

# The Determinants of COVID-19 Vaccine Success

Rena M. Conti, PhD

Associate Professor

Questrom School of Business

Boston University

[Email: rconti@bu.edu](mailto:rconti@bu.edu)

**Twitter: @contirena1**

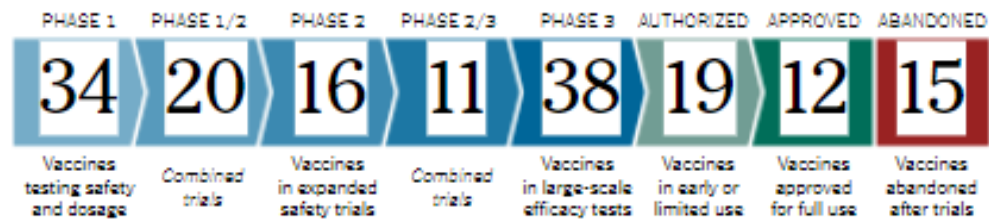
# Vaccines are an important type of infectious disease prophylaxis



# COVID vaccine success

## Coronavirus Vaccine Tracker

By [Carl Zimmer](#), [Jonathan Corum](#), [Sui-Lee Wee](#) and [Matthew Kristoffersen](#) Updated May 2, 2022



Vaccines typically require years of research and testing before reaching the clinic, but in 2020, scientists embarked on a race to produce safe and effective coronavirus vaccines in record time. Researchers are currently testing **119 vaccines** in clinical trials on humans, and 49 have reached the final stages of testing.

### Leading vaccines

Developer	How It Works	Phase	Status
Pfizer-BioNTech	mRNA	3	Approved in U.S., other countries. Emergency use in many countries.
Sinopharm	Inactivated	3	Approved in China, Bahrain. Emergency use in many countries.
Oxford-AstraZeneca	ChAdOx1	2 3	Approved in Brazil, India. Emergency use in many countries.
Sinovac	Inactivated	3	Approved in China. Emergency use in many countries.
Moderna	mRNA	3	Approved in U.S., Canada, Switzerland. Emergency use in many countries.
Novavax	Protein	3	Approved in Canada, South Korea. Emergency use in several countries.
Bharat Biotech	Inactivated	3	Approved in India. Emergency use in other countries.
Johnson & Johnson	Ad26	3	Approved in Canada. Emergency use in many countries.
Baylor-Biological E	Protein	3	Emergency use in India, Botswana.
Gamaleya	Ad26, Ad5	3	Approved in Russia. Emergency use in many countries.

# COVID vaccine setbacks and failures

## COVID-19 vaccine development: Setback for Sanofi and GSK candidate, University of Queensland and CSL abandon trial

By Jane Byrne [↗](#)

11-Dec-2020 - Last updated on 14-Dec-2020 at 16:29 GMT



[Media](#) > [News releases](#) > [News release](#)

Merck Discontinues Development of SARS-CoV-2/COVID-19 Vaccine Candidates; Continues Development of Two Investigational Therapeutic Candidates

# Study objectives

1. What are the drivers of successful COVID vaccine creation and the drivers of vaccine failure?
2. How do these drivers matter in the specific experiences of COVID vaccine candidates?

Final report available at:

[https://www.wipo.int/edocs/mdocs/mdocs/en/wipo\\_gc\\_covid\\_19\\_ge\\_22/wipo\\_gc\\_covid\\_19\\_ge\\_22\\_www\\_572491.pdf](https://www.wipo.int/edocs/mdocs/mdocs/en/wipo_gc_covid_19_ge_22/wipo_gc_covid_19_ge_22_www_572491.pdf)

# Study methods

- Conducted between May 2021 and December 2021:
  - In-depth literature review;
  - Key stakeholder interviews;
  - Case studies on specific vaccines.
- Stakeholders selected from public documents & multidiscipline scholars.
- Case study candidates selected from public documents and diverse.
  - Primary data from shareholder reports.

