Appendix A: Overview of Selected Collaborations

The following appendix provides an overview of selected biopharmaceutical collaborations to advance efforts focused in the following areas: **Research & Development, Public Health & Improving Patient Outcomes, Manufacturing & Distribution, Improving Access**. Partnerships were grouped together based on a singular, or in some cases, overlapping focus area. The selected examples below, provide a brief overview of the collaboration's purpose, partners, approach used to generate results and any successes yielding from the group's efforts.

R&D			
Purpose	Partners	Approach	Recent Successes
Antimicrobial Resistance (AMR) Action Fund			
• Launched on July 9, 2020 seeking to strengthen and accelerate research and development of antibiotics. • Aims to bring 2-4 new antibiotics to patients by 2030. • Work with partners to encourage governments to create market conditions that enable sustainable investment in the antibiotic pipeline.	• **Nonprofit:** International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), • **Industry:** Amgen Inc., Eli Lilly and Company, F. Hoffmann-La Roche AG, Johnson & Johnson, Merck & Co., Novartis International AG, Novo Nordisk A/S and Pfizer Inc., • Broad alliance of industry and non-industry stakeholders, including philanthropies, development banks, and multilaterals.	• Expects to invest more than US $1 billion in smaller biotech companies and provide industry expertise to support the clinical development of novel antibiotics	• Expected to be **operational** during the fourth quarter of 2020
Alzheimer's Disease Neuroimaging Initiative (ADNI)			
• Launched in 2004 as a multi-site, longitudinal, prospective study to develop clinical, imaging, genetic and biomarkers for the early detection and tracking of Alzheimer's. • Seek to detect AD at earliest possible stage (pre-dementia) and identify ways to track disease, support advances in intervention, prevention and treatment all while maintaining open records for all scientists around the world	• Initially **funded as private-public partnership** with contributions from 20 companies and 2 foundations through Foundation for the National Institutes of Health (NIH) and National Institute on Aging. • **Government Agencies:** The National Institutes of Health (NIH) and the Foundation for the National Institutes of Health (FNIH). • Academic Institutions: The Northern California Institute for Research and Education (NCIRE), The Alzheimer's Therapeutic Research Institute (ATRI) at the University of Southern California and the Laboratory of Neuro Imaging at	• Unites researchers with study data • Collect, validate, and utilize data (MRI and PET images, genetics, cognitive tests, CSF and blood biomarkers as predictors of the disease) to develop novel treatments and improve understanding	• **ADNI 3** has been underway since 2016 with the goal of determining the relationship between the clinical, cognitive, imaging, genetic, and biochemical biomarker characteristics across the entire spectrum of AD. • Over 1000 scientific publications have used ADNI data. • Numerous other initiatives related to AD and other diseases have been designed and implemented using ADNI as a model. • Is there any way we can comment on the promise of the pipeline and perhaps correlate how this partnership may have helped? Too far of a stretch?

	the University of Southern California, Nonprofits: Accelerate Cure/Treatments for Alzheimer's Disease (ACT-AD), Alzheimer's Drug Discovery Foundation, AbbVie Inc., Alector, Inc., Alzheimer's Association, Industry: Araclon Biotech, Bioclinica, Biogen Inc., Cogstate Ltd., Denali Therapeutics, DiamiR, Eisai Co., Ltd., Eli Lilly and Company, Euroimmun AG, Fujifilm Toyama Chemical Co., Ltd., General Electric Company, Genentech, Inc., Janssen Pharmaceutical Companies of Johnson & Johnson, H. Lundbeck A/S, MagQu, Merck & Co. Inc., d.b.a., PeopleBio, Inc., Pfizer Inc., Piramal Group, F. Hoffmann-La Roche AG, Saladax Biomedical Inc, Servier Laboratories, Takeda Pharmaceutical Company Limited		
AstraZeneca's Open Innovation			
• Interested in collaborating with research partners across all stages of drug discovery; from the initial idea through to early clinical development. Seek to accelerate the advancement of medical science and bring novel therapies to patients • Platform provides an open, collaborative approach to link AstraZeneca's expertise, research tools, optimized molecules and technologies. • Shares R&D challenges for interested parties to collaborate on. • Focus area: Cardiovascular, respiratory and metabolic	• Not listed on their website	• Offers testing of compound libraries, technologies, additional services and AstraZeneca plc/AB expertise. • Possibility to jointly publish in high-profile journals. • Partner is provided with the results, which it may publish.	• 250 collaborations started to date • 250,000 compounds available from our screening library • 19 challenges completed to date

diseases, oncology, inflammation and autoimmunity			
Biomarkers Consortium			
• Rapidly identify, develop and quantify potential high-impact biomarkers to enable improvements in drug development, clinical care and regulatory decision-making	• Public-private biomedical research **partnership** managed by the Foundation for the National Institutes of Health with participation from government, industry, academia, and patient advocacy and other non-profit organizations • **Founding partners** include Foundation for the National Institutes of Health (FNIH), the U.S. Food and Drug Administration (FDA), National Institute of Health (NIH), Pharmaceutical Research and Manufacturers of America (PhRMA), Centers for Medicare and Medicaid Services (CMS) and Biotechnology Innovation Organization (BIO)	• Discover, develop, and seek regulatory approval for biological markers to support new drug development, preventative medicine and medical diagnostics	• **BC projects** in community-acquired bacterial pneumonia (CABP), acute skin and skin structure infection (ABSSSI), hospital-acquired bacterial pneumonia (HABP), and ventilator-associated bacterial pneumonia (VABP) including plans for biomarker use, biomarker use application and biomarker use approvals (?) • The BC has taken a leading role in driving consensus to define an evidentiary framework for biomarker qualification • 9 publications in the 2019
California Institute for Biomedical Research (Calibr)			
• Advancing non-profit biomedical research to impact patients while reinvesting in further innovative research • Research interests span cancer, autoimmunity and inflammatory diseases, metabolic and cardiovascular diseases, infectious and neglected diseases, age-related and degenerative diseases	• **Nonprofits:** Scripps Research, Bill and Melinda Gates Foundation, Wellcome Trust, Juvenile Diabetes Research Foundation (JDRF), Cure SMA and California Institute for Regenerative Medicine (CIRM), • **Industry:** Bristol Myers Squibb (BMS), Intarcia Therapeutics, Sirenas, Merck & Co., Pfizer Inc. and ShangPharma Innovation Inc.	• Creation of new medicines accelerated by pairing biomedical research with drug discovery and development • Offer postdoctoral associate training program	• **Gates Global Health initiative** (in partnership with BMGF) that supports an integrated drug discovery platform dedicated to diseases with significant impact in developing countries. • **PRIMER initiative** supports taking advanced assets through IND-enabling studies and early clinical development
Cure Huntington's Disease Initiative (CHDI) Foundation			
• Develop drugs that slow progression of Huntington's disease and provide meaningful	• Work in partnership with biotech and pharmaceutical companies to develop potential drugs	• Science management organization	• Sponsor world-side Huntington's disease observational study and registry called Enroll-HD

