

# Cuba's Five COVID-19 Vaccines

The Full Story on Soberana 01/02/Plus, Abdala, and Mambisa

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*Despite its limited material resources, Cuba is responsible for developing two of only 23 coronavirus vaccines to have entered phase III trials anywhere in the world – and it has another three on the way. [Helen Yaffe](#) (University of Glasgow) explains how the Soberana, Abdala, and Mambisa vaccines work; how they will roll out at home and abroad; and how Cuba managed to produce them against the clock and against the odds.*

When COVID-19 arrived in Cuba, the government immediately mobilised its comprehensive public healthcare system and world-leading biotech sector. This decisive action has allowed Cuba to keep both contagion and fatality rates at very low levels. In 2020, Cuba had a total of 12,225 coronavirus cases and 146 deaths from a population of 11.2 million, which are amongst the lowest rates in the Western Hemisphere. In November 2020, however, the reopening of airports led to a new surge, with more infections in January 2021 than in the whole of the previous year. Yet by 24 March 2021, Cuba had registered fewer than 70,000 cases and 408 deaths. The death rate was 35 per million, as compared to 1,857 per million people in Britain, for example. The fatality rate amongst those infected was just 0.59%, compared to an average of 2.2% worldwide and 2.9% in Britain.



Some 57 brigades of Cuban medical specialists have been sent to treat COVID-19 patients in 40 countries ("[Cuban Health Specialists arriving in South Africa to curb the spread of COVID-19](#)" by [GCIS/GovernmentZA, CC BY-ND 2.0](#) licence)

By that point, 57 brigades of medical specialists from Cuba's Henry Reeve International Contingent had been sent to treat 1.26 million coronavirus patients in 40 countries, adding to the [28,000 Cuban healthcare professionals working in 66 countries](#) around the world. Then, in March 2021, Cuba began phase III clinical trials for two domestically produced COVID-19 vaccines, with three other candidate vaccines also in the pipeline. These accomplishments are all the more extraordinary when we consider that since 2017 the US government has unleashed 240 new sanctions, actions, and measures aimed at tightening [the 60-year blockade of Cuba](#). Some 50 of these measures were introduced during the pandemic itself, costing the health sector alone over \$200 million.

### **The full story of Cuba's COVID-19 vaccines**

Some 200 COVID-19 vaccines are being developed worldwide, and 23 candidates have advanced to phase III clinical trials (as of 25 March 2021). Though no other Latin American country has developed a vaccine of its own, two of the 23 now in phase III trials are Cuban: Soberana 02 and Abdala. And Cuba also has three other vaccine candidates in earlier stage trials: Soberana 01, Soberana Plus, and Mambisa. So how has Cuba managed to develop five COVID-19 vaccines in such a short time?

Cuba's biotech sector is unique. It is entirely state-owned and free of private interests, with innovation channelled to meet public health needs and no profit-seeking in the domestic market. Dozens of research and development institutions collaborate, sharing resources and knowledge instead of competing, which facilitates a fast track from research and innovation to trials and application. Cuba has the capacity to produce 60-70% of the medicines it consumes domestically, an imperative due to the US blockade and the cost of medicines in the international market. There is also continuous and comprehensive circulation of information and personnel between universities, research centres, and the public health system. These various elements have proven vital in the development of Cuba's COVID-19 vaccines.

### **How do Cuba's COVID-19 vaccines work?**

There are five types of COVID-19 vaccines being developed globally:

- Viral vector vaccines that use an unrelated and harmless virus modified to deliver SARS-CoV-2 genetic material (as with the Oxford AstraZeneca and Gamaleya SputnikV vaccines)
- mRNA (messenger ribonucleic acid) vaccines which teach cells to make a protein that triggers an immune response (Pfizer, Moderna)
- Inactivated vaccines containing deactivated SARS-CoV-2 virus (Sinovac/Butantan, SinoPharm, Bharat Biotech)
- Attenuated vaccines containing weakened SARS-CoV-2 virus (Codagenix)
- Protein vaccines containing COVID-derived proteins that trigger an immune response (Novavax, Sanofi/GSK)

The five Cuban vaccines undergoing clinical trials are all protein vaccines. This means that they carry a portion of the spike protein that the virus uses to bind to human cells, which in

turn generates neutralising antibodies that block this binding process.