# Case studies – Table 1 in the report

<i>Vaccine Sponsor for Regulatory Approval or Authorization</i>	<i>Vaccine name</i>	<i>Authorized or approved to date in at minimum one OECD country?</i>	<i>Originating countries</i>	<i>Details of availability*</i>	<i>Number of country authorizations and approvals as</i>	<i>Vaccine platform</i>	<i>Selected for Case Study</i>
Astrazeneca/Oxford	Vaxzevria	yes	UK	Approved in Brazil. Emergency use in UK, EU, other countries	96	non-mRNA based	yes
Pfizer/BioNtech	Comirnaty	yes	Germany	Approved in US, other countries. Emergency use in EU, other	105	mRNA based	yes
NIH/Moderna	Spikevax	yes	US	Approved in Switzerland. Emergency use in US, EU, other countries	69	mRNA based	yes
Janssen		yes	US	Emergency use in US, EU, other countries	79	non-mRNA based	yes
Sinovac	CoronaVac	yes	China	Approved in China. Emergency use in other countries	38	non-mRNA based	no
Sinopharm	BIBP vaccine	yes	China	Approved in China, UAE, Bahrain. Emergency use in other countries	63	non-mRNA based	no
Gamaleya	Sputnik V	yes	Russia	Emergency use in Russia, other countries	74	non-mRNA based	no
Merck/Pasteur/IAVI		abandoned	US			non-mRNA based	yes
Sanofi/Translate Bio		abandoned	France			mRNA based	yes
GSK		abandoned	UK			non-mRNA based	no
Curevac	CV2CoV	expected 2022	Germany			mRNA based	yes
Novavax	Novavaxoid	yes	US	Approved in EU, other countries	29	non-mRNA based	yes
Inovio	INO-4800	in Phase III clinical trials	US			non-mRNA based	no
Bharat Biotech/BBIL	Covaxin	yes	India	India, Iran, Mexico, Zimbabwe, Ethiopia, Brazil, Botswana, Bahrain, other countries	16	non-mRNA based	no
Can Sino	Convidecia	yes	China	China, Mexico, Argentina, Chile, Ecuador, Hungary, Indonesia, Malaysia,	9	non-mRNA based	no
Imperial College London/Morningside		abandoned	UK			non-mRNA based	no
Vector Institute	EpiVacCorona	yes	Russia	Russia, Turkmenistan, Venezuela	3	non-mRNA based	no

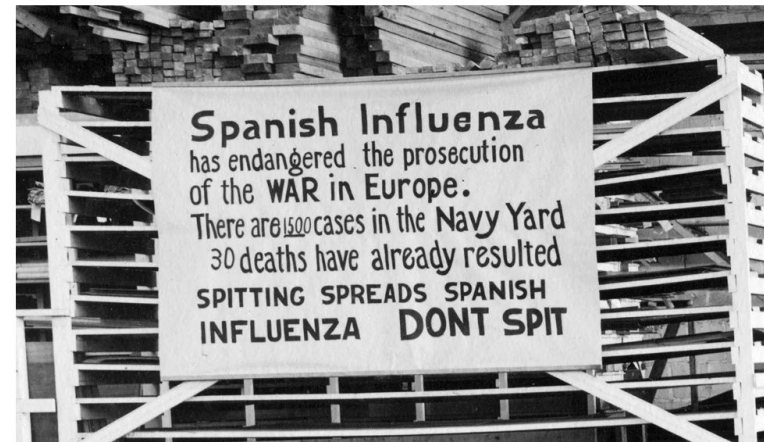
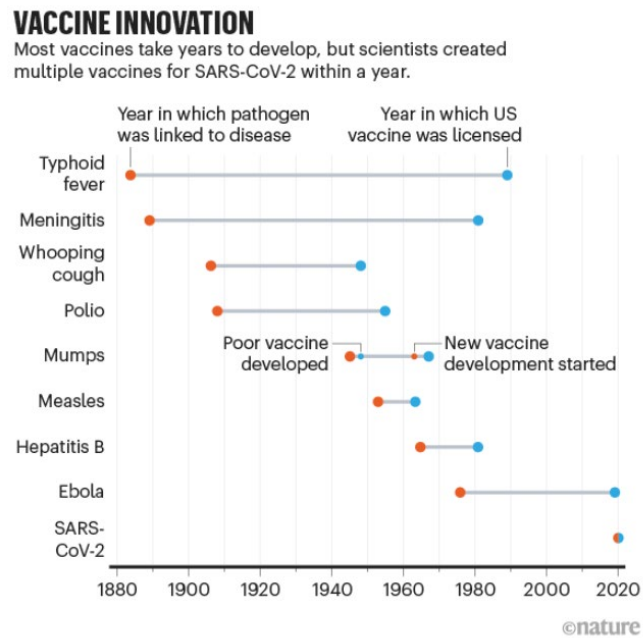
# Vaccine development is costly, risky, uncertain and prone to market failure

- Innovators face time-inconsistent incentives
  - Before a vaccine is developed, consumers want investment in development.
  - But once a vaccine is developed, payers want a vaccine to be sold at the lowest price.
- Firms anticipate this time-inconsistency and are reluctant to make investments.
- Note this is not the same as not being able to afford to purchase a product once made.



