

Case of the Development of a Biomedical Device Innovation Project of a Mexican Public University to Face COVID-19

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ABSTRACT

Through the case study method, in this article, the activities of an innovation project carried out by the Biomedical Devices group of the Institute of Applied Sciences and Technology of the National Autonomous University of México (UNAM) to face Covid-19 pandemic are presented. A notable result is that the drastic reduction of university development times required to deliver results to the health sector in the form of technological products to face the disaster situation is observed. However, it is also noted that some government authorities in the field of intellectual property and health permits act as barriers that make it difficult to reach the innovation frontier because the time required to obtain governmental authorizations. This situation made it difficult to reach the moment of launching the technological product to society. It is concluded that the joint reaction time of the different innovation actors is one of the main variables or dimensions that must be reduced through emergency policies and actions that must be planned, based on the organizational and individual learning that occurs in contingent situations.

Keywords: technology development, dynamic organization systems, pandemic

INTRODUCTION: THE COVID-19 PANDEMIC A WORLDWIDE DISASTER

With the first cases of COVID 19 sickness produced by Sars-Cov-2, announced in Wuhan, China in December 2018 and its rapid world dissemination, the world has lived an unprecedented experience, which has mobilized all governments, health, and social structures. While the global challenges of poverty, inequality, climate change, environmental degradation, the need to ensure peace and justice are far from being satisfactorily addressed, new challenges such as the Covid-19 pandemic have emerged, necessitating countries take emergency measures to deal with them. (Mulgundmath, 2021).

It is interesting to note that close antecedents of SARS-CoV 2, (severe acute respiratory syndrome coronavirus 2), which causes the disease COVID 19, were the SARS-CoV that appeared practically with a difference of approximately ten years during this century. The SARS CoV 2 viruses appeared during the years 2002 to 2003 and the MERS-CoV (Middle East respiratory syndrome coronavirus) that appeared in 2012 at the province of Guangdong, China. The latest of these, named SARSCoV-2 was detected in late December 2019 in Wuhan, China.

All of them are zoonotic viruses that have been transmitted from animals to humans (Perlman, 2020).

The MERS-CoV virus was transmitted from camels to humans, while the SARS-CoV and SARS-CoV2 viruses are believed to have been transmitted from bats to humans. (Guerrero, S., 2020).

The first reported case of COVID-19 was detected in Mexico on February 27, 2020. On April 30, 64 days after this first diagnosis, the number of patients increased exponentially, reaching a total of 19,224 confirmed cases and 1,859 (9.67%) died. Most of the COVID-19 cases were in Mexico City. The average age of the patients was 46 years. Of the 12,656 confirmed cases, the highest number of infected occurs in the age range between 30 and 59 years (65.85%), and there was a higher incidence in men (58.18%) than in women (41.82%).

The deceased patients had one or multiple comorbidities, mainly hypertension (45.53%), diabetes (39.39%) and obesity (30.4%). (Suárez et al. 2020)

In every country fair public policy should be the right of society to have access to primary medical and mental health care, to have social support programs, to carry out intersectoral efforts to improve public health and the use of information technologies to disseminate communications and notices, this does not always happen in Mexico nor in Latin American countries. Therefore, pandemics affected intensively most of Latin-American countries.

Within that critical panorama, in mid-October 2021, the government of Mexico reported that the epidemic has involved an estimated 3,973,789 people who have tested positive, of which there were 39,244 cases of estimated active people and 297,656 deaths. (Government of Mexico, 2021)

Looking for some explanation for this tremendous problem, probably in México, the numbers of infections and deaths obey to the social inequalities and inequities pointed out by Menéndez (2005), existing in the country because of the Mexican Neoliberal Health Sector Politics occurring between 1980 to 2004 where decentralization, reduction of health spending, selective primary care, health commercialism, and privatization of health services were the main processes. Crisis probably began in 1980 when the economic politic process was characterized by the low economic growth, the persistence and deepening of socioeconomic inequalities, the increasing concentration of wealth in a small sector of society, and the expansion of the situation of poverty and extreme poverty that led to talk about two lost decades. Inequalities express themselves through of a whole series of variables, among which stand out economic / occupational levels, if people belong to the rural or urban environment, the condition indigenous / non-indigenous, the situation of marginality and / or poverty,

belonging or not to the official social security, the possibility to have or not a major medical insurance and the situation of genre.

According to the situation described, we can affirm that the main structural factors that explain the situation of health system in México are fragmented society, struggling economies, permanent socio-political crises, precarious living conditions, inadequate health infrastructure and vast socioeconomic inequalities.

Beyond the health aspect, Covid 19 has greatly impacted the Mexican economy. The snowball effect of Covid-19 has spread from health problems to economic problems. Chiatchoua, et al., (2020) point out that during the emergency the Mexican government implemented measures such as the resources gathering to support the health infrastructure, joint work with the armed forces, their health infrastructure, and the increase in the budget to strengthen the shielding of social programs. According to the Mexican Institute of Competitiveness IMCO, (2020), during the pandemic, between January 2022 to May 2021, more than 2 million jobs were lost.

In the country, there also appeared and increased mental health society member's problems. To make things worse, the World Health Organization suggested social isolation, limitation of mobility or quarantine of the population, as the most effective strategy in containing and mitigating the speed of spread of the infection and avoiding the collapse of state health systems. However, social distancing generates adaptive and maladaptive reactions. (Taylor, 2019; Rubin and Wessely, 2020)

Asmundson and Taylor (2020) mention that social isolation functions as a stressor that increases the possibility of presenting mental problems for the first time or the exacerbation or recurrence of pre-existing mental disorders. Among mental illnesses experienced by different members of society there are fear, distress, anxiety, depressive, sleep and acute stress disorders, suicidal ideation, or suicide.

