COVID-19: The biopharmaceutical industry is leading the way in developing & manufacturing vaccines, therapeutics & diagnostics

On 19th May 2021, global vaccine manufacturers and biotech associations have committed to Five Steps to urgently advance COVID-19 vaccine equity. The plan points out that, whilst extraordinary achievements have been made with 11 billion doses produced by the end of 2021, vaccine doses are not reaching all priority populations worldwide. We believe vaccine equity can be a reality if all stakeholders work together to step up dose sharing, eliminate trade barriers, further support for country readiness. Industry is also working tirelessly to continue optimizing production and driving further innovation.

FIVE STEPS TO URGENTLY ADVANCE COVID-19 VACCINE EQUITY

KEY FACTS & FIGURES

<12 MONTHS OF COVID-19 VACCINE DEVELOPMENT
STEP UP DOSE SHARING

Work with governments and expand every effort to make additional COVID-19 vaccine doses available to low- and lower-middle income countries, through COVAX or other efficient established mechanisms.

The key to ensuring dose sharing delivers on its promise of equity goes far beyond pledges, as outlined in our explainer of step 1 of 5 needed to urgently advance COVID-19 vaccine equity. See our video on Step 1 here.

Since the first vaccines became available, the COVAX facility, co-led by Gavi, UNICEF, WHO and CEPI, has signed agreements with several vaccine manufacturers to provide at least 2 billion doses of approved COVID-19 vaccines by the end of 2021.

Find the latest dose donations to COVAX announced for 2021-2022 here.

- 10 December 2021 – Moderna announced a new supply agreement to provide COVAX with an additional 150 million doses in 2022 and advance availability of 20 million doses for 2021.
- 22 November 2021 – As part of Team Europe’s pledge to share at least 500 million doses of vaccines with LMICs through the COVAX Facility, the first shipment of 99.6 million J&J vaccine doses is arriving in African countries the week of 22 November 2021.
- 16 November 2021 – Moderna announced an agreement that enables the EU and European Economic Area (EEA) countries to donate 70 million COVID-19 vaccine doses to COVAX in 2021.
- 10 November 2021 – Johnson & Johnson announced an agreement with the US government and Gavi to provide COVID-19 vaccine doses to conflict zones and humanitarian settings through the COVAX Humanitarian Buffer.
- 04 November 2021 – Novavax announced submission of COVID-19 vaccine for WHO EUL, prerequisite to export the vaccines to countries participating in the COVAX Facility.
- 17 August 2021 – The first 100,000 COVID-19 doses of the 500 million provided by Pfizer and BioNTech to the US. government for donation and distribution reached Rwanda.
• 02 August 2021 – The African Union (AU), the African Vaccine Acquisition Trust (AVAT) and UNICEF announced a partnership to ensure procurement and delivery of vaccines to AU Member States.

• 01 July 2021 – UNICEF signs supply agreement Johnson & Johnson’s Janssen Pharmaceutica to access up to 200 million doses in 2021 for 92 countries.

• 16 June 2021 – Daiichi Sankyo announced that it and the Japanese Government will supply 30 million doses of AstraZeneca’s COVID-19 vaccine to countries participating in the COVAX facility, especially focusing on Southeast Asian countries.

• 10 June 2021 – Pfizer and BioNTech announced that they would provide the US government with 500 million doses of COVID-19 vaccines for donation and distribution amongst the world’s most resource-limited nations.

• 02 June 2021 – UNICEF together with procurement partners announced a long-term agreement with Moderna for the supply of up to 34 million doses in 2021, and 466 million doses in 2022.

• 21 May 2021 – Gavi announced the signing of an agreement with Johnson & Johnson for the supply of 200 million doses in 2021, and a potential additional 300 million doses in 2022.

• 3 May and 6 May 2021 – agreements were signed by Gavi with Moderna and with Novavax for the supply of up to 500 million doses respectively.

• 25 February 2021 – UNICEF, together with procurement partners, signed a long-term supply agreement with AstraZeneca on behalf of the COVAX Facility for 170 million vaccine doses for about 85 LMICs.

• 22 January 2021 – an agreement that saw Gavi securing 400 million doses of the Pfizer-BioNTech vaccine was signed.

• 28 October 2020 – Gavi signed a statement of intent to procure 200 million doses of the Sanofi-GSK COVID-19 vaccine candidate for the COVAX Facility.

• 29 September 2020 – Gavi announced a collaboration between AstraZeneca, the Serum Institute of India, and the Bill & Melina Gates Foundation to accelerate the manufacturing through the sharing of the know-how to produce the AstraZeneca-Oxford vaccine which ultimately should result in the delivery of up to 200 million vaccines for LMICs in 2021 at a maximum of US$ 3 per dose, with an option to secure more.

**CONTINUE TO OPTIMIZE PRODUCTION**

Work with governments and individual suppliers of raw materials and components to undertake all practicable efforts to maximize COVID-19 vaccine output without compromising safety and quality.

Manufacturing COVID-19 vaccines at the volumes the world needs is a colossal challenge and scarcity of raw materials and trade barriers could upset estimates that 11 billion doses – more than double pre-pandemic global manufacturing capacity for all vaccines – can be produced by the end of 2021, as our [explainer on Step 2](#) out of 5 outlines. See our [video on Step 2](#) here.

• 13 December 2021 – Moderna announced a collaboration with the Australian government to build a mRNA vaccine
manufacturing facility in Australia to meet the challenges of the COVID-19 pandemic and future pathogens.

- **30 November 2021** – Johnson & Johnson reported it is in an advanced stage of discussions to license its COVID-19 vaccine to South Africa-based Aspen Pharmacare.

- **09 November 2021** – AstraZeneca announced the creation of a dedicated vaccines and immune therapies unit to bring together R&D, manufacturing, commercial and medical teams.

- **14 October 2021** – CSL reaffirmed its commitment to manufacture 50 million doses of AstraZeneca's COVID-19 vaccine into 2022.

- **07 October 2021** – Moderna announced it will build an mRNA facility in Africa to manufacture up to 500 million vaccines doses per year.

- **08 September 2021** – Moderna and Canada's National Resilience Inc. agreed to manufacture mRNA for Moderna's COVID-19 vaccine, to increase global distribution.

- **27 August 2021** – BioNTech explores mRNA vaccine manufacturing solutions in Rwanda and Senegal to improve sustainable long-term vaccine supply for the Member States of the African Union.

- **26 August 2021** – Pfizer and BioNTech announced a collaboration with a Brazilian biopharmaceutical company, Eurofarma, to manufacture COVID-19 vaccine doses for Latin America.

- **05 August 2021** – Novavax and the Serum Institute of India have established a partnership to manufacture and provide more than 1.1 billion doses to the COVAX Facility.

- **21 July 2021** – Pfizer and BioNTech announced the signing of a letter of intent with Biovac, a Cape Town-based, South African biopharmaceutical company, to manufacture the Pfizer-BioNTech COVID-19 Vaccine for distribution within the African Union. To facilitate Biovac's involvement in the production process, technical transfer, on-site development and equipment installation activities will begin immediately. At full operational capacity, the annual production will exceed 100 million finished doses annually, reaching the 55 Member States that make up the African Union.

- **01 July 2021** – Moderna announced a partnership with Recipharm in France to expand manufacturing for Moderna's COVID-19 vaccine at Recipharm's Monts manufacturing site.

- **22 June 2021** – Novavax entered into a partnership with the National Research Council of Canada Biologics Manufacturing Centre to expand manufacturing capabilities for Novavax' COVID-19 vaccine.

- **02 June 2021** – Moderna expanded its partnership with Lonza to increase drug substance manufacturing for Moderna's global supply chain to support the additional manufacturing of 300 million doses of Moderna's updated booster variant vaccine candidate.

- **24 May 2021** – Moderna and Aldevron announced an expansion of their partnership in support of Moderna's COVID-19 vaccine manufacturing and additional programs such as the supply of plasmid DNA, which serves as the generic template for generating the COVID-19 mRNA vaccine.

- **22 May 2021** – Novavax signed a non-binding memorandum of understanding with the Ministry of Health and Welfare of Korea and SK Bioscience to explore further cooperation in the development and manufacturing of vaccines, including COVID-19 vaccines.

- **22 May 2021** – Moderna signed a Manufacturing Services and Supply Agreement in which Samsung Biologics will
provide large scale, commercial fill-finish manufacturing support for Moderna’s COVID-19 vaccine.

- **22 May 2021** – Moderna announced two memoranda of understanding with the government of South Korea and one with the Korea National Institute of Health to explore local manufacturing opportunities for mRNA vaccines in South Korea, and with Samsung Biologics.

- **20 May 2021** – BioNTech announced plans to expand its global footprint to Asia with the establishment of its Regional Headquarters for Southeast Asia in Singapore and a first mRNA manufacturing facility.

- **07 May 2021** – Pfizer increased their manufacturing projections for 2021 from 2.5 billion to 3 billion as part of their commitment to provide enough COVID-19 vaccines for all.

- **29 April 2021** – Moderna announced new investments to increase global supply for COVID-19 Vaccine at its own manufacturing facilities, which it expects to increase global supply to up to 3 billion doses in 2022.

- **26 April 2021** – Sanofi announced the manufacturing of up to 200 million doses of Moderna’s vaccine in the US starting in September 2021.

- **29 March 2021** – GSK agreed with Novavax and the UK Government Vaccine Taskforce to support the manufacturing of up to 60 million doses of Novavax’ COVID-19 vaccine.

- **22 February 2021** – Sanofi announced it would provide manufacturing support to Johnson & Johnson to formulate and fill vials of Janssen’s COVID-19 vaccine candidate in 2021 at a rate of approximately 12 million doses per month.

### CALL OUT TRADE BARRIERS TO BE ELIMINATED

Urge governments to eliminate all trade and regulatory barriers to the export of essential manufacturing materials and vaccines, while identifying and addressing trade barriers in cooperation with partners.

As our explainer on Step 3 of 5 outlines, trade restrictions, amongst other hurdles, are holding up both upstream and downstream supply, presenting a significant challenge to achieve vaccine equity. See our video on Step 3 here.

- **22 November 2021** – The WTO and IMF launched a COVID-19 Vaccine Trade Tracker in order to provide greater transparency on the cross-border flow of COVID-19 vaccines.

- **27 October 2021** – UNICEF calls out restrictions on the export of syringes due to nationalism and predicts a shortage of auto-disable syringes for 2022.

- **30 September 2021** – 30 CEOs and Chairpersons from five continents called on world leaders to rise above geopolitical tensions and re-engage on trade reform, as advancing health, digital, environmental and investment reform is key to a more inclusive trade and investment.

- **14 May 2021** – CEPI, IFPMA, DCVMN, and other partners in the COVAX Facility announced the establishment of the COVAX Manufacturing Task Force to tackle vaccine supply challenges, including addressing the elimination of potential trade barriers.
23 April 2021 – IFPMA and the COVID-19 vaccine industry cautioned during a press briefing that immediate action would be needed to remove manufacturing supply barriers to meet production targets and keep the goals for equitable and fair access to COVID-19 vaccines on course.

SUPPORT COUNTRY READINESS
Partner with governments on COVID-19 vaccine deployment, particularly in low- and middle-income countries, to ensure that they are ready and able to deploy available doses, while also restoring and maintaining the delivery of routine immunization.

As our explainer on Step 4 outlines, countries must be ready to roll out vaccination programs as soon as doses are delivered. Therefore, countries need adequate resourcing, the right infrastructure, a strong cold supply chain, and trained staff to effectively store, distribute and administer vaccines. See our video explaining Step 4 here.

06 December 2021 – Pfizer Executive said South Africa’s Biovac Institute will start making Pfizer/BioNTech’s COVID-19 vaccine early next year after receiving the drug substance from Europe.

08 November 2021 – Pfizer and the UPS Foundation are committed to accelerating the equitable distribution of COVID-19 vaccines. The UPS Foundation is donating freezers to countries that need assistance with building out ultra-cold chain capacity.

08 November 2021 – Pfizer has signed an MOU with the Global Environment and Technology Foundation to collaborate with Project Last Mile on aligning their supply chain expertise and technical capabilities of Coca-Cola, a company whose supply chain is characterized as one of the widest reaching in the world. Pfizer will provide expertise on vaccine handling, storage and administration in order to improve the availability of vaccines in developing countries.

22 November 2021 – CEPI opened a call for proposals to identify laboratories worldwide to assess the development of vaccines against epidemic and pandemic diseases and to further expand its COVID-19 vaccine testing network.

02 September 2021 – CEPI and the International Finance Corporation (IFC) agreed to collaborate to evaluate and identify countries, partners, and projects best positioned to create commercially viable vaccine manufacturing hubs to increase vaccine access in Africa to enable a rapid response to future outbreaks.

15 July 2021 – CEPI and COVAX partners launched the COVAX Marketplace to match buyers and sellers of critical manufacturing supplies and speed up global access to COVID-19 vaccines through COVAX.

17 June 2021 – Pfizer and Zipline have partnered to design and test delivery solutions, like drone delivery and thermal shipping containers, that can safely and effectively distribute COVID-19 vaccines in difficult-to-reach areas.

10 June 2021 – The UPS Foundation, a longstanding partner of Gavi, is supporting equitable delivery of COVID-19 vaccines to countries with insufficient access. Together with Pfizer, they are donating freezers to countries that need assistance with building their ultra-cold chain capacity.
03 June 2021 – Moderna has committed to a supply agreement on 3 June 2021 with the Republic of Botswana to support the government’s ongoing efforts to secure access to a COVID-19 vaccines for the people of Botswana.

14 May 2021 – CEPI, IFPMA, DCVLN, and other partners in the COVAX Facility announced the establishment of the COVAX Manufacturing Task Force to, amongst other objectives, support the establishment or upgrading of vaccine manufacturing facilities, particularly those in LMICs, leveraging appropriate mechanisms and business processes.

**DRIVE FURTHER INNOVATION**

Prioritize the development of new and next-generation COVID-19 vaccines while urging governments for unhindered access to pathogens and related data.

As our explainer on Step 5 outlines, to improve the efficacy, manufacture and distribution of COVID-19 vaccines and combat emerging variants, governments, regulators, and research scientists must work together to drive further innovation. See our video explaining Step 5 here.

- **20 December 2021** – Novavax announced that the WHO has granted a second Emergency Use Listing (EUL) for its protein-based COVID-19 vaccine (Nuvaxovid).
- **20 December 2021** – Novavax announced that the European Commission has granted conditional marketing authorization to its COVID-19 vaccine in Europe, following a positive recommendation by the EMA.
- **20 December 2021** – Moderna announced that its COVID-19 boosters increase protection against Omicron and that the company will continue to assess the immunity response from its multivalent booster candidates whilst developing an Omicron-specific variant vaccine.
- **20 December 2021** – Pfizer and BioNTech announced an agreement to provide the EU with 200 million additional COVID-19 vaccine doses to meet continued demand, including potential vaccines adapted to the Omicron variant if needed and approved.
- **17 December 2021** – Novavax and the Serum Institute of India (SII) announced that the WHO has granted Emergency Use Listing (EUL) for Novavax’ protein-based COVID-19 vaccine (Covovax), marketed by SII.
- **17 December 2021** – Pfizer and BioNTech will amend the clinical study evaluating their COVID-19 vaccine for children 6 months to 5 years of age to include a third dose.
- **17 December 2021** – Pfizer and BioNTech submitted a supplemental Biologics License Application to the US FDA to expand approval of its COVID-19 vaccine to individuals aged 12 to 15 years old.
- **16 December 2021** – Johnson & Johnson issued a statement reaffirming its confidence in the positive benefits-risk profile of its COVID-19 vaccine and its commitment to work with the US CDC on next steps.

- **15 December 2021** – [GSK](https://www.gsk.com) and [Sanofi](https://www.sanofi.com) announced positive preliminary data for their COVID-19 vaccine booster candidate and expect results from phase 3 clinical trial in Q1 2022 to file with regulatory authorities.

- **15 December 2021** – Johnson & Johnson announced that the EMA issued a positive opinion for the use of its COVID-19 vaccine as a booster dose for adults.

- **15 December 2021** – Novavax announced positive results of its phase 3 clinical trial for its protein-based COVID-19 vaccine, demonstrating 100% protection against moderate and severe disease.

- **09 December 2021** – Johnson & Johnson announced the WHO Strategic Advisory Group of Experts (SAGE) issued an interim recommendation supporting the use of its COVID-19 vaccine as a booster.

- **08 December 2021** – Pfizer and BioNTech announced that the US FDA has granted EUA to its COVID-19 vaccine booster for individuals aged 16 years and older.

- **07 December 2021** – GSK and Medicago announced positive Phase 3 efficacy and safety results for their adjuvanted plant-based COVID-19 vaccine candidate.

- **06 December 2021** – The Oxford University led Com-COV2 study finds that participants receiving a first dose of Oxford-AstraZeneca or Pfizer/BioNTech generate a robust immune response when immunized 9 weeks later with a second dose of COVID-19 vaccines manufactured by Novavax or Moderna. The study might promote further rapid deployment of COVID-19 vaccines in LMICs.

- **05 December 2021** – Johnson & Johnson reports from a Phase 2 clinical trial that its COV2.S COVID-19 vaccine could potentially be used as a booster dose if given six months after an initial two-dose vaccine series with Pfizer/BioNTech’s BNT162b2 COVID-19 vaccine.

- **02 December 2021** – Novavax is evaluating its vaccine against the Omicron variant and has initiated the development of an Omicron-specific vaccine construct. It will begin testing whether antibodies from previously vaccinated individuals can neutralize the Omicron variant.

- **30 November 2021** – Daiichi Sankyo has started to investigate whether its vaccine under development would be effective against Omicron.

- **30 November 2021** – Shionogi announced it is considering making an active vaccine ingredient based on the Omicron virus’ genetic information.

- **29 November 2021** – Johnson & Johnson is testing the effectiveness of its COVID-19 vaccine against the Omicron variant and is pursuing an Omicron-specific variant vaccine that will rapidly progress into clinical studies if needed. The company is also working with scientists in South Africa to generate new data on Omicron.

- **29 November 2021** – AstraZeneca is testing the effectiveness of its COVID-19 vaccine against the Omicron variant and...
is developing an Omicron-specific variant vaccine. The company is also conducting ground research in Africa.

- **26 November 2021** – Novavax began the development of a new recombinant spike protein vaccine based on the known genetic sequence of the Omicron variant that is expected to be ready to start testing and manufacturing within the next few weeks. Novavax is also evaluating its current vaccine against the Omicron variant.

- **26 November 2021** – Pfizer and BioNTech announced that they will be ready to adapt a new vaccine against the Omicron variant within 6 weeks and ship initial batches within 100 days.

- **26 November 2021** – Moderna is currently testing the ability of 3 existing COVID-19 vaccine booster candidates against the Omicron variant, including two multi-valent booster candidates and a high-dose booster candidate and data is expected in the coming weeks. The company is also working on a new variant-specific vaccine candidate against Omicron (mRNA-1273.529), that if needed would advance to clinical trials in 60-90 days.

- **16 November 2021** – AstraZeneca marked the milestone of supplying 2 billion COVID-19 vaccine doses to countries worldwide after first approval, 2/3 of those delivered to LMICs.

- **15 November 2021** – Moderna announced that Health Canada authorized the use of a booster dose of its COVID-19 vaccine for individuals aged 18 and older.

- **11 November 2021** – Pfizer and BioNTech’s collaboration with Zipline will pioneer a new vaccine distribution model using a long-range drone that will allow the delivery of 50,000 COVID-19 vaccine doses in Ghana.

- **09 November 2021** – Moderna filed to expand the conditional marketing authorization for its COVID-19 vaccine in the EU to include children aged 6 to 11 years old.

- **09 November 2021** – Pfizer and BioNTech submitted request to amend US FDA EUA of COVID-19 vaccine booster to include all adults.

- **01 November 2021** – Novavax and Serum Institute of India received EUA for COVID-19 vaccine in Indonesia, the first of many authorizations expected in the coming weeks and months globally.

- **29 October 2021** – Pfizer and BioNTech received first US FDA EUA of COVID-19 vaccine for children 5 to 11 years old.

- **21 October 2021** – Daiichi Sankyo announced positive phase1/2 clinical trial results of its mRNA COVID-19 vaccine in Japan.

- **21 October 2021** – Shionogi announced the initiation of a phase 2/3 clinical trial for its COVID-19 recombinant protein-based vaccine following successful phase 1 trial results.

- **18 October 2021** – The Committee for Medicinal Products for Human Use (CHMP) of the EMA issued a positive opinion on a new formulation of BioNTech/Pfizer’s COVID-19 vaccine.

- **15 October 2021** – BioNTech and Pfizer submitted further data from their Phase 2/3 trial in support of COVID-19 immunization in children aged 5 to 12 years.

- **11 October 2021** – CEPI opened a call to evaluate fractional COVID-19 booster and third shots as part of efforts to stretch global vaccine supply.