# Common ways to resolve vaccine development challenges

- Pull incentives: Patents and other intellectual property protections, advanced market commitments, subscription models
- Push incentives: direct and indirect subsidization of research and development



Vaccines for Pandemic Threats

# Drivers of vaccine success

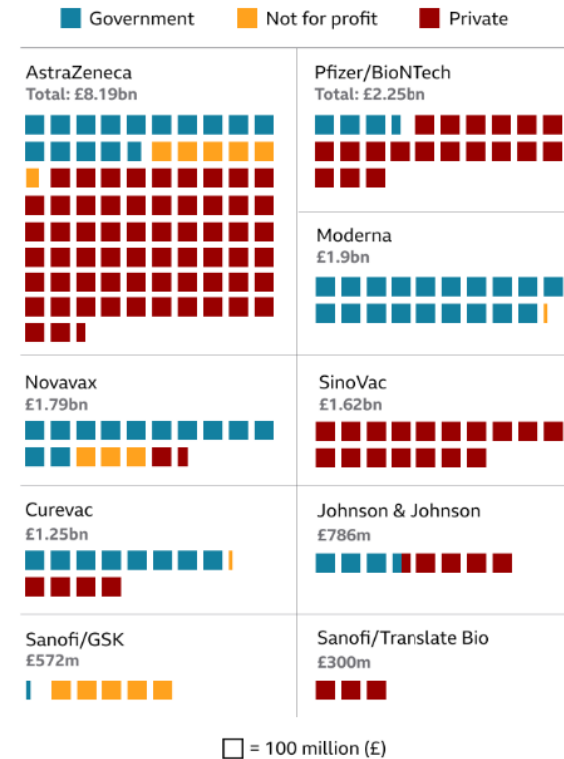
Driver	1	Open science related to national and international research and scientific collaborations	shared across candidates
Driver	2	Pre-pandemic knowledge and technology leveraged by innovators	shared across candidates
Driver	3	Regulatory infrastructure and related activities	shared across candidates
Driver	4	IP, licensing and partnering arrangements	varies by candidate
Driver	5	Willingness of funders to underwrite risks, costs entailed in the development of new technology to meet demand for vaccine/therapeutics across platforms, companies, countries	varies by candidate
Driver	6	Advanced purchasing arrangements to guarantee revenue post-approval/post-authorization to manufacturers, assure supply to populations in need	varies by candidate
Driver	7	The willingness of funders to underwrite costs and risks entailed in the development of new vaccines across platforms, companies and countries in advance of approval.	varies by candidate
Driver	8	Innovators pursuit of manufacturing at scale, including partnerships with other companies, and willingness of funders to support vaccine manufacturing "at risk" pre-product launch appears to vary by vaccine candidate.	varies by candidate
Driver	9	Vaccine sponsor contracts with other manufacturers to scale up vaccine supply post-approval.	varies by candidate

# Driver of success: Knowledge

- Preexisting, public knowledge of coronaviruses.
- Preexisting intellectual property related to therapeutic intervention.
- Emerging development and patenting of specific ingredients, manufacturing.
- Licensing arrangements are highly varied, complex and largely hidden from public scrutiny.