The pandemic also generated several additional problems such as boredom in society due to isolation, difficulties or financial losses generated by the situation and concern about stigma-discrimination, in case of being positive for the infection or, paradoxically, being a worker in the health sector in charge of care direct to convalescent patients. Health personnel in the first line of care for seriously ill patients due to COVID-19 infection, have been equally vulnerable to mental health problems, due to the death of patients, excessive hours and work pressures and the distancing of family members, in some cases.

On the other hand, Carlsten et al., (2021) point out that epidemic and pandemic infections have historically brought devastation to the general population but have had a disproportionate impact on worker's morbidity and mortality that is often overlooked.

A contingent situation is always critical and transforms societies. Notably, in the Covid-19 context, some sectors of the regional economies and societies have been benefited. For example, the demand for agricultural and livestock products increased and the pharmaceutical sector had unusual growth and momentum, emerging groups were formed for the development of drugs, vaccines, medicines, medical devices and diagnostic instruments. The profession of medical doctors and nurses was revalued and the need to modernize and expand hospitals and

distribution systems for drugs, food and goods in general appeared. The demand for agricultural and livestock products and food in general increased.

Within this context, the objective of this article is to identify the organizational aspects and the key variables related to the innovation project development of a medical device realized by the academic group of biomedical devices of the Institute of Applied Sciences and Technology (ICAT) of the National Autonomous University of Mexico (UNAM). This was one of the contributions of the UNAM to face the COVID 19 pandemic.

THEORETICAL FRAMEWORK

Competitiveness, the classic focus of innovation

Crespo (2019) considers that the contemporary academic study of innovation takes place with an evolutionary perspective addressing the *linking among different institutions* and agents to develop entrepreneurial competitiveness strategies to drive social welfare and economic development. The globalization process positioned the knowledge as the fundamental resource of the modern economy and innovation as its practical application process. (Kirshner, 2009)

According to Lundvall and Johnson (1994), acknowledging that knowledge is the most fundamental research output in our contemporary economy and learning is therefore the most important process, the precursor of innovation has been the globalization process that has intensified the interdependence of states by relying on international products commercialization. Nevertheless, the constant increase in travels all over the world for recreation and to carry out international trade has had its effects on the rapid spread of new viruses and diseases.

After disaster: health the new focus of innovation

Schuster (2014) describes what natural disasters means. Amid environmental distress, disaster means the collapse of biodiversity, global warming, melting glaciers, peak extraction of natural resources, structural poverty, intense pollution, high impact industries, large zones of monocropping and pandemics. All those situations anticipate the scenario of a planet becoming orphaned of life.

The Covid-19 pandemic outbreak may be a ubiquitous sign of how much the human species threatens its habitat, to face this situation minimizing losses. Mattietto (2021) proposes the need to develop scientific knowledge of catastrophes towards preparing appropriate responses to these unfortunate events that repeatedly happen in human history.

The world motivations drastically changed after the Covid-19 pandemics; life never be the same in any of its aspects. Mironko (2021) states that one of the many lessons that the COVID-19 pandemics provides is that no business can think of returning to the old ways. Every business large and small needs to develop better habits to survive downturns and succeed in pursuing the vision towards the future.

The lives of millions of people have been affected during the coronavirus pandemic that spread throughout the world in 2020. Pandemics turned into a global disaster; therefore, society is changing establishing new norms for healthcare education, social life, and business.

Confinement measures have focused on the reduction of the spread of the epidemic and the minimization of the load of morbidity and mortality so that healthcare systems remain functional.

During the severe acute respiratory syndrome (SARS) (2002–2004) epidemic, social disengagement, mental stress, and anxiety were associated with increased suicide rates in the elderly population. Parents and children who were quarantined or isolated during pandemic diseases met the clinical criteria for post-traumatic stress disorder. Data from previous economic depressions and recessions suggest profound increases in substance use disorder, depression, and suicide. In the current COVID-19 pandemic, there have been great impacts on mental health, frontline healthcare workers face the possibility of anxiety and burnout and moral injury, alongside fears of becoming ill. (Inkster, et al., 2021)

Healthcare measures have focused on treatment, case isolation and contact tracing. In that regard, many digital tools have been developed to assist with contact tracing and case identification. Kouroubali et.al (2021) propose that after COVID-19 era, digital health will provide the integrated care needed. Moreover, Faragli et al., (2020) emphasize that aging in western countries has led to an increase in the number of patients with multiple comorbidities.

As it is well known, since the very first beginning of medicine and then throughout modern times, healthcare systems have been structured on a face-to face patient–physician interaction. With COVID-19, Chronic Heart Failure (HF) patients are facing an increased challenge regarding the management of body fluids since to avoid contagion, they cannot approach hospital attention. For these reasons, telemedicine has turned from being a “nice to have” approach to an essential requirement.

All over the world, there was a disruption in the medical supply chain caused by the slowdown of conventional manufacturing, supply, and distribution channels during the COVID-19 pandemic. The combined effect caused widespread shortages in personal protective equipment and test kits including swabs for sampling. These shortages catalyzed local efforts to use nontraditional, rapid manufacturing to meet urgent healthcare needs and other medical supplies. (CDC, 2020., Decker, et al, 2020., Gallup, 2020., Ranney et al., 2020., Antonini et al., 2021)

Innovation in healthcare products: the swabs

While the COVID-19 pandemic has placed unparalleled demands on modern healthcare systems, the industry response has vividly demonstrated its resilience and ability to bring innovations to market quickly. According to McKinsey, healthcare company leaders can learn from the rapid response to the COVID-19 crisis when innovating in future. Nevertheless, cost pressures in healthcare systems will likely increase in the coming years due to growing health demands and macroeconomic challenges.

