



European Federation of Pharmaceutical
Industries and Associations

First Pharmaceutical Law Conference

Introductory Remarks

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Declaration of Interest

- Marie-Claire Pickaert is a full-time employee of EFPIA, holding the position of **Deputy Director General** and is a member of its **General Management**.
- Since 2008, Marie-Claire is coordinating EFPIA's ethics and compliance activities. She is acting as the **Chief Ethics & Compliance Officer** at EFPIA.

In 2015, she was asked to take the role of **Ambassador to the Medical Communities**, coordinating EFPIA's relationships with medical & scientific societies, including learned societies, also through professional communities within the pharmaceutical companies that interact with medical communities.

- Marie-Claire Pickaert declares having **no direct / indirect financial interest** in any life science company.
- This slide deck includes **EFPIA public policy positions**, unless otherwise indicated.
- When expressing **personal opinions**, Marie-Claire will clearly indicate so.

EFPIA Mandate



“The aim of the European Federation of Pharmaceutical Industries & Associations is to **promote pharmaceutical discovery and development in Europe** and to bring to the market medicinal products in order to improve human health worldwide.”

EFPIA, which has no profit-making purpose, pursues a mainly scientific aim, ensuring and promoting the technological and economic development of the pharmaceutical industry in Europe.

EFPIA's represents the pharmaceutical industry operating in Europe. Its direct membership includes **33 national associations** and **40+ leading companies**. Two specialised groups within EFPIA represent vaccine manufacturers – **Vaccines Europe - VE**, with 12 member companies and **European Bio-pharmaceutical Enterprises – EBE** with 50+ member companies.

“**Partners in Research**” is constituted of non-pharma companies that collaborate in the IMI public-private membership. This constituent entity, created in June 2014, counts 15+ members.

Outline of EFPIA's Vision & Key Priorities

Vision

Shift the healthcare policy debate from a transactions focus to an outcomes focus

Patient Access

Objective	KPIs	Strategic	Deliverables	Strategic
Maximise patient access to innovative medicines	• Patient access initiatives (e.g. PAM, PAM+, PAM++)	•	• Centralised marketing authorisation (EMA) initiative	•
Improve patient access to innovative medicines	• Centralised marketing authorisation (EMA) initiative	•	• Advance evaluation of innovative medicines through EMA	•
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Develop EU and national competitiveness policies for the pharma industry, focusing on patient access for new products

Innovation

Objective	KPIs	Strategic	Deliverables	Strategic
Maximise patient access to innovative medicines	• Patient access initiatives (e.g. PAM, PAM+, PAM++)	•	• Centralised marketing authorisation (EMA) initiative	•
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Modernise the research, development and regulatory model to restore Europe's competitiveness and speed up access to medicines

International

Objective	KPIs	Strategic	Deliverables	Strategic
Maximise patient access to innovative medicines	• Patient access initiatives (e.g. PAM, PAM+, PAM++)	•	• Centralised marketing authorisation (EMA) initiative	•
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Secure improved market access conditions, high regulatory and IP standards in international growth markets

Ethics & Compliance

Enhance ethical behaviour within a self-regulation (industry) framework to increase reputation and credibility of the pharmaceutical sector

EFPIA Charter



The world population is getting larger and older, but morbidity also increases, with spending projected to double in just over 10 years