# Driver of success: Push and pull financing

## Who has funded the Covid vaccines?

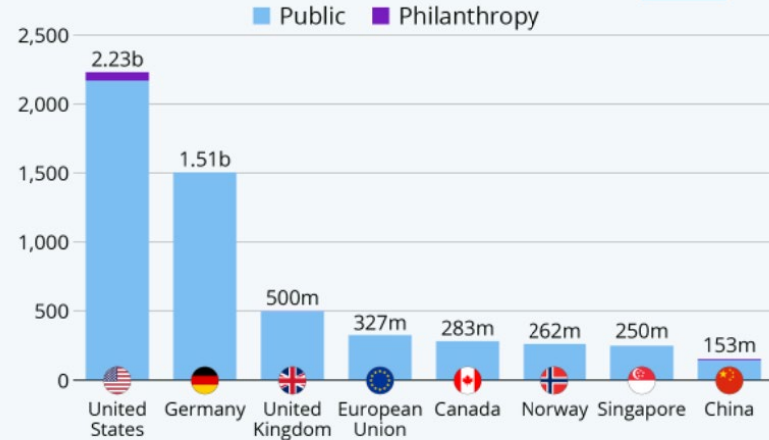


Source: Airfinity



## The Countries Funding Covid-19 Vaccine R&D

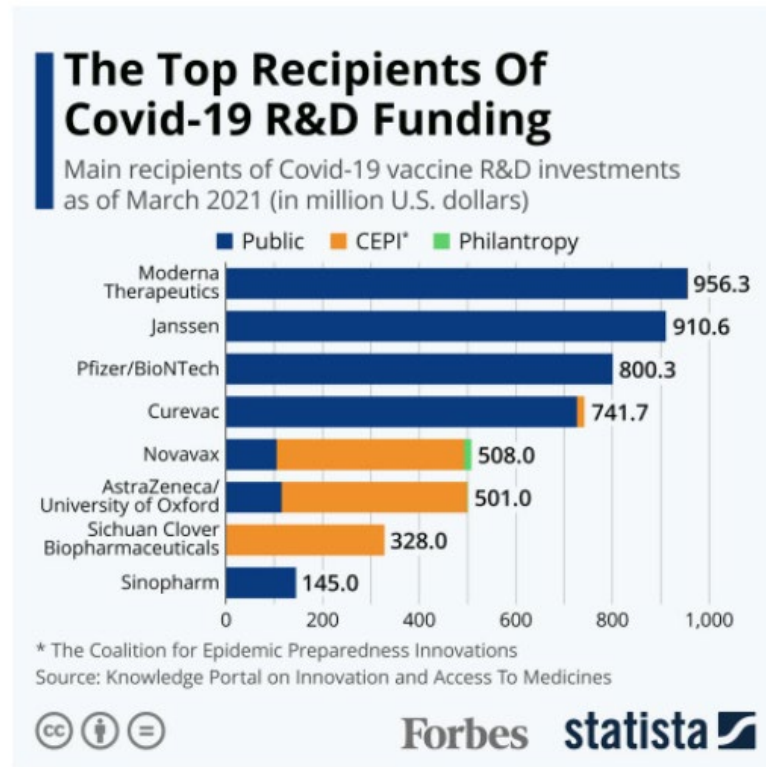
Top sources of Covid-19 vaccine funding as of March 2021 (in U.S. dollars)



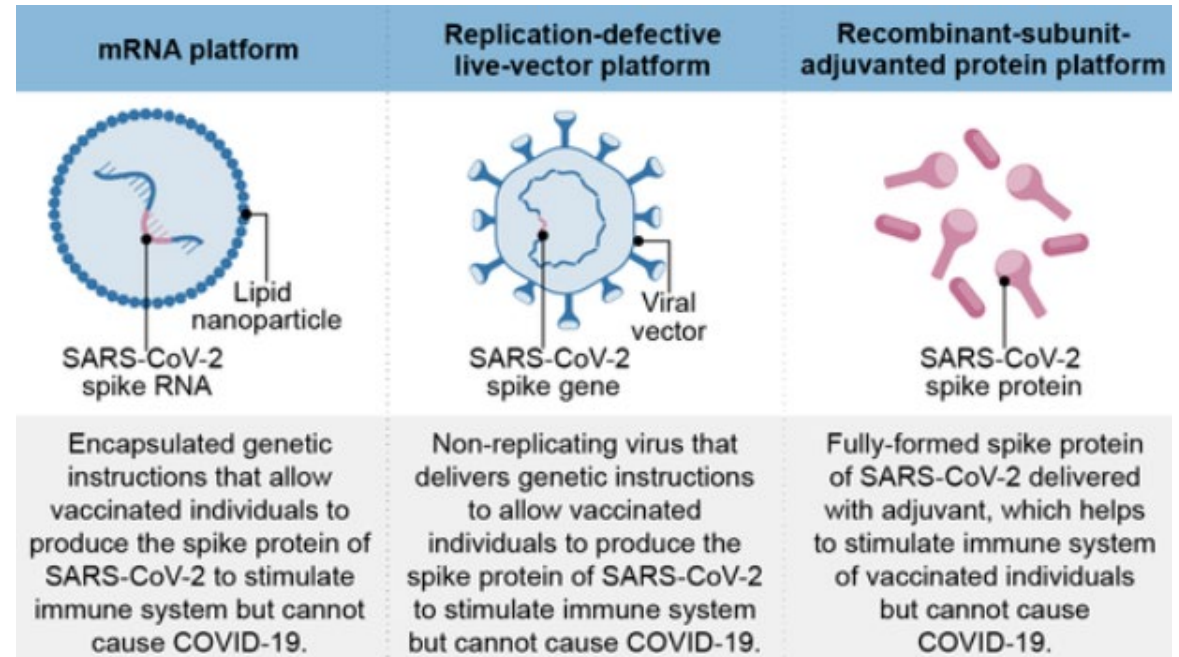
Source: Knowledge Portal on Innovation and Access To Medicines