clinical benefit to patients as quickly as possible • Lower barrier to entry for other not-for-profit entities interested in collaborating on HD therapeutics • Exploratory biology for identification and validation of therapeutic targets from drug discovery to clinical studies and trials	• **Nonprofits:** Huntington's Disease Society of America (HDSA), Healthcare Distribution Alliance (HDA), the HSC Health Care System and Critical Path Institute (C-PATH), Huntington's disease (HD) Legacy • **Industry:** Charles River Laboratories Inc., Ionis Pharmaceuticals, Pfizer Inc.	• Virtual model that encourages scientific collaboration to connect academic research, drug discovery, and clinical development • Act as "collaborative enabler" for any research group by making resources freely available • Work to build clinical capacity so that promising drugs can progress to clinical trials	• Anti-sense oligonucleotide therapeutic approach that CHDI helped develop with Ionis Pharmaceuticals was subject of substantial investment from F. Hoffmann-La Roche AG • Evaluating Pfizer Inc.'s phosphodiesterase 10 inhibitor in humans • CHD's Adult Mental Health team, along with the organization's property management staff, worked amid a tight deadline to ready two new Group Living Environments (GLEs) in order to have them ready before residents moved in by late June • These **new GLEs provide support to women referred by the Mass. Dept. of Mental Health (DMH)** with severe mental health needs, some with co-occurring mental health and substance use issues, who have little to no experience living on their own
Collaborative Novel-Novel Combination Therapies (CoNNCT)			
• Launched in 2016 with a planning workshop establishing the original focus on a pilot study • Making it easier to test multiple combinations per agent, reducing the cost of early investigational studies, shortening the time to demonstrate proof of concept • Collaborative effort to speed the decision-making around go/no-go decisions in oncology combination drug development using higher throughput and early signal finding	• Academic centers • Biopharmaceutical companies • Diagnostic companies • Representatives of cancer non-profits • U.S. Food and Drug Administration (FDA)	• Develop a new paradigm to accelerate and broaden clinical testing of drug combinations to facilitate early decision and assess effective drug combinations • Test multiple combinations per agent helping to reduce cost of early investigational studies, and shorten time to demonstrate proof of concept	

Lung Cancer Master Protocol (Lung-MAP)			
• Launched in 2014, as a clinical trial designed to effectively and rapidly test new treatments for advanced non-small cell lung cancer • In 2018, the clinical trial was expanded to include all lung cancer diagnoses in the U.S. • Seek to create efficiency and operate collaboratively to benefit patients	• **Government Agency:** National Cancer Institute (NCI), National Cancer Trials Network (NCTN), SWOG Cancer Research Network, Friends of Cancer Research and Foundation for National Institutes of Health • **Nonprofit:** Addario Lung Cancer Foundation, Lung Cancer Alliance, LUNGevity Foundation, Lung Cancer Foundation of America, American Lung Association, Lung Cancer Research Foundation and American Cancer Society • **Industry:** Amgen Inc., AstraZeneca plc/AB, Genentech, Merck & Co. Inc., d.b.a. and Pfizer Inc. • Worked with **10 pharmaceutical partners to launch 9 studies**, 6 of which are completed. These organizations include: SWOG Cancer Research Network, National Cancer Institute (NCI), Foundation for the National Institutes of Health (FNIH), Friends of Cancer Research, Foundation Medicine, Amgen Inc., AstraZeneca plc/AB.	• Test multiple treatments simultaneously under one umbrella design to flexibility and effectiveness • Patients who enroll undergo genetic screening to get a genomic profile to determine genetic alterations or mutations and are then matched to a treatment being tested on Lung Cancer Master Protocol (Lung-MAP).	• Trial offered at more than 650 US medical centers and community hospitals • Registered more than 1,800 patients across the country • Opened and completed **eight drug-centered sub-studies** testing 12 novel therapies, additional achievements **highlighted in Lung-MAP's five-year recap**
Multiple Sclerosis Partnership			
• **Launched in 2015,** research collaboration to explain why and how MS progresses differently across patients • Identify prevention methods to address disease at onset and improve patient outcomes • Identify clinical, radiological, biological, behavioral and environmental factors that	• Verily Life Sciences, Biogen Inc., and Brigham and Women's Hospital (BWH)	• Developed **two research initiatives** to leverage big data and provide insight into novel treatment options for a precision medicine approach. (1) SysteMS study seeks to identify the main factors associated with the severity and progression of MS. (2) Pilot study to test feasibility of wearable devices to measure	• In 2017, initial results for SysteMS study were presented at the **MSParis2017**. The use of digital biosensors to assess patients outside of the clinic revealed to assist clinicians with decision-making around treatment as differences exist across MS patients.**Results also generated data** on the possible utility of predictive biomarkers to inform

correlate with MS severity and progression		mobility, gait, and dexterity of MS patients. • Sensor data and software to draw insights by pooling data, running queries, and developing a better understanding of biomarkers and safety markers	MS diagnosis and ongoing disease monitoring
Northeast ALS Consortium			
• **Launched in 1995**, consortium seeks to translate scientific advances into clinical research and new treatments for people with ALS and motor neuron disease	• Consortium is supported through the ALS Association's TREAT ALS Network, Muscular Dystrophy Association, donors and **member sites** (medical institutions equipped to perform clinical trials for ALS and motor neuron diseases) • Two **"Coordinating Centers"** at Massachusetts General Hospital and Barrow Neurological Institute responsible for the management and conduct of "NEALS-affiliated" trials	• Functions as academic research consortium, contracted research organization, and resource tool for ALS community	• **Since its founding,** NEALS has grown from 9 academic clinical centers to over 100 centers in the U.S. and internationally • In 2020, expanded to **Crestwood Medical Center** through a grant awarded to HudsonAlpha Institute for Biotechnology
One Brave Idea			
• **Launched in 2017**, research effort seeking to change how coronary heart disease is detected, prevented, and treated • Focuses on the earliest abnormalities in the development of coronary disease • Seeks to develop new methods of quantifying cardiovascular health and disease, and identifying new biologic mechanisms that contribute to coronary disease • Engages with patients break down traditional barriers between patient care, research, and their daily lives	• American Heart Association, Verily Life Sciences, AstraZeneca plc/AB and Quest Diagnostics awarded **$75 million research grant** to Dr. Calum MacRae, chief of Cardiovascular Medicine at Boston's Brigham and Women's Hospital.	• Team research effort focused on upstream factors of CHD using the following approach to address the development of CHD: **Deep Phenotyping; Genomics and Phenotyping in Clinical Care; Engaging Broad Patient Populations in Research; Early Detection; Integrative Computational Research; Promoting Non-Traditional Partnerships**	• **Phenotype Phorums** bring stakeholders together to discussion major advances in coronary heart disease prevention, diagnosis and treatment • **Most recent Phenotype Phorum (11/15/19)** discussed the rise in new biomarker discovery for clinical development and regulatory approval of novel therapeutics