- **11 October 2021** – WHO’s Strategic Advisory Group of Experts (SAGE) on Immunization recommends an additional COVID-19 vaccine dose for moderately and severely immunocompromised persons using any of the WHO approved vaccines. People aged 60 and older who received the Sinovac and Sinopharm vaccines should receive a third dose using
one of the other approved vaccines.

- **05 October 2021** – Johnson & Johnson announced the submission of an EUA amendment to the US FDA to support a booster of its single-shot COVID-19 vaccine.

- **30 September 2021** – Moderna announced the construction of an environmentally sustainable, digitally enabled Moderna Science Center in the US to advance its pipeline of mRNA medicines.

- **28 September 2021** – BioNTech and Pfizer submitted initial data from their Phase 2/3 trial in support of COVID-19 immunization in children aged 5 to 12 years.

- **22 September 2021** – BioNTech and Pfizer received US FDA EUA for their COVID-19 vaccine to be used as a booster for individuals aged 18 and older.

- **20 September 2021** – BioNTech and Pfizer announced positive results from Phase 2/3 clinical trial of COVID-19 vaccine in children aged 5 to 11 years.

- **16 September 2021** – Novavax announced its participation in a Phase 2 trial, Com-COV3 at the University of Oxford, assessing mixed COVID-19 vaccine schedules in adolescents 12-16 years of age.

- **15 September 2021** – Moderna shared new data from the Phase 3 COVE study that suggests a lower risk of breakthrough infection in participants vaccinated more recently (median 8 months after first dose) compared to participants vaccinated last year (median 13 months after first dose).

- **08 September 2021** – Novavax initiated Phase 1/2 clinical trial to evaluate efficacy and safety of a new combination vaccine for COVID-19 and the Flu (Seasonal Influenza), NanoFlu™/NVX-CoV2373.

- **06 September 2021** – BioNTech and Pfizer have submitted a variation to the EMA with data from their Phase 3 clinical trial in support of a booster dose of their vaccine for individuals aged 16 or older.

- **03 September 2021** – Moderna submitted its data for CMA with the EMA for the evaluation of a booster dose at the 50 µg dose level.

- **01 September 2021** – Moderna initiated its submission to the US FDA to evaluate a booster dose of its COVID-19 vaccine at the 50 µg dose level.

- **16 August 2021** – Pfizer and BioNTech announced the submission of Phase 1 data to the US FDA to support booster dose of COVID-19 vaccine and to support the evaluation of a third dose of the companies' COVID-19 vaccine for future licensure.

- **16 August 2021** – GSK and CureVac announced that their second generation COVID-19 vaccine induced a stronger immune response than its first generation vaccine, including against upcoming variants of SARS-CoV-2.

- **08 July 2021** – Pfizer and BioNTech provided an update on booster program considering the Delta-variant, encouraging data in the ongoing booster trial of a third dose of the companies’ COVID-19 vaccine has been seen.

- **29 June 2021** – Sanofi launched a vaccine mRNA Center of Excellence and will invest approximately €400 million annually to accelerate the development and delivery of next-generation vaccines.

- **27 June 2021** – AstraZeneca announced that the first participants across the UK, South Africa, Brazil, and Poland, were vaccinated in a clinical trial to test their updated COVID-19 vaccines for emerging variants.

- **14 June 2021** – Novavax announced positive results from a first study that administered an influenza vaccine and
COVID-19 vaccine candidate simultaneously.

- **04 June 2021** – IFPMA announced that life science industry leaders are joining forces with governments to prioritize the development of new COVID-19 vaccines, developing a plan to deploy high-quality diagnostics, therapeutics, vaccines and treatments in just 100 days after a new pandemic threat is identified.

As a science-driven industry that aims to address some of the world’s biggest healthcare challenges, the biopharmaceutical industry is uniquely positioned to respond rapidly to COVID-19. It has gained profound scientific insights from decades of experience in developing solutions for infectious diseases such as MERS, SARS, Ebola and influenza as well as in working with health authorities and regulators to swiftly bring safe and effective vaccines, therapeutics and diagnostics to patients.

The rapid worldwide spread of SARS-CoV-2 is a public health emergency. More than ever, we need effective international cooperation to ensure that no-one is left behind in the race to tackle this crisis. This requires coordinated, multi-stakeholder action embracing the private sector as a critical partner. IFPMA members are fully committed to bringing their unique expertise in R&D and manufacturing of vaccines, therapeutics and diagnostics to the table.

IFPMA members are also committed to collaborate closely with national regulatory agencies, academia and global health stakeholders to retain access to existing medicines and vaccines for treatment and prevention of other conditions. Clinical research into new options and treatments for serious, life-threatening diseases also remains a priority (read our Regulatory Guiding Principles here).

IFPMA has joined the global public-private partnership, ACT Accelerator, as founding partner, offering its knowledge and expertise in finding/developing novel therapeutics and vaccines and in building manufacturing capacity and distribution networks. IFPMA has published the Vaccines Policy Principles that will guide its work with the ACT Accelerator Vaccines Partnership (COVAX). On 24 February 2021, COVAX and UNICEF began to roll out 2 billion doses of COVID-19 vaccines (to be delivered by the end of 2021) to protect high risk and vulnerable people, and frontline healthcare workers in low- and middle-income countries (LMICs). Since then, GAVI has announced various deliveries of COVAX COVID-19 vaccines, with millions of doses to reach 147 countries by the end of May 2021.

IFPMA, EFPIA, BIO, PhRMA, ABPI, ICBA, and Vaccines Europe call on manufacturers, governments, and non-governmental organizations to take immediate action to advance COVID-19 vaccine equity, proposing 5 steps to take – step up dose sharing, continue to optimize production, call out trade barriers to be eliminated, support country readiness, and drive further innovation – with urge.

**SEVEN GLOBAL BIOPHARMACEUTICAL INDUSTRY COMMITMENTS TO ADDRESS CORONAVIRUS PUBLIC HEALTH CRISIS**
IFPMA members reviewed their drug portfolios for potentially safe and effective assets that could help with the development of new or repurposed treatments. Gilead’s remdesivir was approved as the first COVID-19 treatment by the US FDA in May 2020, and the EMA in June 2020. Various authorities, including the EMA and US FDA endorsed the use of dexamethasone for treating adult cases requiring respiratory support. Regarding antibodies, in November 2020, the US FDA was the first to grant EUA to Regeneron’s antibody cocktail (casirivimab and imdevimab administered together). In February 2021, the US FDA granted EUA for Eli Lilly’s investigational antibody cocktail of bamlanivimab (LY-CoV555) and etesevimab (LY-CoV016).

Large-scale COVID-19 partnerships with broad industry involvement to speed up COVID-19 Therapeutics R&D

The following IFPMA member companies have partnered with the COVID-19 Therapeutics Accelerator initiative, initiated by the Gates Foundation, Wellcome and Mastercard, to accelerate the development, manufacture, and delivery of vaccines, diagnostics, and therapeutics for COVID-19: Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, Eisai, Eli Lilly, Gilead, GSK, Johnson & Johnson, Merck (known as MSD outside the US and Canada), Merck KGaA, Novartis, Pfizer, and Sanofi.

The NIH set up the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership to develop a coordinated research strategy for prioritizing and speeding development of the most promising therapeutics and vaccines. The following IFPMA member companies have partnered with the ACTIV initiative: AbbVie, Amgen, AstraZeneca, Bristol Myers Squibb, Eisai, Eli Lilly and Company, Gilead, GSK, Johnson & Johnson, Merck & Co., Inc., Novartis, Pfizer, Roche-Genentech, Sanofi, and Takeda.

The Corona Accelerated R&D in Europe (CARE) consortium, a coalition of 37 globally renowned academic institutions, pharmaceutical companies and non-profit research organizations, committed to the development of therapeutics (i) to provide an emergency response towards the current COVID-19 pandemic by drug repositioning and (ii) to address the current and/or future coronavirus outbreaks by broad-spectrum small-molecule drug discovery and/or virus-neutralizing antibody discovery. The following IFPMA members have joined the consortium: AbbVie, Astellas, Boehringer Ingelheim, Johnson & Johnson, Merck, Novartis, Pfizer, and Takeda.

AbbVie partnered with global authorities to determine the effectiveness of HIV drugs lopinavir/ritonavir in treating COVID-19. WHO interim trial results showed that lopinavir/ritonavir produced little or no reduction in mortality of hospitalized COVID-19 patients, hence trials were interrupted with immediate effect.
AbbVie also entered into a collaboration with Harbour BioM, Utrecht University, and Erasmus Medical Center to develop a novel antibody therapeutic. AbbVie, and partners of the COVID R&D Alliance, Amgen, and Takeda, announced the start of the I-SPY COVID trial evaluating the efficacy of cenicriviroc, apremilast, and icatibant in hospitalized COVID-19 patients.

Amgen and Adaptive Biotechnologies are partnering to combine expertise to discover and develop fully human neutralizing antibodies targeting SARS-CoV-2. Amgen, and partners of the COVID R&D Alliance, AbbVie, and Takeda, announced the start of the I-SPY COVID trial evaluating the efficacy of cenicriviroc, apremilast, and icatibant in hospitalized COVID-19 patients.

Astellas In Japan, Astellas is providing compounds in response to a request from the government to cooperate in the “Basic Screening Plan for Drugs for Coronavirus Disease”. Astellas is also responding to requests from EFPIA and IMI to cooperate in “Activities Aimed at Developing Drugs for the Novel Virus” and providing consultation on countermeasures.

AstraZeneca AZD7442 treatment – AstraZeneca signed an agreement with DARPA, part of the US Department of Defense, and BARDA to support the company’s efforts to develop a monoclonal antibody treatment against SARS-CoV-2. The company announced the advancement of its LAAB combination, AZD7442, into two Phase III clinical trials in more than 6,000 participants worldwide. Acalabrutinib – In ongoing trials supported by AstraZeneca, results published in Science Immunology showed that acalabrutinib reduced markers of inflammation and improved clinical outcomes of patients with severe COVID-19 disease.

BMS BMS and The Rockefeller University announced that they entered into a definitive agreement under which Bristol Myers Squibb was granted a global exclusive license to develop, manufacture and commercialize Rockefeller’s novel mAb duo treatment that neutralizes the SARS-CoV-2 virus for therapy or prevention of COVID-19. Xencor announced it has entered into a technology license agreement with Bristol-Myers Squibb under which BMS will have non-exclusive access to Xencor’s Xtend™ Fc technology to extend the half-life of a novel antibody combination therapy that is intended to neutralize the SARS-CoV-2 virus (“SARS-CoV-2 mAb Duo”) for treatment or prevention of COVID-19.

Boehringer Ingelheim Boehringer Ingelheim is a member of the CARE consortium, leading the work stream focusing on the development of virus neutralizing antibodies. The company will also provide antiviral molecules from its legacy HIV and HCV portfolio and small molecule candidates from a complete screen of its molecule library. Boehringer Ingelheim announced the initiation of a Phase 2 clinical trial of BI 764198, an inhibitor of TRPC6 that may alleviate the damage to the lung and decrease the risk or severity of acute respiratory complications in patients hospitalized for COVID-19. Boehringer Ingelheim announced that it has decided to discontinue treatment in the Phase II trial of BI 764198. UKK, UMR, the DZIF and Boehringer Ingelheim announced the initiation of Phase 1/2a clinical investigation of BI 767551, a new SARS-CoV-2 neutralizing antibody. Boehringer Ingelheim announced its decision to focus its COVID-19 therapy research on the development of alteplase as a potential treatment for COVID-19 patients with severe breathing problems. The decision is based on favorable safety and efficacy data from an interim analysis of the TRISTARDS Phase 2/3 study, following completion of the Phase 2b part of the study including 62 patients.

Chugai Chugai Pharmabody Research Pte. Ltd. and the Agency for Science, Technology and Research in Singapore are jointly researching a therapeutic antibody to fight COVID-19.
Chugai entered into a license agreement for worldwide non-exclusive rights of several Chugai’s antibody engineering technologies with Eli Lilly.

Chugai announced that it concluded a license agreement with Roche for the development and commercialization in Japan for the antibody cocktail of casirivimab and imdevimab (formerly known as REGN-COV2) for COVID-19.

Chugai announced that it concluded a license agreement with Roche for the development and marketing in Japan for AT-527, an oral drug candidate for COVID-19.

CSL Group is collaborating with Takeda, Biotest AG, Bio Products Laboratory, LFB and Octapharma to accelerate development of a potential COVID-19 Hyperimmune therapy.

The CoVlg-19 Plasma Alliance announced that the Phase 3 ITAC clinical trial sponsored and funded by the NNIAID, part of the NIH, did not meet its endpoints.

CSL Behring is partnering with SAB Biotherapeutics, a clinical-stage biopharmaceutical company, to advance and deliver a novel immunotherapy targeting COVID-19. The potential therapy would be produced without the need for blood plasma donations from recovered COVID-19 patients.

CSL Behring has launched a clinical trial into the use of CSL312 (garadacimab, Factor XIIa antagonist monoclonal antibody) to treat patients suffering from severe respiratory distress, a leading cause of death in patients with COVID-19 related pneumonia.

Eli Lilly received the rights to use Chugai’s antibody engineering technologies for their research activities to develop next-generation COVID-19 treatments and the rights for the development and marketing of therapeutic antibodies applying the technologies.

Bamlanivimab – In June 2020, Eli Lilly announced a Phase 1 study of LY-CoV555, the lead antibody from Lilly’s collaboration with AbCellera. Eli Lilly also announced the start of a Phase 1 study for its second potential COVID-19 antibody treatment in collaboration with Junshi Biosciences. Eli Lilly and UnitedHealth Group announced a partnership to conduct a pragmatic study of LY-CoV555 in high-risk, individuals with COVID-19.

Eli Lilly, Vir Biotechnology and GSK announced a collaboration to evaluate a combination of bamlanivimab (LY-CoV555) with VIR-7831 (GSK4182136) in low-risk patients with mild to moderate COVID-19.

Eli Lilly announced the US FDA granted EUA for the combination treatment of bamlanivimab (LY-CoV555) and etesevimab (LY-CoV016). Eli Lilly also announced the EMA’s positive scientific opinion for bamlanivimab alone and bamlanivimab administered together with etesevimab.

The U.S. FDA expanded the EUA for bamlanivimab 700 mg and etesevimab 1400 mg administered together to include PEP in certain individuals for the prevention of SARS-CoV-2 infection.

LY3127804 – Eli Lilly advanced to Phase 2 trials for its investigational selective monoclonal antibody LY3127804 against Angiopoietin 2 in hospitalized COVID-19 patients.

Baricitinib – Eli Lilly entered into an agreement with NIAID to study baricitinib as an arm in NIAID’s Adaptive COVID-19 Treatment Trial. Complementing this data, Eli Lilly separately started a Phase 3 study to evaluate efficacy and safety of baricitinib in hospitalized adults with COVID-19.

Eisai, in collaboration with the Global Coalition for Adaptive Research and the University of Pittsburgh Medical Center,
joined REMAP-COVID, a study that tests multiple interventions for the treatment of patients hospitalized with COVID-19. Eritoran, an investigational TLR4 antagonist discovered and developed by Eisai, was selected as the first investigational immune modulation therapy to be evaluated. **Eisai** announced that it has entered into a joint research agreement with four research organizations in Japan concerning the "Development of Therapeutics to Prevent the Aggravation of the Novel Coronavirus Infectious Disease (COVID-19)" (Grant Number: 20fk0108255). On 6 October 2021, **Eisai** announced that it entered into a joint research agreement with four research organizations (KAN Research Institute, National Center for Global Health and Medicine, Nagasaki University, and Yokohama City University) in Japan concerning the "Development of Therapeutics to Prevent the Aggravation of the Novel Coronavirus Infectious Disease (COVID-19)", which is a research project with Eisai as the representative research organization. **Gilead** identified remdesivir as a potential COVID-19 treatment. In April 2020, **positive data** emerged from the NIAID study of remdesivir. **Additional data** from a Phase 3 SIMPLE-severe study, and new analyses of the company's compassionate use program revealed remdesivir to improve recovery time and reduce mortality in COVID-19 patients. **Gilead** received an authorization from the US FDA for remdesivir in October 2020, regulatory approval by **Japan** in May, and conditional approval from the **EMA** in July. **Gilead** initiated a Phase 1a clinical study to evaluate the safety, tolerability and pharmacokinetics of an investigational, inhaled solution of remdesivir in healthy volunteers, for potential outpatient treatment of COVID-19. **Gilead** and the US FDA launched an open-label, single-arm phase 2/3 clinical trial to evaluate safety, tolerability, pharmacokinetics and efficacy of remdesivir in treating **paediatric patients** with moderate-to-severe COVID-19, across 30 sites in the US and Europe. **GSK** VIR-7831 – **GSK** and Vir Biotechnology Inc entered into a collaboration using Vir's proprietary monoclonal antibody platform technology to accelerate existing and identify new anti-viral antibodies. Vir Biotechnology and **GSK** announced that the first patient was dosed in a phase 2/3 study with VIR-7831 (GSK4182136) for the treatment of adult and adolescent COVID-19 patients who are at high risk of progressing to severe disease. For further developments see **GSK** under "Share real-time clinical trial data with governments, companies & the public." **Otilimab** – **GSK** initiated clinical trials of otilimab, an experimental rheumatoid arthritis drug, on patients suffering from severe pulmonary COVID-19 related disease, running from May to December 2020. For further developments see **GSK** under "Share real-time clinical trial data with governments, companies & the public." **Ipsen** donated financial resources to the Institut Pasteur that has devoted a portion of its research, since January, to understanding SARS-CoV-2 in terms of epidemiology, biological characteristics and pathogenicity. **Johnson & Johnson** partnered with BARDA to accelerate the discovery of potential COVID-19 treatments. **Johnson & Johnson**, in partnership with the Rega Institute for Medical Research, and the University of Leuven (Belgium), partnered to identify existing or new compounds with antiSARS-CoV-2 properties. **LEO Pharma** is participating in a pharma industry initiative supported by the EU Commission to identify active compounds and compile a sample library for testing with the potential of reducing lead time for treatment development for COVID-19. **Merck**'s compound M5049 is being clinically tested in a Phase II trial as a treatment for patients with Covid-19 pneumonia. **Merck** has donated a total of 300,000 units of interferon beta-1a (Rebif®) to the French Institut National de la Santé et de la Recherche Médicale (INSERM) for a trial, the World Health Organization (WHO) for use in their global Solidarity trial, and the US National Institute of Allergy and Infectious Diseases (NIAID) for their ACTT 3 trial in combination with remdesivir.
**Merck** is a member of the CARE (Corona Accelerated R&D in Europe) consortium to advance research and future treatments. Studies are also underway to investigate whether existing treatments can be used.

**MSD** MSD and Ridgeback Biotherapeutics LP entered into a collaboration agreement to develop EIDD-2801, an orally available antiviral candidate currently in early clinical development for the treatment of patients with COVID-19. The candidate antiviral, renamed to MK-4882, is currently in phase 2 clinical trials. **MSD** (also known as Merck in the US and Canada) announced on 27 October that it entered into a license agreement with the Medicines Patent Pool for molnupiravir to increase broad access in LMICs.

**Novartis** **Novartis** initiated a 450-person study in the US to determine if the malaria drug hydroxychloroquine can effectively treat COVID-19. **Novartis** discontinued the study due to feasibility of recruitment. **Novartis** initiated a Phase III clinical trial for canakinumab to treat cytokine release syndrome (CRS) in people with COVID-19 pneumonia. **Novartis** announced that interim data showed that the trial failed to meet its primary and secondary endpoint. **Novartis** initiated a Phase III clinical trial in collaboration with Incyte to evaluate the use of ruxolitinib for the treatment of CRS that can lead to life-threatening respiratory complications in patients with COVID-19. **Novartis** and Molecular Partners announced a collaboration in the form of an option and license agreement to develop, manufacture and commercialize Molecular Partners’ anti-COVID-19 DARPin® program, consisting of two therapeutic candidates, MP0420 and MP0423.

**Pfizer** **Pfizer** confirmed a lead compound and analogues as potent inhibitors of a SARS-CoV-2 protease. Preliminary data suggest this lead protease inhibitor shows antiviral activity against SARS-CoV-2. **Pfizer** will perform pre-clinical confirmatory studies. **Pfizer** shared in vitro and clinical data regarding azithromycin to facilitate the use of azithromycin in research on COVID-19. **Pfizer** and the Liverpool School of Tropical Medicine's Respiratory Infection Clinical Research Group launched two studies to provide insights on the interaction between S. pneumoniae and SARS-CoV-2. **Tofacitinib** – **Pfizer** supported an independent Phase 2 investigator-initiated study for the use of tofacitinib in patients with SARS-CoV-2 with a grant. **Pfizer** and The Academic Research Organization from the Hospital Israelita Albert Einstein announced that the *New England Journal of Medicine* has published positive findings from the STOP-COVID study (NCT04469114) evaluating the efficacy and safety of oral Janus kinase inhibitor tofacitinib in 289 hospitalized adult patients with COVID-19 pneumonia who were not on ventilation. The study met its primary endpoint.

