# Trends and Factors affecting R&D in Pharmaceutical Companies

PharmaACE

# Introduction

## Project Description

Objectives :
1.To study the recent trends of R&D in pharma industry
2. To study the factors which influence the efficiency of R&D in pharma companies

Methodology
**Data Source and Sampling**
This is a secondary study includes data from different pharma companies websites and report which are published in the year 2005- 2016

Introduction :
New drugs serving unmet medical needs are one of the key value drivers of research-based pharmaceutical companies. The efficiency of research and development (R&D) can be defined as the successful approval and launch of new medicines (output) in the rate of the monetary investments required for R&D (input), has declined since decades. The objective of this project is to analyse and describe the factors that impact the R&D efficiency

## Project Economics

In 2017, the pharmaceutical industry spent some 181 billion U.S. dollars on research and development

## Studies

Paul et al. reported success rates of 51 % for discovery research, 69 % for preclinical development, 12.8 % for the clinical development phases and 91 % for the submission phase, resulting in an overall probability of technical and regulatory success (PTRS) for drug R&D of 4.1 %.

The FDA approvals in 2017 have been reviewed in this context and lack of efficacy (56 %), safety issues (28%), changing strategies (7%), commercial reasons (5%) and operational challenges (5 %) are the most probable reasons of failures that happened in phase II and phase III of clinical development

# Understanding the recent trends of R&D

## Recent Trends of R&D in pharma industries

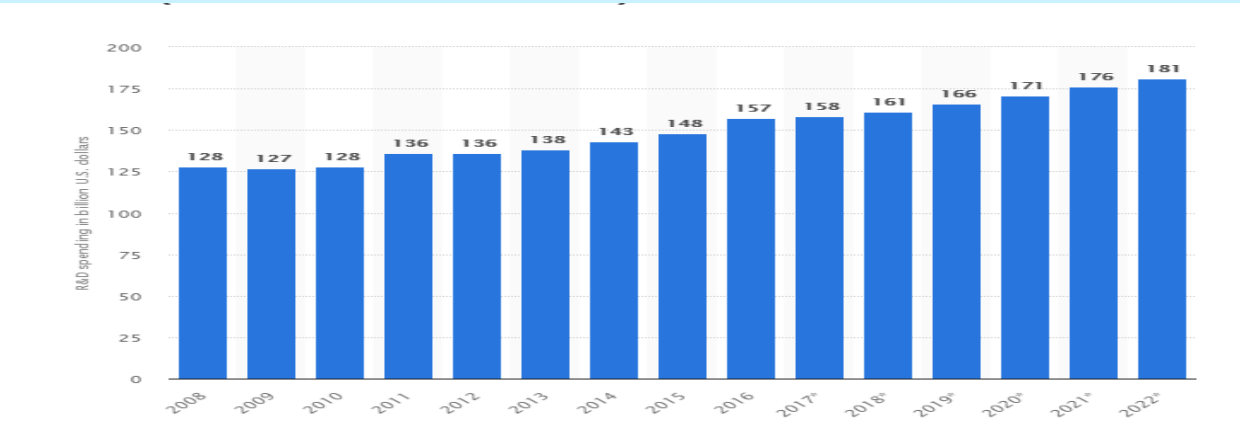



Fig: The Global pharmaceutical research and development spending from 2008 to 2022

