



COVID-19

VACCINES AND TREATMENT: THE EXIT STRATEGY

What is the exit strategy from this pandemic? The world has rightly focused on social distancing and other efforts to slow the spread of the virus. It is a smart strategy to flatten the curve; not a plan to end the pandemic.

Effective treatment and a vaccine provide the only exit strategy. Over 200 research programs have been launched and around 100 potential vaccines and 140 treatments are in the pipeline.ⁱ But viruses move fast. Vaccine and drug development does not.ⁱⁱ On average, it takes at least 10 years for a new medicine to move from initial discovery to approval.ⁱⁱⁱ

There is a major risk that solutions become available but are too expensive or not well suited for low-resource settings. The history of pharmaceutical development shows us that when a new drug or vaccine is produced, it is first available to those able to afford it. There is a typical lag of up to seven years from the time a new medication or vaccine is available in a developed country to the time developing countries have access.

There are two truths that are almost too obvious to state here: First, we can't wait seven years for an exit strategy to this crisis. Second, if COVID-19 is spreading anywhere, it is a threat to people everywhere.

Business as usual won't work. We need to throw all we have at R&D, slow the spread of infection, and simultaneously build the capability to get the successful vaccine and treatment to everyone that needs it fast.

Governments, philanthropists, and businesses must:

- Invest at least \$8 billion in research, development, and supply of vaccines and treatments, and in public health measures in countries with weak health systems
- Pool intellectual property on diagnostics, medicines, and vaccines
- Seek out universal vaccine platform technologies that can be adapted against future coronavirus threats
- Shape the market through innovative financing and coordination so the vaccine gets to those most at risk
- Ensure essential drugs are formulated, priced, and sufficiently available to reach the most vulnerable populations
- Provide at least \$7.4 billion for Gavi, the Vaccine Alliance to ensure immunization is not interrupted in the world's poorest countries

“Coronavirus anywhere is a threat to people everywhere”

Ellen Johnson Sirleaf -
Former President of Liberia.



Key Facts

- It takes, on average, 10 years for a new medicine to move from initial discovery to approval.
- Around 100 COVID vaccine candidates are under development. Of these, five have moved to clinical development, and three are being tested on humans.
- The most promising COVID treatment options include drugs that already exist to combat other diseases like HIV and malaria.
- It costs roughly \$1bn to bring a drug to market in the United States.
- Only one in ten drugs that enter a phase one clinical trial gets approved in the US.
- It commonly takes 7 years from the time a vaccine is first licensed to most developing countries having access.
- In the 2018 Ebola outbreak, Gavi, the vaccines alliance was instrumental in developing and rolling out a successful vaccine.
- During the 2009 H1N1 flu pandemic wealthy nations locked in contracts with vaccine suppliers resulting in severe shortages in poor countries.
- Advance Market Commitments, a market shaping tool enabled the pneumococcal vaccine to be made available to poorer countries at a 90% price reduction.
- Africa imports 94% of its pharmaceuticals. More than half of Africa's medical supply comes from the European Union.
- Nigeria, Senegal and Mali apply an import tariff of 6% on medical supplies and 18.8% on PPE equipment.
- Africa has roughly 375 drug makers, mostly in North Africa, to serve a population of almost 1.3 billion people. China and India serve an equivalent population with 5,000 and 10,500 drug manufacturers respectively.
- Most sub-Saharan African countries rely on India for the supply of generic medicines.



Treatment

Until a vaccine is developed, finding a treatment, often called a therapeutic, can improve the odds of survival for people who become infected. An effective therapeutic could save the lives of severely ill patients, protect health care workers and others at high risk of infection, and reduce the time patients require hospitalization.

