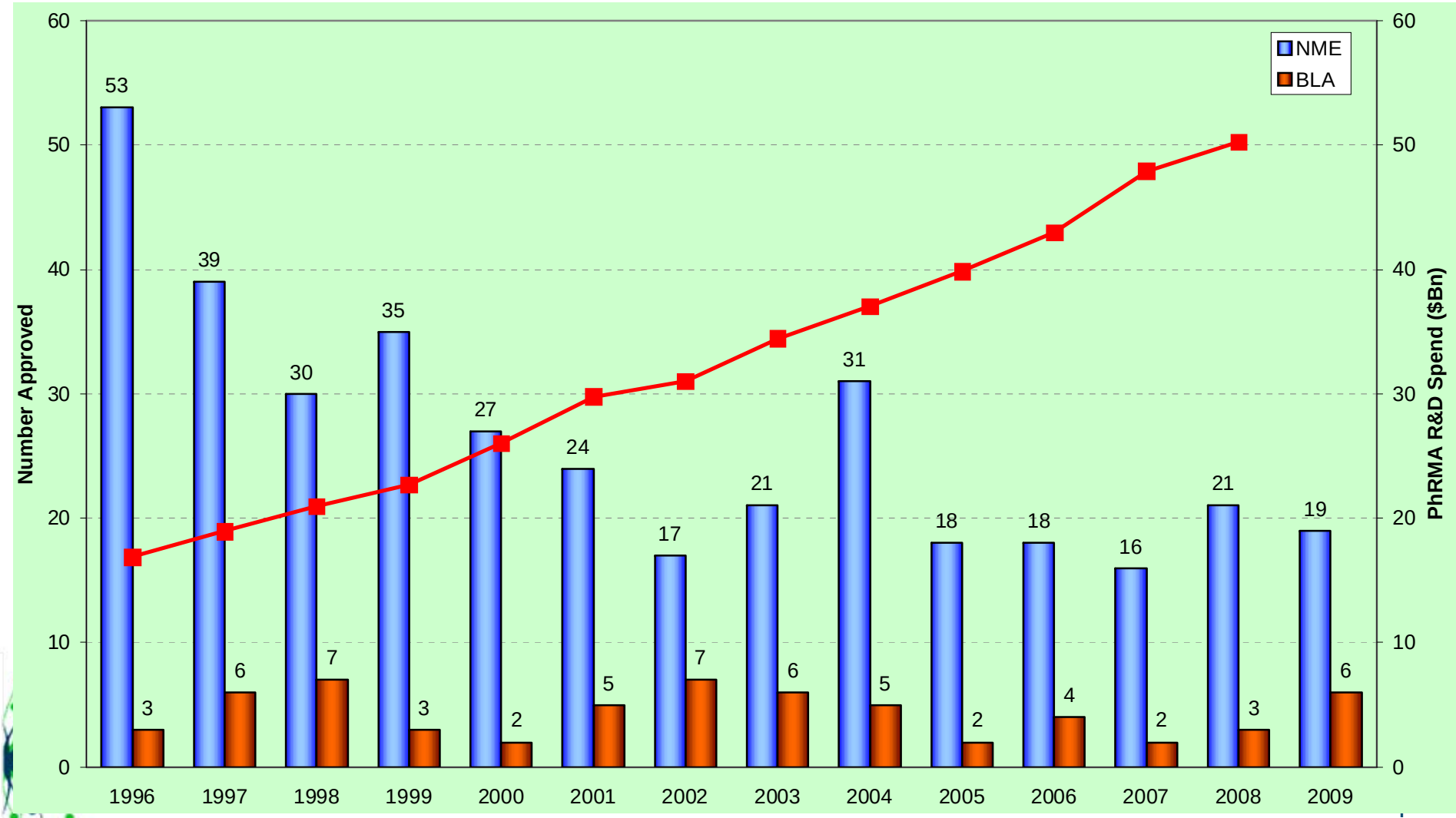
Urgency to reshape pharmaceutical R&D in Europe

