Università degli Studi di Milano
Jean Monnet Centre of Excellence
"The impact of European Union Research and Innovation Policy upon Services of General Interest"
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Mapping of Long-term Public and Private Investments in the Development of Covid-19 Vaccines

Study prepared at request of the European Parliament's Policy Department for Economic, Scientific and Quality of Life Policies to support the Special Committee "COVID-19 pandemic: lessons learned and recommendations for the future" (COVI)

European Parliament, 23 March 2023

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MAIN OBJECTIVES

1. To map the funding for R&D and the expansion of the production capacity for the manufacturing of nine COVID-19 vaccines in order to estimate the relative importance of funds by different actors
2. To ascertain the need for continuing support COVID-19 vaccines with public funds

MAIN FINDINGS IN A NUTSHELL

- Collected evidence suggests that from 2020 to early 2022, **combined support in various forms (mainly grants) by external funds for R&D and the expansion of production capacity for the nine vaccines included in the study were in the range of EUR 9 billion**
- Additionally, there were about **EUR 21 billion of APAs (mainly by the US and EU)**
- **R&D expenditure sustained by companies** for COVID-19 vaccines is not publicly available: our estimate is **in the range of EUR 5 billion for 2020-2021**
- **Corporate investment to sustain production before authorisation is estimated about EUR 11 billion**
- Governments largely **de-risked** corporates' investments in vaccines' development and manufacturing by investing **EUR 30 billion** vs **EUR 16 billion** invested by the companies
- **The role of the EU plus Member States in funding R&D was marginal compared to the US government and to some extent UK** (and Germany)
- Scientific literature reviewed and experts interviewed for this study strongly suggest that **R&D for COVID-19 vaccines should be sustained because of future pandemic risks**

METHODS AND RESEARCH STREAMS

	Q1 - Mapping of funding of R&D and the production of COVID-19 vaccines	Q2 - Relative importance of funds invested into COVID-19 vaccines R&D by different actors	Q3 - Need for continuing support COVID-19 vaccines with public funds
Desk research	✓		✓
Statistical analysis	✓	✓	
Interviews	✓		✓

Source: Authors

THE CONSIDERED VACCINES

Authors, based on ECA (2022) and EMA website

Comirnaty – BioNTech/Pfizer	
Platform	mRNA
Use	Primary vaccination, booster (x3)
Population	• Primary vaccination: ≥6 months - ≥18 years • Booster: ≥5 years - ≥18 years
Phase achieved	Authorised in EU
Date of (conditional) authorisation	21/12/2020

Spikevax – Moderna	
Platform	mRNA
Use	Primary vaccination, booster (x3)
Population	• Primary vaccination: ≥6 months - ≥18 years • Booster: ≥12 years - ≥18 years
Phase achieved	Authorised in EU
Date of (conditional) authorisation	06/01/2021

Vaxzevria - AstraZeneca	
Platform	Adenoviral vector
Use	Primary vaccination, booster (x1)
Population	• Primary vaccination: ≥18 years • Booster: ≥18 years
Phase achieved	Authorised in EU
Date of (conditional) authorisation	29/01/2021

Jcovden - Janssen	
Platform	Adenoviral vector
Use	Primary vaccination, booster (x1)
Population	• Primary vaccination: ≥18 years • Booster: ≥18 years
Phase achieved	Authorised in EU
Date of (conditional) authorisation	11/03/2021

Nuvaxovid - Novavax	
Platform	Protein
Use	Primary vaccination, booster (x1)
Population	• Primary vaccination: ≥12 years - ≥18 years • Booster: ≥18 years
Phase achieved	Authorised in EU
Date of (conditional) authorisation	20/12/2021

COVID-19 Vaccine Valneva - Valneva	
Platform	Inactivated
Use	Primary vaccination
Population	• Primary vaccination: 18-50 years
Phase achieved	Authorised in EU
Date of (conditional) authorisation	24/06/2022

VidPrevtyn Beta – Sanofi Pasteur	
Platform	Protein
Use	Booster
Population	• Booster: ≥18 years
Phase achieved	Authorised in EU
Date of (conditional) authorisation	10/11/2022

COVID-19 Vaccine - HIPRA	
Platform	Recombinant protein
Use	Booster
Population	• Booster: Adults fully vaccinated
Phase achieved	Rolling review
Date of (conditional) authorisation	/

CVnCoV – Curevac	
Platform	mRNA
Use	Booster
Population	• Booster: ≥18 years
Phase achieved	Withdrawn
Date of (conditional) authorisation	/

AMOUNT OF EXTERNAL SUPPORT FUNDS RECEIVED BY ENTITY AND BY TYPE

EUR million	R&D only		R&D + manufacturing		APA***
	Grant*	Loan**	Grant*	Loan**	
Moderna	123.8		838.0		**8,974.8**
Pfizer					**5,929.8**
AstraZeneca	336.8		1,403.5		**1,993.7**
Novavax			1,982.0		
Sanofi			2,185.9		**607.2**
Janssen	46.8		780.6		**2,445.0**
BioNTech	118.4		584.6	100.0	
Valneva	15.2				**489.5**
Oxford University	19.8		57.5		
CureVac	15.6		291.9	25.0	**450.0**
Hipra	6.6	12.9		45.0	
TOTAL	683,0	12.9	8,124.0	170.0	**20,890**

Note: CureVac and Hipra are not part of the vaccines authorised by EMA. * Grant is non-repayable support provided either by the public sector or other private companies. ** Loan is repayable finance provided either by the European Investment Bank or national public entities. *** The APA volume considered is the total volume of the contract for the purchase of doses (excluding optional ones) foreseen in the contract. The amount may or may not include a down payment. APA volumes for BioNTech, and Oxford University are nil because marketing authorization for the vaccines they have developed is held respectively by Pfizer, and AstraZeneca.