To meet both the humanitarian challenge and the obligation to stakeholders, leaders of healthcare organizations need to meet the innovation imperative. If under normal circumstances, healthcare innovation is costly and time-consuming, the difficulties and costs that health organizations encounter when seeking innovation in times of crisis increase strongly but will have their benefits in the medium term. History tells us that organizations that

invest in innovation during a crisis outperform their peers in the recovery. What's more, a crisis can create an urgency that relies collaborative effort, breaks through organizational silos, and outperform institutional inertia. (Jansen et al., 2020)

Palanica and Fossat (2020) state that the COVID-19 pandemic has produced the silver lining of inspiring healthcare innovation around the world, with collaboration across multiple disciplines all working toward the same goal of saving lives. Lessons are that healthcare innovation can develop at unprecedented speed when individuals focus on solving real-world problems and collaborate with cross-functional teams.

Manufacturers throughout the world have ramped up production when possible and the White House recognized that SARS-CoV-2 represented an emergency for the USA and implemented the Defense Production Act (DPA). One of the products the DPA has been applied to is swabs to compel an unnamed company to produce 20 million more coronavirus testing swabs per month. (The White House, 2020)

It is outstanding the use of Antonini et al., (2021) crisis-responsive framework in a case study characterized by stakeholder engagement, comprehensive but efficient needs assessment, rapid manufacturing, and modified product testing to enable accelerated development of healthcare products particularly swabs for collecting infectious samples.

To comply with this, new production techniques have been developed very quickly. Digital manufacturing, especially 3D printing, has been promulgated as an important approach for the rapid development of new products as well as a replacement manufacturing technique for many traditional manufacturing methods, including injection molding, when supply chains are disrupted. Bennett et al (2020) reported the use of Digital Light Synthesis (DLS) for the design and large-scale deployment of nasopharyngeal (NP) swabs for testing of coronavirus SARS CoV-infections in humans.

RESEARCH METHOD: CASE STUDY

The applied research method used in this work was the case study. Martinez (2006) mentions that this research method allows the inductive analysis of the qualitative data that is recovered from the case description. This type of research presents some uncertainty since quantitative methods are not applied. However, for Aguilera (2011), this facet of scientific knowledge requires working with analogies, inferences, presuppositions, and conclusions, to logically structure both the definition and the foundation of the problems.

The above implies having a specific conception of reality. In this case and from the perspective of scientific knowledge, the problems that are studied and analyzed are human elaborations, they are social constructions elaborated in base to certain conceptions of reality.

For Yin (1989, cited by Martinez, 2006), the case study method is a valuable research tool, whose greatest strength lies in the fact that it measures and records the behavior of the people involved in the phenomenon studied, while quantitative methods only focus on verbal information obtained through questionnaire surveys.

For Meyer (2001) a case study consists of detailed investigation of one or more organizations, or groups within organizations, with a view to providing an analysis of the context and processes involved in the phenomenon under study. For Gummesson (1988:76, cited by Meyer, 2001) an important advantage of case study research is the opportunity for a holistic view of the process: "The detailed observations entailed in the case study method enable us to study many different aspects, examine them in relation to each other, view the process within its total environment."

Tellis (1997) considers that a case study can be seen to satisfy the three tenets of the qualitative method: describing, understanding, and explaining. Meanwhile, Ebneyamini & Reza (2018), indicate that a case study is an empirical inquiry that investigates a contemporary phenomenon within its real-life context, especially when the boundaries between the object of study and context are not clear. Yin (2003). It is one of the most powerful methods used by researchers to realize both practical and theoretical aims. Researchers in technology and innovation management need to use more field-based research methods.

THE CASE: DEVELOPMENT OF BIOMEDICAL DEVICES AT ICAT-UNAM

It all started after the declaration of a global and national pandemic of COVID 19 in December 2018. At the beginning of 2019, the Federal Government and the Government of Mexico City convened the research and development institutions of the Universities and the Public and private institutions to urgently develop R&D projects to obtain prototypes, medical supplies, and own technologies to face the health crisis in Mexico.

On March 30, 2020, the UNAM's Program to Support Research and Technological Innovation Projects (PAPIIT) launched the extraordinary call "Development of medical supplies and instrumentation to face the new COVID-19 pandemic in Mexico", for various university institutions to present projects to face the health crisis.

Under the call of the Coordination of Scientific Research, various institutions of the UNAM presented development projects through joint proposal number IV100320, "Development of supplies and instrumentation in attention to the health emergency caused by COVID-19".

The development of 3D printed swabs

Responding to this call, the Group of Biomedical Devices of the Institute of Applied Sciences and Technology (ICAT), presented the project: "development of swabs by means of 3D printing for taking samples of infectious diseases", receiving funding of around \$178,000.00 MX, (~\$8,900.00 USD). Although the resources were available until March 2020, the project started immediately in January 2021.

The project was successful in a timely manner. The first results gave rise to a swab design manufactured by means of 3D printing. Immediately, on May 13, 2020, the ICAT, through the General Directorate of Legal Affairs (DGAJ) of the UNAM, requested the protection of this technology to the IMPI with the file MX/u/2020/000166. At the time of this writing the formal examination has already been passed and the substantive examination is in process.

The ICAT's main researcher carried out various approaches to different public institutions seeking support to test the technology. Likewise, she made the link with the Secretariat of

Education, Science, Technology, and Innovation (SECTEI) of the Government of Mexico City. After various negotiations, on November 14, 2020, the Resource Allocation Agreement SECTEI / 090/2020 was signed to carry out the Project called: "Polymeric swabs manufactured by 3D printing for sampling in the diagnosis of people with suspected SARS-CoV 2 infections". The financing obtained to continue with the works of the project was around \$350,000.00 MX, (~\$17,500.00 USD)

UNAM has no industrial facilities for producing nor medium neither large batch of swab production, while the potential swabs users demanded big numbers of testing samples, therefore ICAT's project responsible contacted several companies dedicated to producing prototypes using 3D printing, both in Mexico City and in the Northwest of the Mexican Republic. Some companies showed interest in the production and commercialization of the products, but at the end the negotiations were not closed.

