


En que punto nos encontramos en el desarrollo de la vacuna para el SARS CoV2

Baylor College of Medicine

NATIONAL SCHOOL OF TROPICAL MEDICINE

Maria Elena Bottazzi PhD FASTMH
Associate Dean and Professor
Co-Section Head, Pediatric Tropical Medicine
Co-Director, Texas Children's Center for Vaccine Development

Texas Children's Hospital®

Leading the development and testing of low-cost and effective vaccines against emerging and neglected tropical diseases

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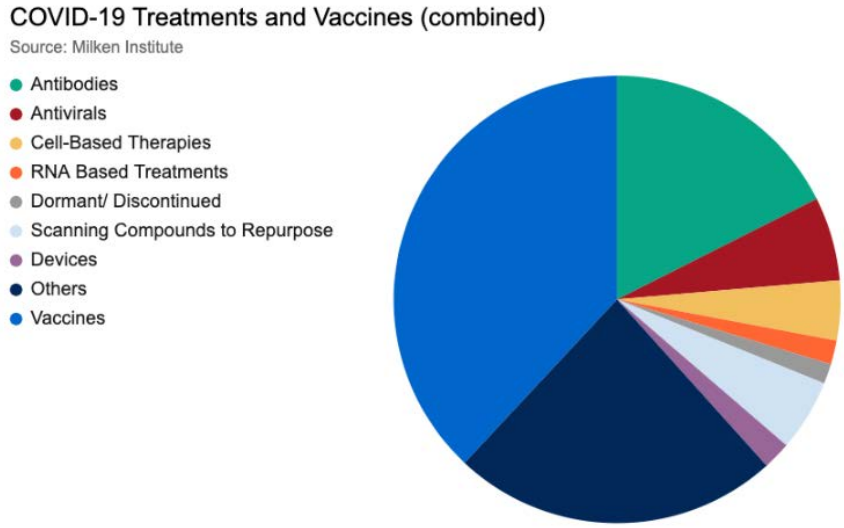
Menu