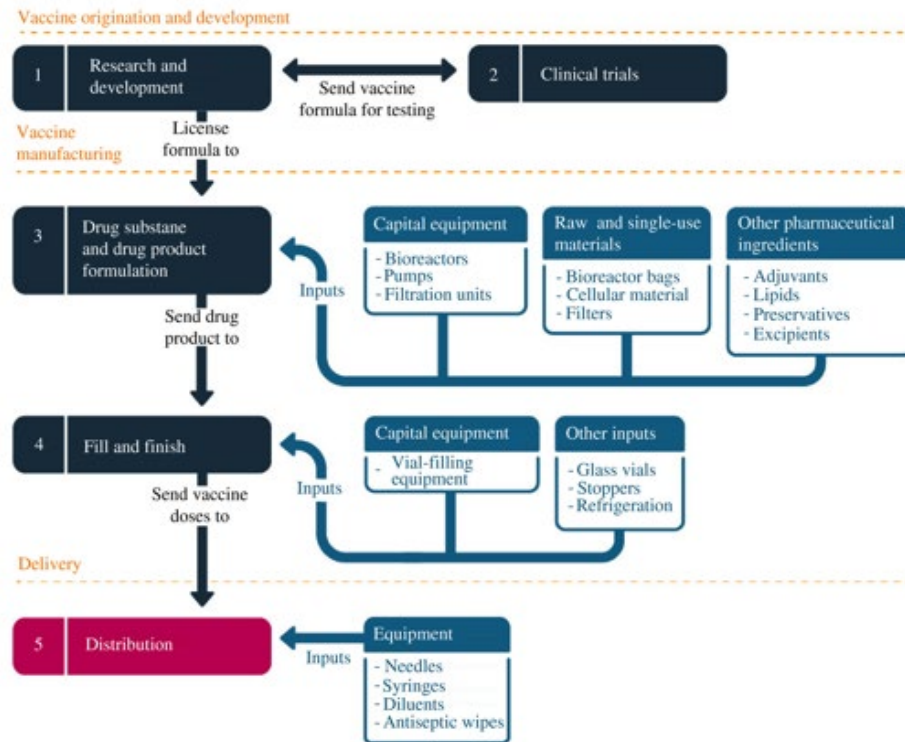
# A portfolio approach to investing in COVID vaccines



Main recipients of Covid-19 vaccine R&D investments as of March 2021. STATISTA



# The product is the process: manufacturing vaccines at risk



How COVID-19 vaccine supply chains emerged in the midst of a pandemic

Chad P. Bown , Thomas J. Bollyky

# Driver of success: Institutions

## BARDA COVID-19 RESPONSE

*Dr. Robert Johnson  
BARDA IEIDD Division Director and BARDA COVID-19 Response Lead  
Recorded February 9, 2021*

[DOWNLOAD VIDEO TRANSCRIPT](#)

