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Global Pharma Awards 2021

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Where pharma's true value gets true recognition

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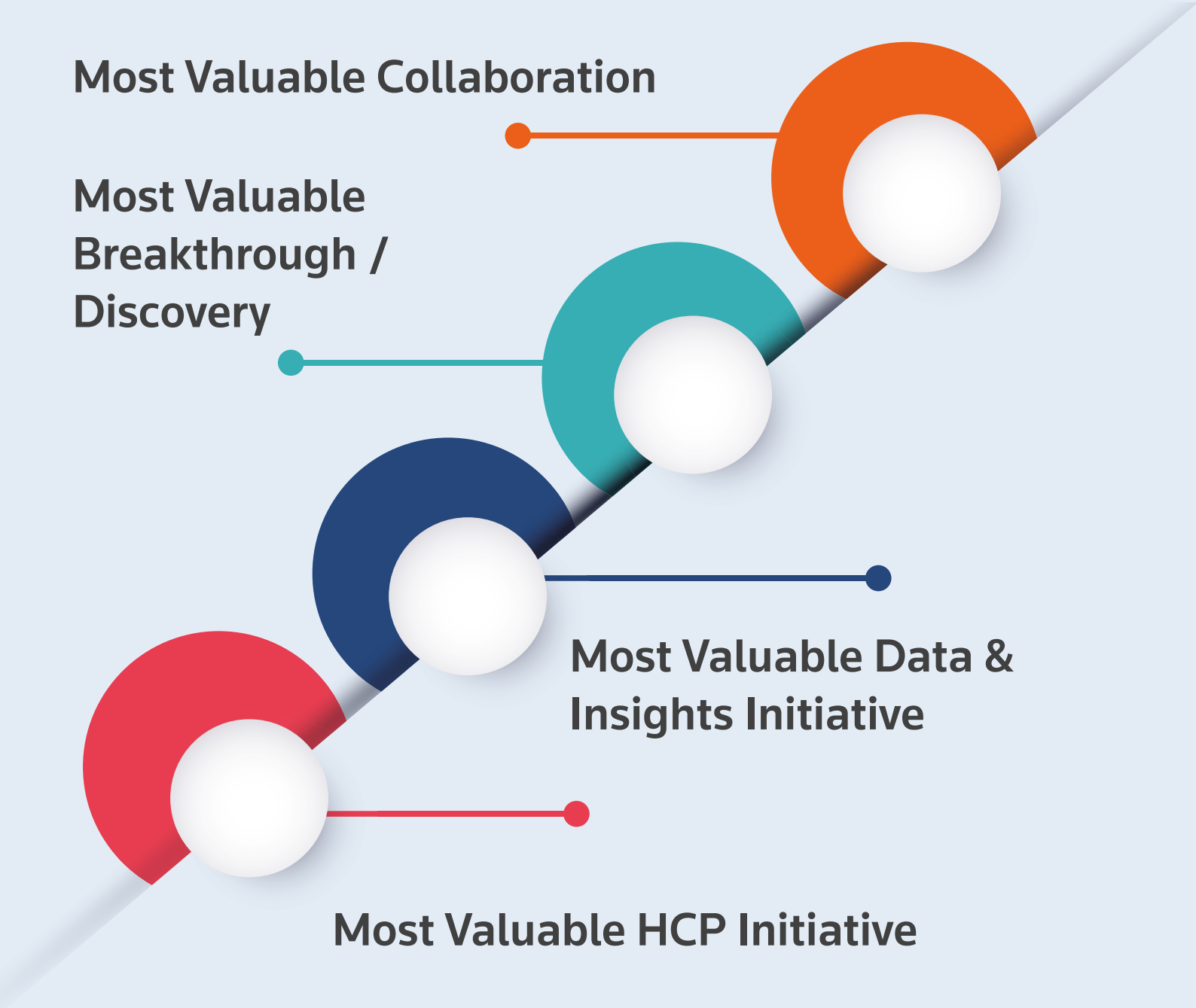
Most Valuable Collaboration
Most Valuable Breakthrough / Discovery
Most Valuable Data & Insights Initiative
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Most Valuable Collaboration

Winner:

Historic Biopharma Industry Pledge to #StandWithScience on Coronavirus Vaccines, Pfizer

When the World Health Organization declared a COVID-19 pandemic on 3/11/20, the best and brightest minds globally set out to do the impossible – create a safe, effective vaccine that would reverse the spread of COVID-19. Leading that charge were Pfizer and BioNTech, which launched Phase I clinical trials on a COVID-19 vaccine in mid-March 2020.

National polls in August/September 2020 unearthed widespread vaccine skepticism and ranked the pharmaceutical industry as the most poorly regarded – even lower than the Federal government, which had drawn heavy criticism for its pandemic response. 62% of Americans believed that political pressure would force the FDA to rush approval of an unproven vaccine. Only 21% of voters said that they would seek vaccination as soon as a vaccine became available.

Pfizer set out to transform this perception by increasing public confidence that the scientific and regulatory process for the COVID-19 vaccine would be held to the highest standards, establishing trust and goodwill and overcoming misinformation that had tainted the public's view of Pfizer's motivations to find a solution for COVID-19.

On 9/8/20, nine CEOs of companies developing vaccines signed the historic Pledge, committing to uphold the integrity of the scientific process and make the safety and well-being of vaccinated individuals their top priority. United under #WeStandWithScience, Pfizer began the virtual handshake on Twitter, then tagged GlaxoSmithKline to join the Pledge, which tagged J&J and so on to establish a bold, multi-Tweet movement. Each company followed up with individualized social posts on Twitter and other social channels.

The #WeStandWithScience Pledge resulted in one of the biggest news days in Pfizer history, garnering blanket top-tier coverage. Pfizer was at the forefront of the conversation and saw positive coverage from virtually every top-tier media outlet, resulting in a 12.8% increase in positive sentiment and a nearly 40% increase in share of voice compared to the 2019 baseline.

Americans feared a vaccine tainted by politics and corporate greed. By assuaging those concerns through transparency and a publicly affirmed commitment to science, Pfizer continued to increase vaccine confidence.

1. What were the challenges you identified when you were developing the initiative?

The public's trust in the pharmaceutical industry was low and nearly two-thirds of Americans feared that vaccine development was politically motivated. National polls in August and September 2020 revealed that pharmaceutical companies ranked as the most poorly regarded industry – even lower than the Federal government, which had drawn heavy criticism for its pandemic response.

Public concern that the political calendar – and not rigorous scientific testing – was shaping the government's vaccine timeline. The President's willingness to openly mix election politics and the complex science of vaccine development alarmed the pharmaceutical industry. 62% of Americans believed that political pressure would force the FDA to rush approval of an unproven vaccine. Only 21% of voters said that they would seek vaccination as soon as a vaccine became available. A CBS News poll found that if a vaccine were made available by Election Day, two-thirds of voters feared it would be rushed through the regulatory process without enough testing.

Fear of a vaccine tainted by corporate greed vs. the public's health. Fear and misinformation tainted the public's view of Pfizer's motivations. They believed pharmaceutical company CEOs should be transparent, holding themselves accountable to the general public, not just their board of directors or shareholders.

2. What's been the main success factors?

Ultimately, Pfizer and Real Chemistry succeeded in their mission to change the perception of the COVID-19 vaccine, and the pharma industry as a whole. Both the Trump and Biden Administrations praised Pfizer throughout the process, speaking to the leadership, guidance, and preparation that Bourla and his company displayed during some of the darkest days in recent American history.

Remaining Steadfast to the Scientific Commitment.

Throughout the vaccine development process, Pfizer committed itself to standing with science and remained focused on the science and the people who desperately needed the vaccine.

Bourla consistently spoke about the vaccine development process in terms that everyday people would understand, and he was effective at assuaging their fears and concerns. By being vocal and forthcoming, he was able to diffuse much of the misinformation surrounding the COVID-19 vaccine. In a report by Business Insider, Bourla noted Pfizer would not "cut the line" to receive vaccine approval and refused to bend to political pressure. It didn't move faster than the process allowed, and met its commitment to transparency.

Public transparency

Data were published and trial protocols were shared on a dedicated site with weekly diversity numbers. FAQs were created that dispelled fake news and conspiracies. Pfizer also refused to allow media to roam its manufacturing facilities since the integrity of vaccine production was more important that a frontpage headline. This was critical to gaining and maintaining trust and set a precedent for other companies to follow.

Although widespread vaccine trust had not yet been established, the public looked to Pfizer for information, guidance and hope, evidenced by 128,000 visits to its website in January 2021 – the most visited COVID-19 or science-related page for the month.

Seizing the leadership position

As the race toward a vaccine continued, Pfizer set itself apart from the eight other pharmaceutical companies as the clear leader in the development process, while remaining centered on the commitment it made with the industry.

