

PUBLIC INVESTMENT IN R&D IN COVID-19

RECOMMENDATIONS TO ENSURE GLOBAL ACCESS TO VACCINES AND MEDICATIONS

CREDITS

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Salud por Derecho is a non-profit foundation that defends human rights so that all people, irrespective of where they live, can exercise their right to health. The organization works to promote a global system for the social protection of health that guarantees access to quality public services for everyone and puts the focus on ensuring universal access to treatment, prevention and care in HIV/Aids to protect the rights of the most vulnerable populations. Salud por Derecho also works on initiatives that review the current model of innovation in medicines and seeks alternatives that guarantee the development of and access to affordable, effective, and quality medications in Spain and abroad.



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PUBLIC INVESTMENT
SALUD POR DERECHO

PUBLIC INVESTMENT
IN R&D IN COVID-19



IN A STATE OF SHOCK

In December 2019, a pneumonia of unknown cause was detected in Wuhan city, Hubei province, China. Since then, the new coronavirus (SARS-CoV-2), which causes the disease COVID-19, started spreading and was declared a pandemic by the World Health Organization (WHO) on 11th March 2020 (1). From the first records in November 2019 (2) till the last update of this report¹, the number of global cases has increased to 1,807,308 cases and 113,513 deaths (3). In Spain, the number of recorded cases has climbed to 169,496 with 17,489 deaths documented, according to official statistics (4).

The pandemic has stalled economies and caused unemployment, and months will pass before the full social and economic impact is known. In addition, the pressure health systems have been subjected to is unprecedented. Hence, if this enormous public health crisis has taught us anything, it is how essential it is to have a strong, solvent, well-funded, universal health care system that has the capacity to attend to the needs of the population at all times.

However, discussing this novel coronavirus brings us to previous crises such as SARS (Severe Acute Respiratory Syndrome) in 2003 (5) that propagated through various countries in Asia, Europe, the United States, and South America and reached a total of 8,098 cases and 774 deaths. Similarly, other relevant cases were MERS (Middle-Eastern Respiratory Syndrome) in 2012 (6) and H1N1, an influenza A subtype virus that caused an outbreak in 2009 and resulted in the WHO declaring a pandemic, with the estimated global cases exceeding half a million (7). But, perhaps, the most recent crisis that comes to mind is the Ebola epidemic that occurred between 2014 and 2016 in West Africa and reached 11,300 deaths and 28,000 people infected (8,9).

Past and present experiences highlight that epidemics and pandemics are one of the principal threats to the world today. However, to spearhead research and development (R&D) in this area has required the commissioning of international initiatives with public funding, given the lack of interest by the private sector. One of the recently created mechanisms is the Coalition for Epidemic Preparedness Innovations (CEPI), which was founded in Davos in 2017, and, as we can see, is playing a significant role in recent months in the research for new vaccines for SARS-CoV-2.

The CEPI is only one example of many that are compiled in this report and that demonstrate the substantial public investment in R&D initiatives to fight against COVID-19. An investment that has always formed part of the chain of innovation, but has been little valued yet, nevertheless, will be crucial in confronting this crisis. However, this amount of public effort will be of limited benefit if we do not avoid patents and data exclusivity and do not guarantee open access to all the information and generated know-how to ensure accessible vaccines and treatments for everyone and all health systems worldwide.

—The public effort ends up invisible, and conditions are not included that ensure future accessibility of the products.

FACING A PANDEMIC WITH A BROKEN INNOVATION MODEL

The question regarding how and with which tools we address R&D to win the pandemic has proven to be fundamental to know in advance if the medications, diagnostics, and vaccines that stem from this research will soon be accessible to every person that needs it when they need it. This question inevitably arises due to recent experience that demonstrates a broken model of innovation and development of medicines, and whose dysfunction should not be a barrier in the context of the current pandemic, which needs urgent, coordinated, effective, efficient, and collaborative answers.

To begin with, we start from a development and innovation model based on patents and exclusivity as incentives for innovation and that permits the establishment of a system of monopolies that not only impose serious limits to the production and availability of new therapies and health technologies, but also allows the businesses that own such technologies or therapies to impose high and unjustifiable prices (10). These high prices make up one of the principal barriers to access for patients around the world, especially those in the most vulnerable populations and low-income countries. At the same time, these high prices significantly strain public healthcare system budgets, weakening them, and causing a significant negative impact on the provision of care.

