

R&D- based pharma industry's innovative partnership to meet urgent global supply needs

Vaccines

IFPMA member companies are at the forefront of the global effort to develop a safe and effective COVID-19 vaccine and scale up manufacturing to ensure equitable access to people around the world. In less than a year, several vaccines candidates have been approved or are in advanced [Phase III](#) clinical trials with encouraging results. An impressive and unprecedented manufacturing scale-up is also taking place. **Most collaborations - if not all - involved some sort of licensing and transfer of technology, which would not be possible in the absence of a robust global IP system.**

The examples below highlight a few selected collaborations with IFPMA companies. According to Airfinity data, as of May 2022 at least 379 manufacturing and production agreements for COVID-19 vaccines - of which 334 agreements involving some sort technology transfer- around the globe were made public:

Pfizer and BioNTech have successfully developed a promising mRNA vaccine, the first to be authorized by a stringent regulatory agency. The collaboration between the companies was agreed in March 2020 and in less than a year, the two companies have developed the vaccine, undertaken vast clinical trials, filed for regulatory approval in multiple geographies, and scaled up manufacturing from zero to supply globally up to 2 billion doses by the end of 2021. Throughout the collaboration, BioNTech and Pfizer have partnered on all stages of vaccine R&D and manufacturing—with BioNTech bringing the novel innovating technology and Pfizer bringing years of expertise in researching, developing, making and distributing vaccines at very large scale.

On 31 December 2020, WHO granted COVAX emergency use authorization, paving the way for its use through COVAX, and in less than a month the companies announced they would [supply COVAX](#). As of November 2021, [COVAX has secured](#) over 1 billion doses of the Pfizer/BioNTech. [Sanofi](#) partnered with Pfizer/BioNTech to support manufacturing and supply of 125 million vaccine doses. In July 2021, [Pfizer](#) announced a landmark agreement with The Biovac Institute in South Africa to manufacture the Pfizer-BioNTech COVID-19 vaccine exclusively for the 55 member states that make up the African Union. Biovac is expected to produce more than 100 million finished doses that will be supplied exclusively to African Union countries annually once at full operational capacity. To facilitate Biovac's involvement in the supply chain, technical transfer, on-site development and equipment installation activities began following the announcement of the agreement and the site was incorporated into the supply chain at the end of 2021. Pfizer and BioNTech expect that Biovac's Cape Town facility will begin the manufacture of finished doses in the second half of 2022. In addition, Pfizer and BioNTech collaborate for manufacturing scale up with various organizations, including [Delpharm](#), [ThermoFisher](#), [Novartis](#), [Baxter](#), [Siegfried](#), [Dermapharm](#), [Fosun](#), [Polymun](#), [Allergopharma](#), [Eurofarma Laboratorios SA](#).

AstraZeneca and the University of Oxford joined forces for the development, worldwide manufacturing and distribution of a vaccine, developed by the Jenner

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Institute and Oxford Vaccine Group. The company has committed to [sell on a not-for-profit](#) basis during the pandemic. In order to improve access to low- and middle-income countries. AstraZeneca reached a [licensing](#) and technology transfer agreement with the Serum Institute of India to supply one billion doses to low- and middle-income countries, and with [Daiichi Sankyo](#) to supply Japan. AstraZeneca also reached a [\\$750m agreement with CEPI and Gavi](#) to support the manufacturing, procurement and distribution of 300 million doses of the vaccine. As of November 2021, COVAX [has secured](#) up to 720 million doses of the AstraZeneca COVID-19 vaccine.