Albert Bourla displayed exemplary leadership in rallying his fellow CEOs to unify around the commitment to a safe and effective COVID-19 vaccine through the pledge that reinforced their commitment to being led only by science – not by political pressure – throughout COVID-19 vaccine development.

Pfizer effectively shifted the news media narrative and was at the forefront of the conversation, relying on science and fact-based messages to increase vaccine confidence. Pfizer saw positive coverage from virtually every top-tier media outlet, resulting in a 12.8% increase in positive sentiment and a nearly 40% increase in share of voice compared to the 2019 baseline.

Real Chemistry's proprietary relevance quotient – which evaluates the perception of companies across a variety of audiences – showed Pfizer made major jumps from Q3 and Q4 of 2020. Pfizer's share of voice (SOV) also spiked nearly 40% in Q4 of 2020 compared to the 2019 baseline and Pfizer's vaccine dominated the news cycle throughout November and December.

3. What barriers did you come up against?

Very short implementation timetable. Real Chemistry and Pfizer had two weeks to implement the historic pledge from the time that Pfizer CEO Albert Bourla made the commitment to do the event until the day it launched, which was the day after Labor Day, September 8, 2020. This included developing messages, materials and plans to jointly launch the announcement with the eight other pharmaceutical companies.

Media leak before launch. Days before the launch, several publications released a story that vaccine manufacturers were planning a public statement. Pfizer/Real Chemistry had planned for this possibility and stayed the course to garner the attention the Pledge rightfully deserved. The teams controlled the story, providing limited information and informing reporters the announcement would be made on Sept. 8.

4. What imminent changes do you think your initiative will make?

The pandemic completely changed the world's view of the biopharmaceutical industry – which has gone from an industry with the lowest reputations to one of the highest.

The biopharmaceutical industry's reputation has soared by 94% since January 2020 – from 32 to 62%, according to Harris Poll data, driven by the lightning speed at which the industry responded to the pandemic, its unprecedented collaboration on vaccines and pledge to uphold the integrity of the scientific process that was led by Pfizer.

Consumer awareness and interest in biopharmaceutical companies has shot up as vaccine makers become household names. "Did you get the Pfizer or Moderna?" and "what is the difference between Pfizer, Moderna and J&J?" are questions that have been bandied about since the vaccines become available.

Although the pandemic still rages in many parts of the world – including the U.S. – we've made huge strides on getting shots in arms. Trust in the scientific and regulatory integrity of vaccine development has led to more than 70% of U.S. adults ages 18 and older, or roughly 180.7 million Americans, receiving at least one vaccine dose as of the beginning of August.

In terms of the actual initiative, according to feedback from news outlets, Pfizer and Real Chemistry's campaign was so successful that fellow pharmaceutical companies said they wanted to emulate it nearly identically.

5. What does the future look like? If you had to do it all again, what would you do differently?

What does the future look like?

Hopefully a world where people are more open to the possibility of vaccination.

What would we do differently?

I would build in more time for breaks and self-care for me and my team! Knowing that long days and nights were going to be common, I would make sure we were taking time to take care of ourselves.

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Finalist: Carer Well-Being Index: Recognizing and Providing Support for Unpaid Carers, Merck

As a healthcare provider, Merck KGaA, Darmstadt, Germany has always been acutely aware of the critical role family carers, often referred to more inclusively as unpaid carers, play in the patient journey. The International Alliance of Carer Organization (IACO)'s 2021 Global State of Caring estimates that there are 259 million of them. At the best of times, carers suffer tremendous stress. With COVID-19, there was the addition of extreme isolation and heightened logistical and financial hardships.

It was time for everyone—private and public sectors alike—to step up and recognize the contribution carers make to our society. Embracing Carers®, led by Merck KGaA, Darmstadt, Germany in collaboration with nine leading carer organizations, set out to quantify, for the first time, the global impact of the pandemic on carers. Engaging our global partner organizations was critical to establishing Embracing Carers credibility and bringing an international community together around one common goal. The Embracing Carers global advisors include the Caregiver Action Network, Carers Australia, Carers Canada, Carers UK, Carers Worldwide, Eurocarers, National Alliance for Caregiving, International Alliance of Carer Organizations (IACO) and Shanghai Roots & Shoots, China.

By surveying more than 9,000 unpaid carers across 12 countries and four continents, Merck KGaA, Darmstadt, Germany identified five key trends related to unpaid carers. Known as the Carer Well-Being Index, it is the first-of-its-kind study focusing on the impact of the pandemic on unpaid carers' holistic well-being, including their emotional, physical and financial health. The survey was met with extraordinary enthusiasm and resulted in extensive coverage in top-tier media outlets and academic publications.

MERCK

By identifying carers' current state, Merck KGaA, Darmstadt, Germany was able to recommend specific actions to help governments and private sectors in these countries alike take immediate action. The survey also spurred action in the form of new research and new proposed legislation to close gaps in support by focused measures from multiple players. And as we look to the future, Embracing Carers plans to continue driving recognition, access to resources, visibility among policymakers and innovative new collaborations with other organizations to ease the burden on unpaid carers.

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Finalist: Roche and Regeneron collaborate to significantly increase global supply of investigational antibody combination REGEN-COV (casirivimab and imdevimab) for COVID-19

In August 2020, Roche and Regeneron announced that we were joining forces in the fight against COVID-19 to develop, manufacture and distribute REGEN-COV (casirivimab and imdevimab), Regeneron's investigational antiviral antibody cocktail, in order to bring the therapy to as many people as possible. Through this collaboration, we expect to increase the global supply of the antibody cocktail to at least 3.5 times of the original capacity and ensure access to more people globally. Regeneron and Roche are responsible for the distribution and manufacturing in and outside the U.S., respectively.

Technology transfers started swiftly and were completed in record time in 2020, enabling Roche to start producing REGEN-COV at its sites. Teams including technical operations, strategy, quality, access and legal were mobilized to support this herculean effort. Positive safety and efficacy data from three Phase 3 studies have proven the effectiveness of the therapy in outpatient, prevention and hospitalization settings. It is also proving to be effective against the emerging COVID-19 variants and will continue to play an important role alongside vaccines. Our partnership underscores what we can accomplish together when we focus our minds on delivering for patients and work as one united community to tackle global public health challenges. It has only been 10 months since our partnership started and we have already delivered 2 million doses (through June 2021) of the therapy to more than 20 countries for emergency use authorization.

This was only possible because everyone at Roche and Regeneron involved in this project collaborated and supported each other on this journey. From manufacturing colleagues who worked overtime, additional shifts and through holidays to colleagues from other functions who volunteered to support shop floor colleagues to speed up packaging work and help in other ways, to medical affairs and policy colleagues liaising with health

REGEN-COV™ (casirivimab and imdevimab)

authorities to accelerate emergency use approvals, everyone worked tirelessly to ensure that we met our commitments to deliver these life-savings therapies to patients in the fastest possible time. Our continued collaboration will ensure that more people, including the most vulnerable, get immediate protection and/or treatment for existing and emerging variants of the virus

The collaboration being discussed in this submission is one between OneThree Biotech and Jubilant Therapeutics that focuses on the identification of specific biomarkers for new indications in targeted oncology patient populations.

Finalist: OneThree Biotech and Jubilant Therapeutics Collaboration

ONETHREE BIOTECH JUBILANT THERAPEUTICS

In the collaboration, Jubilant sought to determine the mechanism for its potentially first-in-class dual epigenetic inhibitor targeting melanoma, myelodysplastic syndrome (MDS), and acute myeloid leukemia (AML) and select solid tumor subsets. Utilizing the OneThree Biotech platform, they were able to:

- Generate new data to support the dual inhibition (LSD1 and HDAC6) to drive inhibition
- Pinpoint molecular markers that could be used to identify patients who might benefit from the dual inhibition
- Determine additional target indications for future trials

OneThree Biotech is a spinout from the largest precision medicine institute in the United States. We have demonstrated great success in drug discovery by applying our biology focused, AI enabled R&D process with partners such as AZ, SPARC, Oncoceutics, and more. In 2021 we began our internal development programs that focus on oncology targets we identified using our AI Platform and validated in early stage development. We won the Reuters Entrepreneur Award in late 2020 and are excited to speak about the results of a partnership we've had since then!

Jubilant Therapeutics, Inc. is a patient-centric biopharmaceutical company advancing potent and selective small molecule modulators to address unmet medical needs in oncology and autoimmune diseases. Its advanced discovery engine integrates structure-based design and computational algorithms to discover and develop novel, precision therapeutics against both first-in-class and validated but intractable targets in genetically-defined patient populations. The Company's entrepreneurial minded leadership and scientific teams strive for speed and efficiency by employing a business model that leverages the proven and synergistic capabilities of Jubilant Life Sciences Limited's value chain and shared services. Jubilant Therapeutics is headquartered in the U.S. and guided by globally renowned key opinion leaders and scientific advisory board members.