**Roche** **Tocilizumab** – Roche's tocilizumab was approved by China on March 5 to treat COVID-19 patients with lung complications and subsequently entered phase III clinical trials in the REMDACA and COVACTA clinical trials. On 29 July, **Roche** announced tocilizumab did not meet its primary and secondary endpoints of improved clinical status and mortality in COVID-19 associated pneumonia. **Roche** initiated a phase 3 clinical trial of tocilizumab plus remdesivir in hospitalised patients with severe COVID-19 pneumonia. Announced on 16 August 2021, the US FDA has granted a EUA for Actemra/RoActemra (tocilizumab) for severe or critical COVID-19 patients above the age of 2, and it is now included in the WHO Therapeutics and COVID-19 living guideline. **Roche** together with Regeneron are also developing and producing Ronapreve, a combination of two antibodies against the coronavirus, which has been granted emergency use authorisation or approval for temporary use in the EU, US, India, Switzerland, Canada, Japan, and the UK.
Roche and Atea Pharmaceuticals announced they are joining forces in the fight against COVID-19 to develop, manufacture and distribute AT-527, Atea's investigational oral and direct-acting antiviral, to people around the globe. AT-527 is being evaluated in the global Phase 3 trial for outpatients, a global Phase 2 study for hospitalized patients with moderate COVID-19, and a Phase 2 virology study in patients with mild or moderate COVID-19 in an outpatient setting. In addition, a Phase 3 long-term follow-on study, will evaluate the impact of prior administration of AT-527 in long COVID.

Casirivimab-imdevimab cocktail – Regeneron announced that the antibody cocktail casirivimab and imdevimab administered together, received EUA from the US FDA. Regeneron is responsible for the development and distribution of the treatment in the US, and Roche for development and distribution outside the US. Roche announced the EMA issued a scientific opinion supporting the use of the investigational antibody cocktail, casirivimab and imdevimab, as a treatment option for patients with confirmed COVID-19 who do not require oxygen supplementation and who are at high risk of progressing to severe COVID-19. The US FDA expanded emergency authorized use of Regeneron’s REGEN-COV, the antibody cocktail casirivimab and imdevimab, for post-exposure prophylaxis in certain people exposed to a SARS-CoV-2 infected individual, or who are at high risk of exposure to an infected individual in an institutional setting. On 20 August 2021, the UK granted a CMA for Regeneron’s casirivimab and imdevimab antibody cocktail to prevent and treat COVID-19.

Sanofi Sarilumab – Sanofi entered into a partnership with Regeneron Pharmaceuticals to evaluate the arthritis drug sarilumab in patients hospitalized with severe COVID-19. The US phase 3 clinical trial in COVID-19 patients requiring mechanical ventilation did not meet its primary and key secondary endpoints, and was subsequently halted.

Shionogi identified various number of promising lead compounds against SARS-CoV-2 through a collaborative research effort with the Hokkaido University Research Center for Zoonosis Control. The company aims to start clinical trials in FY2020. On 26 July 2021, Shionogi announced that it initiated a Japanese Phase 1 clinical trial of the therapeutic agent S-217622 as an orally administered antiviral drug for COVID-19. The first dose was administered successfully on July 22. No safety concerns were identified after the first dose.

Sumitomo Dainippon Pharma donated 10 million yen to the Kitasato Institute’s Project for COVID-19 to identify clinical candidates for the treatment of COVID-19 through a large-scale screening of approved pharmaceuticals.

Takeda and CSL Group formed the CoVlg-19 Plasma Alliance with other leading global plasma companies to develop a potential plasma-derived therapy for treating COVID-19. The CoVlg-19 Plasma Alliance expanded to comprise 10 companies and attracted the support of major companies and organizations. In parallel, the Alliance confirmed it will work with NIAID to test the safety, tolerability and efficacy of the hyperimmune therapy in adult patients with COVID-19. The CoVlg-19 Plasma Alliance announced that the Phase 3 ITAC clinical trial sponsored and funded by the NNIAID, part of the NIH, did not meet its endpoints. Takeda, and partners of the COVID R&D Alliance AbbVie and Amgen, announced the start of the I-SPY COVID trial evaluating the efficacy of cenicriviroc, apremilast, and icatibant in hospitalized COVID-19 patients who require high-flow oxygen.

UCB is actively looking through its range of products to determine if any products may be relevant for COVID-19.

In the US, UCB is working with the Seattle Structural Genomics Center for Infectious Disease to identify crystal structures of SARS-CoV-2 proteins. In the UK, the company partnered with Diamond Light Source and the University of
Oxford to design inhibitors of SARS-CoV-2’s main protease for treatment of COVID-19 patients.

“Open Access” data-sharing channels are key to securing a response capacity as we have seen with influenza networks. The speed with which researchers have understood this novel strain of virus and got therapeutics and vaccines into clinical trials is unprecedented. The Global Initiative on Sharing All Influenza Data (GISAID), an open access platform part-funded by the private sector, played a critical role in sharing the first genome sequences of the novel coronavirus – a vital element in speeding up information sharing among scientists and public health authorities.

IFPMA & EFPIA support the EMA’s initiative to implement exceptional transparency measures that are targeting regulatory activities for the assessment and approval of medicines and vaccines for COVID-19. The biopharmaceutical industry represented by IFPMA and EFPIA encourage other national regulatory authorities to follow the EMA’s example.

In less than a year, several vaccine candidates have concluded or are in advanced Phase III clinical trials with encouraging results. On 31 December 2020, Pfizer and BioNTech announced the granting of a temporary EUL for their COVID-19 mRNA vaccine (BNT162b2) after thorough review of clinical trial data. On 15 February 2020, WHO granted temporary EUL to AstraZeneca’s COVID-19 vaccine (AZD1222). On 12 March 2021, WHO granted EUL to Johnson & Johnson’s COVID-19 vaccine Ad26.COV2.S. All three vaccines are part of the COVAX roll-out.

**AbbVie** worked closely with European health authorities, US FDA, US CDC, NIH, and BARDA to research the effectiveness of lopinavir/ritonavir in clinical studies. Trials were interrupted immediately after no reduction in mortality of hospitalized COVID-19 patients was noticed.

**Amgen**’s subsidiary deCODE genetics, Iceland’s Directorate of Health and the National University Hospital published a population-based study of the early spread of SARS-Cov-2 in Iceland’s population in the *NEJM*. Amgen, together with AstraZeneca, Eli Lilly, Roche’s Genentech subsidiary, GSK and AbCellera, has been allowed to share manufacturing information that could help speed up coronavirus antibody production by the US Department of Justice, since 23 July 2020.

**Astellas** is providing compounds in response to a request from the government to cooperate in the “Basic Screening Plan for Drugs for Coronavirus Disease”. Astellas is also responding to requests from EFPIA and IMI to cooperate in “Activities Aimed at Developing Drugs for the Novel Virus” and providing consultation on countermeasures.

**AstraZeneca** is sharing manufacturing information concerning COVID-19 antibody production with other companies.
AZD7442 treatment – AstraZeneca announced the advancement of its Long-Acting AntiBody (LAAB) combination, AZD7442, into two Phase III clinical trials with more than 6,000 participants at sites in and outside the US. AstraZeneca announced results from the STORM CHASER trial assessing the safety and efficacy of AZD7442. The trial did not meet the primary endpoint of post-exposure prevention of symptomatic COVID-19 with AZD7442 compared to placebo.

On 20 August 2021, AstraZeneca announced AZD7442 reduced the risk of developing symptomatic COVID-19 by 77% compared to placebo, results from the PROVENT Phase III pre-exposure prophylaxis trial.

On 11 October 2021, AstraZeneca announced positive high-level results from the TACKLE Phase III COVID-19 treatment trial showed AstraZeneca’s AZD7442 achieved a statistically significant reduction in severe COVID-19 or death compared to placebo in non-hospitalised patients with mild-to-moderate symptomatic COVID-19.

On 8 November, AstraZeneca announced that new data from the AZD7442 COVID-19 PROVENT prevention and TACKLE outpatient treatment Phase III trials both showed robust efficacy from a one-time intramuscular dose of the long-acting antibody combination. In an analysis of the ongoing PROVENT trial evaluating a median six months of participant follow-up, one 300mg IM dose of AZD7442 reduced the risk of developing symptomatic COVID-19 compared to placebo by 83%.

Acalabrutinib – Results published in Science Immunology for acalabrutinib initially showed promising clinical improvements in hospitalised COVID-19 patients with respiratory symptoms, but did not meet the primary efficacy endpoint in the CALAVI Phase II trials.

AZD1222 vaccine – AstraZeneca and partner Oxford University have co-developed their COVID-19 vaccine AZD1222. Early interim results, published in The Lancet on 20 July 2020, showed that AZD1222 was tolerated and generated a robust immune response against SARS-CoV-2 in all evaluated participants. In November 2020, AstraZeneca announced that its AZD1222 vaccine was highly effective in preventing COVID-19, the primary efficacy endpoint, and no hospitalisations or severe cases of the disease were reported in participants receiving the vaccine. Positive high-level results showed the vaccine had efficacy of up to 90%. Results of an interim analysis of the Phase III programme conducted by Oxford University with AZD1222, peer-reviewed and published in The Lancet, demonstrated that the vaccine is safe and effective at preventing symptomatic COVID-19 and that it protects against severe disease and hospitalisation.

AstraZeneca published the full protocol for its COVID-19 vaccine study. The primary analysis of the Phase III clinical trials from the UK, Brazil and South Africa, published as a preprint in The Lancet confirmed that the vaccine is safe and effective at preventing COVID-19, with no severe cases and no hospitalisations, more than 22 days after the first dose. AstraZeneca’s COVID-19 vaccine has been approved for EUA in the UK on 30 December 2020 and has been granted EUA in India, Argentina, Dominican Republic, El Salvador, Mexico and Morocco for the active immunisation of adults by 6 January 2021.

AstraZeneca’s COVID-19 vaccine has been granted a CMA in the EU for individuals 18 years of age and older, by 29 January 2021.

AstraZeneca’s COVID-19 vaccine has been granted EUL by WHO in individuals 18 years of age and older, including those over 65, on 15 February 2021. On 14 March 2021, AstraZeneca provided an update on the safety of its COVID-19 Vaccine. A careful review of all available safety data of more than 17 million people vaccinated in the EU and UK showed no evidence of an increased risk of pulmonary embolism, deep vein thrombosis (DVT) or thrombocytopenia, in any defined age group, gender, batch or in any particular country. WHO considers that the benefits of the AstraZeneca vaccine outweigh its risks and recommends that vaccinations continue. On 18 March 2021, AstraZeneca announced that the MHRA and EMA
reaffirmed that the benefits of its COVID-19 vaccine continue to outweigh the risks. The AstraZeneca US Phase III trial of AZD1222 demonstrated statistically significant vaccine efficacy of 79% at preventing symptomatic COVID-19 and 100% efficacy at preventing severe disease and hospitalisation. The numbers published were based on a pre-specified interim analysis with a data cut-off of 17 February. AstraZeneca has reviewed the preliminary assessment of the primary analysis and the results were consistent with the interim analysis. Positive high-level results from the primary analysis of the Phase III trial of AZD1222 in the US confirmed vaccine efficacy consistent with the pre-specified interim analysis announced on Monday 22 March 2021. AstraZeneca’s COVID-19 vaccine, Vaxzevria (ChAdOx1-S [Recombinant]), formerly AZD1222, was granted a special approval for emergency use in Japan for active immunisation of individuals aged 18 years and older, to prevent COVID-19 caused by SARS-CoV-2.

Data from PHE demonstrated COVID-19 Vaccine AstraZeneca offers high levels of protection against the Delta variant (B.1.617.2; formerly the ‘Indian’ variant). Real world data from PHE, published as a pre-print, demonstrated two doses of COVID-19 Vaccine AstraZeneca are 92% effective against hospitalization due to the Delta variant and showed no deaths among those vaccinated. The vaccine also showed a high level of effectiveness against the Alpha variant (B.1.1.7; formerly the ‘Kent’ variant) with an 86% reduction of hospitalizations and no deaths reported. The data suggest that vaccine effectiveness against milder symptomatic disease, although significant, was lower. Vaccine effectiveness against symptomatic disease was 74% against the Alpha variant and 64% against the Delta variant.

The data published in The Lancet suggests that rates of the very rare clotting disorder, thrombosis with thrombocytopenia syndrome (TTS), following a second dose of Vaxzevria are comparable to the background rate in an unvaccinated population. In a large real-world study, data published as a pre-print on The Lancet server from over one million individuals assessed the incidence rates of blood clotting disorders of thromboembolism and thrombocytopenia, including the very rare thrombosis with thrombocytopenia (TTS) following vaccination with an mRNA vaccine or Vaxzevria, and compared them with expected rates in a general population and in people with COVID-19. Incidence of very rare thromboembolic events was far lower than in people diagnosed with COVID-19 infection.

Dapagliflozin – AstraZeneca and Saint Luke’s Mid America Heart Institute announced results for the DARE-19 Phase III trial using dapagliflozin to treat hospitalized COVID-19 patients with a risk of developing serious complications. The trial did not achieve statistical significance for the primary endpoint.

Evusheld – AstraZeneca announced that Evusheld (tixagevimab co-packaged with cilgavimab), a long-acting antibody (LAAB) combination, has received EUA in the US for the pre-exposure prophylaxis (prevention) of COVID-19.

Bayer Canada partnered with the Population Health Research Institute to launch a major clinical research program to evaluate the safety and efficacy of different combination therapies including Bayer’s chloroquine and interferon beta-1b.

Biogen, Broad Institute of MIT and Harvard and Partners HealthCare announced a consortium to build and share a COVID-19 biobank to help scientists study a large collection of de-identified biological and medical data, advancing knowledge and the search for potential vaccines and treatments. On 13 October, Biogen announced that results of a new analysis of immune response to the COVID-19 vaccine among people with MS. The results, which demonstrate that patients treated with Biogen’s portfolio of MS therapies mount an effective antibody response to COVID-19 vaccination, would be presented at the 37th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) virtual meeting, October 13-15, 2021.

Boehringer Ingelheim supports scientists worldwide with its open innovation portal opnMe.com, which offers 6 anti-viral compounds out of 43 high quality pharmacological tool compounds at no cost for testing of research hypotheses.
Bristol-Myers Squibb identified 1,000 compounds which it made available to collaborators for screening for potential COVID-19 treatments.

Chugai announced results from Phase III J-COVACTA clinical study in Japan for the humanized anti-human IL-6 receptor monoclonal antibody “Actemra® Intravenous Infusion 80 mg, 200 mg, and 400 mg” in patients with COVID-19 associated pneumonia.

Chugai announced that it filed a new drug application with the MHLW for the antibody cocktail casirivimab and imdevimab for the treatment of COVID-19. The application would seek the Special Approval for Emergency.

Chugai announced that it obtained approval from the MHLW for the anti-SARS-CoV-2 monoclonal antibody RONAPREVE® for the additional indication of the prevention of symptomatic SARS-CoV-2 infection.

On 16 December 2021, Chugai announced that the company would discontinue its development of AT-527, in Japan.

On 13 December 2021, Chugai announced that it filed regulatory applications with the MHLW for the humanized anti-human IL-6 receptor monoclonal antibody, “Actemra® Intravenous Infusion 80 mg, 200 mg, and 400 mg” for the treatment of COVID-19 pneumonia.

Daiichi Sankyo announced that it has made its shipment of VAXZEVRIATM Intramuscular Injection developed by AstraZeneca. This shipment of the COVID-19 vaccine would be provided to Southeast Asian countries and other regions through the Japanese Government.

On 21 October 2021, Daiichi Sankyo announced the progress of development of DS-5670, an mRNA vaccine in Japan, being evaluated against COVID-19, including positive results from a phase 1/2 clinical trial. On 17 November 2021, Daiichi Sankyo announced that the first patient has been dosed in a phase 2 trial in Japan of DS-5670.

Eisai announced enrollment of the first patient in the immune modulation domain of REMAP-COVID, a sub-study of REMAP-CAP that tests multiple interventions for the treatment of patients hospitalized with COVID-19. Amgen’s apremilast and Eisai’s investigational eritoran would be evaluated as potential therapeutice agents.

Eli Lilly is sharing manufacturing information concerning COVID-19 antibody production with other companies. Please see previous entries on Amgen for more info.

Baricitinib – Eli Lilly and Incyte announced positive early data on baricitinib emerging from the ACTT-2 trial sponsored by NIAID and shared additional data on its effectiveness in combination with remdesivir, reducing patient recovery time and improving clinical outcomes. US FDA granted EUA to Eli Lilly and Incyte announced distribution of baricitinib in combination with remdesivir in hospitalized patients with COVID-19.

Eli Lilly and Incyte announced results of COV-BARRIER, a Phase 3 study evaluating baricitinib plus standard of care (SoC) versus placebo plus SoC. The trial did not meet statistical significance on the primary endpoint. Both companies announced on 3 August 2021 that a sub-study had shown that baricitinib reduced deaths among COVID-19 patients receiving mechanical ventilation or ECMO (extracorporeal membrane oxygenation).

Bamlanivimab – Eli Lilly announced that combination therapy of two SARS-CoV-2 neutralizing antibodies (LY-CoV555 and LY-CoV016) reduced viral load, symptoms and hospitalizations in its BLAZE-1 clinical trial. The US FDA granted EUA to Eli Lilly’s bamlanivimab (LY-CoV555) for treatment of mild to moderate COVID-19 in adults and pediatric patients from age 12.

Eli Lilly announced that bamlanivimab (LY-CoV555) significantly reduced the risk of contracting symptomatic COVID-19 among residents and staff of long-term care facilities.

Eli Lilly has requested the US FDA to revoke the EUA for bamlanivimab (LY-CoV555). Lilly made this request due to the
evolving variant landscape and availability of the bamlanivimab and etesevimab cocktail.

**Bamlanivimab combination treatment** – Eli Lilly announced further data from its BLAZE-1 Phase 3 study, demonstrating bamlanivimab (LY-CoV555) and etesevimab (LY-CoV016) together significantly reduced COVID-19 related hospitalizations and deaths in high-risk COVID-19 patients.

Eli Lilly announced the US FDA granting EUA for the combination treatment of bamlanivimab (LY-CoV555) and etesevimab (LY-CoV016).

Eli Lilly, Vir Biotechnology, and GSK announced positive topline data from the expanded Phase 2 BLAZE-4 trial study evaluating bamlanivimab with VIR-7831 in low-risk adults with COVID-19.

Gilead identified remdesivir as a potential COVID-19 treatment. In April 2020, positive data emerged from the NIAID study of remdesivir. Additional data from a Phase 3 SIMPLE-severe study, and new analyses of the company’s compassionate use program revealed remdesivir to improve recovery time and reduce mortality in COVID-19 patients. Further results demonstrate that treatment with remdesivir result in a faster time to recovery than previously reported.

Gilead announced that the US FDA has approved the antiviral drug Veklury® (remdesivir) for the treatment of patients with COVID-19 requiring hospitalization.

Gilead announced positive data from three retrospective studies of the real-world treatment of patients hospitalized with COVID-19, showing that patients who received Veklury treatment had significantly lower risk for mortality compared with matched controls.

On 22 September 2021, Gilead announced positive results from a Phase 3 randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of a three-day course of Veklury® (remdesivir) for intravenous use for the treatment of COVID-19 in non-hospitalized patients at high risk for disease progression.

On 01 December 2021, Gilead Sciences announced preliminary studies demonstrating that Remdesivir is active against the Omicron variant. The company will conduct laboratory testing to confirm this analysis of additional genetic sequences as they become available.

**GSK** is sharing manufacturing information concerning COVID-19 antibody production with other companies. Please see previous entries on Amgen for more info.

**VIR-7831** – GSK and Vir Biotechnology announced the global expansion to Phase 3 of the COMET-ICE study evaluating VIR-7831 in COVID-19 patients at high risk of hospitalisation. The two companies also announced a Phase 1b/2a clinical trial of VIR-7832 through the UK-based AGILE initiative in patients with mild to moderate COVID-19.

In April 2021, both companies announced VIR-7831 demonstrated an 85% reduction in hospitalization or death. GSK and Vir continue discussions with global regulators (EMA, US FDA, Australian TGA) to make VIR-7831 available to patients with COVID-19 through an EUA, based on clinical trial data. In May 2021, GSK and Vir Biotechnology announced the U.S. FDA granted an EUA for sotrovimab (previously VIR-7831).

Eli Lilly, Vir Biotechnology, and GSK also announced positive topline data from the expanded Phase 2 BLAZE-4 trial studying evaluating bamlanivimab with VIR-7831 in low-risk adults with COVID-19.

GSK and Vir Biotechnology announced that the EMA CHMP issued a positive scientific opinion following the referral of sotrovimab to the CHMP. The opinion related to the use of sotrovimab for the treatment of adults and adolescents (aged 12 years and over and weighing at least 40 kg) with COVID-19 who do not require oxygen supplementation and who are at risk of progressing to severe COVID-19.

GSK and Vir Biotechnology announced final, confirmatory results from the Phase 3 COMET-ICE trial demonstrating that sotrovimab significantly reduced the risk of hospitalisation or death among high-risk adult outpatients with mild-to-moderate COVID-19.