On the other hand, with the support and agreement of SECTEI's people, contact was made with several COVID 19 hospitals such as the National Institute of Nutrition, the General Hospital of Mexico, and the Clinic of the Faculty of Medicine of the UNAM who established an area for hospitalization and treatment of infected patients. The idea was to request the testing of the university ICAT's swabs by taking the infectious sample from the patients and obtaining feedback on the improvements that may be required. Immediately, first contacts were made with the companies ADES 3D and TROKAR S.A de C.V., whose leaders showed interest in starting a long-term collaboration with the university to carry out the production and commercialization of swabs in the country. With the participation of the ICAT Liaison Secretariat, various meetings and negotiations were held that led to the signing of two licensing agreements, one with each company.

On January 7, 2021, ICAT/UNAM, and the company ADES 3D, signed the non-exclusive Licensing Agreement for technological development called "Improved Technological Device for taking infectious samples". The agreement was company should cover an initial payment, an annual royalty payment and the payment of taxes.

Similarly, but on March 1, 2021, ICAT/UNAM, signed with the company TROKAR S.A de C.V., the non-exclusive Licensing Agreement for technological development called "Improved Technological Device for taking infectious samples". A payment agreement like the one made with the company ADES 3D was established.

A relevant aspect is that the capabilities that ADES 3D and TROKAR companies have for the manufacture and sale of swabs to the market are complementary; in other words, ADES 3D specializes in the production of polymeric swabs manufactured by 3D printing, while the specialty of the TROKAR company is the production of medical devices such as needles, bags, keys, equipment, cannulas, catheters, masks, among others. TROKAR has the experience of good production practices and sanitary records for its products and good quality control practices required by sanitary standards, as well as industrial sterilization and packaging equipment for swabs.

The teamwork of the two companies made it possible to enhance efforts to disseminate technology to society. This situation of complementarity was considered in the licensing

agreements to avoid the double payment of royalties in those batches of production, distribution, and sale of swabs, in which both companies participate. Instead of being competitors, it is expected that they work in harmony; in other words, in demanding high-production projects, ADES 3D will produce and deliver the polymer swabs to TROKAR, who will sterilize, pack the batches, and distribute them in the market. Nevertheless, as discussed below, a few problems appeared along the project development, and they had to be solved.

Throughout the tests, it was observed that the first swabs shown in Figure 2, made of a single piece and in a single material generated some discomfort in the people from whom the sample was taken due to their lack of flexibility. The results reported in the clinics and hospitals where the tests were performed were adequate in terms of the number of cells obtained in the sample collection by rotating the swab, according to the authorized sample collection procedure.

To solve the problem, the design was improved, facilitating manufacturing and also decreasing its impact on the environment, because the new model that came out in early 2021 is manufactured in two parts, the first is a holding handle made of the biodegradable and biocompatible polymer polylactic acid (PLA), consisting of a comfortable holding area and an extension with dimensions that allow the operator to take a sample safely, since the design respects the necessary distance to facilitate the taking of the sample; in addition, it has a notch to facilitate the safe and fast cutting of the swab for the operator. The second part is the extension or tip for the collection, which should preferably be manufactured with flexible materials such as thermoplastic (TPE), which gives the set the necessary flexibility so that it can be easily manipulated, while being flexible enough for patient comfort.



Figure 2. First generation of polymeric swabs developed at ICAT-UNAM
Source: Group of Biomedical Devices ICAT-UNAM

The new design shown in Figure 2 made the swab more flexible and sustainable since the thermoplastic used in the tip is biodegradable and therefore environmentally friendly. This new production technology allowed the manufacture of a model for use in children.

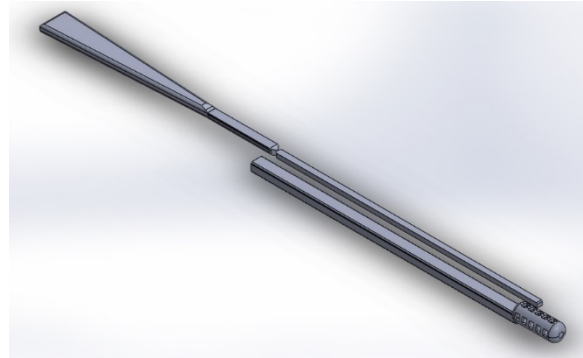


Figure 3. Second generation of polymeric swabs developed at ICAT-UNAM Complete polymeric device assembly with flexible side tip for infectious sampling

Source: Group of Biomedical Devices ICAT-UNAM

The first concern on intellectual property, was to define the most appropriate strategy to protect the swabs for taking samples since the situation imposed some restrictions. The first requirement was the necessity to obtain the certificates and protection titles as soon as possible to be able to deal with the contingency. On the other hand, it was clear that the time required to obtain patents would cancel the commercial opportunity of the project. Another aspect to consider was to protect the technology within the maturity period of its life cycle. The most appropriate solution was the request for a first utility model to protect the technological characteristics of the product and processes of the first swab model obtained in 2020. The copyright of manuals and industrial designs were also protected.

Later, at the beginning of 2021, when the technology of manufacturing the swab base was improved, enhancing its performance and sustainability, a second utility model was immediately filed to protect the new technological characteristics including the protection of the manufacture of a pediatric model.