Source: Authors

SUMMARY FICHES BY COMPANY

SUMMARY FICHE
ASTRAZENECA

The company has preferred not to comment on this Fiche or on information from the public domain

1. KEY INFO

Name	AstraZeneca plc
Headquarters	Cambridge, England, UK
Year of foundation	1999
Type of firm	Public limited company
Listed	LSE: AZN

2. PRODUCTS AND TURNOVER (£ MILLIONS)

Product portfolio	Oncology, biopharmaceuticals, cardiovascular, renal, metabolism, respiratory and immunology, vaccines, rare diseases	Website
Revenue (Net income) 2019	19114 (+1046)	Financial Report
Revenue (Net income) 2020	21518 (+2492)	Financial Report
Revenue (Net income) 2021	27509 (+81)	Financial Report

3. COVID-19 VACCINE

Name	Vaxzevria or COVID-19 Vaccine AstraZeneca
Type	Viral vector
EMA status	Approved
Date of the authorization request	01/2021
Date of EMA conditional marketing authorization	29/01/2021
Date of EMA standard marketing authorisation	31/10/2022
Date of FDA marketing authorization	/

SUMMARY FICHE
BIONTECH

The company never replied to principal investigator's requests of contact.

1. KEY INFO

Name	BioNTech SE
Headquarters	Mainz, Germany
Year of foundation	2008
Type of firm	Public company
Listed	Nasdaq: BNTX

2. PRODUCTS AND TURNOVER ($ MILLIONS)

Product portfolio	Immunotherapies for oncology and infectious diseases	Website
Revenue (Net income) 2019	122 (-200)	Financial Report
Revenue (Net income) 2020	550 (+17)	Financial Report
Revenue (Net income) 2021	22430 (+12166)	Financial Report

3. COVID-19 VACCINE

Name	Cominarty or Pfizer–BioNTech COVID-19 vaccine
Type	mRNA
EMA Status	Approved
Date of the authorization request to EMA	12/2020
Date of EMA conditional marketing authorisation	21/12/2020
Date of EMA standard marketing authorisation	10/10/2022
Date of FDA marketing authorisation	12/2020, then approved in 08/2021

SUMMARY FICHE
CUREVAC

The fiche has been read and validated by CureVac's representative.

1. KEY INFO

Name	CureVac
Headquarters	Tübingen, Germany
Year of foundation	2000
Type of firm	Public company
Listed	Nasdaq: CVAC

2. PRODUCTS AND TURNOVER ($ MILLIONS)

Product portfolio	Therapies using messenger RNA technology, focusing on three therapeutic areas: prophylactic vaccines, cancer immunotherapies and molecular therapies	Website
Revenue (Net income) 2019	19 (-112)	Financial Report
Revenue (Net income) 2020	56 (-147)	Financial Report
Revenue (Net income) 2021	122 (-487)	Financial Report

3. COVID-19 VACCINE

Name	(CVnCoV))
Type	mRNA
EMA Status	Withdrawn[48]
Date of the authorization request to EMA	02/2021

SUMMARY FICHE
GSK

The company stated in writing that GSK did not receive direct public funding related to the vaccine, while Sanofi, which is the marketing authorisation holder and developed the antigen, was the recipient of some support.

1. KEY INFO

Name	GSK plc
Headquarters	London, England, UK
Year of foundation	2000
Type of firm	Public limited company
Listed	LSE: GSK

2. PRODUCTS AND TURNOVER (£ MILLIONS)

Product portfolio	Infectious diseases, HIV, oncology, and immunology	Website
Revenue (Net income) 2019	33754 (+4645)	Financial Report
Revenue (Net income) 2020	34099 (+5749)	Financial Report
Revenue (Net income) 2021	34114 (+4385)	Financial Report

3. COVID-19 VACCINE

Name	VidPrevtyn Beta
Type	Subunit (adjuvanted recombinant)
EMA Status	Approved
Date of the authorization request	07/2021
Date of EMA marketing authorization	10/11/2022
Date of FDA marketing authorization	/

SUMMARY FICHE
HIPRA

This fiche includes the feedback received by Hipra's representatives.

1. KEY INFO

Name	Hipra
Headquarters	Amer, Girona, Spain
Year of foundation	1954
Type of firm	Biotechnological pharmaceutical company
Listed	No

2. PRODUCTS AND TURNOVER (EUR MILLIONS)

Product portfolio	Prevention for animal and human health, with a broad range of highly innovative vaccines and an advanced diagnostic service	Website
Revenue (Net income) 2019	40,1	
Revenue (Net income) 2020	48,7	
Revenue (Net income) 2021	50,1	

3. COVID-19 VACCINE

Name	COVID-19 Vaccine HIPRA (PHH-1V)
Type	Recombinant protein
Status	EMA: rolling review
Date of the authorization request	03/2022

SUMMARY FICHE
JANSSEN

After an initial contact with a senior representative, the company never provided a feedback.

1. KEY INFO

Name	Janssen Pharmaceuticals
Headquarters	Beerse, Belgium
Year of foundation	1953 (from 1961 part of J&J)
Type of firm	Pharmaceutical company
Listed	No (but Johnson & Johnson is listed)

2. PRODUCTS AND TURNOVER ($ MILLIONS)

Product portfolio	Cardiovascular, Immunology, Infectious Diseases, …	Website
Revenue (Net income) 2019	82059 (+15119)	Financial Report
Revenue (Net income) 2020	82584 (+14714)	Financial Report
Revenue (Net income) 2021	93775 (+20878)	Financial Report

3. COVID-19 VACCINE

Name	Jcovden or COVID-19 Vaccine Janssen (Ad26.COV2.S)
Type	Viral vector
EMA Status	Approved
Date of the authorization request	02/2021
Date of EMA conditional marketing authorisation	11/03/2021
Date of EMA standard marketing authorisation	10/01/2023
Date of FDA marketing authorisation	02/2021

SUMMARY FICHE
MODERNA

No feedback was provided on this fiche by the company due to their confidentiality policy.

1. KEY INFO

Name	Moderna
Headquarters	Cambridge, Massachusetts, U.S.
Year of foundation	2010
Type of firm	Public company
Listed	Nasdaq: MRNA

2. PRODUCTS AND TURNOVER ($ MILLIONS)

Product portfolio	Therapies using messenger RNA technology, such as for infectious, immuno-oncology, and cardiovascular diseases	Website
Revenue (Net income) 2019	60 (-514)	Financial Report
Revenue (Net income) 2020	803 (-747)	Financial Report
Revenue (Net income) 2021	18413 (+12202)	Financial Report

3. COVID-19 VACCINE

Name	Spikevax or COVID-19 Vaccine Moderna (mRNA-1273)
Type	mRNA
EMA Status	Approved
Date of the authorization request to EMA	11/2020
Date of EMA conditional marketing authorisation	06/01/2021
Date of EMA standard marketing authorisation	03/10/2022
Date of FDA marketing authorisation	12/2020

SUMMARY FICHE
NOVAVAX

This fiche includes the feedback received by Novavax's representative.

