La "Iniciativa Medicamentos Innovadores" para crear un liderazgo biomédico en Europa que beneficie a los pacientes y a la sociedad

Helmut Buschmann

La "Iniciativa Medicamentos Innovadores" (IMI) es una exclusiva colaboración paneuropea de los sectores público y privado que engloba a organizaciones de pacientes, universidades, hospitales, autoridades reguladoras y varias pequeñas y grandes empresas biofarmacéuticas y sanitarias. El objetivo de la IMI es fomentar un descubrimiento y desarrollo más rápido de mejores medicamentos.

Más de 350 representantes de organizaciones de pacientes, universidades, hospitales, autoridades reguladoras y varias pequeñas y grandes empresas biofarmacéuticas y sanitarias trabajaron juntos para crear la Agenda Estratégica de Investigación (*Strategic Research Agenda [SRA]*). Este documento aporta recomendaciones para prever la seguridad y eficacia de nuevos medicamentos, así como planes para llenar las lagunas en gestión del conocimiento y en educación y formación, que son las principales causas de demora en el complejo proceso de desarrollar nuevos medicamentos.

La Agenda Estratégica de Investigación es asimismo un "mapa de carreteras" para guiar en la rápida implementación de la IMI. La Comisión Europea y la Federación Europea de Industrias y Asociaciones Farmacéuticas (EFPIA) proponen la creación y funcionamiento de una nueva sociedad público-privada que dirija y coordine el desarrollo de Proyectos Centrados en Pacientes para acelerar el descubrimiento y el desarrollo de medicamentos innovadores más eficaces. La creación real de esta organización está pendiente de una decisión favorable por parte de las instituciones de la UE.

La visión de la IMI es crear un liderazgo en I+D biomédico para Europa que beneficie a los pacientes y a la sociedad. La IMI es una poderosa asociación estratégica entre la Comisión Europea y la EFPIA, las cuales apoyan a la Plataforma Tecnológica Europea de Medicamentos Innovadores con recursos estratégicos y financieros.

El objetivo de la IMI es fomentar un descubrimiento y desarrollo más rápidos de mejores medicamentos para los pacientes, así como potenciar la competitividad de Europa asegurando que su sector biofarmacéutico siga siendo un dinámico sector de alta tecnología. La IMI garantizará que el sector biofarmacéutico europeo reciba apoyo estratégico específico para beneficio de pacientes, científicos y ciudadanos de Europa. La IMI propone varias vías prácticas y claras para acelerar el descubrimiento y el desarrollo de más medicamentos innovadores eficaces con menos efectos secundarios.

La IMI implementará innovadores proyectos de investigación centrados en pacientes que aborden, mediante poderosas asociaciones público-privadas, las principales causas de demora o cuellos de botella que se producen actualmente en el proceso de descubrimiento y desarrollo de nuevos medicamentos. Estos cuellos de botella han sido identificados como predicción de seguridad, predicción de eficacia, superación de lagunas en gestión del conocimiento y superación de lagunas en educación y formación. La Agenda Estratégica de Investigación, en un documento vivo que se irá actualizando con los avances científicos, describe las recomendaciones para abordar estos cuellos de botella y proporciona un plan guía para su implementación.

Mayor competitividad europea

- La Plataforma Tecnológica Europea de Medicamentos Innovadores es importante para Europa porque contribuye al objetivo del Consejo Europeo de Lisboa de construir, para 2010, la economía basada en el conocimiento más competitiva y dinámica del mundo.
- La Plataforma Tecnológica Europea de Medicamentos Innovadores es importante para Europa porque los retos científicos a los que debe enfrentarse son demasiado complejos para que las organizaciones los aborden de forma aislada. Por tanto, la colaboración y la coordinación de los sectores público y privado a escala paneuropea son esenciales para garantizar que los pacientes puedan beneficiarse de los avances en biotecnología, como la descodificación del genoma humano.
- La Plataforma Tecnológica Europea de Medicamentos Innovadores es importante para Europa porque asegura su prosperidad a largo plazo a través de la biotecnología, considerada por la Unión Europea como esencial para desarrollar una economía basada en el conocimiento dinámica e innovadora.

Claros beneficios para pacientes, científicos y Europa

- Los pacientes se beneficiarán de un descubrimiento y desarrollo más rápidos de medicamentos de mayor calidad.
- Los científicos se beneficiarán de un entorno profesional más atractivo, evitando fugas de cerebros.
- La creación de experiencia y *know-how* europeo en nuevas tecnologías atraerá inversiones en I+D biomédico en Europa.
- La creación y el apoyo de ventajas competitivas sostenibles para micro, pequeñas y medianas empresas (PyMES), *spin-offs* y *start-ups*, potenciarán la economía europea.

La plena implementación de la IMI requerirá una inversión de aproximadamente 460 millones de euros anuales por un periodo inicial de siete años con inicio en 2007, una inversión compartida por la Comisión Europea y la Federación Europea de Industrias y Asociaciones Farmacéuticas.

Una potencial inyección global de nuevos fondos de más de 3000 millones de euros para impulsar la base científica europea y estimular el descubrimiento y desarrollo más rápido de medicamentos de mayor calidad. Como parte del VII Programa Marco de Investigación de la Unión Europea, se propondrá que la IMI tenga rango de Iniciativa Tecnológica Conjunta –sujeta a aprobación por el Consejo de Competitividad de la UE en 2007.

La Comisión Europea y la Federación Europea de Industrias y Asociaciones Farmacéuticas se responsabilizarán conjuntamente de la creación y funcionamiento de una nueva organización internacional, sin ánimo de lucro, basada en el artículo 171 del Tratado Constitutivo de la Comunidad Europea. Esta organización tendrá mandato legal para conceder importantes becas de investigación a colaboraciones público-privadas europeas para conducir proyectos de investigación innovadores centrados en pacientes y que se ocupen de las principales causas de demora o cuellos de botella en el descubrimiento y el desarrollo de nuevos medicamentos.

El VII Programa Marco de Investigación de la Unión Europea financiará a los académicos que participen en dichas colaboraciones público-privadas y brindará apoyo a las PyMES, mientras que las compañías biofarmacéuticas financiarán sus propias contribuciones al 100%. El apoyo prestado a otros tipos de organizaciones que participen en dichas colaboraciones público-privadas se evaluará caso por caso. Con esta estructura, el dinero público se utilizará exclusivamente para impulsar el potencial de I+D del sector público y de las pequeñas empresas de biotecnología, pero no de las compañías biofarmacéuticas. Los socios de la industria biofarmacéutica equipararán los fondos del VII Programa Marco de Investigación de la Unión Europea con recursos I+D como personal, laboratorios, materiales e instalaciones de investigación clínica.

The "Innovative Medicines Initiative" for creating biomedical leadership for Europe to benefit patients and society

Helmut Buschmann

The Innovative Medicines Initiative (IMI) is a unique pan-European public and private sector collaboration between patient organizations, universities, hospitals, regulatory authorities, as well as small and large biopharmaceutical and healthcare companies. The objective of IMI is to support the faster discovery and development of better medicines.

Over 350 senior representatives of patient organizations, universities, hospitals, regulatory authorities as well as small and large biopharmaceutical companies worked together to produce the Strategic Research Agenda. This document describes recommendations on predicting safety and efficacy of new medicines as well as plans to bridge gaps in knowledge management and in education and training. These are the principal causes of delays in the complex process of developing new medicines.

The Strategic Research Agenda is also a roadmap to guide the rapid implementation of IMI. The European Commission and EFPIA are proposing to create and operate a new public private partnership to lead and co-ordinate the development of patient-centred projects to accelerate the discovery and development of more effective innovative medicines. Building this organization is pending a favorable decision by the EU Institutions.

Creating biomedical R&D leadership for Europe to benefit patients and society is the vision of IMI, which is a powerful strategic partnership between the European Commission and EFPIA, who are supporting the Innovative Medicines Initiative with strategic and financial resources.

The aim of IMI is to support the faster discovery and development of better medicines for patients and enhance Europe's competitiveness by ensuring that its biopharmaceutical sector remains a dynamic high-technology sector. IMI will ensure that Europe's biopharmaceutical sector receives targeted strategic support for the benefit of patients, scientists and citizens of Europe. IMI proposes a number of clear, practical paths that will accelerate the discovery and development of more effective innovative medicines with fewer side effects.

IMI will implement innovative patient-centred research projects that address the principal causes of delay or bottlenecks in the current process of discovering and developing new medicines through powerful public–private collaborations. These bottlenecks have been identified as predicting safety, predicting efficacy, bridging gaps in knowledge management and bridging gaps in education and training. The Strategic Research Agenda, a living document that will be updated based on scientific advances, describes the recommendations to address these bottlenecks and provides a plan to guide their implementation.

Enhanced European Competitiveness

- The Innovative Medicines Initiative is important for Europe because it contributes to the European Union's Lisbon Objective of building the most competitive and dynamic knowledge-based economy in the world by 2010.
- The Innovative Medicines Initiative is important for Europe because the scientific challenges facing

Europe are too complex for organizations to address in isolation. Therefore pan-European public and private sector collaboration and coordination is essential to ensure that patients benefit from advances in biotechnology, such as the decoding of the human genome.

- The Innovative Medicines Initiative is important for Europe because it secures long-term prosperity for Europe through biotechnology, which the European Union considers to be essential for developing a dynamic and innovative knowledge-based economy.

Distinct Benefits for Patients, Scientists and Europe

- Faster discovery and development of better medicines will benefit patients.
- A more attractive professional environment will benefit scientists, addressing the brain-drain.
- The creation of European expertise and know-how in new technologies will attract biomedical R&D investment in Europe.
- The creation and support of sustainable competitive advantage for Micro, Small and Medium-Sized Enterprises (SME), spin-offs and start-ups will enhance Europe's economy.

To fully implement IMI would require an investment of about €460 million per year for an initial seven-year period, starting in 2007, shared between the European Commission and the European Federation of Pharmaceutical Industries and Associations.

A potential overall injection of over €3 billion of new funding to boost Europe's science base and stimulate the faster discovery and development of better medicines. As part of the European Union's 7th Research Framework Program, IMI will be proposed for Joint Technology Initiative status – subject to approval by the European Competitiveness Council in 2007.

The European Commission and European Federation of Pharmaceutical Industries and Associations will take joint responsibility for creating and operating a new international not-for-profit organization based on article 171 of the Treaty establishing the European Community. This organization will have a legal mandate to award significant research grants to European Public–Private Collaborations to conduct innovative patient-centred research projects focused on the principal causes of delay or bottlenecks in discovering and developing new medicines.

The European Union's 7th Research Framework Program will fund academic participants of Public–Private Collaborations and support SMEs, while the biopharmaceutical companies will fund their own contributions to 100%. Other types of organizations participating in Public–Private Collaborations will be supported on a case-by-case basis. With this structure, public money will be used to exclusively boost the R&D capabilities of the public sector and small biotech companies and not biopharmaceutical companies. The biopharmaceutical industry partner(s) will match the funds from the European Union's 7th Research Framework Program with R&D resources such as staff, laboratories, materials and clinical research capabilities.

