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## COVID-19 Requires Innovation, Regulation and Rigor: Amaylid Arteaga-García MD MS

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The effects and implications of COVID-19 are global, comprehensive and long-term. The pandemic has exposed inequities, the fragility of economic and political systems, and in many cases, skewed priorities. Population health, not to mention planetary health, is suffering as a result. Nevertheless, the global health crisis in which we are embroiled has provided opportunities for effective collaboration, scientific innovation and real dialog around health and equity.

Dr Amaylid Arteaga-García, director of Cuba's National Clinical Trials Coordinating Center (CENCEC), emphasized these opportunities when discussing Cuba's clinical trials in times of COVID-19. Founded in 1991 in response to the groundbreaking research emerging from the country's biopharmaceutical sector—including the first safe, effective vaccine against serogroup B meningococcal disease, VA-MENGOC-BC in 1989 and a recombinant vaccine against hepatitis B, Heberbiovac in 1990—CENCEC now coordinates some 100 clinical trials annually, many of them multi-site trials involving thousands of volunteers. Little did Dr Arteaga García know what problems lurked when she became CENCEC director in 2019.

In February 2020, Cuba implemented its National COVID-19 Prevention & Control Plan. This included a scientific Innovation Committee tasked with evaluating promising projects, products and research that might be used in the health system to control and treat COVID-19. This approach taps into two of Cuba's strengths: biotechnology and primary health care. Given the volume and complexity of COVID-19 clinical trials, Dr Arteaga-



García's background as a family doctor with a master's degree in primary health care and a passion for research, augured well for marshaling these strengths. She is also a professor at the Medical University of Havana. Dr Arteaga-García spoke to *MEDICC Review* about Cuba's regulatory framework and clinical trials currently underway to detect, treat and control COVID-19.

***MEDICC Review:* Multi-center research is your area of expertise. Can you describe your professional journey from family doctor to CENCEC director?**

**Amaylid Arteaga:** Scientific research fascinates me—it has since I was a medical student. I find primary care-level research more fascinating still; it's why I specialized and sought out opportunities in this area. I realized the allure of research and the impact it can have on population health when I was asked to coordinate a study across 75 community polyclinics. This was in 2005–2006, a transformative moment in our medical education and primary care systems when in-classroom instruction was complemented by teaching at academically-accredited 'university polyclinics.' Our study looked at how this hands-on learning in the community affected the delivery of health services and patient satisfaction.

The study spanned more than two years, during which I was director of the Héroes de Girón Polyclinic in Havana's Cerro municipality. Subsequently I was offered a position at the

Ministry of Public Health (MINSAP), but I didn't want it. I sought more on-the-ground experience. What convinced me to accept the job was the prospect of conducting more community-based participatory research. The study that made me fall in love with my work and set me on my definitive career path looked at the introduction and use of six domestically-produced biotech products into the primary health care system. I directed the Health Technologies Innovation Department within MINSAP by this time, driven by a passion for research. When I began at CENCEC two years ago and immersed myself in the world of clinical trials, I found my life's work; I hope to spend the rest of my career here.

***MEDICC Review:* Can you explain CENCEC's role in the clinical trial process?**

**Amaylid Arteaga:** CENCEC was formed to conduct clinical trials for our nascent biotech industry, working closely with products developed by the Molecular Immunology Center (CIM) and the Genetic Engineering and Biotechnology Center (CIGB). As time

went on and Cuban researchers made more scientific innovations, Cuba's regulatory framework was overhauled to create a national clinical trials system and our role expanded.

Today, our clinical trials system is designed as a unified, integrated network where we serve as the link between Cuba's national regulatory authority, the Center for State Control of Medicines and Medical Devices (CECMED), the biotech industry and the health system. While we used to coordinate individual trials, today we coordinate Cuba's entire clinical trial system, monitoring each trial in that system from conception to execution, ensuring adherence to best practices and design protocols. Our trial control and oversight mechanisms are designed and evaluated together with MINSAP.

CENCEC offers all the services necessary to conduct clinical trials: trial design analysis; data collection and management; pre-certification evaluation of clinical sites; problem solving within clinical trials, etc. It's a mix-and-match model where institutions can contract all or some of our services, similar to Contract Research Organizations (CROs) typically used by pharmaceutical companies elsewhere. Any foreign entity wishing to conduct clinical trials in Cuba must contract CENCEC—the only entity authorized to control trials within our health system.

