

## Roundtable: SHOULD WE QUESTION OUR CURRENT MODEL FOR ENCOURAGING INNOVATION IN THE PHARMACEUTICAL SECTOR?

16 March 2022

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Failure to meet the public interest:

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1. Lack of medicines when market incentives inadequate (e.g. neglected diseases of poverty, bacterial infections and emerging infectious diseases)

2. Slow pace of progress in some areas (e.g. Alzheimer's disease)

nature > com 3. Risk of harm (e.g. adverse drug reactions)

**4. Restricted access** to technologies: high prices, insufficient production or supply

COMMENT 09 February 2022 Update 10 February 2022

### Reboot biomedical R&D in the global public interest

Inequitable access to the fruits of research during the COVID-19 pandemic urgency – and feasibility – of overhauling the R&D system.

Citizens, researchers, governments, intergovernmental organizations, regulators, funders, industry and universities are all stakeholders in public-Interest research and development (R&D). They must collaborate to:

- Prioritize public-health needs through structured, inclusive, transparent and informed processes.
- · Require that R&D is ethically conducted and scientifically sound.
- Mandate, incentivize and facilitate rapid. open sharing of inputs, processes and outputs.
- Invest in the long term to strengthen scientific, technological and regulatory capacity across all countries.
- Provide timely access to health technologies that are safe, efficacious and offer therapeutic advances.
- . Ensure R&D meets the needs of subpopulations such as children, older people and those who might become pregnant.
- Recognize all contributions fairly.
- Share all benefits equitably.
- · Build affordability, availability and suitability into the R&D process.

Source: https://www.nature.com/articles/d41586-022-00324-v

# Current and alternative R&D models: How well do they deliver? 3 criteria

Model Type	Description	1. Invention generated?	2. Globally available?	3. Globally affordable?

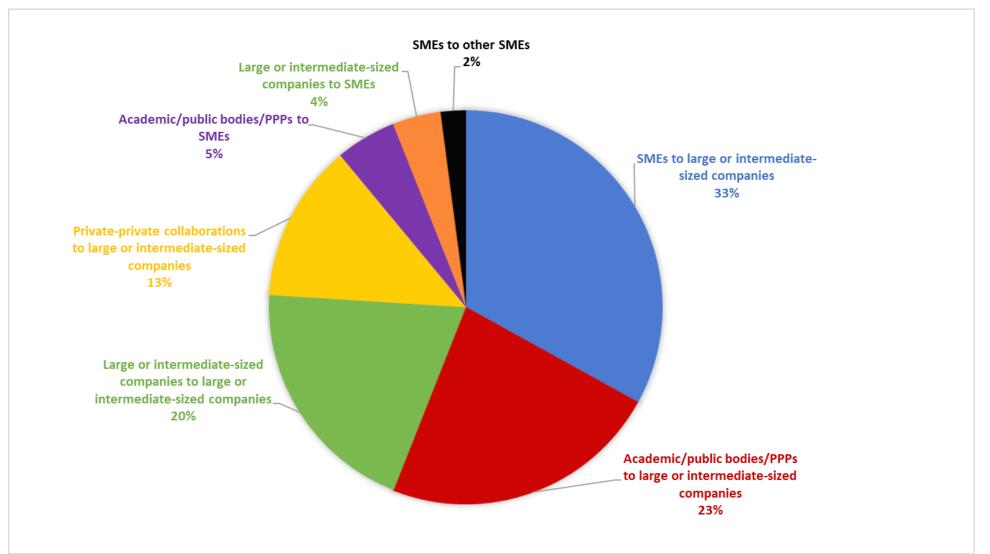
Source: Table 3. Summary of current and alternative business models for delivering GPGs, Moon et. al., forthcoming.

### Current and alternative R&D models: How well do they deliver medicines? 3 criteria

Model Type	Description	1. Invention generated?	2. Globally available?	3. Globally affordable?
Mainstream: current business model	Market-driven large- scale, relay race	Yes, but with gaps	No	No