This R&D model, also, as has been shown, responds to an agenda of investigation removed from the actual needs of the health of the population. Previous experiences with other coronaviruses and serious infectious diseases warned of the possibility of an inevitable tragedy (11,12). However, attention to these threats and, in general, viral and bacterial infectious diseases has continued to be scarce and dependent on the commitment of the public sector² (13,14) as these are considered unprofitable in the pharmaceutical industry.

The public sector has taken the reins in these areas of low interest for industry by directly funding projects that are undertaken in public institutions or launched via public-private partnerships that motivate the participation of the pharmaceutical industry. In both cases, the public effort ends up invisible, and conditions are

not included that ensure future accessibility of the products resulting from the research, even when the public contribution has been the majority (15). At the same time, the total absence of accountability of public institutions is frequently observed, making it impossible to discern or keep track of these contracts or collaboration agreements with private companies.

Added to this is the inefficiency of the system that is more focused on protecting knowledge and safeguarding intellectual property and company secrets than sharing any advances, development of know-how, or the results of studies to benefit scientific progress and the development of health technologies as global public assets. This situation blocks independent studies, generates duplication and biases, and, ultimately, prevents new ideas from being developed that meet scientific quality criteria with the speed that global health needs, and above all, in this type of health crisis (16). In addition, it reduces the capacity of professionals and administrators to make informed decisions. Recent experiences, as in the case of oseltamivir, keep reminding us for the need for transparency in clinical evidence and the impact it has on patients and healthcare systems (17,18).

This is also an innovation model in which it is impossible to know how much it costs to develop a drug, vaccine, or new technology or where to evaluate and analyze private and public resources invested in R&D. Hence, setting prices transparently or balancing the negotiation process of procurement (19) is an almost impossible task.

² Just before the start of this new pandemic, only six clinical trials on coronavirus were recorded as under way and all relied on public funding (14). A study by Salud por Derecho (pending publication) has already shown that clinical studies of viral and infectious diseases were also already very few in Spain, and warned of the risk of abandoning these areas of investigation.

THE PUBLIC SECTOR RESPONSE TO THE COVID-19 CRISIS



Preclinical and clinical research of vaccines and treatments has been accelerated in recent months, and there are reasons to believe that, in the near future, we will have vaccines and effective treatments. A study in Nature Review Drug Discovery had recorded by 8 April, a total of 115 vaccine candidates, of which 78 are under investigation, 73 in exploratory or preclinical stages, and 5 are in clinical phases (20).

One of the principal driving forces of this investigative activity is thanks to the public investment in R&D, not only in the United States, but also from other international spaces, such as the European Union, or through other initiatives whose main donors are countries who contribute voluntarily (21).

A demonstration of this rapid response is the number of clinical studies that have already been registered and are increasing daily worldwide, and those that are led by public centers are considerable. Since January 1st this year, there are 557 clinical trials related to COVID-19 registered in China³ (15), the current leading country in related clinical investigation. Next is the United States register with 424 trials, of which 360 are non-commercial⁴. In Europe, the register records 44 trials⁵, of which the majority (36 trials) are led by universities, public research centers, and other not for profit entities, while only seven are exclusively funded by the pharmaceutical industry. This same tendency is observed in Spain. The Spanish Clinical Studies Registry contains 31 trials and, of these, 23 are non-commercial.

Many of these clinical studies and other relevant R&D initiatives that are occurring at a global level stem from the contribution of countries that have committed to financing research on COVID-19 with public funds. This is the case of Canada that has invested more than 275 million Canadian dollars in national R&D projects on coronavirus, around 180 million Euros (22).

In the European region, the funding of R&D by Germany and the United Kingdom stand out. Germany has committed a total of 145 million Euros, which will principally be destined to fund the CEPI initiative (23), and the United Kingdom has supported various investigative initiatives totaling more than 200 million pounds (24,25). Nevertheless, the current map of public expenditure in R&D is expanding and increasingly complex, with new contributions and projects are being added daily throughout the world.