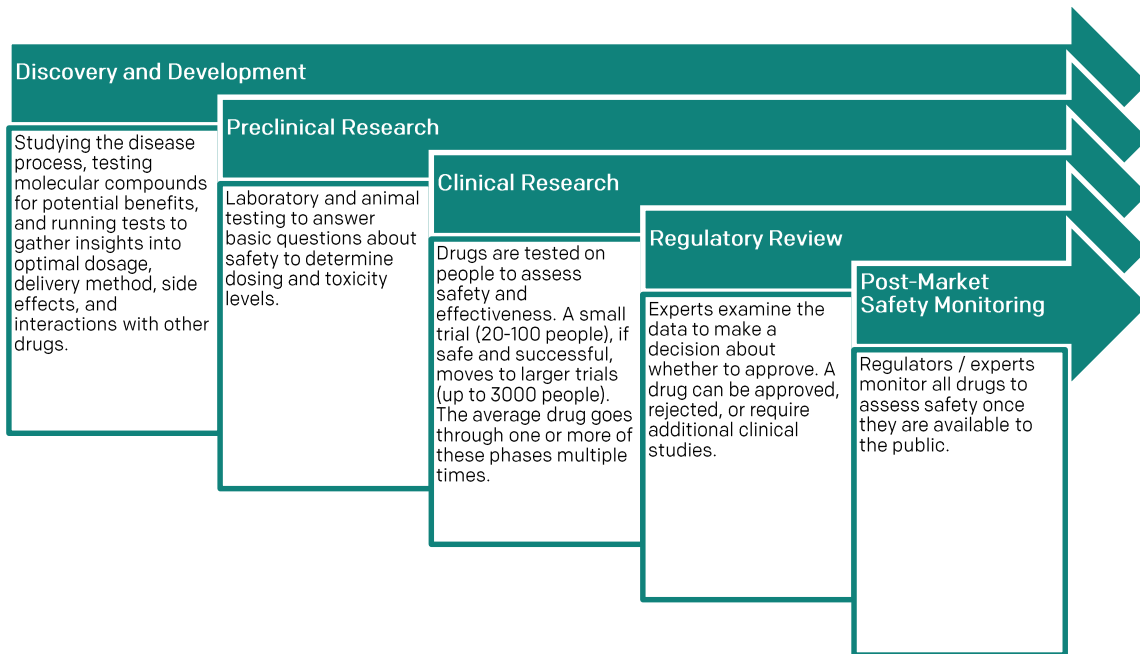
Bringing a new drug to market is a lengthy and expensive process: In the U.S., the cost of bringing a drug to market is can range from \$1bn to \$2.6 billion^{iv} and only 13.8% of drugs that enter a phase one clinical trial eventually get approved.^{vi} On average, it takes at least 10 years for a new medicine to move from initial discovery to approval,^{vii} though the development and review processes can be expedited for drugs designed to treat a serious or life threatening disease or condition.^{viii} Just over a third (39%) of the drugs receiving that designation have been approved.^{ix}

The 2014–16 West African Ebola epidemic taught us that clinical trials -- which can take years to design and implement under normal circumstances -- need to start early and progress rapidly in a health emergency.^x To that end, the World Health Organization (WHO) launched a global clinical trial for COVID-19 treatments called SOLIDARITY that is enrolling thousands of patients in dozens of countries and collecting streamlined data to be able to quickly assess which drugs are improving survival. The trial is currently testing four drugs.^{xi}

Similarly, the COVID-19 Therapeutics Accelerator was set up in March 2020 to coordinate research and development efforts and remove barriers to drug development. This global initiative launched in March by the Bill & Melinda Gates Foundation, Wellcome, and Mastercard, has committed \$125 million in support of efforts to identify repurposed drugs and immunotherapies for COVID-19.

At the time of writing, of the 211 treatments under development, 72 were in active trials due in part to these types of efforts to coordinate and accelerate research and development.^{xii} The most promising treatment options are drugs that already exist to combat other diseases and could also be effective against COVID-19.^{xiii}
^{xiv} But no treatments have been approved for use against COVID-19 yet.