1. KEY INFO

Name	Novavax
Headquarters	Gaithersburg, Maryland, U.S.
Year of foundation	1987
Type of firm	Public company
Listed	Nasdaq: NVAX

2. PRODUCTS AND TURNOVER ($ MILLIONS)

Product portfolio	Transformational vaccines	Website
Revenue (Net income) 2019	19 (-133)	Financial Report
Revenue (Net income) 2020	476 (-418)	Financial Report
Revenue (Net income) 2021	1146 (-1744)	Financial Report

3. COVID-19 VACCINE

Name	Nuvaxovid and Covovax (NVX-CoV2373)
Type	Subunit (adjuvanted recombinant)
EMA Status	Authorised
Date of the authorization request to EMA	02/2021
Date of EMA conditional marketing authorisation	20/12/2021
Date of FDA marketing authorisation	07/2021

SUMMARY FICHE
PFIZER

No comment on this fiche was provided by the company due to their confidentiality policy

1. KEY INFO

Name	Pfizer
Headquarters	New York City, New York, U.S.
Year of foundation	1849
Type of firm	Public company
Listed	NYSE: PFE

2. PRODUCTS AND TURNOVER ($ MILLIONS)

Product portfolio	Largest drug company (cardiovascular, vaccines, antidepressants, …)	Website
Revenue (Net income) 2019	41172 (+10838)	Financial Report
Revenue (Net income) 2020	41651 (+6630)	Financial Report
Revenue (Net income) 2021	81288 (+22415)	Financial Report

3. COVID-19 VACCINE

Name	Cominarty or Pfizer–BioNTech COVID-19 vaccine
Type	mRNA
EMA Status	Approved
Date of the authorization request to EMA	12/2020
Date of EMA conditional marketing authorisation	21/12/2020
Date of EMA standard marketing authorisation	10/10/2022
Date of FDA marketing authorisation	12/2020, then approved in 08/2021

SUMMARY FICHE
SANOFI

The company has declined to comment on this Fiche and stated that information linked to the APA are proprietary or from external sources.

1. KEY INFO

Name	Sanofi Pasteur
Headquarters	Lyon, France
Year of foundation	2004
Type of firm	Vaccines division of Sanofi
Listed	No (but Sanofi S.A. is listed, Euronext Paris: SAN)

2. PRODUCTS AND TURNOVER (EUR MILLIONS)

Product portfolio	Vaccines	Website
Revenue (Net income) 2019	36126 (+2907)	Financial Report
Revenue (Net income) 2020	36041 (+12294)	Financial Report
Revenue (Net income) 2021	37761 (+6223)	Financial Report

3. COVID-19 VACCINE

Name	VidPrevtyn Beta
Type	Subunit (adjuvanted recombinant)
EMA Status	Approved
Date of the authorization request	07/2021
Date of EMA marketing authorization	10/11/2022
Date of FDA marketing authorization	/

SUMMARY FICHE
VALNEVA

The company declined the participation in the study, as for communication to Vaccine Europe, due to the fact they are under confidentiality with some governments

1. KEY INFO

Name	Valneva SE
Headquarters	Saint-Herblain, France
Year of foundation	2013
Type of firm	Public company
Listed	Euronext Paris: VLA

2. PRODUCTS AND TURNOVER (EUR MILLIONS)

Product portfolio	Vaccines	Website
Revenue (Net income) 2019	126 (-2)	Financial Report
Revenue (Net income) 2020	110 (-64)	Financial Report
Revenue (Net income) 2021	348 (-73)	Financial Report

3. COVID-19 VACCINE

Name	Valneva COVID-19 vaccine
Type	Inactivated
EMA Status	Approved
Date of the authorization request to EMA	05/2022
Date of FDA marketing authorization	/
Date of EMA marketing authorization	24/06/2022

EXAMPLE: SUMMARY FICHE BY COMPANY

SUMMARY FICHE

NOVAVAX

This fiche includes the feedback received by Novavax's representative.

1. KEY INFO

Name	Novavax
Headquarters	Gaithersburg, Maryland, U.S.
Year of foundation	1987
Type of firm	Public company
Listed	Nasdaq: NVAX

2. PRODUCTS AND TURNOVER ($ MILLIONS)

Product portfolio	Transformational vaccines	Website
Revenue (Net income) 2019	19 (-133)	Financial Report
Revenue (Net income) 2020	476 (-418)	Financial Report
Revenue (Net income) 2021	1146 (-1744)	Financial Report

3. COVID-19 VACCINE

Name	Nuvaxovid and Covovax (NVX-CoV2373)
Type	Subunit (adjuvanted recombinant)
EMA Status	Authorised
Date of the authorization request to EMA	02/2021
Date of EMA conditional marketing authorisation	20/12/2021
Date of FDA marketing authorisation	07/2021