In this section we address, in general terms and non-exhaustively, some of the initiatives that, thanks to public investment, will be essential for the near future; both for their results as well as the knowledge generated that provides a basis for further research.

³ Search from 01/01/2020 to 13/04/2020; "covid-19". / "Search from 01/01/2020 to 13/04/20; "SARS-CoV-2", "2019 novel coronavirus", "2019-nCoV". The type of funding "non-commercial" includes that managed via the NIH, federal agencies, universities, investigation centers, and other non-profit institutions.

⁵ Search from 01/01/2020 to 13/04/2020; "covid-19". / ⁶ Search from 01/01/2020 to 13/04/2020; "covid".

---- CEPI estimates
that a budget of
2,000 million dollars
will be needed
between 2020 and
2021 to develop a
vaccine for the
coronavirus.



COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS (CEPI)

CEPI is a non-governmental initiative focused on the development of vaccines, funded by the Wellcome Trust, The Bill & Melinda Gates Foundation, the European Commission, and eight countries: Australia, Belgium, Canada, Ethiopia, Germany, Japan, Norway, and the United Kingdom. This program commenced in 2017 with project funding for the vaccines prioritized by the WHO. This prior work has helped CEPI widen several of its programs in vaccine R&D for COVID-19 in 2020 (26).

By 6 April 2020, CEPI was assured of a contribution of 690 million dollars from the governments of Denmark, Finland, Germany, Norway, the United Kingdom, Belgium, and Canada (27). CEPI estimates that a budget of 2,000 million dollars will be needed between 2020 and 2021 to develop a vaccine for the coronavirus (28).

One of the first projects approved by this coalition is now one of the most promising vaccines and currently, in a phase I clinical trial (29). The funding awarded by CEPI to Moderna (30), an American biotechnology company, is enabling a trial of the vaccine mRNA-1273 against the SARS-CoV-2 to be conducted, together with the National Institutes of Health (NIH).

Other projects have been awarded to the German biotech company CureVac. These are based on previous collaborations between CEPI and the biotech company to launch a platform for vaccines and include accelerated development of a vaccine against SARS-CoV-2 with additional funds of up to 8.3 million dollars for production and clinical tests (31,32).

The biotech company Inovio has also established another collaboration with CEPI to develop a vaccine. This collaboration began in 2018 with a contract of 56 million dollars (33) for preclinical and clinical development of a vaccine against MERS. The current collaboration, with a vaccine already in phase I for COVID-19 (34–36), is supported with nine million dollars in funding (37).

CEPI has also reached a four million dollar agreement with Novavax, an American biotech company with an R&D platform for vaccines based on nanoparticle technology (38). The start of the clinical trials is expected by the end of spring 2020.

The University of Oxford has also received a CEPI project (39) and has started a phase I clinical trial (40). The vaccine candidate is the result of a collaborative project with UK Research and Innovation (UKRI), the National Institute of Health Research (NIHR), the Chinese Academy of Medical Sciences Innovation Fund for Medical Sciences (CIFMS), among others. Currently, they have launched a call to gather 510 volunteers to start the clinical trial (41). Another university center of research with CEPI funding is the University of Queensland (42,43).

Finally, two other projects funded by CEPI stand out. The first at the University of Hong Kong, with initial funding for 620,000 dollars to conduct preclinical tests of their candidate vaccine, although continued funding depends on the results (44). The second is at the Pasteur Institute, Themis, and the University of Pittsburg. CEPI will provide an initial 4.9 million dollars so that the consortium can develop a candidate vaccine for COVID-19 (45).

— The COVID-19
Response Fund, an initiative to raise funds managed by the UN Foundation and the Swiss Philanthropy Foundation.



WORLD HEALTH ORGANIZATION (OMS)

The WHO, mindful of this critical time and the need for a massive global effort to control the pandemic, launched the COVID-19 Response Fund in March (46), an initiative to raise funds managed by the UN Foundation and the Swiss Philanthropy Foundation. Funds will be destined for the actions outlined in the COVID-19 Strategic Preparedness and Response Plan (47). With a general character, it will support all countries around the world—in particular those most vulnerable, that have a higher risk, or with the weakest health systems—in their response to the crisis, including actions for the rapid detection of cases, to halt transmission of the virus, and for the care of those infected. The Fund collects contributions from countries, foundations and philanthropies, private companies, and individuals.