Parkinson's Disease Education Consortium (PDEC)			
• Alliance that supports the development of educational resources for the Parkinson's community and conducts patient-centered care research studies	• Parkinson's Disease Education Consortium (PDEC) is part of the Michael J. Fox Foundation who aim to find a cure for Parkinson's Disease through research and development of improved therapies • Acadia Pharmaceuticals, Inc., Voyager Therapeutics, Inc., Acorda Therapeutics, Inc., Adamas Pharmaceuticals, Inc., Amneal Pharmaceuticals, Inc., GE Healthcare Systems, Kyowa Kirin Co., Ltd., H. Lundbeck H/S, Neurocrine Biosciences, Sunovion Pharmaceuticals Inc., US WorldMeds.	• Since its initial launch, the alliance as developed educational programs to increase research participation, bridged the communication gap between patients and health care providers, and connected the Parkinson's community to resources through Parkinson's IQ + You events • Provides ongoing education through MJFF website content; "Ask the MD" blog and video series; Monthly interactive online events with patient, clinician and researcher panelists discussing and answering questions on a Parkinson's care or research topic; Podcasts with experts who delve into a Parkinson's research question or issue	• Provide annual education campaigns to help promote more effective, patient-centered care for Parkinson's including: Bridging the Communication Gap (2019), a study to better understand the patient and care partner language of Parkinson's; Parkinson's Clinical Trial Companion (2018), a suite of toolkits to support patient and trial teams as part of an ongoing effort to increase patient participation in clinical trials; Parkinson's 360 (2017) serves as an online resource for caregivers and families with videos explaining the basics of the disease and living with the disease • 1 million social media followers to date; 425,000+ email subscribers to date; 335,000+ monthly website visits; 100,000 annual views of "Ask the MD" video series; 22,000 annual attendees to our monthly interactive webinars
PatientsLikeMe-AstraZeneca Collaboration			
• Launched in 2015, collaboration combining access to PatientsLikeMe's global network in support of AstraZeneca's patient-driven research initiatives • PatientsLikeMe's seeks to improve patient's lives through new knowledge derived from shared real-world experience and outcomes	• Signed 5-year agreement between AstraZeneca plc/AB and PatientsLikeMe	• AstraZeneca plc/AB will use patient-reported data from PatientsLikeMe to inform development and help improve outcomes across its main therapeutic areas, with an initial focus on respiratory disease, lupus, diabetes and oncology	• Publication (2018): Patient perceptions of their glycemic control and its influence on type 2 diabetes outcomes/ an international survey of online communities

Rare Disease Cures Accelerator Data and Analytics Platform (RDCA-DAP)			
• Launched September 17,2019, the platform provides a centralized and standard infrastructure to support and accelerate rare disease characterization • Enables sharing of existing patient-level data and encourages standardization of new data collection	• Funded through a FDA grant • Critical Path Institute (C-Path) and National Organization for Rare Disorders (NORD).	• Integrated database and analytics hub that provides data-driven solutions to help accelerate and optimize drug development across rare diseases • Data contributed from clinical trials, longitudinal observational studies, patient registries, real-world data and negotiate agreements between data suppliers	• Presentation entitled "Shortening the Timeline for Developing New Treatments" (2020)
Target ALS			
• Launched in 2013, to create a collaborative framework for scientists and clinicians across academia and industry working to accelerate the development of an ALS treatment • Priority areas include target discovery and strengthening therapeutic pipeline and drug development/fast-tracking promising therapeutic areas in the clinic	• Collaborate with academic institutions, biotech and pharmaceutical companies, patient advocacy groups and other non-profits.	• ALS Innovative Ecosystem addresses barriers to progress and accelerate drug discovery and development • The Innovative Ecosystem is comprised of various components including: collaborative funding, scientific tools and resources, industry engagement, independent grant review, no IP restrictions, networking and communication	• 150 research collaborators • 60 pharma and biotech partners • 12 therapeutic approaches • 2019 publication / see full list of publications • The Association for Frontotemporal Degeneration (AFTD) and Target ALS announced a 2019 partnership and call for proposals to identify treatments and biomarkers for FTD and ALS ($5 million, multi-year) • Through Innovation Ecosystem, Target ALS helped connect consortium leaders with Karyopharm Therapeutics to validate drug that was acquired by Biogen Inc. (2018)

Public Health & Improving Patient Outcomes			
Purpose	Partners	Approach	Recent Successes
Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)			
• Launched on April 17, 2020 to develop a coordinated research strategy for developing a COVID-19 treatment or vaccine • Develop a collaborative, streamlined forum to identify preclinical treatments for COVID-19. • Accelerate clinical testing of the most promising vaccines and treatments for COVID-19. • Improve clinical trial capacity and effectiveness for a COVID-19 treatment. • Accelerate the evaluation of vaccine candidates to enable rapid authorization or approval for a COVID-19 treatment.	• Launched on April 17, 2020 to develop a coordinated research strategy for developing a COVID-19 treatment or vaccine • Develop a collaborative, streamlined forum to identify preclinical treatments for COVID-19. • Accelerate clinical testing of the most promising vaccines and treatments for COVID-19. • Improve clinical trial capacity and effectiveness for a COVID-19 treatment. • Accelerate the evaluation of vaccine candidates to enable rapid authorization or approval for a COVID-19 treatment.	• Launched on April 17, 2020 to develop a coordinated research strategy for developing a COVID-19 treatment or vaccine • Develop a collaborative, streamlined forum to identify preclinical treatments for COVID-19. • Accelerate clinical testing of the most promising vaccines and treatments for COVID-19. • Improve clinical trial capacity and effectiveness for a COVID-19 treatment. • Accelerate the evaluation of vaccine candidates to enable rapid authorization or approval for a COVID-19 treatment.	• Launched on April 17, 2020 to develop a coordinated research strategy for developing a COVID-19 treatment or vaccine • Develop a collaborative, streamlined forum to identify preclinical treatments for COVID-19. • Accelerate clinical testing of the most promising vaccines and treatments for COVID-19. • Improve clinical trial capacity and effectiveness for a COVID-19 treatment. • Accelerate the evaluation of vaccine candidates to enable rapid authorization or approval for a COVID-19 treatment.
AstraZeneca, CEPI, Gavi, Oxford University and SII COVID-19 Agreement			
• Launched June 4, 2020, as part of a broader commitment to broad and equitable access to COVID-19 vaccine	• Coalition for Epidemic Preparedness Innovations (CEPI) • **Academic Institutions:** Oxford University and Serum Institute of India (SII) • **Nonprofit:** Coalition for Epidemic Preparedness Innovations (CEPI) • **Industry:** AstraZeneca plc/AB	• $750m agreement with Coalition for Epidemic Preparedness Innovations (CEPI) and Gavi, the Vaccine Alliance to support the manufacturing, procurement and distribution of 300 million doses of the vaccine by the end of next year • Licensing agreement with SII to supply one billion doses for low and middle-income countries	• AstraZeneca plc/AB's COVID response efforts include accelerated efforts in testing new and existing medicines including the CALAVI and ACCORD trials (Calquence/ acalabrutinib) and DARE-19 trial (Farxiga/dapagliflozin)
Combating Antibiotic-Resistant Bacteria (CARB-X)			
• Launched in 2016, to accelerate antibacterial research in order to	• Affiliated with Boston University	• Up to $500 million available to invest in pipeline of new	• 30 active projects as of July 31, 2019. Projects are in the early

