



# Backgrounder COVID-19

## **The biopharmaceutical industry is leading the way in developing vaccines and treatments for COVID-19**

The rapid spread of the novel coronavirus across the globe is a major public health threat for all, with profound health, social and economic impacts around the world.

As a science-driven industry that aims to address some of the world's biggest healthcare challenges, the research-based biopharmaceutical industry is uniquely positioned to respond rapidly to COVID-19. It has deep scientific knowledge gained from decades of experience working on developing solutions for combatting a range of infectious diseases such as MERS, SARS, Ebola and influenza, as well as experience working with health authorities and regulators to find a fast-tracked approach to bringing safe and effective medicines to market for patients.

Biopharmaceutical companies are committed to developing solutions to help diagnose, treat and prevent COVID-19.

### **Sharing the novel COVID-19 virus sequence helped to galvanise the research community**

The rapid virus sequencing by the scientific community enabled researchers to characterize and begin to understand the new threat posed by COVID-19. Biopharmaceutical companies with potentially relevant knowhow were thereby enabled to get their scientists to check their R&D libraries for potential assets that could fight coronaviruses.

“Open Access” data-sharing channels are the backbone to securing a response capacity and have proven their worth with influenza networks. This speedy sharing of the novel coronavirus pathogen sequence was instrumental in galvanising global collaboration with the private and public sector: a pre-requisite for timely development of vaccines and treatments.

The Global Initiative on Sharing All Influenza Data or [GISAID Initiative](#), an open access platform partly funded by the private sector, played a critical role in sharing the first genome sequences of the novel coronavirus and centralizing their collection. This has proven vital in speeding up the sharing of information among scientists as well as public health authorities.

### **Accelerating research and innovation for novel coronavirus (COVID-19)**

The rapid pace with which researchers have been able to understand this novel strain of virus and get medicines into human clinical trials is a testament to the lessons learned from past public health emergencies.

IFPMA members have been manufacturing thousands of doses of investigational and previously approved medicines that could treat coronavirus for emergency use and for use in clinical trials around the globe, including compounds formerly tested on other viral pathogens such as Ebola and HIV.

As of March 2020, there are a number of therapeutics currently in clinical trials and more than 20 vaccines in development for COVID-19.



**Scientists checking libraries of assets** – From the outset of the epidemic (and now pandemic), member companies reviewed their drug and vaccine portfolios to see if there is any research that could be of help. Analysis of drugs and vaccines portfolios involved scientists searching for potentially useful assets that could help with the development of new or repurposed treatments or vaccines to fight against the novel coronavirus.

Relevant assets include diagnostics and biomarkers, approved therapies or compounds in development which could be repurposed. In addition, member companies undertook to identify any ACE inhibitors, protease inhibitors or immunotherapies that could be relevant in the context of novel coronavirus.

**No time wasted in engaging in R&D collaboration** – R&D biopharmaceutical companies are part of a wider research community which is collaborating to fast-track the development of therapeutics, diagnostics and new vaccines. R&D biopharmaceutical companies are already engaging with existing networks such as CEPI (Coalition for Epidemic Preparedness Innovations) and Europe's IMI (Innovative Medicines Initiative).

Several biopharmaceutical companies are researching vaccine candidates for prevention and collaborating in the share of existing technologies that can be leveraged to allow a rapid upscale of production once a vaccine candidate is identified. IFPMA members are also sharing technologies that act as an adjuvant that can boost the effectiveness of a potential vaccine.

Collaborating in this way could hasten development of resources to tackle this outbreak. It creates networks of centres of excellence that can deliver a real impact and a preparedness infrastructure which can be mobilized for future outbreaks.

**Biopharmaceutical industry leads the way in making diagnostics kits, developing new vaccines and treatments to contain COVID-19**

There are companies working on phase I studies for both vaccines and treatments, and one potential treatment already being tested for another disease is now in Phase III clinical trials. Potential treatments include both antiviral medicines and immunotherapies.

It is estimated that there are as of now (March 2020) nearly 80 clinical trials for experimental new treatments and vaccines in development for coronaviruses including COVID-19, Novel Coronavirus Pneumonia, SARS and MERS.