Other United Nations programs, such as UNITAID and the Medicines Patent Pool (MPP), have also authorized the temporary expansion of their actual mandate to include COVID-19. This will allow the MPP to promote licenses and agreements that ensure affordable and accessible medications and diagnostic tests in middle and low-income countries so they can confront the pandemic (48).

Coordinated clinical studies

With the flood of new research projects and treatment promises, the WHO has also coordinated a global clinical trial initiative: the Solidarity Trial (49–51). This project consists of a macro clinical trial that unifies the criteria for studies investigating treatment with the remdesivir, chloroquine and hydroxychloroquine, ritonavir/lopinavir, and ritonavir/lopinavir with interferon. The results will be collected under the same umbrella to avoid the dispersion of the evidence and to make faster progress. In addition, these drugs have the advantage of a known safety profile and, therefore, the process and possible approval of the drugs is expected to be expedited. The inclusion procedure of a patient in the study is simple and designed to allow any medical team of any hospital to do so easily with the informed consent of the patient. This study will include at least ten countries—among which is Spain—although more countries are expected to join following its commencement. Norway included its first patient at the end of March (52,53).

In parallel, another clinical trial was started in France—the Discovery trial—coordinated by INSERM, the French National Institute of Health and Medical Research, as part of the French consortium REACTing (54). This trial is funded by the French Ministries of Education, Innovation and Development (MERSI) and Health (MSS), and the European projects COMBACTE, PREPARE, and RECOVER. The Discovery trial, led by the University Hospital of Lyon, will test the same drugs in seven European countries—France, United Kingdom, Germany, Spain, Belgium, The Netherlands, and Luxembourg— and will form part of the study network of the WHO Solidarity trial (55).

EUROPEAN UNION

In the case of Europe, the principal actions in R&D material is centered on three programs: Horizon 2020, IMI, and PREPARE, through which the main funding lines have been channeled. At the same time, networks and initiatives have been activated that are important in tackling the pandemic. These include the GLoPID-R (Global Research Collaboration for Infectious Disease Preparedness Network), VEO (Versatile Emerging infectious Disease Observatory), and MOOD (Monitoring Outbreak events for Disease surveillance in a data science context) (56).

The contribution provided from the Horizon 2020 program has to date translated to a provision of 48.5 million Euros divided⁷ among 18 projects (57). In total, 136 research groups have been funded under four lines of research: improving epidemiology and public health, diagnostic tests, treatment development, and vaccine development.

The first of these focuses on improving epidemiology and public health, including the preparation and response to outbreaks, and includes seven projects:

The second line of investigation is focused on the development of rapid diagnostic tests. Three projects have been funded along these lines:

CoNVat (Combating 2019 nCoV) "Point of care" type platform, based on optic biosensor nanotechnology for rapid diagnostics and surveillance of the coronavirus on a global level.

CoronaDX

Development of three "point of care" rapid diagnostic tests for the coronavirus-COVID-19; improve the epidemic preparedness; public health, and socio-economic benefits.

AHG nCoV19 Test

Development and validation of a molecular rapid diagnostic test for nCoV19.

Finally, the two lines funded for the development of treatments and vaccines include six and two projects, respectively:

I-MOVE-COVID19

Multidisciplinary European network for the investigation, prevention, and control of the pandemic.

RECOVER

Collaboration network to study the experience and impact of COVID-19 on public health, and the transmission of the virus. Development of recommendations for its control and prevention.

HERoS

Improve the efficiency of the response to outbreaks and improve governance of the crisis.

EpiPose

"Epidemic intelligence" to minimize the economic, social, and public health impact of the epidemic.

CORESMA

E-health, genomics, modeling, artificial intelligence, and investigation on the implementation of the best response to the pandemic.

RiPCoN

Mapping and network interaction for the identification and re-purposing of drugs for COVID-19.

EXSCALATE4CoV

Identification of new molecules through the EXaSCale Smart (super computation) platform.

