Contemporary Issues in the For-Profit Mouse Community

"Promoting International Exchange of Mouse Mutant Resources"

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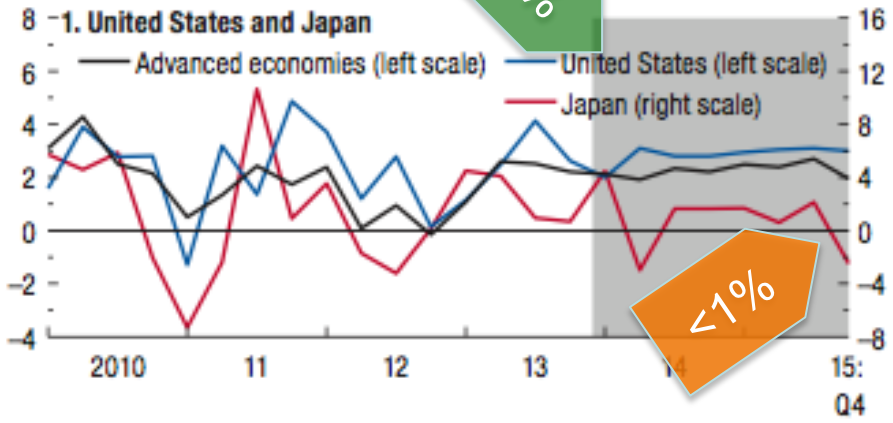
Dr Colin Dunn

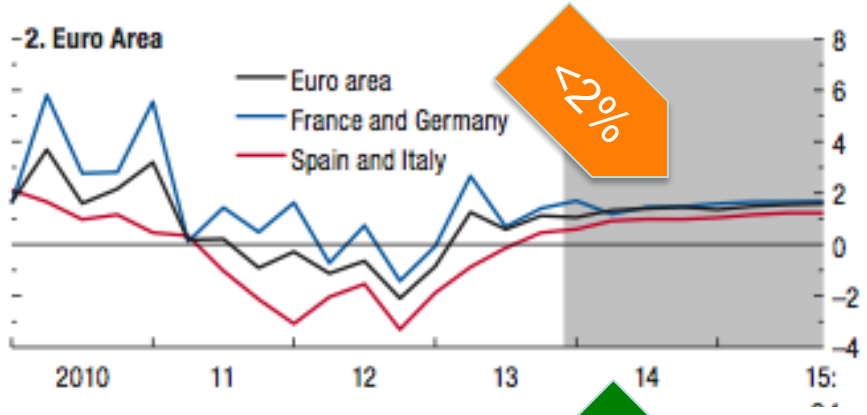
Corp SVP, Research Models and Services, EU and Asia

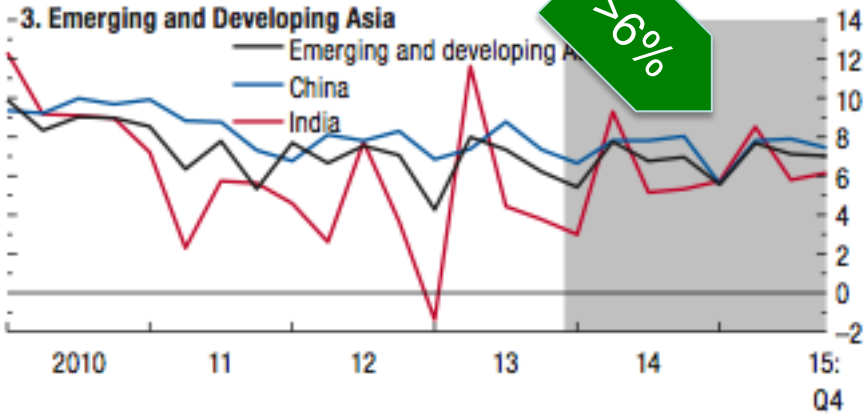
Economic growth returns to “advanced economies” and the business landscape has changed

Figure 1.2. GDP Growth Forecasts
(Annualized quarterly percent change)

Growth in advanced economies is projected to strengthen moderately in 2014–15, building up momentum from the gains in 2013. Growth in the United States will remain above trend, and growth in Japan is expected to moderate, mostly as the result of a modest fiscal drag. Among emerging market economies, growth is projected to remain robust in emerging and developing Asia and to recover somewhat in Latin America and the Caribbean.







