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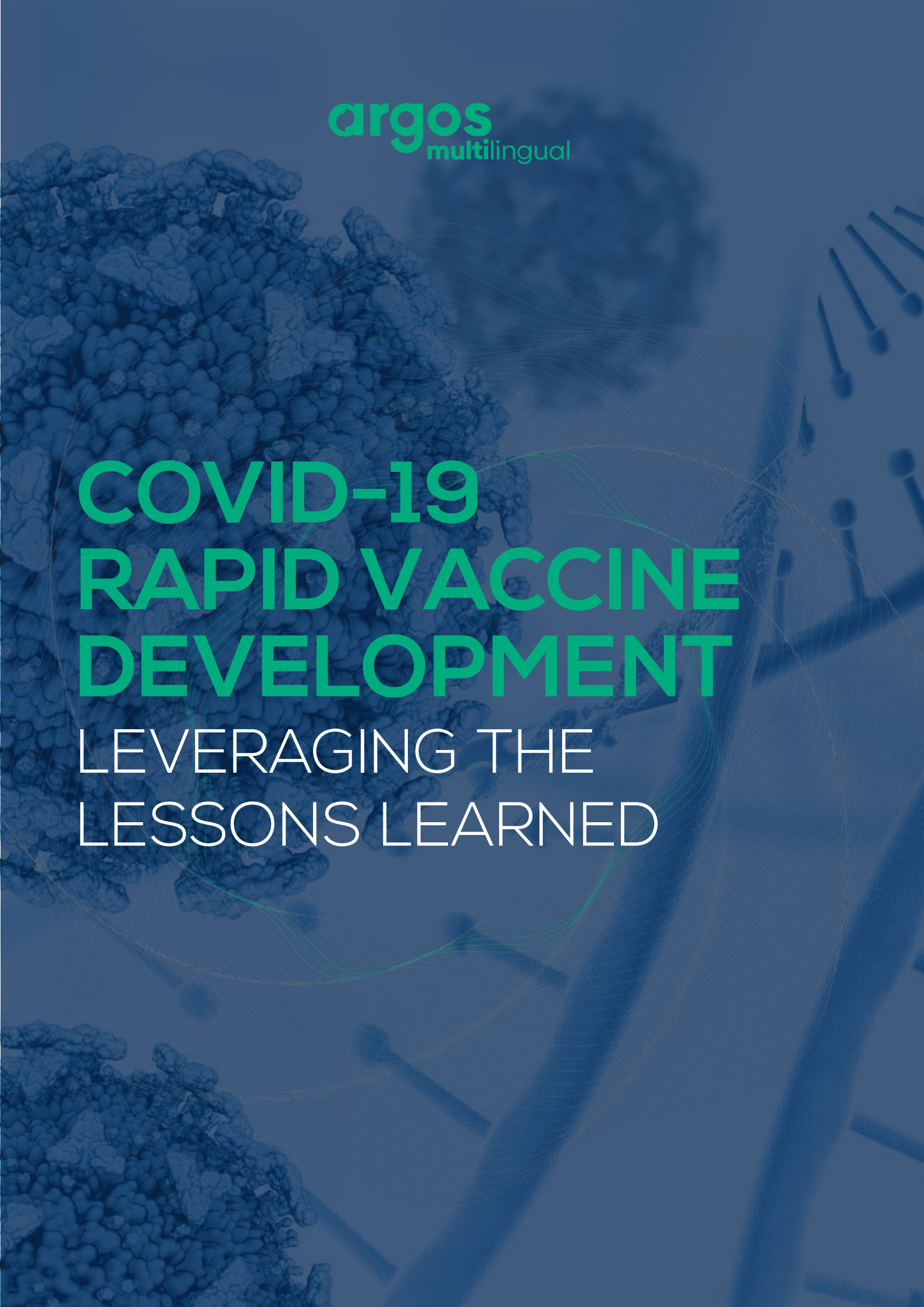
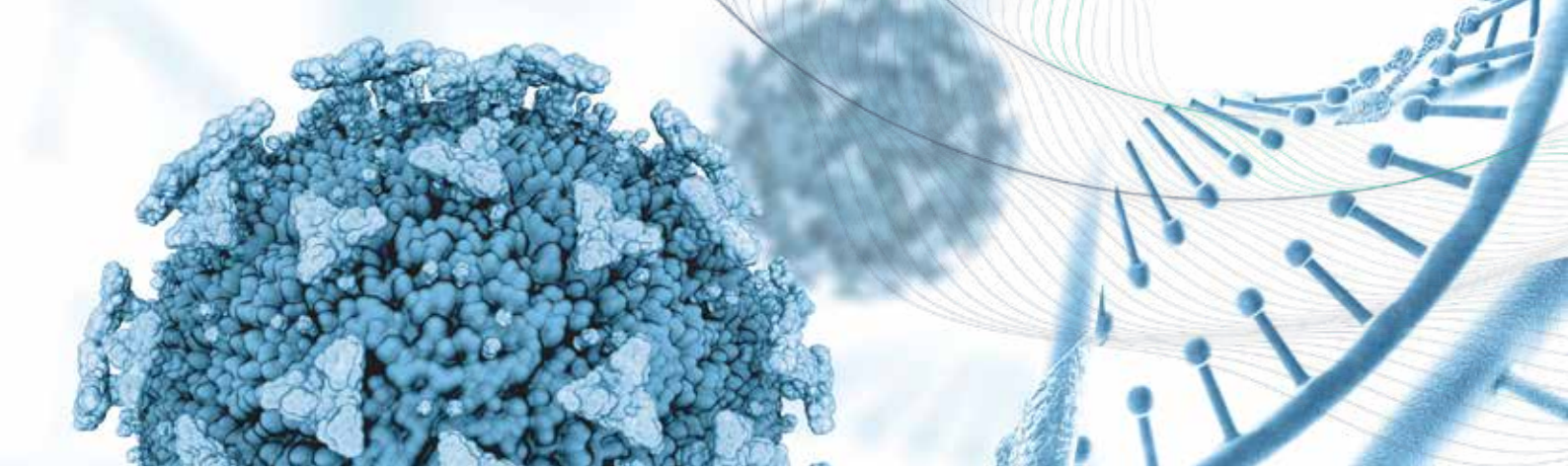
COVID-19 RAPID VACCINE DEVELOPMENT