4. EXTERNAL FUNDING SOURCES

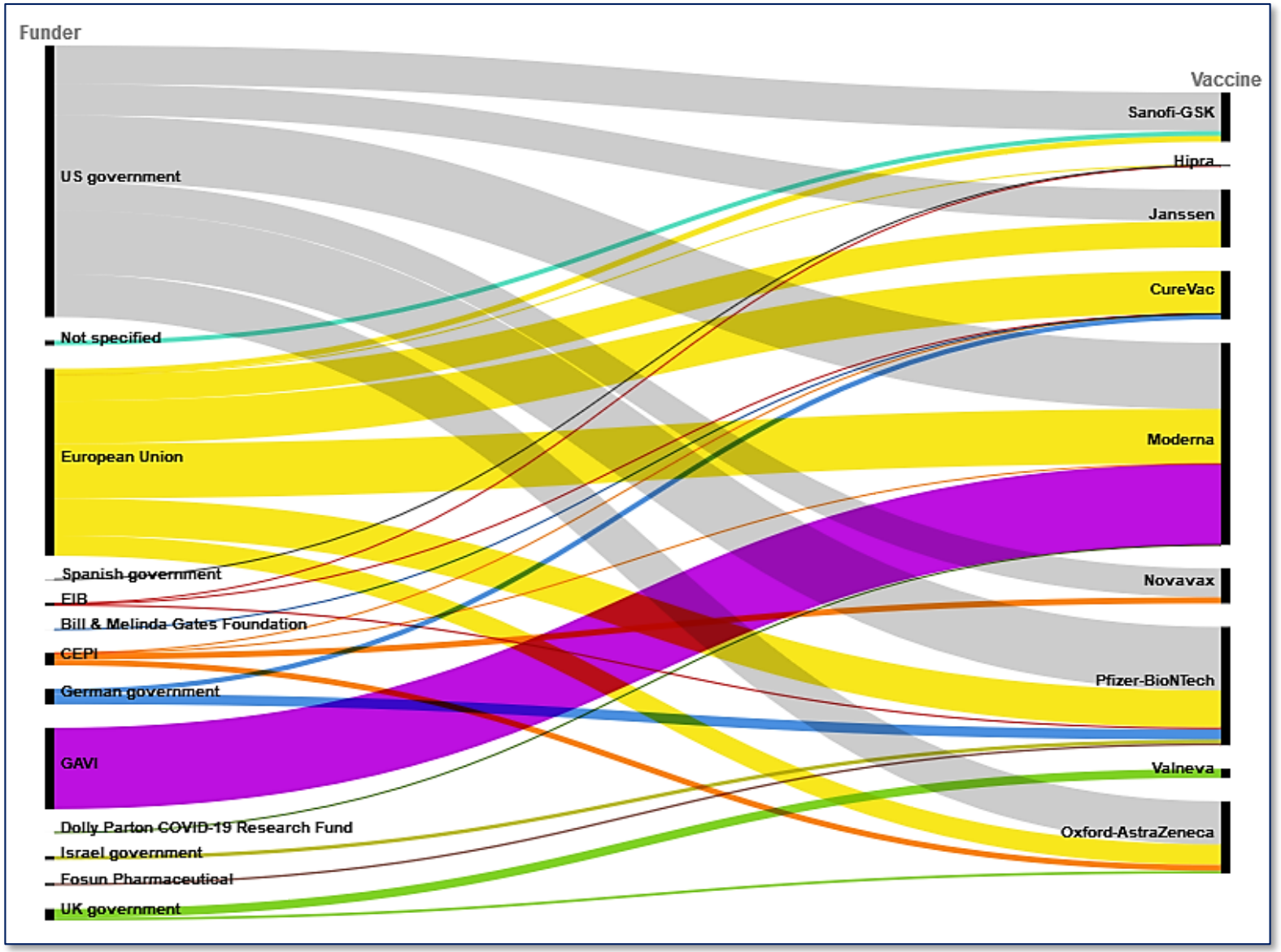
FUNDING FOR R&D + MANUFACTURING CAPACITY

Date	Funder	Amount ($ Millions)	Typology	Source
2020	US government	60	Direct funding (RD+ manufacturing)	Novavax, 2021, "A New Era Has Begun", Annual Report.
07/2020	US government	1800	Direct funding (RD+ manufacturing)	BARDA's Expanding COVID-19 Medical Countermeasure Portfolio
Until 2021	CEPI	399.5	Direct funding (RD+ manufacturing)	Novavax, 2021, "A New Era Has Begun", Annual Report. CEPI portfolio.

ADVANCE PURCHASE AGREEMENTS (APA)

Date	Funder	Number of doses	Price/dose	Amount ($ Millions)	Typology	Source
2021	Gavi	300	missing	missing	APA	Novavax, 2021, "A New Era Has Begun", Annual Report.
2021	EU	100 million doses for 2021[67]	missing	missing	APA	Novavax, Inc., 2021, "Novavax and European Commission Finalize Advance Purchase Agreement for up to 200 million doses of COVID-19 Vaccine", PRNewswire

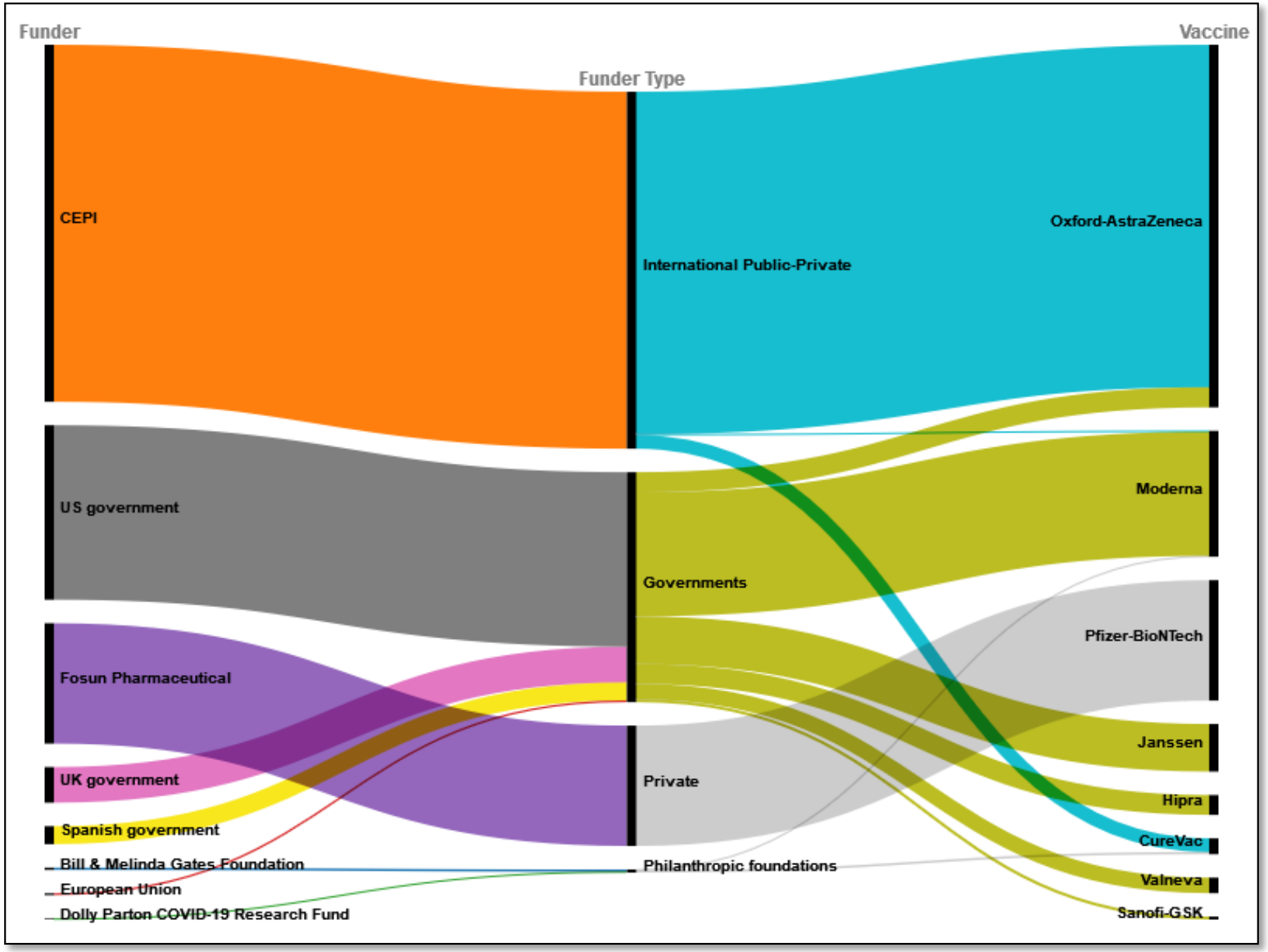
SOURCES OF COVID-19 VACCINE FUNDING BY FUNDER*



