PUBBLICO E PRIVATO NELLA GESTIONE DEI RISCHI PER LA SALUTE: IL CASO DEI VACCINI COVID-19

Massimo Florio
Università degli Studi di Milano

con

Chiara Pancotti - CSIL e **Simona Gamba** - Università degli Studi di Milano

«LIBERARE LA CONOSCENZA PER RIDURRE LE DISUGUAGLIANZE»
Forum Disuguaglianze e Diversità
12 Aprile 2023

OBIETTIVI PRINCIPALI

1. Mappare i finanziamenti per R&S e l'ampliamento della capacità di produzione per la fabbricazione dei principali vaccini contro la COVID-19 al fine di valutare l'importanza relativa dei finanziamenti da parte dei diversi attori
2. Accertare la necessità di continuare a sostenere i vaccini contro la COVID-19 con fondi pubblici

https://www.europarl.europa.eu/RegData/etudes/STUD/2023/740072/IPOL_STU(2023)740072_EN.pdf

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

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

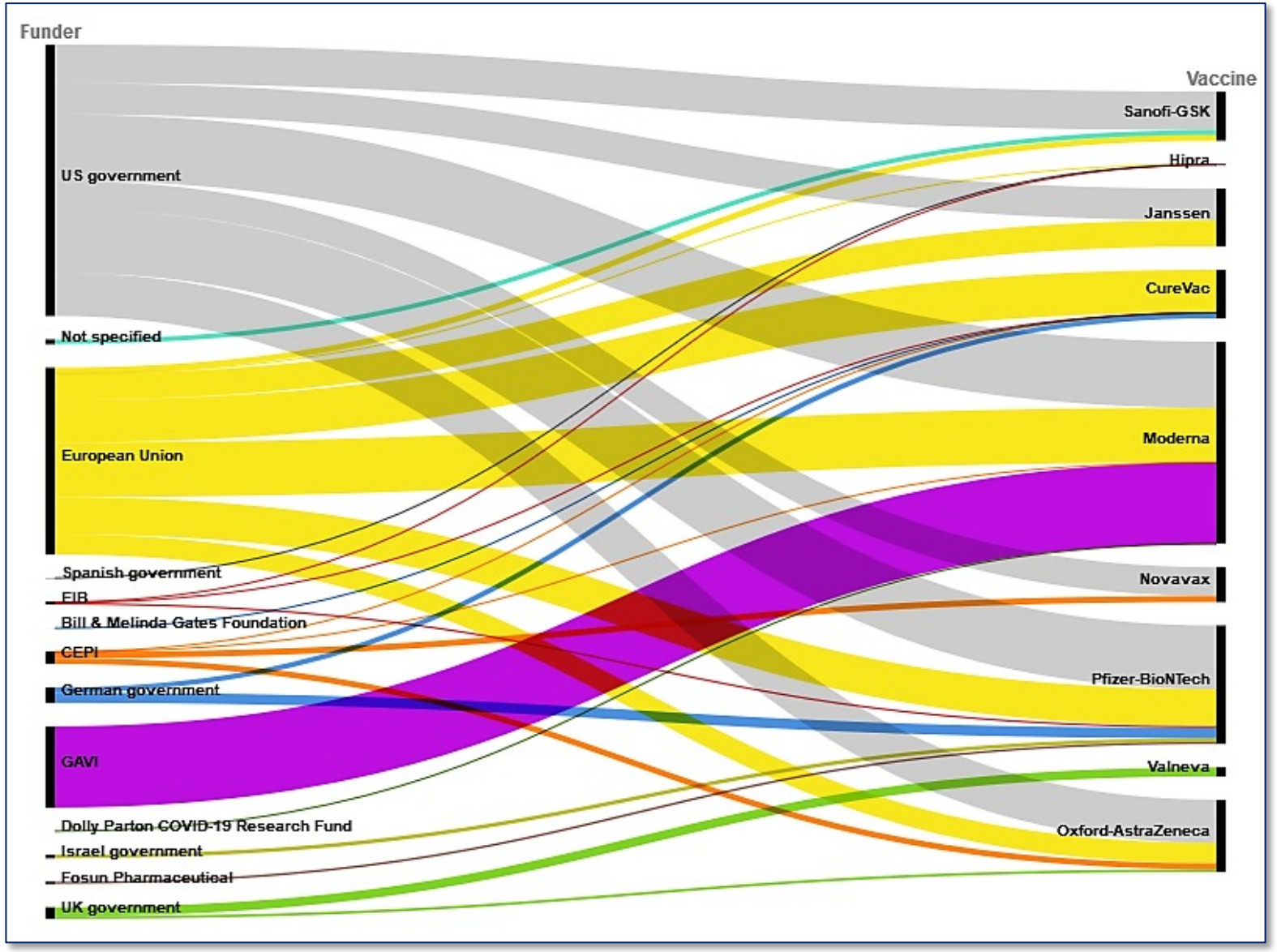
FUNDING FOR R&D + MANUFACTURING CAPACITY