## Treatment development

Currently a number of existing and new treatments are in various research phases and clinical trials to test their efficiency and safety for treating COVID-19. Listed below is a snapshot of the different areas of research focused on finding an effective treatment.

- [Abbott](#) launched an antibody test for coronavirus and plans to ramp up manufacturing to produce 20 million tests by June.
- [AbbVie](#) announced it is partnering with global authorities to determine the effectiveness of HIV drugs in treating COVID-19. AbbVie is supporting clinical studies and basic research with lopinavir/ritonavir, working closely with European health authorities and the U.S. Food and Drug Administration (FDA), Centers for Disease Control and Prevention,



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National Institutes of Health and the Biomedical Advanced Research and Development Authority to coordinate these efforts.

- [Amgen](#) and Adaptive Biotechnologies (Seattle, USA) are partnering to combine expertise to discover and develop fully human neutralizing antibodies targeting SARS-CoV-2 to potentially prevent or treat COVID-19.
- [AstraZeneca's](#) Research and Development (R&D) teams have also been working expeditiously to identify monoclonal antibodies to progress towards clinical trial evaluation as a treatment to prevent COVID-19. More than 50 virology, immunology, respiratory, and protein engineering experts across research, clinical, regulatory, and manufacturing are placing the highest priority on developing a treatment to minimise the global impact of the disease.
- [AstraZeneca](#) will initiate a randomised, global clinical trial to assess the potential of Calquence (acalabrutinib) in the treatment of the exaggerated immune response (cytokine storm) associated with COVID-19 infection in severely ill patients. Calquence is approved for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) in the US and a few other countries with an active global filing programme.
- [Boehringer Ingelheim](#) is searching for novel virus-neutralizing antibodies. It is also screening its entire molecule library for compounds that could target the virus. [Boehringer Ingelheim](#) actively participates with its COVID-19 projects in the Innovative Medicines Initiative (IMI) of the European Union and the COVID-19 Therapeutics Accelerator, coordinated by the Bill & Melinda Gates Foundation.
- [Bristol Myers Squibb](#) (BMS) identified 1,000 compounds in its discovery library that they are making available to [collaborators](#) for screening for potential treatments for COVID-19. BMS is actively evaluating certain medicines in its portfolio that could be included in near-term clinical trials with a focus on agents impacting the inflammatory immune response associated with COVID-19.
- [Chugai](#) (daughter of Roche) is working to start a Phase III clinical trial in Japan with Actemra® Chugai filed a clinical trial notification with the Pharmaceuticals and Medical Devices Agency on April 8<sup>th</sup>, 2020. It hopes to enroll patients hospitalized with severe COVID-19 soon.
- [CSL Behring](#) (CSL Limited is the parent company) together with Takeda set up a partnership bringing together world-leading plasma companies to focus on developing and delivering a hyperimmune immunoglobulin in the global fight against COVID-19.
- [CSL Group](#) is evaluating potential treatment candidates with SAB Therapeutics as part of its previously announced collaboration to investigate new therapies to treat infectious diseases as well as immunological and neurological conditions. CSL Group is also engaging with investigators regarding its monoclonal antibodies to identify treatment candidates from the portfolio that have the potential to treat Diffuse Alveolar Damage caused during COVID-19.