## A global coalition for a global problem

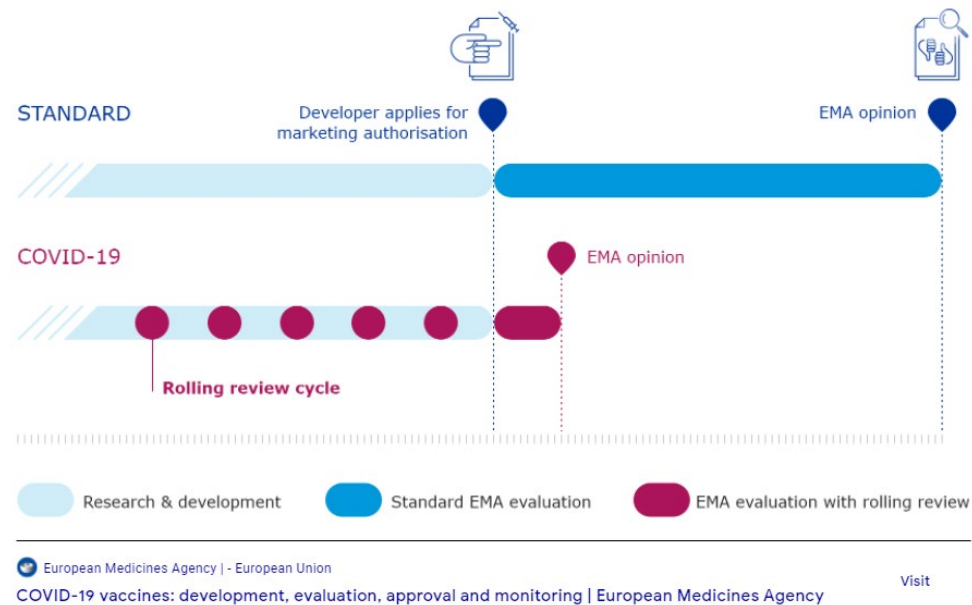
Epidemic diseases affect us all. They do not respect borders. CEPI is an innovative global partnership between public, private, philanthropic, and civil society organisations. We're working together to accelerate the development of vaccines against emerging infectious diseases and enable equitable access to these vaccines for people during outbreaks.

THE CEPI TEAM



## Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials

# Drivers of success: Regulations



Funding, Eligibility, and Administration Options for No-Fault Compensation for Injuries Attributable to Covid-19 Vaccines.*			
Factor	World Health Organization	COVAX Facility	National or Provincial System
Funding	Insurance premium paid from general WHO revenues	Per-dose or per-volume fee	Tax on manufacturers (based either on a percentage of manufacturers' annual sales or number of doses sold), distributors, or suppliers; general revenues
Eligibility	Based on temporal relationship between immunization and serious adverse event	Criteria jointly developed by CEPI; Gavi, the Vaccine Alliance; and the WHO that could include temporal association or tables of injuries based on phase 3 trial data	Existing criteria for other vaccines that are eligible for compensation programs, including vaccines deployed under criteria for a national public health emergency, e.g., "balance of probabilities" or "compelling" evidence of a relationship between immunization and serious adverse event
Administration	WHO compensation-claims personnel and insurance-claims administrators	Third-party claims administrator, including claims-administration services available from global insurers	Designated national judicial or administrative authorities
Elements of compensation	Lump-sum payment based on weighted average of claims histories for injury compensation in national systems adjusted for relative purchasing value	Lump-sum payment based on weighted average of claims histories for injury compensation in national systems adjusted for relative purchasing value	Nationally determined compensation (based on lost wages, nonreimbursed medical expenses, disability per and noneconomic loss, and death benefits)

\* CEPI denotes Coalition for Epidemic Preparedness Innovations, and WHO World Health Organization.

## COVID-19 EMA pandemic Task Force

The role of the COVID-19 EMA pandemic Task Force (COVID-ETF), chaired by Marco Cavaleri, head of Biological Health Threats and Vaccines Strategy, is to help European Union (EU) Member States and the European Commission to take quick and coordinated regulatory action on the **development, authorisation and safety monitoring** of treatments and vaccines intended for the treatment and prevention of COVID-19.

## Perspective

### No-Fault Compensation for Vaccine Injury — The Other Side of Equitable Access to Covid-19 Vaccines

Sam Halabi, J.D., Andrew Heinrich, J.D., and Saad B. Omer, M.B., B.S., Ph.D., M.P.H.



# Results: Drivers of failures

Driver	1	Pre-approval/authorization scientific risks	varies by candidate
Driver	2	Pre-approval/authorization manufacturing risks	varies by candidate
Driver	3	Post-approval/authorization scientific risks	varies by candidate
Driver	4	Post-approval/authorization manufacturing risks	varies by candidate
Driver	5	Business decisions	varies by candidate

- Among “failures”, decisions driven by scientific & business rationales.
- No credible evidence that patents have forestalled vaccine success.
- Scientific knowledge has many uses.