TREATMENTS

Fight-nCoV

Animal models in the study of wide-spectrum antivirals against SARS-CoV-2.

SCORE

Rapid therapeutic response with new antivirals.

SOLNATIDE

Study of the safety, tolerance, and clinical efficacy of Solnatide IMP in patients with SARS-CoV-2 infection.

ATAC

Study of therapy with monoclonal antibodies obtained from the plasma of recovered patients.

MANCO

Development of monoclonal antibodies against SARS-CoV-2.

CoroNAb

Production, study, and identification of monoclonal antibodies.

VACCINES

OPENCORONA

Platform for the accelerated development of a candidate vaccine.

PreventnCoV

Development and clinical study of a vaccine for the prevention of infection by coronavirus SARS-CoV-2.

⁷ Data from March 2020.

The Innovative Medicines Initiative (IMI) has also launched a call for the funding of projects on COVID-19, in particular treatments and diagnostic tests. The European Commission is expected to contribute 45 million Euros and the pharmaceutical industry the same amount in kind; a combined total of 90 million Euros (58).

Finally, and within the European region, is the project PREPARE. This EU funded initiative started in 2014, launched a platform to prepare Europe for emerging epidemics and to guarantee clinical research. The platform response is a function of levels (from 0 to 4) that reaches the pandemic stage. At the time of writing this report, the response met level 3 with the design of clinical research for COVID-19, having passed through the previous levels of defining clinical protocols, pandemic data collection, and previous identification of 270 laboratories, distributed in 42 countries, to determine their capacity to respond to the detection of the virus (59).

The countries that participate in this platform are Belgium, that acts as the coordinator, Italy, The Netherlands, Germany, United Kingdom, Switzerland, Spain, France, Ireland, Croatia, and Australia. The EU contribution is 23 million Euros.

— The Innovative Medicines Initiative (IMI) has also launched a call for the funding of projects on COVID-19.

UNITED STATES

In the United States, the main lines of public funding are managed through the United States Department of Human and Health Services (HHS) and the Department of Defense (DoD). The HHS administers this via the National Institutes of Health (NIH) (60), among which are the National Institute of Allergies and Infectious Diseases (NIAID) (61), and BARDA, the Biomedical Advanced Research and Development Authority (62,63). The DoD administers the funding through the DARPA (Defense Advance Projects Research Agency) (64).

At the beginning of March, the United States government approved a new act for the funding of the pandemic that included 826 million dollars for the development of treatments, vaccines, and tests (65) and extended the possibility of the 11 federal agencies (including BARDA and DARPA) to sign research agreements not subject to the standard conditions. Some organizations have denounced that these agreements, called OTAs (Other Transaction Agreements), are not subject to the usual conditions and do not guarantee either the ownership of patents or an economic return for public centers in compliance with the Bay-Dohle Law (66) and the inclusion of conditions of accessibility or non-exclusivity in these contracts would not be expected either.

At the time of writing this report, there are 105 active projects administered through the NIH that total 138 million dollars⁸ and encompass the investigation of infections caused by the coronavirus. The majority of the 26 that were activated in 2020 are coordinated by the National Institute of Allergies and Infectious Diseases (NIAID).

The contribution of the NIH has led to the development of promising vaccines. An advanced project that stands out is for the mRNA-1273 vaccine, co-developed by Moderna, CEPI, and NIAID, already in the clinical phase (67), and referred to previously. The work of the Baylor College of Medicine in Houston (Texas) also stands out, which has continued from the research and development of vaccines for SARS and MERS starting in 2011 with funding from the NIH (14,68,69).

In terms of treatments in the clinical phase, the Phase II trial of remdesivir (Gilead) stands out. This trial focuses on the treatment of hospitalized adults, promoted and funded by the NIAID (NIH), and includes 440 participants in 75 hospitals in the United States (70).



There are numerous open projects in the preclinical phase for the development of treatment with monoclonal antibodies, in collaboration with other federal agencies and small biotech companies such as Vir Biotechnology and Abcellera Biologics.