On 12 November 2021, GlaxoSmithKline and Vir Biotechnology announced headline data from the randomised, multi-centre, open-label COMET-TAIL Phase III trial, which achieved its primary endpoint, demonstrating intramuscular administration of sotrovimab was non-inferior to intravenous administration for the early treatment of mild-to-
moderate COVID-19 in high-risk, non-hospitalised adults and adolescents (12 years of age and older).

On 02 December 2021, GSK and Vir Biotechnology announced an update to bioRxiv, a preprint server, with preclinical data demonstrating that sotrovimab, an investigational monoclonal antibody, retains activity against key mutations of the new Omicron SARS-CoV-2 variant (B.1.1.529), including those found in the binding site of sotrovimab. On 17 December 2021, GSK and Vir Biotechnology announced that the EC granted marketing authorisation to Xevudy (sotrovimab) for the early treatment of COVID-19.

**Otilimab** – Results from GSK’s phase 2 trials suggest a potentially important clinical benefit for its investigational monoclonal antibody otilimab in a pre-defined sub-group of high-risk patients. GSK has amended and expanded the OSCAR study to confirm potentially significant findings.

**Sanofi-GSK vaccine** – Sanofi and GSK announced the initiation of a Phase 2 study with 720 volunteers aged 18 and over to select the most appropriate antigen dosage for Phase 3 evaluation of their adjuvanted recombinant protein COVID-19 vaccine candidate. The Sanofi and GSK adjuvanted recombinant COVID-19 vaccine candidate achieved strong rates of neutralizing antibody responses. A global pivotal Phase 3 study started in May 2021, to assess the safety, efficacy and immunogenicity.

On 15 December 2021, GSK and Sanofi announced that a single booster dose of their recombinant adjuvanted COVID-19 vaccine candidate delivered consistently strong immune responses.

**Adjuvant vaccine technology** – Medicago and GSK announced Phase 3 clinical trials of Medicago’s plant-derived COVID-19 vaccine candidate in combination with GSK’s pandemic adjuvant, as part of GSK’s Phase 2/3 study. For more developments on Sanofi’s vaccine technology see “Develop and test vaccine candidates for COVID-19.”

Medicago and GSK announced positive efficacy and safety results from the global Phase 3 placebo-controlled efficacy study of Medicago’s plant-based COVID-19 vaccine candidate in combination with GSK’s pandemic adjuvant, conducted in over 24,000 subjects (adults 18 years and above) across six countries.

**CureVac-GSK vaccine** – A preclinical study provides evidence for strongly improved immune responses with second-generation mRNA backbone jointly developed by CureVac and GSK (CV2CoV) compared to CureVac’s first-generation mRNA backbone.

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Johnson & Johnson

**Ad26.COV2.S vaccine** – Johnson & Johnson and BARDA partnered in August 2020 for phase 1/2a first-in-human clinical trials for a vaccine candidate, announcing they selected a lead COVID-19 vaccine candidate, Ad26.COV2-S, in March 2020. Results from pre-clinical studies showed a robust immune response in non-human primates against SARS-CoV-2. Following positive interim results, from Phase 1/2a clinical study, a Phase 3 clinical trial commenced in September 2020, and enrolled up to 60,000 volunteers across three continents in order to study the safety and efficacy of a single vaccine dose versus placebo. In addition to the single-dose regimen ENSEMBLE study, Janssen also initiated a two-dose regimen ENSEMBLE 2 trial that would study safety and efficacy in up to 30,000 participants worldwide. On 13 January 2021, interim Phase 1/2a data were published in the New England Journal of Medicine demonstrating that Johnson & Johnson’s single-dose investigational COVID-19 vaccine candidate provided an immune response in participants aged 18-55 years.

Johnson & Johnson announced on 29 January 2021 efficacy and safety data from the Phase 3 ENSEMBLE clinical trial, demonstrating that the investigational single-dose COVID-19 vaccine met all primary and key secondary endpoints. Among all participants from different geographies and including those infected with an emerging viral variant, the COVID-19 vaccine candidate was 66% effective overall in preventing moderate to severe COVID-19, 28 days after vaccination. Johnson & Johnson’s single-dose COVID-19 vaccine was granted EUA by the US FDA to prevent COVID-19 in individuals aged 18 years and older. The European Commission granted CMA for J&J’s COVID-19 vaccine to prevent COVID-19 in individuals aged 18 years and older. Johnson & Johnson welcomed the interim recommendation by the WHO’s SAGE on Immunization supporting the use of its single-shot COVID-19 vaccine in persons aged 18 years and above. Johnson &
Johnson has submitted a request for WHO EUL on 19 February 2021. Following rigorous evaluation of data relating to a very rare adverse event, the US FDA and US CDC recommended the single-shot vaccine is safe for use and resuming immunization in the earlier designated age-group. The US CDC ACIP convened to consider reports of an extremely rare disorder involving blood clots in combination with low platelets observed in a small number of individuals following vaccination with Ad26.COV2.S. The US CDC and FDA recommended a pause in the use of the vaccine. Johnson & Johnson made the decision to proactively delay the rollout of its vaccine in Europe and pause vaccinations in all Janssen COVID-19 vaccine clinical trials while they update guidance for investigators and participants. Johnson & Johnson announced data that demonstrated its single-shot COVID-19 vaccine generated strong, persistent activity against the rapidly spreading Delta variant and other highly prevalent SARS-CoV-2 viral variants. Johnson & Johnson confirmed that the U.S. FDA extended the shelf life for the Johnson & Johnson single-shot COVID-19 vaccine to six months. The decision was based on data from ongoing stability assessment studies, which demonstrated the vaccine is stable at six months when refrigerated at temperatures of 36 – 46 degrees Fahrenheit (2 – 8 degrees Celsius). Johnson & Johnson announced data supporting the use of its COVID-19 vaccine as a booster shot for people previously vaccinated with the single-shot vaccine. It demonstrated strong durability through eight months after immunization. Johnson & Johnson announced it has submitted data to the U.S. FDA to support use of a booster shot of the Johnson & Johnson COVID-19 vaccine in individuals 18 years of age and older. On 20 October 2021, Johnson & Johnson announced the U.S. FDA has issued EUA for a booster dose of the Johnson & Johnson COVID-19 vaccine for adults aged 18 and older at least two months following primary vaccination with single-shot Johnson & Johnson COVID-19 vaccine; and for eligible individuals who received a different authorized or approved COVID-19 vaccine. On 21 October 2021, Johnson & Johnson announced that the U.S. CDC ACIP has recommended its COVID-19 vaccine as a booster for all eligible individuals who receive an authorized COVID-19 vaccine. On 24 November 2021, Johnson & Johnson announced that Health Canada had approved its single-shot COVID-19 vaccine to prevent COVID-19 in individuals 18 years of age and older. J&J announced that it was testing blood serum from participants in completed and ongoing booster studies to look for neutralizing activity against the Omicron variant. In addition, J&J was pursuing an Omicron-specific variant vaccine and will progress it as needed. Merck's Life Science business sector participates in the MIT Pandemic Response CoLab, which will help individuals and groups work together to solve practical problems created by the Covid-19 pandemic. By leveraging an open online collaboration platform, the CoLab mobilizes innovators, communities, businesses, and others to develop actionable solutions to real problems. Merck awarded the Future Insight Prize 2019 for outstanding research in the field of Pandemic Preparedness to Pardis Sabeti of Harvard University and the Broad Institute and to James Crowe of Vanderbilt University Medical Center. The awarded grants support Sabeti’s and Crowe's research on new diagnostics and treatment options for Covid-19. Merck offered a research grant of up to € 500,000 per year for three consecutive years to external research teams working on pandemic preparedness projects in 2020. Moderna On 5 August and 12 August 2021, Moderna announced data on the durability of its COVID-19 vaccine mRNA-1273, generating neutralizing antibodies for at least six months after receiving the second dose, including against variants of
Moderna booster candidates demonstrate robust antibody responses to COVID-19 variants of concern, including Gamma (P.1); Beta (B.1.351); and Delta (B.1.617.2), in Phase 2 studies. The booster candidates included mRNA-1273, investigational mRNA-1273.351, and investigational mRNA-1273.211. Moderna announced it initiated its submission to the U.S. FDA and the EMA for the evaluation of a booster dose of the Moderna COVID-19 vaccine (mRNA-1273) at the 50 µg dose level.

A final blinded analysis of a study on Moderna’s COVID-19 vaccine shows 93% efficacy, which remains durable six months after the second dose. Moderna confirmed that the U.S. FDA VRBPAC recommended that the FDA grant an EUA for a booster dose of the Moderna COVID-19 vaccine (mRNA-1273) at the 50 µg dose level for people aged 65 and older; people aged 18 to 64 who are at high risk of severe COVID-19; and people aged 18 to 64 whose exposure to COVID-19 puts them at risk for COVID-19 complications or severe illness. The positive vote was unanimous with 19 VRBPAC members recommending EUA. The booster dose is to be administered at least six months after completion of the primary series. Moderna announced that the U.S. CDC ACIP unanimously voted to recommend the use of a booster dose of the Moderna COVID-19 vaccine.

Moderna announced that the EMA CHMP concluded that a booster dose of Spikevax, the Company's vaccine against COVID-19, at the 50 µg dose level may be considered in people aged 18 years and older at least six months after completion of the primary series.

On 19 November 2021, Moderna announced that the U.S. FDA extended the emergency use authorization of a booster dose of the Moderna COVID-19 vaccine at the 50 µg dose level to all adults aged 18 and older. On 19 November 2021, Moderna announced that the U.S. CDC ACIP voted to recommend the use of a booster dose of the Moderna COVID-19 vaccine at the 50 µg dose level for people aged 18 and older under the EUA issued by the U.S. FDA.

On 26 November 2021, Moderna announced updates to its strategy to address SARS-CoV-2 variants of concern, given the emergence of the B.1.1.529 (Omicron) variant. First, Moderna had already tested a higher dose booster of mRNA-1273 (100 µg) in healthy adults. Second, Moderna was already studying two multi-valent booster candidates in the clinic that were designed to anticipate mutations such as those that have emerged in the Omicron variant. Third, Moderna would rapidly advance an Omicron-specific booster candidate (mRNA-1273.529).

On 20 December 2021, Moderna announced preliminary neutralizing antibody data against the Omicron variant following the Company's booster candidates at 50 µg and 100 µg dose levels. The currently authorized 50 µg booster of mRNA-1273 increased neutralizing antibody levels against Omicron approximately 37-fold compared to pre-boost levels and a 100 µg dose of mRNA-1273 increased neutralizing antibody levels approximately 83-fold compared to pre-boost levels.

MSD MSD, BARDA and the US-based ISB are collaborating to investigate and define the molecular mechanisms of SARS-CoV-2, COVID-19 and identifying targets for medicines and vaccines. Findings will be made available to the worldwide scientific and biomedical community.

MSD, known as Merck in the US and Canada, announced the discontinuation of development of MK-7110 (formerly known as CD24Fc) for the treatment of hospitalized patients with COVID-19.

MSD, known as Merck inside the United States and Canada, and Ridgeback Biotherapeutics announced the initiation of the Phase 3 MOVE-AHEAD clinical trial to evaluate molnupiravir, an investigational oral antiviral therapeutic, for the prevention of COVID-19 infection.

Molnupiravir – MSD and Ridgeback Biotherapeutics announced that preliminary results from Ridgeback's Phase 2a clinical trial to evaluate the safety, tolerability, and efficacy of molnupiravir (EIDD-2801/MK-4482), an investigational oral antiviral agent, showed that viral load decreased faster in patients receiving molnupiravir compared to patients
receiving a placebo. 

MSD, known as Merck in the US and Canada, and Ridgeback Biotherapeutics announced that clinical trials for molnupiravir (MK-4482/EIDD-2801), an investigational orally antiviral therapeutic, would not continue to Phase 3 trials in hospitalized patients. Clinical trials would proceed to Phase 3 clinical trials for non-hospitalized patients.

MSD, known as Merck in the US and Canada, and Ridgeback Biotherapeutics announced the presentation of previously announced Phase 2 interim results from two Phase 2/3 clinical trials of molnupiravir (MK-4482/EIDD-2801). The data were presented during the late-breaking clinical trials session at the ECCMID. The Phase 3 portion of the global MOVe-OUT trial studying molnupiravir in non-hospitalized adult patients with laboratory-confirmed COVID-19 and at least one risk factor associated with poor disease outcomes was underway. In addition, Merck planned to initiate a clinical program to evaluate molnupiravir for post-exposure prophylaxis in the second half of 2021.

MSD, known as Merck in the US and Canada, and Ridgeback Biotherapeutics announced that molnupiravir (MK-4482, EIDD-2801), significantly reduced the risk of hospitalization or death at a planned interim analysis of the Phase 3 MOVe-OUT trial in at risk, non-hospitalized adult patients with mild-to-moderate COVID-19.

MSD, known as Merck in the US and Canada, and Ridgeback Biotherapeutics announced that MSD submitted an EUA application to the U.S. FDA for molnupiravir, for the treatment of mild-to-moderate COVID-19 in adults who are at risk for progressing to severe COVID-19 and/or hospitalization.

MSD, known as Merck in the US and Canada, and Ridgeback Biotherapeutics announced that the EMA initiated a rolling review for molnupiravir.

On 4 November, MSD, known as Merck in the United States and Canada, and Ridgeback Biotherapeutics announced that the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) has granted authorization in the United Kingdom (U.K.) for molnupiravir (MK-4482, EIDD-2801)

On 17 November 2021, MSD, known as Merck in the United States and Canada, and Ridgeback Biotherapeutics announced that new Phase 3 data for molnupiravir, an investigational oral COVID-19 antiviral medicine, would be presented as a late-breaking poster (#LB-5319) at the ASTMH 2021 Annual Meeting taking place virtually from Nov. 17-21.

On 30 November 2021, MSD, known as Merck in the United States and Canada, and Ridgeback Biotherapeutics announced that the conclusion of the U.S. FDA AMDAC regarding the Emergency Use Authorization (EUA) application for molnupiravir (MK-4482, EIDD-2801), voted 13-10 that the known and potential benefits of molnupiravir outweigh its known and potential risks for the treatment of mild to moderate COVID-19 in high risk adult patients who are within five days of symptom onset.

On 26 November 2021, MSD, known as Merck in the US and Canada, and Ridgeback Biotherapeutics provided an update on the MOVe-OUT study of molnupiravir (MK-4482, EIDD-2801). In this study population, molnupiravir reduced the risk of hospitalization or death.

Novartis announced that the Phase III RUXCOVID study evaluating ruxolitinib on top of standard of care (SoC) therapy compared to SoC treatment alone in patients with COVID-19 did not meet its primary endpoint

Molecular Partners, a clinical-stage biotech company that is developing a new class of custom-built protein drugs known as DARPin® therapeutics, and its collaborator Novartis, announced initial results from its phase 1 study of its first tri-specific COVID-19 antiviral treatment, ensolvibep (MP0420), in healthy volunteers. The initial findings show ensolvibep to be safe and well tolerated with no significant adverse events.

Novartis and Molecular Partners announced the start of the clinical trial EMPATHY, a Phase 2 and 3 study, to explore the use of its novel DARPin therapeutic candidate ensolvibep (MP0420) for the treatment of COVID-19.
Novavax announced that NVX-CoV2373, its recombinant nanoparticle protein-based COVID-19 vaccine, demonstrated 100% protection against moderate and severe disease, 90.4% efficacy overall, and met the primary endpoint in its PREVENT-19 pivotal Phase 3 trial. The study enrolled 29,960 participants across 119 sites in the U.S. and Mexico to evaluate efficacy, safety and immunogenicity, with an emphasis on recruiting a representative population of communities and demographic groups most impacted by the disease. Novavax’s PREVENT-19 vaccine trial in the US and Mexico has demonstrated 100% protection against moderate and severe disease and 90.4% efficacy overall in a Phase 3 trial. Preliminary studies of a NanoFlu™/NVX-CoV2373 combination vaccine (qNIV/CoV2373) targeting both influenza and SARS-CoV-2, indicate positive results. On 5 August 2021, Novavax announced preliminary data demonstrating that a single booster dose of its recombinant nanoparticle protein-based COVID-19 vaccine with Matrix-M™ adjuvant, NVX-CoV2373, given six months after an initial two-dose regimen, elicited a significant immune response, including against the Delta (B.1.617.2) variant. On 2 December 2021, Novavax announced it was evaluating its vaccine against the Omicron variant, and had initiated development of an Omicron-specific vaccine construct. On 17 December 2021, Novavax and SII, announced that the WHO granted EUL for NVX-CoV2373, Novavax' recombinant nanoparticle protein-based COVID-19 vaccine with Matrix-M™ adjuvant, for active immunization of individuals 18 years of age and older for the prevention of coronavirus disease 2019 caused by SARS-CoV-2. On 20 December 2021, Novavax announced that the European Commission (EC) has granted Novavax conditional marketing authorization (CMA) for Nuvaxovid™ COVID-19 Vaccine (recombinant, adjuvanted) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

Pfizer has committed to making tools that they develop available on an open source platform and to share data and learnings gained with other companies in real time to advance therapy and vaccine development. The company also commits to sharing clinical development and regulatory expertise to support promising drug candidates of smaller biotech companies. Azithromycin – Pfizer shared data regarding azithromycin which may facilitate the use of azithromycin in future research on COVID-19. BNT162b2 vaccine – In July 2020, early positive data and updated data from the Pfizer/BioNTech Phase 1/2 trial demonstrated the ability of the BNT162b1 vaccine candidate to elicit high SARS-CoV-2 neutralizing titers. In August 2020, the companies shared additional Phase 1 safety and immunogenicity data. Pfizer and BioNTech announced preliminary preclinical data in mouse and non-human primate models from their BNT162b2 mRNA-based vaccine development program against SARS-CoV-2. Pfizer published the full protocol for its COVID-19 vaccine study to reinforce its commitment to scientific and regulatory rigor. Pfizer and BioNTech announced their mRNA-based vaccine candidate, BNT162b2, demonstrated evidence of efficacy against COVID-19 in participants without prior evidence of SARS-CoV-2 infection. Primary efficacy analysis demonstrated the vaccine to be 95% effective against COVID-19, 28 days after the first dose. Pfizer and BioNTech announced additional data demonstrating that BNT162b2 elicits a combined adaptive humoral and cellular immune response. Pfizer and BioNTech announced results showing the BNT162b2 vaccine effectively neutralizing SARS-CoV-2 with a key mutation found in highly transmissible variants. Pfizer and BioNTech announced additional data showing the BNT162b2 vaccine eliciting antibodies that neutralize pseudovirus bearing the SARS-CoV-2 UK strain spike protein in cell culture. Pfizer/BioNTech were granted EUA by UK-based MHRA for their mRNA vaccine BNT162b2. Pfizer/BioNTech were
granted EUA by the US FDA for their vaccine in individuals aged 16 or older. Pfizer/BioNTech were granted CMA by the EU for their vaccine in individuals aged 16 or older. WHO granted EUL on 31 December 2020, making the Pfizer/BioNTech vaccine the first to receive emergency validation since the outbreak began. Pfizer/BioNTech announced that the first healthy pregnant women aged 18 or older had been dosed in a global Phase 2/3 study to further evaluate the safety, tolerability, and immunogenicity of the vaccine. Pfizer/BioNTech announced data demonstrating stability of their COVID-19 vaccine when stored between -25°C to -15°C (-13°F to 5°F), approved by the EMA. In February 2021, Pfizer/BioNTech announced the evaluation of the safety and immunogenicity of a third booster dose of the BNT162b2 vaccine to understand the effect of a booster on immunity against COVID-19 caused by circulating and emerging SARS-CoV-2 variants. Pfizer/BioNTech and Israel's MoH announced real-world evidence demonstrating dramatically lower incidence rates of COVID-19 disease in fully vaccinated individuals with the BNT162b2 vaccine. Pfizer/BioNTech announced their vaccine demonstrated 100% efficacy and robust antibody responses in a Phase 3 trial in adolescents aged 12 to 15. Pfizer and BioNTech confirmed high efficacy and no serious safety concerns through up to six months following second dose in an updated topline clinical trial analysis. Phase 1 safety and immunogenicity data in individuals who received a third dose of the Pfizer-BioNTech BNT162b2 vaccine show a favorable safety profile and robust immune responses. New Phase 3 data show booster dose of Pfizer-BioNTech COMIRNATY® induces significant SARS-CoV-2 neutralizing antibody titers after one month – 3.3 times more than what has been seen one month after second dose – and demonstrated a favorable safety and tolerability profile. Pfizer and BioNTech announced that the U.S. FDA authorized for emergency use a booster dose of the Pfizer-BioNTech COVID-19 Vaccine for individuals 65 years of age and older, individuals 18 through 64 years of age at high risk of severe COVID-19, and individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19. On 28 September 2021, Pfizer and BioNTech announced they had submitted data to the U.S. FDA from the Phase 2/3 trial of their COVID-19 vaccine in children 5 to <12 years of age. On 27 October 2021, Pfizer and BioNTech announced that the U.S. FDA VRBPAC voted 17 to 0, with 1 abstention, to recommend the FDA grant EUA for the companies' COVID-19 vaccine in children 5 to <12 years of age. On 29 October 2021, Pfizer and BioNTech announced that the U.S. FDA authorized for emergency use the Pfizer-BioNTech COVID-19 Vaccine for children 5 through 11 years of age. On 19 November 2021, Pfizer and BioNTech announced that the U.S. FDA expanded the EUA of a booster dose of the Pfizer-BioNTech COVID-19 Vaccine to include individuals 18 years of age and older. The booster dose is to be administered at least six months after completion of the primary series, and is the same dosage strength as the doses in the primary series. On 22 November 2021, Pfizer and BioNTech announced topline results from a longer-term analysis of the safety and efficacy of their COVID-19 vaccine in individuals 12 through 15 years of age. The updated findings from the companies' pivotal Phase 3 trial show that a two-dose series of the Pfizer-BioNTech COVID-19 Vaccine (30-µg per dose) was 100% effective against COVID-19, measured seven days through over four months after the second dose. On 25 November 2021, Pfizer and BioNTech announced that the CHMP of the EMA issued a positive opinion on the administration of the companies' COVID-19 vaccine COMIRNATY® in children 5 to under 12 years of age. On 8 December 2021, Pfizer and BioNTech announced results from an initial laboratory study demonstrating that serum antibodies induced by the Pfizer-BioNTech COVID-19 Vaccine (BNT162b2) neutralize the SARS-CoV-2 Omicron variant after three doses. On 17 December 2021, Pfizer and BioNTech shared that following a routine review by the external independent Data
Monitoring Committee, the companies would amend the clinical study evaluating the safety, tolerability, and immunogenicity of the Pfizer-BioNTech COVID-19 Vaccine in children 6 months to under 5 years of age. The study would include evaluating a third dose of 3 µg at least two months after the second dose of the two-dose series to provide high levels of protection in this young age group.