# Ensuring COVID vaccine access worldwide is critical

- More than 5.15 billion people have received a dose of a Covid-19 vaccine (67.1% population).
- Vaccination rates vary by region.
- Vaccination rates continue to lag in low-income countries, where only 16 percent of the population has received at least one dose of a vaccine.

# Therapeutics aim to reduce infection incidence, person to person transmission, disease severity & death



## USAID ANNOUNCES NEW \$125 MILLION PROJECT TO DETECT UNKNOWN VIRUSES WITH PANDEMIC POTENTIAL

For Immediate Release

Tuesday, October 5, 2021

Review Article | Published: 13 October 2021

### Infectious disease in an era of global change

[Rachel E. Baker](#)  [Ayesha S. Mahmud](#), [Ian F. Miller](#), [Malavika Rajeev](#), [Fidisoa Rasambainarivo](#), [Benjamin L. Rice](#), [Saki Takahashi](#), [Andrew J. Tatem](#), [Caroline E. Wagner](#), [Lin-Fa Wang](#), [Amy Wesolowski](#) & [C. Jessica E. Metcalf](#) 

*Nature Reviews Microbiology* **20**, 193–205 (2022) | [Cite this article](#)

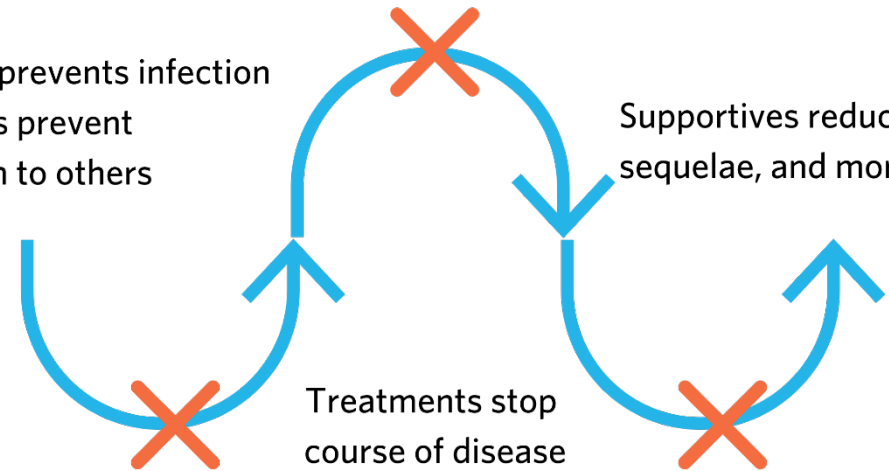
23k Accesses | 15 Citations | 151 Altmetric | [Metrics](#)

## Therapeutics We Need

Prophylaxis prevents infection and vaccines prevent transmission to others

Supportives reduce symptoms, sequelae, and mortality

Treatments stop course of disease



# Future topics of study

- More transparency and analysis of patents and contracts.
- Push and pull activities may be more impactful under specific conditions.
- Drivers of follow on innovation to address emerging variants and pathogens.
- Application of modern financial tools to address emergent threats in candidate discovery, development and manufacturing.

# Thank you!

## *WIPO*

Carsten Fink, Marion (Amy)  
Dietterich, Sasha Wunsch-Vincent,  
Jhon Carmona, Hans Georg  
Bartels,  
Tatiana Hartop and  
Christy Nomura  
And many others

## *Research team*

Lauren Rice, Carina Seo and  
Edric San.

## *Helpful discussions and suggestions*

Bhaven Sampat, Richard Frank,  
Iain Cockburn, Andy Lo, Kevin  
Outterson, CARB-X, NIEDL, Cornell  
Stamoran, Tim Simcoe, Justin  
Hughes, Nicole Lurie, Shanelle Hall,  
Axel Metzger, Julie Weise-Barnes,  
Tom Johnston, Dimitrios Gouglas,  
Zain Rizvi, Suerie Moon, Peter  
Sands, Jeff Silsbee, Muna Bhanji,  
Richard Wilder and Tom Bollyky.

Boston University Questrom School of Business