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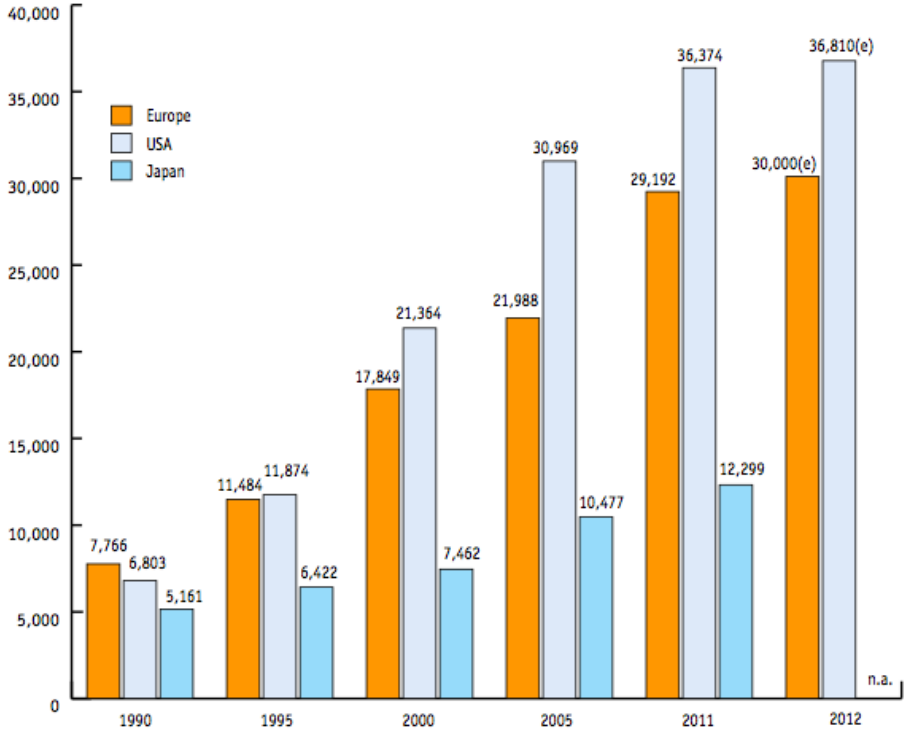
Source: IMF WEO Apr ‘14

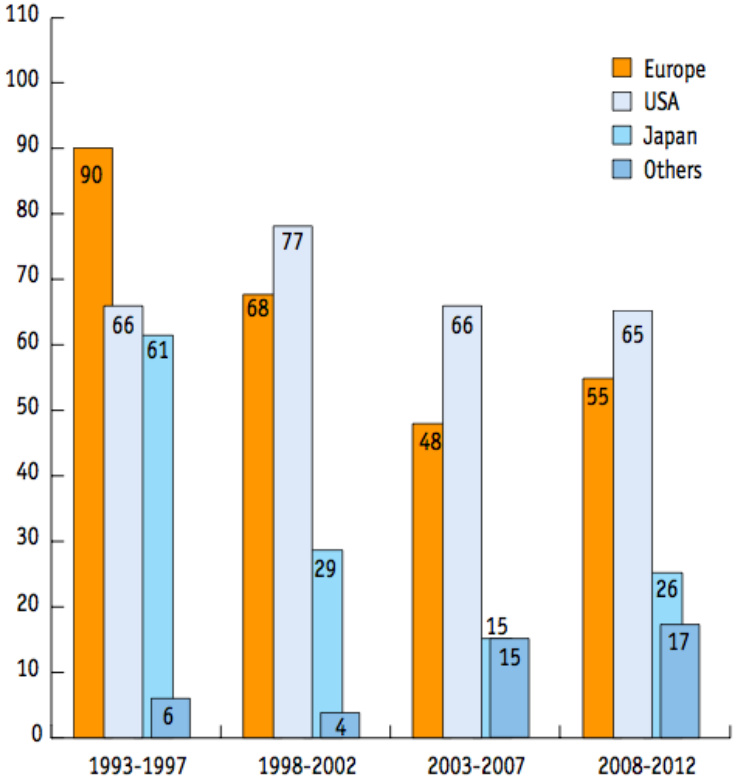
Drug discovery is a key engine in driving the for-profit community

PHARMACEUTICAL R&D EXPENDITURE IN EUROPE, USA AND JAPAN (MILLION OF NATIONAL CURRENCY UNITS*), 1990-2012



* Note: Europe: € million; USA: $ million; Japan: ¥ million x 100
(e): estimate
Source: EFPIA member associations, PhRMA, JPMA