Diapositivas / *Slides*

The EU must turn political objectives into policy reality

Lisbon Objectives March 2000

The most competitive and dynamic knowledge based economy in the world by 2010

3% of GDP invested in R&D (public and private)

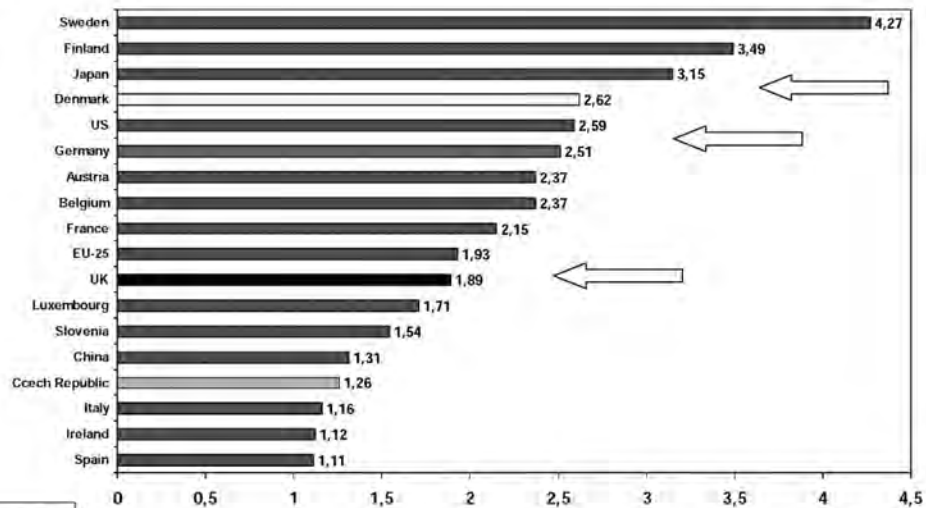
EC Policy Initiatives

European Technology Platforms
(To define Research agenda for important sectors with all stakeholders and industry leadership)

Proposed doubling of the EU budget for Research

R&D intensity as % of GDP, 2003

Source: European Commission - DG Research, Key Figures 2005



R & D Expenditure in the European Union (2004)

- In 2004 the **EU25** spent nearly 200 billion euro on Research & Development (R&D).
- R&D intensity (i.e. expenditur as a percentage of GDP) in the **EU25** stood at 1.90% compared to 1.92% in 2003.
- R&D intensity remained significantly lower in the **EU25** than in other major economies. In 2003, R&D expenditure was 2.59% of GDP in the **United States**, 3.15% in **Japan**, while it was 1.31% in **China**.
- In 2003 the business sector financed 54% of total **EU25** R&D expenditure, while the shares of the business sector in the **United States** and **Japan** were 63% and 75% respectively.
- The EU goals in Research and Development, as set by the Lisbon summit strategy, are to achieve by 2010 a R&D intensity of at least 3% for the EU as a whole, and to have two thirds of R&D expenditure financed by the business sector.

Source: eurostat news release 156/2005 – 6 December 2005

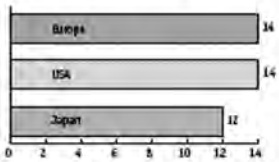
R&D intensity varies from 0.3% of GDP in Malta to 3.7% in Sweden

- In 2004, the highest R&D intensities among the Member States were registered in **Sweden** (3.74% of GDP) and **Finland** (3.51%), followed by **Denmark** (2.63%), **Germany** (2.49%), **Austria** (2.26%) and **France** (2.16%). The
- lowest intensities were found in **Malta** (0.29%), **Cyprus** (0.37%), **Latvia** (0.42%) and **Slovakia** (0.53%).
- Annual average growth rates of R&D expenditure over the period 2001 to 2004 ranged from +16% in **Estonia**, +15% in **Cyprus**, +12% in **Lithuania** and +10% in **Spain** (between 2001 and 2003) to -4% in **Portugal** (2001-2003) and -2% in **Belgium**, **Slovakia** and **Sweden**.

Source: eurostat news release 156/2005 – 6 December 2005

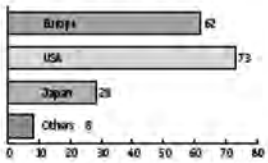
United States vs Europe (EU25)

ORIGIN OF THE TOP 40 COMPANIES BY R&D EXPENDITURES, 2002



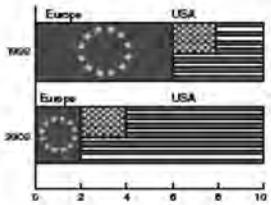
Source: UK Department of Trade and Industry, R&D Scoreboard, 2002-2003 - EFPIA calculations

NEW CHEMICAL AND BIOLOGICAL ENTITIES LAUNCHED IN THE PAST FIVE YEARS, 1999-2003



Source: SCRIP, 2004 - EFPIA calculations

ORIGIN OF THE TOP 10 MEDICINES BY WORLDWIDE SALES

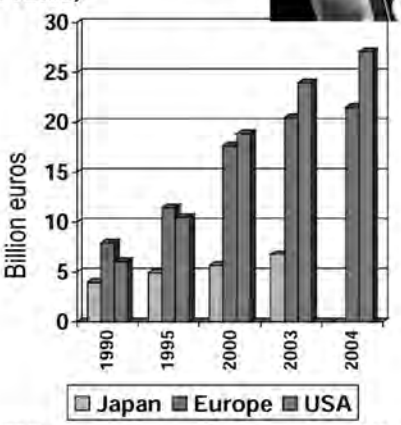


Source: IMS Health, 2003

It's time to re-establish our science base – before it's too late

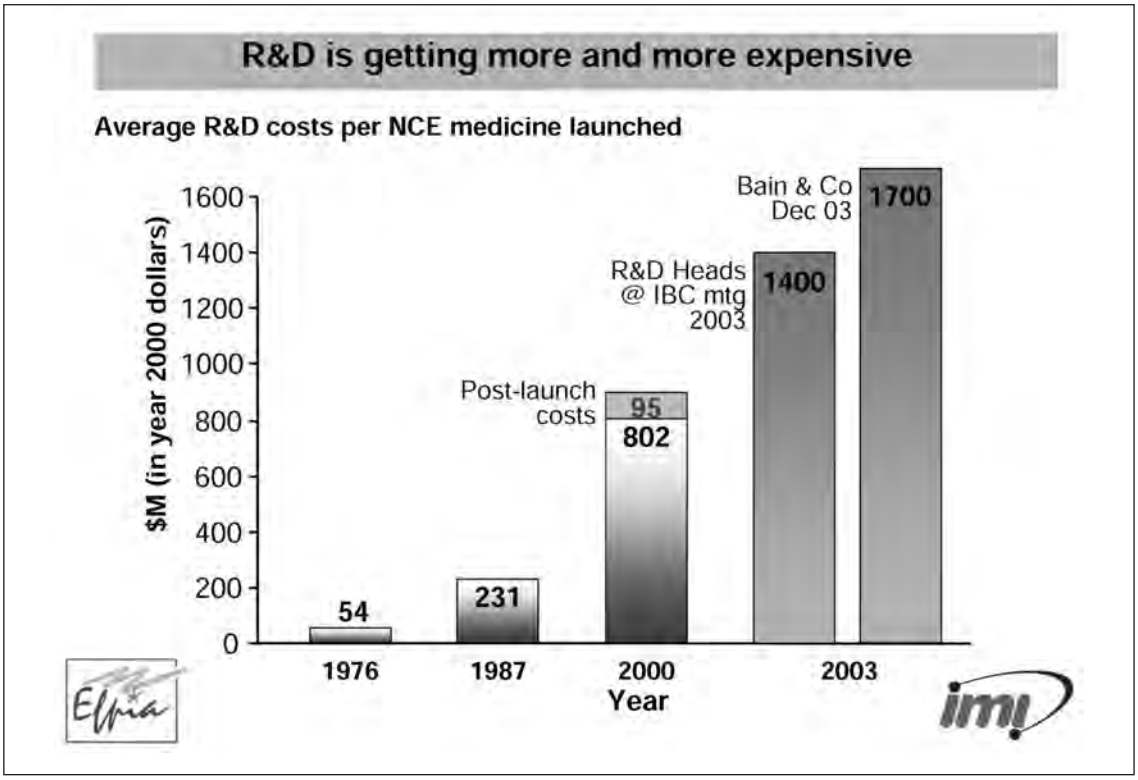
Pharmaceutical R&D expenditure in Europe, USA and Japan (at 2003 constant exchange rates)

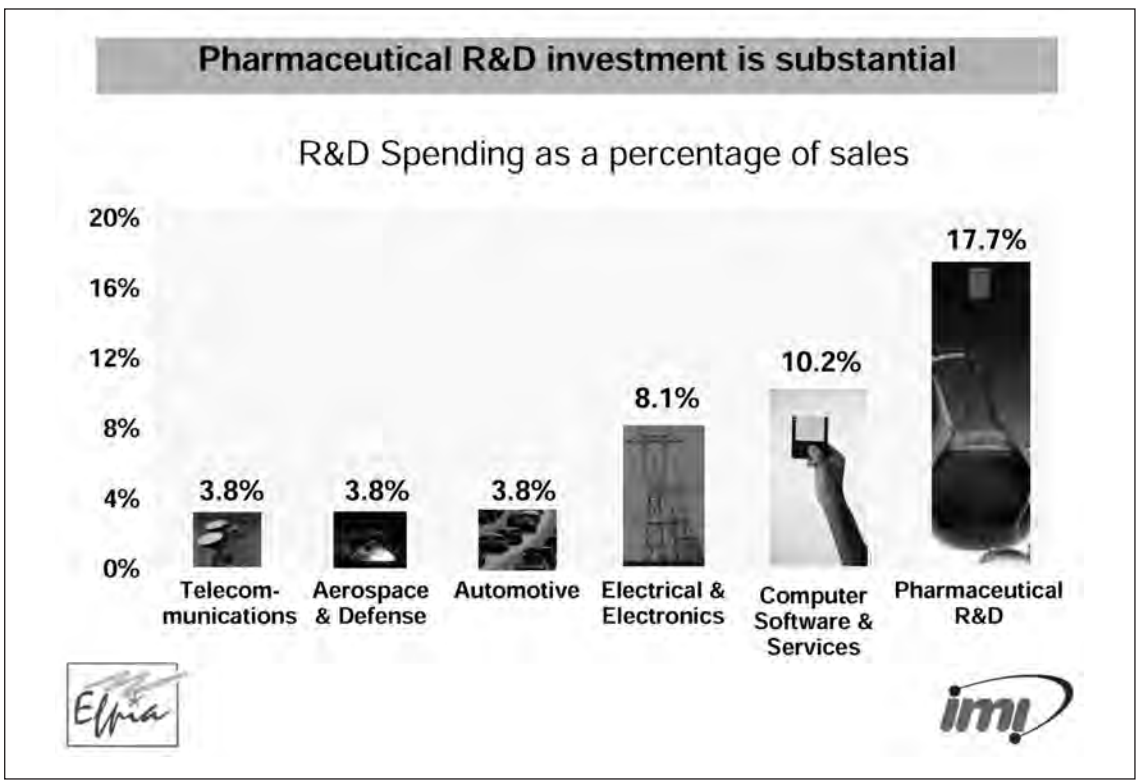
- Declining investment in R&D in Europe
- European Commission is exploring ways to achieve the Lisbon goals
- EFPIA sets the Priority of "Strengthening the EU Science base"