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- [Eli Lilly](#) and AbCellera (Canadian biotech firm) have entered into an agreement to co-develop antibody products for the treatment and prevention of COVID-19. The collaboration will leverage AbCellera's rapid pandemic response platform, developed under the DARPA Pandemic Prevention Platform (P3) Program, and Lilly's global capabilities for rapid development, manufacturing and distribution of therapeutic antibodies.
- [Eli Lilly](#) has entered into an agreement with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), to study baricitinib as a potential treatment for hospitalized patients diagnosed with COVID-19. Baricitinib is approved in more than 65 countries as a treatment for adults with moderately to severely active rheumatoid arthritis.
- [EFPIA is working with the Innovative Medicines Initiative \(IMI\)](#) on potential actions to support collaborative research programs in order to fast-track the development of therapeutics.
- [Gilead](#) has initiated two Phase 3 clinical trials of remdesivir in countries with high prevalence of COVID-19. The company is also supporting two Phase 3 trials in China and a global Phase 2 trial led by the U.S. National Institute of Allergy and Infectious Diseases. Gilead donated drug and provided scientific input for these studies. Gilead has provided remdesivir to physicians for compassionate use to treat several hundred severely ill patients with confirmed COVID-19, and has accelerated manufacturing of remdesivir at risk, in anticipation of potential future supply needs.
- [GSK](#) is entering into the new collaborative research effort, the COVID-19 Therapeutics Accelerator. The aim of the Accelerator is to bring pharmaceutical companies and expert academic institutions into coordinated research programs, with the aim of bringing the most promising molecules forward that could be used to treat cases of COVID-19. GSK will contribute by making available compounds from its libraries for screening for activity against COVID-19. In addition, GSK is evaluating its marketed pharmaceutical products and medicines in development to determine if any could be used beyond their current indications in response to the pandemic. Further, GSK is evaluating options to make available specialised laboratory space to help in research and testing of COVID-19.
- [GSK](#) and Vir Biotechnology, Inc. signed a binding agreement to enter into a collaboration to research and develop solutions for coronaviruses, including SARS-CoV-2, the virus that causes COVID-19. The collaboration will use Vir's proprietary monoclonal antibody platform technology to accelerate existing and identify new anti-viral antibodies that could be used as therapeutic or preventative options to help address the current COVID-19 pandemic and future outbreaks.
- [GSK](#) announced plans to collaborate with China's Xiamen Innovex on a potential vaccine to treat the COVID-19 coronavirus. The companies are testing a recombinant protein-based coronavirus vaccine candidate, which is being developed by Innovax with Xiamen University.
- [Ipsen](#) donated financial resources to the Institut Pasteur to support research on COVID-19. Since January, the Institut Pasteur has devoted a portion of its research to



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understanding the emerging COVID-19 virus, in terms of epidemiology, biological characteristics, pathogenicity.

- [Johnson & Johnson](#), in partnership with the Rega Institute for Medical Research, University of Leuven (Belgium), are working to identify existing or new compounds with antiviral activity against COVID-19 that could contribute to providing immediate relief to the current outbreak.
- [Merck](#), as part of the global effort to investigate potential therapeutics for COVID-19 and their support of independent research, recently donated a supply of interferon beta-1a (Rebif®) to the French Institut National de la Santé et de la Recherche Médicale (INSERM) following a request for use in a clinical trial. To date, Merck's interferon beta-1a is not approved by any regulatory authority for the treatment of COVID-19 or for use as an antiviral agent.
- [Novartis](#) announced that it has entered new collaborative research efforts such as the COVID-19 Therapeutics Accelerator, coordinated by the Bill & Melinda Gates Foundation, Wellcome, and Mastercard, as well as a COVID-19 directed partnership organized by the Innovative Medicines Initiative. Novartis is contributing by making available several compounds from its libraries that are considered suitable for in vitro antiviral testing. In addition, the company is rapidly evaluating other existing products to see if any could be utilized beyond their approved indications in response to the pandemic.
- [Novartis](#) plans to initiate a Phase III clinical trial in collaboration with Incyte to evaluate the use of Jakavi® (ruxolitinib) for treatment of a type of severe immune overreaction called cytokine storm that can lead to life-threatening respiratory complications in patients with COVID-19.
- [Pfizer](#) announced that it completed a preliminary assessment of certain antiviral compounds that were previously in development and that inhibited the replication of coronaviruses similar to the one causing COVID-19 in cultured cells. Pfizer is engaging with a third party to screen these compounds under an accelerated timeline and expects to have the results back by the end of March.
- [Pfizer](#) also outlined a detailed 5-point action plan to battle COVID-19. The plan includes a commitment to sharing its clinical development and regulatory expertise to support other smaller biotech companies that are screening compounds or existing therapies for activity against the virus causing COVID-19.
- [Regeneron Pharmaceuticals](#) announced an expanded agreement with the U.S. Department of Health and Human Services (HHS) to develop new treatments combating the novel coronavirus.
- [Regeneron Pharmaceuticals and Sanofi SA](#) started a clinical program evaluating Kevzara, originally a drug to treat arthritis, in patients hospitalized with severe COVID-19. Kevzara is a fully-human monoclonal antibody that inhibits the interleukin-6 (IL-6) pathway by binding and blocking the IL-6 receptor. IL-6 may play a role in driving the



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overactive inflammatory response in the lungs of patients who are severely or critically ill with COVID-19 infection.