- Huge unmet medical need
  - Too many patients still suffering from severe diseases
  - Urgency driven by the number of untreated pathologies
- Ageing global population
  - As Europe's population grows older demands for healthcare provision increase, a scenario of rapidly increasing healthcare costs.
  - By 2050 there will be only two working age citizens for each elderly person in the EU, instead of the current four*
- Greater R&D competition from emerging markets
  - Improving scientific capabilities in developing countries
    - Exponential growth in number of Chinese research publications. More primary research publications than the US**

*EU Economic Policy Committee, on the *"Budgetary challenges posed by ageing populations"*

**http://www.natureasia.com/en/publishing-index/graphs/2010

The challenge: drug approvals decline whilst R&D spend increases



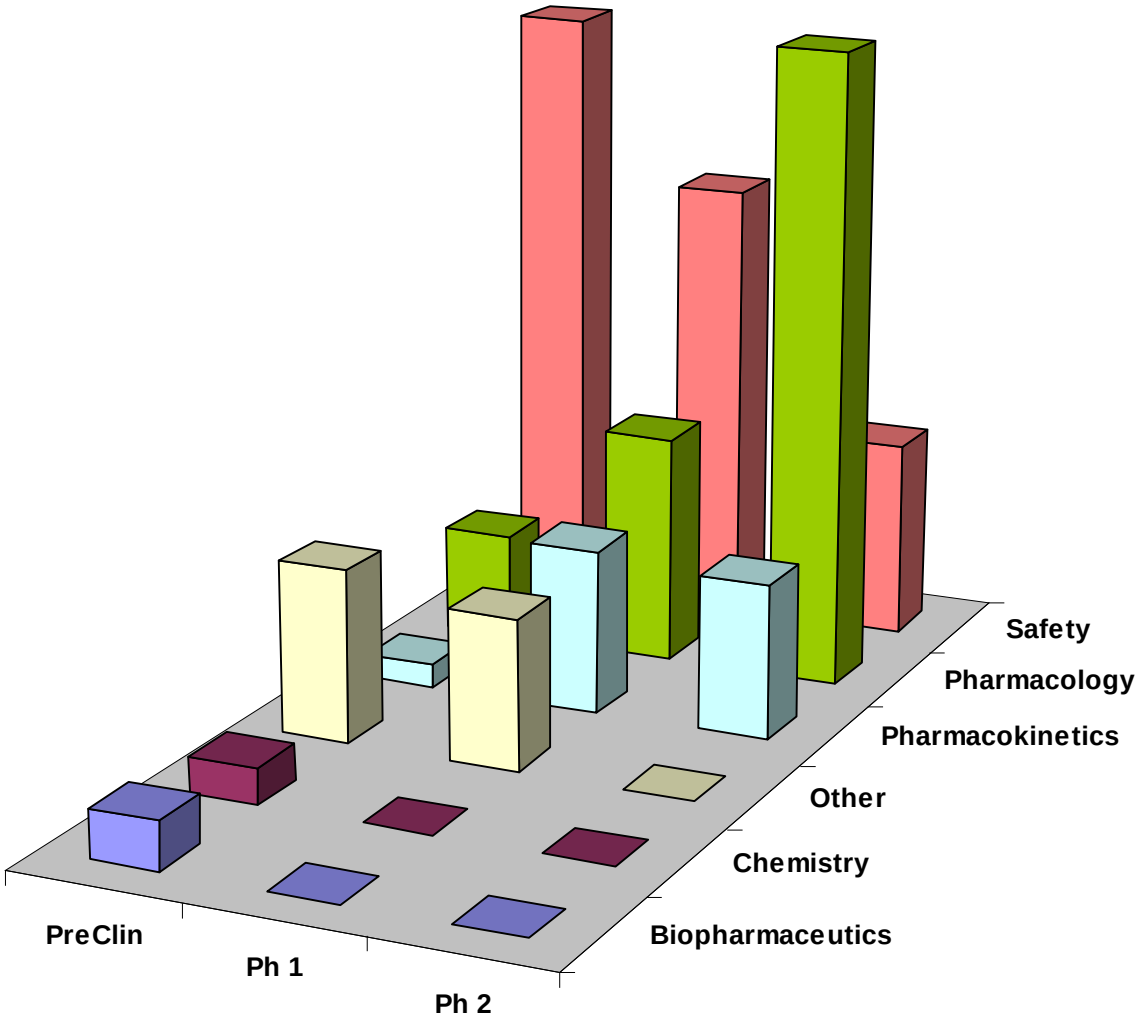
FDA Drug Approvals vs PhRMA Spend 2009