LEVERAGING THE LESSONS LEARNED





A GLOBAL THREAT

In early January 2020, the World Health Organization announced the emergence of a mysterious pneumonia-like illness in Wuhan, China that appeared to be coronavirus related. At that time there were 59 known cases.

By late January, the government of China had placed Wuhan in lockdown and imposed restricted access protocols on Huanggang, 30 miles to the east, effectively placing 18 million people under quarantine. Transmission was increasing rapidly with confirmed cases rising exponentially to 9,800, emerging across the globe in the United States, Germany, Japan, Vietnam, and Taiwan.

On January 30, the World Health Organization declared a global health emergency. This was only the sixth time in the organization's history it had issued such a declaration, which is reserved for "extraordinary events" posing an international threat.

Suddenly, the world was challenged with finding an accelerated path to immunization against a rapidly spreading virus, SARS-CoV-2 – the pathogen identified as causing the disease.

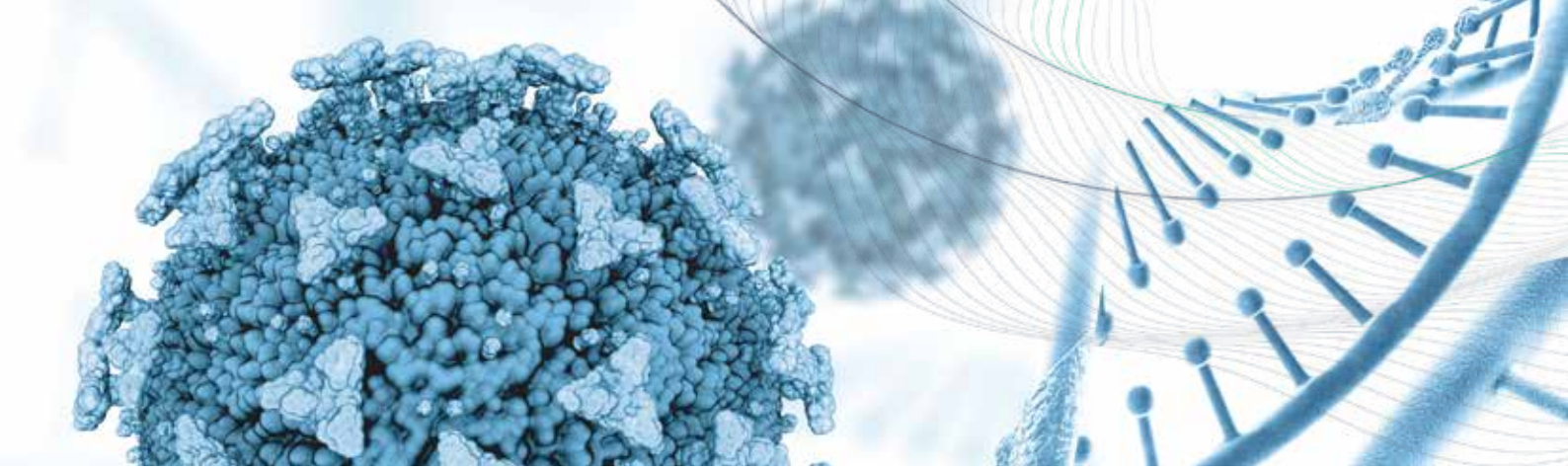
The global situation was changing almost daily. Just days after the WHO emergency declaration, several countries began restricting air travel.

On March 11, citing "alarming levels of spread and severity," the WHO declared COVID-19 a pandemic.

MEETING THE CHALLENGE

Vaccine developers were called to the forefront of the effort to contain the virus, partnering with governments and even with business rivals to expedite a path to the creation of an effective vaccine.

The situation was dire. Prior to this point, the most rapid vaccine development from viral sample to approval had taken four years in the 1960s to prevent mumps.