address the global rising threat of drug-resistant bacteria • Eliminate inappropriate use of antibiotics • Use alternative approaches to reduce the need for antibiotics • Ensure that antibiotics are available to those in need	• **Funding partners**: Biomedical Advanced Research and Development Authority (BARDA), Office of the Assistant Secretary for Preparedness and Response (ASPR), National Institute of Allergy and Infectious Diseases, UK Aid Direct, Bill & Melinda Gates Foundation, Wellcome Trust, Germany's Federal Ministry of Education and Research • **Accelerators/Other Partners:** California Life Sciences Institute (CLSI), Centre for Cellular and Molecular Platforms (C-CAMP), Foundation for Innovative New Diagnostics (FIND), German Center for Infection Research (DZIF), Institute for Life Sciences Entrepreneurship (ILSE), Massachusetts Biotechnology Council (MassBio), RTI International, Cystic Fibrosis Foundation, The Defense Threat Reduction Agency, Medicines for Malaria Venture.	antibiotics, diagnostics, vaccines and other life-saving products to address drug resistant bacterial infections • Portfolio consists of high-quality antibacterial products focused on the most serious drug-resistant bacteria identified by the WHO and CDC • **Global Accelerator Network** provides scientific and business support to speed up the development of products. The goal is to support these new products through the early stages of product development and Phase 1 to help attract private or public investment for further clinical stage development	stages of preclinical development through the end of Phase 1 • **In the 2018-19 fiscal year**, announced seven new awards for product developers. Also announced funding for more than 20 new projects has been approved, awaiting finalization of the contracts. • 47 projects to date funded • 10 accelerators worldwide • Of the $500 million available to invest, $133.5 million invested already
Gilead and Satcher Health Leadership Institute at Morehouse School of Medicine Partnership			
• Launched in 2020, to better understand the racial disparities that are occurring during the COVID-19 pandemic • Develop a real time, public-facing and comprehensive health equity data platform to help track and address the impact of COVID-19 and other diseases on communities of color in the United States	• Satcher Health Leadership Institute at Morehouse School of Medicine, Gilead Sciences, Inc.	• Gilead initially provided $1 million to support resources for tracking health inequities. Also supports the creation of a Black Health Equity Alliance which will help coordinate COVID-19 education, training, information exchange and dissemination, and policy analysis	

Lilly-Indiana University Diabetes Impact Project			
• Launched in May 2018, and is a neighborhood-based, data-driven pilot in Indianapolis. • Seeks to address high incidence of diabetes by focusing on three neighborhoods with significant health disparities and diabetes prevalence rates that are substantially higher than state and national estiamtes • Builds off existing efforts Lilly has developed in lower-income communities in Mexico, India and South Africa	Implementing partners: • Eli Lilly & Company • Indiana University Richard M. Fairbanks School of Public Health (project lead) • Eskenazi Health • Local Initiatives Support Corporation Indianapolis • Marion County Public Health Department	• The $7 million, five-year pilot has a multipronged approach targeting primary to tertiary prevention of type 2 diabetes and utilizes community health workers to: ○ help identify people with diabetes and connect them with quality care. ○ reduce complications and improve quality of life of people living with diabetes ○ increase awareness of risk factors for diabetes and encourage people at high risk to be screened so they can take action to prevent future complications. ○ The pilot also includes resident-led neighborhood steering committees to: ○ assist the community health workers in reaching residents, and ○ to foster an environment (physical and social) that supports greater health and well-being for all residents.	• Community health workers hired and actively connecting residents to care. • Resident-led steering committees conducting monthly meetings to advance Diabetes Impact Project, including identification of primary prevention focus areas for each neighborhood, such as food access, physical activity and life stressors affecting health. • Pilot is adapting to COVID-19 pandemic with community health workers increasing virtual connections to enroll patients and leveraging social media for communications. Resident-led steering committees continue to meet virtually. • Global Lilly employees participating in pilot through volunteer opportunities. • Part of Lilly's 30×30 goal to reach 30 million people in resource-limited settings annually by 2030.
National Diabetes Prevention Program (National DPP)			
• **Launched in 2010**, to address the increasing burden of prediabetes and type 2 diabetes in the U.S. through evidence-based, affordable and high-quality lifestyle change programs • Provides a framework for diabetes prevention efforts to help prevent	• Partnership of **public and private organizations including**, federal agencies, state and local health departments, national and community organizations, employers, public and private insurers, health care professionals, university	• Collaboration develops lifestyle change programs, a key component of the National DPP • These programs must meet certain standards in order to be **formally recognized by the CDC** • Programs are required to use the **CDC-approved curriculum**	• **2016 ICER report** concludes that the DPP programs provided "an incremental or better" net health benefit • CMS **finalized 2016 rule** to expand coverage of DPP program (called the Medicare Diabetes Prevention Program)

type 2 diabetes and improve overall patient health	community education programs, businesses that focus on wellness • Does not publicly disclose any direct biopharmaceutical partnerships • Collaboration is the largest national preventative effort to address type 2 diabetes.	regarding the duration, intensity and reporting requirements. • **Programs seek** to train community organizations so that they can run the lifestyle change program effectively; increase referrals to and participation in CDC-recognized lifestyle change programs; Increase coverage by employers, public and private insurers • Programs are **research-based** and focus on healthy eating and physical activity	• **CDC expands DPP infrastructure in 2017** to 12 corporative agreements for a 5 year timeframe to build out the National DPP infrastructure in underserved areas in an effort to reduce health disparities for adults with prediabetes or at high risk for type 2 diabetes
NIH Helping to End Addiction Long-Term (HEAL) Initiative			
• **Launched in 2018**, the trans-agency initiative seeks to provide scientific solutions to the national crisis of opioid misuse, overdose and addiction by accelerating research, discovery and preclinical development of non-addictive treatments for pain to address the opioid crisis • **Initiative seeks** to inform and establish the best pain management strategies for acute and chronic pain conditions	• National Institutes of Health (NIH) engaged in **a yearlong consultation** with patients, advocates, academic experts, private sector leaders, and federal partners to identify the greatest research needs and areas of opportunity to address the opioid crisis • **Government Agencies:** National Institutes of Health (NIH), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA) • **Academic Institutions:** University of California – San Francisco, UPenn Medical School, Harvard Medical School, University of Washington, University of Utah, Washington University, University of Vermont, University of California- San Diego, University of North Carolina, Northwestern University, Virginia Commonwealth University • **Nonprofits:** Advanced Medical Technology Association (AdvaMed), American Medical	• **Study areas of focus** include therapeutic options for opioid addiction, overdose prevention, and reversal; Treatments for infants with NAS/NOWS; prevention and treatment strategies for opioid addiction; biological underpinnings of chronic pain • Initiative supports the full spectrum of research efforts to improve pain management and enhance treatment for opioid misuse and addiction	• HEAL has contributed $500 million annually to over **400 research projects** • **Research highlights** span across the following **areas**: Translation of research to practice for the treatment of opioid addiction; New strategies to prevent and treat opioid addiction; Enhanced outcomes for infants and children exposed to opioids; Novel medication options for opioid use disorder and overdose; Clinical research in pain management; Preclinical and translational research in pain management