However, the main problem in terms of intellectual property was the response times of both the university legal offices and the Mexican Institute of Industrial Property (IMPI), which is the Mexican authority on the matter. Faced with the impossibility of carrying out personal procedures to submit the applications, the IMPI developed an online platform to obtain the required documentation and formats, make the payments of the corresponding fees and submit the validated documentation signed by the institutional proxies. The average time required to draft and submit a utility model application under normal conditions; that is, without a pandemic, is about three to four months of writing and a couple of months of administrative procedures. Given the contingency, those times were reduced by half.

It is remarkable that an excellent relationship and communication was always maintained with the directors of the companies ADES 3D and TROKAR, with which licensing agreements were signed, this facilitated the negotiation of their contractual terms, such as scope, exclusivity, royalties' percentage, and front payment, among others. However, one of the main problems in negotiating and signing the licensing agreements with the companies was to demonstrate and convince those responsible for the General Directorate of University Assets (DGPU, from Spanish) about the value of the technology. The time that was required to develop the agreements and the negotiations took an average of two months, while the authorization and legal certification of the DGPU took more than four months.

Once the licensing problem had been solved, the next phase of the project was the accompaniment of the companies for the establishment of the swab production line, distribution logistics, packaging, and sterilization of swabs. At this point, the main problem has been obtaining the health permit from the Federal Commission for Protection against Health Risks (COFEPRIS). TROKAR manager submitted a first application for sanitary registration to COFEPRIS in January 2021 and a second one dated July 2021. By July, 2022 there have been no results, although it is assumed that COFEPRIS must respond within 90 days at the latest.

This is one of the aspects in which SECTEI, as a government entity, could assist the project team by taking steps with COFEPRIS in order to release the required sanitary registration. Once this problem is overcome, the launch and sale strategy will come.

It is estimated that by first quarter 2023, two modifying agreements will be signed with the companies ADES 3D and TROKAR to extend the scope of the original licensing and include the new swab models.

RESULTS

At the beginning of October 2022, the situation of the polymeric swab project developed by ICAT-UNAM is as follows:

3D polymeric swabs

- **Technology**

Technology developed for two models: (a) basic model manufactured in one piece with special reticular tip design to obtain enough infectious sample without producing disturbing or damage to patient during the patient's sampling process; (b) improved model manufactured in two pieces, giving more flexibility and sustainability.

- **Performance Tests**

Swabs were approved for their use at the Hospital General de México "Eduardo Liceaga" and the UNAM's Faculty of Medicine Covid Coordination Group

- **Intellectual property**

Two utility models have been filed at the Instituto Mexicano de la Propiedad Intelectual (IMPI). Due to the health crisis, the documentation was submitted digitally, and the authority handled the matter through a digital file. The formal and substantive examinations have followed the normal process times and a more expeditious procedure has not been handled to grant the certificates or titles that allow the project to be expedited. By the first week of April 2022 the IMPI sent to UNAM as second requirement for the examination of the utility models.

- **Technology transfer**

Two technology transfer agreements signed with two enterprises, one on the field of 3D Printing and the other in the manufacturing and sale of expendable medical devices

- **Manufacturing**

Printing, sterilization, and packaging implemented and tested at the technology transferred company using good manufacturing procedures complying with a quality system approved for medical devices.

- ***Government Liaisons***

Permanent and continuous work with the Secretaría de Educación, Ciencia Tecnología e Innovación (SECTEI) of the Mexico City Government entity that have pursue relations with other federal government levels, hospitals, regulation entities, potential users, enterprises and so on. With the SECTEI's promotion there has been promotion to sign a Triple Helix Agreement including of course government, licensed companies, and the university through the ICAT to define the best procedures to follow so that the swabs reach the market and have a positive impact on society by contributing to the attack on the health crisis.

- ***Health Regulation Permits***

Tests, device samples and paperwork submitted and filled by TROKAR, the licensee and manufacturing company at the Federal Commission for the Protection against Sanitary Risks (COFEPRIS, for Spanish). More than a year after, company didn't receive the certificate that allowed to put the swabs on the market and sale them. This situation is clearly the main project bottleneck.

DISCUSSION

To understand the phenomena that occurred in this project, let's review what was the role of the participating actors. After reviewing the requirements of the health sector, the ICAT's team realized that there were no swabs on the market for taking infectious samples, since they are normally imported and were not manufactured in Mexico. In a couple of months from the moment the pandemic was declared, the swab inventories ran out in the country and in the shortage, they could not be purchased even imported.

Therefore, the objective of the ICAT's group of biomedical devices for participating in the call, was to develop biomedical devices to face the health crisis, intending to reach society and contribute in some extent to fight the pandemic through the development of swabs for taking infectious samples. All this in accordance with ICAT's mission, which is to apply a multi and interdisciplinary approach to integrate research and technological development activities seeking to apply the knowledge generated to the solution of relevant problems in country's environment.

The SECTEI acted in the project as a Mexico City government development institution which objective was to foster, align and tune the efforts of companies, public university's R&D institutions and the health sector institutions as Covid's hospitals and health Research Institutes. Figure 3 shows the chronology of the events occurred in the project.

In addition, Figure 4 shows a different representation of the development of the innovation project presented. The initial driving force was the declaration of the pandemic. The dynamic project response was driven by the external society needs and market "forces" that interacted in the development of the 3D polymer swabs project life span.

Figure 4 also allows us to view other aspects to discuss the phenomena. By the end of 2021 it became clear that there were some barriers impeding innovation. The first one came from the IMPI which is the intellectual Property authority in México delaying the granting of intellectual property titles to UNAM although they were biomedical devices to help facing the enormous demand of sampling and diagnosis devices in the pandemics.