Current Count of Treatments and Vaccines

210 treatments
in consideration

125 vaccines
in development



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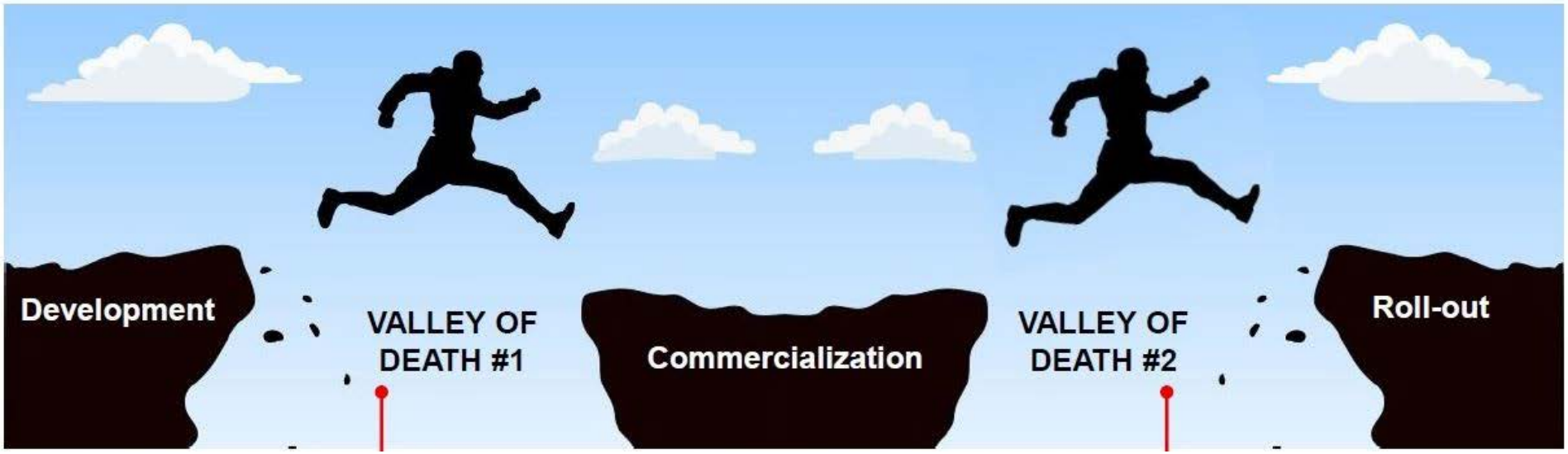
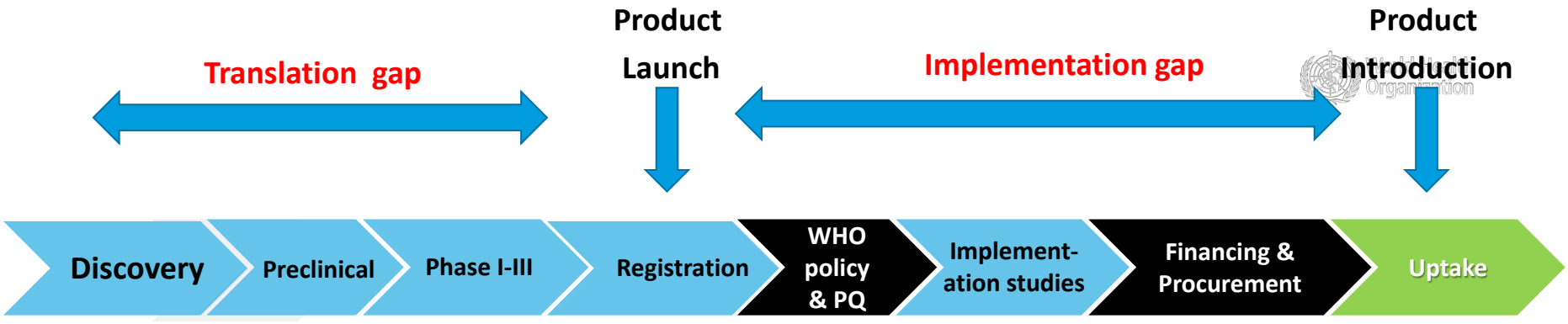
https://milkeninstitute.org/covid-19-tracker


Development
VALLEY OF DEATH #1
Commercialization
VALLEY OF DEATH #2
Roll-out


Translation gap
Product Launch
Implementation gap
Product Introduction
Discovery
Preclinical
Phase I-III
Registration
WHO policy & PQ
Implement-ation studies
Financing & Procurement
Uptake