	Association (AMA), Biotechnology Innovation Organization (BIO), Chronic Pain Research Alliance, Pharmaceutical Research and Manufacturers of America (PhRMA) • **Insurer:** Kaiser Permanente • **Industry:** Amgen Inc., Avid Radiopharmaceuticals Inc., Janssen Pharmaceutical Companies of Johnson & Johnson, Pfizer Inc., Indivior PLC, Medtronic plc.		
Operation Warp Speed			
• **Launched on May 15, 2020**, partnership aims to deliver 300 million doses of COVID-19 vaccine by January 2021, as part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID-19 countermeasures (vaccines, therapeutics, and diagnostic) • Support investment and coordination of countermeasure development allowing for accelerated delivery to patients while adhering to standards for safety and efficacy	• Partnership effort among components of the Department of Health and Human Services (HHS), including the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense (DoD). OWS engages with private firms and other federal agencies, including the Department of Agriculture, the Department of Energy, and the Department of Veterans Affairs. It will coordinate existing HHS-wide efforts, including the NIH's Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership, NIH's Rapid Acceleration of Diagnostics (RADx) initiative, and work by BARDA. • Congress has directed almost **$10 billion to this effort through** supplemental funding, including the CARES Act, and Congress	• The partnership will **accelerate the development, manufacturing, distribution** of COVID-19 countermeasure • Partnership will select the most promising countermeasure candidates and provide coordinated government support to accelerate development while maintaining standards for safety and efficacy • Through federal government investment, manufacturing capacity for selected candidates is advanced while they are still in development, rather than scaled up after approval or authorization; • Partnership will expand domestic manufacturing and supplies of specialized materials and resources, such as glass vials, that can be necessary for distribution	• Efforts to support vaccine development as of **8/7/20**: • Treatment candidates include Johnson & Johnson, Moderna, Inc., and AstraZeneca plc/AB, Regeneron Pharmaceuticals, Novavax, Inc., Pfizer Inc., GlaxoSmithKline plc. • Manufacturing capacities granted to Johnson & Johnson, Moderna, Inc., AstraZeneca plc/AB, Emergent BioSolutions, Texas A&M University and Fujifilm Holdings Corporation, Grand River Aseptic Manufacturing Inc., (GRAM) • Distribution efforts include ApiJect, Systems, Corp. and SiO2 Materials Science.

	has appropriated other flexible funding.		
Gilead HepConnect			
• Five year initiative to help address the **increase in Hepatitis C virus and support community partnerships** in Indiana, Kentucky, Tennessee and North Carolina.	• **44 grantees representing local community based organizations** in Indiana, Kentucky, Tennessee and North Carolina • Grantees range from non-profits to local health departments and ministries.	• In partnership with community organizations, the initiative provides grants to develop and implement evidence-based solutions the meet the needs of people most affected by the opioid crisis • Expand screening and linkage to care by testing for the virus and ensuring those who need it can access appropriate care • Support harm reduction and community education • Activate healthcare infrastructure by building resources know-how and capacity in communities where the need is greatest • Grantee funding for harm reduction services and new strategies to engage and educate the community on harm reduction	• In 2019, HepConnect announced 44 grantees representing $5.3 million in local support across Indiana, Kentucky, Tennessee and North Carolina.

Manufacturing & Distribution			
Purpose	Partners	Approach	Recent Successes
Accelerating Medicines Partnership (AMP)			
• Launched in 2014 with three focus areas: address relevant challenges to rheumatoid arthritis, systemic lupus erythematosus, Alzheimer's disease, and type 2 diabetes • Generate pre-competitive, disease-specific data that will be made publicly accessible to the broad biomedical community • Enhanced systems-level understanding of gene expression and signaling in specific tissues from affected end organs and blood cells • Ascertain and define biological pathways in order to identify relevant drug targets for the treatment of autoimmune diseases • Increase number of new diagnostics and therapies for patients and reduce time and cost of developing them	• Government: National Institutes of Health (NIH), U.S. Food and Drug Administration (FDA). • Industry: AbbVie Inc., Biogen Inc., Bristol Myers Squibb (BMS), Celgene Corporation, GlaxoSmithKline plc, Janssen Pharmaceutical Companies of Johnson & Johnson , Eli Lilly and Company, Merck & Co. Inc., d.b.a., Pfizer Inc., Sanofi Pasteur, Takeda Pharmaceutical Company Limited, Verily Life Sciences • Non-profit: Alzheimer's Association, Alzheimer's Drug Discovery Foundation, American Diabetes Association, Arthritis Foundation, Foundation for the National Institutes of Health (FNIH), Geoffrey Beene Foundation, Juvenile Diabetes Research Foundation (JDRF), Lupus Foundation of America, Alliance for Lupus Research, The Michael J. Fox Foundation for Parkinson's Research, Pharmaceutical Research and Manufacturers of America (PhRMA), Rheumatology Research Foundation, US Against Alzheimer's	• Identify novel way of validating promising biological targets for diagnostic and drug development • Initial focus on RA and lupus with potential to expand 2018 project on Parkinson's disease	

Advanced Regenerative Manufacturing Institute			
• Seeks to make practical the large-scale manufacturing of engineered tissues and tissue-related technologies, to benefit existing industries and grow new ones. • Develop disruptive cell- and tissue-based technologies across five thrust areas • Produce modular and scalable GMP-compliant manufacturing processes and integrated technologies across technology and manufacturing-readiness levels • Develop and standardize manufacturing best practices throughout the industry • Close the skills gap in tissue and organ manufacturing by providing training opportunities to interested students • Disseminate knowledge and enabling technologies to encourage continued innovation.	• Manufacturing USA (MII) initiated BioFabUSA program and is sustained in-part by the Advanced Regenerative Manufacturing Institute (ARMI) and the Department of Defense (DoD). • **Industry:** Advanced Silicon Group, Advanced Solutions Life Sciences, Boston Scientific Corporation, Cell X Technologies, CollPlant Biotechnologies Ltd., Curable, DEKA Research and Development, Embody, Inc., Fibercell Systems Inc, GE Healthcare, Johnson & Johnson, Mayo Clinic, Medtronic plc, Microsoft Corporation, Miromatrix Medical, Inc., O2M Technologies, OrganaBio, STEL Technologies, LLC, Rockwell Automation Inc., Rooster Bio Inc., United Therapeutics Corporation, Pluristyx, Inc., Trailhead Biosystems Inc. • **Academics:** Arizona State University, University of California Los Angeles, Carnegie Mellon University, University of Connecticut, University of Massachusetts Lowell, University of New Hampshire, Texas Heart Institute, University of Virginia, Worcester Polytechnic Institute	• **Regulatory and preclinical consulting** are some of the member support services Advanced Regenerative Manufacturing Institute (ARMI) provides to its members as part of the Advanced Regenerative Manufacturing Institute's BioFabUSA program. • Regulatory and preclinical consulting services seek to support the Advanced Regenerative Manufacturing Institute's BioFabUSA program as part of ARMI's larger mission to support existing industries and grow new ones. • Advanced Regenerative Manufacturing Institute's BioFabUSA integrates innovative cell and tissue cultures with advances in biofabrication, automation, robotics, and analytical technologies to create disruptive research and development tools and manufacturing processes.	• **2019 developments**: Announced the Fall 2019 Project and are seeking applications. Projects are divided into three areas: Education and Workforce Development, Technology, and the Tissue Foundry.