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Finalist:
NCD Academy, Viatris

Each year noncommunicable diseases (NCDs) kill 41 million people worldwide, and NCDs account for seven of the top ten leading causes of death globally. Four major disease groups (i.e., cardiovascular disease [CVD], cancer, chronic respiratory diseases, and diabetes) account for over 80% of all premature NCD deaths. However, NCDs can often be prevented through education and regular screening.

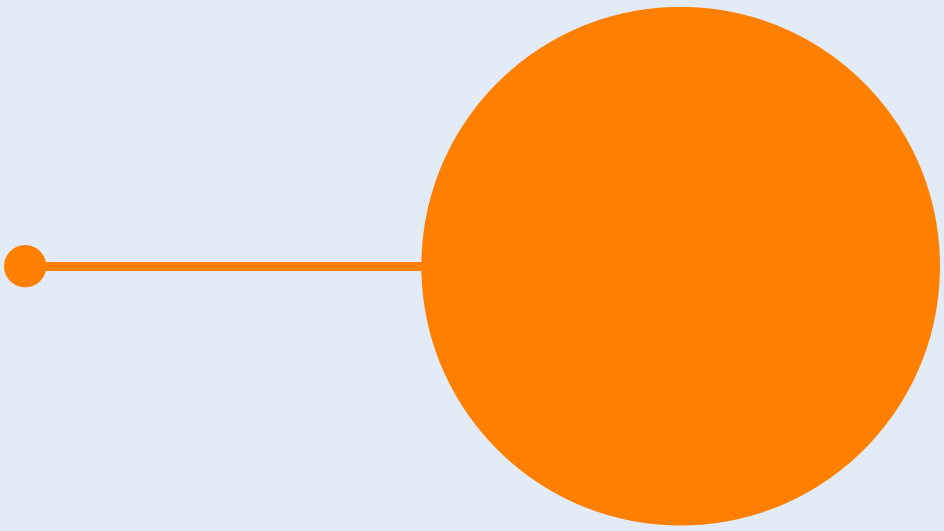
Through our partnership projects, Viatris is working to foster progress toward achieving United Nations (UN) Sustainable Development Goals (SDGs). The SDG target 3.4 aims to reduce premature mortality from NCDs in 2030 by 33% compared with 2015 levels through prevention and treatment strategies and the promotion of mental health and wellbeing.

Together with NCD Alliance we conducted research to understand the role of primary care health workers in combating NCDs and to understand the gaps and potential solutions to optimize their efforts. Optimize Multi-Disciplinary Care Teams and Leverage Digital Tools were identified as solutions and initiated a partnership with NCD Alliance, World Heart Federation (WHF) and the American College of Cardiology (ACC) to develop the NCD Academy.

The NCD Academy is an interactive, web-based educational platform for healthcare providers worldwide to improve the prevention and treatment of NCDs based on a patient centric approach, acknowledging the multiple comorbidities that exists in many people living with NCDs. The courses on the platform are free, CME-accredited and have been translated into a variety of languages.

The NCD Academy partners with key global scientific societies covering major therapeutic areas, and will have released courses on all 'big five' NCDs (CVD, cancer, COPD, mental health and diabetes) by the end of 2021. Three courses have been released including CVD by ACC, oncology in partnership with American Society of Clinical Oncology (ASCO) () and a mental health course with World Psychiatry Association (WPA).

Viatris is the founding sponsor of NCD Academy. Our current contribution focusses on the implementation of NCD Academy in countries across the globe. Due to our global footprint and extensive network we support the expansion of NCD Academy partners with many regional and local stakeholders to together ensure optimal uptake and value.



Most Valuable Breakthrough /Discovery

Winner:

REGEN-COV™, Regeneron

REGEN-COV™ (casirivimab and imdevimab)

COVID-19 has had a devastating impact worldwide. In early 2020, Regeneron leapt into action, applying its homegrown technologies and infectious disease expertise to combat COVID-19. Predicting the virus would mutate, Regeneron used a strategic multi-antibody approach to increase the likelihood the treatment would remain potent against future variants.

Within five months, REGEN-COV™ (casirivimab and imdevimab), an innovative antibody cocktail, was ready for clinical trials. It was the first therapy of its kind to be authorized to treat COVID-19. Today, more than 20 countries have granted it emergency or temporary pandemic use authorizations and Japan has fully approved the cocktail. It is also authorized in the US and UK for post-exposure prophylaxis. Notably, REGEN-COV is recommended by the NIH and maintains potency against all variants of concern.

Regeneron strongly believes in the importance of getting vaccinated; but should someone get sick, REGEN-COV is one of the only COVID-19 treatments proven to reduce symptoms and hospitalizations.

As many worldwide remain at risk, either because they are unvaccinated, or are not completely protected by vaccination, REGEN-COV continues to be an important tool to stem the impact of this virus. Regeneron is committed to working with partners – whether government, local hospitals and physicians – to help fight this disease and help prepare for future outbreaks.

1. What were the challenges you identified when you were developing the initiative?

Developing a new medicine amidst a pandemic: Drug discovery and development is time intensive and notoriously challenging. It takes decades to develop a therapy safe and effective enough to advance into clinical trials and even then, around 90% of investigational therapies fail. Thankfully, Regeneron's investment in our core VelociSuite® technologies and experience in infectious diseases laid the groundwork for our approach to SARS-CoV-2.

In June 2020, just five months after our discovery program launched, we had a medicine ready to enter human clinical trials.

Ensuring the design would remain potent against variants: At times working 90-hour weeks, our preclinical research team screened thousands of antibodies to identify candidates. Our team knew if they selected just one antibody and the virus mutated, the virus may learn to escape, rendering the treatment ineffective. By taking a multi-antibody approach from the beginning, we foresaw and avoided loss of potency issues facing single antibodies today due to variants. Having two antibodies that bind to different epitopes, REGEN-COV™ (casirivimab and imdevimab), has a "built-in" insurance policy against random mutations and has shown to retain potency against all variants of concern identified by the World Health Organization (WHO).

Quick kick off of clinical trials: Discovering and readying a new drug candidate for human trials normally takes years. Our team did it five months, while their home base of Westchester was the center of the pandemic. We hit the ground running on trials, as the team had designed a clinical program concurrently to our discovery work.

In doing so, we navigated the unique challenges of testing a medicine amid a pandemic – like implementing safety protocols at our research facilities; monitoring local hotspots to enroll patients; and striving for diverse recruitment to ensure that trial enrollment reflected the population impacted by COVID-19, as it relates to age, risk factors and other demographics.

The team continued to look for ways to ensure the quality of the trials were maintained while also striving to speed up the process, using adaptive phase 1/2/3 trials to allow for efficiencies, conducting some trials independently and – for maximum impact – others collaboratively, including with the National Institute of Allergy and Infectious Diseases and the UK's RECOVERY Trial.

Amplifying supply and distribution: Given the scale of the pandemic, we foresaw potential challenges related to the sufficient supply and global distribution. Regeneron worked to maximize capacity early on, moving manufacturing for all our non-COVID-19 medicines to Ireland and dedicating our New York facility to producing REGEN-COV. In anticipation of a global rollout, we collaborated with

Roche to maximize supply and access, more than tripling our production capacity and maximizing our global reach to more people who may benefit. This was a unique move as Roche is traditionally seen as a competitor in our industry. Over the past year, we've established three contracts with the U.S. government to provide nearly three million doses of our antibody cocktail, which people in the U.S. can receive at no cost (depending on insurance, some may be charged an administration co-pay).

