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Feasibility of Building a Biotech Industry

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Short Communication

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ABSTRACT

The performance of Cuban biotechnology from 2008 to 2021 has shown a growing pipeline of valuable biomedical solutions. As the transformation of this sector into an industrial group has changed its R&D productivity and bio manufacturing capacity, we summarize here the results of R&D projects with impact on public health, constraints found in Cuba, lessons, and opportunities to develop this science-based industry in developing countries.

Keywords: Bio manufacturing; COVID-19; vaccine; know-how; innovation; R&D.

1. INTRODUCTION

In April, the international conference Bio Habana 2022 has taken place at the Convention Centre in Havana to show the research and development (R&D) of biotechnology in both industrialized and developing countries. COVID-19, immunotherapy, and regulatory issues were major subjects of discussion at this international meeting. With the transformation of the Western Havana Bio cluster [1] into an industrial group, Bio Cuba Farma has changed the R&D

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productivity and bio manufacturing capacity of the Cuban biotechnology, we summarize here recent results of projects with an impact on public health.

A science-based industry has an intrinsic capacity to transform ideas into solutions for unmet needs. We have developed a biotechnology industry following a different approach, and facing challenges, which are different from those found in developed nations. A founder usually finds abundant unforeseen obstacles to transforming R&D into solutions in industrialized countries. Valuation, start-up management, outsourcing, institutional approvals, legal protection, licensing, conflict management, and raising funds are some of the best-known [2]. Cuban biotechnology has been developed in a different environment, and absence of these challenges. A notable difference is that freedom-to-operate search is part of R&D projects, which accumulate proprietary knowledge used in many projects. Other remarkable differences are that projects develop from discovery to commercialization at the same institution, and market research does not start at the Technology Transfer Office.

The performance of Cuban biotechnology from 2008 to 2021 has been outstanding [3]. Its growing pipeline of biomedical solutions shown in Table 1 is evidence in favour of this argument. After building manufacturing expertise, this science-based industry progressed to a new level of innovation to address unmet medical needs, and transfer knowledge to developing countries long before the COVID-19 pandemic. The medicine shortage in this period has demonstrated the urgency of expanding bio manufacturing capacities on every continent [4].

Table 1. The R&D pipeline of Cuban biotechnology. B.C.C: basal cell cancer, D.F.U: diabetic foot ulcer, R.A: rheumatoid arthritis, M.I: myocardial infarction, I.I.I: Innate immune response to viral diseases, H.I.V: human immunodeficiency virus, A.M.D: Age-related macular degeneration, Lkm: leukaemia, K.H.S: Keloids and hypertrophic scars, D.N: diabetic neuropathy, rSk: recombinant streptokinase, GnRHm1-TT: gonadotropin-releasing hormone-tetanus toxoid

Project/Product	Indication	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Market
CIGB-66	COVID-19						
CIGB-258	COVID-19						
CIGB-128	COVID-19, B.C.C.						
Nasal IFN-α	COVID-19						
Nasal vaccine	Hepatitis B						
EGF injection	D.F.U.						
rSk suppository	Hemorrhoid						
CIGB-845	Neuroprotection						
CIGB 300	Cervical cancer						
Nasal CIGB-66	COVID-19						
GnRHm1-TT	Prostate cancer						
CIGB-247	Ovarian cancer						
CIGB-814	R.A.						
CIGB-500	M.I.						
CIGB-247	Hepatocarcinoma						
CIGB-552	Cancer						
CIGB-325	COVID-19						
CIGB-300	Lung cancer, Lkm						
CIGB-470	A.M.D.						
CIGB-210	COVID-19, H.I.V.						
CIGB-50	R.A.						
CIGB-540	K.H.S.						
CIGB-55	R.A.						
CIGB-428	Diabetic neuropathy						
CIGB-530	Liver fibrosis						

The reaction of Cuban scientists to COVID-19 was an aggressive deployment of scarce available resources to fight a duel to the death against the consequences of the pandemic. R&D of COVID-19 vaccine (CIGB-66) has been performed at major research institutions, with massive backup from the health system [5] to obtain regulatory approval of three vaccines with more than 90.0% efficacy, and conducts vaccination programs in Cuba and abroad. An immunomodulatory peptide with anti-inflammatory properties (CIGB-258), designed at CIGB with bioinformatics [6] has been approved for the treatment of hyper inflammatory response induced by infection with SARS-CoV-2, after confirmation of safety and efficacy [7]. The efficacy of the peptide CIGB-325 to reduce pulmonary lesions in adults hospitalized with COVID-19 has also been demonstrated in a randomized, controlled clinical trial [8]. A nasal vaccine for the treatment of chronic Hepatitis B showed safety and efficacy three years after the end of treatment [9].

The pipeline, composed of projects in various disease areas, using different technology platforms, and mechanisms of action, shows a notable diversification. Major risk factors in the Cuban context are different from those found in developed countries. An embargo that restricts foreign trade, external financing, technology transfers, and scientific exchange is the predominant barrier [10]. Additional economic measures against Cuba, implemented during the COVID-19 pandemic, have affected airlines, shipping companies, financial transactions, tourism, energy, and foreign investments, which implied risk to R&D, licensing, manufacturing, and commercialization.

Genomics, proteomics, bioinformatics, diagnostics, agriculture, and animal biotechnology are other research fields of the Cuban biotechnology. Sustainability of this growing activity depends on a well-designed intellectual property (IP) policy to protect the commercial value of scientific results. In line with this course of action, specific strategies of intellectual property protection are designed, implemented, and managed for each R&D project, starting from systematic analysis of novelty before publication, and active search of strategic alliances and collaboration.

After COVID pandemic, clinical development has been focussed on coronavirus vaccines for children, generating an interesting question: How was it possible?. Developing biotechnology in a poor country requires the participation of the government in social and economic investment, collaboration across all sectors, coordination between institutions, suitable intellectual property policy, project planning, and rational resource allocation. Taking into account the complexity of this process, and the country's characteristics, following the same pathway should not be recommended, but this approach could be feasible for developing countries. The pipeline shown in Table 1 represents an opened pathway to perform early-stage associations for joint development, and sharing commercial opportunities, according to flexible business structures, and international trade practices.

2. CONCLUSION

The CIGB is a research-production facility with a steady stream of technology transfer to companies from industrialized and developing countries. This institution has transferred technologies to private and public sectors from Algeria, Brazil, China, India, Russia, and South Africa. Finally, the vitality of biotechnology in a developing country under economic sanctions has demonstrated its feasibility and intrinsic capacity, as a science-based industry, to add significant value to the economy.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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