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

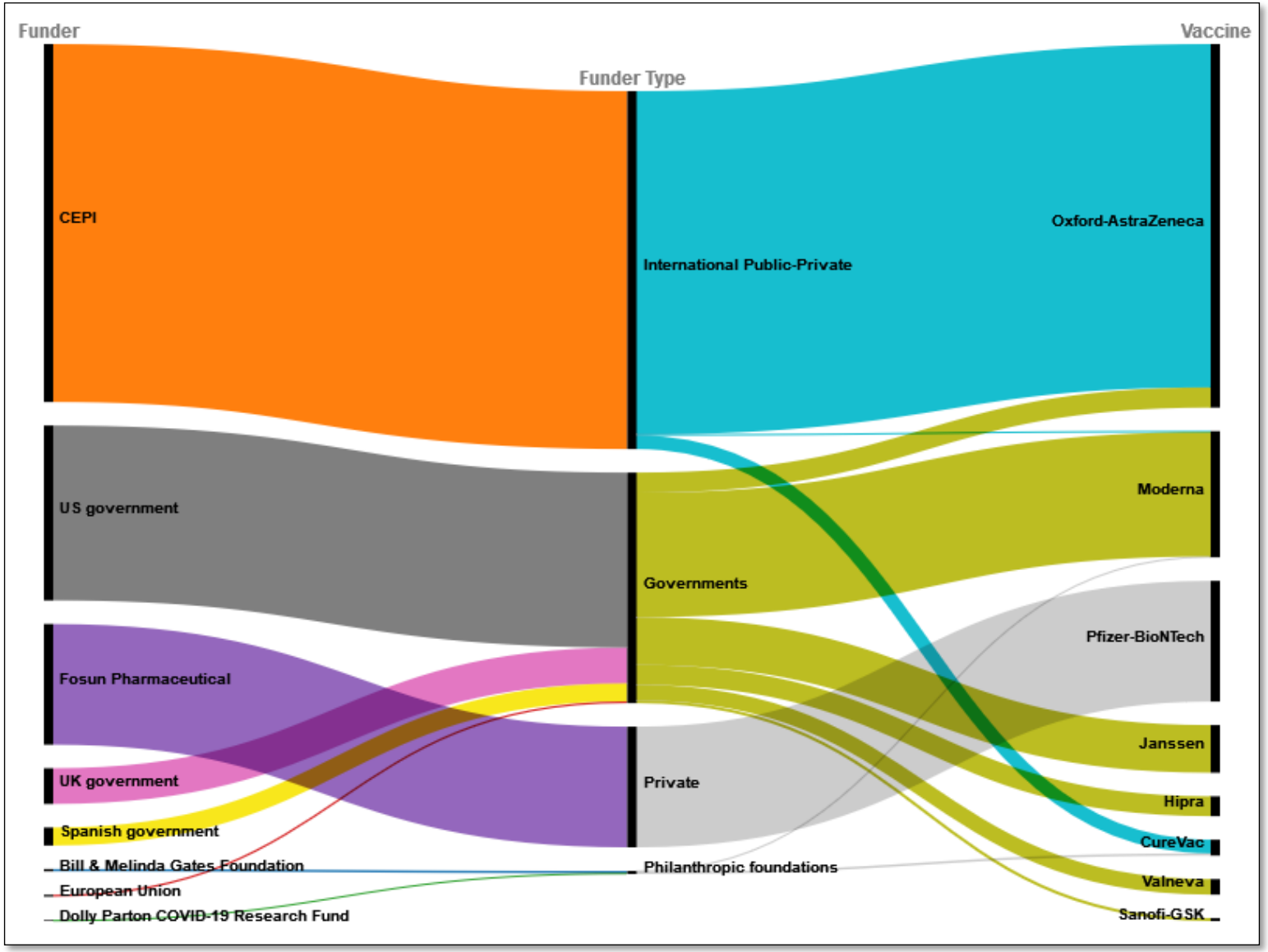
SOURCES OF COVID-19 VACCINE FUNDING BY FUNDER*