Critical Path Institute (C-PATH)			
• Launched in 2005 seeking to speed up and reduce the costs of medical product development by creating new data standards, measurement standards, and methods standards to aid in the scientific evaluation of the efficacy and safety of new therapies • Created under the FDA's Critical Path initiative program	• U.S. Food and Drug Administration (FDA), University of Arizona, State of Arizona, SFAZ – Science Foundation of Arizona • Partnership with CDISC (Clinical Data Interchange Standards Consortium) to form CFAST (Coalition For Accelerating Standards and Therapies) in 2012 • Additional partnerships listed in **annual reports**	• Acts as an independent third party to form and lead public-private consortia/programs in a pre-competitive collaboration and data sharing effort • Consortium model helps to de-risk decision during development and regulatory review process for novel medical products • Unique expertise working to achieve outlined **core competencies**: Regulatory qualification of preclinical, and clinical biomarkers and novel methodologies for safety, efficacy, and trial enrichment; Development and qualification of clinical outcome assessment tools; Development of quantitative modeling and simulation tools; Regulatory acceptance of nonclinical tools for medical product development; Clinical data standards development; Provision of large-scale data solutions for scientific research; Forming and managing large international consortia; Impact on Regulatory Science	• COA Qualification from U.S. Food and Drug Administration for *Asthma Daytime Symptom Diary* (*ADSD*) and *Asthma Nighttime Symptom Diary* (*ANSD*) • Qualification of drug-induced kidney injury (DIKI) clinical safety biomarker, composite measure • COA Qualification from U.S. Food and Drug Administration for the *Non-Small Cell Lung Cancer Symptom Assessment Questionnaire* (*NSCLC-SAQ*) • COA qualification from FDA for the *Symptoms of Major Depressive Disorder Scale* (*SMDDS*) • PKDOC Secures EMA Qualification Opinion for Enrichment Biomarker in ADPKD • More listed under **successes** and **timeline**

Machine learning ledger orchestration for drug discovery (MELLODDY)			
• **Launched in 2019**, seeks to enable research across a decentralized and highly proprietary database of annotated chemical libraries for the purposes of accelerating drug discovery and improving patient outcomes • Improve collaboration across biopharmaceutical companies participating • Improve predictability of a molecular compound's potential in later stages of drug discovery and development	• Industry: Amgen Inc., Astellas Pharma Inc., AstraZeneca plc/AB, Bayer AG, Boehringer Ingelheim, GlaxoSmithKline plc, Janssen Pharmaceutical Companies of Johnson & Johnson, Merck & Co. Inc., d.b.a., Novartis International AG, Servier Laboratories • Public/Non-profits: Budapest University of Technology and Economics, Katholieke Universiteit Leuven, • Private organizations: Iktos, Katholieke Universiteit Leuven, Kubermatic, Nvidia Corporation, Owkin, Inc., Substra Foundation	• Three-year project from **Innovative Medicines Initiative** funded in part by the **European Commission** • Consortium effort to develop a machine learning platform containing multiple sets of proprietary data without comprising privacy or security • Develop a multi-task predictive machine learning algorithm, without exposing proprietary information • Leverage a collection of over 10 million small molecules with known biochemical or cellular activity to improve the accuracy of predictive models increase efficiencies in drug discovery	• **Announced** successful deployment of the platform and have completed the platform's first federated learning runs. This federated learning can help accelerate the process through which drugs enter clinical trials.
Merck Blockchain Partnership			
• Pilot program to leverage blockchain technology to improve security of prescription drug supply and distribution • Intended to **assess blockchain as a suitable technology** to address needs of the pharmaceutical supply chain • Potential to reduce time needed to track and trace prescription drugs, improve access to reliable distribution information and ensure products are handled appropriately and stored at the right temperature while being distributed	• International Business Machines Corporation (IBM), Merck & Co. Inc., d.b.a., Walmart Inc., KPMG International Limited • The project was selected by the U.S. Food and Drug Administration (FDA) in an effort to implement the **US Drug Supply Chain Security Act (2013)**	• Shared blockchain network that allows real-time monitoring of products in pharmaceutical supply chain • Builds off of work done by International Business Machines Corporation (IBM), and Walmart Inc. in retailer's system for tracking fresh produce and meat	• Program completed in 2019 and provided a **report to the FDA in 2020** outlining the success of the pilot. The pilot met the objectives to demonstrate that blockchain can provide a common record of product movement by connecting disparate systems and improve patient safety by triggering product alerts.

National Cell Manufacturing Consortium (NCMC)			
• **Consortium effort focused** on developing, maturing, and implementing technologies that can enable large-scale, cost-effective manufacturing of therapeutic cells • Seek to transform the manufacturing process for cell-based therapeutics into a large-scale, lower-cost, reproducible, and high-quality engineered process, for broad industry and clinical use	• First U.S.-based national consortium • Over **25 companies, 15 academic**, clinical facilities, private foundations, and government agencies. • National Cell Manufacturing Consortium (NCMC) was established through the Advanced Manufacturing Technologies (AMTech) grant from the National Institute of Standards and Technologies (NIST) • NCMC initiative is in partnership with **the National Science Foundation (NSF) Engineering Research Center (ERC) for Cell Manufacturing Technologies (CMaT)** • Government Agencies: National Institute of Standards and Technologies (NIST) • **Industry:** ACEA Biosciences, Inc., Axion BioSystems, Applied Materials, Inc., ArunA Bio, Bristol Myers Squibb (BMS), CDI Laboratories, Inc., Century Therapeutics, Cytiva Life Sciences, Etaluma Inc., Evolved Analytics Inc., Janssen Pharmaceutical Companies of Johnson & Johnson, Lonza Group AG, Lucid Scientific, MilliporeSigma, Nucleus Biologics, RoosterBio, Inc., Sangamo Therapeutics, Inc., Terumo BCT, Inc., and ViCapsys, Inc.	• Through a collaborative process, the initiative produced a national roadmap on cell therapy manufacturing to advance efforts across the following workstreams: Cell Processing and Automation, Process Monitoring and Quality Control, Supply Chain and Transport Logistics, Standardization, Regulatory Support, and Cost Reimbursement, Workforce Development • Released a **2019**, **2017**, and **2016** roadmap each designed to serve as an update to the previous version	• The **2019** roadmap reports progress in the following areas: Improving understanding of the cell types present in various cell therapies and the properties of these cells, Documenting impacts of trace elements in culture media on product quality, Designing and developing closed, automated, small-footprint cell processing systems, Developing allogeneic and universal T-cell therapies, Improving the scale of mesenchymal stem cell (MSC) production, Increasing understanding of the limits of population doubling, senescence, and exhaustion, Using synthetic biology to better control development of cell therapies

