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

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 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** 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** 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** 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.

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.

**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/Seqirus** 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 NNI/AID, 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 Xlla antagonist monoclonal antibody) to treat patients suffering from severe respiratory distress, a leading cause of death in patients with COVID-19 related pneumonia.

**Daiichi Sankyo** reached a basic agreement with the University of Tokyo, RIKEN and Nichi-Iko Pharmaceutical Co., Ltd. on collaborative R&D on a Nafamostat inhalation formulation for treating COVID-19.

**EFPIA**, through the IMI, IMI associated partners and other organisations provided up to 45 million EUR to fund 8 COVID-19 R&D projects with 3 focusing on treatments.

**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.

**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
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 donated a supply of interferon beta-1a (Rebif®) to the French Institut National de la Santé et de la Recherche Médicale (INSERM) following a request for use in a clinical trial to investigate it as a potential therapeutic for COVID-19. Merck donated 290,000 units of its interferon beta-1a (Rebif®) to the WHO for use in their global SOLIDARITY trial which investigates several potential therapeutics for the treatment of COVID-19.

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.

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** 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.

**Roche** confirmed 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 REMDACTA 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.

**AT-527** — 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.

**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.

**Sanofi** Sarilumab — Sanofi entered into a partnership with Regeneron Pharmaceuticals to evaluate the arthritis drug sarilumab in hospitalised patients 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.

**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 CoVig-19 Plasma Alliance announced that the Phase 3 ITAC clinical trial sponsored and funded by the NNIAD, 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. Teva is actively looking through its range of products to determine if any products may be relevant for COVID-19.

UCB 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.

SHARE REAL-TIME CLINICAL TRIAL DATA WITH GOVERNMENTS, COMPANIES & THE PUBLIC

Share real-time clinical trial data with governments and other companies around the world to advance the development of additional therapies.

“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.

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.

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

**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.

**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.

**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.

**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.

**Boehringer Ingelheim** supports scientists worldwide with its open innovation portal opnMe.com, which offers 6 antiviral 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.

**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.

**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
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 \( ^\text{\textregistered} \) (remdesivir) for the treatment of patients with COVID-19 requiring hospitalization.

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.

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.

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.

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.”

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.

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.

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.

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

Merck, known as MSD outside the United States and Canada, and Ridgeback Biotherapeutics provided an update on the clinical development program for molnupiravir (MK-4482/ EIDD-2801), an investigational oral antiviral agent. The companies reported findings on one secondary objective from the Phase 2a study, showing a reduction in time (days) to negativity of infectious virus isolation in nasopharyngeal swabs from participants with symptomatic SARS-CoV-2 infection, as determined by isolation in Vero cell line culture.

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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, ensovibep (MPO420), in healthy volunteers. The initial findings show ensovibep to be safe and well tolerated with no significant adverse events.

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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.

Pfizer confirmed that a lead protease inhibitor shows antiviral activity against SARS-CoV-2. Pfizer will perform preclinical confirmatory studies.

Azithromycin – Pfizer shared data regarding azithromycin which may facilitate the use of azithromycin in future
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 that showing the BNT162b2 vaccine effectively neutralizing SARS-CoV-2 with a key mutation found in highly transmissible variants. Pfizer and BioNTech announced additonal 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 EU-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.

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. 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. 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.

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

MRT5500 vaccine – Sanofi and Translate Bio announced the 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.

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 CoVig-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 CoVig-19 Plasma Alliance, as well as by two other companies. The CoVig-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.

As of 27 April 2021, WHO reports 92 candidate vaccines are in clinical evaluation and 184 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.

Bayer 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 CSL/ 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 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
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 older. 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.

MSD 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 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.

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.

**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.

**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.

**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™ 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.

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.

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
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.

**SECURE ESSENTIAL SUPPLIES FOR OTHER MEDICINES & VACCINES**

Work to secure continuity of supply for all essential medicines, and vaccines for patients with other life-threatening diseases, urging governments to implement policies and decisions that facilitate access for all those in need.

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.

Grüenthal 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.

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 and 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.
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 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).

Johnson & Johnson announced a collaboration with Emergent BioSolutions to expand the manufacturing capacity of its lead investigational COVID-19 vaccine candidate. Johnson & Johnson, and subsidiary Janssen Pharmaceuticals, have entered into manufacturing partnerships with Sanofi, MSD (known as Merck in the US and Canada), Catalent, Emergent BioSolutions, and Biological E for its single-dose COVID-19 vaccine.

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. 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.

Merck partnered with the Jenner Institute for the large-scale production of its Covid-19 vaccine candidate, ChAdOx1 nCoV-19. Merck expanded its capacity to keep up with a surge in demand of materials to mass-produce COVID-19 vaccines. Merck and BioNTech announced the further expansion of their strategic partnership to significantly accelerate the supply of urgently needed lipids and increase the amount of lipid delivery towards the end of 2021, which will be used for the production of the Pfizer-BioNTech Covid-19 Vaccine (BNT162b2).
MSD, amid humanitarian crisis in India, announced voluntary licensing agreements with five Indian generics manufacturers to accelerate and expand global access to molnupiravir, an investigational oral therapeutic for the treatment of COVID-19.

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.

Pfizer 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.

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 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.
Takeda, Novavax and the Japanese Ministry of Health, Labour and Welfare are partnering to increase manufacturing capacity of Novavax’s COVID-19 vaccine candidate NVX-CoV2373 in Japan. Takeda anticipates to manufacture over 250 million doses of the COVID-19 vaccine per year. Takeda 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.