*Regardless the incentive mechanism (and including APAs)

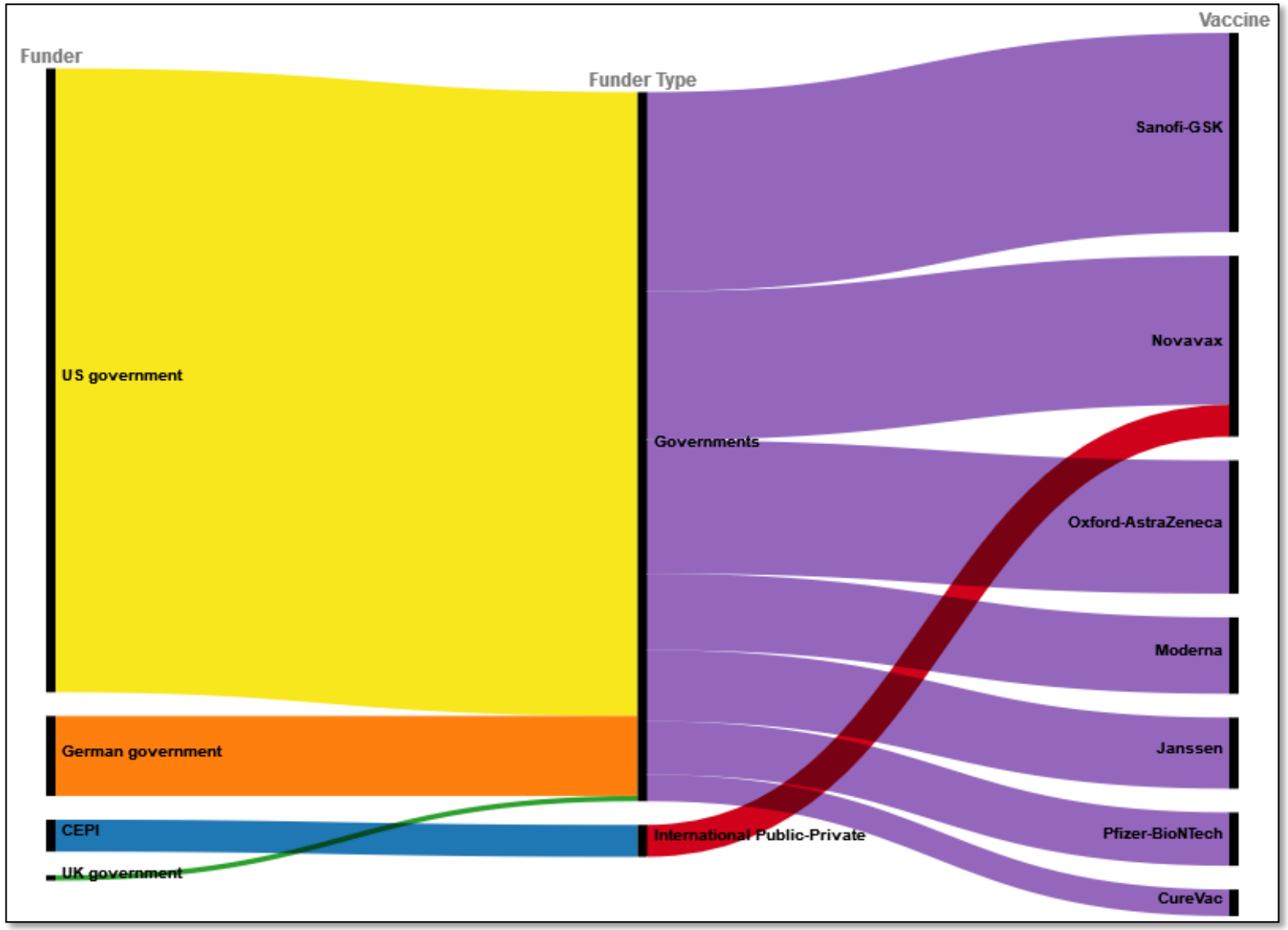
Source: Authors

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



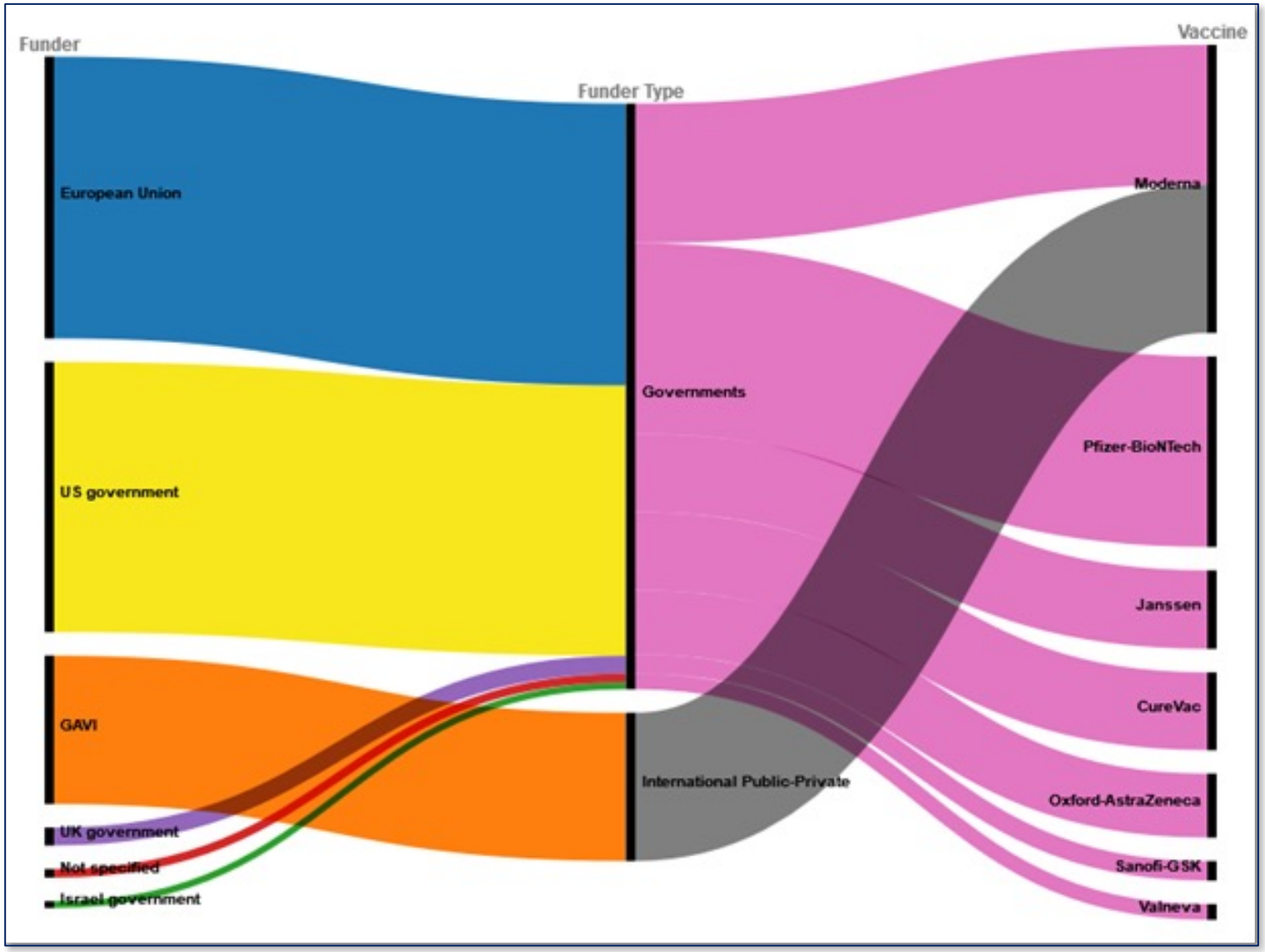
Source: Authors

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



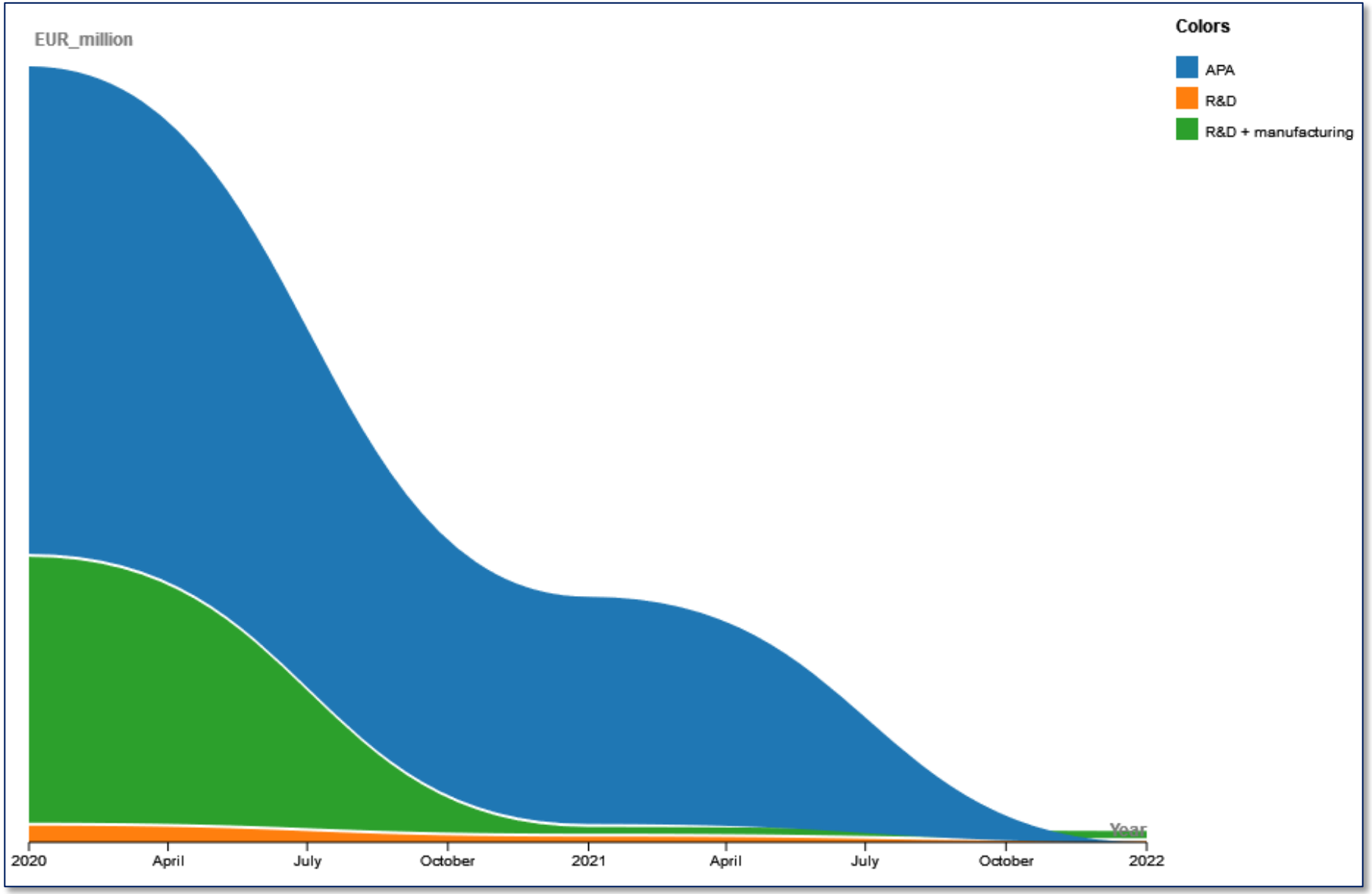
Source: Authors

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**

LESSONS TO BE LEARNED FROM THE RECENT EXPERIENCE IN EU

1. Evitare la frammentazione e la duplicazione dei finanziamenti per R&S sui vaccini contro la COVID-19

2. Garantire il sostegno pubblico allo sviluppo clinico dei vaccini contro la COVID-19 di prossima generazione o dei vaccini che proteggono da coronavirus sconosciuti

3. Creare un ambiente normativo e infrastrutturale favorevole alle sperimentazioni cliniche in Europa