Improving Access			
Purpose	**Partners**	**Approach**	**Recent Successes**
Duke-Margolis Value Based Payment (VBP) Consortium			
• Improve the value of health care by developing evidence-based policy solutions • Develop approaches to payment reform that support better outcomes for patients and better value across the system • Seeks to overcome current barriers to VBP arrangements by identifying and developing solutions to legal and regulatory issues, and by addressing operational challenges such as fragmented and difficult-to-track patient outcome data.	• Partners also include academic institutions, patients and providers including: Aetna Foundation, American College of Cardiology Foundation, Behavioral Economics and Healthy Food Choice Research (BERC) Center at Duke University, Laura and John Arnold Foundation, Bass Connections, Center for Health Policy & Inequalities Research at Duke University, Center for Medicare and Medicaid Innovation, The Commonwealth Fund, Duke Cancer Institute, Duke Clinical Research Institute, Duke Global Health Institute, Duke Population Research Institute, Global Health Technologies Coalition, The Health Foundation, Medical Device Epidemiology Network, Merck & Co., Inc., d.b.a., U.S. Food and Drug Administration (FDA), World Innovation Summit for Health. • Industry: Allergan plc, BioMarin Pharmaceutical Inc., Novartis International AG, bluebird bio, inc., Pfizer Inc., Spark Therapeutics, Amgen Inc., Gilead Sciences inc., GlaxoSmithKline plc, Regenxbio Inc., Medtronic plc, Boston Scientific Corporation, Sarepta Therapeutics, Edwards Lifesciences	• The Consortium hosts regularly scheduled events to convene stakeholders on value-based payment • Develop conceptual frameworks for structuring VBP arrangements • Facilitate stakeholder input and support • Lead health policy research efforts to explore other novel approaches leading to greater value • Focus on healthcare transformation, biomedical innovation, global health policy, education and workforce development	• Publication: **Advancing Value-Based Payment for Transformative Therapies** • Publication: **Overcoming Legal and Regulatory Hurdles to Value-Based Payment Arrangements for Medical Products** • Publication: **Clarifying Medicaid Best Price Regulations In the Context of Value-Based Payment Arrangements** • Publication: **Value-based Payment Consortium Explores Novel Payment Arrangements for Transformative Therapies**

	• Non-profits: National Health Council, FasterCures, Kaiser Permanente, • Insurers: Employees' State Insurance (ESI), Harvard Pilgrim Health Care, HCA Healthcare, Anthem, Inc.		
MIT NEW Drug Development ParadIGmS (NEWDIGS)			
• Focused on enhancing the capacity of the global biomedical innovation system to improve reliability, sustainability, affordability and access • Develop solutions for systemwide impediments to biomedical innovation and patient care All initiatives seek to drive sustainable patient-centered innovation	• Members and Collaboration Partners include: **Government Agency**: The National Institutes for Health (NIH), Nonprofits: Alliance for Regenerative Medicine (ARM), American College of Rheumatology, FasterCures Center, Innovative Medicines Initiative (IMI), IQVIA, Milken Institute, NORD (National Organization for Rare Disorders), **Insurers**: Anthem, Inc., Humana Inc., Kaiser Permanente, Industry: AveXis/ Novartis International AG, bluebird bio, Inc., Biogen Inc., BioMarin Pharmaceutical Inc., Bristol Myers Squibb (BMS), Cardinal Health ,Inc., Janssen: Pharmaceutical Companies of Johnson & Johnson, Merck & Co., Inc., d.b.a., Orchard Therapeutics, **Academic Institutions**: Johns Hopkins University, Massachusetts General Hospital, Dana-Farber Cancer Institute.	• Bring together diverse multi-stakeholder to participate in case-based simulation exercises • Provides a pre-competitive "laboratory" to help advance hands-on collaborative system re-engineering • The Adaptive Biomedical Innovation project seeks to align stakeholders in an effort to advance sustainable patient-centered innovation by applying the principles of continuous learning and improvement across the product life span in ways that: (1) optimize benefit/minimize harm for patients, (2) progressively enhance knowledge and reduce uncertainties about the treatment, and (3) incorporate acceptable tradeoff decisions for all stakeholders • The FoCUS project seeks to collaboratively address the need for novel financing and reimbursement models for durable therapies in the US that ensure (1) patient access for needed treatments; (2) affordability for public and private payers; and (3) the sustainability of innovation by manufacturers The LEAPS project provides the opportunity for various	• Publication: **Payer Perspectives on Reimbursement of One-Time High-Cost Durable Therapies** • Publication: **Are Payers Ready, Willing, and Able to Provide Access to New Durable Gene Therapies?** • Publication: **Leaping Together Toward Sustainable, Patient-Centered Innovation: The Value of a Multistakeholder Safe Haven for Accelerating System Change** Publication: **Alternative State-Level Financing for Hepatitis C Treatment- The "Netflix Model"**

		stakeholders to collaborate on the design and piloting of an innovation ecosystem for a specific disease. In a series of 2 meetings (in 2017 and 2018), elements of the strategic vision of the program, as well as several diseases for the pilot programs were discussed. The 2-year pilot design phase of LEAPS, using rheumatoid arthirits as the primary focus of the Pilot program was launched in January 2018	
Adult Vaccine Access Coalition (AVAC)			
• Work to address lack of information about recommended vaccines, financial hurdles, technological and logistical challenges adults often face when they seek access to and coverage for vaccines. • Seek to develop legislative and regulatory solutions to strengthen and enhance access to and utilization of adult immunization services across the health care system. Committed to improving adult immunization rates among the general and at-risk populations.	• Numerous groups including health care providers, vaccine makers, pharmacies, public health organizations, patient and consumer groups. • Industry: GlaxoSmithKline plc, Merck & Co. Inc., d.b.a., Novavax, Inc., Pfizer Inc., Sanofi Pasteur, Takeda Vaccines, Pte. Ltd. Nonprofit: Biotechnology Innovation Organization (BIO), Pharmaceutical Research and Manufacturers of America (PhRMA).	• Improve reporting of adult vaccinations to state immunization registries • Encourage greater utilization of health information technology to track adult vaccination status and improve patient outcomes and care. Establish additional federal benchmarks and measures to encourage health plans to track, report, and achieve increased adult immunization rates.	• Advocacy: **AVAC Support Letter: Protecting Seniors Through Immunization Act** • Production of educational materials: **Fact Sheet: Financial Barriers to Adult Immunization** • AVAC has cited concerns about the proposed reduction in vaccine administration reimbursement and is also concerned about the Pneumonia Vaccination Status for Older Adults measure (ACO #15) in the Medicare Shared Savings Program (MSSP's) but applauds the addition of zoster, pneumococcal and influenza measures in several Alternative Payment Models (APMs) as well as a number of specialty provider measure sets. Numerous worries about CMS-1717-P Medicare Program). Most recent update regarding COVID-19: AVAC led a diverse group of stakeholders in a letter sent to Congressional leadership providing recommendations on how Congress should invest in immunization infrastructure to