*Regardless the incentive mechanism (and including APAs)

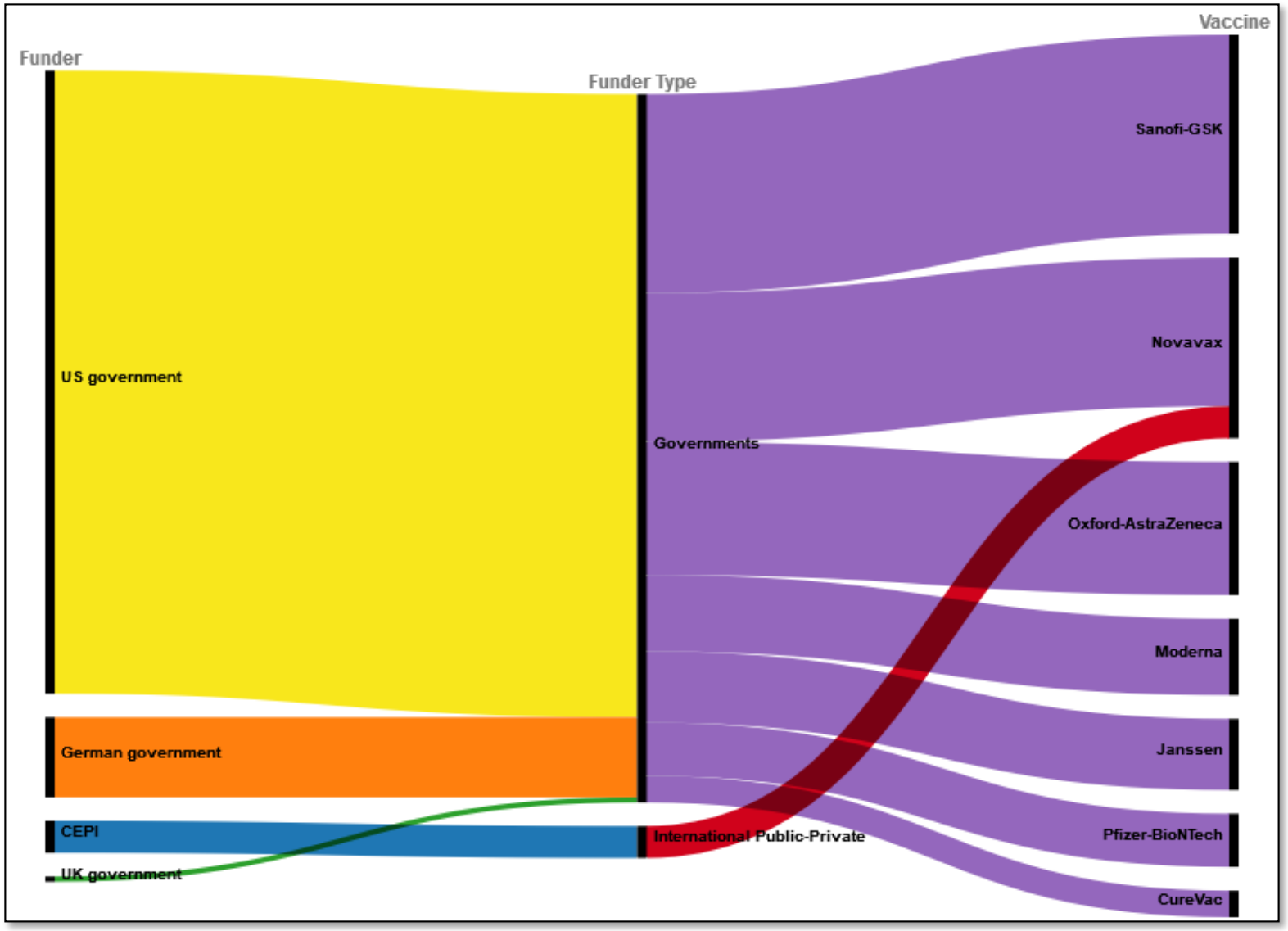
Source: Authors

SOURCES OF GRANTS FOR COVID-19 VACCINE "R&D ONLY" BY FUNDER



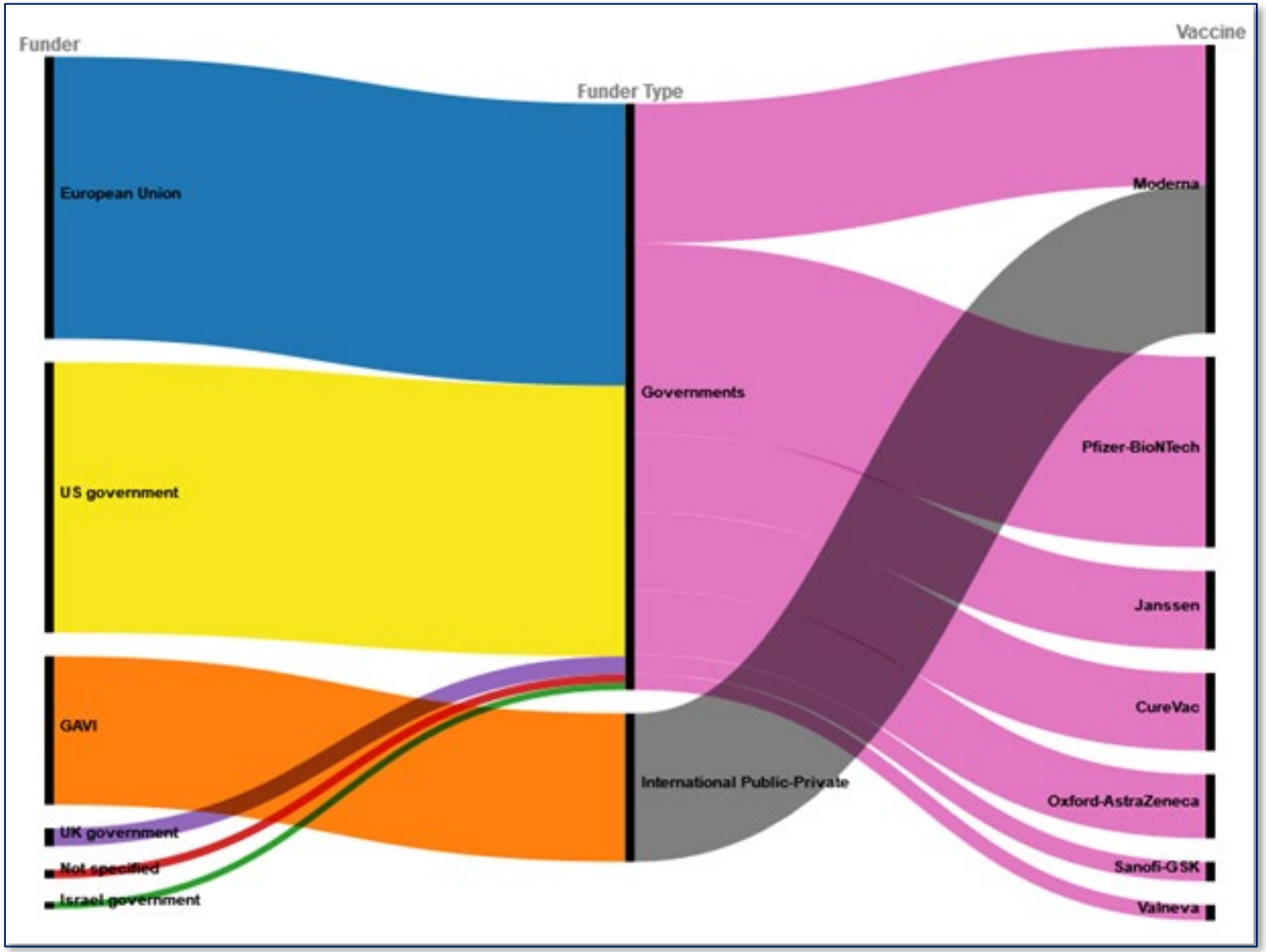
Source: Authors

SOURCES OF GRANTS FOR COVID-19 VACCINE "R&D + MANUFACTURING" BY FUNDER



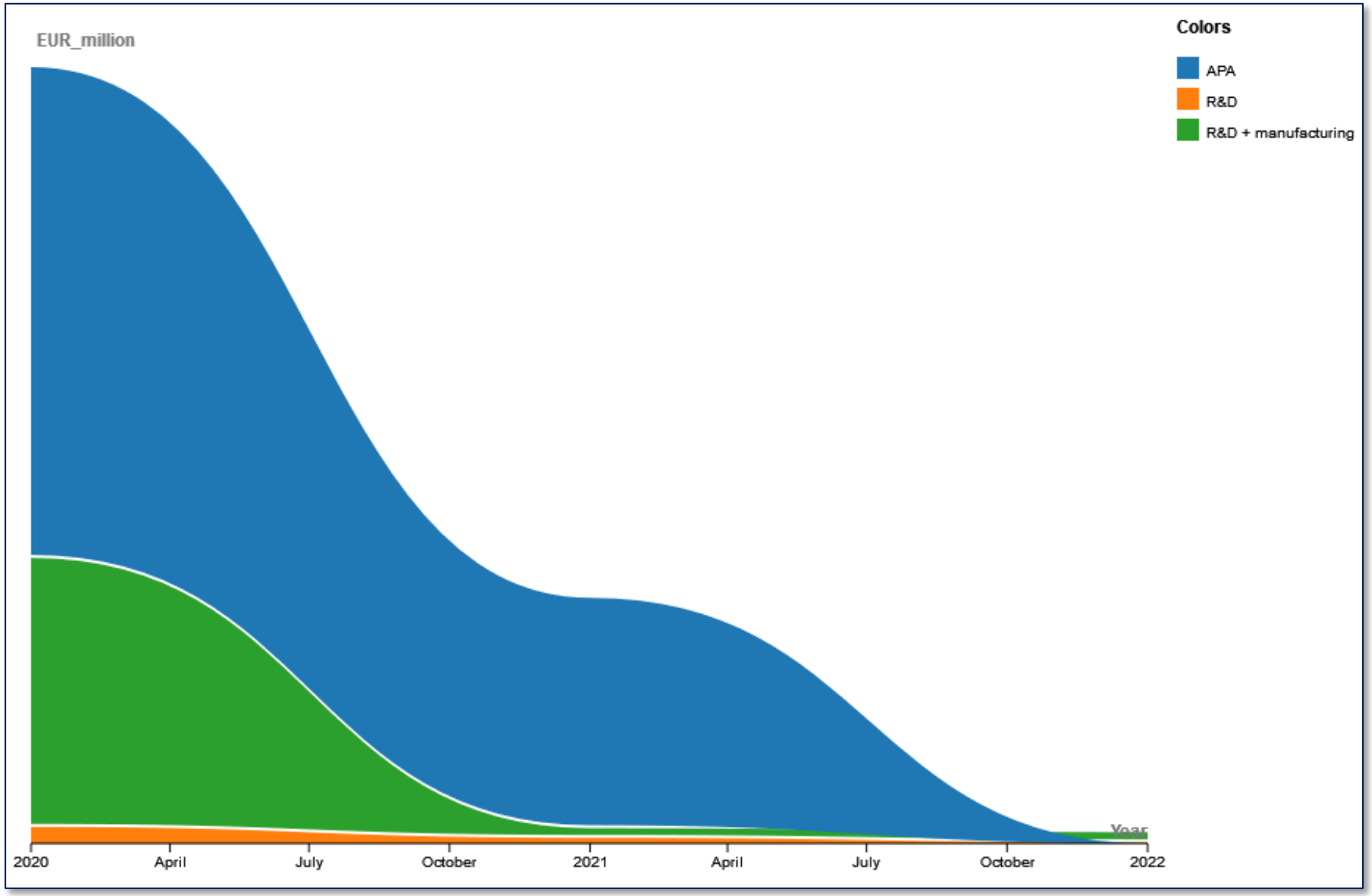
Source: Authors

SOURCES OF COVID-19 VACCINE APAs BY FUNDER



Source: Authors

EXTERNAL FUNDING OVER TIME



Source: Authors

TOTAL CORPORATE R&D EXPENDITURE, 9 COMPANIES, 2018-21

Company		2018	2019	2020	2021	Note
Pfizer	USD	7,760	8,385	9,393	13,829	Conditional marketing authorisation issued: 21/12/2020.
Novavax	USD			609	2,246	Figures specific for Nuvaxovid. Conditional marketing authorisation issued: 20/12/2021.
Janssen	USD	8,446	8,834	9,563	11,882	Figures specific for "pharmaceutical". Conditional marketing authorisation issued: 11/03/2021.
Sanofi	EUR	5,894	6,018	5,530	5,692	Marketing authorisation issued: 10/11/2022.
Moderna	USD	454	496	1,370	1,991	Conditional marketing authorisation issued: 06/01/2021.
Valneva	EUR			19.0	113.9	Figures specific for COVID-19. Marketing authorisation issued: 24/06/2022.
AstraZeneca	USD	5,932	6,059	5,991	9,736	Conditional marketing authorisation issued: 29/01/2021.
BioNTech	EUR	n.a.	226.5	645	949	See Pfizer for the authorization date.
GSK	GBP	3,893	4,568	5,098	5,278	See Sanofi for the authorization date.

Source: Authors based on companies annual reports

TOTAL CORPORATE R&D EXPENDITURE, 9 COMPANIES, 2018-21

- **The cumulated volume of corporate R&D expenditure incurred by producers** (of the **seven** authorised vaccines only) **somehow attributable to COVID-19 vaccines is** in the range EUR 4-5 billion of corporate R&D