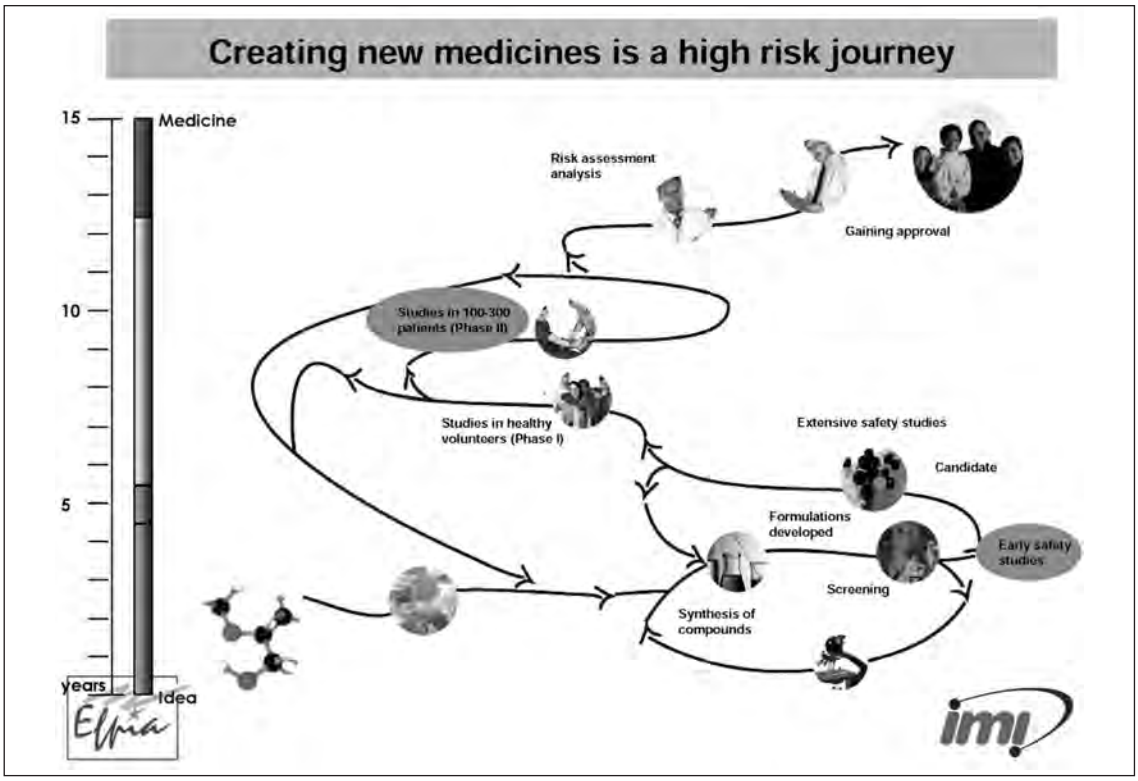


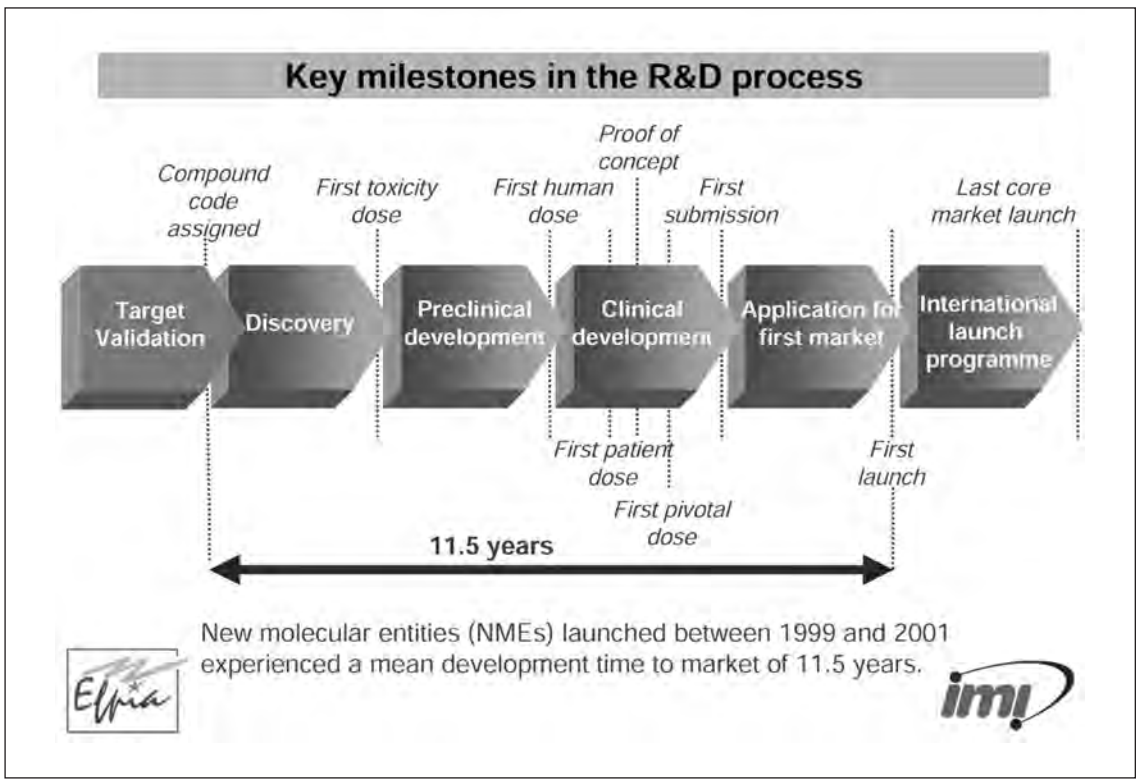
2004 figures are estimated, Source: EFPIA, PhRMA, JPMA

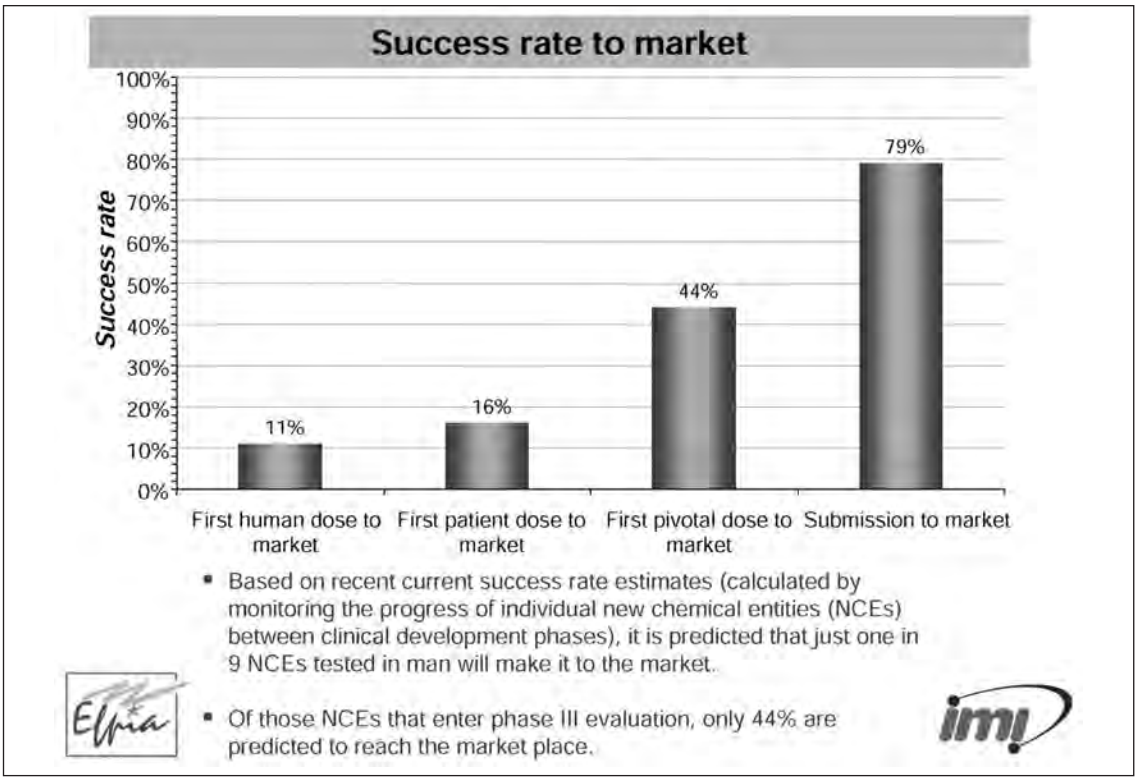
Over the last decade, Europe's share of the world's pharmaceutical research and development has steadily decreased

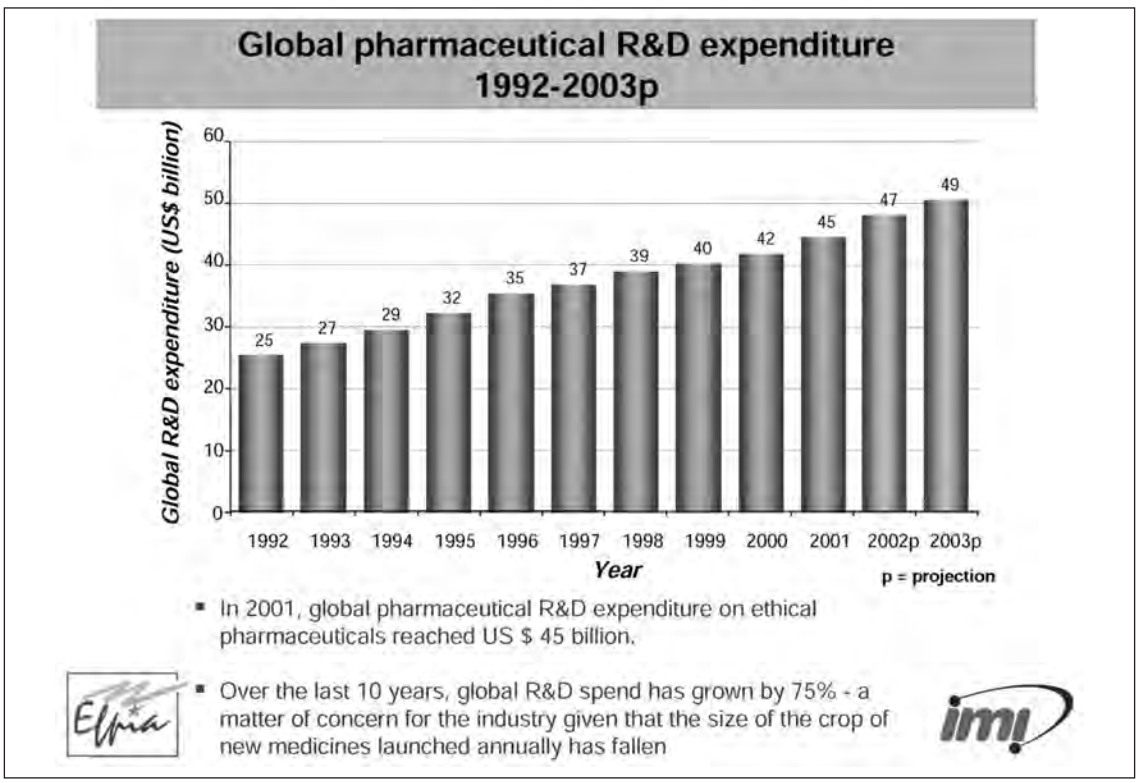

R&D is getting more and more expensive
Average R&D costs per NCE medicine launched
$M (in year 2000 dollars)
1600
1400
1200
1000
800
600
400
200
0
54
231
Post-launch costs
95
802
R&D Heads @ IBC mtg 2003
1400
Bain & Co Dec 03
1700
1976
1987
2000
2003
Year