Johnson & Johnson's vaccine brings the promise of single-dose efficacy that is compatible with standard vaccine distribution channels, and received its first [authorization](#) by a stringent regulatory agency in February 2021. Johnson & Johnson has publicly committed to bringing an affordable vaccine to the public on a [not-for-profit basis](#) for emergency pandemic use, and has entered into manufacturing agreements with multiple companies, including [Aspen](#) in South Africa, [Sanofi](#) in France, [MSD](#) (known as Merck in the US and Canada), and [Biological E.](#) in India. J&J is making available up to 900 million doses of its vaccine to the [COVAX Facility](#) and the [African Union](#). Additionally, J&J is facilitating the donation of 150 million vaccine doses by the US Government and EU Member States to COVAX for lower income countries. In 2021, approximately 70% of J&J's global vaccine supply was made available to low and middle-income countries (through supply agreements and country donations), with approximately 40% going to COVAX. On 8 March 2022, [Johnson & Johnson](#) announced an agreement with Aspen, based in South Africa, enabling the first COVID-19 vaccine to be manufactured and distributed by an African company.

GSK and Sanofi committed to join forces to develop a vaccine using innovative adjuvanted recombinant protein-based technology. Though the development has faced delays, the companies are working to improve the antigen formulation and conduct additional trials in 2021. These two leading vaccine manufacturers bring significant manufacturing capacity, and, if successful, will be able to make hundreds of millions of doses annually. They have [publicly committed](#) to making any vaccine that is developed through the collaboration affordable to the public and through mechanisms that offer fair access for people in all countries. The companies have [signed](#) a Statement of Intent with Gavi to make available 200 million doses of their COVID-19 vaccine, if approved by regulatory authorities, to the COVAX Facility. **GSK** also reached an [agreement in principle](#) with Novavax and the UK Government Vaccines Taskforce to support manufacturing of up to 60 million doses of Novavax' COVID-19 vaccine. **Sanofi** reached a manufacturing agreement with Moderna to produce its mRNA COVID-19 vaccine in the US for up to 200 million doses, starting September 2021.

Takeda, Novavax and the Japanese Ministry of Health, Labour and Welfare are [partnering to increase manufacturing capacity](#) of Novavax's COVID-19 vaccine candidate NVX CoV2373 in Japan. Takeda anticipates to manufacture over 250 million doses of the COVID-19 vaccine per year. Takeda is also partnering with [Moderna](#) to import and distribute 50 million doses in Japan.

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Novartis has entered an initial agreement to manufacture up to 50 million doses of the mRNA and bulk drug product needed for **CureVac**'s COVID-19 vaccine candidate in 2021 and up to a further 200 million doses in 2022. **Bayer** has also signed a collaboration and services agreement with CureVac, and **plans** to add an additional 160 million doses of CureVac's vaccine in 2022. **GSK** would support the manufacture of up to 100 million doses of CureVac's COVID-19 vaccine candidate in 2021.

Moderna and Lonza joined forces to **support drug substance manufacturing** for its global supply chain of its COVID-19 vaccine, to establish a new production line at Lonza's Geleen site in the Netherlands, contributing to the supply of an additional 300 million doses. Moderna also signed two **MoU** with the government of South Korea: one to collaborate on mRNA vaccine research in South Korea; and an additional MoU to explore local manufacturing opportunities for mRNA vaccines in the country. **Moderna** will build a state-of-the-art mRNA facility in Africa with the goal of producing up to 500 million doses of vaccines each year at the 50 µg dose level. **Moderna** signed an agreement in principle with the Australian Government to build a state-of-the-art mRNA vaccine manufacturing facility in Victoria, Australia including access to Moderna's mRNA development engine. On 16 February 2022, **Moderna** announced plans to expand its commercial network across six additional European countries to support the delivery of mRNA vaccines, followed by **Moderna's** commercial partnership with Adium Pharma to deliver its vaccine to 18 countries in Latin America. Moderna also announced a 15-year collaboration agreement with **Thermo Fisher Scientific** to scale up manufacturing. On 7 March 2022, **Moderna** announced that it entered into a M.O.U. with the Government of the Republic of Kenya to establish Kenya as the location for its mRNA manufacturing facility, with the goal of producing up to 500 million doses of vaccines each year.