We could see a viable treatment option if one of the existing drugs under trial is approved.^{xv} Remdesivir, a drug developed by Gilead Sciences, is the first medicine identified as having the potential to impact SARS-CoV-2, the coronavirus that causes COVID-19, in lab tests and early indications from clinical trials are also promising.^{xvi} In the U.S., this drug has already been approved by the Food and Drug Administration (FDA) for treating COVID-19 patients under compassionate-use and, if shown to be safe and effective, it could become the first approved treatment against the disease. The FDA has also granted an emergency use authorization for chloroquine and hydroxychloroquine as clinical trials are ongoing.^{xvii} If existing treatments are not approved, it could take well into 2021 until a new drug is developed.^{xviii}



Developing therapeutics: a five stage process ^{xix xx}

Vaccines

Taking a vaccine from conception to clinic is a long path, and for good reason: it is essential to show that vaccines are safe and effective, so they undergo rigorous testing in multiple phases before they reach humans. There are six stages in vaccine research and development ^{xxi} and the rate of failure in each of these stages is high. Very few candidates that emerge in the Exploratory Stage actually make it to Regulatory Approval and even fewer are successfully manufactured and delivered.

This means that vaccine trials are long and expensive. Companies often invest in parallel studies on multiple vaccine candidates to increase the likelihood of success, and eliminate the need to wait for one candidate to prove unsafe or ineffective before pursuing a new one. Over 80 COVID-19 vaccine candidates are under development.^{xxii xxiii} Of these, five candidates have moved to clinical development, and three have already started testing in humans.^{xxiv xxv xxvi}

While scientists have not developed a vaccine for coronaviruses before, they have spent significant time studying the previous outbreaks of the Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The Exploratory and Pre-Clinical phases have been accelerated, which is why, only a few months into the COVID-19 outbreak, there are vaccines already in the Clinical Testing Phase.^{xxvii}