Dr Marlene Ramírez González [explained to the British Medical Journal that the Cuban vaccines are subunit vaccines](#), “one of the most economical approaches, and the type for which Cuba has the greatest know-how and infrastructure ... [They are] based only on the part [of the COVID antigen] that is involved in contact with the cell’s receptor [the receptor-binding domain], which is also the one that induces the greatest amount of neutralizing antibodies”. She added that while Cuba’s vaccines are not alone in using this strategy, Soberana 02 is unique amongst COVID vaccines for another reason: it combines the antigen’s receptor-binding domain with a deactivated form of tetanus in order to boost immune response, making it the only existing “conjugate vaccine” for COVID-19.

Over email, Idania Caballero, a pharmaceutical scientist at BioCubaFarma, pointed out that these vaccines build on decades of medical science and work on infectious diseases:

The rate of mortality from infectious diseases in Cuba, even during COVID, is less than 1%. Cuba today vaccinates against 13 diseases with 11 vaccines, eight of which are produced in Cuba. Six diseases have been eliminated as a result of vaccination schedules. Vaccines produced with these technologies have been administered even to children in the first months of life.

The Soberana vaccines are produced by the Finlay Institute in partnership with the Centre for Molecular Immunology and the National Biopreparations Centre. The name Soberana means “sovereign”, reflecting their economic and political importance for the island – without this domestic production, Cuba would struggle to access foreign vaccines either because of their cost in international markets or because of [the longstanding US embargo](#). These vaccines work by inserting genetic information into superior mammalian cells. Soberana Plus is the first vaccine for convalescent COVID-19 patients to reach the clinical trial stage.

The other vaccines, Abdala and Mambisa (an intranasal, needle-free vaccine), are produced by the Centre for Genetic Engineering and Biotechnology (CIGB). Abdala is named for a poem by the national hero José Martí, and Mambisa is named for soldiers who fought against Spanish rule in the mid- to late 19th century. These vaccines insert genetic information into a less evolved, unicellular microorganism (the yeast *Pichia pastoris*). They build on the long experience and impressive record of the CIGB, whose hepatitis B vaccines have been in use in Cuba for 25 years.



Cuba's COVID-19 vaccines build on decades of experience and expertise in medicine and biomedical science ([“Cuban-Haitian medical brigade treats patients in Port-au-Prince”](#), by Pasqual Gorriiz/[UN Photo, CC BY-NC-ND 2.0](#))

By focusing on development of different vaccine platforms, the institutions involved have avoided competing for resources. Caballero explains that “Cuba has the capacity to produce two independent vaccine chains, with over 90 million vaccines annually, while also maintaining production of other products for the domestic market and for export”. Cuba’s vaccines require three doses, but because they are stable at temperatures of 2-8 degrees (Celsius), they do not require extra expenditure on specialist refrigeration equipment.

### **How do Cuba’s phase III vaccine trials work?**

By late March, phase III trials were underway for both Soberana 02 and Abdala, each incorporating tens of thousands of adult volunteers in regions with high a incidence of COVID-19. Soberana 02 is being administered in Havana and Abdala in Santiago de Cuba and Guantánamo. Analysis and follow-up for phase III trial patients will continue until January 2022 to investigate whether the vaccines prevent transmission, how long immunity lasts, and other long-term questions that manufacturers worldwide have been unable to answer due to the urgent need to make working vaccines available.