Pharmaceutical R&D investment is substantial
R&D Spending as a percentage of sales
20%
16%
12%
8%
4%
0%
3.8%
3.8%
3.8%
8.1%
10.2%
17.7%
Telecom-munications
Aerospace & Defense
Automotive
Electrical & Electronics
Computer Software & Services
Pharmaceutical R&D

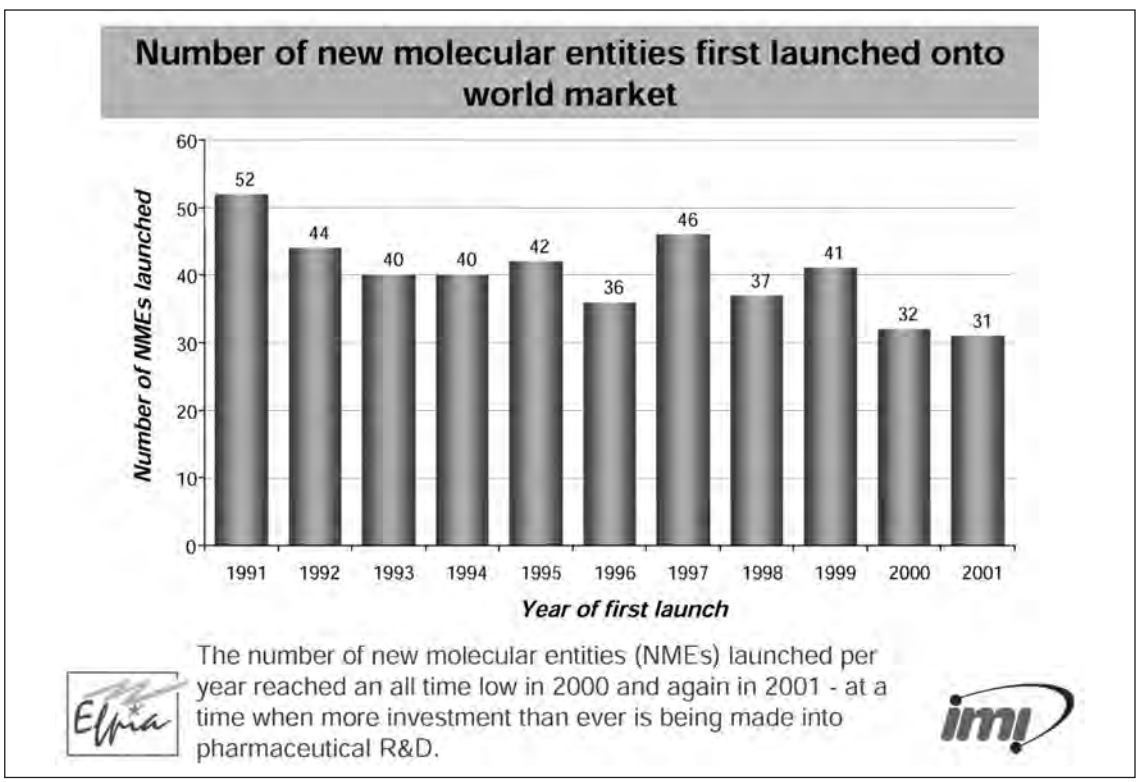

Creating new medicines is a high risk journey
15
10
5
years
Medicine
Idea
Risk assessment analysis
Gaining approval
Studies in 100-300 patients (Phase II)
Studies in healthy volunteers (Phase I)
Extensive safety studies
Candidate
Formulations developed
Early safety studies
Screening
Synthesis of compounds
Elpria
imi

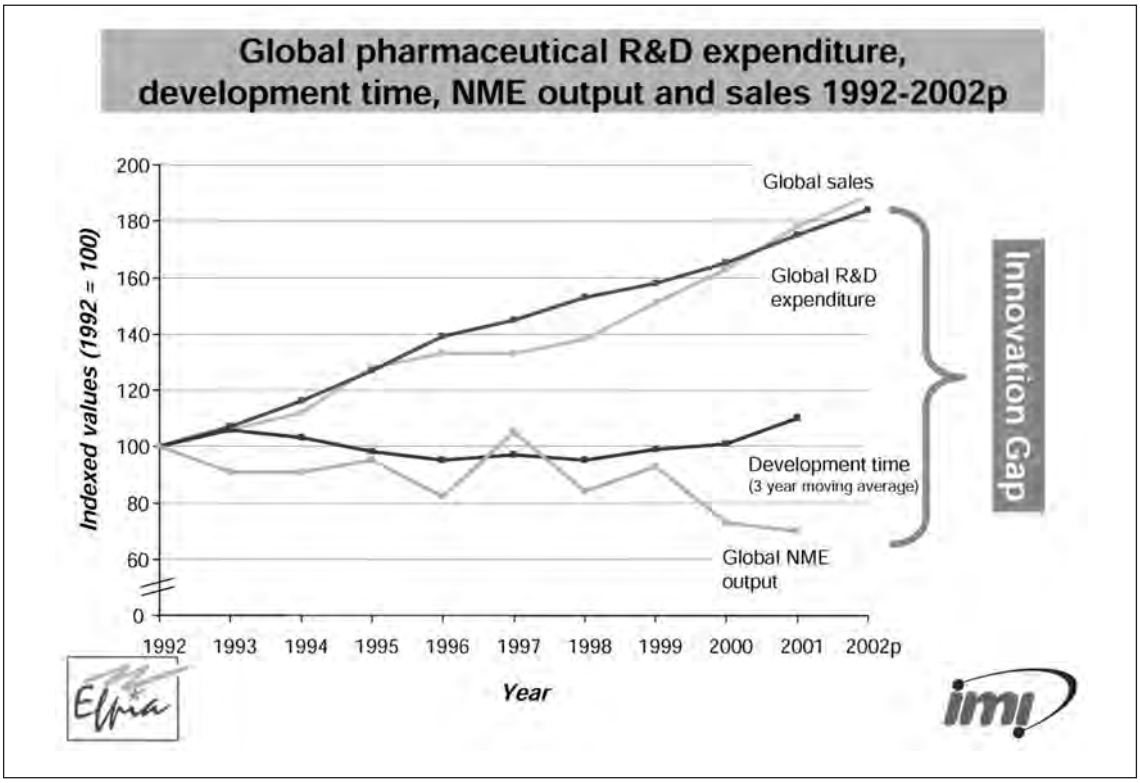

Key milestones in the R&D process
Compound code assigned
First toxicity dose
First human dose
Proof of concept
First submission
Last core market launch
Target Validation
Discovery
Preclinical development
Clinical development
Application for first market
International launch programme
First patient dose
First pivotal dose
First launch
11.5 years
New molecular entities (NMEs) launched between 1999 and 2001 experienced a mean development time to market of 11.5 years.
Elpria
imi


Success rate to market
Success rate
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
11%
16%
44%
79%
First human dose to market
First patient dose to market
First pivotal dose to market
Submission to market
Based on recent current success rate estimates (calculated by monitoring the progress of individual new chemical entities (NCEs) between clinical development phases), it is predicted that just one in 9 NCEs tested in man will make it to the market.
Of those NCEs that enter phase III evaluation, only 44% are predicted to reach the market place.

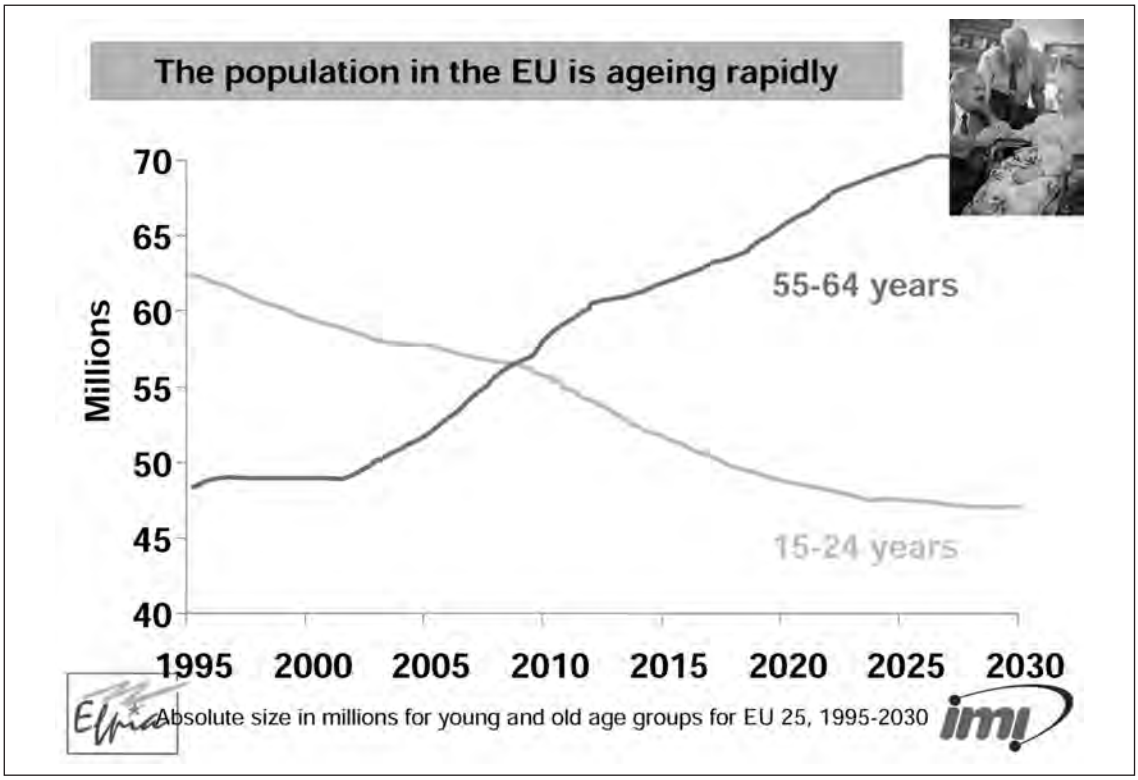

Global pharmaceutical R&D expenditure 1992-2003p
Global R&D expenditure (US$ billion)
60
50
40
30
20
10
0
25
27
29
32
35
37
39
40
42
45
47
49
1992
1993
1994
1995
1996
1997
1998
1999
2000
2001
2002p
2003p
Year
p = projection
In 2001, global pharmaceutical R&D expenditure on ethical pharmaceuticals reached US $ 45 billion.
Over the last 10 years, global R&D spend has grown by 75% - a matter of concern for the industry given that the size of the crop of new medicines launched annually has fallen