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.

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.

Eli Lilly announced an initial agreement with the U.S. government to supply 300,000 vials of bamlanivimab (LY-CoV555) 700 mg, an investigational neutralizing antibody, for $375 million. The U.S. government will accept the vials of bamlanivimab if it is granted an EUA by the U.S. FDA.

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 U.S. 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 U.S. government agreed to modify the purchase agreement of bamlanivimab alone and focus on supply of bamlanivimab and etesevimab together.

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.

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

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.

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.

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**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 spreaded 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)**

<table>
<thead>
<tr>
<th>Company</th>
<th>Description</th>
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<tbody>
<tr>
<td>AbbVie</td>
<td>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 healthcare workers and vulnerable populations in hard-hit communities.</td>
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<tr>
<td>AFIDRO</td>
<td>AFIDRO donated medical equipment to the Central Military Hospital of Bogota (Colombia) to strengthen the COVID-19 pandemic response.</td>
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<tr>
<td>Almirall</td>
<td>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.</td>
</tr>
<tr>
<td>Amgen</td>
<td>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.</td>
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<tr>
<td>APCRG</td>
<td>APCRG donated 35,000 Georgian lari to the STOPCOV fund (State Treasury Fund) created by the Government of Georgia to fight COVID-19.</td>
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<tr>
<td>APIFARMA</td>
<td>APIFARMA and associated pharmaceutical companies supported the fight against the COVID-19 pandemic and donated more than €3 million to Portuguese organisations and institutions.</td>
</tr>
<tr>
<td>Astellas</td>
<td>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.</td>
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<tr>
<td>AstraZeneca</td>
<td>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.</td>
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<tr>
<td>Bayer</td>
<td>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.</td>
</tr>
<tr>
<td>Biogen</td>
<td>The 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.</td>
</tr>
</tbody>
</table>
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 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 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 donated JPY 50 million to support healthcare professionals fighting COVID-19 in Japan.

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 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 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.

Farminstria 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 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 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.

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. 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/Seqirus** 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** Eli Lilly China 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.
<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>
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<td>ACTIV</td>
<td>Accelerating COVID-19 Therapeutic Interventions and Vaccines</td>
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<td>AHA</td>
<td>American Hospital Association</td>
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<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>AU</td>
<td>African Union</td>
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<td>BARDA</td>
<td>Biomedical Advanced Research and Development Authority</td>
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<td>CDC</td>
<td>Centers for Disease Control</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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<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>DSMB</td>
<td>data safety monitoring board</td>
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<td>DZIF</td>
<td>German Center for Infection Research</td>
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<td>Acronym</td>
<td>Full Form</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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<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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<tr>
<td>INSERM</td>
<td>Institut National de la Santé et de la Recherche Médicale (France)</td>
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<tr>
<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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<tr>
<td>mAbs</td>
<td>Monoclonal antibodies</td>
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<td>MIT</td>
<td>Massachusetts Institute of Technology</td>
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<td>MHRA</td>
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<td>MoH</td>
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<td>mRNA</td>
<td>Messenger ribonucleic acid</td>
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<td>NEJM</td>
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<td>Full Form</td>
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<td>NIAID</td>
<td>National Institute of Allergy and Infectious Diseases (US)</td>
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<td>National Institute of Infectious Diseases (Japan)</td>
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<td>OSCAR</td>
<td>Otilimab in Severe COVID-19 Related Disease</td>
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<td>PHRI</td>
<td>Population Health Research Institute</td>
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<td>PPE</td>
<td>Personal Protection Equipment</td>
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<td>UKK</td>
<td>Cologne University Hospital</td>
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<td>University of Marburg</td>
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<td>US CDC</td>
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<tr>
<td>WHO</td>
<td>World Health Organisation</td>
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**Videos**

![Video Thumbnails]
Thomas Cueni statement – 1-Year Anniversary of the Access to COVID-19 Tools Accelerator (Video)
April 23, 2021

BIO-DCVMN-IFPMA COVID-19 Press Briefing - 23 April 2021 (Video)
April 23, 2021

Global Biopharma CEO/Top Executives COVID-19 Media Briefing / COVID-19 diagnostics, treatments and vaccines (Video)
December 8, 2020

Global Biopharma CEO/Top Executives COVID-19 Media Briefing – COVID-19 therapeutics-3 September 2020 (Video)
September 3, 2020

Global Biopharma CEO/Top Executives COVID-19 Media Briefing - 28 May 2020 (Video)
May 28, 2020

IFPMA President David Ricks on Global Pledge Committing to Work Together to Beat COVID-19 (Video)
May 5, 2020

Global Biopharma CEO/Top Executives Virtual Press Briefing - 30 April 2020 (Video)
April 30, 2020

The value of the Ethos in the context of COVID-19
April 17, 2020

The biopharmaceutical industry commitments to tackle the coronavirus pandemic (Video playlist)
March 24, 2020

Pharma CEO/Top Executives Global Response to COVID-19 - Virtual Press Briefing - 19 March 2020 (Video)
March 19, 2020
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

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

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

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

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
R&D-based pharmaceutical industry’s innovative partnerships to meet urgent global supply needs

April 27, 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

COVID-19 Biopharmaceutical Industry – Regulatory Guiding Principles

May 14, 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

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