Coronavirus Vaccine Landscape

As of 8 April 2020, the global COVID-19 vaccine R&D landscape includes

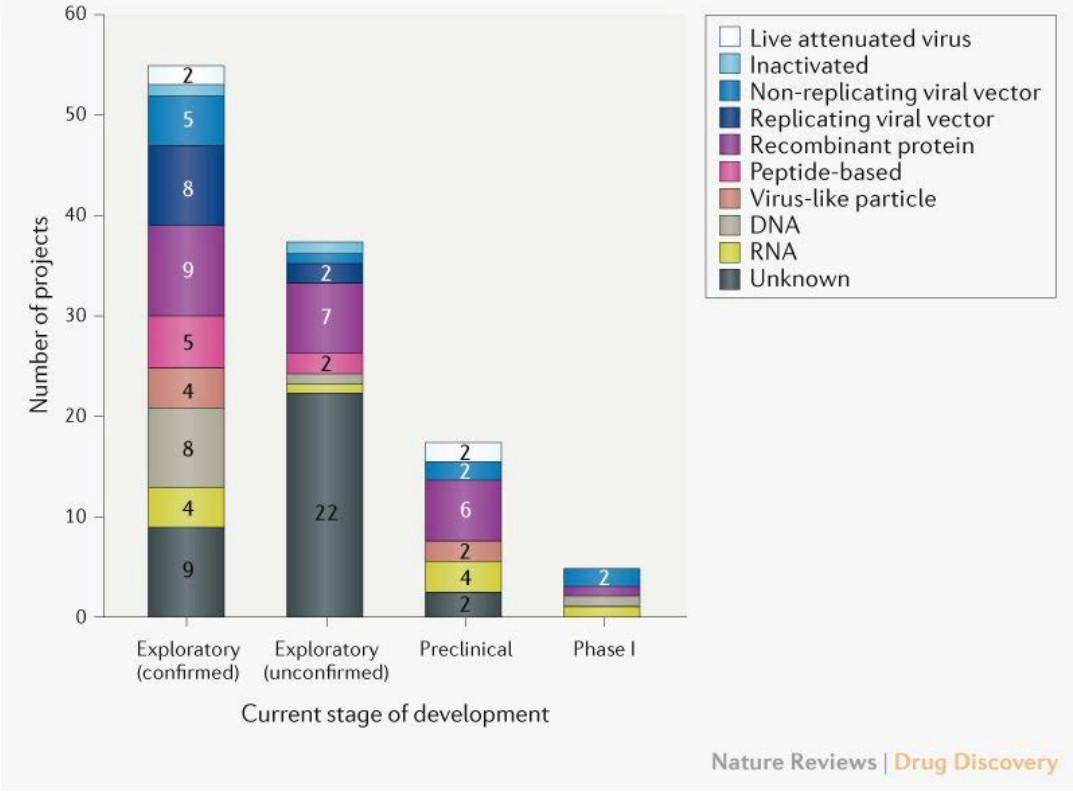
115 vaccine candidates

- 78 are confirmed as active
- 37 are unconfirmed
- 5 with open INDs

Diversity of technology platforms

Need several to suited to specific **population subtypes**

- elderly
- children
- pregnant women or
- immunocompromised patients



https://www.nature.com/articles/d41573-020-00073-5

Who is Developing COVID Vaccines for Latin America, Africa, and India?

Many platforms are not currently the basis for licensed vaccines

For some platforms, adjuvants are proprietary

Public information on the specific SARS-CoV-2 antigen(s) used is limited

Most candidates aim to induce neutralizing antibodies against the viral spike (S) protein, preventing uptake via the human ACE2 receptor

Prior SARS vaccine development experience indicates the need to assess the potential for immune enhancement effects

Gavi The Vaccine Alliance

Global call to action by Dr. Seth Berkley, CEO of Gavi, the Vaccine Alliance: **"...how do we produce vaccines specifically for the developing world if this is a truly global epidemic?"**
....."In the race to develop a coronavirus vaccine, everyone everywhere should be winners."

https://www.gavi.org/news/media-room/gavi-board-calls-bold-engagement-respond-covid-19