**PF-07321332** – Pfizer confirmed that a lead protease inhibitor shows antiviral activity against SARS-CoV-2. Pfizer will perform pre-clinical confirmatory studies.

On 23 March 2021, Pfizer initiated clinical trials for a novel oral antiviral therapeutic agent (PF-07321332) against SARS-CoV-2 and future coronavirus threats. This is an investigational orally administered protease inhibitor antiviral therapy designed specifically to combat COVID-19 in non-hospitalized, symptomatic adult participants who have a confirmed diagnosis of SARS-CoV-2 infection and are not at increased risk of progressing to severe illness, which may lead to hospitalization or death. The drug is now in Phase 2/3 trials.

On 1 September 2021, Pfizer shared that the first participant has was dosed in the Phase 2/3 clinical trial to evaluate the safety and efficacy of PF-07321332.

On 27 September, Pfizer announced the start of the Phase 2/3 EPIC-PEP study to evaluate the investigational novel oral antiviral candidate PF-07321332, co-administered with a low dose of ritonavir, for the prevention of COVID-19 infection.

On 5 November, Pfizer announced its investigational novel COVID-19 oral antiviral candidate, PAXLOVID™, significantly reduced hospitalization and death, based on an interim analysis of the Phase 2/3 EPIC-HR study that showed an 89% reduction in risk of COVID-19-related hospitalization or death from any cause compared to placebo in patients treated within three days of symptom onset.

On 16 November, Pfizer announced it is seeking EUA of its investigational oral antiviral candidate, PAXLOVID™, for the treatment of mild to moderate COVID-19 in patients at increased risk of hospitalizations or death.

On 14 December 2021, Pfizer announced final results from an analysis of all 2,246 adults enrolled in its Phase 2/3 EPIC-HR trial of its novel COVID-19 oral antiviral candidate PAXLOVID™. These results were consistent with the interim analysis announced in November 2021, showing PAXLOVID significantly reduced the risk of hospitalization or death for any cause by 89% compared to placebo in non-hospitalized, high-risk adult patients with COVID-19 treated within three days of symptom onset.

On 16 December 2021, Pfizer announced that the CHMP of the EMA issued advice on the use of PAXLOVID™, stating that PAXLOVID can be used to treat adults with COVID-19 who do not require supplemental oxygen and who are at increased risk of progressing to severe disease.

**Tofacitinib** – Initial findings from Brazilian multicenter study demonstrated effectiveness of anti-arthritis drug, Tofacitinib, in patients hospitalized with COVID-19 pneumonia.

**Roche** Roche’s subsidiary Genentech is sharing manufacturing information concerning COVID-19 antibody production with other companies. Please see previous entries on Amgen for more info.

**AT-527** – Phase 2 study interim results from Roche and Atea Pharmaceuticals showed potent and rapid antiviral activity in hospitalized patients; the study will advance to keep pace with the changing COVID-19 environment. Atea announced that exploratory analyses of infectious virus from the Phase 2 MOONSONG trial indicate potent antiviral activity of AT-527 with a rapid reduction in viral load in the overall (low and high-risk) patient population and high-risk patient subgroup with AT-527 1,100 mg BID.

**Casirivimab-imdevimab cocktail** – Regeneron announced changes to the Phase 3 trial assessing investigational casirivimab with imdevimab in non-hospitalized COVID-19 patients following the IDMC finding clear clinical efficacy on reducing the rate of hospitalization and death. Regeneron has partnered with Roche to develop and manufacture the antibody cocktail outside the US. Regeneron announced positive topline results from the largest trial to date assessing the investigational antibody cocktail. Roche confirmed positive results from the Phase 3 REGN-COV 2069 trial assessing
the ability of the investigational antibody cocktail to reduce the risk and burden of COVID-19 infection among household contacts of SARS-CoV-2 infected individuals. On 4 August 2021, Regeneron reported further positive phase 3 trials results showing promise as post-exposure prophylaxis for SARS-CoV-2. On 24 September 2021, the WHO welcomed the addition of imdevimab, another therapeutic to the world’s arsenal against COVID-19. On 30 September 2021, Roche confirmed positive data from the phase II/III 2066 study, investigating Ronapreve™ in patients hospitalised with COVID-19.

On 12 November 2021, Roche announced that the EC granted a marketing authorisation for Ronapreve™ (casirivimab and imdevimab), for treating COVID-19 in adults and adolescents (from 12 years of age and weighing at least 40 kilograms) who do not require supplemental oxygen and who are at increased risk of their disease becoming severe, and for preventing COVID-19 in people aged 12 years and older weighing at least 40 kilograms (pre- or post-exposure prophylaxis).

**Tocilizumab** – In July 2020, Roche announced that tocilizumab did not meet its primary and secondary endpoints of improved clinical status and mortality in COVID-19 associated pneumonia in their global clinical trial. Roche announced the Phase 3 EMPACTA study meeting its primary endpoint, showing a positive effect of tocilizumab on COVID-19 patients. Roche announced that the global Phase 3 REMDACTA study of tocilizumab plus remdesivir did not meet its primary endpoint. Roche announced that the US FDA issued an EUA for intravenous Actemra/RoActemra® (tocilizumab) for the treatment of COVID-19 in hospitalised adults and paediatric patients. The WHO recommended using arthritis drug Actemra from Roche with corticosteroids for Covid-19 patients after data from around 11,000 patients showed they cut the risk of death. Roche announced that the European Commission extended the marketing authorisation for Actemra®/RoActemra® (tocilizumab) to include the treatment of COVID-19 in adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation. On 7 December 2021, Roche announced that the European Commission extended the marketing authorisation for Actemra®/RoActemra® (tocilizumab) to include the treatment of COVID-19 in adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation.

**Sanofi**

Sanofi is collaborating with CEPI and sharing its vaccine R&D experience and expertise to advance vaccine solutions. Sanofi-GSK vaccine – Sanofi and GSK started the Phase 1/2 clinical trial for their adjuvanted COVID-19 vaccine, which has been to improve immune response in older adults. Phase 1/2 interim trial results showed an immune response comparable to patients who recovered from COVID-19 in adults aged 18 to 49 years, but a low immune response in older adults. Sanofi and GSK announced the initiation of a Phase 2 study with 720 volunteers aged 18 and over to select the most appropriate antigen dosage for Phase 3 evaluation of their adjuvanted recombinant protein COVID-19 vaccine candidate. The Sanofi and GSK adjuvanted recombinant COVID-19 vaccine candidate achieved strong rates of neutralizing antibody responses. A global pivotal Phase 3 study is expected to start. MRT5500 vaccine – Sanofi and Translate Bio announced preclinical results for their MRT5500 mRNA-based vaccine candidate, which demonstrated a favorable immune response profile. Sanofi and Translate Bio started Phase 1/2 clinical trials in March 2021.

Sarilumab – In July 2020, Sanofi announced that a US phase 3 clinical trial of sarilumab in COVID-19 patients requiring mechanical ventilation did not meet its primary and key secondary endpoints. In September 2020, the company also announced that sarilumab did not meet its primary endpoint and key secondary endpoint in severely or critically ill patients hospitalized with COVID-19. The WHO recommended using arthritis drug Kevzara from Sanofi with corticosteroids for Covid-19 patients after data from around 11,000 patients showed they cut the risk of death.
On 21 October 2021, Shionogi presented positive results from non-clinical studies and from the Japanese Phase 1 clinical trial of S-217622, an investigational oral antiviral drug for COVID-19, at the ISIRV-WHO Virtual Conference.

Sumitomo Dainippon Pharma collaborates in the "COVID-19 Research Database" consortium to provide researchers with free access to the medical information database.

Takeda partnered with IMI to leverage collective expertise to develop inhibitors to help prevent future outbreaks. The CoVlg-19 Plasma Alliance, an unprecedented collaboration of leading plasma companies supported by global organizations outside the plasma industry, confirmed that patients are being enrolled in the ITAC Phase 3 clinical trial sponsored by the NIAID, part of the NIH. The investigational H-Ig materials for the trial would be provided by CSL Behring and Takeda on behalf of the CoVlg-19 Plasma Alliance, as well as by two other companies. The CoVlg-19 Plasma Alliance announced that the Phase 3 ITAC clinical trial sponsored and funded by the NIAID, part of the NIH, did not meet its endpoints. Takeda announced that the MHLW granted special approval for emergency use of Moderna’s mRNA COVID-19 vaccine, TAK-919, now known as COVID-19 Vaccine Moderna Intramuscular Injection, in Japan.

As of 7 December 2021, WHO reports 136 candidate vaccines are in clinical evaluation and 194 candidate vaccines are in preclinical evaluation. 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 vaccines around the world. CEOs of of AstraZeneca, BioNTech, GSK, Johnson & Johnson, MSD (known as Merck in US and Canada), Moderna, Novavax, Pfizer, and Sanofi, have made a historic pledge to the world, outlining a united commitment to uphold the integrity of the scientific process as they work towards potential regulatory filings and approvals of COVID-19 vaccines.

In less than a year, several vaccine candidates have concluded or are in advanced Phase III clinical trials with encouraging results. On 31 December 2020, Pfizer and BioNTech announced the granting of a temporary EUL for their COVID-19 mRNA vaccine (BNT162b2) after thorough review of clinical trial data. On 15 February 2020, WHO granted temporary EUL to AstraZeneca's COVID-19 vaccine (AZD1222). On 12 March 2021, WHO granted EUL to Johnson & Johnson's COVID-19 vaccine Ad26.COV2.S. All three vaccines are part of the COVAX roll-out. For more information on the EUL of the individual vaccines and their manufacturer, please refer to the commitment “Share real-time clinical trial data with governments, companies & the public”.

AstraZeneca AZD1222 vaccine – AstraZeneca and the University of Oxford joined forces for the development and distribution of the
University's recombinant adenovirus vaccine. A Phase I/II vaccine clinical trial to assess safety, immunogenicity and efficacy of the vaccine candidate, AZD1222, was initiated in April 2020. Interim results, published in *The Lancet*, showed it was tolerated and generated robust immune responses against the SARS-CoV-2 virus in all evaluated participants. AstraZeneca received support of more than $1bn from BARDA for development, production and delivery of the vaccine. The development programme would include a Phase 3 clinical trial with 30,000 participants and a paediatric trial. AstraZeneca’s COVID-19 vaccine has been granted EUA in the UK, CMA in the EU for individuals aged 18 and older, and EUL by WHO in individuals aged 18 and older, including those over 65. AstraZeneca’s COVID-19 vaccine has further been granted EUA in India, Argentina, Dominican Republic, El Salvador, Mexico, Morocco, and others for the active immunisation of adults. AstraZeneca announced that a sub-analysis from the Oxford-led COV001 and COV002 trials with Vaxzevria induced strong immune responses following either a prolonged second dose interval of up to 45 weeks or following a third boosting dose. The results, published by the University of Oxford on the pre-print server of *The Lancet*, demonstrated that antibody levels remain elevated from baseline for at least one year following a single dose.

Bayer has signed a collaboration and services agreement with CureVac. Under the terms of the agreement, Bayer will support the further development, supply and key territory operations of CureVac’s COVID-19 vaccine candidate CVnCoV.

CSL Group/Seqirus partnered with the University of Queensland’s COVID-19 vaccine development program to provide technical expertise as well as a donation of Seqirus’ proprietary adjuvant technology, MF59®, to the University’s pre-clinical development program. CSL announced that its vaccine candidate would not proceed to Phase 2/3 clinical trials. Daiichi Sankyo is developing an mRNA vaccine for COVID-19. The company is also participating in “Fundamental Research on the Control of a Novel Coronavirus”, an initiative supported by the AMED. Daiichi Sankyo announced today it has started the first vaccinations in a phase 1/2 clinical trial in Japan of an mRNA vaccine, DS-5670 that is being developed by the company against the novel coronavirus infectious disease.

GSK Adjuvant vaccine technology – GSK and Sanofi joined forces to develop an adjuvanted vaccine for COVID-19, using innovative technologies from both companies. The vaccine candidate started the Phase 1/2 clinical trial. GSK and Medicago collaborate on developing and evaluating a COVID-19 candidate vaccine combining their technologies. They announced Phase 2/3 clinical trials of its plant-derived vaccine candidate for COVID-19 to evaluate its efficacy, safety, and immunogenicity. mRNA vaccine technology – GSK and CureVac announced a €150m collaboration, building on their existing relationship, to jointly develop next generation mRNA vaccines for COVID-19 with the potential for a multi-valent approach to address multiple emerging variants in one vaccine.

Johnson & Johnson Ad26.COV2-S vaccine – Johnson & Johnson expedited its investigational coronavirus vaccine program through an expanded collaboration with BARDA. Both have committed more than $1 billion of investment to co-fund vaccine research, development, and clinical testing. Research teams at Janssen, in collaboration with the Harvard Medical School, constructed and tested multiple vaccine candidates using the Janssen AdVac® technology. Johnson & Johnson selected a lead COVID-19 vaccine candidate, Ad26.COV2-S, in March 2020. Results from pre-clinical studies showed a robust immune response in non-human primates against SARS-CoV-2. Following positive interim results from Phase 1/2a clinical study, a Phase 3 clinical trial commenced in September 2020, in order to study the safety and efficacy of a single vaccine dose. Johnson & Johnson also established a collaboration with Beth Israel Deaconess Medical Center to support the development of a preventive vaccine candidate for COVID-19. Johnson & Johnson was granted EUA by the US FDA for its single-dose COVID-19 vaccine in individuals aged 18 and
Johnson & Johnson was granted CMA by the European Commission for its single-dose COVID-19 vaccine in individuals aged 18 and older. Johnson & Johnson submitted a request for EUL to WHO for its single-dose COVID-19 vaccine. Johnson & Johnson began vaccinating adolescent aged 12 to 17 in a Phase 2a clinical trial.

India has approved Johnson & Johnson's (JNJ.N) single-dose COVID-19 vaccine for emergency use.

Merck's Life Science business sector is supporting a total of more than 50 vaccine projects in different stages with products and services. Merck partnered with the Jenner Institute of the University of Oxford to develop a manufacturing process for a vaccine in 2020. This vaccine has been approved for emergency use in multiple countries. Merck partnered with the Baylor College of Medicine in Houston, Texas, to develop manufacturing platforms for two vaccines in 2020. Those vaccines are in clinical trials.

The CMA for Spikevax, Moderna's COVID-19 vaccine, in the EU has been expanded to include adolescents 12 years of age and older. In addition, the Japanese Ministry of Health, Labor and Welfare also approved Moderna Inc.'s COVID-19 vaccine for ages 12 to 17. Moderna has filed for a EUA for adolescents with the US FDA as well as additional regulatory agencies around the world. Enrollment has completed for the Phase 1 study of mRNA-1283, Moderna's next-generation COVID-19 vaccine, a potential refrigerator-stable vaccine that could facilitate easier distribution and administration by healthcare providers. Moderna announced on 13 August 2021 that the US FDA has updated the EUA for the COVID-19 vaccine mRNA-1273. On 25 August 2021, Moderna announced it had completed the rolling submission process for its BLA to the US FDA for the full licensure of the COVID-19 vaccine for individuals aged 18 and older.

MSD and IAVI, a nonprofit scientific research organization dedicated to addressing urgent, unmet global health challenges, partnered to advance the development and global clinical evaluation of a SARS-CoV-2 vaccine candidate. This vaccine candidate would use the recombinant vesicular stomatitis virus (rVSV) technology that is the basis for MSD's Ebola Zaire virus vaccine, ERVEBO®. MSD acquired Vienna-based biotech company Themis. The acquisition is expected to accelerate the development of Themis' COVID-19 vaccine candidate in the near term and in the longer-term MSD is planning to establish a pandemic preparedness capability. MSD announced the discontinuation of the development of its SARS-CoV-2/COVID-19 vaccine candidates, V590 and V591. This decision follows Merck's review of findings from Phase 1 clinical studies for the vaccines. In these studies, both V590 and V591 were generally well tolerated, but the immune responses were inferior to those seen following natural infection and those reported for other SARS-CoV-2/COVID-19 vaccines.

Novartis' AveXis division partnered with Massachusetts Eye and Ear and Massachusetts General Hospital, members of Mass General Brigham, entering into a manufacturing agreement to contribute to the development and production of their novel genetic vaccine.

Novavax announced that NVX-CoV2373, its recombinant nanoparticle protein-based COVID-19 vaccine, demonstrated 100% protection against moderate and severe disease, 90.4% efficacy overall, and met the primary endpoint in its PREVENT-19 pivotal Phase 3 trial. The study enrolled 29,960 participants across 119 sites in the U.S. and Mexico to evaluate efficacy, safety and immunogenicity, with an emphasis on recruiting a representative population of communities and demographic groups most impacted by the disease. On 5 August 2021, Novavax and Serum Institute of India announced submission to regulatory agencies in India, Indonesia, and the Philippines for EUA of Novavax' Recombinant Nanoparticle COVID-19 vaccine. Novavax expects to complete its requests for regulatory filing with the UK's MHRA, the EMA, Australian Therapeutic Goods Administration,
Health Canada, and New Zealand Medsafe in the third quarter of 2021. Novavax will request EUA for its vaccine to the US FDA in the fourth quarter of 2021.

**Pfizer**

**BNT162b2 vaccine** – Pfizer and BioNTech entered into a partnership to jointly develop BioNTech's mRNA-based vaccine candidate. Early positive data from the most advanced of four investigational vaccine candidates emerged in early July 2020. Initial data from their German Phase 1/2 trial, released in July 2020, demonstrated the ability of BNT162b1 to elicit high SARS-CoV-2 neutralizing titers. In August 2020, the companies shared additional Phase 1 safety and immunogenicity data. A global Phase 2/3 safety and efficacy clinical study to evaluate their chosen lead COVID-19 vaccine, BNT162b2, commenced on 28 July 2020.

Pfizer/BioNTech also received a Fast Track designation from the US FDA for its vaccine candidates. In November 2020, Pfizer/BioNTech announced that the final Phase 3 study efficacy analysis met all of the study's primary efficacy endpoints and indicates a vaccine efficacy rate of 95%. In December 2020, Pfizer/BioNTech were granted EUA by UK-based MHRA. The US FDA granted EUA in individuals aged 16 or older. The European Commission granted CMA in individuals aged 16 or older. WHO granted EUL to the BNT162b2 vaccine, making the Pfizer/BioNTech vaccine the first to receive WHO emergency validation since the outbreak began.

In May 2021, Pfizer announced the start of a study in adults ages 65 or older exploring the coadministration of the company's 20-valent pneumococcal conjugate vaccine (20vPnC) candidate following a booster dose of the Pfizer-BioNTech COVID-19 Vaccine.

Pfizer and BioNTech announced that the US FDA and the EMA expanded respectively the EUA and CMA for their COVID-19 vaccine to include individuals 12 to 15 years of age.

The FDA announced its full approval of the Pfizer-BioNTech COVID-19 vaccine COMIRNATY® for individuals aged 16 and over on 23 August 2021. Two days later, Pfizer and BioNTech initiated a rolling submission of an sBLA to the US FDA for approval of a booster dose of COMIRNATY® for individuals aged 16 and over.