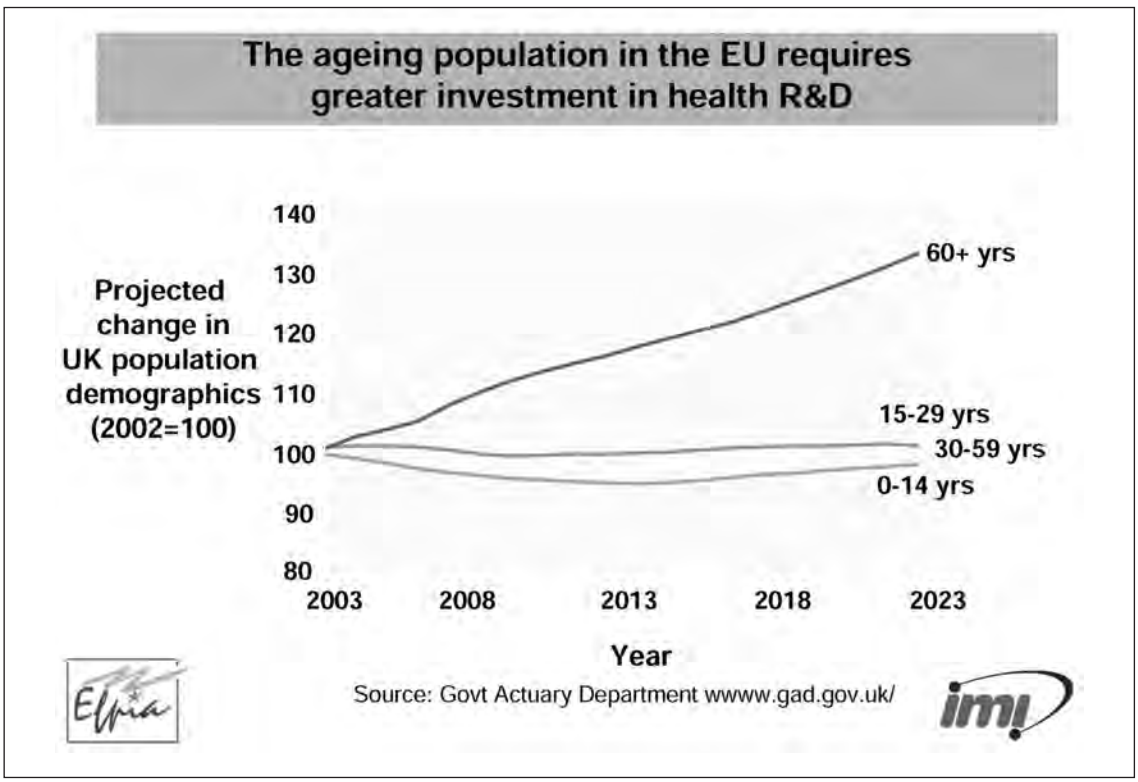

Global Pharmaceutical Sales 1992-2003p
Global pharmaceutical sales (US$ billion)
600
500
400
300
200
100
0
223
236
249
285
296
297
308
337
364
396
420
445
1992
1993
1994
1995
1996
1997
1998
1999
2000
2001
2002p
2003p
Year
p = projection
Source: Sales data for 1992-2001 supplied by IMS Health; projections for 2002 and 2003 calculated by CMR International


Number of new molecular entities first launched onto world market
Number of NMEs launched
60
50
40
30
20
10
0
52
44
40
40
42
36
46
37
41
32
31
1991
1992
1993
1994
1995
1996
1997
1998
1999
2000
2001
Year of first launch
The number of new molecular entities (NMEs) launched per year reached an all time low in 2000 and again in 2001 - at a time when more investment than ever is being made into pharmaceutical R&D.


Global pharmaceutical R&D expenditure, development time, NME output and sales 1992-2002p
Indexed values (1992 = 100)
200
180
160
140
120
100
80
60
0
Global sales
Global R&D expenditure
Development time
(3 year moving average)
Global NME output
Innovation Gap
1992
1993
1994
1995
1996
1997
1998
1999
2000
2001
2002p
Year
Efpia
imi


Europe is losing it's scientists
The 'brain drain' of researchers away from Europe is increasing
7 out of 10 European-born US doctorate recipients who graduated between 1991 and 2000 had no plans to return to Europe
Source: According to the European Commission 2003 'Brain Drain Study'
Efpia
imi


The population in the EU is ageing rapidly
Millions
70
65
60
55
50
45
40
55-64 years
15-24 years
1995
2000
2005
2010
2015
2020
2025
2030
Absolute size in millions for young and old age groups for EU 25, 1995-2030


The ageing population in the EU requires greater investment in health R&D
Projected change in UK population demographics (2002=100)
140
130
120
110
100
90
80
60+ yrs
15-29 yrs
30-59 yrs
0-14 yrs
2003
2008
2013
2018
2023
Year
Source: Govt Actuary Department wwww.gad.gov.uk/

The European Technology Platform for Innovative Medicines Initiative
A Strategic Research Agenda

- **Backround - Facts**
  - Europe has lost its lead as a global centre for biomedical research.
  - Despite a five-fold increase in the Pharmaceutical trade surplus over the last 5 years, investment in R&D is declining markedly in comparison with the US.
  - Over the last decade the US has been increasing its investment in publicly funded biomedical research and Europe has not matched this level of investment.
  - This is affecting growth and development of the Pharmaceutical industry in Europe, to the detriment of both patients and society.

The European Technology Platform for Innovative Medicines Initiative
A Strategic Research Agenda

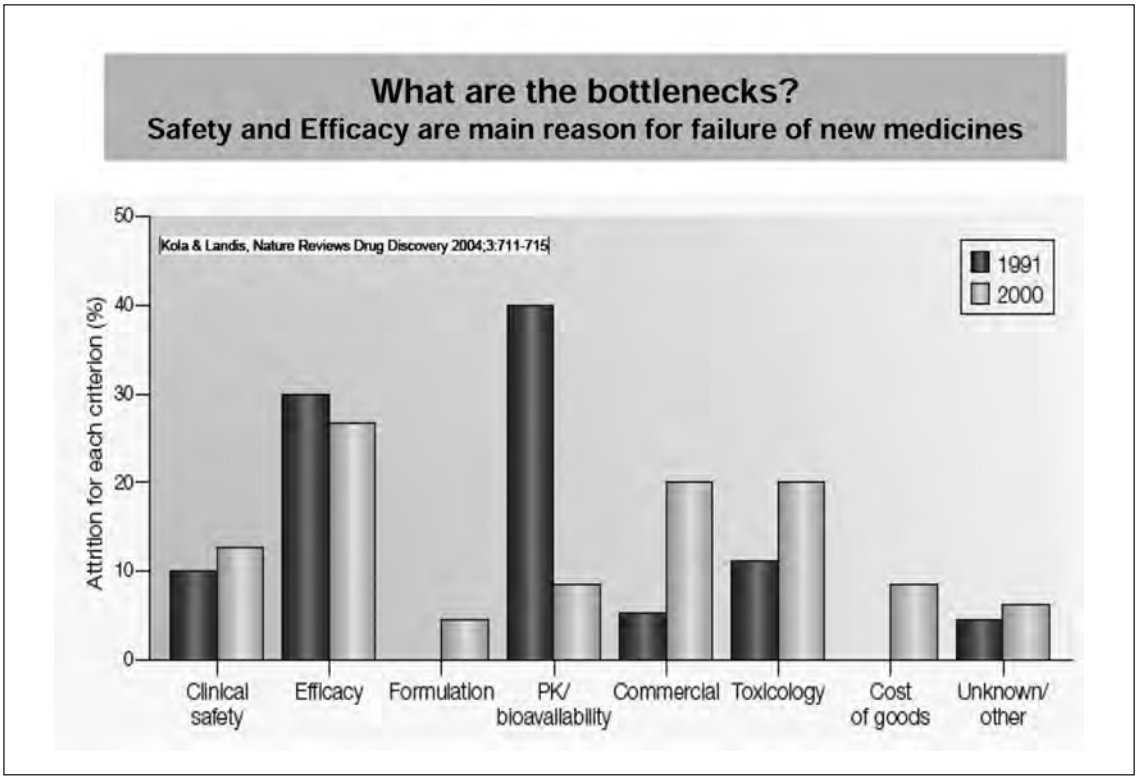
- **Backround – The Initiative**
  - In order to strengthen the European competitiveness, the European Commission is developing the idea of the ***European Technology Platforms (ETP)*** to address major economic or technological challenges.
  - These are intended to foster public-private partnerships between all relevant stakeholders to implement the ***Strategic Research Agenda***.
  - To drive this forward the European Commission has encouraged the European Federation of Pharmaceutical Industries and Associations' (EFPIA) to identify the main barriers to innovation in biomedical research with the objective of establishing a ***European Technology Platform for Innovative Medicines*** to tackle these.