**Population
will increase by**



**Additional
50+ year olds**



**Chronic
diseases**



**Healthcare spending
to double**

1
billion

>500
million

70%
of all illnesses

2x

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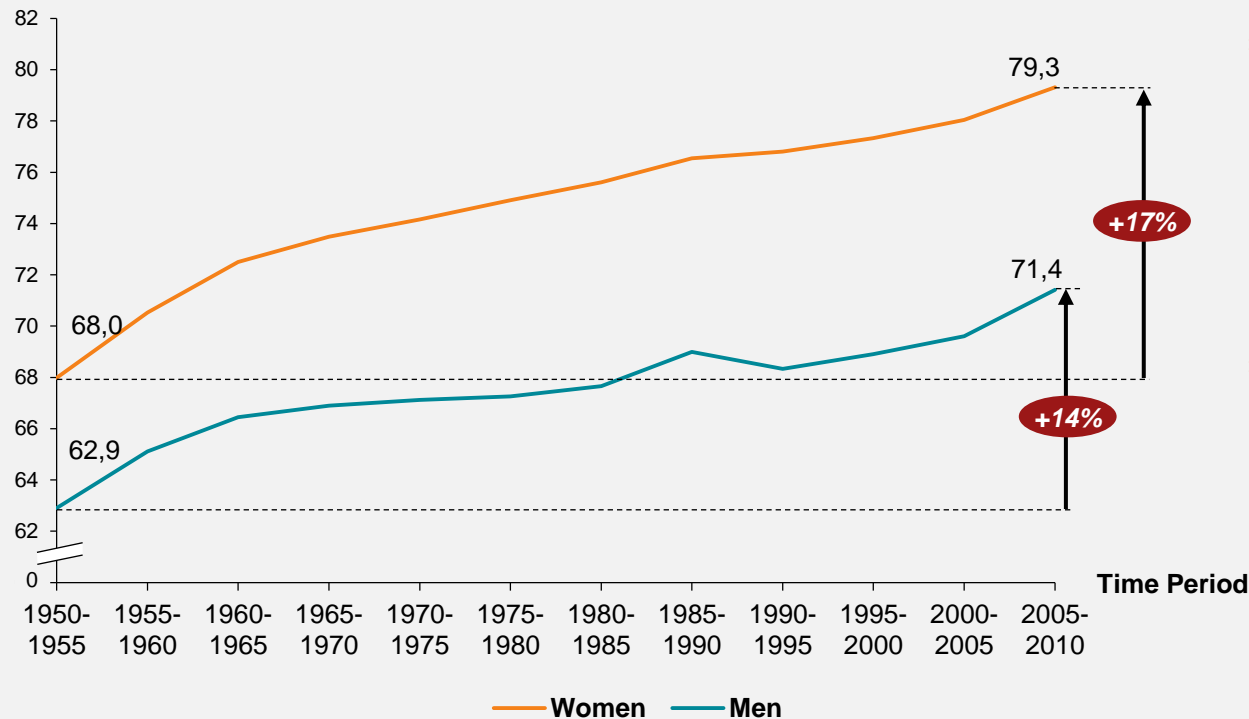
Source: Projections from UN; WHO; Projected Global Healthcare Spend, expressed in nominal terms | Source: Economist intelligence Unit, World Bank, Global Insights, BMI, OECD, McKinsey Strategy & Trend Analytic Center

Over the last 60 years, Europe has made great strides in improving life expectancy (increasing by 14-17 %)

Life expectancy at birth for EU27 countries (1950-2010)



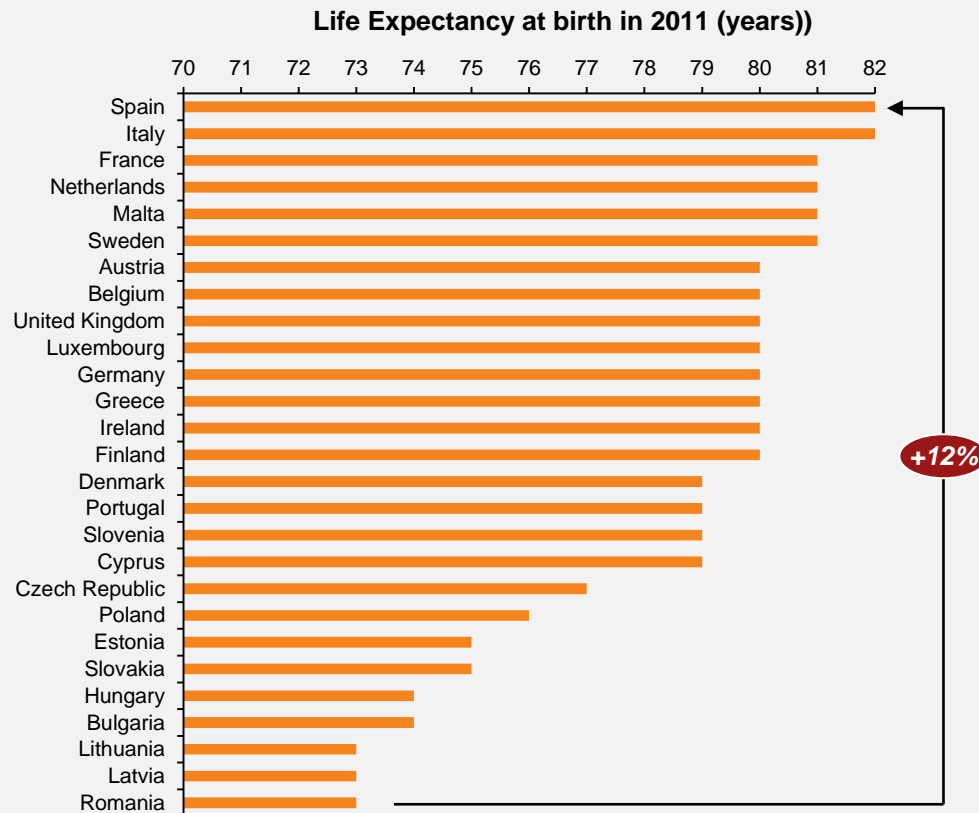
Life Expectancy
(years)