Pfizer and BioNTech announced topline results from a Phase 3 randomized, controlled trial evaluating the efficacy and safety of a 30-µg booster dose of the Pfizer-BioNTech COVID-19 Vaccine in more than 10,000 individuals 16 years of age and older. In the trial, a booster dose administered to individuals who previously received the Pfizer-BioNTech primary two-dose series restored vaccine protection against COVID-19 to the high levels achieved after the second dose, showing a relative vaccine efficacy of 95.6% when compared to those who did not receive a booster.

**Sanofi**

Sanofi announced a collaboration with BARDA to advance a novel COVID-19 vaccine candidate using Sanofi's recombinant DNA technology, leveraging previous efforts to create a SARS vaccine candidate. Sanofi-GSK vaccine – Sanofi and GSK joined forces to develop an adjuvanted vaccine for COVID-19, and started Phase 1/2 clinical trials in September 2020. Phase 1/2 study interim trial results showed an immune response comparable to patients who recovered from COVID-19 in adults aged 18 to 49 years, but a low immune response in older adults likely due to an insufficient concentration of the antigen.

Sanofi and GSK announced the initiation of a Phase 2 study with 720 volunteers aged 18 and over to select the most appropriate antigen dosage for Phase 3 evaluation of their adjuvanted recombinant protein COVID-19 vaccine candidate.

MRT5500 vaccine – Sanofi and Translate Bio partnered to develop a mRNA vaccine for COVID-19. Sanofi and Translate Bio started Phase 1/2 clinical trials in March 2021 with results expected in Q3 2021. Sanofi announced it intends to acquire Translate Bio to advance its mRNA vaccine R&D.

**Shionogi**

Shionogi’s subsidiary UMN Pharma Inc. is pursuing the discovery and development of a recombinant protein vaccine,
supported by the AMED. Shionogi reports that, in parallel and in collaboration with the NIID, an immunogenicity testing of protein antigens and adjuvant candidates added to vaccine formulations have been initiated. Shionogi announced that it initiated a Japanese Phase 1 clinical trial of the therapeutic agent S-217622 as an orally administered antiviral drug for COVID-19. The first dose was administered successfully on July 22, 2021.

**Takeda** announced today that the first subject was dosed in its Phase 1/2 immunogenicity and safety study of Novavax’ COVID-19 vaccine candidate (TAK-019) in Japan. Earlier in February 2021, Takeda completed enrollment in the company’s Phase 1/2 immunogenicity and safety study of Moderna’s COVID-19 vaccine candidate (TAK-919) in Japan.

**UCB** is collaborating with the University of Oxford on developing a vaccine.

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**DEVELOP DIAGNOSTIC TESTING & SECURE CONTINUOUS SUPPLY**

Develop and scale up the capacity of diagnostics testing for COVID-19 patients as much as possible and secure the continuous supply of diagnostic test kits to countries around the world.

Rolling out diagnostics to detect whether patients are genuinely infected with SARS-Cov-2 is a key step in preventing or slowing its spread. However, the rapid spread of SARS-CoV-2 and variants has drastically increased demand for testing kits around the world and governments are ramping up their testing capacities. Moreover, diagnostics are an essential enabler of COVID-19 vaccine development, both in the R&D phase and for monitoring the impact of the introduction of vaccines, as part of public health surveillance. The biopharmaceutical industry is therefore pushing the boundaries, uniting and collaborating to increase and secure the production and development of COVID-19 diagnostics.

**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. **AstraZeneca** is collaborating with GSK and Cambridge University by setting up a new testing laboratory at the University’s facilities for high throughput screening for COVID-19 testing. It will also explore the use of alternative chemical reagents for test kits to help overcome current supply shortages.

**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. It is also freeing up specially trained personnel for this purpose.

**EFPIA**, through the IMI, with IMI Associated Partners and other organisations has provided up to 45 million EUR to fund 8 COVID-19 R&D projects with 5 focusing on diagnostics.

**GSK** partnered with AstraZeneca and Cambridge University to create a state-of-the-art, high-throughput testing laboratory in Cambridge, the UK. **GSK** has conducted large-scale COVID-19 testing at its facility in Rixensart, Belgium. **GSK** Consumer Healthcare and Mammoth Biosciences are developing a CRISPR-based, over-the-counter coronavirus test.

**Johnson & Johnson** entered into a research collaboration with Alveo Technologies to advance Alveo’s be.well™
Johnson platform of analyzers, nasal swabs and cartridges for the detection of viral infectious diseases, including potentially SARS-CoV-2. J&J will provide Alveo with financial support as well as technical and regulatory counsel.

Menarini Diagnostics and Credo Diagnostics Biomedical entered into an exclusive distribution agreement for the VitaPCR™ SARS-CoV-2 assay kit.

Merck supports more than 35 Covid-19 test systems with raw materials and services. Merck entered into a collaboration with Mammoth Biosciences Inc., California, USA, in 2020. As part of this collaboration, Merck is taking on the contract manufacture of DETECTR BOOST™ SARS-CoV-2 Reagent Kit, which will enable the quick processing of patient samples using standard equipment for the automated handling of liquids.

Novo Nordisk scientists are working in R&D laboratories to boost Denmark’s COVID-19 testing capacity.

Otsuka and Denka Company announced to co-market the rapid-diagnostic test kit QuickNavi™ to medical institutions across Japan.

Roche received an EUA from the US FDA for its diagnostic kit cobas® SARS-CoV-2 Test. Roche is committed to delivering as many tests as possible and is going to the limits of production capacity. Roche has also received an EUA from the US FDA for its diagnostic kit the cobas® SARS-CoV-2 & Influenza A/B Test for use on the cobas® 6800/8800 Systems. This test is intended for the simultaneous qualitative detection and differentiation of SARS-CoV-2, Influenza A and Influenza B. Roche announced the launch of its Elecsys® Anti-SARS-CoV-2 S antibody test for markets accepting the CE Mark. Roche filed for EUA from the US FDA. The company intends to launch a high-volume SARS-CoV-2 Antigen test as an aid in the diagnosis of SARS-CoV-2 infection. Roche also received an EUA from the US FDA for its COVID-19 antibody test. Roche has already started shipping the new antibody test to leading laboratories globally and will ramp up production capacity to high double-digit millions per month. Roche announced the upcoming launch of a SARS-CoV-2 Rapid Antigen Test, for markets accepting the CE Mark. Roche also intends to file for EUA to the US FDA.

Sanofi joined forces with Luminostics to develop a COVID-19 smartphone-based self-testing solution. Luminostics would contribute its proprietary technology for consumer-diagnostics for COVID-19 testing while Sanofi would bring its clinical research testing experience and capabilities.

Shionogi marketed the IgG/IgM Antibody-test Kit for COVID-19 as a research reagent in Japan since June 3, 2020 to be useful for epidemiological surveillance and studies of SARS-CoV-2/COVID-19 aiming to determine the number of individuals previously infected with SARS-CoV-2. Shionogi had entered into an agreement with Micro Blood Science Inc., the licensor of the kit. Shionogi signed a license agreement with Nihon University, Gunma University, and Tokyo Medical University to develop new rapid diagnostic methods for COVID-19, using an innovative nucleic acid amplification technique.

Takeda is partnering with public entities and other pharmaceutical companies through the IMI in Europe to leverage collective expertise in the hope of developing diagnostics for COVID-19.

UCB is working closely with the Belgian government to scale up COVID-19 testing capabilities. It is looking at similar possibilities in the UK.
IFPMA member companies are committed to ensure the continued supply of essential medicines and vaccines for patients suffering from chronic illnesses and other health conditions. So far, they have found no obvious near-term impacts on medicine and vaccine availability. Companies are working to prevent and mitigate any potential shortages through close coordination with national regulatory authorities and other global stakeholders, including the WHO.

The threat of falsified medicines is rising and targeting existing products but also new potential treatments against COVID-19. IFPMA and its members continue to tackle the global public health threat posed by falsified medical products, and to support the [Fight the Fakes](#) Alliance (Statement).

- **AbbVie** does not anticipate disruption to the supply of HIV medicines as a result of investigating their effectiveness against COVID-19.
- **Almirall** continued production of all its essential products and increased production of specific medicines, such as paracetamol.
- **Astellas** maintains an adequate inventory level of raw materials and finished products, cooperating with outsourcing manufacturers and suppliers of raw materials.
- **Bayer** continued the production of medicines and health care products at their plant in Garbagnate, Italy for both the Italian and global market during the lockdown.
- **Biogen** does not anticipate any interruptions to its supply chain, and is diminishing any impact the COVID-19 pandemic has on future manufacturing capabilities.
- **Boehringer Ingelheim** ensured further discovery, development, production and supply of its products that are needed by patients around the globe.
- **Bristol-Myers Squibb** has made sure raw materials and products reach their markets and clinical sites and does not foresee any disruption due to the pandemic.
- **Chiesi** continued production of all medicines without interruption at sites in Italy, Brazil, France and other countries.
- **CSL Group/Seqirus** has enacted its business continuity plans across the globe to minimise disruption to the manufacturing and supply of influenza vaccines.
- **Daiichi-Sankyo** was monitoring the evolving situation very carefully to maintain supply and delivery of these medicines, and does not foresee any shortages.
- **Eisai** maintained necessary stocks for the stable supply of medicines in addition to stable production.
Eli Lilly launched the Lilly Insulin Value Program in the US allowing anyone with commercial insurance and those without insurance to fill their monthly prescription of Lilly insulin for $35.

Gilead has no manufacturing issues or supply shortages with any Gilead products, including HIV and hepatitis portfolios.

Grünenthal is not experiencing any significant supply shortages and is continuously monitoring the current situation.

GSK increased production of high demand products (e.g. multi-vitamins, respiratory medicines and antibiotics).

Ipsen is monitoring supply chains with national and international suppliers and does not anticipate any supply shortages.

LEO Pharma is taking additional measures to avoid any shortages of medicines or raw materials and to mitigate any interruptions.

Lundbeck announced that its supply chain remains intact and it has not experienced any supply disruptions.

Merck maintained the production and supply chains of its Healthcare business sector across the globe in all affected regions and supplied more than 85 million patients worldwide with their (non-Covid-19-related) medication since the beginning of the pandemic.

Novartis subsidiary Sandoz was maintaining prices on a basket of essential medicines that may help in the treatment of COVID-19.

Novartis and the AU through the AMSP announced a new collaboration to facilitate the supply of medicines from the Novartis Pandemic Response Portfolio to the AU member states and Caricom countries.

Novo Nordisk is ensuring the supply of lifesaving medicines for people with serious chronic diseases across the globe, using their experience with Chinese lockdown measures to assure continuity of service.

Roche is ensuring an adequate supply of medicines, calling upon governments to work with the industry to keep global manufacturing and supplies running.

Servier is ensuring the continuity of its products and is providing its expertise to the multi-stakeholder partnership “Health Innovation Coalition – Health Crisis” in France.

Sumitomo Dainippon Pharma strives to ensure a stable supply of products and business continuity.

Takeda is monitoring the situation as it evolves and will take all necessary actions in an effort to ensure supply continuity for patients.

Teva has inventory and redundancy plans in place to address potential shortfalls, with their supply chain remaining largely uninterrupted.
Collaboration in fast-tracking the development of therapeutics and new vaccines creates networks of centres of excellence that can deliver a real impact and a preparedness infrastructure that in turn can be mobilized for future outbreaks. Companies are partnering with manufacturers and other biopharmaceutical companies to extensively scale-up at-risk production capacity, particularly for COVID-19 vaccines.

IFPMA has joined the global public-private partnership, ACT Accelerator, as founding partner, offering its knowledge and expertise in building manufacturing capacity and distribution networks. IFPMA has published the Vaccines Policy Principles that will guide its work with the ACT Accelerator Vaccines Partnership (COVAX). On 24 February 2021, COVAX and UNICEF began to roll out 2 billion doses of COVID-19 vaccines to protect high risk and vulnerable people, and frontline healthcare workers in low- and middle-income countries (LMICs).

Chatham House in collaboration with COVAX, IFPMA, DCVMN, and BIO convened a Global COVID-19 Vaccine Supply Chain & Manufacturing Summit on 8 and 9 March 2021 to discuss COVID-19 vaccine manufacturing bottlenecks that urgently need to be tackled.

COVID-19 vaccines

AstraZeneca AZD1222 vaccine – In April 2020, AstraZeneca (AZ) and the University of Oxford to jointly develop, manufacture and distribute their COVID-19 vaccine. 
By May 2020, AZ concluded the first agreements for at least 400 million doses and secured manufacturing capacity for one billion doses.
In June 2020, AZ reached a $750m agreement with CEPI and Gavi to support manufacturing, procurement and distribution of 300 million vaccine doses to LMICs. AstraZeneca has also partnered with the Serum Institute of India to supply one billion doses to a large number of LMICs through the COVAX Facility.
AZ reached manufacturing und supply deals with various countries and regional organisations, including the European Union, India, Switzerland. The company also entered into collaborations with Catalent Biologics (Italy), Symbiosis Pharmaceutical Services (UK), Oxford Biomedica (UK), Emergent BioSolutions, Biokangtai (China), R-Pharm (Russia), CSL (Australia), IDT Biologika (Germany/Europe).
On 2 March 2021, AstraZeneca announced that the first doses of its vaccine had begun arriving in LMICs across the world through the COVAX initiative. Further shipments aim to supply a total of 142 countries with hundreds of millions of doses.
On 16 November 2021, AstraZeneca announced that they released for supply two billion doses of their COVID-19 vaccine to more than 170 countries across every continent on the planet in the last 11 months. Approximately two-thirds of these have gone to low- and lower-middle-income countries, including more than 175 million doses delivered to 130 countries through the COVAX Facility.
Bayer has signed a collaboration and services agreement with CureVac. Under the terms of the agreement, Bayer will support the further development, supply and key territory operations of CureVac’s COVID-19 vaccine candidate CVnCoV. Bayer plans to add an additional 160 million doses of CureVac’s vaccine in 2022 to further expand their supply network and overall capacity using the manufacturing network of Bayer.

Daiichi Sankyo was selected by the Ministry of Health, Labour and Welfare of Japan to be a provider for the Japanese Government’s “Emergent Initiative to Build Production Capacity for COVID-19 Vaccines” with respect to Daiichi Sankyo’s mRNA vaccine for COVID-19. Daiichi Sankyo announced that it entered into an outsourcing agreement with AstraZeneca to manufacture the AstraZeneca-developed COVID-19 vaccine, AZD1222, in Japan. Daiichi Sankyo announced that it started manufacturing the AstraZeneca COVID-19 vaccine in Japan. The marketing approval application for AZD1222 in Japan was submitted by AstraZeneca on 5 February 2021.

GSK-Sanofi vaccine – GSK and Sanofi are collaborating on a vaccine candidate with the purpose of manufacturing hundreds of millions of doses annually by the end of 2021. Both committed to making their jointly developed vaccine affordable to the public and through mechanisms that offer fair access for all. GSK and Sanofi reached manufacturing and supply deals with various countries and regional organisations, including UK, US, European Union, Canada and Gavi. For more info on their vaccine development progress see “Share real-time clinical trial data.”

Adjuvant vaccine technology – In May 2020, GSK confirmed its intention to manufacture 1 billion doses of its pandemic vaccine adjuvant system, in 2021, to support the development of multiple adjuvanted COVID-19 vaccine candidates.

CVnCoV vaccine – GSK would support the manufacture of up to 100 million doses of CureVac’s first generation COVID-19 vaccine candidate CVnCoV in 2021.

NVX-CoV2373 vaccine – GSK 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 candidate (NVX-CoV2373).


South Africa-based Aspen announced entered into an agreement with J&J’s Janssen Pharmaceuticals, for the technical transfer and commercial manufacture of Ad26.COV2-S. To support the development of vaccines for African countries, IFC, DEG and the U.S. International DFC announced a joint €600 million long-term financing package for Aspen Pharmcare, which aims to produce more than 500 million doses of the J&J vaccine by the end of 2022.

Johnson & Johnson is committed to bringing an affordable vaccine to the public on a not-for-profit basis for emergency pandemic use.

Johnson & Johnson announced it would provide up to 500 million doses of its COVID-19 vaccine candidate to lower-income countries through the COVAX Facility as part of an agreement in principle with Gavi.

Johnson & Johnson signed manufacturing and supply deals with various countries and regional organisations, including Canada, European Union, UK, US, AVAT, COVAX Facility, UNICEF.

On 18 October 2021, Johnson & Johnson welcomed the US government’s decision to donate 17 million doses of its J&J COVID-19 vaccine to countries in the AU.

On 10 November 2021, Johnson & Johnson entered into an agreement with the U.S. Government and Gavi to enable access to its single-shot COVID-19 vaccine through a novel mechanism – the COVAX Humanitarian Buffer – that would serve to protect the world’s most vulnerable people.

Johnson & Johnson welcomed the decision of EU Member States along with Norway and Iceland (Team Europe) to
donate almost 100 million doses of its COVID-19 vaccine through the COVAX Facility. As a practical rapid response to the urgent need to scale up equitable access to vaccines, these doses will be utilized to help protect individuals in low-income countries.

On 30 November 2021, Johnson & Johnson reached an advanced stage in its discussions for a potential licensing agreement for its COVID-19 vaccine with Aspen, which is based in South Africa. The parties would continue to work toward a definitive agreement that builds on their existing manufacturing collaboration and would enable the COVID-19 vaccine to be manufactured and sold by an African company, in Africa and for people living in Africa.

On November 22, 2021, Johnson & Johnson welcomed the decision of EU Member States along with Norway and Iceland (Team Europe) to donate almost 100 million doses of its COVID-19 vaccine through the COVAX Facility.

Merck announced comprehensive expansions with a combined € 40 million investment at its production facilities in Danvers, Massachusetts, and Jaffrey, New Hampshire, USA. These sites supply critical products to customers developing lifesaving therapies, including Covid-19 vaccines. These expansions will significantly increase capacity and output at these facilities by the end of 2021.

Merck acquired AmpTec, a leading Hamburg, Germany-based, mRNA contract development and manufacturing organization (CDMO). This acquisition strengthened Merck’s capabilities to develop and manufacture mRNA for its customers for use in vaccines, treatments and diagnostics applicable in Covid-19 and many other diseases.

Merck announced the expansion of its strategic partnership with BioNTech and will increase the supply volume of lipids needed for the Pfizer-BioNTech vaccine towards the end of 2021.

Merck is adding a single-use assembly production unit at its Life Science Center in Molsheim, France. With the € 25 million investment, the company is accelerating its European expansion plans for this key technology, which is used to produce Covid-19 vaccines and other lifesaving therapies.

Merck has launched a new, high-purity synthetic cholesterol product, nine months ahead of schedule to meet the high demand for lipids, a key component of mRNA-based vaccines and therapeutics.

Moderna would expand its agreement with Lonza to establish a new production site in the Netherlands that would manufacture the drug substance of Moderna’s updated booster variant vaccine candidate, if authorized.

Thermo Fisher in North Carolina would support fill-finish manufacturing of Moderna’s COVID-19 vaccine.

Samsung Biologics would provide large-scale, commercial fill-finish manufacturing for Moderna’s COVID-19 vaccine. Moderna would expand its collaboration with Aldevron which supplies plasmid DNA to serve as the genetic template for generating the COVID-19 mRNA vaccine.

Sanofi would provide fill-finish manufacturing for 200 million doses of Moderna’s COVID-19 vaccine starting September 2021, at their site in New Jersey.

Rovi would produce bulk substance for Moderna’s COVID-19 vaccine, expanding an agreement between the companies. Rovi currently provides fill-finish for the vaccine, receiving substance from a Lonza plant in Switzerland. A new production line at Rovi’s plant in Granada, Spain, would make ingredients for up to 100 million vaccine doses a year.

Baxter BioPharma Solutions in Indiana would support fill-finish manufacturing of Moderna’s vaccine in the US. Moderna would partner with Takeda which would support the import and distribution activities of the vaccine in Japan.

Moderna would collaborate with Catalent in Indiana for vial filling and packaging capacity.

Lonza’s sites in Switzerland and New Hampshire would support drug substance and manufacturing of Moderna’s vaccine.

Recipharm would support formulation and fill-finish for Moderna’s vaccine at their site in France.

Laboratorios Farmacéuticos Rovi would support large-scale, commercial fill-finish manufacturing of Moderna’s vaccine at their site in Madrid, Spain.