- This number has to be compared to the **EUR 9 billion of external support** provided in years 2020 and 2021 (for **nine** vaccines), **out of which about EUR 8 billion is provided by the public sector**
- The EUR 9 billion figure (mostly in the form of grants), however, includes support to increasing production capacity
- This number does not include APAs
- This number does not consider additional funding, particularly by BARDA, to suppliers (such as Merck) related products, such as vials, biocontainers, needles, syringes, etc.

TOTAL CORPORATE FIXED ASSETS, 9 COMPANIES, 2018-21

MAY INCLUDE INVESTMENT FOR COVID-19 VACCINES IN 2020-2021*

Company	2018	2019	2020	2021
Pfizer	95,630	119,985	97,109	107,525
Novavax	77	67	272	372
Janssen Pharmaceutica	9,926	9,712	10,110	n.a.
Sanofi	1,636	1,583	n.a.	1,490
Moderna	349	410	847	7,591
Valneva	104	136	141	232
AstraZeneca	39,354	40,782	38,452	69,856
BioNTech	n.a.	237	651	759
GSK	45,896	70,758	65,915	71,676

*EUR Million. Source: Authors based on Orbis

CORPORATE INVESTMENT: 9 COMPANIES

- **The cumulative production investments of the nine companies in 2020-2021 may be in the range of EUR 11 +/- 3 billion**
- Mostly depending on the missing data about Pfizer investments outside Europe, about AstraZeneca worldwide, and how to interpret the total asset increase of some other companies, particularly the very high fixed investment of Moderna

SUMMING UP THE FIGURES

- Given this evidence, **we can confidently conclude that – albeit with significant differences across companies – US taxpayers were the major funders of corporate R&D and initial productive investment for most of the nine COVID-19 vaccines considered**