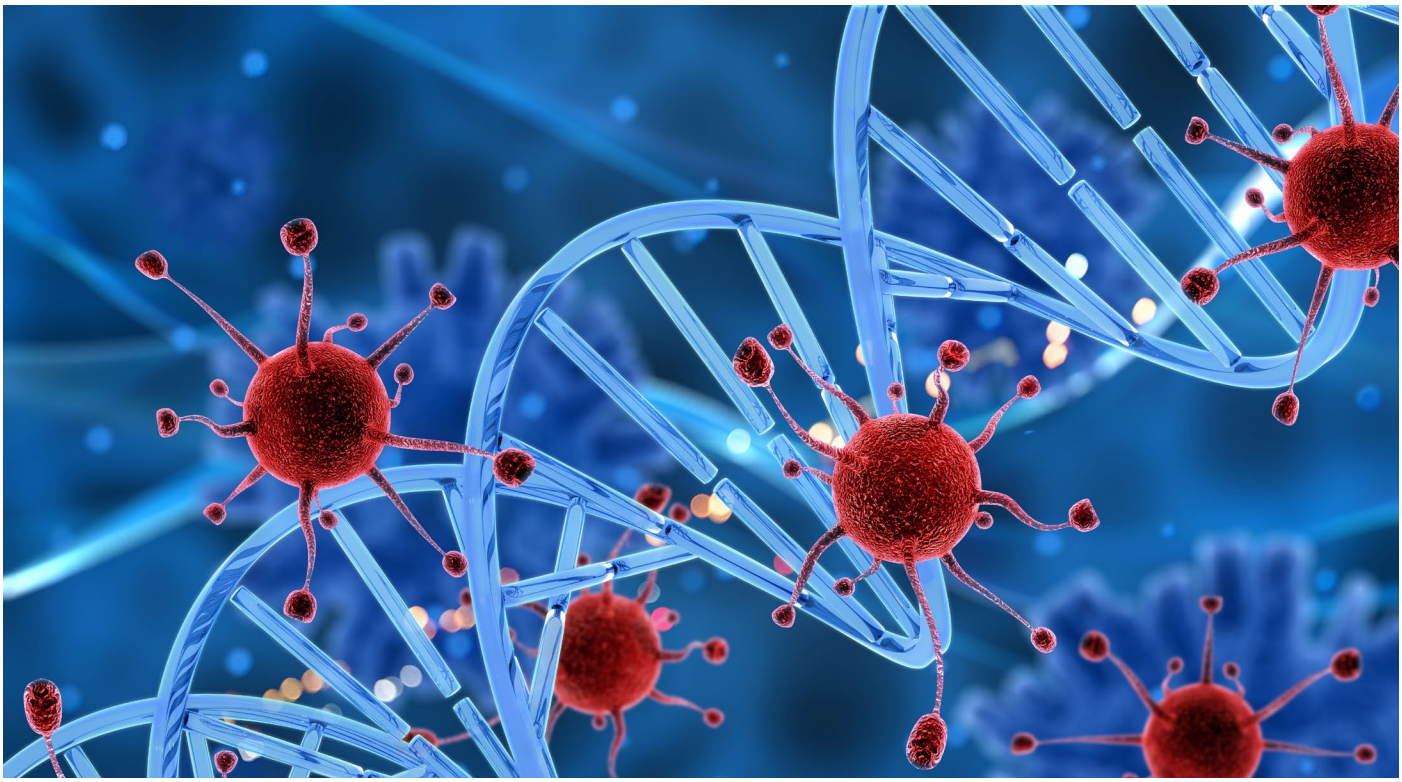
2. What's been the main success factors?

Regeneron scientists and colleagues: Over the past three decades, we have built a team of scientists committed to diving deep into the biological basis of disease. With experience in Ebola, Zika virus, Middle East Respiratory Syndrome (another coronavirus), influenza and more, the infectious disease team knows how to apply our homegrown *VelociSuite* technologies in "rapid response" fashion for the purposes of swiftly fighting infectious diseases. This decades-long investment and the learnings that have come from it have shaped the trajectory of Regeneron's approach to infectious disease, making us capable of responding to urgent public health crises.

Technology: Equally as important to Regeneron's success is our technologies. As noted, our unique approach and innovative technologies allowed our team to hit the ground running. Regeneron's proprietary *VelociSuite* technologies have accelerated and improved the traditional drug discovery and development process, enabling us to quickly mobilize against emerging pathogens. These tools allow for a rapid response because they enable efficient generation of multiple fully-human antibodies in *VelocImmune* mouse models instead of relying on survivor plasma donations for the creation of investigative antibody therapies. Our *VelociSuite* tools ultimately allowed our team to cut the prior record-setting timeline – e.g., from discovery to clinical testing – in half.

Strategic development/dual antibody approach: REGEN-COV was strategically designed as a combination of two complementary antibodies to retain potency against potential viral variants. With the two antibodies binding in different locations on the SARS-CoV-2 spike protein, the virus would need to mutate in two distinct locations to evade the binding/neutralizing capacity of both antibodies – a highly unlikely event. While other therapies have faltered, REGEN-COV is the only antibody cocktail that successfully neutralizes all variants of concern, including those now classified by the WHO as Alpha, Beta, Gamma, Lota, Epsilon and Delta, as well as Mu, categorized as a variant of interest. REGEN-COV continues to be strongly recommended by the National Institutes of Health COVID-19 Treatment Guidelines Panel in hospitalized COVID-19 patients at high risk of clinical progression.

Investment: As early as 2014, Regeneron scientists voiced concern that society was underprepared for pandemics, prompted by the Ebola outbreak in West Africa. Regeneron testified before Congress on the need for investment in centralized government manufacturing capabilities for vaccines and biologic treatments to help the country be ready. While that did not come to fruition at the time, Regeneron continued to invest in our team and technologies, including $2,7 billion back into our research and development (R&D) efforts. The company's rapid pace of drug R&D as well as our gold standard for safety and quality has set new standards in the industry – demonstrating that a long-term view, investments in technology and people, and an openness to collaboration can lead to transformative medicine.



3. What barriers did you come up against?

In November 2020, REGEN-COV became the first therapy of its kind to receive emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA) to treat COVID-19 in certain high-risk populations – disrupting how COVID-19 was treated and giving healthcare providers a novel, meaningful tool in their arsenal to fight the pandemic. However, rapidly deploying the treatment and reaching patients in need amid a pandemic was no small task.

Amidst the pandemic when hospitals and healthcare providers were already overwhelmed, administering these treatments to outpatients with mild and moderate disease added an additional layer of complexity.

Additionally, fielding the latest information and data to healthcare providers and institutions proved challenging during a time when information and protocols seemed to be changing almost daily. At first, physicians displayed a reluctance to prescribe REGEN-COV. In response, Regeneron worked to educate healthcare providers on the safety and efficacy of the treatment and provide resources for patients to implement a plan should they contract the virus.

In terms of access, the rollout for monoclonal antibody treatment came before the introduction of vaccines, though, until recently, monoclonal antibodies have not been as widely used as originally intended. Not only was the demand from patients weaker than expected, but hospitals and clinics also struggled to get these treatments to patients due to factors including timing of testing and ability to get the treatment in time, as well as administration through an infusion, which generally requires going to a hospital or infusion center. One of the recent updates to the EUA included simplifying administration options to include subcutaneous injection.

Regeneron's collaborative culture allowed our team to move quickly, focusing on getting the therapy to patients as quickly and safely as possible, and continuing our other important areas of research into a wide range of diseases.

4. What imminent changes do you think your initiative will make?

REGEN-COV continues to provide value for patients, caregivers and healthcare professionals today, and will likely continue to play a critical role alongside vaccines in addressing the COVID-19 pandemic. Importantly, while many Americans are entering a new phase of the pandemic bolstered by the incredible speed with which vaccinations have been rolled out, many people remain at risk, including those for whom vaccinations do not provide complete protection or those who remain unvaccinated.

To help address the ongoing threat, we continue to work, in collaboration with the medical community, to ensure REGEN-COV can improve care for as many patients as possible and have the greatest possible societal benefit. In fact, every day, our Medical Affairs team speaks with healthcare providers on the frontlines, hearing directly from them what is needed to better treat the patients that remain at risk and quickly implementing solutions that will help them combat this deadly pandemic.

For example, our team has worked diligently to reduce barriers to access, in part by working to simplify our cocktail's administration – i.e., to make it easier for patients to receive, and less resource-intensive for health care workers/institutions to distribute. The new route of administration is a great example of this. The FDA also granted the use of a lower dose of REGEN-COV, effectively doubling the number of doses that are available to patients.

5. What does the future look like? If you had to do it all again, what would you do differently?

The future of R&D: We believe that REGEN-COV demonstrates a pioneering approach to addressing pandemics and emerging pathogens, shedding light on the need for a strategic multi-antibody approach to viruses and creating a roadmap for future biopharma efficiency. More broadly, REGEN-COV has proven that innovation is possible even in times of crisis. COVID-19 has changed the way we, and our industry, envision the drug development timeline and roadmap for how to tackle future pandemics.

The future of REGEN-COV: We are continuing to study REGEN-COV as a therapy for the treatment and prevention of COVID-19, as well as keep additional investigational antibody candidates at the ready. Meanwhile, we are having discussions with regulatory bodies to expand the ways REGEN-COV can be used to keep pace with the pandemic and address patient needs.

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Finalist: ADUHELM, Biogen

On June 7, 2021, the U.S. Food and Drug Administration granted accelerated approval for ADUHELM® (aducanumab-avwa) as the first Alzheimer's disease (AD) treatment to address a defining pathology of the disease by reducing amyloid beta plaques in the brain. The approval represents the culmination of years of collaboration between global pharmaceutical companies Biogen and Eisai, each which have worked tirelessly to address significant unmet needs in this space.