In addition, when everything was ready to launch the product to market by the licensed companies, and once they integrated the sterilization, packaging, and overcome the quality control system problems, the market launch of the polymeric 3D swabs stopped until obtaining the sanitary register and permission from COFEPRIS.

In April 2022, the Ministry of Health of the Mexican Government publicly announced that the pandemic had resigned, in consequence, in a term of weeks there were available at market imported swabs. This situation naturally offered a big obstacle to sell the ICAT's technology product. Nevertheless, according with the Secretary General of the United Nations (2019), COVID-19 will not be the last pandemic that the world must face, then it is necessary to continue working on preparing for new infectious outbreaks. Furthermore, the PAHO Director asked to invest in the prevention, preparation, and response to events with epidemic and pandemic potential, because, she said, the question is not if there will be a new pandemic, but when. (OPS, 2022). Therefore, the project presented in this work must continue.

CONCLUSION

A work team made up of two small companies and researchers from a public university research institute joined forces to carry out the adventure of an innovation project. They did everything in their power and everything necessary to achieve an innovation that could help face the COVID-19 health crisis in the country and may be beyond. The work team understood that COVID-19 became a trigger not just for business and SME's but for health innovation; nevertheless, after two and a half years (March 2020- October 2022) they did not be able to go to the market for the reasons beyond their control, explained above.

Historically, great crises generate great reactions, to face similar future situations, it is necessary to transform and create a new health system with a social vision in Mexico. It is also necessary to form government emergency reaction groups capable of processing and issuing fast track permits allowing project teams not to abandon the matter because the epidemic seems to subside.

The UNAM is doing its job, however the formation of triple helix groups to carry out the projects seems to be insufficient. To overcome all barriers, it is required a lot of persistence, thrust, and not get demoralized. The working group needs to maintain its innovative spirit, they learned a lot with the project and fortunately the crisis subsided. As stated in the theoretical framework of this article, *for a successful project, it is imperative to ensure a harmonious balance of all key entities that are responsible for the innovation system*. That means that every institution that takes part in the innovation process must do their job properly.

Even that the dynamic response of the project presented in this case had obstacles, actors will continue doing their best efforts to reach the innovation objective and contributing with the fighting to the actual or the pandemics to come. In the upper right corner of Figure 4, it is suggested that once the required sanitary permits are obtained, the project will be reactivated and probably the collaboration agreements and the intellectual property strategy will surely have to be updated. At that time, market conditions will have changed, and new obstacles must be overcome. However, the project team will continue to work to be prepared and in time to deal with any future epidemics related to respiratory tract diseases.

Referencias

- Antonini, M.-J., Deborah Plana D., Srinivasan S., Atta, L., Aditya Achanta, A., Helen Yang, H., Avilash K. Cramer, A. K., Jacob Freake, J., Michael S. Sinha, M. S., Yu, S. H., LeBoeuf, N. R., Ben Linville-Engler, B., and Sorger, P. K., (2021). A Crisis-Responsive Framework for Medical Device Development Applied to the COVID-19 Pandemic. *Frontiers in Digital Health*. Volume 3, Article 617106, pp. 1-16. DOI: 10.3389/fdgth.2021.617106
- Asmundson G, Taylor S., (2020). How health anxiety influences responses to viral outbreaks like COVID-19: What all decision-makers, health authorities, and health care professionals need to know. *Anxiety Disord*. Vol. 71: 102211. DOI: <http://dx.doi.org/10.1016/j.janxdis.2020.102211>
- Bennett, I., L. Bulterys, P. L., Chang, M., DeSimone, J. M., Fralick, J., Herring, M., Kabaria, H., Kong, C. S., Larson, B., Owen, L., Maxner, A., Meyer, E., Patterson, S., Pollack, S., Rolland, J., Schmidt, S., Seshadri, S., Swarup, K., Thomas, Ch., and Ryan Van Wert, R., (2020). The Rapid Deployment of a 3D Printed "Latticed" Nasopharyngeal Swab for COVID-19 Testing Made. *medRxiv preprint*, <https://doi.org/10.1101/2020.05.25.20112201>
- Carlsten, Ch., Gulati, M., Hines, S., Rose C., Scott, K., Tarlo, S. M., Torén, K., Sood, A., De la Hoz, R. E., (2021). COVID-19 as an occupational disease. *American Journal of Industrial Medicine*. Vol. 64, pp.227–237. DOI: 10.1002/ajim.23222
- Chiatchoua, C., Lozano, C., Macias-Durán, J., (2020). Análisis de los efectos del COVID-19 en la economía mexicana. *Revista del Centro de Investigación de la Universidad La Salle*. Vol. 14, No. 53, pp. 265-290. DOI: <http://doi.org/10.26457/recein.v14i53.2683>
- Crespo, P. D. F., (2019). Comparando sistemas de innovación: una revisión de la literatura sobre Alemania y China. *Revista Economía y Política*. Año XV, No. 29, pp. 87-103. DOI: 0.25097/rep.n29.2019.05
- Decker, S. J., Goldstein, T. A., Ford, J. M., Teng, M. N., Pugliese, R. S., Berry, G. J., Matthew Pettengill, M., Silbert, S., Hazelton, T. R., Wilson, J. W., Shine, K., Wang, Z-X., Hutchinson, M., Castagnaro, J., Bloom, O. E., Breining, D. A., Goldsmith, B. M., Sinnott, J. T., O'Donnell, D. G., Crawford, J. M., Lockwood, Ch. J., and Kim, K., (2020). 3D Printed Alternative to the Standard Synthetic Flocked Nasopharyngeal Swabs Used for COVID-19 testing. *Clinical Infectious Diseases*. Oxford.
- Faragli, A., La Porta, E., Campana, C., Pieske, B., Kelle, S., Koehler, F., Alogna, A., (2020). Out-of-Hospital Care of Heart Failure Patients During and After COVID-19 Pandemic: Time for Telemedicine? *Frontiers on Digital Health*, Vol. 2., Article 593885, pp. 1-4., doi: 10.3389/fdgth.2020.593885
- Gallup, N., Pringle, A. M., Oberloier, S., Nagendra G. Tanikella, N. G., Pearce, J. M., (2020). Parametric nasopharyngeal swab for sampling COVID-19 and other respiratory viruses: Open source design, SLA 3-D printing and UV curing system. *Hardware X* Vol. 8, pp. 1-25., e00135. <https://doi.org/10.1016/j.ohx.2020.e00135>
- Gil, M., Undurraga, E. A., (2020). COVID-19 Has Exposed How "The Other Half" (Still) Lives. *Bulletin of Latin American Research*, Vol. 39, No. S1, pp. 28–34. Disponible en: <https://onlinelibrary.wiley.com/doi/full/10.1111/blar.13175>
- Government of Mexico, (16/10/2021). Covid-19 México. Available at <https://datos.covid19.conacyt.mx/#DOView>
- Guerrero, S., (2020). Coronavirus en Ecuador: una opinión desde la Academia. *LA GRANJA: Revista de Ciencias de la Vida*. Vol. 32, No. 2, pp.127-133. Universidad Politécnica Salesiana, Ecuador. pISSN:1390-3799; eISSN:1390-8596., <http://doi.org/10.17163/lgr.n32.2020.10>
- IMCO, (2020,18 de mayo). Todavía falta recuperar cerca de dos millones de empleos perdidos durante la pandemia. Available at: <https://imco.org.mx/todavia-falta-recuperar-cerca-de-2-millones-de-empleos-perdidos-durante-la-pandemia/>
- Inkster, B., and Digital Mental Health Data Insights Group (DMHDIG) (2021). Early Warning Signs of a Mental Health Tsunami: A Coordinated Response to Gather Initial Data Insights from Multiple Digital Services Providers. *Front. Digit. Health*. Vol. 2:578902 doi: 10.3389/fdgth.2020.578902
- Jansen, L., Furstenthal, L., Cohen, D., (2020). Industry innovation: How has COVID-19 changed global healthcare? *World Economic Forum*, pp. 1-12. Available at: [What the pandemic has meant for innovation in healthcare | World Economic Forum \(weforum.org\)](https://www.weforum.org/publications/industry-innovation-how-has-covid-19-changed-global-healthcare/)