- The incentive in grant form was about one billion per vaccine on average (including one withdrawn), but with a vast variance across the considered vaccines and companies
- Moreover, **some of these incentives and the almost EUR 21 billion of APAs** (that we have been able to track) **may have also contributed to de-risking around EUR 11 billion of corporate investments for the production capacity of vaccines until 2021**

EIB SUPPORT FOR VACCINES R&D AND MANUFACTURING

- 2019, the EIB supported **BionNTech** with a **EUR 50 million loan agreement under the European Growth Finance Facility for BioNTech's personalised cancer immunotherapy programme**
- June 2020, the EIB and **BioNTech** signed a **EUR 100 million loan agreement for the development and large-scale production of portfolio of vaccines**, including a vaccine candidate against SARS-CoV-2
- July 2020, **the EIB and CureVac signed a EUR 75 million loan agreement for the development and large-scale production of vaccines**, including CureVac's vaccine candidate against SARS-CoV-2
- June 2021, **the EIB and Univercells signed a EUR 30 million loan agreement to enable the production of large volumes of COVID-19 vaccines** in a new facility and to co-develop a pipeline of COVID-19 vaccines
- October 2021, **the EIB and Hipra signed a loan agreement worth EUR 45 million to support the development of a new COVID-19 vaccine**
- April 2022, the EIB signed a **EUR 15 million loan with the Italian Biomedical Research Company (IRBM) to expand the capacity to make vaccines and increase research into the coronavirus and other diseases**