Impact of healthcare reform and cost containment

- Downward pressure on drug prices
  - Economic necessity for governments globally to reduce national drug budgets
  - US Healthcare Reform will cost $2bn in lost sales in 2010*
  - Increase in generic substitution / impact of generic erosion on Pharma revenues
- Cost containment increases pressure on industry and its ability to maintain investment in R&D

*Financial Times, June 2010
**The Economist Pharma Summit, February 2010

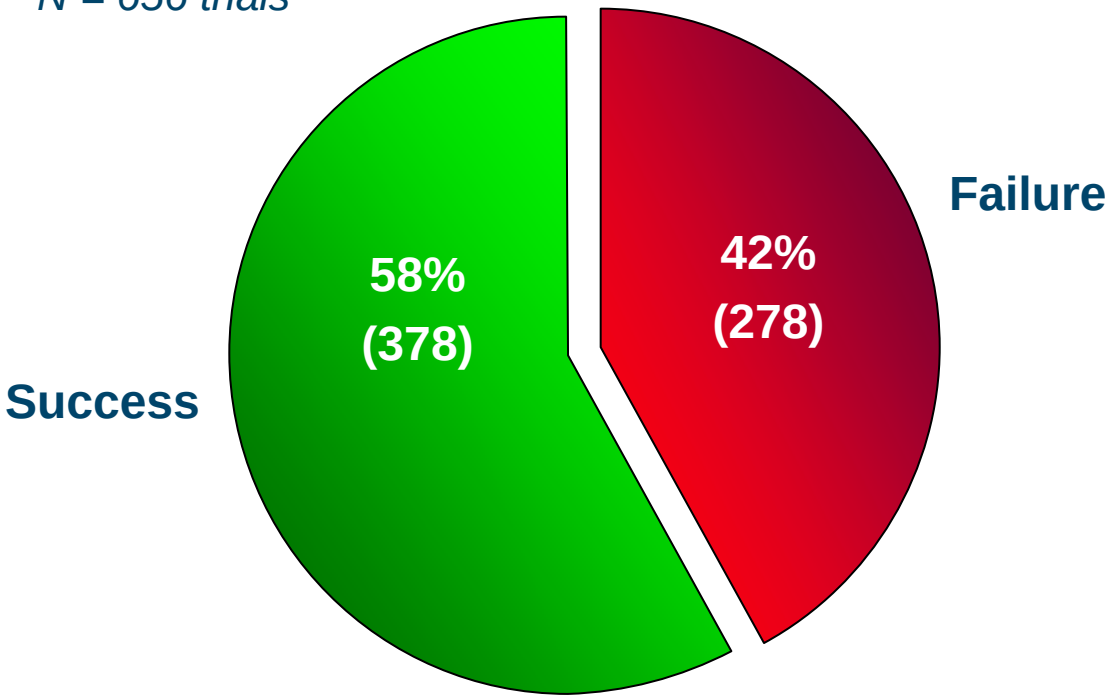
Safety and Efficacy – the major causes of attrition in drug development



Safety and Efficacy – the major causes of attrition in drug development

Phase III trials conducted by large pharmacos (1990-2002)

N = 656 trials



Lack of efficacy versus placebo is the predominant cause of Phase III failures

Source: “Why drugs fall short in late stage trials”, McKinsey Quarterly, Pharmaprojects, Evaluate

How is industry addressing this challenge?