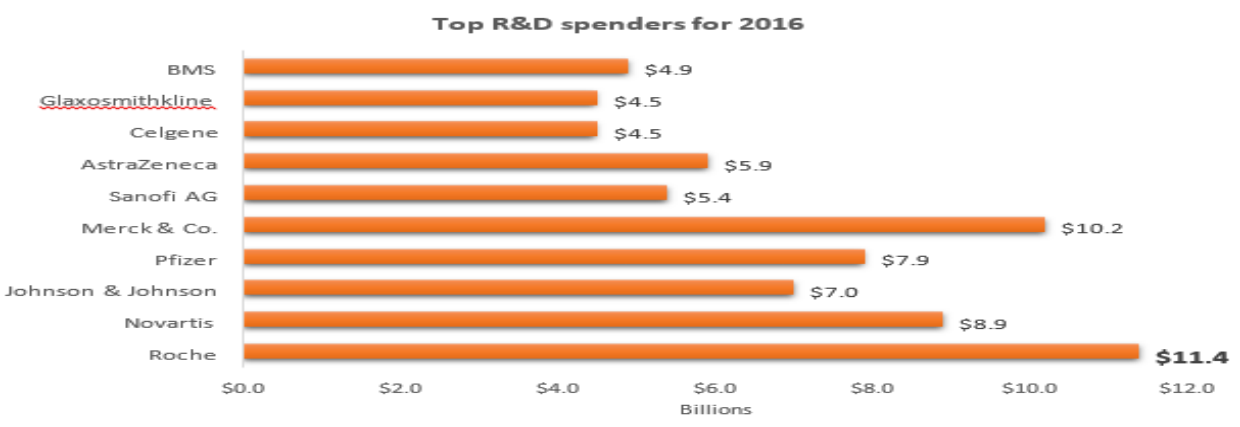
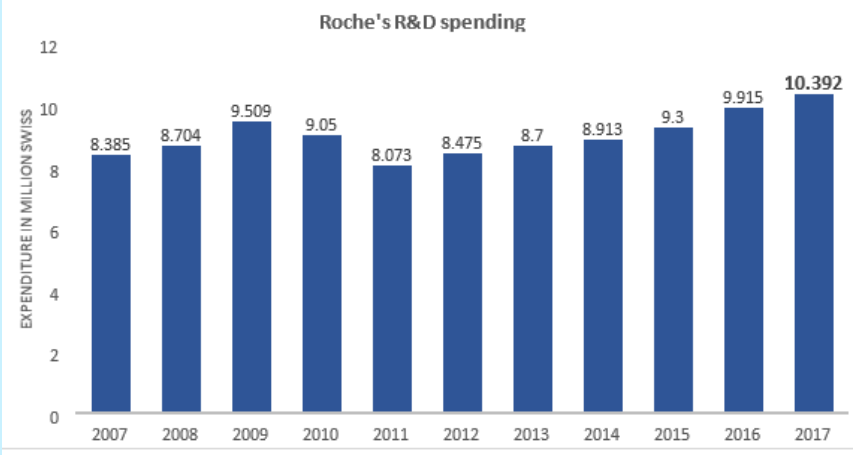
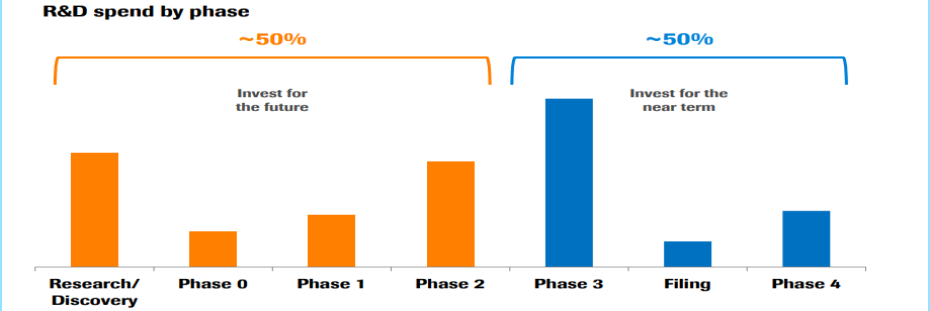



Fig : Major Players

## Roche Spending Pattern

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# Factors Effecting R&D efficiency

## Risk Factors

Probability of technical and regulatory success (PTRS) for drug R&D of 4.1 %. In general, the reasons of the reported high attrition rates are diverse and comprise:

- lack of reliability of published data,
- biopharmaceutical issues including suboptimal PK,
- poorly predictive preclinical models in discovery research and preclinical testing,
- the concept of target-based drug discovery with the related advanced complexity of target selection, a competition for proprietary targets and the complex process of target validation,
- complexity of clinical trials (to treat chronic diseases), together with increasing demands from regulatory authorities and payers, and
- the lack of know-how of smaller organizations resulting in a lower PTRS from Phase I to submission than large organizations

## Impact of Interval for development of any new drug molecule

According to Paul et al. [drug R&D (across all therapeutic areas) takes on average 14 years [Discovery research lasts for 4.5 years, preclinical testing continues for 1 year, the three clinical development phases take 1.5, 2.5 and 2.5 years, respectively, and the phase from submission to launch requires another 18 months. Interval durations for basic research and post-approval Phase IV trials need to be added to the overall R&D time to consider the entire pharmaceutical R&D process

There are two additional findings when reviewing drug R&D timelines: Clinical development today takes more time than in the past. While the average clinical development time for drugs approved between 2005 and 2009 was 6.4 years, newer data from the 2014 CMR

Factbook show that the composite median interval duration for ongoing development projects (2008–2012) is 9.1 years.
The CMR data clearly show a trend toward increased interval  preclinical development (+17 %, 2004–2012) and in phase I of clinical development (+58 %, 2004–2012).

The average time for the FDA review and approval has decreased significantly since the enactment of the Prescription Drug User Fee Act (PDUFA)

# Factors Effecting R&D efficiency

## Time influence R&D costs

The long overall time of pharmaceutical R&D impacts the total R&D costs, the risk of industry rivalry and the uncertainties of generic competition.

First, investments in R&D projects were incurred many years ago and need to be capitalized till the date of ROI of the new drug. The capitalization of R&D costs results in an enormous increase in the overall R&D expenditures.

Second, as many pharmaceutical companies follow comparable strategies as to therapeutic areas, target diseases, biologic mechanisms and drug targets, the long R&D timelines increase the risk of competition, reduce the chance to be first-in market, cut the market potential and the commercial success of a drug candidate.