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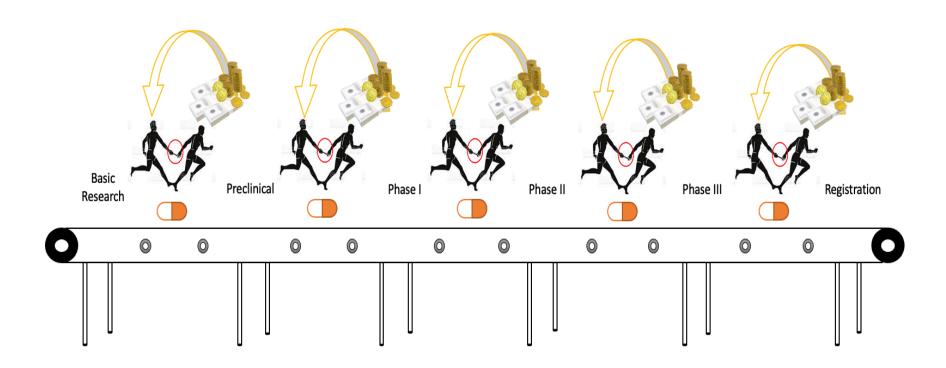
#### The current model: origins of innovation



Notes: SMEs = Small and Medium-sized Enterprises; PPP = Public-private partnership

Source: Fig. 3. Origins and transfers of new medicines, by type of developer Moon et. al., forthcoming, based on data from Lincker et al. (2014).

#### The current model: relay-race



Source: Fig. 4. Staged rewards of investment in a simplified linear relay race R&D model Moon et. al., forthcoming.

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Alternative model: neglected diseases	Publicly financed, non-profit, needs- driven	Yes, for some	Yes for PDPs; not necessarily for PRVs	Yes for PDPs; not necessarily for PRVs

Source: Table 3. Summary of current and alternative business models for delivering GPGs, Moon et. al., forthcoming.

Notes: PDPs = Product Development Partnerships; PRVs = Priority

Review Vouchers; CEPI = Coalition for Epidemic Preparedness

Innovations; TBD = to be determined

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Alternative model: rare diseases	Mix of market- and public policy-driven	Yes, for some	No	No

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**Review Vouchers** 

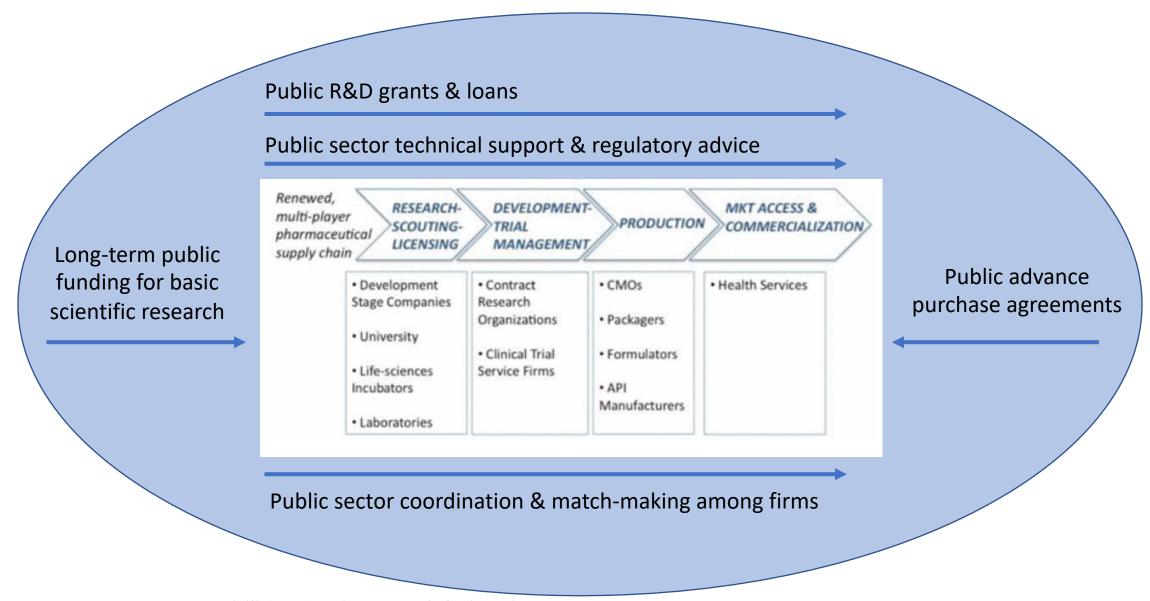
#### Delivering medicines: current and alternative models

Model Type	Description	Invention generated	Globally available	Globally affordable
Mainstream: current business model	Market-driven large- scale, relay race	Yes, but with gaps	No	No
Alternative model: neglected diseases	Publicly financed, non-profit, needs- driven	Yes, for some	Yes for PDPs; not necessarily for PRVs	Yes for PDPs; not necessarily for PRVs
Alternative model: rare diseases	Mix of market- and public policy-driven	Yes, for some	No	No
Alternative model: biosecurity	Publicly financed, policy-driven	Yes, for some	No (with potential exceptions)	No (with potential exceptions)

Source: Table 3. Summary of current and alternative business models for delivering GPGs, Moon et. al., forthcoming.