- [Roche's](#) Actemra was approved by China on March 5 to treat Covid-19 patients with lung complications. Roche has donated nearly \$2m-worth of Actemra to China to help the country manage the COVID-19 outbreak". Actemra has been on the European market since 2010 for treatment of several kinds of arthritis.
- [Roche](#) announced that they are working with the Food & Drug Administration (FDA) to initiate a Phase III clinical trial to evaluate the safety and efficacy of Actemra in hospitalised adult patients with severe COVID-19 pneumonia. This is the first global study of Actemra in this setting and is expected to begin enrolling as soon as possible in early April with a target of approximately 330 patients globally, including the US.
- [Shionogi](#) and the Hokkaido University Research Center for Zoonosis Control are in early stages of identifying drugs active against COVID-19. Shionogi has also just entered into an agreement with Micro Blood Science to test an antibody test kit.
- [Takeda](#) announced that it is initiating the development of a drug to treat people infected with the novel coronavirus. The experimental drug would be derived from the blood of coronavirus patients who have recovered from the respiratory disease. In parallel, Takeda is also exploring whether currently marketed and pipeline products may be an effective treatment option for infected patients.
- [Takeda](#) together with CSL Behring set up a partnership bringing together world-leading plasma companies to focus on developing and delivering a hyperimmune immunoglobulin in the global fight against COVID-19.

## Vaccine development

While vaccines and small molecule treatments are approved through different regulatory pathways and their development programs vary, they generally both must complete three phases of clinical trials. However, there are differences in the data required to show the safety of vaccines and the size of clinical trials for vaccines relative to small molecules.

Experts are hoping it will take as little as 12 to 18 months before there is a vaccine available. This is a best-case estimate that assumes one or two of the first few vaccines that enter development will be successful. Typically, only approximately one in ten experimental vaccines make it all the way through to regulatory approval. Therefore, the more companies taking different approaches to find a vaccine, the more "shots on goal" and significantly greater chances of success.

- [CEPI and GSK](#) will collaborate to help the global effort to develop a vaccine for the novel coronavirus. GSK is making its adjuvant technology available to support rapid development of candidate vaccines and is working with The University of Queensland, Australia.
- [CSL Limited/ Seqirus](#) is providing scientific and technical expertise and its established MF59® adjuvant technology to the University of Queensland in Australia to help fast-



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track the development of their CEPI-funded COVID-19 vaccine candidate, which uses novel molecular-clamp technology.

- [GSK](#) announced it would partner with the Chinese biotech company Clover Biopharmaceuticals. Under the partnership, GSK will provide Clover with its proprietary adjuvants – compounds that enhance the effectiveness of vaccines. By mid-March, GSK expanded their collaborations and is now working with five partner companies and research groups across the world, including in the USA and China.
- [GSK and Sanofi](#) entered into a collaboration to develop an adjuvanted vaccine for COVID-19, using innovative technology from both companies, to help address the ongoing pandemic. The vaccine would be ready to begin testing in humans in the second half of 2020.
- [Johnson & Johnson](#) expanded its collaboration with the Biomedical Advanced Research and Development Authority (BARDA), part of U.S. Department of Health & Human Services (HHS), and established a [new collaboration](#) with Beth Israel Deaconess Medical Center (BIDMC), to accelerate development of a potential novel coronavirus vaccine.
- [Johnson & Johnson](#) announced the selection of a lead COVID-19 vaccine candidate from constructs it has been working on since January 2020; the significant expansion of the existing partnership between the Janssen Pharmaceutical Companies of Johnson & Johnson and the Biomedical Advanced Research and Development Authority (BARDA); and the rapid scaling of the Company's manufacturing capacity with the goal of providing global supply of more than one billion doses of a vaccine.
- [Pfizer](#) and BioNTech have entered into a partnership to jointly develop BioNTech's mRNA-based vaccine candidate BNT162 to prevent COVID-19 infection. The collaboration aims to accelerate global development of BNT162, which is expected to enter clinical testing by the end of April 2020. BioNTech and [Pfizer](#) will also work jointly to commercialize the vaccine worldwide (excluding China which is already covered by BioNTech's collaboration with Fosun Pharma) upon regulatory approval.
- [Sanofi](#) announced a collaboration with the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services (HHS), to advance a novel COVID-19 vaccine candidate. Work is underway to leverage previous development of a SARS vaccine candidate using Sanofi's recombinant DNA technology. Sanofi is also coordinating with the Coalition for Epidemic Preparedness Innovations (CEPI) and sharing its vaccine R&D experience and expertise to advance vaccine solutions.
- [Sanofi](#) and U.S. company Translate Bio announced plans to collaborate on developing a vaccine to treat the coronavirus. The companies said Translate Bio would work on discovering, designing, and manufacturing a number of SARS-CoV-2 vaccine candidates, while Sanofi would provide its expertise in the field of vaccines and support from its research networks.