- * During the last 60 years, both male and female life expectancies have improved substantially across Europe.
- * Better health status resulting from improved care and prevention has its part in this improvement

However wide variations in health attainments remain across Europe, amounting to almost a decade of life expectancy

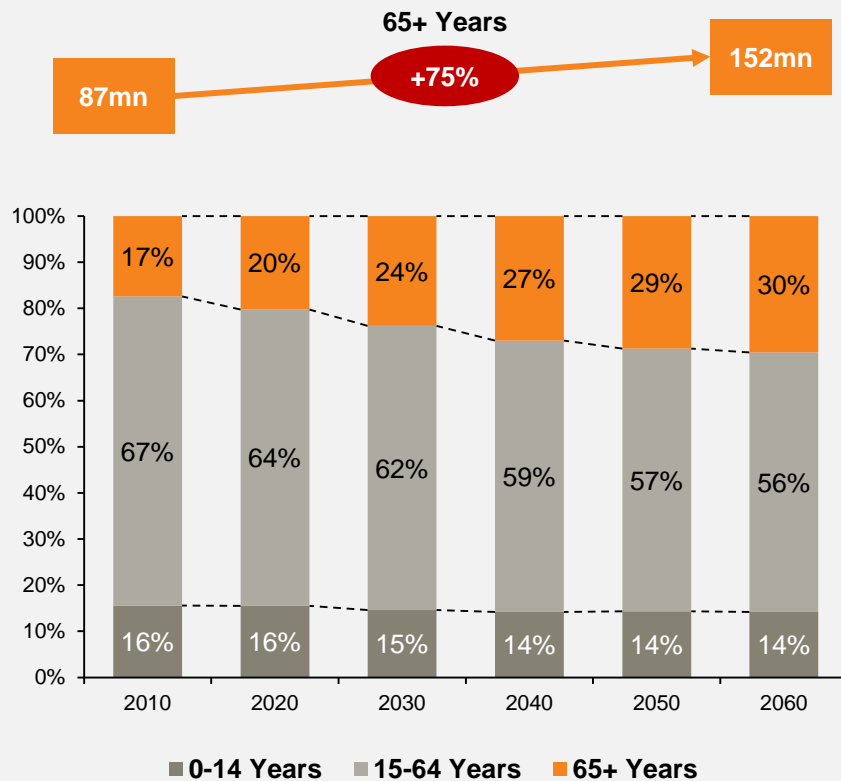
Life expectancy at birth – 2011



- * While health outcomes have improved throughout Europe over the last 50 years, a 12% variation (equal to 9 years) in life expectancy exists between country with highest and lowest life expectancy.
- * Cumulative differences in life expectancy between each country and highest life expectancy amounts to over 1.22 billion life years.
- * While variations are most observable with countries that joined the EU just over 10 years, wide variations also exist between countries with highest life expectancy.