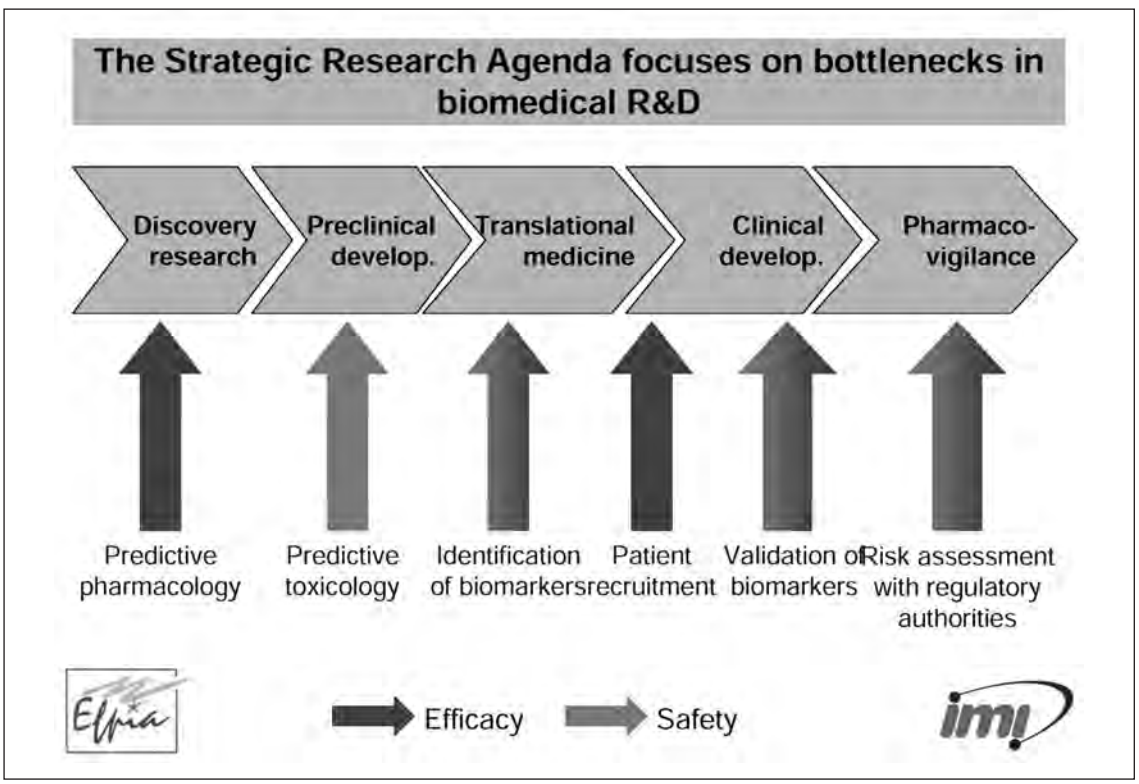
In our discussion today …

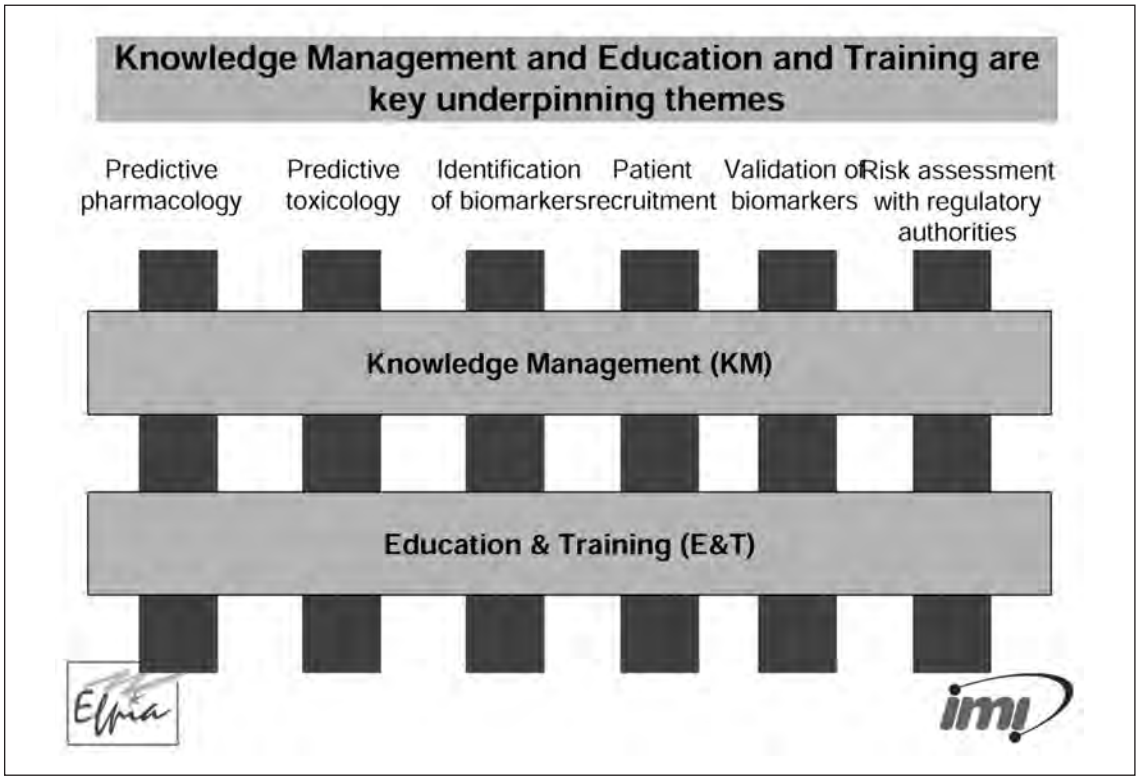
- Why Europe needs the Innovative Medicines Initiative
- **About the Innovation Medicines Initiative**
- Implementation

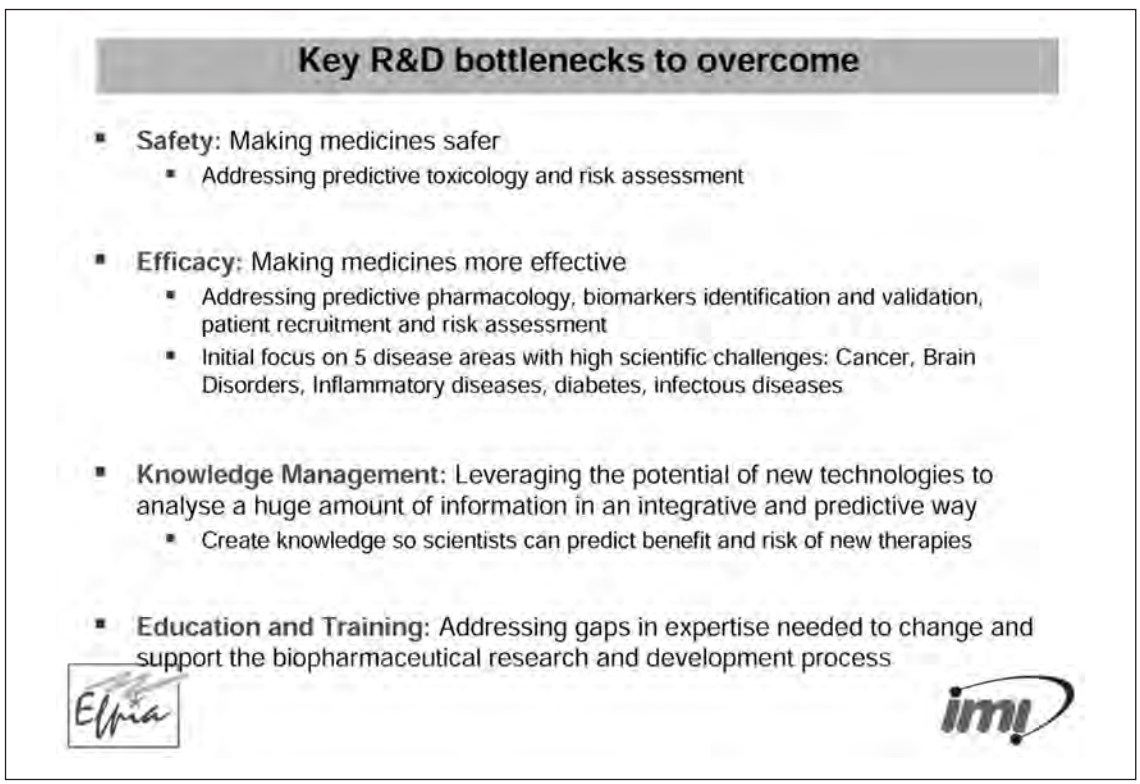
Components of the Strategic Research Agenda for Innovative Medicines

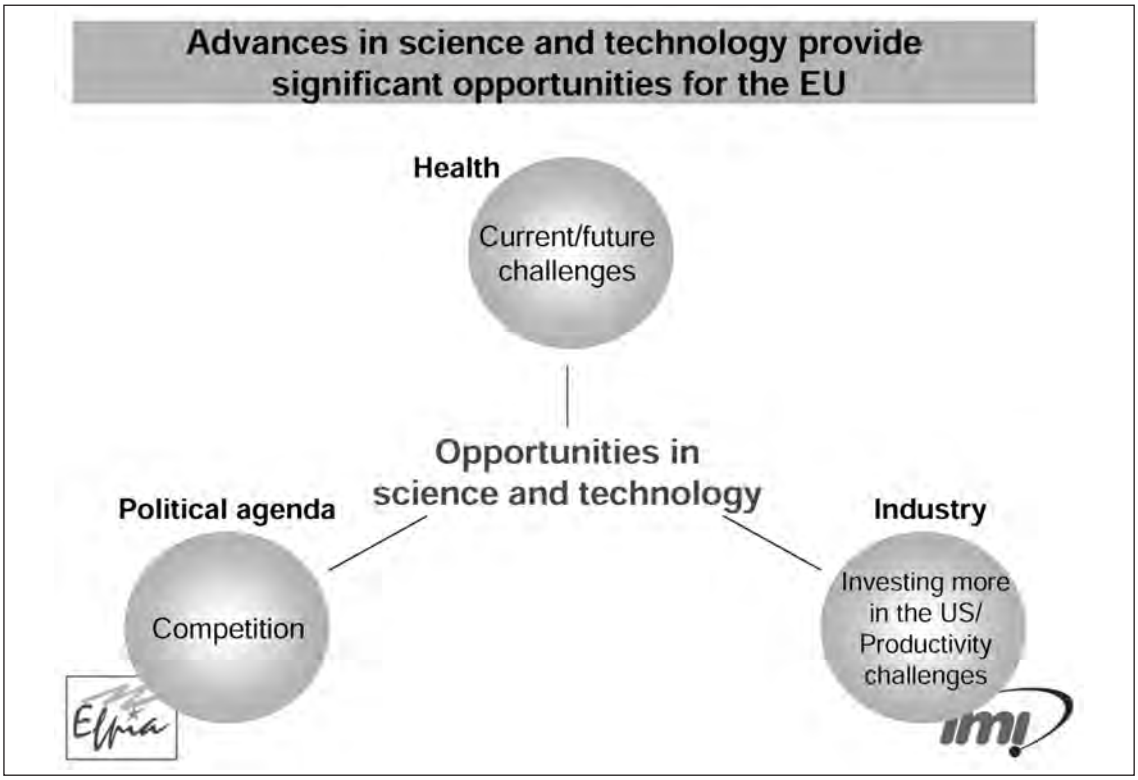
- Identification of the R&D bottlenecks for new medicines
- Analysis of current strengths and weakness in Europe
- Recommendations to address bottlenecks
- Definition of the necessary research and technical priorities in the medium to long term
- Estimation of resources and timelines
- Framework agreed upon by all stakeholders to foster productive Public-Private-Partnerships

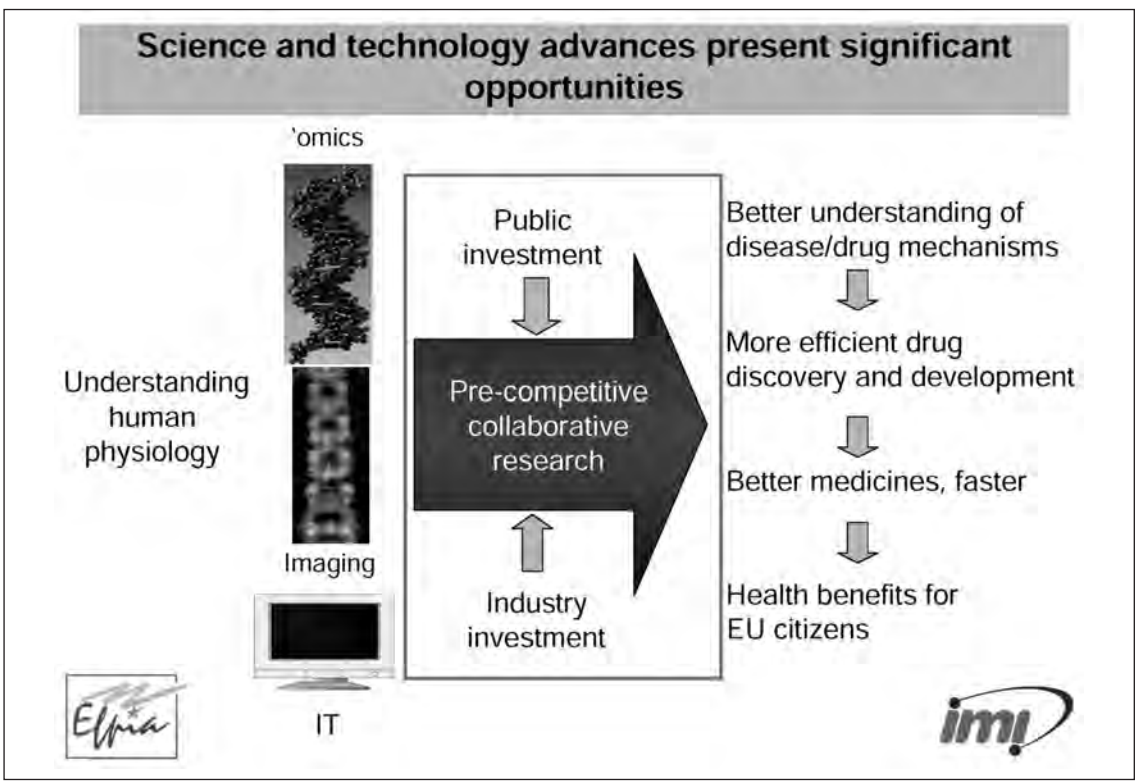

What are the bottlenecks?
Safety and Efficacy are main reason for failure of new medicines
Kola & Landis, Nature Reviews Drug Discovery 2004;3:711-715
1991
2000
Attrition for each criterion (%)
0
10
20
30
40
50
Clinical safety
Efficacy
Formulation
PK/ bioavailability
Commercial
Toxicology
Cost of goods
Unknown/ other