Third, the effective date of generic competition influences the ROI of a new drug, as any delay in drug development results in a reduction of the commercially usable patent term

## Cost Evaluation

The costs for pharmaceutical R&D increased in the past decades significantly. It was reported that an annual inflation-adjusted increase of R&D costs of 8.6 % for the period of 2009-2016 . Other studies support this view: while the costs per NME were published to be USD 250 million before the 1990s, the average out-of-the-pocket costs per NME have been calculated to be USD 403 million (2000s) and USD 873 million (2010), respectively

Split to the phases of R&D, Paul et al. reported that drug discovery and preclinical development account for 33 % of the total cost per NME (USD 281 million), clinical development (phase I to submission) represents 63 % (USD 548 million) and submission to launch costs 5 % (USD 44 million) of the overall expenditures per NME.

# Factors Effecting R&D

## Research collaborations are another helping hands

Traditionally, the pharmaceutical industry has collaborated with third parties to access specialty know-how?

As the complexity of pharmaceutical R&D increased fundamentally, nowadays collaborations are more and more used to get access to the required enlarged set of skills and technologies, such as novel drug targets, validation of targets, signal transduction pathway knowhow, animal models, disease expertise, translational medicine know-how and biomarkers
As for example, GSK is spending nearly half of its R&D budgets to collaboration partners from academia or the biotechnology industry.

Discovery Partnerships with Academia (DPAc), an alliance program starting from early screening to late optimization in any disease area and any treatment modality. While the academic collaboration partner can profit from GSK's know-how in drug discovery and from its resources in medicinal chemistry, preclinical safety and pharmacokinetics, GSK can access ideas from academia to boost its innovation potential
The new facility brings together around 1000 employees from Pfizer in one of the most well-known science hubs with famous universities, such as the Massachusetts Institute of Technology
(MIT) or Harvard University, and more than 150 companies of the biopharmaceutical/biotechnology sector, amongst others Eli Lilly, Millennium (Takeda), AstraZeneca, Sanofi, GSK and Novartis

## M&As and Project Acquisitions is helping R&D to grow and compensate revenue Losses

**Since the financial crisis of 2007, M&As have become increasingly important in the biopharmaceutical sector.** Pharmaceutical companies use M&As to compensate revenue losses of blockbuster patent expirations, to access strategically important intellectual property (IP), to exploit technology-based treatment innovations, to develop new core competencies, or to fill R&D pipeline gaps.

Most of the research-based pharmaceutical companies widened the breadth of their portfolio by accessing research projects and drug candidates from external sources to supplement their in-house pipeline and to meet at least part of their growth objectives by product innovation.

Today, 50 % of the R&D pipelines of multinational pharmaceutical companies come from external sources**.**

# New opportunities

## Out sourcing can provide services along the whole value chain

The global drug discovery outsourcing market was USD 14.9 billion (2014) and is expected to reach USD 25 billion by 2018, while the market for CRO-conducted clinical trials was USD 23.1 billion (2014) and is expected to increase to USD 35.8 billion by 2020

## Innovation Centres can improve the structure

GSK launched in 2007 its Centre of Excellence for External Drug Discovery (CEEDD), an externally focused R&D centre that facilitates drug discovery alliances up to clinical proof of-concept (PoC) with external partners working across all therapeutic areas
Pfizer established the Global Centres for Therapeutic Innovation (CTIs) in 2010, an open innovation model that aims at founding global partnerships between Pfizer and academic medical centers

## Virtual R&D new development model used for reducing financial risk

A virtual R&D model can be defined as an organization which works with a limited number of internal staff and which uses external resources, technologies and facilities on demand to develop their R&D projects efficiently

Pharmaceuticals. Chorus, an entity of Eli Lilly, has proven that virtual R&D can help to reduce both cost and time needed in pharmaceutical R&D

Approximately 25 % of Chorus' budget are fixed overhead costs, the remaining 75 % are allocated to the external costs of the drug projects. The success of Chorus is outstanding, as since 2002, the productivity of Chorus has been 3–10 times higher than the traditional pharmaceutical R&D model of Eli Lilly—in particularly the improved PTRS in Phase II provided the greatest potential to increase the R&D efficiency

# Conclusion

M&As have become increasingly important in the biopharmaceutical sector and its an easy way to expand the business and come up with new drug.

Companies need to identify the right growth strategies, need to build up the right core competences for drug R&D internally, need to build external networks with academic partners and service providers and need to accept the high costs for product innovation and ensure a sustainable investment in R&D to generate a steady flow of new innovative drugs.

Finally, research-based pharmaceutical companies that cannot afford to diversify or to follow the knowledge creator and integrator models need to have an eye on other R&D concepts that are more appropriate for their set-up. Certainly, open innovation has proven to be a concept of significant attention for the pharmaceutical industry.

# Thank You

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