Looking to the future, Europe needs to find solutions to pressing demographic challenges that will impact health and social spending

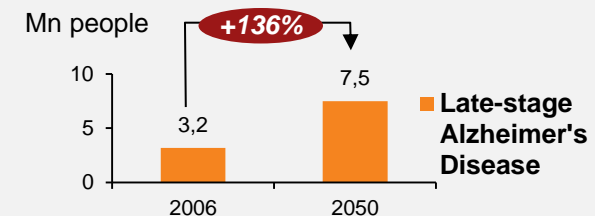
Demographic Development*



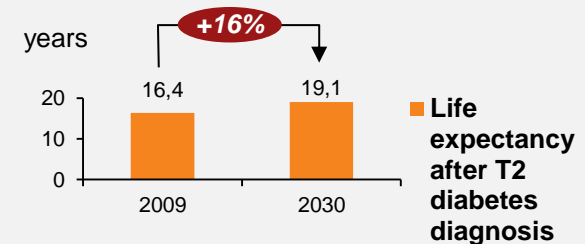
System Impact: Severity, length and increased incidence



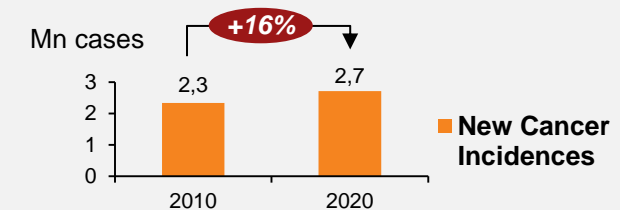
Increase in severity of Degenerative Diseases[†]



Extended impact of Chronic Diseases^Δ



Increased incidence of Cancer[#]

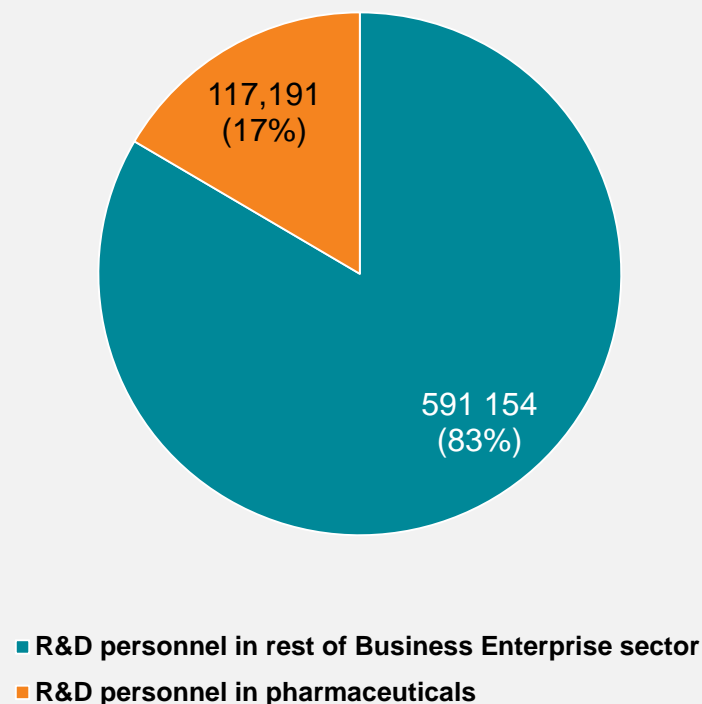


The industry employs over 700 000 people in Europe, accounting for 17% of total business enterprise R&D employment