The company Abcellera Biologics develops, in collaboration with the NIAID (NIH) and the DARPA (Department of Defense) (71), a monoclonal antibody as a continuation of an agreement signed with DARPA in 2018, to develop a rapid response platform against viral threats and pandemics, the Pandemic Prevention Platform (P3). The economic terms of the agreement are unknown. Lilly laboratories recently entered into the collaboration to produce the antibodies.

BARDA, the other principal funding source of the NIH, has numerous open public-private agreements for treatments and vaccines with major laboratories. Those that stand out are Regeneron, Janssen, Sanofi, Roche, and Grifols, to mention a few.

In the area of new treatments, first, we note the agreement of Regeneron with BARDA. This collaboration springs from an expansion of previous agreements with BARDA, in 2015 and 2017, for the testing of monoclonal antibodies against Ebola, the influenza virus, and other emerging pathogens, developed with a technology in common (72). The process is still in the preclinical phase, and in June this year, two monoclonal antibodies are expected to be selected to start phase I clinical trials (73,74). Another agreement can be added to their list of agreements with BARDA, one that was closed in 2016 for research on MERS. Regeneron also relied on NIAID (NIH) funding for the clinical development of treatments based on monoclonal antibodies in the recent outbreak in the Democratic Republic of Congo (75).

Clinical studies include the agreement with Roche, which has commenced an international phase III study (CONVACTA study) on

the potential therapeutic usefulness of tocilizumab, a treatment used in rheumatoid arthritis, in patients with severe pneumonia due to COVID-19 (76).

In a totally different therapeutic line, BARDA funds the development of immunoglobulins and hyperimmune plasma with Grifols Laboratories (77,78). They will launch several clinical trials in collaboration with the FDA and "other federal agencies", without specifying which ones, in the United States, where the production and necessary preclinical studies will also be carried out. Stemming from this agreement, Grifols has also launched a center of development specifically for a therapeutic line of study that will consist of a direct transfusion of the plasma of patients that have recovered from the infection.

BARDA is also making agreements for the development of vaccines with large companies such as Sanofi (79) and Janssen, both in preclinical phases, among others.

The BARDA-Janssen (Johnson&Johnson) agreement (80,81), that is also an extension of a pre-existing agreement, has pledged a total of 1000 million dollars and involves two lines of research: the development of a vaccine and a project for the screening of compounds to identify possible antiviral therapies against SARS-CoV-2 that is being conducted in Belgium at the Rega Institute of Medical Research (Catholic University of Leuven). In terms of the development of a vaccine, the Beth Israel Deaconess Medical Center, Harvard Medical School, is conducting preclinical tests of various candidates (82). The selected vaccine is based on the same technologies developed by Janssen for the Ebola, zika, HIV, and respiratory syncytial virus vaccines and, although it is still in the early stages, clinical trials are planned to start in autumn. They assure that they will be able to obtain authorization for its use by the beginning of 2021.

SPAIN

Like other countries, Spain has also provided economic support for innovation in COVID-19 (83). Previous experiences of research groups on other coronaviruses have provided a springboard in the fight against the new pandemic and, with this, the possibility to strengthen work in both candidate vaccines as well as treatments and devices. Spain has pledged 30 million Euros divided principally between two institutions: the Carlos III Health Institute (ISCIII) and the Spanish National Research Council (CSIC). Additionally, various Spanish research groups join this initiative in our country via European projects that accumulate 2.4 million Euros in funding.

The ISCIII is the institute with the largest allocation of funds and administers a call for 24 million Euros to fund research projects on SARS-CoV-2. The following four lines of research have been proposed: improve the public health response, and develop new preventative, diagnostic, and therapeutic tools (84).

At the time of closing this report, two projects have been approved through this call. They are two non-commercial clinical studies in differing therapeutic options (85). The first, led by the Research Institute of the Hospital de la Santa Creu i Sant Pau in Barcelona, the TOCOVID study, focuses on three drugs that are already commercialized for other medical indications: hydroxychloroquine, azithromycin, and tocilizumab. This study is being conducted in at least three autonomous communities, and its objective is the early treatment of patients to reduce ICU admissions and intrahospital mortality. The second clinical study is led by the Research Institute Sanitaria Puerta de Hierro, and seven hospitals will participate. Its objective is to evaluate the efficacy and safety of the use of hyperimmune plasma from patients who have recovered from COVID-19 to treat new cases of pneumonia that require hospitalization.

