



Note on Novel Coronavirus (2019-nCoV) outbreak

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“We need our collective knowledge, insight and experience to answer the questions we don’t have answers to, and to identify the questions we may not even realize we need to ask.”

- Dr Tedros, Director General, World Health Organisation

The research-based pharmaceutical industry is fully supportive of efforts that will ensure the scientific community can respond quickly to the challenges the novel coronavirus (nCov-2019) presents. As a science-driven industry that aims to address some of the world’s biggest health care challenges, the research-based pharmaceutical industry clearly has a role to play in developing new and improved medicines and vaccines to help respond to this epidemic. R&D biopharmaceutical companies with potentially relevant knowhow have teams of scientists checking their libraries of potential assets that could fight coronaviruses.

COVID-19

The COVID-19 virus is a new pathogen that is highly contagious, can spread quickly, and must be considered capable of causing enormous health, economic and societal impacts in any setting. It is not SARS and it is not influenza. Building scenarios and strategies only on the basis of well-known pathogens risks failing to exploit all possible measures to slow transmission of the COVID-19 virus, reduce disease and save lives.

For example, COVID-19 transmission in children appears to be limited compared with influenza, while the clinical picture differs from SARS. Such differences, while based on limited data, may be playing a role in the apparent efficacy of rigorously applied non-pharmaceutical, public health measures to interrupt chains of human-to-human transmission in a range of settings.

The COVID-19 virus is unique among human coronaviruses in its combination of high transmissibility, substantial fatal outcomes in some high-risk groups, and ability to cause huge societal and economic disruption. For planning purposes, it must be assumed that the global population is susceptible to this virus. As the animal origin of the COVID-19 virus is unknown at present, the risk of reintroduction into previously infected areas must be constantly considered.

China’s experience strongly supports the efficacy and effectiveness of anchoring COVID19 readiness and rapid response plans in a thorough assessment of local risks and of utilizing a differentiated risk-based containment strategy to manage the outbreak in areas with no cases vs. sporadic cases vs. clusters of cases vs. community-level transmission. Such a strategy is essential for ensuring a sustainable approach while minimizing the socio-economic impact.

COVID-19 is spreading with astonishing speed; COVID-19 outbreaks in any setting have very serious consequences; and there is now strong evidence that non-pharmaceutical interventions can reduce and even interrupt transmission.

However, to reduce COVID-19 illness and death, near-term readiness planning must embrace the large-scale implementation of high-quality, non-pharmaceutical public health measures. These measures must fully incorporate immediate case detection and isolation, rigorous close contact tracing and monitoring/quarantine, and direct population/community engagement.



Studies can be prioritized in terms of the largest knowledge gaps that can be most rapidly addressed to have greatest immediate impact on response operations and patient management. This suggests prioritizing studies to identify risk factors for transmission in households, institutions and the community; convenience sampling for this virus in the population using existing surveillance systems; age-stratified sero-epidemiologic surveys; the analysis of clinical case series; and cluster investigations.

Industry perspective

From our industry's perspective, there are three reasons to feel cautiously optimistic that the scientific community can respond quickly to the challenges this epidemic faces. Firstly, rapid access to the virus can speed up the process of kick starting the search for solutions, secondly, there is global recognition, funding and structures in place to share the burden of R&D. Last but not least, there are tried and tested sharing platforms in place for influenza that can be leveraged.

For example, the [GISAID Initiative](#), set up twelve years ago has played an essential role in the sharing influenza virus sequences to help researchers understand how the viruses evolve, spread and potentially become pandemics among the WHO Collaborating Centers and National Influenza Centers. This open access platform, partly funded by the private sector, is going to play an important role in centralizing the collection of the novel coronavirus sequences and will be critical in speeding up the sharing of information among scientists as well as public health authorities. This includes streamlining the use of existing networks to improve response, such as Global Initiative on Sharing All Influenza Data / sharing data & clinical trials outcomes.

The speedy sharing of the 2019_nCoV pathogen sequence, followed by the declaration of the novel coronavirus as an international emergency and the convening of an R&D Forum, should further galvanise global collaboration with the private and public sectors as required for timely development of vaccines and treatments. 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). In addition to R&D efforts, many research-based biopharmaceutical companies with a presence in China are donating funds, medicines, diagnostics and medical protective products.

Accelerating research and innovation for COVID-19

Going forwards, it will be crucial that the WHO continue to involve researchers, government, industry and coordinate efforts to help make informed decisions on how best to prioritize and collaborate on a shared research agenda for this virus. Speed and coordination, evidence-based response, involvement of those who already have the knowledge and expertise (in particular scientists on the front line in China), avoiding duplication, are all going to be paramount to ensure that lives will be saved and the spread of virus would stemmed and if possible be stopped.

The longer term research agenda should not detract taking the necessary immediate steps to contain the COVID-19 outbreak and support first-line responders while vaccines are being developed & therapeutics are researched. The declaration of the novel coronavirus as an international emergency signals the fundamental need for epidemic preparedness. This should further galvanise global collaboration with the private and public sector required for timely development of vaccines and treatments.



As a science-driven industry that aims to address some of the world's biggest health care challenges, the research-based pharmaceutical industry clearly has a role to play in developing new and improved medicines and vaccines to help respond to this epidemic. All information on the member companies involvement in countering the COVID-19 can be accessed on this link: <https://www.ifpma.org/wp-content/uploads/2020/02/IFPMA-Members-involvement-in-countering-the-novel-coronavirus-2019-nCoV.pdf>

Scientists checking libraries of assets - From the outset of the epidemic, member companies have reviewed their drug and vaccine portfolios to see if there is any research that could be of help. This analysis involved scientists assessing the companies' libraries 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 for use in treating patients with the coronavirus. In addition, member companies are undertaking to identify any ACE inhibitors, protease inhibitors or immunotherapies that could be relevant in the context of novel coronavirus.

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.

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



- [Eli Lilly](#) and AbCellera (Canadian biotech firm) have entered into an agreement to codevelop 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.
- [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.
- [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.
- [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 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.
- [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.

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-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.



- [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 vaccines.
- [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.
- [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.

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.
- [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.

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.

Source: <https://www.ifpma.org/subtopics/novel-coronavirus-covid-19-industrys-rd-efforts/>

Pharmaceutical manufacturing supply chain

OPPI and its member companies are monitoring the coronavirus situation, globally. Member companies are consistently and diligently monitoring the supply chain for medicines both at their own sites and for their suppliers globally. Currently, member companies have inventory in India which will cover around two months.

Recent News from India

Helpline Number for corona-virus : +91-11-23978046

Helpline Email ID for corona-virus : ncov2019[at]gmail[dot]com

Latest updates are available on the link provided by Ministry of Health:
<https://www.mohfw.gov.in/>

OPPI will continue to monitor the situation as it develops and will update this information accordingly. Last updated: April 01, 2020

Some useful links

- WHO:
<https://www.who.int/>
- John Hopkins University:
<https://qz.com/1814380/interactive-map-from-johns-hopkins-shows-coronavirus-in-real-time/>
- OPPI:
https://www.indiaoppi.com/wp-content/uploads/2020/03/Revised_Corona_ad_Eng.pdf
- IFPMA
<https://www.ifpma.org/subtopics/novel-coronavirus-covid-19/?parentid=268>
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