Employment in the pharmaceutical industry in EU (1990-2012)*

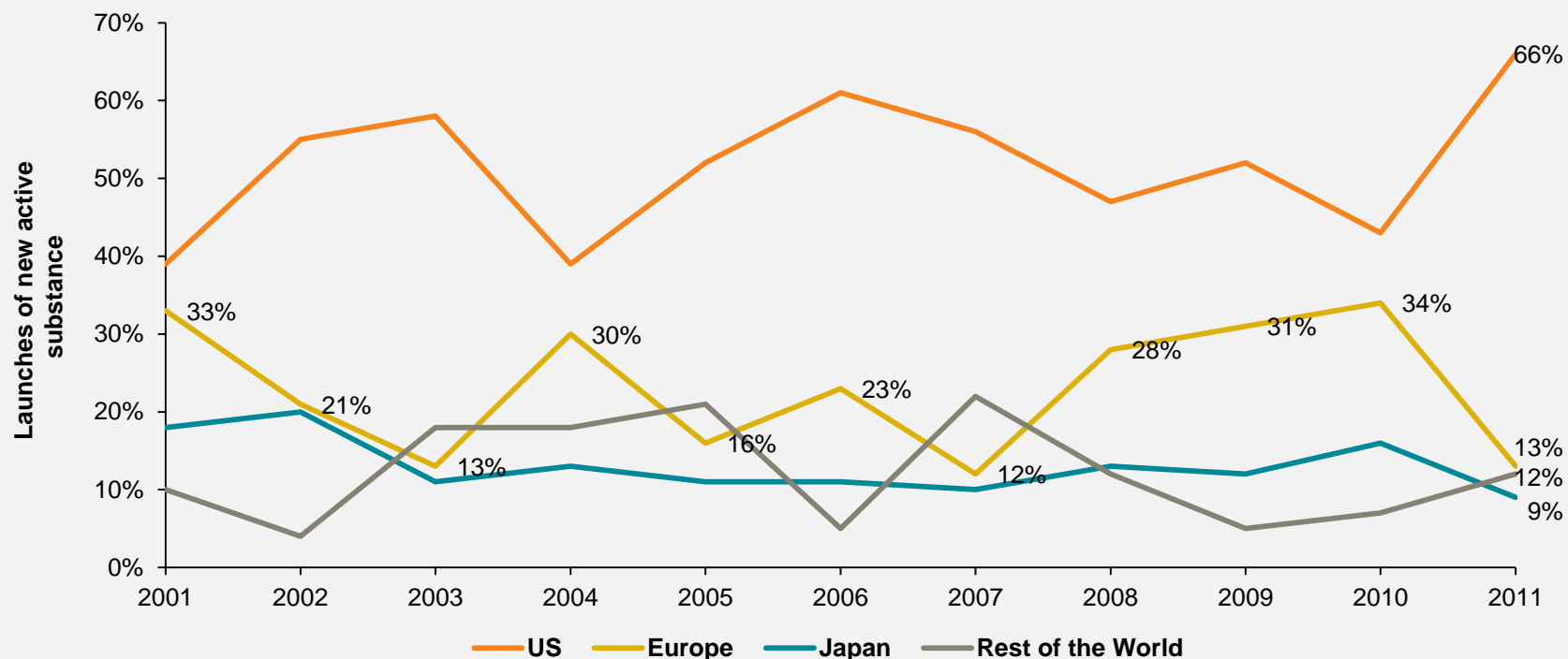


R&D jobs in pharmaceutical as a % of total R&D jobs across all business enterprises†



...But Europe is consistently lagging behind the US as the place where innovators want to launch their products first

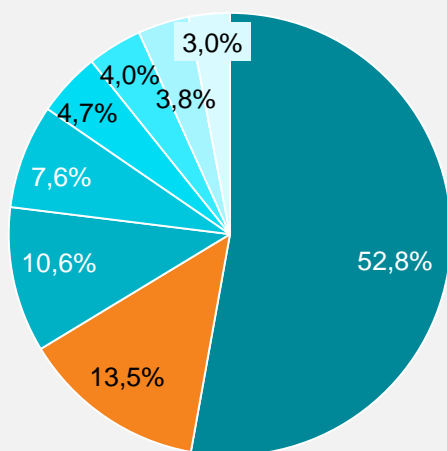
Launches of new active substance by region, 2001 - 2011



Note: Only includes entirely novel products that were first introduced in any worldwide market during 2010 – as such it includes new chemical entities and biologics but excludes novel formulations or combination products. To be included in this analysis, the products also need to be actively launched on the market, not just approved for sale.