NUMBER OF NEW CHEMICAL OR BIOLOGICAL ENTITIES (1993-2012)



Source: SCRIP – EFPIA calculations (according to nationality of mother company)

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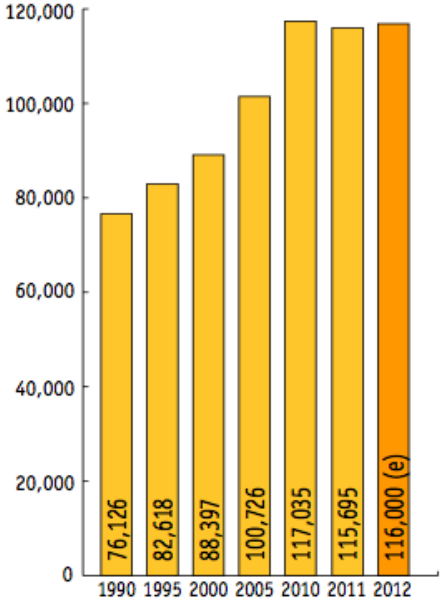
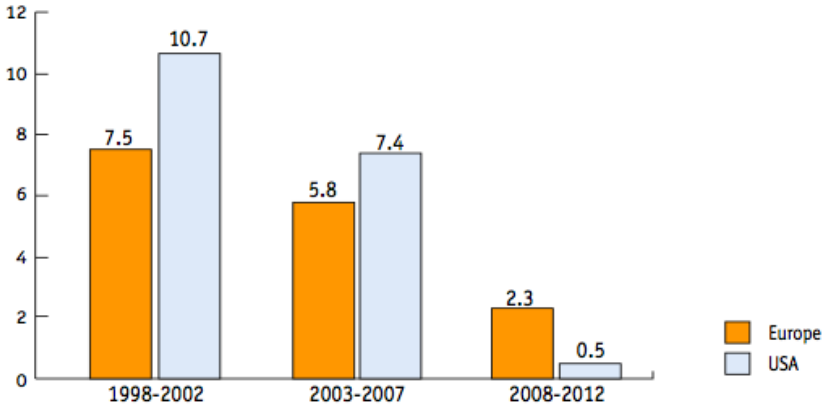
Source: EFPIA Facts and Figures 2013

Pharma R&D has extensively restructured, refocused its innovation

EMPLOYMENT IN PHARMACEUTICAL R&D

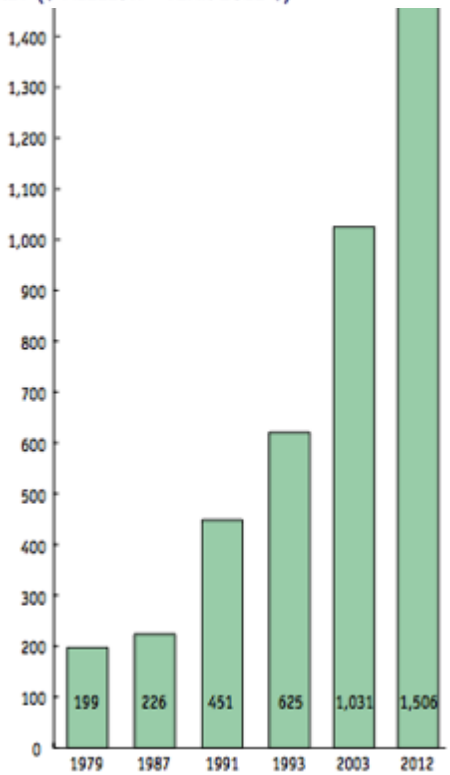


PHARMACEUTICAL R&D EXPENDITURE - ANNUAL GROWTH RATE (%)