First beginning in October 2017, both Cambridge-based Biogen and Tokyo-based Eisai entered an agreement to jointly develop and commercialize ADUHELM. Accordingly, in terms of the structure of the agreement, Biogen led the development of ADUHELM, while both Biogen and Eisai worked on co-commercializing the treatment so it would be ready for distribution in the event of approval. Through this innovative structure, both companies aimed to combine their complementary, and regionally specific expertise, with the goal of making an immediate, tangible impact in the fight against Alzheimer's disease.

Throughout the past year – even as other biotech companies gave up on this high-risk area Biogen and Eisai have worked diligently, and with a global lens, in order bring forward a new AD therapy.

ADUHELM is the realization of both companies' decades-long commitment to innovation in AD.

To-date, the journey to find a treatment that addresses a defining pathology of the disease has taken more than 25 years of investment and innovation and has involved more than $50 billion spent on R&D, 100 drug candidates, 176,000 patients and at least 36 Phase 3 failures (Source: Biogen data). But now, with the approval of ADUHELM in 2021, both Biogen and Eisai have showcased that through collaboration, innovation in this space is possible.

Finalist: GAVRETO - Rapid Path to FDA Approval, Blueprint Medicines

Blueprint Medicines is a global precision therapy company that aims to invent life-changing medicines for people with cancer and hematologic disorders. We create therapies that selectively target genetic drivers, with the goal of staying one step ahead across stages of disease. Since its founding just a decade ago, Blueprint Medicines is now delivering two approved medicines – including GAVRETO® (pralsetinib) – directly to patients. GAVRETO is one of nine approved or investigational precision therapies designed by scientists at Blueprint Medicines.

GAVRETO is a kinase inhibitor approved by the FDA for the treatment of three indications: adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test, adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy, and adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate). These indications are approved under accelerated approval based on overall response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

The RET tyrosine kinase is an oncogenic driver in subsets of patients across multiple tumor types. RET fusions are implicated in approximately 1-2% of patients with NSCLC and approximately 10-20% of patients with papillary thyroid cancer, while RET mutations are implicated in approximately 90% of patients with advanced MTC. In addition, oncogenic RET alterations are observed at low frequencies in colorectal, breast, pancreatic and other cancers. Prior to 2020, therapeutic options for patients with RET-altered cancers were limited.

From 2017 to 2020, Blueprint advanced the development of GAVRETO® (pralsetinib) from clinical trial initiation to FDA approval, representing one of the fastest registration paths for a targeted cancer therapy. Beginning in 2013, the year after the discovery of RET fusions as an oncogenic driver in NSCLC, Blueprint Medicines initiated a research program to design a selective and potent inhibitor of oncogenic RET alterations.

For more information, visit GAVRETO.com.

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Finalist: Gene Writing, Tessera Therapeutics

TESSERA

While we know that small and large errors in genes can cause disease, most genetic diseases lack effective or curative treatments today. The ability to write and rewrite the genetic code -- the very code of life as we know it -- will drive a fundamental change in medicine.

By building upon recent breakthroughs in gene therapy/editing, Tessera Therapeutics' Gene Writing platform has the potential to unlock cures to previously untreatable genetic diseases as well as create potentially life-changing therapeutics for cardiovascular, oncological, neurodegenerative, and chronic diseases.

The Gene Writing platform has its biological origins in mobile genetic elements (MGEs), which are mined and engineered by Tessera. Previously thought of as "junk DNA" by scientists, MGEs make up over 50% of the genome and have evolved over millennia to have the unique ability to naturally write new sequences into the genome or make any type of genomic alteration precisely and scarlessly.

Tessera is focused on developing Gene Writers that can be delivered as RNA molecules contained within lipid nanoparticles (the same type of delivery molecules used in RNA Covid vaccines). Tessera has shown that its Gene Writing technology can be used to add an entire gene to the human genome after RNA-only delivery. RNA is an ideal molecule because it's versatile, programmable, and -- relatively speaking -- easy and cost-effective to manufacture at scale.

In contrast, current gene editing platforms, like CRISPR, evolved to destroy DNA as means to protect bacteria against invading viral pathogens. While CRISPR offers an efficient and precise method to disrupt a gene by making a double-strand break in DNA, its capability to insert a new sequence, or precisely alter an existing sequence, is more limited and error-prone.

Tessera's Gene Writing technology could potentially cure rare and more common genetic diseases that gene therapy and gene editing cannot address, with the hope of achieving a future in which millions more patients are free from disease for the rest of their lives.

Finalist: SH-111, Shorla Pharma

SHORLA PHARMA®
THE HEART OF INNOVATION

Shorla Pharma ("Shorla") is a specialty pharmaceutical company that develops innovative oncology drug products for women's and paediatric cancers. Located in Cambridge, Massachusetts and headquartered in Tipperary, Ireland, we focus on indications where existing treatments are limited, in shortage or inadequate for the target population.

New therapies for women and children are often overlooked by large pharmaceutical companies. Our goal is to bring to market products that represent a new standard of treatment for these patients. Our first therapy, SH-111, is a nucleoside metabolic inhibitor indicated for the intravenous treatment of patients with T-cell acute lymphoblastic leukemia and T-cell (T-ALL) lymphoblastic lymphoma (TLBL), an aggressive blood and bone marrow cancer which progresses quickly. While most leukemias present in older people, T-cell leukemia is most common among children, adolescents, and young adults.

With no alternative source of SH-111 currently approved, the drug supply has had severe shortages. Targeting this unmet clinical need ensures we bring this life saving treatment to the most vulnerable patients. Although all phases of the innovation cycle are crucial, access to treatment for patients have the greatest societal impact and we have prioritised the development of SH-111 to mitigate this. This innovative treatment has been investigated by leading oncology groups and has yielded successful outcomes and improvement of survival rates. In March 2021, Shorla filed its application for SH-111 with the FDA which was subsequently accepted and granted priority review. We anticipate approval to bring this much needed product to market later this year. We have made a collective effort and worked with various stakeholders to develop SH-111 efficiently and effectively to improve accessibility of a drug that significantly improves outcomes in newly diagnosed patients and mitigate against shortages of the drug product. At Shorla Pharma, the patient's needs are at the heart of our innovation, and SH-111 is one of our products that will help to improve patient care.

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Finalist: Development of a New Technology for Obtaining a New Highly Effective Active Substance, MARGALI

Everything is brilliant - simply, on this principle, the action of our drugs is based. They include components that suppress the process of propagation of viral cells and activate the regeneration of healthy liver cells, which first leads to improvement of the condition, and then to complete recovery. Why can MARGALI drugs be trusted? MARGALI offers a number of unique preparations based on plant substances, useful minerals and vitamins.

These are drugs:

- MAC - CIR - for the treatment of all types of hepatitis and cirrhosis of the liver.
- KOHALON - MAC - for the treatment of genital herpes, pyelonephritis, myoma, fibroma, lymphosarcoma and tuberculosis.

Our company's drugs:

- Do not reduce immunity.
- Easy to use.
- Do not cause hallucinations.
- Do not cause deterioration of well-being.
- Do not have any other side effects.

Subjective improvement of condition, change of complexion and improvement of appetite are observed after the first week of administration of the drug.

- The size of lymph nodes in the treatment of lymphosarcoma decreases after two to three weeks of taking the drug, and the absolute result is achieved after 6-7 months.
- Liver size in cirrhosis and hepatitis normalizes after two to two and a half weeks of taking the drug. In the treatment of hepatitis B and C, the viral load is reduced by half after 26 days, and the absolute result is achieved after 5-6 months - 78% of patients have a complete absence of hepatitis virus in the blood.
- When treating an open form of tuberculosis of stage 4, it goes into a closed form of stage 3 after 26 days of taking the drug, and the absolute result is achieved after 6-7 months. What is the point? Our drugs not only successfully fight various diseases. They improve the performance of hormonal glands, increase life expectancy and prolong the reproductive period of stem cells. When taking MARGALI drugs, blood is updated every 4 days and the body is gradually rejuvenated. Each of the drugs activates the regeneration of the cells of those organs for the treatment of which it is intended.

For example, for cell regeneration: • renal and pulmonary tissue is intended for KOHALON - MAC;

- liver is intended MAC - CIR;

Most Valuable Data & Insights Initiative

Winner:

OneThree Biotech and Jubilant Therapeutics Collaboration

The initiative being discussed in this submission is one between OneThree Biotech and Jubilant Therapeutics that focuses on the identification of specific biomarkers for new indications in targeted oncology patient populations.