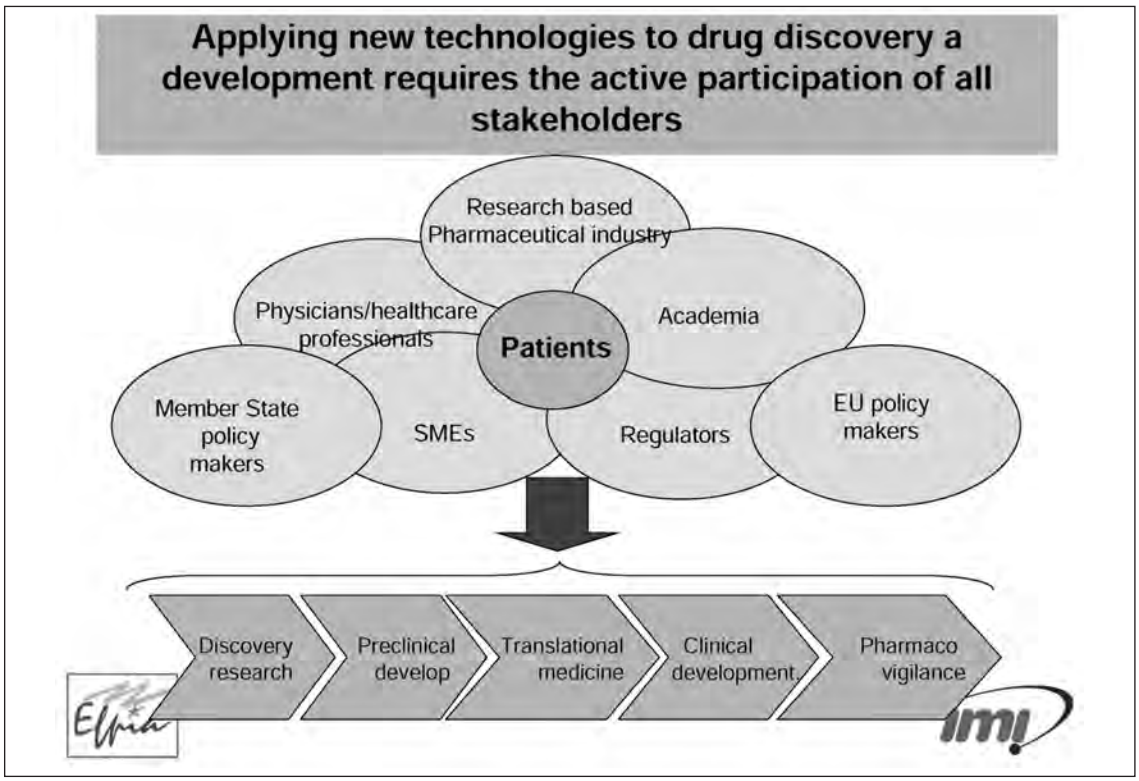

The Strategic Research Agenda focuses on bottlenecks in biomedical R&D
Discovery research
Preclinical develop.
Translational medicine
Clinical develop.
Pharmaco-vigilance
Predictive pharmacology
Predictive toxicology
Identification of biomarkers
Patient recruitment
Validation of biomarkers
Risk assessment with regulatory authorities
Efficacy
Safety

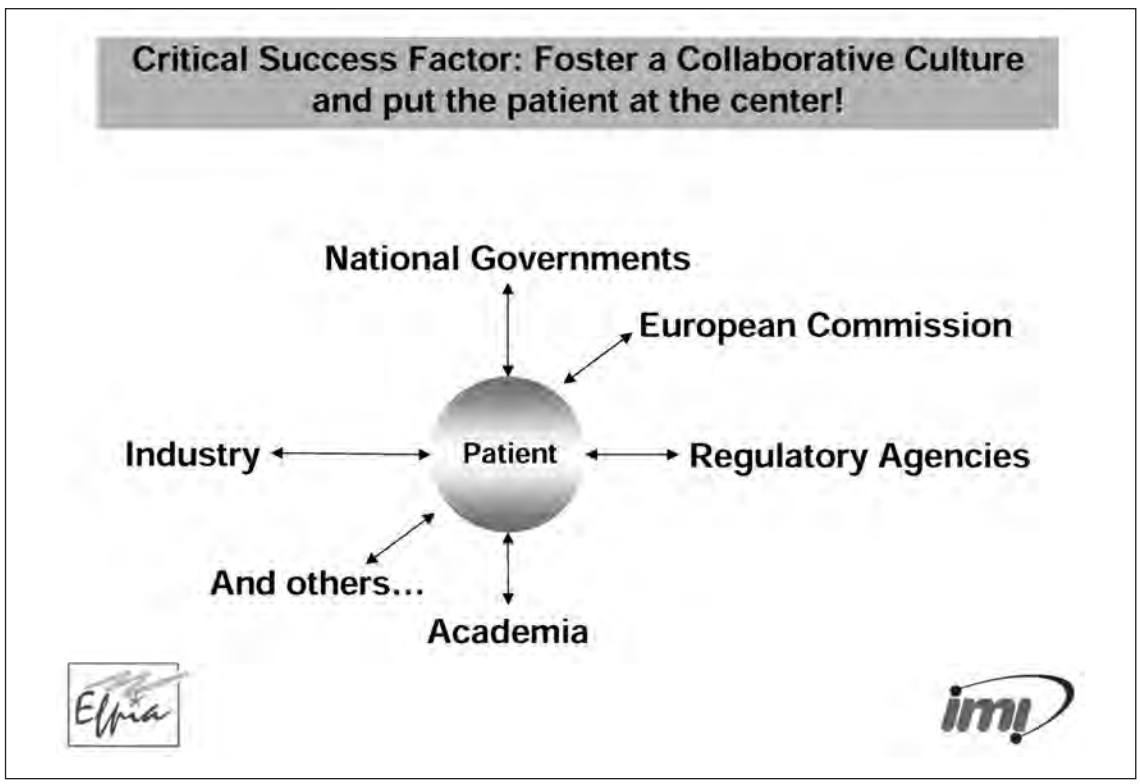

Knowledge Management and Education and Training are key underpinning themes
Predictive pharmacology
Predictive toxicology
Identification of biomarkers
Patient recruitment
Validation of biomarkers
Risk assessment with regulatory authorities
Knowledge Management (KM)
Education & Training (E&T)
Efpia
imi


Key R&D bottlenecks to overcome
Safety: Making medicines safer
Addressing predictive toxicology and risk assessment
Efficacy: Making medicines more effective
Addressing predictive pharmacology, biomarkers identification and validation, patient recruitment and risk assessment
Initial focus on 5 disease areas with high scientific challenges: Cancer, Brain Disorders, Inflammatory diseases, diabetes, infectous diseases
Knowledge Management: Leveraging the potential of new technologies to analyse a huge amount of information in an integrative and predictive way
Create knowledge so scientists can predict benefit and risk of new therapies
Education and Training: Addressing gaps in expertise needed to change and support the biopharmaceutical research and development process
Efpia
imi


Advances in science and technology provide significant opportunities for the EU
Health
Current/future challenges
Opportunities in science and technology
Political agenda
Competition
Industry
Investing more in the US/ Productivity challenges


Science and technology advances present significant opportunities
'omics
Understanding human physiology
Imaging
IT
Public investment
Pre-competitive collaborative research
Industry investment
Better understanding of disease/drug mechanisms
More efficient drug discovery and development
Better medicines, faster
Health benefits for EU citizens

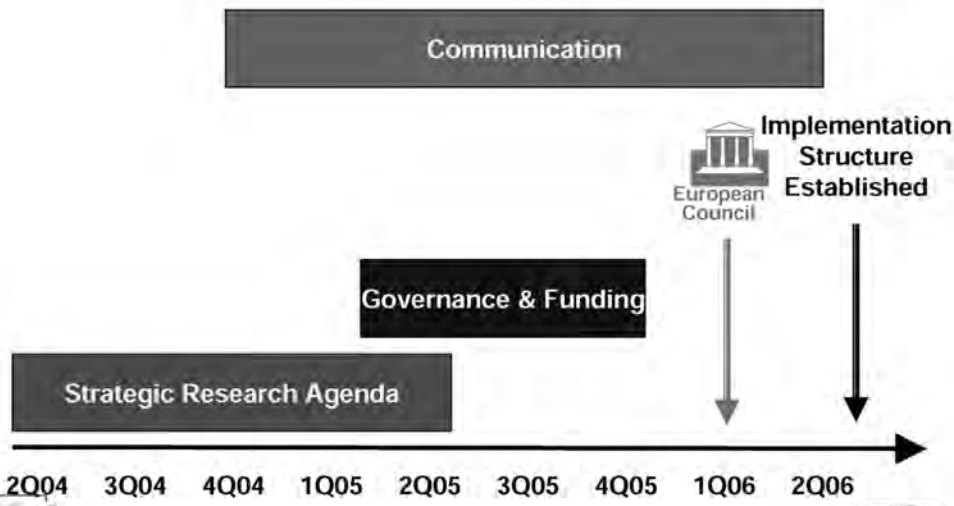

Applying new technologies to drug discovery a development requires the active participation of all stakeholders
Research based Pharmaceutical industry
Physicians/healthcare professionals
Academia
Patients
Member State policy makers
SMEs
Regulators
EU policy makers
Discovery research
Preclinical develop
Translational medicine
Clinical development
Pharmaco vigilance
imi


Critical Success Factor: Foster a Collaborative Culture and put the patient at the center!
National Governments
European Commission
Industry
Patient
Regulatory Agencies
And others…
Academia
imi

In our discussion today …

- Why Europe needs the Innovative Medicines Initiative
- About the Innovation Medicines Initiative
- **Implementation - Status**
- The Benefit – A Winning Case for all Stakeholders