An additional 150,000 healthcare workers in Havana are receiving Soberana 02 shots as part of an “interventional study”, which is a type of trial that can be authorised after drug safety has been demonstrated in phase II. Intervention studies do not involve double-blind testing or placebos. Another 120,000 healthcare workers in western Cuba will receive Abdala in the next few weeks. Other interventional studies in the capital will see 1.7 million people in Havana, constituting most of the city’s adult population, vaccinated by the end of May 2021, which means that two million Cubans will have been fully vaccinated by that stage.

Assuming these trials prove successful, a national vaccination campaign will begin in June, with priority given according to risk factors and age (initially those aged 60 and over). By the end of August 2021, the government aims to have vaccinated six million Cubans, representing over half of the total population. Before the end of 2021, Cuba hopes to count itself amongst the few countries in the world to have fully vaccinated its entire population.

Cuban medical scientists are also confident that they have the capacity and experience to adapt their vaccine formulations, technologies, and protocols in order to tackle new variants. But for now the next step is to launch a new study involving 5- to 18-year-olds and begin phase II trials for Soberana 01 and Soberana Plus.

### **Cuba and China's Pan-Corona vaccine will target multiple strains of COVID-19**

Cuba's CIGB has also teamed up with colleagues in China to work on [a new vaccine called Pan-Corona](#), designed to be effective against different strains of the coronavirus. The idea is that this vaccine will stimulate generation of antibodies by using parts of the virus that are conserved rather than those prone to variation (alongside parts directed at cellular responses). Cuba provides the experience and personnel, while China provides the equipment and resources. The research will take place at the Yongzhou Joint Biotechnology Innovation Center in China's Hunan Province, which was established last year using equipment and laboratories designed by Cuban specialists. Gerardo Guillén, director of biomedical science at CIGB, believes that this approach "could [protect against epidemiological emergencies of new strains of coronavirus](#) that may exist in the future". The project builds on nearly two decades of medical science collaboration between Cuba and China, including five joint ventures in the biotech sector.

Dr Helen Yaffe has also co-produced a documentary on Cuba's response to COVID-19 (with Dr Valia Rodríguez, Aston University, UK)

### **A vaccine for the Global South**

Cuban professionals have received ten gold medals from the World Intellectual Property Organisation (WIPO) over 26 years, and their biotech products were already being exported to 49 countries prior to the pandemic, including vaccines used in childhood immunisation programmes in Latin America. Cuba has stated that its COVID-19 vaccines will also be exported to other countries. This brings hope to low- and middle-income nations that simply cannot afford to vaccinate their populations at the high prices demanded by major pharmaceutical companies (between \$10 and \$30 per dose). Even worse is the case of the US multinational Pfizer, [which was recently accused of "bullying" Latin American countries](#) into putting up sovereign assets - such as embassy buildings and military bases - as guarantees against the cost of any future litigation relating to the company's vaccines.

Through an agreement with Iran's Pasteur Institute, 100,000 Iranians will take part in phase III clinical trials for Soberana 02, with another 60,000 to be enrolled in Venezuela. Other countries including Mexico, Jamaica, Vietnam, Pakistan, and India have expressed an interest in the Cuban vaccines, as has the African Union (on behalf of all 55 of the African nations). It is likely that Cuba will apply a sliding scale when pricing its exports of COVID-19 vaccines so as to reflect the importer's ability to pay, just as it does when charging for the services of overseas medical professionals.

What Cuba has achieved is remarkable, but as Caballero underlined, "without the unjust US blockade, Cuba could have achieved bigger and better results". Cuba spends a tiny proportion of what Britain and the United States spend on healthcare, but by maximising scarce resources the country has managed to mount a highly effective response to a global pandemic. The key to Cuba's success has not just been state intervention per se, but rather the nature of that intervention: Cuba's socialist system is set up to prioritise social welfare

over private profit.

It may not be a lesson that other countries are ready to hear, but Cuba's international assistance during the pandemic shows the benefits of global cooperation and solidarity in addressing global problems.

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Featured image: The Soberana 02 vaccine is one of two Cuban vaccines undergoing stage III clinical trials, out of just 23 worldwide (© 2021, BioCubaFarma)

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