In the collaboration, Jubilant sought to determine the mechanism for its potentially first-in-class dual epigenetic inhibitor targeting melanoma, myelodysplastic syndrome (MDS), and acute myeloid leukemia (AML) and select solid tumor subsets. Utilizing the OneThree Biotech platform, they were able to:

- Generate new data to support the dual inhibition (LSD1 and HDAC6) to drive inhibition
- Pinpoint molecular markers that could be used to identify patients who might benefit from the dual inhibition
- Determine additional target indications for future trials

OneThree Biotech is a spinout from the largest precision medicine institute in the United States. We have demonstrated great success in drug discovery by applying our biology focused, AI enabled R&D process with partners such as AZ, SPARC, Oncoceutics, and more. In 2021 we began our internal development programs that focus on oncology targets we identified using our AI Platform and validated in early stage development. We won the Reuters Entrepreneur Award in late 2020 and are excited to speak about the results of a partnership we've had since then!

Jubilant Therapeutics, Inc. is a patient-centric biopharmaceutical company advancing potent and selective small molecule modulators to address unmet medical needs in oncology and autoimmune diseases. Its advanced discovery engine integrates structure-based design and computational algorithms to discover and develop novel, precision therapeutics against both first-in-class and validated but intractable targets in genetically-defined patient populations. The Company's entrepreneurial minded leadership and scientific teams strive for speed and efficiency by employing a business model that leverages the proven and synergistic capabilities of Jubilant Life Sciences Limited's value chain and shared services. Jubilant Therapeutics is headquartered in the U.S. and guided by globally renowned key opinion leaders and scientific advisory board members.

1. What were the challenges you identified when you were developing the initiative?

The challenges that existed from the identification of this initiative were ones that have existed within drug discovery for a very long time. The failure rate of bringing life saving drugs from discovery to market is at 96%, and many of those failures happen at the efficacy level in human trials. Jubilant Therapeutics and OneThree Biotech began this initiative to help determine the ideal patient population for Jubilant therapeutic, JBI-802 to increase the probability of success of getting Jubliant's drug JBI-802 to the patients that need them the most.

2. What's been the main success factors?

The success factors of the project come from the strengths of each company.

Jubilant and OneThree's capabilities are very complementary in nature. OneThree has demonstrated a clear ability to predict novel biological mechanisms utilizing our AI platform when applied to our massive, curated database. Whereas Jubilant has the proven ability to create and develop therapeutics to target specific biological pathways. For this project Jubilant was also able to bring assay and genetic data on their therapeutic, JBI-802, which was added to OneThree's database for the collaboration.

OneThree's database pulls from over 200 data sources which include both private institutions and publicly available data sets. We have over 50 different types of data which span the clinical, biological, and chemical domains. Our massive database consists of trillions of data points that have been organized and linked (e.g. every study using one chemical compound will be collated together) using technology akin to the google search engine. The data Jubilant had supplied added to this database which increased our ability to run high confidence predictions and identify the patient group that their therapeutic would be most efficacious against.

The database, with the added strength of Jubilant's dataset was applied to OneThree's AI platform which has demonstrated the proven ability to analyze multiple data types at once. Due to the complexities of biology this ability allows us to decode key biological mysteries in order to bring results into the clinic. An example of decoding a biological mystery is being able to answer not only if a gene is relevant to a specific cancer type, but also exactly why it's relevant.

Once we ran the data through our AI platform and after several meetings with each of our scientific teams; we were able to identify new indications and patients where their drug was efficacious. After this discovery, we were able to utilize Jubilant's clinical expertise to move the therapeutic further downstream.

3. What barriers did you come up against?

Any multidisciplinary scientific collaboration has the potential to be rife with challenges and we were certainly not exempt!

The first obstacle to overcome was that of data harmonization. Each data source is typically in a different format, but must be able to integrate with the rest of the database. Jubilant's data was in a different format than the rest of our database so there was a large engineering and quality assurance lift required before moving into the meat of the collaboration.

Another challenge was learning how to communicate our novel scientific findings generated from AI predictions. It's one thing if our technology scours the combined data and concludes with a known indication for the drug being studied. It's another thing if our studies conclude with a novel indication. The latter was the optimal outcome of the project, which occurred, and therefore the challenge was for us to explain how this conclusion was derived.

With a high degree of confidence, we predicted a novel biomarker for JBI802 that subsequently led us to predict it would be efficacious in a novel indication. First, we had to break down the quantitative explanation and then work with the team to evaluate the qualitative reasoning as to why we were showing such strong confidence. The combination of these activities helped us form a strong hypothesis to move Jubilant's therapeutic forward.

4. What imminent changes do you think your initiative will make?

This collaboration created new opportunities for the outlook of JBI-802 and subsequently its eventual patients. Our initiative has helped shed light on very clear optionality as to what patients this drug may be efficacious against. Our hope is that our work together helps get this drug to the patients that need it the most, faster, and more efficiently.

5. What does the future look like? If you had to do it all again, what would you do differently?

We believe this collaboration will pave a way for future collaborations in the same way the path was paved for the collaboration itself. Jubilant and OneThree originally got in touch after the release of a well documented instance of clinical validation from a previous OneThree partnership. Now that we are experiencing positive results from the Jubilant collaboration we will be able to release further publications. This in turn will continue to develop a higher degree of confidence in the predictive capabilities of AI in drug discovery. Furthermore, with each new partnership we get a step closer to getting the medicines to the patients who need them the most by eliminating inefficiencies in drug discovery and development.

The challenges we experienced with data integration and communication will be brought forward the better future partnerships. We established many best practices and organizational processes to better handle these obstacles.

We have noticed our past experiences paving way for new collaborations, ourselves. We will be making an announcement this year on several other collaborations including a top 5 pharma company and have also announced a collaboration with SPARC this year!

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Finalist: ImmunoLab - Sanofi Immunology Data Discovery Lab, Sanofi

SANOFI

The Sanofi Immunology Data Discovery Lab ("ImmunoLab") is a transformative platform which maximizes the use of digitized healthcare data to standardize and enable rapid generation of robust insights. It enables understanding of the dynamic patient need in the real-world, all at the user's fingertips. By changing how we use real world data, we aim to improve patient outcomes through optimized management and care.

With the increasing availability of digitized healthcare data and broadening demand for RWE across pharma, scalable platforms like ImmunoLab are a required alternative to the current one-question-at-a-time approach for generating evidence.

ImmunoLab uses an intuitive interface and applies artificial intelligence to analyze an Immunology and Inflammatory Disease Patient Cohort from the US Optum Electronic Health Record. The platform facilitates real-world hypothesis generation across a range of diseases. Optum data enables Sanofi teams and external partners to analyze patient data from over 16 million patients. The patient cohort includes over 30 inflammatory diseases (and related comorbidities) with more than 1,500 features available per patient, spanning a 5-year time-frame. This expansive data-set enables over 83 million analyses that may explored through three analytical modules.

In each user-centric module, inclusion criteria and input variables can be easily modified and are analyzed by machine learning algorithms. The analyses outcomes are presented in intuitive visual formats. The three modules include the Patient Journey Mapper which describes patient characteristics and drug treatment patterns, the Switch Modeler which analyzes treatment switching behavior and its drivers, and the Head-to-Head Simulator which models comparative effectiveness of treatments.

ImmunoLab can help shape the way that life sciences companies generate insights, innovating from traditional approaches to more scalable tools. We have seen how research is evolving and are proud to be identifying faster routes to understand how diseases might be predicted, prevented, or cured. To turn the analysis of patient journeys into improved patient care is the ultimate goal of ImmunoLab.

Finalist: VALINOS, Studies & Me

VALINOS CARE YOUR WAY

VALINOS is an abbreviation of Validating Novel Clinical Outcome Measurements - an initiative aiming to advance remote disease assessment.

Using digital tools to enable remote data collection has clear advantages in both clinical practise and in decentralized clinical trials. In a digital world, in-clinic visits can be replaced by remote visits, hence patients need to travel less, while their doctor maintains the clinical oversight remotely. Such a remote approach has become increasingly relevant in the face of the COVID pandemic.

In addition, digital enables more frequent data acquisition, because the patients report data directly to the doctor from his/her own home. The continual data monitoring allows for a better understanding of the treatment and other influencing factors. VALINOS is determined to realise this potential.

Within dermatology, VALINOS validates the outcomes of remote assessments in skin disease by comparing them with in-person assessments by dermatologists. VALINOS currently focuses on psoriasis, atopic dermatitis and actinic keratosis.

The comparative data is collected through a series of clinics, in which multiple dermatologists physically evaluate a patient - to establish a baseline of the patient's condition. The same patient subsequently uploads photos of their skin to a designated app, which are assessed remotely by a panel of dermatologists. The comparison of the in-clinic assessments and the photo-based assessments form a data set that is used to establish the validity and reliability of the remote method.

All in-clinic evaluations are performed using well-established severity tools specific to a given disease, such as Eczema Area and Severity Index (EASI), Psoriasis Area severity Index (PASI), and Olsen grade for actinic keratosis severity. The remote assessments are based on the same principles and methods as the in-clinic evaluations.