			prepare for the allocation, distribution, and administration of a new COVID-19 pandemic vaccine
Gilead Truvada CDC Partnership			
• Launched May 9, 2019, large supportive donation seeking to support the CDC national effort to help prevent HIV and end the epidemic • Part of Gilead's broader ongoing initiatives to ensure all patients can access PrEP (COMPASS)	• **Government Agency:** Centers for Disease Control and Prevention (CDC) • **Industry:** Gilead Sciences, Inc.	• Gilead Sciences, Inc. will provide to Centers for Disease Control and Prevention (CDC) up to 2.4 million bottles of Truvada® annually for uninsured Americans. • The donation, which extends up to 2030, will transition to Descovy®, if it is approved for use as PrEP • This donation will support a greatly accelerated effort to reach these individuals, as well as create an opportunity for state and local partnerships to develop and implement protocols that are intended to ensure uninsured people at risk for HIV are given access to PrEP at no cost	

Appendix B: Publicly Available Press Releases

The following appendix provides a list of publicly available press releases on selected biopharmaceutical collaborations to advance efforts focused on the COVID-19 Response. This is a selected list of examples of collaborations at the date of report publication. For the latest on the Biopharmaceutical Industry's Efforts to Beat Coronavirus please visit www.phrma.org/Coronavirus.

- AbbVie, Harbour BioMed, Utrecht University and Erasmus Medical Center Announce Collaboration to Develop Monoclonal Antibody Therapy to Prevent and Treat COVID-19, June 5, 2020 (Company press release)
- Amgen and Adaptive Biotechnologies Announce Strategic Partnership To Develop a Therapeutic To Prevent or Treat COVID-19, April 2, 2020 (Company press release)
- AstraZeneca and Oxford University announce landmark agreement for COVID-19 vaccine, April 30, 2020 (Company press release)
- AstraZeneca advances response to global COVID-19 challenge as it receives first commitments for oxford's potential new vaccine, May 21, 2020 (Company press release)
- Bristol Myers Squibb and The Rockerfeller University Announce License Agreement for SARS-CoV-2 Neutralizing Monoclonal Antibody Combination for the Treatment of COVID-19, February 2, 2021 (Company press release)
- CoVIg-19 Plasma Alliance Builds Strong Momentum Through Expanded Membership and Clinical Trial Collaboration, May 7, 2020 (CSL Behring, Takeda press release)
- CureVac and Bayer join forces on COVID-19 vaccine candidate CVnCOV, January 7, 2021 (Company press release)
- DAARPA's Early Investment in COVID-19 Antibody Identification Producing Timely Results, November 10, 2020 (DARPA press release)
- Department of Justice Issues Business Review Letter to Monoclonal Antibody Manufacturers To Expedite and Increase The Production of Covid-19 Mab Treatments, July 23, 2020 (Press release)
- FUJIFILM Diosynth Biotechnologies Texas Facility to Support COvID-19 vaccine candidate Manufacturing, July 27, 2020 (Company press release)
- Gilead Sciences and Satcher Health Leadership Institute at Morehouse School of Medicine Partner to Study Racial Health Inequities Associated with COVID-19, July 28, 2020 (Company press release)
- GSK and CureVac announce strategic mRNA technology collaboration, July 20, 2020 (Company press release)
- IAVI and Merck Collaborate to Develop Vaccine Against SARS-CoV-2, Mary 26, 2020 (Company press release)

- Johnson & Johnson Announces a Lead Vaccine Candidate for COVID-19; Landmark New Partnership with U.S. Department of Health & Human services; and Commitment to Supply One Billion Vaccines Worldwide for Emergency Pandemic Use, March 30, 2020 (Company Press Release)
- Johnson & Johnson Announces Collaboration with the Beth Israel Deaconess Medical Center to Accelerate COVID-19 Vaccine Development, March 13, 2020 (Company press release)
- Johnson & Johnson Announces Collaboration to Expand Manufacturing Capabilities For its COVID-19 Vaccine Candidate in Support of the Company's Goal to Supply More than One Billion Vaccine Doses Globally, April 23, 2020 (Company press release)
- Life Science Companies Commit Expertise and Assets to the Fight Against COVID-19 Pandemic Alongside Bill & Melinda Gates Foundation, March 25, 2020 (Company press release)[1]
- Lilly and Amgen Announce Manufacturing Collaboration for COVID-19 Antibody Therapies, September 17, 2020 (Company press release)
- Lilly and UnitedHealth Group partner on pragmatic study of neutralizing antibody bamlanivimab (LY-CoV555) for COVID-19, December 4, 2020 (Company press release)
- Members of the COVID R&D Alliance and Quantum Leap Healthcare Collaborative Enroll First Patients in I-SPY COVID Trial, August 3, 2020 (AbbVie, Amgen, Takeda press releases)
- Merck and institute for Systems Biology Collaborate to Define Molecular Mechanisms of SARS-coV-2 infection and Identify Potential prognostic Biomarkers, April 27, 2020 (Company press release)
- Moderna Announces Expansion of BARDA Agreement to Support Larger Phase 3 Program for Vaccine (mRNa-1273) Against cOVID-19, July 26, 2020 (Company press Release)
- NIH to launch public-private partnership to speed COVID-19 vaccine and treatment options, April 17, 2020 (Press release)
- Novartis signs initial agreement to provide manufacturing capacity for Pfizer-BioNTech COVID-19 vaccine, January 29, 2021 (Company press release)
- Sanofi and GSK to join forces in unprecedented vaccine collaboration to fight COVID-19, April 14, 2020 (Company press release)
- Sanofi and GSK to support COVAX with 200 million doses of adjuvanted, recombinant protein-based COVID-19 vaccine, October 28, 2020 (Company press release)
- Sanofi joins forces with U.S. Department of Health and Human Services to advance a novel coronavirus vaccine, February 18, 2020 (Company Press Release)
- Sanofi to provide support to BioNTech in manufacturing their COVID-19 vaccine to help address public health needs, January 27, 2021 (Company press release)
- World's leading Life Science Companies Now Enrolling Community, A Global, Platform Trial for Hospitalized Patients with COVID-19, November 30, 2020 (AMGEN, Takeda, UCB press releases)

[1] Press releases announcing collaboration also found on websites of: Boehringer Ingelheim, Bristol-Myers Squibb, Eisai, Eli Lilly, Gilead, GSK, Johnson & Johnson, Merck, Pfizer and Sanofi