Overall medicines across Europe represent less than 15 % of total expenditure although variances exist between therapy areas

Total healthcare expenditure by function
(2010, pop.-weighted, current prices, PPP, \$)*



- Curative and rehabilitative care
- Medicines
- Long-term nursing care
- Other Medical Goods
- Ancillary services
- Health administration and health insurance
- Other
- Prevention and public health services

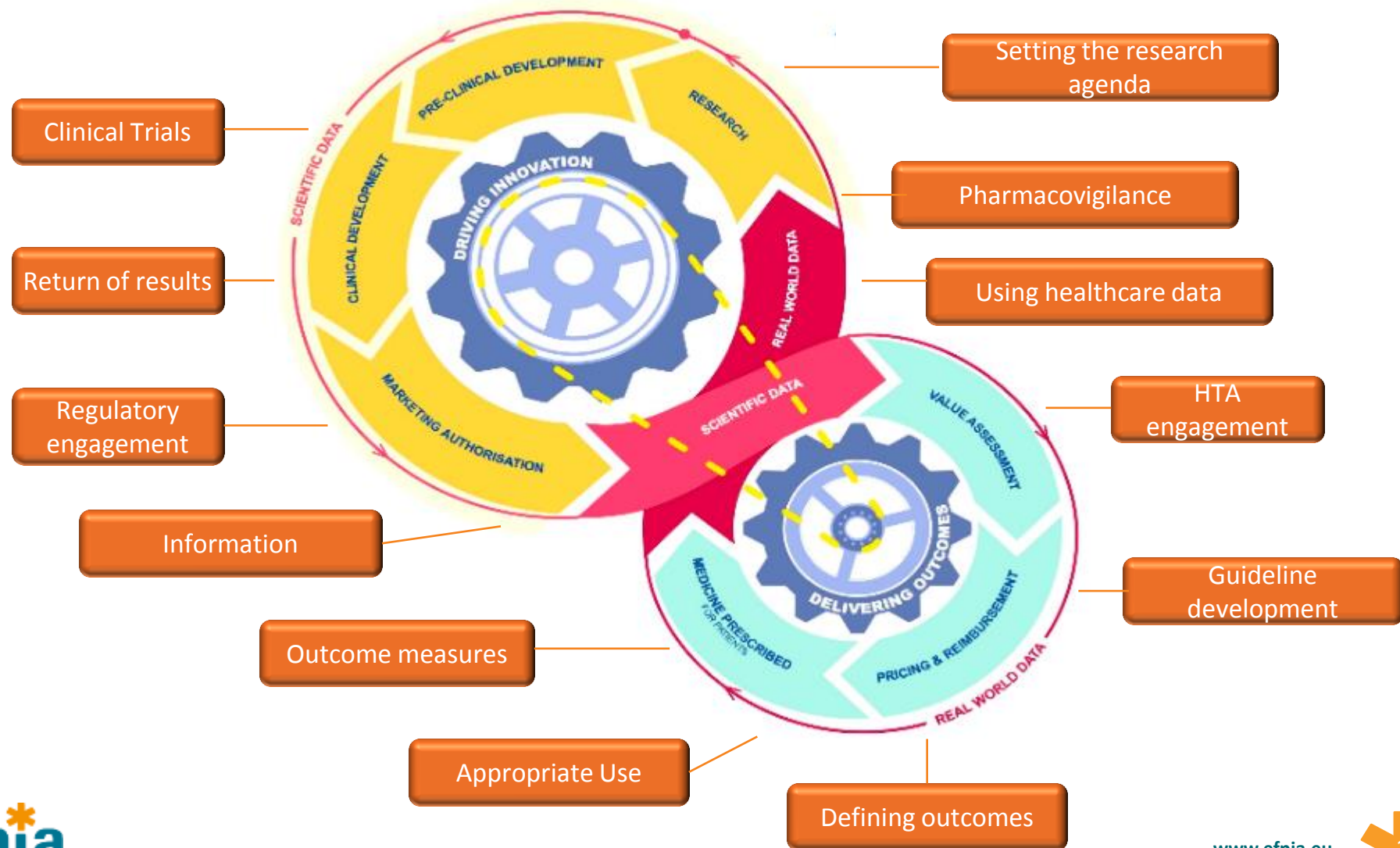
Medicines contribution to disease cost
(2011, various diseases)



Cost factor	COPD†	Diabetes†	CHF†	Alzheimers ^Δ	Prostate Cancer [#]
Care	21%	8%	6%	9%	34%
Hospitalisation	30%	22%	64%	11%	31%
Indirect Cost	22%	35%	18%	76%	N/A
Other Cost	14%	20%	6%	1%	2%
Medication	14%	15%	5%	3%	34%