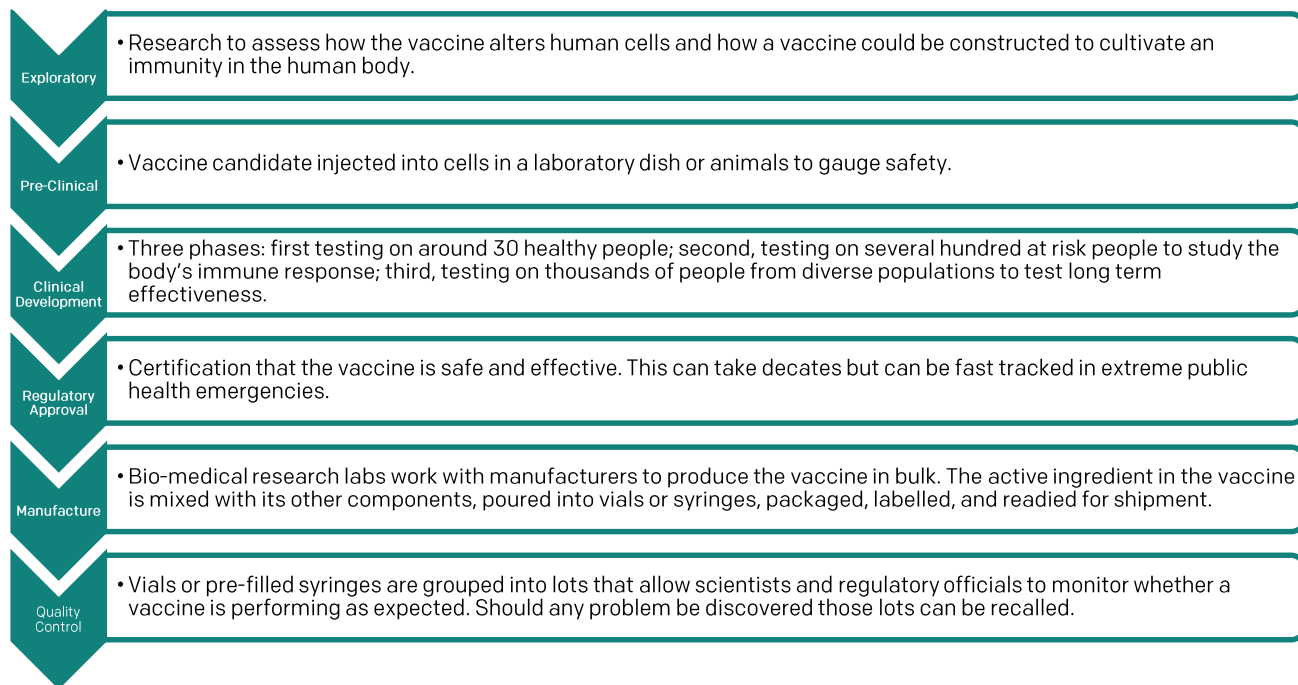


Testing the effectiveness of other approved vaccines for treating COVID-19 may also prove to be a short-cut. Scientists are studying whether Bacillus Calmette–Guérin, otherwise known as the BCG vaccine typically given to children to prevent tuberculosis, could be helpful in the current pandemic. Because this vaccine has previously gone through safety testing, its application against COVID-19 has been fast-tracked to Clinical Testing.^{xxviii}

About three-quarters of the vaccine candidates are being developed by private or industry developers while a quarter are being led by academic, public sector, and other not-for-profit organizations.^{xxix} This includes investment from the Coalition for Epidemic Preparedness Innovations (CEPI) and other non-governmental organizations that play significant roles in product development for emerging epidemics, and ensure they are accessible, available, and affordable.

Once a vaccine candidate is approved, regulatory bodies monitor manufacturing and use. Given how lengthy this process is, governments may allow experimental vaccines to be given to high risk patients before they are approved for widespread use. This is sometimes called expanded access^{xxx} or compassionate use.^{xxxi} In the 2018 Ebola outbreak, the governments of Rwanda, South Sudan, Uganda, Burundi, and the Democratic Republic of the Congo, with the support of the U.S. Centers for Disease Control, the World Health Organization, and the United Nations, authorized vaccinating front-line health workers and high risk individuals Ebola vaccine before formal approval.

Another way to accelerate the regulatory process is by the World Health Organization pre-qualifying a vaccine, meaning the vaccine has met international standards for safety and efficacy. That designation allows Gavi, the Vaccine Alliance and U.N. Agencies to procure the vaccine for at-risk countries.^{xxxii}



Vaccine research and development:^{xxxiii xxxiv}

Ensuring Everyone Has Access

The COVID-19 pandemic is a stark reminder that diseases do not respect borders; if Coronavirus is spreading anywhere, it is a threat to people everywhere. Once identified, an effective vaccine or treatment must be made available to all people regardless of their wealth or nationality. But there is a major risk that this does not happen.

Producing and distributing health technologies equitably is a persistent challenge in public health even under normal circumstances. There is a typical lag of up to seven years from the time a new medication or vaccine is first licensed in a developed country to the time developing countries have access.^{xxxv}

Part of the challenge is ensuring products are formulated to address the unique needs of low-resource settings. For example, low-income settings with limited infrastructure such as electricity require drugs to be transported and stored without cold chain. Similarly, drugs must be easily administered and should not require delivery by highly trained healthcare workers.

Cost and capacity is also likely to be a major factor, with 75% of vaccine candidates being developed by private companies which need a return on their R&D investments. Large multinational manufacturers typically do not prioritize early registration and introduction of their new products into low-income countries due to limited commercial potential in most of those countries.^{xxxvi}



This inherent imbalance between need and purchasing power for vaccines and drugs is further exacerbated during a crisis. For example, it took a decade and a major global effort to ensure regions like sub-Saharan Africa had access to new treatments for HIV. During the 2009 H1N1 flu pandemic wealthy nations were able to lock in contracts with vaccine supplies early on resulting in severe shortages in poor countries.^{xxxvii} For COVID-19, we must short-circuit these inequities before they come to pass. The following tools could help:

- **Advanced Market Commitment (AMC):** Donors commit in advance to buy vaccines at a set price when they are developed. This creates incentives for industry to invest in research and development and expand manufacturing capacity. In exchange, companies sign a legally-binding commitment to provide the vaccines at a price affordable to developing countries over a set period of time. As a result, the pneumococcal vaccine was made available at a 90% reduction in price for poorer countries. In 2019 the price for 73 developing countries was dropped further saving US\$ 4.1 million in 2019 alone.^{xxxviii}
- **Advanced Purchase Commitment (APC):** Donors agree to buy a particular amount of vaccine for an agreed price. This helped accelerate the development of an Ebola vaccine after the 2014 West Africa outbreak allowing Merck, a pharmaceutical company to create and store a stockpile of 300,000 doses of the investigational vaccine. This was a critical part of curbing the 2019 Ebola outbreak in DRC.
- **International Financing Facility for Immunization (IFFIm):** Donors pledge future aid allowing IFFIm to raise money from international markets for immediate use. This funding provides reliable, predictable funding for immunization programs and health systems strengthening over long periods of time.