**MEDICC Review: Cuban clinical trials are officially registered, correct?**

**Amaylid Arteaga:** That's right. All clinical trials need to be published in a public registry to comply with best practices related to transparency, patient recruitment and other fundamental principles. The Cuban Public Registry of Clinical Trials (<https://rpcec.sld.cu/>) was launched in 2007—the first in Latin America—and in 2011 was accredited as a WHO Primary Registry. Today, all Cuban clinical trials are registered on this platform.

**MEDICC Review: How about training and other 'behind the scenes' work necessary for clinical trials coordination?**

**Amaylid Arteaga:** CENCEC is also the national coordinating center for ethics in health research. Every clinical trial must be approved by an independent ethics committee. As the coordinating center, we participate in the composition of all the ethics committees related to vaccine production in Cuba.

A large part of our work is also related to organizing multi-center clinical trials in terms of guaranteeing compliance with trial protocols, designing proper patient flow at vaccination sites and training our professionals in clinical best practices. CENCEC coordinates certification of vaccination sites and nurses administering the vaccines, as well.

**MEDICC Review: Scores of clinical trials were underway when you became director of CENCEC. Then the COVID-19 pandemic hit, generating many more trials. How was the work organized to incorporate new trials?**

**Amaylid Arteaga:** By February 2020, we had a national, intersectoral plan in place. In terms of clinical trials for treatments, vaccines and diagnostics, our most urgent endeavor was to identify Cuban research and products that might be useful in addressing

the pandemic. Two scientific taskforces were convened as part of the national plan to achieve this: the Science Group and the Innovation Committee. It is led by the Director of Science and Technology Innovation at MINSAP and her counterpart at BioCubaFarma (Cuba's biotech conglomerate), and includes specialists from individual biotech institutions, CENCEC and CECMED. It is responsible for evaluating which Cuban biotech products might be used in our COVID-19 response. The Science Group, meanwhile, is tasked with analyzing research that might be useful. Together, these groups developed national, pandemic-specific protocols.

By the time we detected our first cases here in Cuba in March 2020, these protocols were in place. But within a month, the global epidemiological situation worsened considerably, with rapid increases in transmission and mortality. This was a dramatically different panorama, making our search for solutions more urgent still. Our imperative at this point was to adjust regulatory mechanisms for the global health emergency, while maintaining standardized best practices required for new products.

**MEDICC Review: Regulatory authorities worldwide made adjustments in response to COVID-19. What did Cuba do in this regard?**

**Amaylid Arteaga:** We streamlined our clinical trial process, making it more efficient, without compromising scientific and ethical quality. We went from a silo model, where each step was conducted independently by the corresponding entity—CENCEC, CECMED, Independent Ethics Committees for Scientific Research, CEI—to an integrated, collaborative model coordinated by the Innovation Committee. Under this new model, the Innovation Committee vets and recommends the most promising products, with CENCEC, CECMED and the CEI analyzing the proposed trial together according to established guidelines; CECMED does not green light any clinical trial before receiving MINSAP and CEI authorization. The transition was arduous. We worked around the clock organizing this new process.

The products currently used in our national COVID-19 treatment protocols were authorized according to this streamlined model. The new process has been quite a revelation...it's more dynamic and innovative, while maintaining the same scientific and methodological rigor. Like many national regulatory authorities, CECMED can also issue emergency use authorization (EUA) and we're using this mechanism as well.

**MEDICC Review: Which brings us to Cuba's vaccine candidates...**

**Amaylid Arteaga:** All trials for our COVID-19 vaccine candidates—SOBERANA 01, 02 and Plus; Abdala and Mambisa—were authorized according to this streamlined model. Today we have over 10 regulatory-approved clinical trials testing these five candidates; all five have concluded phase 1, plus we have a pair—Abdala and SOBERANA 02—that have concluded phase 2 and are now in phase 3 trials. These two candidates are also in parallel intervention trials vaccinating frontline health workers in Havana that will eventually be broadened to include most adults in the province.

**Conducting concurrent phase 3 trials and intervention studies allows us to test and reaffirm efficacy and gather preliminary data on effectiveness by approximating real-world conditions**

dates, and we will be able to begin mass vaccination of our population. We should know soon.

Other candidates in different stages of evaluation include SOBERANA Plus, currently in phase 2 trials to evaluate safety, reactogenicity and immunogenicity in COVID-19 convalescent patients. Initial results from this trial are encouraging, with the vaccine generating impressive levels of neutralizing antibody titers. Pending further results, we may be able to immunize all our convalescent patients with SOBERANA Plus.