Source: EFPIA, PhRMA

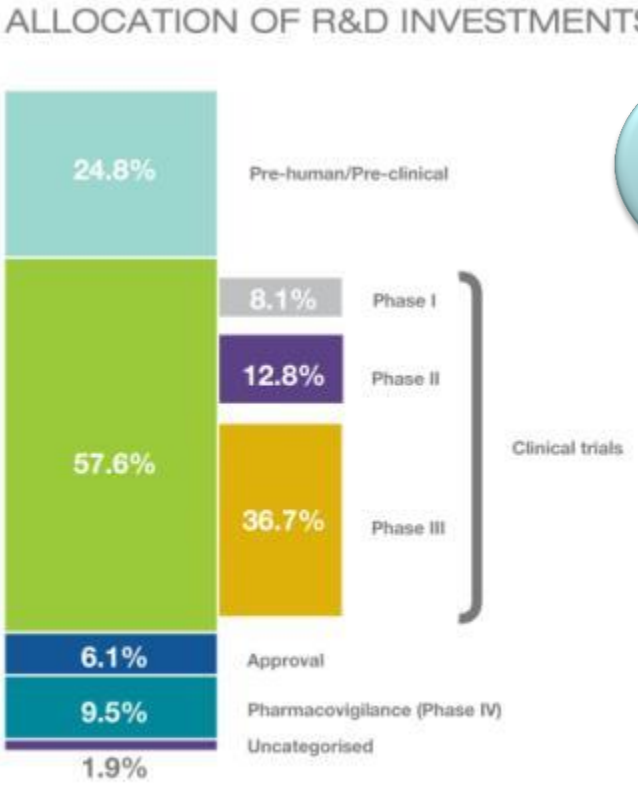
ESTIMATED FULL COST OF BRINGING A NEW CHEMICAL OR BIOLOGICAL ENTITY TO MARKET ($ MILLION - YEAR 2011 $)

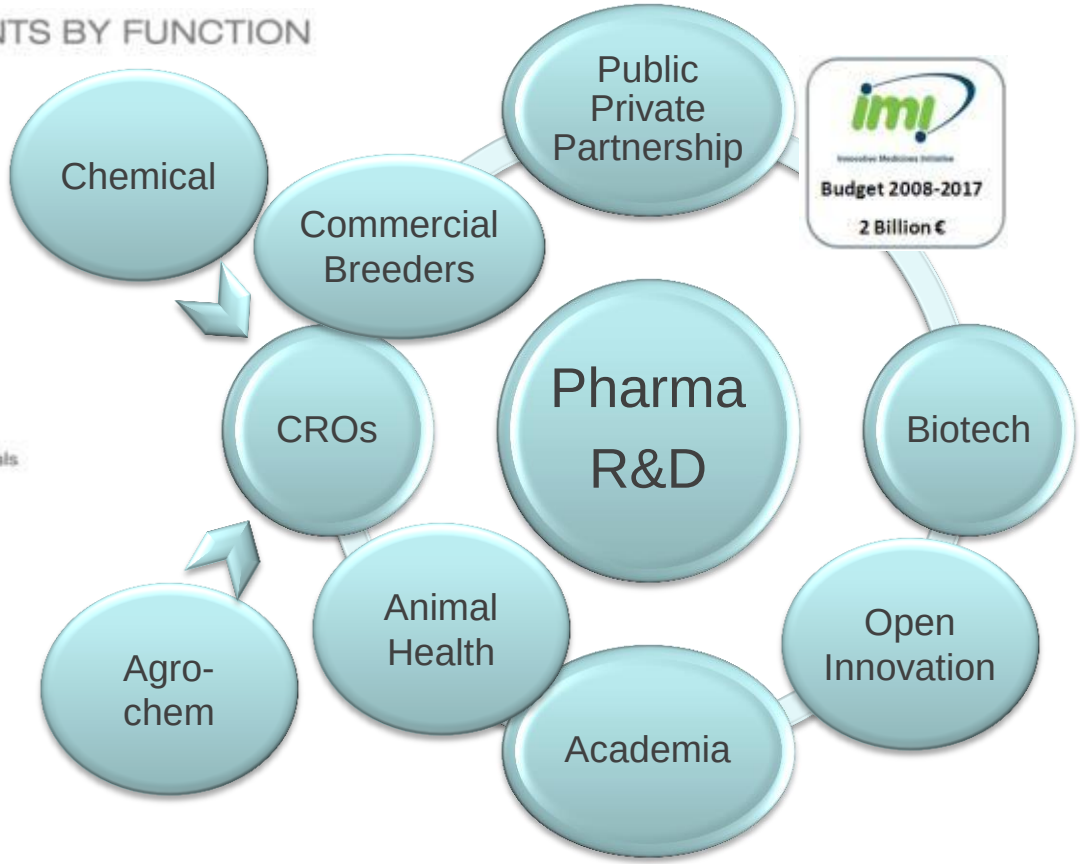


Source: EFPIA Facts and Figures 2013

Structure of industry: new R&D models emerging

Only 25% of total pharmaceutical R&D investment is preclinical and other industries also drive CRO activity