4. Esaminare attentamente, nell'interesse della salute pubblica, le condizionalità delle future sovvenzioni di R&S e dei meccanismi di riduzione dei rischi

POLICY OPTIONS

ACTIONS NEEDED FOR THE EUROPEAN UNION

SHORT TERM

- Dovrebbe essere elaborato un **quadro giuridico dell'UE stabile e chiaro a sostegno delle attività di R&S** delle imprese sui vaccini contro la COVID-19
- **Il ruolo di HERA dovrebbe essere riconsiderato**. L'attuale configurazione di HERA non prevede gli stessi punti di forza in termini scientifici e di gestione di cui gode BARDA, nel più ampio quadro dell'amministrazione per la preparazione e la risposta strategiche, e non può avvalersi di alcun ruolo simile al ruolo combinato di NIH e di BARDA negli Stati Uniti

LONG TERM

Creare un'infrastruttura paneuropea di R&S e predisporre la fornitura di medicinali in determinati settori critici, con una dotazione di bilancio e un'ambizione scientifica paragonabili a quelle dell'NIH statunitense, combinando gli sforzi dell'UE e degli Stati membri

(precedente studio condotto per il Parlamento europeo - Florio et al., 2021)

PROPOSTA N.2 Il "modello Ginevra" per un'Europa più giusta

Si propone di promuovere a livello europeo degli "**hub tecnologici sovranazionali di imprese**" che si occupino di produrre beni e servizi che mirino al benessere collettivo, partendo dalle **infrastrutture pubbliche di ricerca** esistenti ed estendendo il loro ambito di azione dalla fase iniziale della **catena di creazione di valore** a quelle successive. L'obiettivo è quello di sfruttare il successo di forme complesse e autonome di organizzazione per rendere accessibili a tutti i frutti del progresso scientifico e affrontare il **paradosso** attuale per cui un patrimonio di **open science** prodotto con fondi pubblici viene di fatto appropriato privatamente da pochi grandi **monopoli**.

GRAZIE PER L'ATTENZIONE

massimo.florio@unimi.it
www.massimoflorio.com

STREAMING:

https://multimedia.europarl.europa.eu/en/webstreaming/covi-committee-meeting_20230323-1630-COMMITTEE-COVI

SLIDES:

https://www.europarl.europa.eu/cmsdata/267263/COVI_23March2023%20-%20Slides%20-%20Presentation%20-%20Vaccines%20investment%20mapping.pdf

EXECUTIVE SUMMARY:

https://www.europarl.europa.eu/RegData/etudes/STUD/2023/740072/IPOL_STU(2023)740072(SUM01)_IT.pdf