**MEDICC Review: Can you talk specifically about CENCEC's responsibilities around Cuba's COVID-19 vaccines?**

**Amaylid Arteaga:** As I mentioned, CENCEC oversees the entire clinical trial process from conception to conclusion, but also can be contracted by research centers to assume individual steps in that process. All the SOBERANA candidates are products of the Finlay Vaccine Institute (IFV); the institute's in-house specialists authored the trial design. Once that design was approved by CECMED, IFV contracted us to conduct all trial phases for SOBERANA 01, 02 and Plus.

Our role was more limited with phases 1 and 2 of Abdala and Mambisa, both Cuba's Genetic Engineering and Biotechnology Center (CIGB) products, but now is intensifying as the number and types of clinical trials multiply. Which is another challenge because we're reaching our limit. Although we haven't had to decline any new contracts, we're trying to figure out ways to increase our output without affecting service quality. One solution is a push for new hires at CENCEC to increase our workforce; we're working on that initiative right now.

In preparation for the phase 3 trials and intervention studies, we designed and implemented a standardized methodology all vaccine sites across the country must follow. This includes but is not limited to: a waiting area, a vaccination room, an area for one-hour post-vaccination observation and another area for attending any adverse events that may arise. Each person to be vaccinated must receive a pre-vaccination consult and another after the one-hour observation period.

Finally, we have a monitoring role, performing site visits to ensure trial design, documentation and data collection protocols are being followed. This is fundamental: we cannot have the quality of a trial compromised by faulty documentation. Due to the magnitude of our intervention study, during which 1.7 million people will be vaccinated, we've trained facilitator-monitors—mostly university professors with backgrounds in research. CENCEC just doesn't have enough monitors for all the clinical sites.

**MEDICC Review: You mentioned the intervention study—which has been anxiously awaited in Havana, Cuba's COVID-19 epicenter. Can you explain how this works?**

**Amaylid Arteaga:** This is a 'real-world scenario' study conducted simultaneously with phase 3 trials in a large number of volunteers. The goal is two-fold: to supplement efficacy data gathered from phase 3 trials and to begin demonstrating effectiveness. Due to the gravity of this pandemic and the global health emergency it represents, the scientific community is compelled to conduct parallel studies such as these, with combined phases—an unusual, but necessary, process and only pursued when it is safe to do so. The key is to remain true to the criteria, protocols and schedule established by the national regulatory authority. Introducing a more flexible, agile system to provide a faster response to COVID-19 is not unique to Cuba.

**MEDICC Review: How many people work at CENCEC and how are they distributed?**


**Amaylid Arteaga:** We have 150 people on our team, 60% of whom are women. Each and every one of us is working on the clinical trials—visiting health services and institutions, evaluating vaccination sites, ensuring they meet the criteria necessary for a phase 3 clinical trial, preparing them for certification and establishing conditions for the population intervention study. In the phase 3 trial in Havana alone, there are 35 CENCEC specialists working full time.

We've had to request all hands on deck to prepare for the intervention study. We have the entire institution working on this, including specialists from our quality and regulatory divisions, from our control department...By design, CENCEC is a national network, with specialists working as regional coordinators around the country, including in Santiago de Cuba and Guantánamo in the eastern region where COVID-19 clinical trials are also ongoing.

**MEDICC Review: Has the work generated by the pandemic affected trials that were already underway?**

**Amaylid Arteaga:** Prior to the pandemic, 40% (nearly 50) of the clinical trials already underway were evaluating innovative treatments for cancer. None of those treatments or trials has been halted even though we're coordinating an additional 25 new COVID-19-related trials. Trials that have been halted or suspended since the pandemic was declared is due to material shortages or lack of eligible candidates, not personnel shortfalls at CENCEC. In summary, we've maintained pre-COVID-19 trials, plus incorporated all the trials related to the pandemic including vaccines, treatments and medical devices.

**MEDICC Review: Your job can't be easy...any final considerations?**

**Amaylid Arteaga:** The past two years were a steep learning curve for me. But I love working on clinical trials—it consolidates my experience as a family doctor, polyclinic director and researcher. Also, CENCEC has a professional, well-prepared team conducting rigorous research. The work is demanding, but dynamic, the way I like it. 

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