Source: EFPIA Facts and Figures 2013

IMI and IPR

Marquette Intellectual Property Law Review

Volume 18 | Issue 1 Article 19

IP Policy Forum: Intellectual Property Rights (IPR) In Collaborative Drug Development in the EU: Helping a European Public-Private Partnership Deliver - The Need for a Flexible Approach to IPR

Hugh Laverty

Magali Poinot

becoming a partner in an IMI project. Information and IP that are necessary for the completion of the project are identified by each owner prior to the start of the project and defined as 'Background.' The results that are generated during the course of the project as part of its objectives are defined as 'Foreground.' Ownership rights to Foreground can be negotiated and be adapted to the project needs—and here lies one of the key flexibilities in IMI's IP policy. 'Background' and 'Foreground' are then accessible on a royalty-free basis to project participants to the extent necessary for undertaking the project.

Scope of the meeting: external environment

"… Simplify the international exchange of resources …"

- Many elements combine to make this a complicated operating environment
  - Highly regulated activity, highlighted by complexity of guidance and interpretation of EU Dir 2010/63; China has now announced extending existing regulation to include lab animal welfare and ethics
  - Complexity of regulation of genetically engineered lines and consolidation of data to evidence lack of harmful phenotype when transfering between Member States of EU
  - Mutual recognition of competency within EU is driving a common framework for training and education to enable authorisation to conduct regulated procedures
  - Constant pressure in EU political arena to restrict or ban activity, eg Citizen's initiative, STOP Vivisection
  - Pressure on third party service providers to limit or constrain access for research, focus on transport
  - Ambiguity on extension of regulation relating to GMO and containment during transport to protect environment

Scope of the meeting: opportunities

"… Simplify the international exchange of resources …"

- Industry and business has restructured subsequent to the deep economic crisis and patent cliff issues in pharma
  - Public private partnerships are now established with IMI being a flagship, including established IP policy
  - Pre-competitive space has expanded and new approaches to innovation adopted with "open innovation" now common
  - Biotech benefits from spin outs and pharma in-licensing models, VC funding continues to bounce back from 2009
  - CROs benefit from expansion of biotech which has research rather than a development engine
    - pharma also adopting more flexible operating models and redefining what constitutes core expertise
  - CROs integrating commercial breeding operations into business model to extend product/service offer

Scope of the meeting: opportunities

"… Simplify the international exchange of resources …"

- Bioscience hubs and campuses are under development on ex-pharma sites
  - Co-location of biotech and sometimes pharma with developed centralised resources
  - Provides a capacity to supplement or complement the academic cores
  - Managed full service provision allows more flexible exploitation of this available space
- CRO competencies extending into the discovery space and offering efficiency of scale
  - Services based on multiple platforms including biomarker assays
  - Therapeutic and disease area alignment
- Commercial breeders continue to evolve service offers
  - Includes line creation capacity with full service around expansion
  - Strategic alliances are developed and sophisticated relationships managed
  - Strategic relationship between breeders and CRO platforms

Scope of the meeting: competencies

"… Simplify the international exchange of resources …"

- Supply chain concept: more than physical distribution/logistics
  - Hub locations for mice and materials with established and resourced processes to handle the administrative burden with IT tools to support stock/inventory management
  - Integration of reconstitution from cryopreserved materials
- Management of hub to best practices
  - Regulatory authorisations (welfare, GMOs, scientific procedures, transport and shipments, customs)
  - Health status that enables acceptance at receiving facilities
  - Genetic integrity maintained with identity documented
- Diagnostic tools to support rapid quarantine/HM status
  - Non-terminal sampling methodologies vs live animal submission
  - Diminished reliance on sentinel programmes
  - Risk management approach to health status, focus on key agents
  - Consistent/standardised HM report format is realistic
- Management of IPR and MTA administration
  - Clarity of ownership, reach-through and agreed template agreements

Summary

"… Simplify the international exchange of resources …"

- The principle of supply chain is core to what the consortium wishes to achieve
- The private sector has extensively restructured and this has brought flexibility
- The private sector has tools and resources that facilitate the operation of a supply chain
- Challenges in the external environment need collaboration as much as the science does
- IPR models now exist to enable public private partnerships