Notes: PDPs = Product Development Partnerships; PRVs = Priority Review Vouchers; CEPI = Coalition for Epidemic Preparedness Innovations

### Public & private roles for pandemic health technologies



Sources: Capo, Brunetta & Boccardelli (2014) and Moon et al (forthcoming)

Figure 3.1. Vaccine R&D Funding Flow: direct funding, secondary funding and funding to intermediaries (in millions USD)

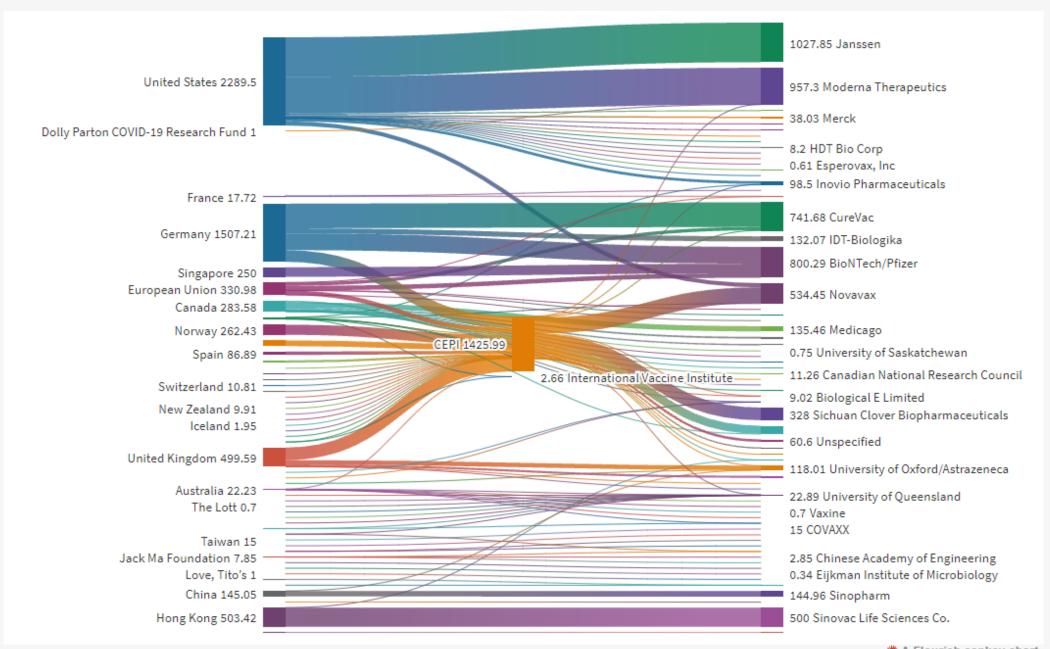
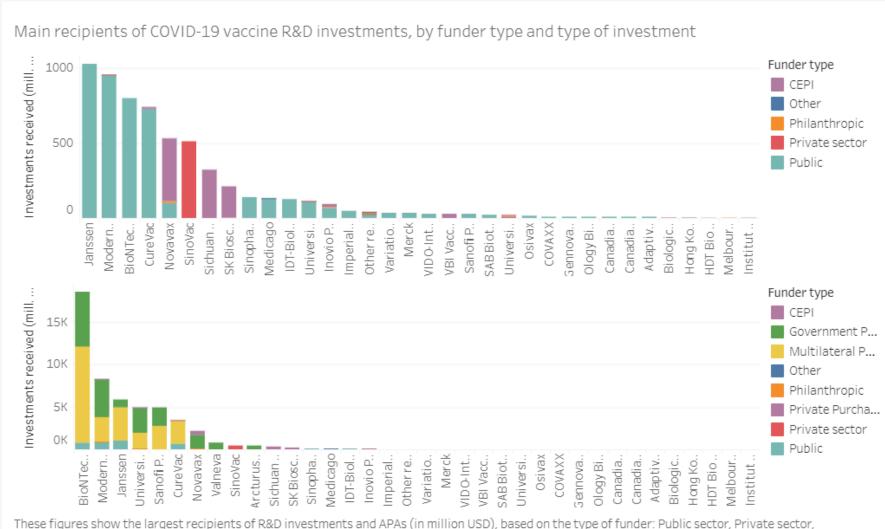