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- [Shionogi](#)'s subsidiary UMN Pharma Inc. is pursuing the discovery and development of a recombinant protein vaccine in a project supported by the Japan Agency for Medical Research and Development (AMED).
- [UCB](#) is collaborating with The University of Oxford on a vaccine development.

## Diagnostics

Rolling out diagnostics to detect whether patients are genuinely infected with the new coronavirus is a key step in preventing or slowing its spread. However, the rapid spread of COVID-19 has drastically increased the demand for testing kits around the world, especially in the United States and Europe, and governments are trying to ramp up their testing capacities.

- [AstraZeneca](#) is accelerating the development of its diagnostic testing capabilities to scale-up screening and is also working in partnership with governments on existing screening programmes to supplement testing.
- [Bayer](#) is making more than 40 virus diagnostics devices available from its research operations to scale up Germany's COVID-19 analysis by several thousand tests daily.
- [Roche](#) announced that the FDA issued an Emergency Use Authorization for its diagnostic kit cobas® SARS-CoV-2 Test, advancing coronavirus testing to meet urgent medical needs. Roche is committed to delivering as many tests as possible and is going to the limits of production capacity.
- [Takeda](#) is partnering with public entities and other pharmaceutical companies through the Innovative Medicines Initiative (IMI) in Europe to leverage collective expertise in the hope of developing diagnostics for COVID-19 as well as inhibitors to help prevent future outbreaks.
- [UCB](#) is working closely with the Belgian government to scale up COVID-19 testing capabilities. It is looking at similar possibilities in the UK.

In addition to the individual contributions companies are already making, a consortium of life sciences companies announced an important [collaboration](#) on March 25 to accelerate the development, manufacture, and delivery of vaccines, diagnostics, and treatments for COVID-19, alongside the Gates Foundation. Co-chaired by Vas Narasimhan, chief executive officer of Novartis, the consortium seeks out to accelerate solutions to this pandemic.

Companies participating in the collaboration include BD, bioMérieux, Boehringer Ingelheim, Bristol-Myers Squibb, Eisai, Eli Lilly, Gilead, GSK, Johnson & Johnson, Merck (known as MSD outside the U.S. and Canada), Merck KGaA, Novartis, Pfizer, and Sanofi.

## Pharmaceutical manufacturing supply chain

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IFPMA and its member companies are monitoring the coronavirus situation closely. Currently, IFPMA member companies are not aware of any near-term impacts on the availability of medicines and vaccines. They are continuously monitoring and proactively handling the situation as it develops and do not expect, furthermore, any long-term impact on the availability of medicines and vaccines, unless any disruption caused by the pandemic is sustained over the next several months.

R&D biopharmaceutical companies are working to prevent and mitigate any shortages through close coordination with national regulatory authorities and other global stakeholders, including the World Health Organization.

**IFPMA will continue to monitor the situation as it develops and will update this information accordingly. Last updated: 16 April 2020.**

### **About IFPMA**

IFPMA represents the research-based pharmaceutical companies and associations across the globe. The research-based pharmaceutical industry's 2 million employees discover, develop, and deliver medicines and vaccines that improve the life of patients worldwide. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community find solutions that improve global health.

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