In terms of CSIC, the 4.5 million Euros in funding has been destined to the National Center of Biotechnology (CNB-CSIC). Its proposal is for the development of vaccine candidates, but also includes other lines, such as the development of specific monoclonal antibodies for protection against infection, among others (86).

The same team, in collaboration with the Spanish pharmaceutical company Pharmamar, has shown that the drug Aplidin (plitidepsin), used to treat multiple myeloma, can stop the multiplication in vitro of another coronavirus that belongs to the current coronavirus family.

Now, researchers will study if this drug is also effective against the SARS coronavirus, very similar to SARS-CoV-2 (87).

Additionally, the CSIC has recently launched a thematic interdisciplinary platform (PTI), known as Salud Global/Global Health, with funding from the MAPFRE Foundation. This multidisciplinary platform aims to

bring together 150 research groups across diverse projects and research areas to face current and future challenges of the pandemic.

In terms of the R&D funding that stems from European projects, Horizon 2020 has been the principal source. In Spain, six further projects are added to the total research projects on COVID-19 in centers such as the Catalan Institute of Nanoscience and Nanotechnology (ICN2), the University of Barcelona, the National Center of Supercomputation, the Institute of Public and Occupational Health of Navarra, the Biomedical Research Institute, and BCN Peptides (88).

The projects are divided in lines of investigation including epidemiological improvement, treatment, and technologies. In the line of epidemiological improvement, we find three programs. The first, I-MOVE-COVID-19, has launched a multidisciplinary European network for the investigation, prevention, and control of the COVID-19 pandemic, in which the Public and Occupational Health Institute of Navarra participates with 110,000 Euros in funding (89).

The second, the project RIPCOM, an initiative that studies the interactions between the coronavirus and human cells to identify drugs (either already on the market or being tested) that could combat the expansion of the virus. The Institute of Research in Biomedicine participates in this research, with 197,500 Euros in European funding (89).

The last of this set is EXSCALATE4CoV, a program in which the Barcelona Supercomputing Center (National Supercomputing Center) participates. The objective of this project is to launch a platform for the immediate identification of molecules effective against the coronavirus and new tools against future pandemics. Along with the objective of strengthening the intelligent design of drugs (90).

In terms of the European research lines for treatments, there are two projects: the MANCO initiative, that investigates monoclonal antibodies against COVID-19 and in which the National Center of Biotechnology of the CSIC participates; and the initiative SOLNATIDE, that includes the participation of the Catalan Biotechnology company BCN Peptides, whose objective is test the effectiveness of a treatment developed by an Austrian biotech company.

Last, in the line of research centered on devices, Spain leads the European consortium CoNVat from the Catalan Institute of Nanoscience and Nanotechnology (ICN2). The objective is to develop a device that will allow the detection of coronavirus, within 30 minutes, straight from a patient sample without the need for analysis in centralized clinical laboratories (91).



URGENT MEASURES TO ENSURE ACCESS AND SUPPLY AMID THE COVID-19 CRISIS

Governments worldwide are facing one of the greatest crises of recent times with this pandemic. A crisis that first affects healthcare systems and their capacity to respond in terms of infrastructure, personnel, treatments, diagnostics, and the medical supplies needed to cure thousands of patients and to protect all healthcare workers. Without a doubt, overcoming the current challenge in the best possible conditions depends on the best management of the system. However, there are other elements related to the R&D of new therapies, vaccines, and devices to combat COVID-19 that should urgently be considered. Now more than ever, the application of laws relating to intellectual property rights should be reconsidered.

Firstly, because experience has demonstrated that the current model of intellectual property rights generates monopolies and high prices that place pressure on health budgets, which are increasingly strangled and that increasingly absorb higher expenditure relating to the purchase and acquisition of innovative drugs. Intellectual property rights, justified as an incentive for innovation, has been converted into a shield for the interests of the private sector versus public interest and the right to health. All this has been facilitated by the lack of transparency in the costs of development, investments in innovation, and technology transfer agreements.