This far, VALINOS has demonstrated a good agreement between the assessments performed remotely and in-clinic. Our findings show excellent reliability of the photo-based remote assessments and clearly indicate that we are on the right track; that remote assessments have the potential to replace and/or support in-clinic visits in dermatology and potentially also other disease areas for the future benefit of patients and doctors alike.

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Finalist: **Trial Pathfinder: Using Machine Learning to Advance Inclusive Research, Genentech**

Trial Pathfinder, created in partnership between Genentech and the Stanford University Institute for Human-Centered Artificial Intelligence, uses real-world data (RWD) and artificial intelligence (AI) to evaluate and predict eligibility criteria's impact on clinical trials. Incorporating RWD can potentially lead to more inclusive trials, while reducing time and costs needed to bring new medicines to patients faster.

Specifically, through Trial Pathfinder we emulated 10 completed lung cancer trials and showed we could increase the pool of eligible patients by 107% on average -- including expanding inclusion of women, African-Americans, and a broader range of ages -- while maintaining treatment efficacy and patient safety.

The team leveraged RWD from 61,094 individuals with advanced non-small cell lung cancer from the nationwide Flatiron Health electronic health record-derived database. Trial emulation included selecting individuals who met the available eligibility criteria as originally published in clinical trial protocols. The team developed a computational pipeline which optimised data-driven eligibility criteria that would benefit the most patients by systematically emulating thousands of trials with varying combinations of eligibility criteria.

Survival analysis was performed using the hazard ratio of overall survival as the outcome. A novel implementation of the Shapley value was created to provide a principled way to evaluate each eligibility criterion's effect on the resulting hazard ratio across the thousands of experiments.

Trial Pathfinder demonstrated it can help select an optimal subset of eligibility criteria that consistently maintains or reduces the hazard ratio, while maximising the pool of eligible patients. Additionally, since Trial Pathfinder is open-source, the scope of applications will hopefully expand to other types of cancer, and potentially other diseases.

The emergence and combination of quality RWD and advanced technologies, including AI and machine learning, present new opportunities to accelerate R&D, bring effective medicines to the right people quickly, and potentially reduce the burden on healthcare systems. This is why projects like Trial Pathfinder are central to realising the future of personalised healthcare.

Finalist: **NMQF Clinical Trial Index and Learning Community, Biogen**

At Biogen, we are committed to the power of diversity - in our organization and among our patients. Every day we work toward helping to close the access gap in both clinical trials and the healthcare system. The National Minority Quality Forum (NMQF) is a research and educational organization dedicated to reducing patient risk for underrepresented populations, by integrating data and community expertise. Biogen partnered exclusively with NMQF to develop data tools and community level initiatives geared specifically at informing, listening, and designing blueprints to build representative clinical trials.

NMQF built the Biogen-NMQF Clinical Trial Index, a bespoke data and geomapping tool for Biogen comprised of Medicare and Medicaid beneficiary data in Biogen's disease areas of research. By reporting and displaying real world evidence (RWE) and epidemiologic estimates of disease areas of interest by geography and demography, the Index allows Biogen to be more strategic with identifying the right sites in the right locations to bring clinical trials to the communities we need to serve.

Based on the Index data, NMQF and Biogen are building a Clinical Trial Learning Community (CTLC). The CTLC is a virtual space where local investigator sites can interact with local providers, community leaders, and industry towards a common objective: reduce disparities in care and outcomes for underrepresented patient populations by ensuring awareness of and access to available clinical trials close to home.

The novel Biogen-NMQF Clinical Trial Index leverages real-world evidence and population data to improve diversity in all aspects of clinical trial planning, recruitment, and execution. The CTLC enables clinical trial leaders to develop an action plan and blueprint for successful site and patient engagement in clinical trials at the community level including site selection, outreach, education, access & referral.

Most Valuable HCP Initiative

Winner:

CHIEF-HF: reimagining clinical trials for the future, Janssen

CHIEF-HF is Janssen's first-ever fully decentralized, randomized, interventional clinical trial. The trial deploys a novel method, re-imagining clinical trial design to accelerate research while prioritizing patient safety and convenience.

Cardiovascular disease remains the leading cause of death in the U.S., and widespread concerns have arisen about the costs, inefficiencies, and complexities of clinical trials. Against this backdrop, Janssen designed the CHIEF-HF trial, which directly engages participants without in-person contact. Data is collected directly from participants via a phone app, a wearable device and insurance claims. Trial participants are supported by a virtual PI within their health network and a virtual coordinating center. An unplanned benefit of the trial design was its relevance and feasibility during the COVID-19 pandemic, which had major disruptive consequences on traditional clinical trials. The study was designed by Janssen Scientific Affairs, LLC, with an Executive Steering committee, and PRA Health Sciences.

In addition to prioritizing patient convenience, Janssen is committed to ensuring our clinical trials ease burdens to participation for historically underrepresented communities. The design and operational execution of CHIEF-HF, driven by innovation and forward thinking, include a deliberate approach to enable recruitment of a diverse participant group.

We know that to develop more effective, life-changing therapies faster, we must continue to challenge the status quo and reimagine how we conduct clinical trials today. By bringing cutting-edge science, creative approaches, and innovative technologies together, Janssen believes we can create more inclusive clinical trials that deliver an understanding of which drugs and treatments have the best results for all patients.

1. What were the challenges you identified when you were developing the initiative?

Traditional heart failure studies have struggled with long enrolment periods and a lack of diversity. CHIEF-HF is Janssen's first-ever completely decentralized, randomized, interventional study. With this novel trial design, there was a significant amount of stakeholder alignment required in order to bring our vision to light. All data was collected directly from participants via a phone app, a wearable device and insurance claims. We kept a keen focus on participant safety, privacy, regulatory compliance and scientific/data integrity.

One of the challenges was finding investigators and hospitals who were both willing and able to adapt to a decentralized study. Not all healthcare systems are well adapted for this type of research.

2. What's been the main success factors?

The COVID-19 pandemic has been challenging for clinical trials, causing significant disruption. Although unplanned, the novel decentralized method deployed for CHIEF-HF allowed this research to continue. Most of the enrollment period for CHIEF-HF took place during the pandemic and lockdowns. Participants, not allowed to visit or fearful of visiting medical facilities during the pandemic, were willing to enroll and participate in CHIEF-HF as it allowed them to participate without visiting the clinical trial site. Heart failure studies in general have struggled with long enrollment periods, with a median enrolment rate of 0.5 patients/site/month . CHIEF-HF enrolled at a rate of more than four times the heart failure standard.

We engaged with HCPs and hospitals to share our vision and strategy, and we were able to find several health networks who were very open to a new way of conducting research.

The decentralized nature of the study allowed for a wider outreach to potential participants. We were able to take an intentional, strategic approach to ensuring the trial was inclusive and equitable.

Trial participants were able to integrate the clinical trial into their daily lives. Important to the success of the CHIEF-HF was the support provided to participants by a virtual principal investigator within their health network and a virtual coordinating center.

3. What barriers did you come up against?

The COVID-19 pandemic resulted in reallocation of health network staff away from research to focus on COVID management. Despite this, CHIEF-HF still enrolled at a faster rate than traditional heart failure studies.

Given the novel approach utilized in the study, not all health networks had the resources to embrace this new way of working, and some institutions were not yet confident in their role in piloting a new way of conducting research.

4. What imminent changes do you think your initiative will make?

What we learn from CHIEF-HF will be invaluable in helping to advance new methodologies for decentralized clinical trials and further support patient centricity in clinical research. We hope to demonstrate how it is possible to leverage established and validated outcome measurements in clinical trial design, how to integrate technologies, and to help reduce costs and shorten timelines versus the more traditional trial design pathways.

We intend to show how decentralized clinical trials may be one way to deliver greater access, inclusivity and diversity so that the trial participant population is more representative of a patient population with heart failure. We will learn how to best engage and support participants when a trial is largely or entirely virtual.

5. What does the future look like? If you had to do it all again, what would you do differently?

Institute of Leadership Excellence, PharmEvo

At Janssen, we believe that to develop more effective, life-changing therapies faster, we must continue to challenge the status quo. We will apply insights from CHIEF-HF to make early informed decisions in an effort to transform future trial design and improve the trial experience for all patients and sites we serve.

Traits such as Emotional Expressiveness, Self-Confidence, Self-Determination, Freedom from Internal Conflict and Communication Skills are crucial for any leader, especially Healthcare Leaders. Undoubtedly, the Healthcare professionals (HCPs) of Pakistan are some of the most technically skilled among the world. However, they lack the necessary soft skills and the above-mentioned traits for these are not taught academically, or incorporated into the HCP's on-job training.