https://www.nature.com/articles/d41573-020-00073-5

Profile of Vaccine Developers

56 (72%) private/industry developers

22 (28%) of projects led by academic, public sector and other non-profit organ

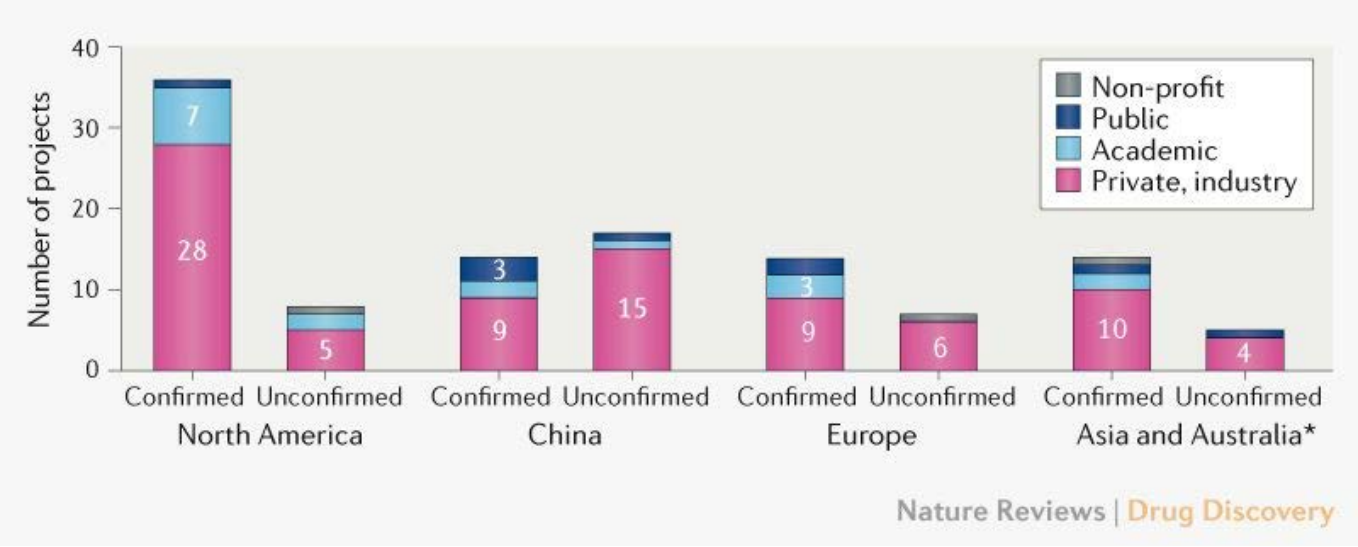
Many of the lead developers are small and/or inexperienced in large-scale vaccine manufacture

North America 36 (46%) of developers

China 14 (18%)

Asia (excluding China) and Australia 14 (18%)

Europe 14 (18%)



https://www.nature.com/articles/d41573-020-00073-5

The US Approach

Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)

Goal: A harmonized and collaborative approach for

- clinical testing
- scale-up
- distribution

More than one effective vaccine (drug) approach likely will be required

Studies conducted in parallel to generate essential safety and efficacy data and accelerate the licensure and distribution

NIH to facilitate collaborations with discussions on trial designs and data sharing between government, academics industry, and funders

The 16 drug companies involved are:
AbbVie, Amgen, AstraZeneca, Bristol Myers Squibb, Evotec, GlaxoSmithKline, Johnson & Johnson, KSQ Therapeutics, Eli Lilly, Merck, Novartis, Pfizer, Roche, Sanofi, Takeda, and Vir Biotechnology.

https://www.nih.gov/news-events/news-releases/coordinated-strategy-accelerate-multiple-covid-19-vaccine-candidates-key-nih-experts-say

The Rest of the World - A Commitment to Global Access

ACT Accelerator

Equitable global access to innovative tools for COVID-19 for all

Unprecedented level of partnership

Create a strong unified voice to maximize impact

Build on past experiences towards achieving this objective

Accountable to the world, to communities, and to one another.

ACCESS TO COVID-19 TOOLS (ACT) ACCELERATOR

24 April 2020

A Global Collaboration to Accelerate the Development, Production and Equitable Access to New COVID-19 diagnostics, therapeutics and vaccines

COMMITMENT and CALL TO ACTION

Our Vision and Mission

Grounded in a vision of a planet protected from human suffering and the devastating social and economic consequences of COVID-19, we, an initial group of global health actors (BMGF, CEPI, Gavi, Global Fund, UNITAID, Wellcome Trust, WHO) and private sector partners and other stakeholders, are launching

Our Mission is not only accelerated development and availability of new COVID-19 tools – it is to accelerate equitable global access to safe, quality, effective, and affordable COVID-19 diagnostics, therapeutics and vaccines, and thus to ensure that in the fight against COVID-19, no one is left behind.