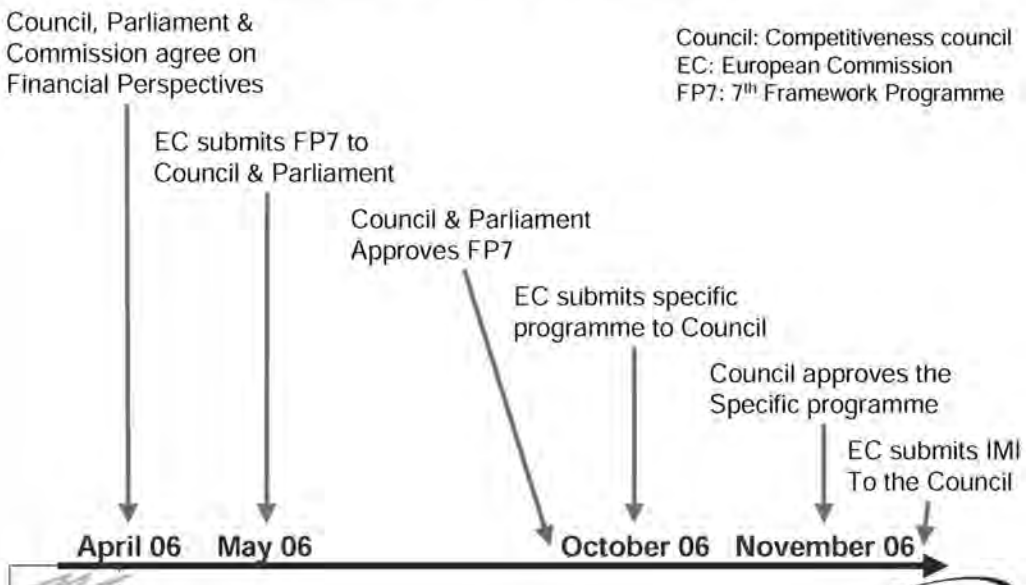
Implementation Timelines
Best case scenario



Achievements in 2005

- The Strategic Research Agenda rose consensus amongst all EFPIA companies and important stakeholders such as the EMEA.
- The visibility of the industry in the scientific and medical community has been raised significantly.
- The pilot project InnoMed started October 1st, 2005:
  - InnoMed is an industry wide collaboration on toxicogenomics and biomarkers for Alzheimer's disease.
  - Total budget of 18 million euros, EU contribution of 12 million euros.

EU Decisions in 2006 - Estimated timelines

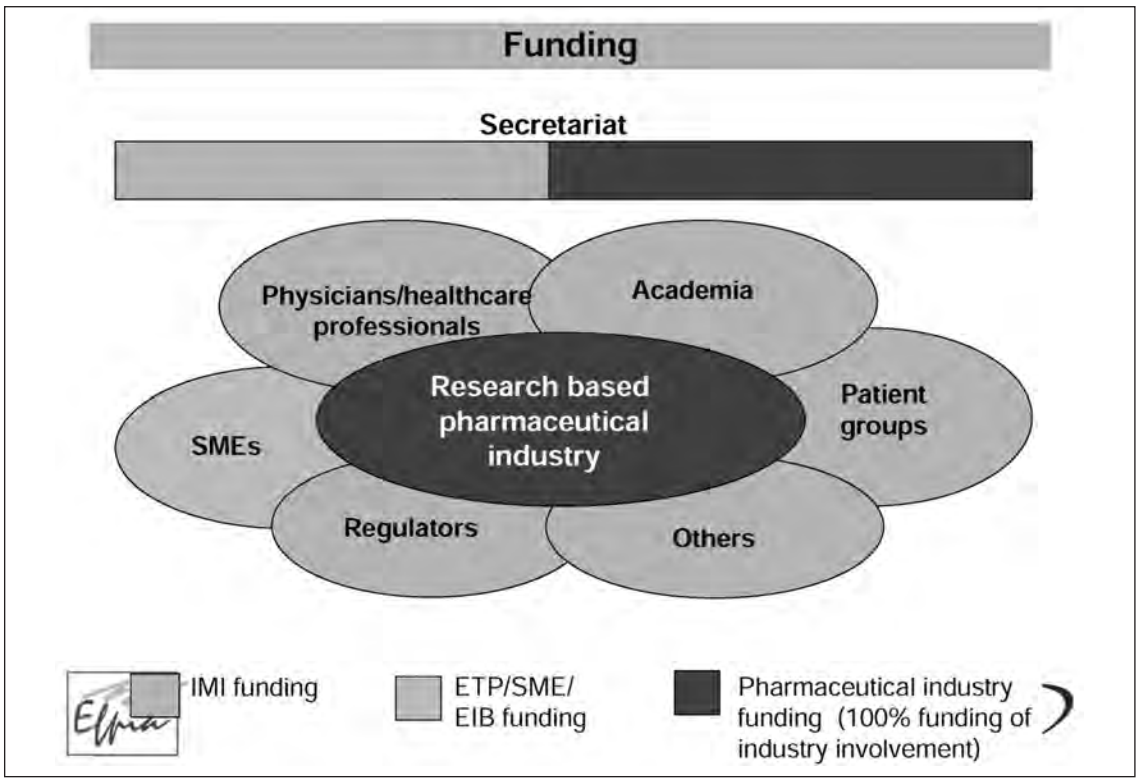


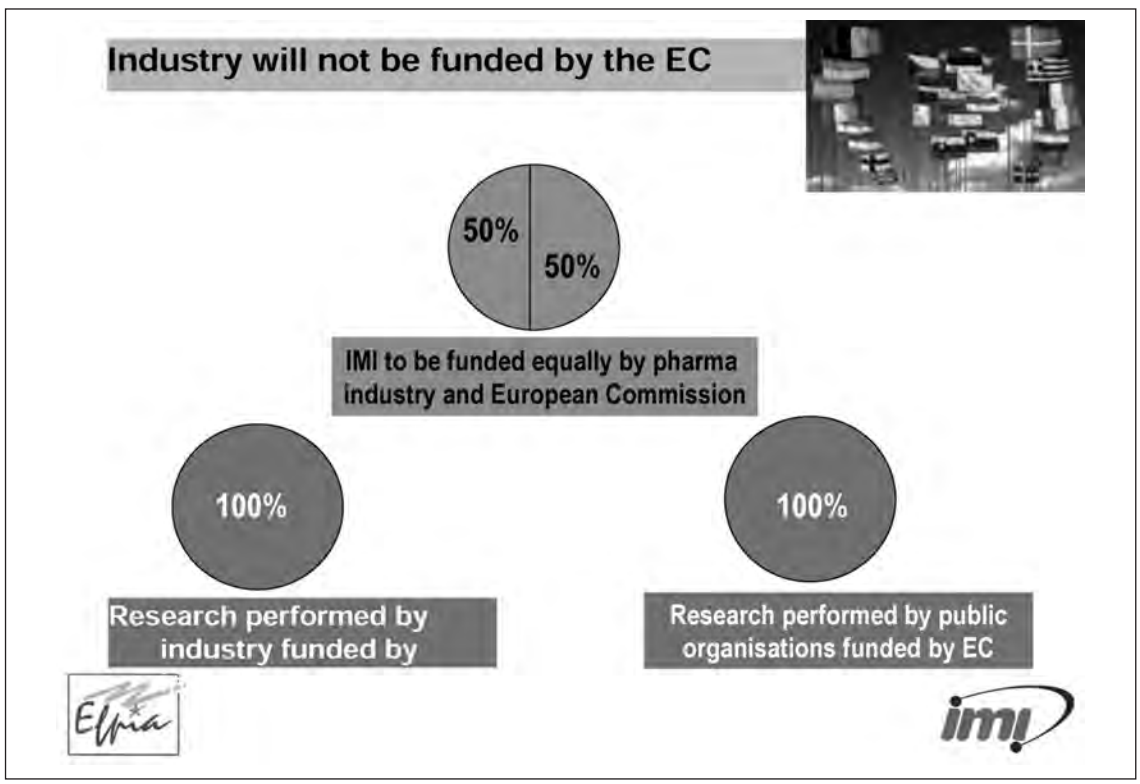
EU Decisions in 2006 - Estimated Amounts

Budget Line	Amount in Billion Euros
The financial perspectives 2007-2013 (EU budget)	~ 811
Heading 1: Sustainable growth	~ 379
Heading 1A: Competitiveness for growth and employment	~ 72
7th Framework Programme budget	~ 50
Specific programme budget	~ 45
Innovative Medicines Initiative	~ 1,4

Estimated costs: 440 mio euros per year

Stakeholder	Contribution	How
EC	Funding of the secretariat Funding of research	Contract between EC and secretariat and EFPIA and secretariat (50% each)
EFPIA	Funding of the secretariat	Contract between EC and secretariat and EFPIA and secretariat (50% each)
Pharmaceutical companies	Research Data Infrastructure Expertise	Funding via companies
Academia	Research Data Infrastructure Expertise	Funding via IMI
SME	Research Data Expertise	Funding via IMI and possibly loans from European Investment Bank
Patients groups	Disease knowledge	Funding via IMI


Funding
Secretariat
Physicians/healthcare professionals
Academia
Research based pharmaceutical industry
Patient groups
SMEs
Regulators
Others
IMI funding
ETP/SME/ EIB funding
Pharmaceutical industry funding (100% funding of industry involvement)


Industry will not be funded by the EC
50%
50%
IMI to be funded equally by pharma industry and European Commission
100%
Research performed by industry funded by
100%
Research performed by public organisations funded by EC

IMI Costs to the Industry

Represents less than 1% of Pharmaceutical R&D expenditure in Europe (21.5 billion euros in 2004)

	Funding	Euros per year
EFPIA	Executive office	3 million
Biopharmaceutical companies	• Own research • Data • Expertise	• In kind • 150 to 200 million
European Community	• Executive office • Public & SME research	• 3 million • 150 to 200 million

Competitive Environment in the EU

Platform	Industry Competitive Position	Directorate General
Aeronautics (ACARE) *Clean Sky*	Plane manufacturers Strong Member States Support	Research
Innovative Medicines Initiative (IMI) *Partnering for Health*	EFPIA Maturity and Industry alignment	Research
Hydrogen & Fuel Cells (HFP)	Automobile and energy companies Less mature	Research
Nanoelectronics (ENIAC)	Semi-conductor companies Strong Member States Support	Information Society
Embedded Systems (ARTEMIS)	Electronics and software companies Strong Member States Support	Information Society

Competitive Environment in the World
It will be done…

	Innovative Medicines Initiative (EFPIA-European Commission)
	FDA Critical Path Initiative (NIH)
	Safe and Innovative Medicines (PhRMA)
	Biomarker Initiative (PhRMA)
	Critical Path Institute (University of Arizona)
	Center for Biomedical Innovation (MIT)
	Toxicogenomics Project (JPMA)
	Proteome Factory Consortium (JPMA)
	Large-scale Clinical Trial Network

In our discussion today …

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- Implementation - Status
- **The Benefit – A Winning Case for all Stakeholders**

IMI - A compelling case for JTI Status

- Innovation and development of science base is crucial to Europe
- Health is high on the political agenda with our ageing population
- Pharmaceutical innovation brings benefits to people's health and wealth to society
- Focused on creating the environment which will enable important new medicines get to patients faster
- IMI has a clear focus on outcomes, an agreed and proven collaborative approach, and is ready to start implementation
- Commitment of industry to contribute 100% of own costs

And most importantly …

- Patients / society
  - Faster access to innovative therapies such as personalised medicines
  - More knowledge-based jobs in the EU
  - More education and training available in the biomedical arena

Main long term benefits of the Innovative Medicines Initiative for the Industry

- Faster approval through better collaboration with the regulatory authorities
- Less post marketing withdrawals through better pharmacovigilance tools
- Less patients needed in pivotal trials through optimized trial design
- Validation of new assessment methods such as biomarkers
- More skilled professionals available to the industry

⇨ More cost-efficient R&D