QUALITATIVE LONG-TERM SCENARIOS

A diminished threat	Regular reinfections	Barely manageable winters	Unmanageable winters	A new pandemic
• Hospitalisations and mortality very low • Routinely manageable	• New variants • Waning immunity and non-negligibile rates of hospitalisations and mortality among at-risk populations	• SARS-CoV-2 variants with higher intrinsic severity, combined with waning immunity • Declining vaccination willingness among the population	• Hospitalisation rates among the general population that exceed healthcare system capacities • Unpopularity of mandatory measures • General vaccination fatigue	• Novel pandemic strains • Return to 'flattening the curve' approaches for buying time to introduce revised vaccine • Stringent restrictions but careful assessment

Source: Authors, based on ECDC (2022)

R&D NEEDS

- The scientific knowledge about how to design COVID-19 vaccines has made significant progress in the last three years, but it is **far from having achieved a steady state**
- Along with major companies, many clinical trials are supported by public sector organisations, universities, and not-for-profit entities
- **Consensus exists on continuing support for COVID-19 vaccines adopting a portfolio strategy**
- Where to invest:
  - **novel vaccine platform to target some more stable features of the virus in order to induce durable sterilising immunity**
  - **next/new/second generation COVID-19 vaccines**
  - **fundamental research for the so-called universal coronavirus vaccines, or at least a pan-betacoronaviruses vaccine**
  - **sophisticated monitoring system**
  - **studies on under-investigated topics on existing vaccines**
  - **needle-free vaccines**
  - **comparative studies**
  - **stabilisation of vaccines**

MARKET MECHANISMS AND POSSIBLE FAILURES

- Disconnection between corporate R&D choices and public health priorities
- Mismatch between open science in the public sector and patents protecting the investors
- Excessive rents for financial investors in the industry
- Oligopolistic market power on the supply side, and issues of access and affordability affecting the demand
- Inadequate optimisation studies after market authorisation
- Information asymmetries in the public procurement

POLICY OPTIONS

- Betting on a benign evolution of the COVID-19 pandemic does not seem in compliance with a **precautionary principle** from a health policy perspective
- The forecast that SARS-CoV-2 will be around for at least the next ten years calls for sustained attention
- It seems clear that the industry will continue to invest in the R&D of adapted vaccines
- **The industry is unlikely to deploy the effort needed on all or most of the research avenues previously discussed**

LESSONS TO BE LEARNED FROM THE RECENT EXPERIENCE IN EU

1. Avoiding fragmentation and duplication of funding of R&D on COVID-19 vaccines
2. Ensuring public support for clinical development of the next generation COVID-19 vaccines or vaccines protecting against unknown coronaviruses
3. Creating a favourable regulatory and infrastructural environment for clinical trials in EU
4. Careful examination, in the public health interest, of the conditionalities of future R&D grants and de-risking mechanisms

POLICY OPTIONS

ACTIONS NEEDED FOR THE EUROPEAN UNION

SHORT TERM

A stable and clear legal **EU framework for corporate R&D support** on COVID-19 vaccines (and, more broadly, on vaccines for pathogens with pandemic potential) should be designed

SHORT TERM

The design and role of HERA should be revised to ensure it possibly becomes an autonomous entity with its own budget. HERA is burdened with being at the flagship of the capacity of the EU to react to future pandemics. Still, its leverage in terms of legal instruments, political consensus, and funding is not yet proportionate to its ambition

LONG TERM

Radically change the EU approach to support frontier biomedical science, a previous study for the EP (Florio et al. 2021) suggests exploring a more direct public intervention: the **creation of a pan-European R&D infrastructure** and delivery organisation for medicines in certain critical areas, with the budgetary scale and scientific ambition comparable to the US NIH, combining EU and MS efforts.

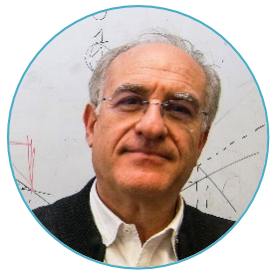
CONCLUSIONS

- Our results point out that, although revenues from COVID-19 vaccines were fully privatised, external funds provided during the pandemic were critically important, with **grants per vaccine of about EUR one billion, with a high variance across companies**
- If **APAs** are considered as an incentive, the role of external funds becomes even more significant (**nearly EUR 30 billion**)
- **Governments played a central role** as a major partner of private firms in the development of vaccines. Nevertheless, the amount of public funding, the type of funds, and the share of public funding over corporate ones, strongly vary from company to company
- **COVID-19 is here to stay**, and further R&D is required in order to improve vaccines for what concerns the resilience to virus mutations and more durable immunity

CONCLUSIONS

- **IPR arrangements should take into account the role of public funds, and pricing policies should reflect public R&D investments**
- Similarly, clauses to ensure **supply security** should be carefully listed
- A **stable legal environment** is also in the long-term interest of the competitiveness of the European industry
- In the long run, the creation of a **pan-European R&D infrastructure ("Biomed Europe")** and delivery organisation focusing on threats and areas of research and development that are underinvested under the current business model should be considered: STOA Study **"European pharmaceutical research and development. Could public infrastructure overcome market failures?"**
- The infrastructure should have the **budgetary scale and scientific ambition** of the US NIH and be equipped with home-grown research and development capacity

THANK YOU



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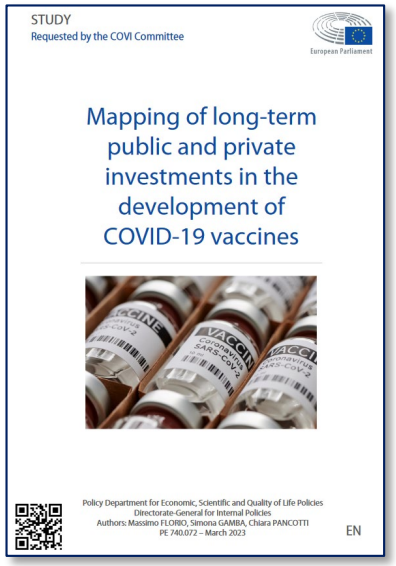

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