Bill & Melinda Gates foundation · dcvmn Developing Countries Vaccine Manufacturers Network · The Global Fund · IGBA · wellcome · CEPI · Gavi The Vaccine Alliance · IFPMA International Federation of Pharmaceutical Manufacturers & Associations · Unitaid Innovation in Global Health · World Health Organization

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https://www.who.int/who-documents-detail/access-to-covid-19-tools-(act)-accelerator

Potential mechanisms for immune-enhancement

- T_H17 responses may direct cellular responses observed by inactivated viruses and vaccines delivered in virus vectors
- Link between T_H17 cell development and IL-6 in patients with COVID-19 who experience cytokine storm (together with IL-8 induction)
- Role of IL-17 in promoting the activation, recruitment and extravasation of eosinophils into target organs
- Finding that immunopathology is least with alum vaccines

Editorial • Full text access

The potential role of Th17 immune responses in coronavirus immunopathology and vaccine-induced immune enhancement

Peter J. Hotez, Maria Elena Bottazzi, David B. Corry

In Press, Corrected Proof, Available online 17 April 2020

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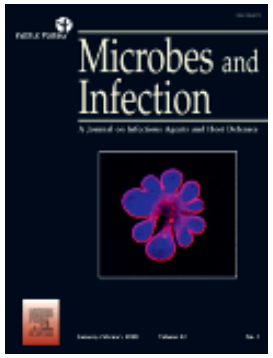

Comment | Published: 28 April 2020

COVID-19 vaccine design: the Janus face of immune enhancement

Peter J. Hotez, David B. Corry & Maria Elena Bottazzi

Nature Reviews Immunology (2020) | Cite this article

https://www.nature.com/articles/s41577-020-0323-4

Texas Children's Hospital Center for Vaccine Development

Closing the Global Health Gaps with Vaccines for Neglected and Emerging Infectious Diseases

Texas Children's Hospital Center for Vaccine Development is dedicated to the discovery and **development** of **vaccines** against neglected tropical diseases and other emerging infectious diseases. The **center** has **developed vaccines** against hookworm and schistosomiasis that are currently in clinical trials.

www.texaschildrens.org › departments › vaccine-development

Vaccine Development - Texas Children's Hospital

COMPLEX FUNDING PORTFOLIO

PRODUCT DEVELOPMENT

BENCH CLINIC POLICY

TRUSTED COLLABORATIONS

STRICT COMPLIANCE

SARS CoV RBD RBD219-N1

- cGMP Manufactured in 2016
- "Shovel ready" start of phase 1 clinical trial Q3 2020
- Investigational vaccine recommended for outbreak use in 2021

SARS CoV2 RBD

- cGMP manufacture targeted for Q3 2020
- Start of phase 1 clinical trial 2021
- Investigational vaccine recommended for outbreak use in 2022, possibly earlier

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https://www.bcm.edu/departments/pediatrics/sections-divisions-centers/tropical-medicine/research/vaccine-development/coronavirus-vaccines

Aligning to Achieve Global Access

Partnership between PATH Center for Vaccine Innovation and Access (CVIA) for a 2-stage approach

- An accelerated US-based time schedule for FIH
- Transition to a developing country vaccine manufacturer

A shovel-ready SARS C0V candidate as a heterologous vaccine against COVID-19

- cGMP Formulation, Fill-and-Finish
- Parallel GLP (Rabbit) Toxicology Testing
- All-in Strategy: securing a SARS CoV-2 regulatory strategy with a SARS CoV vaccine candidate
- Proposed Phase 1 randomized, placebo-controlled, observer-blind trial to assess the safety and immunogenicity in healthy adults 18 through 45 years of age.

David C. Kaslow
VP, Essential Medicines; and Head CVIA, PATH

Deborah Higgins
Scientific Director
& Project Lead, CVIA, PATH

BCM Vaccine Research Center

https://www.bcm.edu/news/infectious-diseases/partnership-research-covid-19-vaccine

THANK YOU

Coronavirus Product Development Partnership

Led by Texas Children's Hospital Center for Vaccine Development, Baylor College of Medicine

Partnership with New York Blood Center (Jiang, S. & Du, L.), University of Texas Medical Branch (Tseng, C-T) & WRAIR

New York Blood Center

utmb Health
Working together to work wonders.

WRAIR
Walter Reed Army Institute of Research
Soldier Health • World Health

NIH National Institute of Allergy and Infectious Diseases

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Twitter: @mebottazzi
Email: bottazzi@bcm.edu