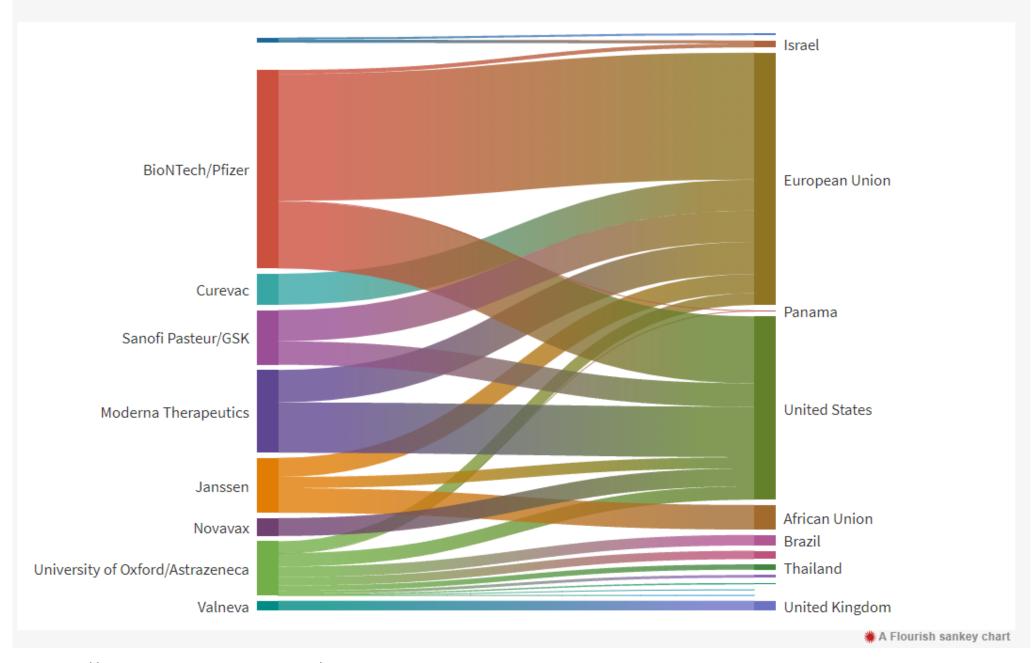
Figure 2. Main recipients of COVID-19 vaccine R&D investments, by funder type



These figures show the largest recipients of R&D investments and APAs (in million USD), based on the type of funder: Public sector, Private sector, Philanthropic, Other and funding from CEPI. The figure at the top shows the funding received by organizations conducting R&D activities coming directly from the funding agency/institution (Direct Funding) or from intermediaries (Secondary Funding). The bottom figure includes the funding dedicated to APAs. The "Other recipients" group encompasses those receiving investments below the median value of R&D investments (excluding advanced purchase agreements). Both R&D investments and APAs represented in the figures might include investments to scale-up manufacturing capacity, and some APAs might also include investments to accelerate clinical development (see data limitations). Sources are publicly available information such as news releases, and publicly available data sources such as Policy Cures Research Covid-19 R&D Tracker and ACT-Accelerator funding tracker. Data for APAs comes from the COVID-19 Vaccine.

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Figure 3.2. Vaccine R&D Funding Flow: Advanced purchase agreements (in millions USD)



Source: https://www.knowledgeportalia.org/covid19-r-d-funding

#### Delivering medicines as GPGs: current and alternative models

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Mainstream: current business model	Market-driven large- scale, relay race	Yes, but with gaps	No	No
Alternative model: neglected diseases	Publicly financed, non-profit, needs- driven	Yes, for some	Yes for PDPs; not necessarily for PRVs	Yes for PDPs; not necessarily for PRVs
Alternative model: rare diseases	Mix of market- and public policy-driven	Yes, for some	No	No
Alternative model: biosecurity	Publicly financed, policy-driven	Yes, for some	No (with potential exceptions)	No (with potential exceptions)
Alternative model: antibiotics	Mix of market- and public policy-driven	TBD	TBD	TBD

Source: Table 3. Summary of current and alternative business models for delivering GPGs, Moon et. al., forthcoming.

Notes: PDPs = Product Development Partnerships; PRVs = Priority Review Vouchers; CEPI = Coalition for Epidemic Preparedness

Innovations; TBD = to be determined

#### Conclusions

- 1. R&D model failing to fully meet societal needs
- 2. Pharmaceutical R&D models changing and increasingly complex:
  - From large vertical firms to relay races
  - Globalizing: from a few advanced countries to networks and emerging powers
- 3. Alternative R&D models have emerged and can be **effective**.
  - But small-scale and limited
  - Must be constructed, financed, organized, incentivized
  - Supportive laws and policies "rules of the game" needed