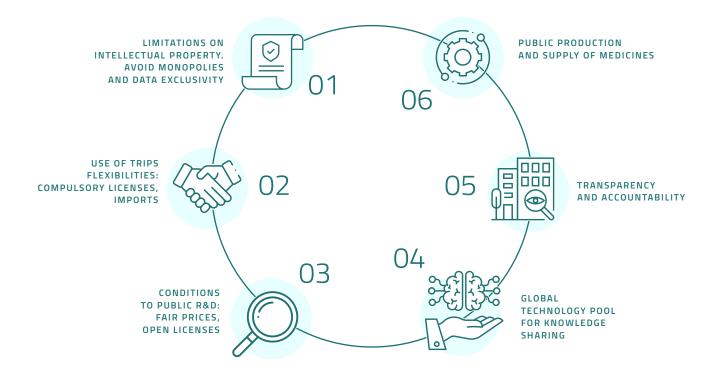
At this time, it is critical to limit the application of national and international intellectual property norms and make use of all the instruments granted by the State to take measures that safeguard the public interest, affordability, and fair price of products developed for COVID-19.

Ensure the transparency of the decision-making process, both in funding and price setting, as well as in everything related to the funding of R&D for COVID-19.

Secondly, as shown by the data, public funding is increasingly playing a crucial role. Along these lines, countries such as Australia and Canada contemplate clauses in R&D funding contracts that safeguard the public interest and the availability of the products developed for COVID-19 (92–94). Nevertheless, other initiatives, such as in the case of the European initiatives IMI and Horizon 2020, have ignored this question, despite the importance of the public contribution. That the health technologies that stem from these projects do not have the desired public return in terms of availability and access is worrying.

PUBLIC INVESTMENT

URGENT MEASURES TO ENSURE AFFORDABILITY AND AVAILABILITY IN THE COVID-19 CRISIS



Moreover, Costa Rica (95) has proposed in the WHO the creation of a "pool" of technology or a global mechanism that unites intellectual property rights and the data related to COVID-19 research. The holders of the rights would commit themselves to yield to this shared "pool" their intellectual property rights in these investigations. This would allow open licenses for the production and sales of those products, accelerating global access to new diagnostic tests, therapies, vaccines, and other medical devices.

There is an urgent need for the Government of Spain and funding agencies to introduce conditions and provisions in their funding contracts that ensure fair prices and complete access to the data stemming from research projects and that ensure that the health technologies are open and non-exclusive so that they can be manufactured and commercialized by diverse suppliers.

Spain should promote a technology "pool" on the international stage that allows the sharing of and access to all of the knowledge and data on COVID-19 that stem from public research in R&D, so that the treatments, vaccines, and health technologies are developed as global public goods.

Thirdly, it will be necessary to face the challenges of supply and delivery. Governments such as those of Israel (96,97), Germany (98), Brazil, and Canada (99,100) have already issued or considered the use of compulsory licenses for this pandemic. Other countries, including Chile and Ecuador (101), have also taken preliminary parliamentary measures to initiate compulsory licenses for therapies, vaccines, and products needed to face COVID-19.

However, some actions that have come from the private sector as a responsible response are also remarkable. Examples include the Medtronic company, which has published the specifications of a portable respirator so that others can also manufacture it (102); and the pharmaceutical company Abbvie, which has agreed to waive the intellectual property rights of its antiviral treatment Kaletra® (ritonavir/lopinavir) allowing the production of the generic worldwide (97). Additionally, some scientific journals have permitted free access to their contents, and the European Union has released the standards for the manufacture of products such as medical masks, gloves, and gowns (103).

It is crucial that the Government of Spain apply the flexibilities of the TRIPS agreements to tackle possible challenges in terms of abusive prices, supply and delivery of medicines, diagnostics, and other necessary products. Compulsory licenses can be found among these flexibilities. Additionally, it should be accompanied by an agreement on the import of medications, vaccines, and diagnostics that are manufactured under a compulsory license in another country, something that commercial rules contemplate, but which Spain, and also other countries, have currently renounced.

Spain has the Defense Military Pharmacy Center (CEMILFARDEF), the body responsible for the manufacture of drugs and other medical resources that can be key in supplying certain drugs during the crisis.

PUBLIC INVESTMENT

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