Therapeutics

IFPMA member companies are committed to work with governments, insurers and international organizations to ensure equitable access to COVID-19 medicines. The examples below illustrate different initiatives IFPMA companies are taking to enhance access. In all of them, licensing, enabled by a well-functioning intellectual property system, is a key enabler. Sector-wide, according to Airfinity data, at least 191 manufacturing and production deals for COVID-19 therapeutics around the globe were made public (as of May 2022).

Eli Lilly and Company (Lilly) and the Bill & Melinda Gates Foundation, as part of the COVID-19 Therapeutics Accelerator, **have entered into an agreement to facilitate access** to future Lilly therapeutic antibodies under development for the prevention and treatment of COVID-19, to benefit low- and middle-income countries. Commercial manufacturing would commence in April 2021 at the FUJIFILM Diosynth Biotechnologies facility in Denmark, where the Therapeutics

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Accelerator reserved manufacturing capacity. Lilly started the manufacturing technology transfer at risk, but due to the emergence of COVID-19 variants, partners decided not to push through with procurement. In the interest of making a supply of COVID-19 therapeutic innovations available globally as quickly as possible, Lilly will make certain volumes of its antibody therapeutic manufactured in other facilities available to lower-income countries prior to April 2021. Lilly's collaborators, AbCellera Biologics Inc., Shanghai Junshi Biosciences Co., Ltd. and Columbia University have agreed to waive their royalties on the Lilly therapeutic antibodies distributed in low- and middle-income countries as part of this initiative. Eli Lilly entered into royalty-free, limited, non-exclusive voluntary licensing agreement with [Lupin](#), [Cipla](#), [Sunpharma](#) for manufacturing and selling of Lilly's drug Baricitinib in India.

Gilead Sciences has entered into [voluntary licensing agreements](#) with 9 generics manufacturers to further expand supply of remdesivir to 127 countries, representing nearly all low-income and lower-middle income countries. Gilead has completed technology transfers with these companies. Moreover, Gilead has expanded its global network of both internal manufacturing sites and external organizations, including partnering with industry peers, to add manufacturing capacity around the world. The remdesivir manufacturing network includes more than 40 companies in North America, Europe and Asia. [Pfizer](#) announced a multi-year agreement with Gilead to manufacture and supply Gilead's remdesivir and is looking to further [expand availability](#) in low- and middle-income countries. In response to the rapid increase in COVID-19 cases in India, [Gilead](#) would provide its voluntary licensing partners with technical assistance, support for the addition of new local manufacturing facilities and the donation of API to rapidly scale up production of remdesivir.

MSD (known as Merck in the US and Canada), amid humanitarian crisis in India, announced [voluntary licensing agreements](#) with five Indian generics manufacturers, including Cipla Limited, Dr. Reddy's Laboratories Limited, Emcure Pharmaceuticals Limited, Hetero Labs Limited and Sun Pharmaceutical Industries Limited, to accelerate and expand global access to molnupiravir, an investigational oral therapeutic for the treatment of COVID-19. Moreover, on 27 October 2021, the MPP and [MSD](#), known as Merck in the US and Canada, announced the signing of a voluntary licencing agreement to facilitate affordable global access for molnupiravir. This agreement would help create broad access for molnupiravir use in 105 LMICs following appropriate regulatory approvals.

Roche and Regeneron joined forces to [significantly increase global supply](#) of casirivimab/imdevimab, Regeneron's investigational antiviral antibody combination, to at least three and a half times the current capacity, with the potential for even further expansion. Roche signed an initial agreement with [Novartis](#) to reserve capacity and implement the technology transfer for the production of the active pharmaceutical ingredient (API) for Roche's tocilizumab.

Pfizer and the MPP announced the signing of a voluntary license agreement for Pfizer's COVID-19 oral antiviral treatment candidate PF-07321332, which is administered in combination with low dose ritonavir. The agreement would enable the MPP to facilitate additional production and distribution of the investigational

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antiviral, pending regulatory authorization or approval, by granting sub-licenses to qualified generic medicine manufacturers, with the goal of facilitating greater access to the global population.

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