CordenPharma would manufacture large-scale volumes of Moderna’s lipid excipients to be used in the manufacture of Moderna’s vaccine.
Moderna announced that the government of India issued a registration certificate and a permission to import the COVID-19 Vaccine Moderna for restricted use in an emergency situation. On 10 August 2021, Moderna and Canada announced a collaboration to bring mRNA manufacturing to Canada, with the goal of providing Canada with direct access to rapid pandemic response capabilities and vaccines in development for respiratory viruses. Additionally, on 16 August, they announced a revised supply agreement for up to 105 million doses of the vaccine and its booster candidate for delivery through 2024. On 7 October, Moderna announced it 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. The Company anticipates investing up to $500 million in this new facility which is expected to include drug substance manufacturing with the opportunity for fill/finish and packaging capabilities at the site. The Company expects to begin a process for country and site selection soon. Moderna announced that Gavi, the Vaccine Alliance has exercised its option to purchase an additional 176.5 million doses of the Moderna COVID-19 vaccine for the COVAX Facility. Of these additional doses, 116.5 million doses are expected to be delivered in the first quarter of 2022 and 60 million doses are expected to be delivered in the second quarter of 2022. All doses are offered at Moderna's lowest tiered price, in line with the Company's global access commitments. Moderna announced a new MoU to make up to 110 million doses of the Moderna COVID-19 vaccine available to the African Union. All doses were offered at Moderna's lowest tiered price, in line with the Company's global access commitments. On 16 November 2021, Moderna announced an agreement that enables the EU and EEA countries to donate more than 70 million doses of the Moderna COVID-19 vaccine.

Novartis announced that it signed an initial agreement to leverage its manufacturing capacity and capabilities in order to address the COVID-19 pandemic by supporting the production of the Pfizer-BioNTech COVID-19 Vaccine. Novartis announced that it signed an initial agreement to manufacture the mRNA and bulk drug product for the COVID-19 vaccine candidate CVnCoV from CureVac to aid in the fight against the COVID-19 pandemic. Novartis plans to produce up to 50 million doses of the mRNA and bulk drug product for the CureVac vaccine in 2021 and up to a further 200 million doses in 2022. First deliveries of the bulk drug product to CureVac are expected in the summer 2021. On 21 October 2021, Novartis announced that it signed an initial agreement to leverage its manufacturing capacity and capabilities to address the COVID-19 pandemic by expanding its support of the fill and finish of the Pfizer-BioNTech COVID-19 vaccine. Novartis would use its sterile manufacturing facilities at its Novartis Technical Operations site in Ljubljana, Slovenia, to fill at least 24 million doses in 2022.

Novavax announced that it signed an agreement with SK Bioscience to increase production of its COVID-19 vaccine. Novavax and the European Commission finalized an advance purchase agreement for up to 200 million doses of the
COVID-19 vaccine NVX-CoV2373, the company’s recombinant nanoparticle protein-based COVID-19 vaccine candidate, through 2023.

**Novavax** is increasing manufacturing capacity to 100 million doses per month by the end of the third quarter of 2021 and to 150 million doses per month by the fourth quarter of the year.

**Novavax** has initiated technology transfer at National Research Council of Canada Biologics Manufacturing Centre to produce NVX-CoV2373.

**Novavax** has entered into advance purchase agreement with Gavi to provide 350 million doses to the COVAX Facility. SII is to manufacture and distribute additional vaccines for the combined total of 1.1 billion doses.

**Pfizer**/BioNTech – In April 2020, **Pfizer** and BioNTech jointly develop and scale up manufacturing for their COVID-19 vaccine. The companies planned to at least supply approximately 1.3 billion doses by the end of 2021. In May 2021, the CEO of Pfizer announced targeting 3 bn doses produced by end of 2021. **Pfizer**/BioNTech reached an advance purchase agreement with COVAX for up to 40 million doses to be delivered throughout 2021. **UNICEF** partnered with Pfizer on behalf of the COVAX Facility for the supply of the Pfizer-BioNTech vaccine through 2021.

**Pfizer** and BioNTech collaborate for manufacturing scale up with various organizations, including **Delpharm**, **Thermofisher**, **Novartis**, **Sanofi**, **Baxter**, **Siegfried**, **Dermapharm**, **Fosun**, **Polymun**, **Allergopharma**. **Pfizer** and BioNTech also reached manufacturing and supply deals with various countries and regional organisations, including **Australia**, **Canada**, European Union (1, 2, 3, 4, 5, 6), **Japan**, **UK**, **US** (1, 2, 3, 4), **IOC**.

On 21 May 2021, at the **Global Health Summit**, **Pfizer** and BioNTech pledged to provide 2 billion doses of their COVID-19 vaccine to middle- and low-income countries over the next 18 months. They expected to provide 1 billion of these doses to low- and middle-income countries in 2021. And they pledged to deliver another 1 billion doses to these countries in 2022.

**Pfizer** and BioNTech announced plans to provide the U.S. government at a not-for-profit price 500 million doses of the companies’ COVID-19 vaccine, 200 million doses in 2021 and 300 million doses in the first half of 2022, to further support the multilateral efforts to address the surge of infection in many parts of the world and to help end the pandemic. The government would, in turn, donate the Pfizer-BioNTech vaccine doses to low- and lower-middle-income countries and organizations that support them.

**Pfizer** and BioNTech announced the signing of a letter of intent with Biovac, a Cape Town-based, South African biopharmaceutical company, to manufacture the Pfizer-BioNTech COVID-19 Vaccine for distribution within the African Union. To facilitate Biovac’s involvement in the production process, technical transfer, on-site development and equipment installation activities would begin immediately. At full operational capacity, the annual production would exceed 100 million finished doses annually. All doses would exclusively be distributed within the 55 member states that make up the African Union.

On 26 August 2021, **Pfizer** announced the signing of a letter of intent with Eurofarma Laboratorios SA, a Brazilian biopharmaceutical company, to manufacture COMIRNATY® for distribution within Latin America.

On 22 September 2021, **Pfizer** and BioNTech announced plans to expand their agreement with the U.S. government by providing an additional 500 million doses of the companies’ COVID-19 vaccine at a not-for-profit price for donation to low- and lower-middle-income countries and the organizations that support them.

On 21 October 2021, **Novartis** announced that it signed an initial agreement to leverage its manufacturing capacity and capabilities to address the COVID-19 pandemic by expanding its support of the fill and finish of the Pfizer-BioNTech COVID-19 vaccine. Novartis would use its sterile manufacturing facilities at its Novartis Technical Operations site in Ljubljana, Slovenia, to fill at least 24 million doses in 2022.

On 28 October 2021, **Pfizer** and BioNTech announced that the U.S. government purchased 50 million more doses of the companies’ COVID-19 vaccine.

On 11 November 2021, **Pfizer** and **BioNTech** announced a collaboration with Zipline that would pioneer a new vaccine
distribution model using a long-range drone that will allow the delivery of 50,000 COVID-19 vaccine doses in Ghana.

**Sanofi** will invest €610 million to create a new production site and research center in France to increase its vaccines research and production capacities, contributing to future pandemic responses.

**Sanofi-GSK vaccine** – Sanofi and GSK are collaborating and committing to creating and supplying sufficient quantities of their vaccine candidate. See GSK for more details regarding their joint COVID-19 vaccine development.

**BNT162b2 vaccine** – Sanofi partnered with Pfizer/BioNTech to support manufacturing and supply of 125 million vaccine doses.

**Ad26.COV2-S vaccine** – Sanofi partnered with Johnson & Johnson's Janssen Pharmaceuticals to support manufacturing of the Ad26.COV2-S vaccine. Sanofi provides access to established infrastructure and vaccine manufacturing expertise to formulate and fill vials at a rate of approximately 12 million doses per month.

**Moderna vaccine** – Sanofi entered into an agreement with Moderna, under which Sanofi would help manufacture Moderna’s COVID-19 vaccine, supporting the COVID-19 pandemic and vaccine supply needs. Sanofi would leverage its established infrastructure and manufacturing expertise to perform fill and finish of up to 200 million doses of Moderna’s COVID-19 vaccine, starting in September 2021.

**CSL/Seqirus** partners with CEPI and the University of Queensland to accelerate the development, manufacture and distribution of the University's COVID-19 vaccine candidate. If trials are successful, initial large-scale production of the vaccine will happen at CSL's biotech manufacturing headquarters in Melbourne. The company estimates that the scale-up can help generate millions of doses by the end of next year.

CSL announced it has signed a Heads of Agreement (HoA) with the Australian Government for the supply of 51 million doses of the University of Queensland’s (UQ) COVID-19 vaccine candidate (V451), and a separate HoA with AstraZeneca to manufacture the Oxford University candidate (AZD1222), should clinical trials of both prove successful. CSL announced that its vaccine candidate would not proceed to Phase 2/3 clinical trials.

**Shionogi** is making preparations to offer its vaccine to 10 million people as early as possible by collaboration with Api Co., Ltd. and its group company UNIGEN Inc. It also applied for the "Grant to Promote the Domestic Investment Project to Combat the Supply Chain" publicly established by the Japanese Ministry of Economy, Trade and Industry and three companies. It has begun preparing commercial production in advance of the Ministry's review of the application. Shionogi announced that it was in discussions with Vietnam regarding technology transfer for the manufacturing of the COVID-19 recombinant protein-based vaccine that Shionogi is developing in Japan.

**Takeda** and 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 also announced that it would import and distribute 50 million doses of Moderna's COVID-19 vaccine candidate, mRNA-1273, pending licensure in Japan. Takeda announced a mutual agreement with IDT Biologika GmbH to utilize capacity at IDT previously reserved for Takeda's dengue vaccine candidate (TAK-003) to manufacture the single-shot COVID-19 vaccine developed by the Janssen Pharmaceutical Companies of Johnson & Johnson. At the end of a three-month period, the capacity would be returned to Takeda to resume critical manufacturing for the planned launch of its dengue vaccine, subject to regulatory approvals.

**COVID-19 therapeutics**

**AstraZeneca** modified an agreement with the US Government to supply up to 500,000 additional doses of AZD7442, a
long-acting antibody (LAAB) combination which is in late-stage development for the prevention and treatment of COVID-19.

**Chugai** announced that they agreed with the Japanese government to supply the antibody cocktail casirivimab and imdevimab for the year 2021 for domestic supply if it is approved by the regulatory authority in Japan.

**Eli Lilly** and AbCellera collaborate on AbCellera's rapid pandemic response platform for the rapid development, manufacturing and distribution of therapeutic antibodies. **Eli Lilly** and Amgen announced a global antibody manufacturing collaboration to significantly increase the supply capacity available for Lilly's potential COVID-19 therapies. **Eli Lilly** is collaborating with Fujifilm and the Bill & Melinda Gates Foundation for Supply of Potential COVID-19 Antibody Therapy for LMICs.

**Eli Lilly** and Samsung Biologics entered into the manufacturing partnership agreement in May of 2020 to address the increasingly urgent demand for COVID-19 treatments worldwide.

**Bamlanivimab** – **Eli Lilly** announced an initial agreement with the US government to supply 300,000 vials of bamlanivimab (LY-CoV555) 700 mg, an investigational neutralizing antibody, for $375 million. The US government will accept the vials of bamlanivimab if it is granted an EUA by the US FDA. **Eli Lilly** announced that it was working with global regulators to make bamlanivimab available for emergency use in countries around the world. Global allocation would be made based on Lilly's guiding principles that aim to ensure access for patients with high unmet need, no matter where they live.

**Bamlanivimab/etesevimab** – **Eli Lilly** announced that the U.S. government agreed to purchase a minimum of 100,000 doses of bamlanivimab (LY-CoV555) 700 mg and etesevimab (LY-CoV016) 1400 mg together. **Eli Lilly** announced changes to the purchase agreements with the US government for its neutralizing antibody therapies authorized for emergency use as a treatment for COVID-19. As part of Lilly's planned transition to only supply bamlanivimab and etesevimab together, Lilly and the US government agreed to modify the purchase agreement of bamlanivimab alone and focus on supply of bamlanivimab and etesevimab together. **Eli Lilly** announced a Joint Procurement Agreement with the EC to supply up to 220,000 doses of bamlanivimab and etesevimab for the treatment of confirmed COVID-19 in patients aged 12 years and older who do not require supplemental oxygen for COVID-19 and who are at increased risk of progressing to severe COVID-19. On 15 September 2021, **Eli Lilly** announced an additional purchase by the U.S. government for bamlanivimab with etesevimab for administration together. On 2 November 2021, **Eli Lilly** announced an additional purchase by the U.S. government for bamlanivimab with etesevimab for administration together.

**Baricitinib** – Eli Lilly entered into royalty-free, limited, non-exclusive voluntary licensing agreement with **Lupin**, **Cipla**, **Sunpharma**, Natco Pharma for manufacturing and selling of Lilly's monoclonal antibody treatment Baricitinib in India.

**Gilead** has proactively scaled up manufacturing of remdesivir to increase available supply as rapidly as possible in anticipation of potential future supply needs. In August 2020, Gilead announced that it had increased supply more than 50-fold since January, and was likely able to meet real-time global demand starting in October. The company is planning to produce more than two million treatment courses by the end of 2020, and several million more in 2021, if needed. To further expand global supply, **Gilead** is in discussions with leading chemical and pharmaceutical manufacturing companies about their ability, under voluntary licenses, to produce remdesivir for Europe, Asia and the developing world at least through 2022. **Gilead** also negotiated long-term voluntary licenses with several generic drugmakers in India and Pakistan and is in active discussions with the Medicines Patent Pool to license remdesivir, and with UNICEF to deliver the drug using its established distribution networks.

As of August 2020, **Gilead’s manufacturing network for remdesivir** includes more than 40 companies in North America,
Europe and Asia.

**Gilead** announced that in response to the rapid increase in COVID-19 cases in India, the company 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.

Gilead also reached an **agreement with the EU Commission** to secure sufficient doses of remdesivir for 30,000 patients presenting severe COVID-19 symptoms. In addition, the company also **signed a JPA with the EU Commission** that will enable rapid and equitable access to remdesivir.

On 19 October 2021, **Gilead** announced that the company would donate 100,000 vials of Veklury® (remdesivir) to help address the recent surge of COVID-19 cases in Indonesia and 3,000 vials of Veklury to help patients hospitalized with COVID-19 in Armenia.

**GSK**

On 17 November 2021, **GlaxoSmithKline** and **Vir Biotechnology** announced US government contracts to purchase sotrovimab, which GSK would supply by December 17, 2021, enabling further expanded nationwide access to sotrovimab for patients.

**MSD**, known as Merck inside the United States and Canada, announced it has entered into a procurement agreement with the US government for molnupiravir (MK-4482). Through the agreement, if molnupiravir receives EUA or approval by the US FDA, Merck will supply approximately 1.7 million courses of molnupiravir to the US government. Merck has been investing at risk to support development and scale-up production of molnupiravir and expects to have more than 10 million courses of therapy available by the end of 2021.

**Molnupiravir** – **MSD**, known as Merck in the US and Canada, amid the humanitarian crisis in India, announced voluntary licensing agreements with five Indian generics manufacturers to accelerate and expand global access to molnupiravir, an investigational oral COVID-19 treatment.

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.

On 10 November 2021, **MSD**, known as Merck in the United States and Canada, and Ridgeback Biotherapeutics announced that the Japanese government will purchase, upon authorization or approval, approximately 1.6 million courses of molnupiravir (MK-4482, EIDD-2801).

On 6 December 2021, **MSD**, known as Merck in Canada and the United States, announced it entered into an agreement with Thermo Fisher Scientific to manufacture molnupiravir. Thermo Fisher’s manufacturing site in Whitby, Ontario, would manufacture molnupiravir for distribution in Canada and the United Kingdom as well as markets in the European Union, Asia Pacific and Latin America, pending local market approvals.

**Pfizer**

**Pfizer** announced a multi-year agreement with Gilead to manufacture and supply Gilead’s remdesivir.

On 16 November 2021, **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 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.

On 18 November 2021, **Pfizer** announced an agreement with the U.S. government to supply 10 million treatment courses of its investigational COVID-19 oral antiviral candidate, PAXLOVID™ (PF-07321332; ritonavir), subject to regulatory authorization from the U.S. FDA.

**Roche**

**Roche** and Regeneron joined forces to significantly increase global supply of REGN-COV2, 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 confirmed that the U.S. HHS and DOD will purchase additional supply of Regeneron's casirivimab and imdevimab antibody cocktail for use in non-hospitalised COVID-19 patients as part of Operation Warp Speed. Novartis signed an initial agreement with Roche to reserve capacity and implement the technology transfer for the production of the active pharmaceutical ingredient (API) for Roche’s Actemra/RoActemra® (tocilizumab), a treatment for rheumatoid arthritis which is also being tested in various clinical trials investigating the safety and efficacy in COVID-19 associated pneumonia.

In May 2021, Roche and Cipla announced that the first batch of the Antibody Cocktail (Casirivimab and Imdevimab) was available in India while a second batch would be made available by mid-June 2021. Roche and Chugai decided not to assert any patents against the use of Actemra/RoActemra in COVID-19 in LMICs during this current pandemic. Regeneron announced that the U.S. HHS and the DOD will purchase 1.4 million additional doses of REGEN-COV (casirivimab and imdevimab).

Sanofi increased production capacity of hydroxychloroquine by 50% and is on track to further increase production over the coming months. Teva is assessing additional production of hydroxychloroquine sulfate tablets with materials that are being sent to Teva from its ingredient supplier. Teva’s global manufacturing network has been working tirelessly on securing and scaling production of both API and finished doses for potential treatments that my prove essential in treating COVID-19 everywhere Teva does business.

SUPPORT GLOBAL HEALTHCARE SYSTEMS IN THE FIGHT AGAINST COVID-19

Use our medical expertise to support global healthcare systems to manage the unprecedented increase in the pressure they are experiencing.

IFPMA member companies are committed to helping to boost healthcare system capacities and protect healthcare workers, particularly in the hardest-hit and vulnerable countries that are ill prepared to cope with an accelerating outbreak of COVID-19. When the novel coronavirus first emerged in Wuhan, China, IFPMA and its member companies started working with their teams on the ground, and with the Chinese authorities to ensure people gain access to necessary health care services. This experience has since repeated around the world as the virus spread with increased efforts by member companies donating PPE and money to ease burdens on hard-pressed health services.

Support to affected countries worldwide (on-going)

AbbVie donated $35 million to COVID-19 relief efforts. In the US, it supported healthcare capacity for hospitals and secured access to food and essential supplies for vulnerable populations. In Europe, it provided critical equipment and supplies to patients and front-line healthcare workers in hard-hit countries. AbbVie made donations to 26 community non-profit organizations to support COVID-19 relief efforts, totaling $5 million. The AbbVie COVID-19 Community Resilience Fund helped these organizations to support front-line
AFIDRO donated medical equipment to the Central Military Hospital of Bogota (Colombia) to strengthen the COVID-19 pandemic response.

Almirall donated topical cream to healthcare professionals in Spain and the UK, repurposed production facilities in Germany to manufacture antibacterial gels, and donated PPE to healthcare workers in Spain.

Amgen and the Amgen Foundation donated $12.5 million to support US and global relief efforts for communities with critical needs impacted by COVID-19.

Amgen donated $1 million to support AHA’s COVID-19 rapid response efforts in the cardiovascular health community.

APCRG donated 35,000 Georgian lari to the STOPCOV fund (State Treasury Fund) created by the Government of Georgia to fight COVID-19.

APIFARMA and associated pharmaceutical companies supported the fight against the COVID-19 pandemic and donated more than €3 million to Portuguese organisations and institutions.

Astellas and the Astellas Global Health Foundation donated up to $2 million of financial assistance to meet the urgent demand for resources to help US patients, healthcare workers, and first responders in the fight against COVID-19.

Astellas also donated €150,000 euros worth of necessary supplies to public medical institutions and civil society organizations in Italy, and €200,000 to Spain’s health ministry to secure the supply of goods to medical institutions. Astellas authorized paid leave (in accordance with each country’s provision) to employees who are medically qualified and wish to volunteer within their community.

AstraZeneca donated 9 million face masks to healthcare workers around the world and partnered with WEF’s COVID Action Platform to identify countries in greatest need.

Bayer made financial donations to Lombardy, Brazil (€1 million), and France (€1 million) to support COVID-19 relief efforts. The company also donated 1 million chloroquine tablets to Italy; and another 3 million tablets to the US. Bayer produced hand sanitizers in Indonesia based on their expertise from their plants in Germany. Bayer supplied German hospitals with ventilators, provided health care workers with masks, provided the German Army with 600,000 chloroquine tablets, and supported employees wishing to volunteer in the local health system by offering 4 weeks paid leave.

Biogen Foundation has committed $10 million to support global response efforts and communities around the world. Biogen employees donated more than $300,000 to NPOs and volunteered in their communities.

Boehringer Ingelheim contributed €5.8 million from their Global Support Program donations fund, provided paid leave for its 51,000 employees to volunteer for COVID-19 relief, donated over $1 million to protect health care professionals, and established a €580,000 relief fund for social entrepreneurs and their communities in Kenya and India via its Making More Health program.

Bristol-Myers Squibb (BMS) and the BMS Foundation have contributed more than $31 million in financial support and needed products (e.g. PPE and medical equipment) to relief efforts in 43 countries. The BMS Foundation has supported nearly 50 organizations in the U.S. and more than 150 organizations globally that care for patients and that support those on the frontlines of the COVID-19 response. In addition, it has contributed funding to support the work of more than 40 patient advocacy groups and professional societies. Also, to support research, education, and a wide
range of efforts to benefit patients in need, BMS is engaging with more than 250 patient and professional
organizations. BMS partnered with GRYT Health to develop the COVID Advocacy Exchange, a virtual platform to unite patient advocacy organizations, patients, policy makers, healthcare practitioners and industry in the exchange of information.