- Kouroubali, A., Kondylakis, H., Katehakis, D. G., (2021). Integrated Care in the Era of COVID-19: Turning Vision into Reality with Digital Health. *Frontiers in Digital Health*. Vol. 3, Article 647938; doi: 10.3389/fdgth.2021.647938
- Lundvall, B., Johnson, B., (1994). The Learning Economy, *Journal of Industry Studies*, pp. 23-42. DOI: 10.1080/13662719400000002
- Mattietto, L. (2021). Disasters, pandemic and repetition: a dialogue with Maurice Blanchot's literature. *Academia Letters*, Article 1825. <https://doi.org/10.20935/AL1825>.
- Menéndez, E. L., (2005). Mexican Health Sector Policies (1980-2004): Structural Adjustment and Pragmatism in Neoliberal Proposals. *Salud Colectiva*, La Plata, 1(2), pp.195-223. Available at <https://www.scielosp.org/article/scol/2005.v1n2/195-223/es/>
- Mironko, A., (2021). Entrepreneurial imperative: How can businesses thrive in the Post Covid-19 world commentary. *American Journal of Management*. Vol. 21 Issue 2, pp. 103-106. <https://doi.org/10.33423/ajm.v21i2.4230>
- Mulgundmath, V. (2021). Reimagining the Academia-Industry Duology. *Academia Letters*, Article 2118. <https://doi.org/10.20935/AL2118>
- OPS, (2022, 17 de agosto). OPS busca fortalecer la preparación y respuesta a futuras pandemias por virus respiratorios en América Latina y el Caribe. Available at: <https://www.paho.org/es/noticias/17-8-2022-ops-busca-fortalecer-preparacion-respuesta-futuras-pandemias-por-virus>
- Palanica, A., Fossat, Y., (2020). COVID-19 has inspired global healthcare innovation. *Canadian Journal of Public Health*, Vol. 111 pp. 645–648. <https://doi.org/10.17269/s41997-020-00406-2>
- Pérez S. I., (2021). Coronavirus. Las inquietantes secuelas de la COVID-19. Proyecto PAPIME PE306815. Ciencia UNAM. Disponible en <http://ciencia.unam.mx/leer/1091/despues-del-coronavirus-las-inquietantes-secuelas-de-la-covid-19->
- Ranney M. L., Griffeth V., Jha A.K., (2020). Critical supply shortages—the need for ventilators and personal protective equipment during the Covid-19 pandemic. *N Engl J Med*, pp. 382:e41.
- Rubin, J., Wessely, S., (2020) The psychological effects of quarantining a city. *BMJ*. Vol. 368, N° 313. DOI: <http://dx.doi.org/10.1136/bmj.m313>
- Schuster, J., (2014). How to Write the Disaster, *Minnesota Review*., Issue 83, pp.163-171. Duke University Press. DOI:10.1215/00265667-2782363
- Statista Research Department, (2021, 7 October). Número de casos confirmados de coronavirus (COVID-19) en América Latina y el Caribe al 6 de octubre de 2021, por país. Available at <https://es.statista.com/estadisticas/1105121/numero-casos-covid-19-america-latina-caribe-pais/>
- Suárez, V., Suarez, Q. M., Oros, R. S., De Jesús, R. E., (2020). Epidemiología de COVID-19 en México: del 27 de febrero al 30 de abril de 2020. *Rev Clin Esp*. Vol. 220(8): pp.463–471. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7250750/>; doi: 10.1016/j.rce.2020.05.007
- Sungkawati, E., Suarniati, N. W., Hernanik, N. D., & Anugera, R. (2021). SMEs Creative Economy in The Covid-19. *Archives of Business Research*, Vol. 9(1), pp. 97-105.
- Taylor, S., (2019). *The psychology of pandemics: Preparing for the next global outbreak of infectious disease*. New Castle: Cambridge Scholars Publishing.
- The White House., (2020). Memorandum on Order Under the Defense Production Act Regarding 3M Company. Available at: <https://www.whitehouse.gov/presidential-actions/memorandum-order-defense-production-act-regarding-3m-company/>
- United Nations, (2021, 17 diciembre). La humanidad debe prepararse para la siguiente pandemia. Noticias ONU. Available at: <https://news.un.org/es/story/2021/12/1501942>