In addition, existing institutions like The Global Fund to Fight AIDS, TB, and Malaria, and PEPFAR, the U.S. President's Emergency Plan for AIDS Relief, have helped open up access in low- and middle-income countries to high-quality drugs at affordable prices. Strategies, partnerships, and systems set up by these effective institutions should be used as a blueprint for the COVID-19 response to ensure we heed the lessons already learned in the field.

Other barriers like restrictive tariffs on medical supplies and intellectual property rights could slow manufacturing and limit the global supply of lifesaving medical supplies. The European Union has called on World Health Assembly member states to contribute to a voluntary "patent pool", which has proven effective for other infectious disease responses.^{xxxix} These voluntary system for countries and companies to "pool" patents and other intellectual property would enable developers and generic manufacturers to produce large volumes of COVID-19 drugs and vaccines at an affordable price. The Medicines Patent Pool (MPP) has, for over a decade, enabled low-income countries to purchase affordable treatments for HIV, TB, and Hepatitis C.^{xl}

Africa imports 94% of its pharmaceutical products.^{xli} While tariffs on medicines tend to be zero, a number of African countries have high tariffs on the import of medical supplies and personal protective equipment (PPE) which could hamper the response. Nigeria, Senegal, Mali apply an import tariff 6% on medical supplies and 18.8% on PPE equipment.^{xlii} The continent has roughly 375 drug makers, mostly in North Africa, to serve a population of almost 1.3 billion people. In contrast, China and India serve an equivalent population with as many as 5,000 and 10,500 drug manufacturers respectively. Most sub-Saharan African countries rely on India for the supply of generic medicines.^{xliii}



The Exit Strategy

Ending the global threat of COVID-19 will require efforts to speed up research and development, while simultaneously slowing the spread of infection. The following funding and policies must be prioritized now to fast-track the development of COVID-19 vaccines and therapeutics and ensure these health technologies are distributed equitably once available.

- Invest at least \$8 billion to fund research, development, and supply of treatments for all, and support for public health measures in countries with the weakest health systems.^{xliv} This includes \$2 billion for CEPI.
- Funders, the research community and multilaterals should pursue greater collaboration to ensure efficient R&D and expedited access to the resulting products.
- Support proven innovative financing mechanisms to facilitate market shaping needed to enable equitable distribution of a vaccine.
- Countries should ensure essential drugs are reaching the most vulnerable by enforcing the Doha Declaration of 2001. Developed countries should enact price controls for vaccines. This will help developing countries negotiate a lower price without compromising on the incentive for investing resources in R&D.^{xlv}
^{xlv}
- Countries, where viable, should pool intellectual property on diagnostics, medicines, and vaccines for COVID-19 to ensure equitable access.^{xlvii}

In addition to addressing the current crisis, the outbreaks of SARS, MERS, and now COVID-19 indicate that coronaviruses will continue to be a global threat to human health. More than ever before we can appreciate the importance of preventing future pandemics. To ensure today's investments in vaccines and therapeutics have a long term impact, donors and companies should take the following steps:

- Donors should provide at least \$7.4 billion for Gavi, the Vaccine Alliance. This investment will help ensure immunization is not interrupted in the world's poorest countries and prevent additional stress on already stretched health care systems during the COVID-19 response. We need to invest resources in preventing future pandemics while responding to COVID-19.
- Companies and researchers should seek out "universal" coronavirus vaccines or vaccine platform technologies that can be rapidly adapted for use against future coronavirus threats;
- Countries should assess and strengthen national and global mechanisms we have in place that can rapidly respond to global R&D needs. This includes investment in CEPI and other non-governmental organizations that play significant roles in product development.



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