



Is internal R&D,  
M&A or licensing  
**most impactful** on  
the number of FDA  
drug approvals?



## Key Findings from

“A case study assessing the impact of M&A and licensing on FDA drug approvals of leading pharmaceutical companies”

*A. Schuhmacher et al (2025)*

[www.sciencedirect.com/science/article/pii/S1359644625000194](https://www.sciencedirect.com/science/article/pii/S1359644625000194)



# Study Purpose

Assess relationship between

①

R&D Expenditure

②

Number of M&A deals

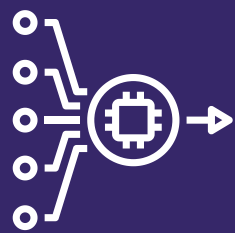
③

Number of in-licensing agreements

④

R&D Intensity  
(Expenditure/revenue)

&



The number of FDA approvals (R&D output)



# Data from 2012-2021

## Sources:

REFINITIV<sup>®</sup>  
EIKON

Specifically  
reports  
internal R&D

FDA

Drug approvals

 GlobalData.

Supplementary  
in-licensing  
details

## Statistical analysis:

Calculation of Pearson's correlation coefficients, 95% confidence intervals and two-sided p-values



# Limitations:

A critical point to consider when reviewing the findings is the varying timeframes for the approval of drugs as a result of internal R&D, M&A and in-licensing activities



# In Scope Companies:

14 of the top 20 by 2022 Revenue

**AMGEN**



*Lilly*

**sanofi**



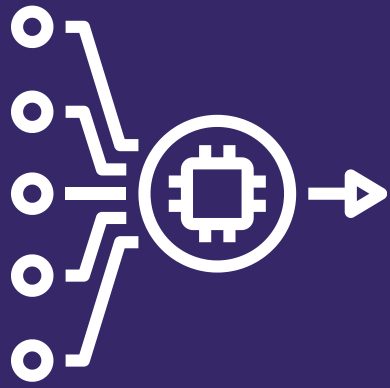
**GSK**

**abbvie**



Excluded those who had less than 50% revenue from pharmaceuticals, non-research driven organisations and those lacking consistent data over the 10 years





**Total FDA-  
approved drugs:  
155**

**Mean FDA-approved  
drugs:  
11.07  
(SD = 3.73)**



1

**Total R&D  
Expenditures:**  
**\$910.55 Bn**

**Mean R&D  
Expenditures:**  
**\$65.04 Bn**  
**(SD = 24.99)**

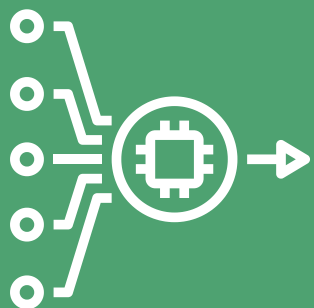


# 1

## R&D Expenditure



Cumulative R&D expenditure positively correlated with the number of FDA-approved new drugs



\$1 billion in expenditure = 0.12 outputted new drugs



60% of the variability in new drug approvals is explained through R&D expenditure



②

**Total Number  
of M&A Deals:**

**144**

**Mean M&A Deals:**

**10.29**

**(SD = 4.1)**

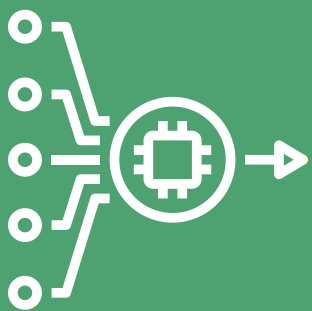


# 2

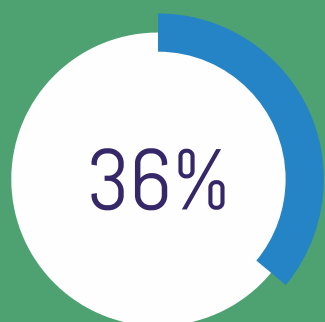
## Number of M&A deals



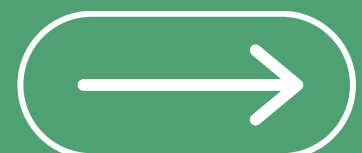
The number of new drugs correlated with the number of M&A Deals



1 deal led to 0.53 new drug approvals



of the variability of new drugs is explained by the number of M&A deals



③

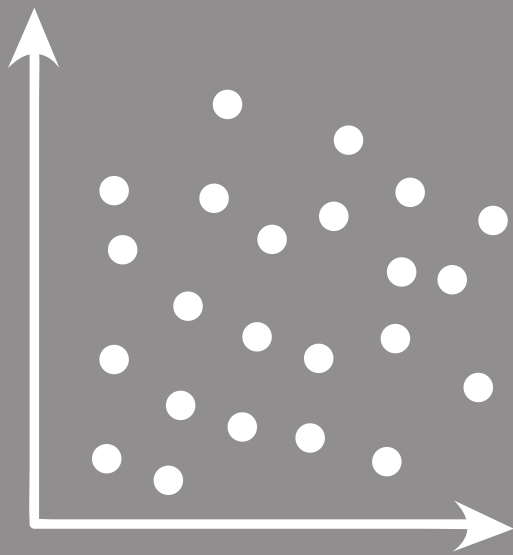
**Total Number of  
In-licensing Deals:  
402**

**Mean In-licensing Deals:  
28.71  
(SD = 7.46)**



3

**No correlation  
between the # of  
in-licensing deals  
and their R&D  
output**



The authors' analysis does not suggest licensing agreements are ineffective; just that there is no correlation



**Don't stop  
your licensing  
activities!**



**Challenge  
your  
organisation's  
approach**





What measurable contributions does the license offer?



What added value does it provide beyond acquiring knowledge and building competencies?



What is the tangible R&D output?



4

**Average R&D  
intensity:**

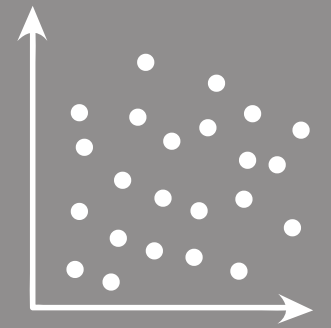
18.1%

(SD = 3.16%)



# 4

## No positive relationship between R&D intensity and R&D output



Substantiates a claim from a previous paper that flexible R&D investment is better than a fixed value of intensity



Being able to spend more in the years where more drugs, or drugs with a higher probability of success, need investment may avoid pushing drugs with a lower probability because “We need to spend the money”





**Future studies  
proposed by the  
authors:**

Assess the  
commercial success  
of the drugs and look  
at correlations





## Future studies proposed by the authors:

Explore the relationship  
between the variables  
(R&D expenditure,  
intensity, M&A, and  
licensing)





## Future studies proposed by the authors:

Follow up in 10 years to  
strengthen findings  
especially for longer  
term projects



## Questions for Corporate Strategy, BD and R&D leaders:



How does your company compare on the metrics (if not included in this list) ?



How can you ensure your licensing activities are maximally beneficial?



How well do your R&D initiatives mesh with your overall business development strategy?





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