**Chiesi**
Chiesi donated €3 million to COVID-19 relief efforts in Italy, donated 50,000 units of sanitizing hand gel to public transport operators and PPE to hospitals, partnered with associations of general practitioners providing advice and guidance, and supported the purchase of respiratory equipment in hospitals.

**Chugai**
Chugai donated JPY 50 million to support healthcare professionals fighting COVID-19 in Japan.

**Daiichi-Sankyo**
Daiichi-Sankyo donated $1 million to the WHO COVID-19 Solidarity Response Fund through the Japan Center for International Exchange, supporting COVID-19 relief efforts.

**Eisai**
Eisai provided $250,000 in funding to US civil society organisations, and provided PPE to local healthcare providers in the US.
Eisai provided €945,000 to professional organizations such as the WHO, as well as healthcare providers and vulnerable communities in the UK, Italy, Germany, Spain, Belgium, France, Portugal, and Slovakia.
Eisai donated 11.8 million rupees to federal emergency funding in India, and donated funding and supplies in Indonesia, Thailand, the Philippines, Malaysia, and Vietnam.
Eisai announced that it has committed the equivalent of 1 million USD in aid towards various activities in response to the spread of the novel coronavirus infection in Africa.

**Eli Lilly**
Eli Lilly deployed medical professionals to staff a free drive-through COVID-19 testing facility at its corporate headquarters in Indianapolis.
Eli Lilly and Company Foundation contributed $500,000 to the Central Indiana COVID-19 Community Economic Relief Fund.
Eli Lilly partnered with local health systems to launch dedicated infusion center locations serving central, northern, and now southern Indiana that are intended to provide Hoosiers with access to important COVID-19 treatments.
Eli Lilly and Direct Relief would provide patients in need in LMICs with COVID-19 treatments, free of charge. Lilly donated baricitinib, bamlanivimab (LY-CoV555) and etesevimab (LY-CoV016).

**Farmindustria**
Farmindustria and member companies donated over €9.4 million worth of medicines to Italian hospitals, €21.8 million of financial and medical equipment donations, and 4 members modified their production lines to meet health needs during the pandemic.

**Gilead**
Gilead provided remdesivir to physicians for compassionate use to treat hundreds of severely ill COVID-19 patients. Gilead committed another 1.5 million individual doses of remdesivir for donation, representing 140,000 treatment courses based on a 10-day treatment duration.
Gilead announced the $20 million Gilead CARES (COVID-19 Acute Relief and Emergency Support) Grantee Fund to support civil society organisations impacted by the COVID-19 pandemic.
Gilead partnered with Satcher Health Leadership Institute at Morehouse School of Medicine to study racial health inequities associated with COVID-19.

**GSK**
GSK donated $10 million to the WHO COVID-19 Solidarity Response Fund to enable distribution of essential supplies to frontline health workers.
GSK donated lab equipment, instruments, and scientific kits to support government testing and donated over 700,000 PPE units to frontline health workers in 29 countries.
GSK donated more than 660,000 GSK products to more than 24 countries in Asia, Americas and EU.
HKAPI delivered 17,000 surgical face masks to patient organizations together with the continued support of their member companies in sourcing PPE.

Johnson & Johnson committed $50 million to support frontline health workers during the COVID-19 pandemic. Johnson & Johnson encouraged medically trained employees worldwide to take paid leave and volunteer within their community. Financial donations made by employees or retirees to the Covid-19 Solidarity Response Fund or the CDC Foundation’s All of Us Campaign were matched, dollar for dollar, up to a total of $1 million for each organization.

LEO Pharma made donations supporting local hospitals and communities in Northern Italy, Spain and New Jersey (US) in fighting COVID-19.

Lundbeck supported fundraising activities in Italy, donated PPE to France and the US, committed $1 million to COVID-19 relief efforts in North America, and donated to the COVID Response Funds in regions where the company is present.

Medicines Australia joined forces with 15 healthcare organisations in the Continuity of Care Collaboration to stress the importance for people to continue monitoring their health and maintaining regular medical care.

Menarini converted a topical pharmaceutical producing plant in Florence into a antibacterial gels producing plant, donated products across Italy and increased production from 20 to 100 tons per month.

Merck engaged in multiple donation efforts in more than 40 countries, adding up to cash and goods worth millions of Euros, including in-house 3D-printed face shields and disinfectant. Merck donated two million FFP2 masks, e.g. in Germany, France, Brazil, the United States, Ethiopia, Ghana, Central America, Cameroon, Nigeria, Mexico, Lebanon, Mauritania to support frontline healthcare workers. Merck supports employees in heavily affected countries: E.g. in India, Merck provided € 2 million for vaccinations and medical equipment, and vaccination programs are being prepared for Peru, Indonesia, and the Philippines, among others.

MSD committed more than $30 million to COVID-19 relief efforts, including donations of medicines, PPE and funding to relief organizations, and pledged another $10 million to support disparately impacted patients and communities in the US and globally.

MSD's $3 million through MSD for Mothers, MSD committed $3 million to address critical maternal health needs during COVID-19. MSD encouraged medically trained employees to volunteer in local communities, providing paid leave. MSD announced it was taking a number of new steps to support patients in the US who may have lost their jobs and health insurance coverage.

Merck donated 150,000 liters of disinfectant to the German state of Hesse.

Novartis donated up to 130 million doses of hydroxychloroquine. Novartis’ COVID-19 Response Fund provided $20 million in support to the most impacted communities around the world. Novartis and the Novartis US Foundation established a $5 million US COVID-19 Community Response Fund. Novartis Canada and Sandoz Canada donated $500,000 to community and patient groups via the Community Strong COVID-19 response program. Novartis contributed $1 million to the International Rescue Committee to support the COVID-19 response in East Africa. Novartis and its subsidiary Sandoz launched a not-for-profit portfolio of medicines for symptomatic treatment of
COVID-19, which were made available to governments, NGOs and other institutional customers in up to 79 eligible countries.

**Novo Nordisk** donated PPE, provided 20 tons of hand sanitizer to hospitals, and through its Novo Nordisk Foundation donated more than $7 million to fight COVID-19 in Denmark.

**Pfizer** created a Global COVID-19 Medical Service Program to empower medical colleagues to provide diagnostic, treatment, and public health support. Pfizer and the Pfizer Foundation provided $40 million in medical and charitable cash grants to combat the COVID-19 pandemic.

**Roche**'s subsidiary, Genentech and the Genentech Foundation, provided $42 million to address the devastating impact of the COVID-19 pandemic.

**Sanofi** made a charitable gift of 100 million euros to help tackle the coronavirus crisis in France, with the money going to hospitals, care homes and other initiatives. Sanofi also donated 100 million doses of hydroxychloroquine across 50 countries globally.

**Servier** provided PPE to hospitals in affected countries, donated to foundations and NGOs, and encouraged medically-trained staff to volunteer in the French healthcare system to combat COVID-19.

**Sumitomo Dainippon Pharma** (SDP) manufactured 20,000 face shields and procured PPE through its Chinese subsidiary for use in the worst affected Japanese prefectures. SDP subsidiary Sunovion Pharmaceuticals provided a monetary donation to the US CDP COVID-19 Response Fund, donated PPE, delivered food donations to a food bank and sent out volunteers to support the activities of the NHS in the UK, and provided further financial support to several organizations. SDP also joined forces with Innovative Medicines Canada to set up a Canadian COVID-19 fund.

**Takeda** donated $6.25 million to the American Red Cross, the city of Cambridge, and the town of Lexington to fight COVID-19.

**Teva** donated more than 10 million hydroxychloroquine doses to hospitals in the US, and another 2 million hydroxychloroquine units to the Israeli Ministry of Health. The company also donated hydroxychloroquine as well as PPE to Spain and allowed UK employees to volunteer with the NHS, providing paid leave. Teva provided PPE, kits and food to populations in need in India.

**UCB** donated hydro-alcoholic solutions to the Belgian and Swiss authorities which it started producing at its own manufacturing sites. UCB encouraged healthcare professionals to volunteer in line with local government needs and guidance. UCB donated PPE to Belgian healthcare authorities and local hospitals.

**Support to China during the start of the outbreak (Jan/ Feb 2020)**

**AbbVie** donated older antiviral drugs upon request from the Chinese government as an experimental option to support the growing public health crisis.

**Astellas** Pharma China donated 1 million yuan to the Red Cross Society of China for purchasing PPE and procuring medical treatment equipment and donated 300,000 yuan worth of PPE to hospitals in Wuhan, China.

**Bayer** made financial contributions and donations of several medicines to the Chinese Red Cross.
Boehringer Ingelheim made financial donations to the Chinese Red Cross to purchase PPE and made donations of medicines.

Bristol-Myers Squibb (BMS) and the BMS Foundation provided more than $5 million in financial support and essential products to COVID-19 relief efforts.

CSL Group donated 1 million RMB to the China Red Cross in support of COVID-19 relief efforts.

Eisai donated 1 million yuan to the Wuhan Charity Federation and provided local healthcare providers with medicines and medical relief supplies.

Johnson & Johnson donated 300 boxes of HIV medication to the Shanghai Public Health Clinical Centre and Zhongnan Hospital of Wuhan University. The company also provided drug-screening for antiviral properties against SARS-CoV-2 to assist laboratory-based investigations of the Chinese CDC.

Eli Lilly donated 1 million yuan to the Chinese Red Cross. The Lilly Foundation donated $100,000 to Direct Relief, and $150,000 to Project HOPE to support their COVID-19 relief efforts.

Lundbeck supported local communities and societies with monetary and medicine donations to Wuhan, China.

MSD donated 1 million RMB to the Chinese Red Cross Foundation and supported the construction of a second specialty hospital (Leishenshan Hospital) to treat COVID-19 patients in Wuhan. MSD launched online campaigns to educate the public about respiratory disease and helped provide up-to-date articles on treatment guidelines for health care professionals.

Otsuka donated 1 million RMB to the Red Cross located in Jinnan Community Hangzhou Lin'an Area for medical supplies and PPE, 500,000 RMB to the Sichuan Red Cross, medical supplies to the Hubei Charity Federation, and provided supportive nutritional products to medical staff, the Tianjin Red Cross and designated hospitals in Beijing.

Pfizer made cash contributions to its global NGO partners who shipped supplies to hospitals in China. The Pfizer Foundation provided $500,000 in grants for direct COVID-19 relief efforts of Direct Relief and Project HOPE.

Roche donated diagnostics tests, medical supplies and financial support, including a donation of $2 million worth of tocilizumab to China to help manage the COVID-19 outbreak. Roche subsidiary Genentech also worked with Chinese government and health authorities to provide screening and health care.

Sumitomo Dainippon Pharma subsidiary Sumitomo Pharmaceuticals donated 1 million RMB to the Chinese Red Cross Foundation for prevention and containment efforts.

Teva donated 9,600 packs of azithromycin to 15 hospitals in Hubei.

Abbreviations

Boehringer Ingelheim
Bristol Myers Squibb
CSL Group
Eisai
Johnson & Johnson
Lundbeck
MSD
Otsuka
Pfizer
Roche
Sumitomo Dainippon Pharma
Teva

Abbreviations
<table>
<thead>
<tr>
<th>Abbreviated Term</th>
<th>Full name</th>
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<tbody>
<tr>
<td>ACT Accelerator</td>
<td>The Access to COVID-19 Tools Accelerator</td>
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<tr>
<td>ACIP</td>
<td>Advisory Committee on Immunization Practices</td>
</tr>
<tr>
<td>ACTIV</td>
<td>Accelerating COVID-19 Therapeutic Interventions and Vaccines</td>
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<tr>
<td>AHA</td>
<td>American Hospital Association</td>
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<tr>
<td>AMED</td>
<td>Agency for Medical Research and Development (Japan)</td>
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<td>AMSP</td>
<td>Africa Medical Supplies Platform</td>
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<td>anti-GM-CSF</td>
<td>anti-granulocyte macrophage colony-stimulating factor</td>
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<td>CEPI</td>
<td>Coalition for Epidemic Preparedness Innovations</td>
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<td>CHMP</td>
<td>Committee for Medicinal Products for Human Use</td>
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<td>CMA</td>
<td>Conditional Marketing Authorisation</td>
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<td>cMAA</td>
<td>conditional Marketing Authorisation Application</td>
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<td>COMET-ICE</td>
<td>COVID-19 Monoclonal antibody Efficacy Trial - Intent to Care Early</td>
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<tr>
<td>CRS</td>
<td>Cytokine Release Syndrome &quot;cytokine storm&quot;</td>
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<td>CoVax</td>
<td>Vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator</td>
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<td>DARPA</td>
<td>The Defense Advanced Research Projects Agency (US)</td>
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<td>DFC</td>
<td>Development Finance Corporation</td>
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<td>DSMB</td>
<td>data safety monitoring board</td>
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<td>Acronym</td>
<td>Full Form</td>
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<td>DZIF</td>
<td>German Center for Infection Research</td>
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<tr>
<td>ECCMID</td>
<td>European Congress of Clinical Microbiology &amp; Infectious Diseases</td>
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<td>EFPIA</td>
<td>European Federation of Pharmaceutical Industries Associations</td>
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<td>EMA</td>
<td>European Medicines Agency</td>
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<tr>
<td>EUA</td>
<td>Emergency Use Authorization</td>
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<td>GISAID</td>
<td>The Global Initiative on Sharing All Influenza Data</td>
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<td>HHS</td>
<td>U.S. Department of Health and Human Services</td>
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<td>H-IG</td>
<td>Hyperimmune globulin</td>
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<td>IAVI</td>
<td>International AIDS Vaccine Initiative</td>
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<td>IDMC</td>
<td>Independent Data Monitoring Committee</td>
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<td>IMI</td>
<td>Innovative Medicines Initiative</td>
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<td>INSERM</td>
<td>Institut National de la Santé et de la Recherche Médicale (France)</td>
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<td>IOC</td>
<td>International Olympic Committee</td>
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<td>ISB</td>
<td>Institute for Systems Biology (US)</td>
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<td>ITAC</td>
<td>Inpatient Treatment with Anti-Coronavirus Immunoglobulin</td>
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<td>JPA</td>
<td>Joint Procurement Agreement</td>
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<td>LAAB</td>
<td>long-acting antibody</td>
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<td>LSTM</td>
<td>Liverpool School of Tropical Medicine</td>
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<td>mAbs</td>
<td>Monoclonal antibodies</td>
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<tr>
<td>MIT</td>
<td>Massachusetts Institute of Technology</td>
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<td>MHLW</td>
<td>Ministry of Health, Labour and Welfare</td>
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<td>MHRA</td>
<td>Medicines &amp; Healthcare Products Regulatory Agency</td>
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</table>
11 billion COVID-19 vaccines produced in 2021 has resulted in the biggest immunization campaign in human history and 2022 will require more and better vaccine redistribution and innovation

December 16, 2021

Momentum of COVID-19 vaccine manufacturing scale up sufficient for step change in distribution

September 7, 2021

Global biopharmaceutical industry sees upcoming World Health Assembly as a critical milestone to take stock of progress achieved and discuss enablers for future pandemic preparedness

May 24, 2021

Five steps to urgently advance COVID-19 vaccine equity

May 19, 2021

ACT-Accelerator 1-Year Anniversary: the biopharmaceutical industry is committed to continue to play a critical role across ACT-A and accelerate equitable and fair access to COVID-19 tools

April 23, 2021
**COVID-19 vaccine industry cautions immediate action needed to remove manufacturing supply barriers to meet production targets and keep on course to equitable and fair access to COVID-19 vaccines**

April 23, 2021

**Meeting discusses COVID-19 vaccine manufacturing bottlenecks that must be urgently tackled for C19 vaccine output to reach its full potential**

March 9, 2021

**Pharma delivers COVID-19 solutions, but calls for the dilution of intellectual property rights are counterproductive**

December 8, 2020

**Biopharma industry updates on COVID-19 treatments progress and warns about upholding regulatory standards of quality**

September 3, 2020

**Pharma partners in efforts to give coronavirus vaccine for everyone**

May 28, 2020

**Pharma industry updates advice on engaging with healthcare professionals as countries emerge from COVID-19 lockdown**

May 28, 2020

**Pharma and other innovative health groups tell World Health Assembly it stands united with governments and global health stakeholders worldwide to combat COVID-19**

May 19, 2020

**Pharma Joins Global Pledge Committing to Work Together to Beat COVID-19**

May 4, 2020

**Global Pharma update on unprecedented efforts to collaborate in speeding up the search for safe and effective COVID-19 therapies**

April 30, 2020

**Pharma industry body joins as founding partner a new global collaboration to accelerate the development, production and equitable access to new COVID-19 tools**

April 24, 2020

**Global Biopharmaceutical Industry pulling out all the stops to address Coronavirus public health crisis**

March 19, 2020
IFPMA EFPIA PhRMA BIO ABPI Statement
- Global COVID-19 Summit: Ending the Pandemic and Building Back Better
September 22, 2021

IFPMA Statement at 76th Session of the UN General Assembly
September 21, 2021

Five steps to urgently advance COVID-19 vaccine equity
May 19, 2021

COVID-19 vaccine and treatment innovators response to global leaders urgent call for international pandemic treaty
March 30, 2021

IFPMA, GSCF, ICBA Joint Statement on the item 14.2 Strengthening preparedness for health emergencies: implementation of the IHR @EB148
January 20, 2021

Innovative biopharmaceutical industry comment on COVID-19 vaccines dosing strategies and recommend following the science
January 13, 2021

Biopharmaceutical industry support EU regulators exceptional transparency measures and call other regulatory authorities to follow suit to help ensure confidence in the science and the decision-making
October 13, 2020

IFPMA statement on "Intellectual Property and COVID-19"
October 16, 2020
Safety of vaccinated individuals is the top priority in development of COVID-19 vaccines

September 15, 2020

COVID-19 Vaccine Maker Pledge
September 8, 2020

Innovative vaccine industry strongly committed to rigorous regulatory standards for approval of COVID-19 vaccines
August 27, 2020

IFPMA Statement on the “Solidarity Call to Action to realize equitable global access to COVID-19 health technologies through pooling of knowledge, intellectual property and data”
May 28, 2020

Joint Statement – Innovative Health Industries @ WHA73
May 18, 2020

Pharma Statement for The Coronavirus Global Response Pledging Marathon
May 4, 2020
IFPMA Statement on the launch of a new global collaboration to accelerate the development, production and equitable access to new COVID-19 tools
April 24, 2020

Innovative health industries united in welcoming United Nations General Assembly Resolution on “International Cooperation to ensure global access to medicines, vaccines and medical equipment to face COVID-19”
April 21, 2020

IFPMA remarks on intellectual property management and the global response to COVID-19
April 6, 2020

Global Biopharmaceutical Industry Commitment to Address Coronavirus Public Health Crisis
March 19, 2020

IFPMA and WHO Global Research and Innovation Forum
February 12, 2020

IFPMA Members’ support in countering the novel coronavirus (2019-nCoV)
February 10, 2020
R&D-based pharmaceutical industry’s innovative partnerships to meet urgent global supply needs
December 20, 2021

Call to Action On Routine and Life-Course Immunization in the Context of the COVID-19 Pandemic
December 9, 2020

IFPMA Policy Principles on COVID-19 Vaccines Initiative
September 15, 2020

Ethical Considerations for Resuming In-Person Interactions with Healthcare Professionals Post COVID-19: A Guidance Document
May 28, 2020
WHO LINKS

WHO - COVID-19 situation dashboard
WHO - WHO R&D Blueprint
WHO - Coronavirus Diseases (COVID-19) Outbreak
WHO - Coronavirus Diseases (COVID-19) Situation Reports
WHO - Q&A on the Coronavirus
WHO - Global Research on Coronavirus Disease (COVID-19)
WHO - Speeches of WHO DG Dr Tedros at daily media briefings
WHO - Updated Country Preparedness and Response Status for COVID-19 as of 6 March 2020
WHO COVID-19: WHO’s Global Research Roadmap
WHO - A Coordinated Global Research Roadmap: 2019 Novel Coronavirus
WHO - Draft landscape of COVID 19 candidate vaccines
Access to COVID-19 Tools (act) Accelerator
Act-Accelerator update
WHO Regulatory Updates on COVID-19

OTHER LINKS
Dose sharing is a critical urgent step towards vaccine equity: it needs support to be successful (Step #1) Blog
COVID-19 vaccines: Meeting the world's need (Step #2) Blog
Why we must remove barriers to trade to achieve vaccine equity (Step 3) Blog
Each and every country faces unique challenges in rolling out COVID-19 vaccination (Step 4) Blog
International Clinical Trials Registry Platform
Policy Cures Research - COVID-19 R&D Tracker
COVID-19 NMA - a living mapping of ongoing research.
Global Coronavirus COVID-19 Clinical Trial Tracker
FDA - Emergency Use Authorization (EUA) information, and list of all current EUAs
COVID-19 Therapeutic Development Tracker
FasterCures (center of the Milken Institute) Tracker
Global COVID-19 Access Tracker