- Identifying and addressing bottlenecks
- Improved disease understanding and stratification
- Improved understanding of toxicological liabilities and ,for Biologicals, immunogenicity liabilities
- Improved Biomarkers to gain early, robust, measurement of drug function, duration of action and dose responsiveness
- Improved quality of compounds progressing, eg selectivity, DMPK properties, pharmaceutical properties
- Improved knowledge management and decision making
- More active collaboration to synergise with complementary skill providers

- ***Some of these solutions will be addressed by company-specific inventions***
- ***Others can be viewed as pre-competitive, generating tools and information to enable the process of drug discovery and development***

How is industry addressing this challenge?

- Industry continues to assess R&D investment rigorously
  - Many pharmas assessing the balance of internal vs external research
- Reaching earlier decisions on drug candidates
  - Generating key data that de-risks the project / increases probability of success, so-called POC-lite
  - ‘Killing’ earlier
- Portfolio segmentation
  - Moving ‘preferred’ candidates faster through R&D
  - To drive efficiency and reduce attrition
- Collaborating more intensely
  - Sharing costs and risk
  - Exploiting ‘open innovation’

Why is industry enthusiastic to collaborate through IMI?

- A unique project with collaboration and open innovation at its heart
  - Truly partnering to increase value and efficiency
- Objectives fully aligned with the current needs to reshape industry R&D in Europe
  - To remove the bottlenecks in drug development
  - To increase the competitiveness of the European pharmaceutical sector
  - To foster Europe as the optimal place to conduct pharmaceutical R&D
  - To bring societal and socio-economic benefits to European citizens

To contribute to the goal of bringing better, more innovative medicines to the patients of tomorrow

Why is industry enthusiastic to collaborate through IMI?

- The ‘research’ pillars of IMI – were developed under the lead of industry and are therefore critical areas for us
  - Predicting **safety**, predicting **efficacy**, improving **knowledge management**, addressing gaps in **education & training**
- IMI is uniquely providing access to world-class research consortia spanning the breadth of Europe
  - Helping industry to forge collaborative relationships with ‘Scientific Excellence Networks’
- IMI is enabling consortia to access new technologies, tools, and knowledge
  - bringing collective improvements in drug R&D productivity
- IMI is setting new standards in sharing pre-competitive data / intellectual property
  - Allowing issues to be addressed beyond the reach of individual companies or institutes
  - Establishing models for collaborative research that will be critical for future progress in areas such as predictive toxicology

What is industry bringing to IMI?

- EFPIA membership has committed to match the EC's €1bn funding through both cash and in-kind contributions (2008-13)
- Beyond that, industry is bringing to the consortia:
  - Provision of high-calibre industrial R&D expertise and insight
    - >400 industry scientists engaged on Call 1/Call 2 projects
  - Access to industry labs and technologies
  - Multi-disciplinary skills (science, training, project management)
  - International reach and critical mass
  - Knowledge of best practice outside Europe

A few challenges

- A project of this scale cannot progress smoothly without a few challenges
  - The complexity of running such large consortia
    - Establishing the best mix of industry and academic cultures within the consortia
    - Encouraging face-to-face meetings under time, travel and budget constraints
  - Difficulties in planning resources and budgets 5 years ahead
  - Industrial organisations offer *similar* in-kind resources – greater diversity would help
  - Importance of managing IP issues

Moving forward

- It has been a remarkable achievement in establishing such complex, international, multi-cultural consortia
  - Very positive feedback received on progress in Call 1 topics
  - Call 2 and Call 3 projects getting underway
- The IMI project has the potential to set a new benchmark in research collaboration and working practice
- Industry reconfirms its commitment to IMI and will work with other stakeholders to ensure delivery of successful outcomes
  - Collectively, we need to improve output and success rates
- There is much at stake – for European R&D, our competitiveness…but most importantly for patients