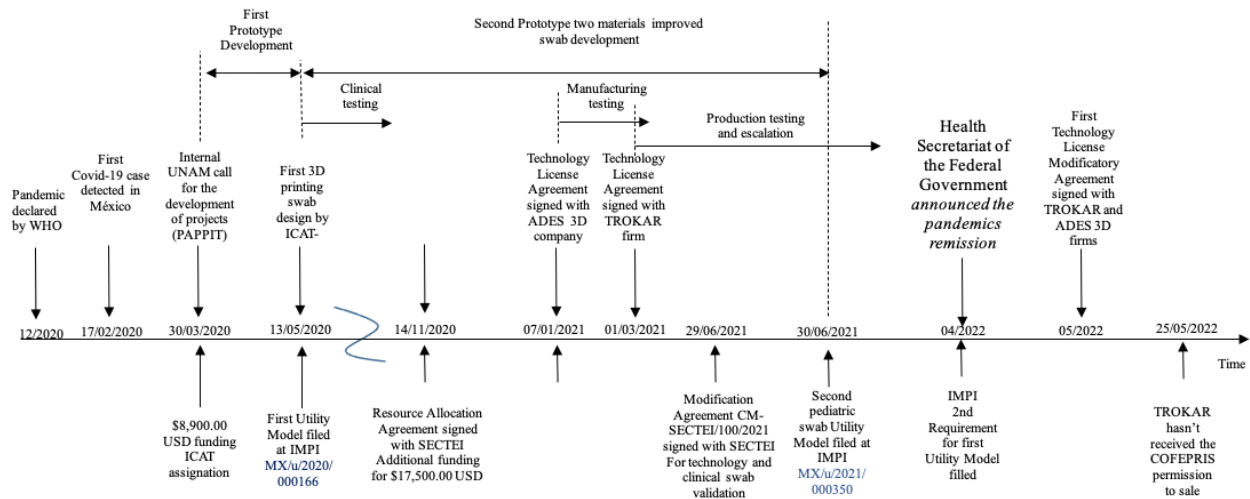


Figure 3 Events chronology for pandemic ICAT's biomedical devices projects

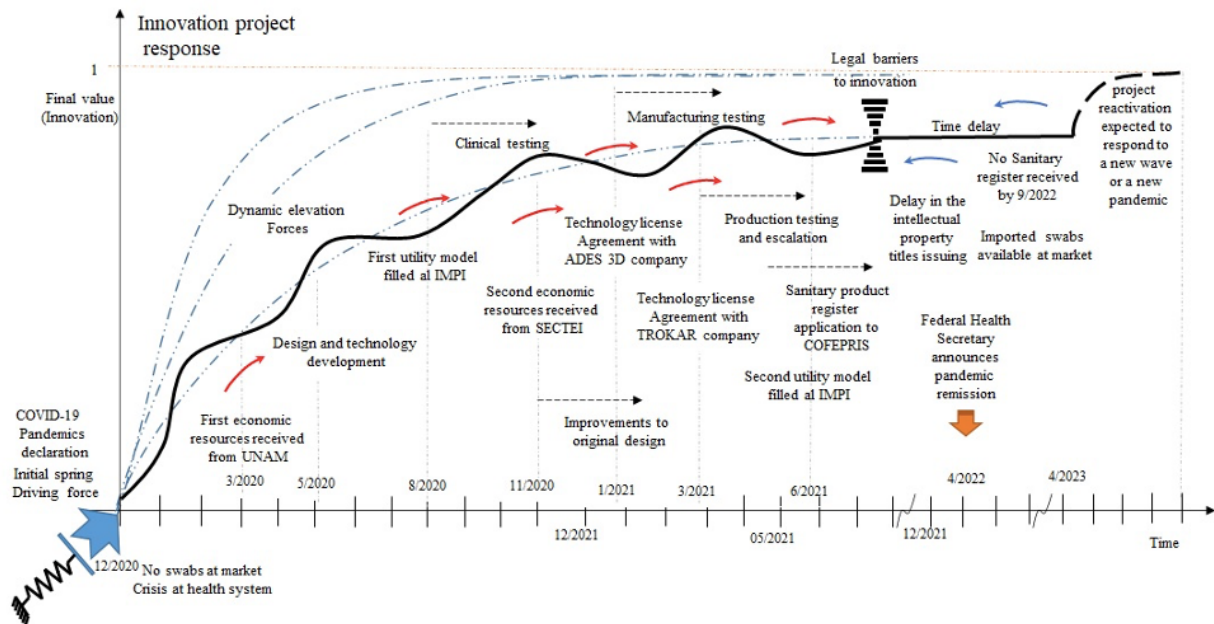


Figure 4. Innovation project response to Covid-19 impulse