As part of our vision to promote "A Healthier Society", PharmEvo stepped in to bridge this gap in healthcare management. We launched the Institute of Leadership Excellence (ILE), a CSR initiative to develop healthcare leaders who could work to improve overall healthcare delivery. Our focus was on 3 key areas:

1. Developing leadership Skills: Through programs such as Grid Leadership Model, 7 habits of highly effective people program, Speak like a Leader program etc.
2. Strategy Formulation & Development: Through trainings on identifying purpose, setting vision/mission etc.
3. Execution of Strategy: Through different training modules on learning to execute the developed strategy.

ILE became the first platform in Pakistan to be certified by the Franklin Covey institute for 'The 7 Habits of Highly Effective People' training for healthcare professionals. ILE has a Leaders Club for healthcare executives that provides content for learning and intellectual engagement. We also collaborated with Talisium to provide leadership courses tailored for healthcare professionals from prestigious institutes such as Royal College of Physicians (UK), NHS Academy of Leaders (UK) and others.

These efforts have resulted in improvement of health outcomes, improvement in the quality of healthcare services, enhanced patient safety, and cost efficiency.

ILE has received recognition from international management and marketing gurus. Recently ILE was included as a case study in Philip Kotler's upcoming book "Essentials of Modern Marketing".

ILE plans to establish Centers of Healthcare Leadership (CoHLs) in 100 institutes across Pakistan in the next 5 years, and by 2026 employing a sizeable number of training personnel for these CoHLs.

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Finalist: **Finalist: Institute of Leadership Excellence, PharmEvo**

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Finalist: 'Hands-on' technical training in a virtual world, Organon

Necessity drives innovation, engaging us to rethink existing paradigms and leverage new opportunities. Our HCP focused initiative showcases exactly that, highlighting the provision of technical medical skills training (in this case, the insertion and removal of a subdermal contraceptive implant to healthcare professionals (HCPs) across Canada), amidst a global pandemic and nationwide lockdowns.

In this context, we developed a virtual technical skills training platform, with a focus on simulation-based insertion and removal procedures, conducted on a model arm. We were able to effectively translate a traditional face-to-face experience to a virtual setting, with a digital solution that could rapidly scale-up to meet the anticipated volume of training needs.

To this end, a key innovation was the development of a single-source web platform for training, providing HCPs with clear, simple guidance to access training and integrating pre-requisite online training content, as a precursor to registering for a 'hands-on' practical training event. All these elements were delivered as a seamless 'end-to-end' user experience for HCPs, while meeting their training needs.

The scale and impact of this initiative has been notable: over 2200 HCPs trained since September 2020, including physicians, nurse-practitioners and nurses across all provinces and territories in Canada. Beyond numbers, we've witnessed an unprecedented level of HCP engagement: of the two-thirds who completed post-training evaluation forms, over 97% of respondents validated that the virtual format met its objective. Our approach also allowed us to have much broader HCP reach (and so impact), than would have been possible face-to-face, especially in context of resource limitations.

Advancements in virtual medical (especially technical) training have the potential to facilitate wider access to knowledge, not only in gynecology, but other medical disciplines as well, satisfying two important needs: 1) an 'active' and enriched experience to learn; and 2) a remote education experience that reduces geographical and resource-based constraints, particularly in a vast and not densely populated country such as Canada. Whilst the COVID-19 pandemic may have been the catalyst, the 'pearls' gained in this endeavor can be more broadly applied across fields of medicine.

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Finalist: The AMAZE Disease Management Platform

AstraZeneca

Chronic disease is a tremendous burden in the US, where 6 out of 10 patients have at least one chronic disease. Due to the episodic nature of these conditions, most of a patient's chronic disease management takes place outside of the clinical setting. Because symptoms do not always present at the doctor's office, clinicians are often unable to observe a patient's condition in real-time, resulting in gaps in patient care. The COVID-19 pandemic has exacerbated these challenges and highlighted the need for remote patient monitoring tools that deliver better outcomes.

AstraZeneca's AMAZETM Disease Management Platform was co-developed with clinicians at world-class healthcare organizations to equip patients and clinicians with the tools they need to improve patient care. Through remote monitoring, AMAZETM identifies at-risk patients and delivers insights to the clinical team to improve the management of complex patient populations. The digital platform, including a patient app and clinician dashboard, is intended to accelerate evidence-based clinical practice with the aim of continuously improving healthcare efficiency and the standard of care.

AstraZeneca has partnered with Greater Austin Allergy and Mass General Brigham Hospital to pilot AMAZETM with asthma and heart failure patients. Throughout these clinical pilots, patients and clinicians have utilized AMAZETM in a real-world setting with the goals of improving patient engagement, care-team communication, and clinical outcomes, while reducing healthcare costs.

Initial results indicate positive findings around engagement and usability, including patient engagement levels 2-3 times higher than the industry average after 90 days on the platform. Additionally, AMAZETM has helped clinicians proactively manage patients' treatment. In the heart failure pilot, a clinician intervened to titrate a patient's diuretics based on weight gain recorded in AMAZETM, preventing an episodic care event. In the asthma pilot, clinicians proactively initiated outpatient visits which, in many cases, helped patients avoid an ER or urgent care visit. Given the value they see in AMAZETM, clinicians are now asking to integrate devices into the platform to streamline remote monitoring through a single user experience.

Following the completion of the clinical pilots, AstraZeneca plans to continue expanding to additional health systems and add three new disease states: chronic obstructive pulmonary disease, severe renal dysfunction, and diabetes.

Finalist: Medtronic PVI Occlusion App

Medtronic
Further, Together

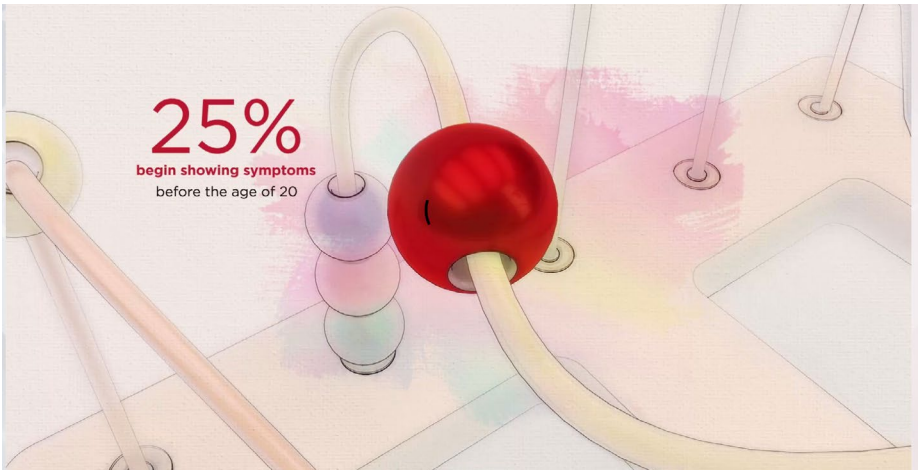
Medtronic partnered with Tipping Point Media to enhance their current methods for training health care providers and sales representatives in the proper usage of the Arctic Front™ family of cryoablation catheters and various techniques for how to properly perform the cryoablation procedure to treat atrial fibrillation.

The Medtronic team identified two major issues with their previous training techniques, which involved setting up a silicone model of a heart and having HCPs and sales representatives meet to perform the training in-person.

First, the silicone heart model is static and did not respond to the steps of the procedure as a live heart would during a real procedure. Learners were learning the step-by-step process but not gaining key decision-making skills. In addition, the silicone heart model is fixed to a standardized anatomy, meaning learners could not practice how to perform the procedure on abnormal anatomy or unique cases.

Second, the silicone model training was cost-prohibitive and cumbersome to transport, schedule, and set-up. Having a digital training solution that was easy to deploy and access would increase scalability and translate to a greater consistency in language, terminology, and best practices, which would improve patient safety.

https://www.tipmedia.com/demos/PedsBrandonHall/



2021 Awards Judges

Greg Apostol
Vice President
Alkermes

Isabelle Bocher-Pianka
Chief Patient Officer
Ipsen

Chapman Richardson
Global Head of Data Consumerization
Sanofi

Michael Zaiac
Head of Medical Affairs Oncology Region Europe
Novartis

Jill Donahue
Founder, CEO
Aurora Project

Vanessa Pott
Director of patient advocacy and strategic partnerships
Merck Group

Eric Racine
Vice President & Head, Public Affairs & Patient Advocacy
Sanofi

Emma Booth
Director, Medical Capabilities, EU Medical
Amgen

Keri Yale
Head, Patient Affairs & Engagement
BI International GmbH

Binyah Kesselly
VP, Strategic Business Improvements
Janssen

Mo Ali
VP Digital Analytics and Performance
GSK

Robin Kamen
Global Lead, Omnichannel & Customer Experience
Galderma

Amy Turnquist
Principal, Life Sciences
North Highland

Sam Hariry
Global Head Clinical Innovation
Novartis

Desiree Priestley
Senior Director, Patient Support
Otsuka

Mamta Chhabra
Global Associate Marketing Director
UCB