Knowledge Exchange & Areas of Collaboration

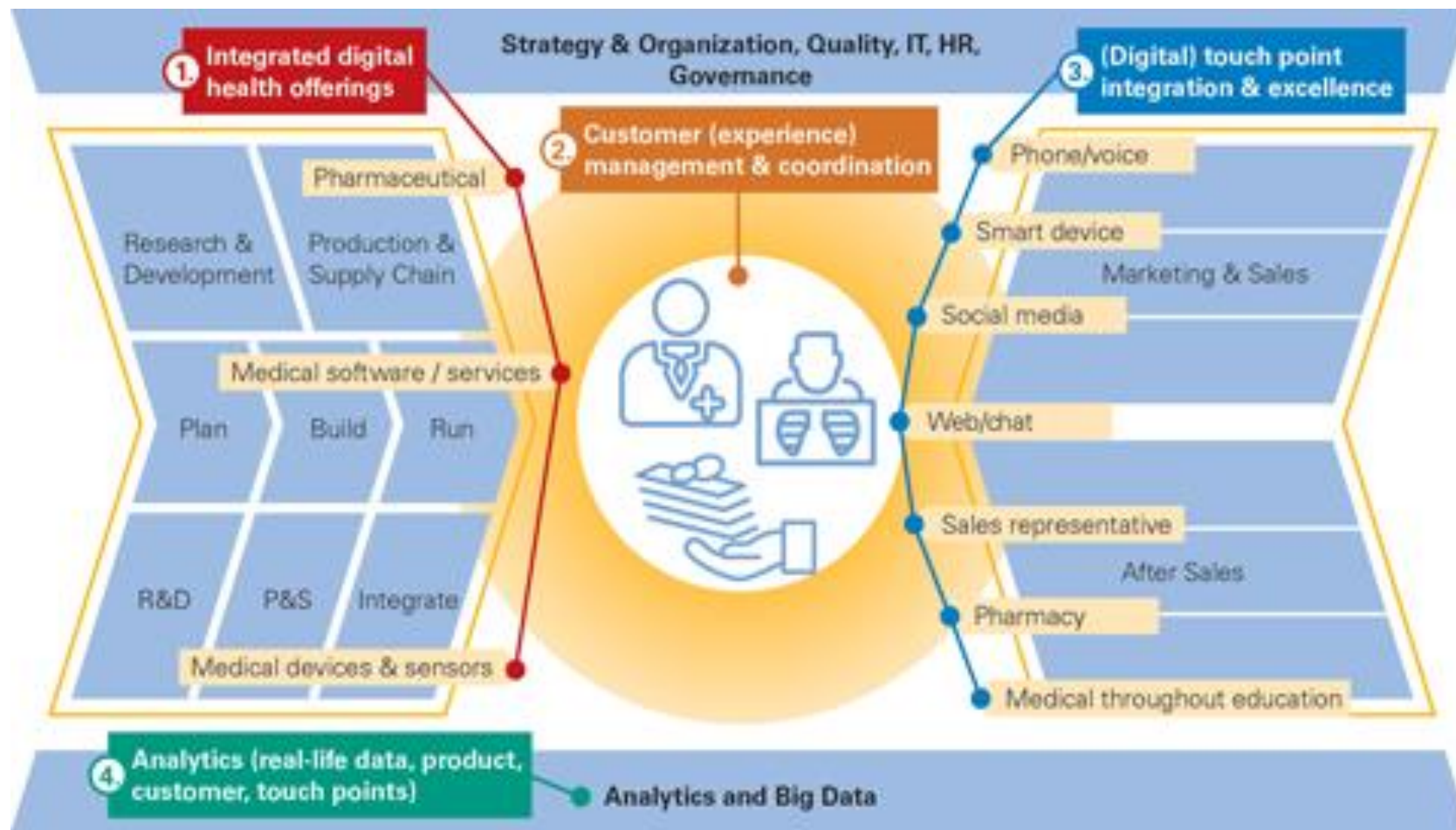


Classical Organisation of Pharma in Healthcare



Source: Arthur D. Little, in SCRIP Intelligence, 24 February 2016

Key Factors determining FUTURE Success in Healthcare



Source: Arthur D. Little, in SCRIP Intelligence, 24 February 2016



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