Several companies began expedited development and clinical trials, including Pfizer/BioNTech, Moderna, AstraZeneca, and Johnson & Johnson. Many of these efforts were aided by underwriting from the US government and the European Union to offset the risks introduced with new processes, concurrent clinical trial phases, and manufacturing commitments made without guaranteed approval.

In the case of Pfizer/BioNTech, they received no direct funding but benefited from US government intervention via the Defense Production Act, which allowed them to acquire scarce materials and equipment to continue ramping up manufacturing capability.

Meanwhile, the pandemic continued to cause severe illness, death, and economic contraction around the world. By mid-October 2020, global COVID-19 cases were above 40 million with 1.1 million fatalities. The global economy was contracting by 3.5 percent, causing the deepest global recession since the end of World War II.

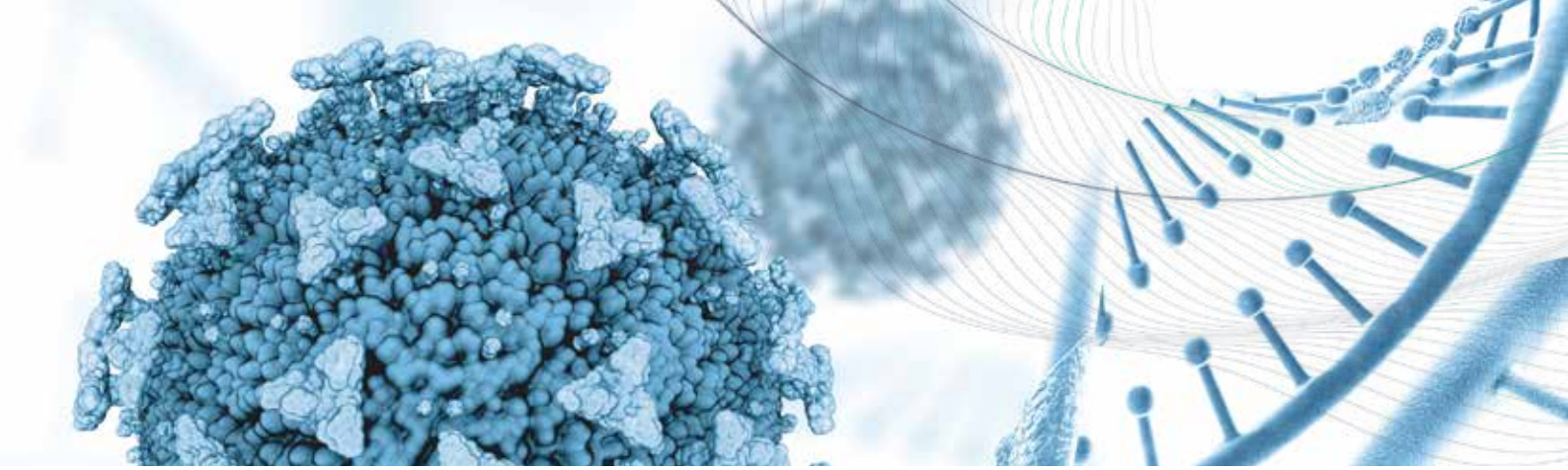
On November 9, the world finally received some good news, with Pfizer/BioNTech publishing clinical trial results for its COVID-19 vaccine showing 90% efficacy. Moderna would follow suit a week later with results showing a reduced risk of COVID-19 infection by 94.5%. On the same day, the US FDA announced that it would expedite emergency use authorization (EUA) for these vaccines if the data supported the authorization and that they would assist the companies by "removing any unnecessary bureaucratic barriers."

Mere days later, Pfizer/BioNTech completed a larger trial with 44,000 participants, showing increased efficacy to 95% and submitted the first EUA application to the FDA on November 20, 2020.

On November 23, AstraZeneca reported trial results showing their vaccine was 90% effective.

Many encouraging developments followed in rapid succession:

- December 11 — Pfizer/BioNTech receives EUA from the FDA for their COVID-19 vaccine.
- December 18 —Moderna is granted EUA for its COVID-19 vaccine.
- December 30 — AstraZeneca and Oxford receive UK Emergency Authorization for their COVID-19 vaccine.



By the first day of February 2021, the US reported 26.5 million vaccinations administered, surpassing the rate of infected individuals for the first time since the beginning of the pandemic.

Shortly thereafter, a real-world study using evidence from Israel's rapid vaccination rollout showed that 2 doses of the Pfizer/BioNTech COVID-19 vaccine reduced symptomatic cases by 94% across all age groups.

These vaccines were not only developed in record time but have greatly exceeded the FDA defined efficacy requirement of 50% with three endpoints – a reduction in COVID-19 cases, a reduction in COVID-19 severity, and a reduction in SARS-CoV-2 infections.

CURRENT STATE

As of June 16, 2021, the World Health Organization had received confirmation of 176,303,596 COVID-19 cases, including 3,820,026 deaths worldwide. A total of 2,310,082,345 vaccine doses had been administered.

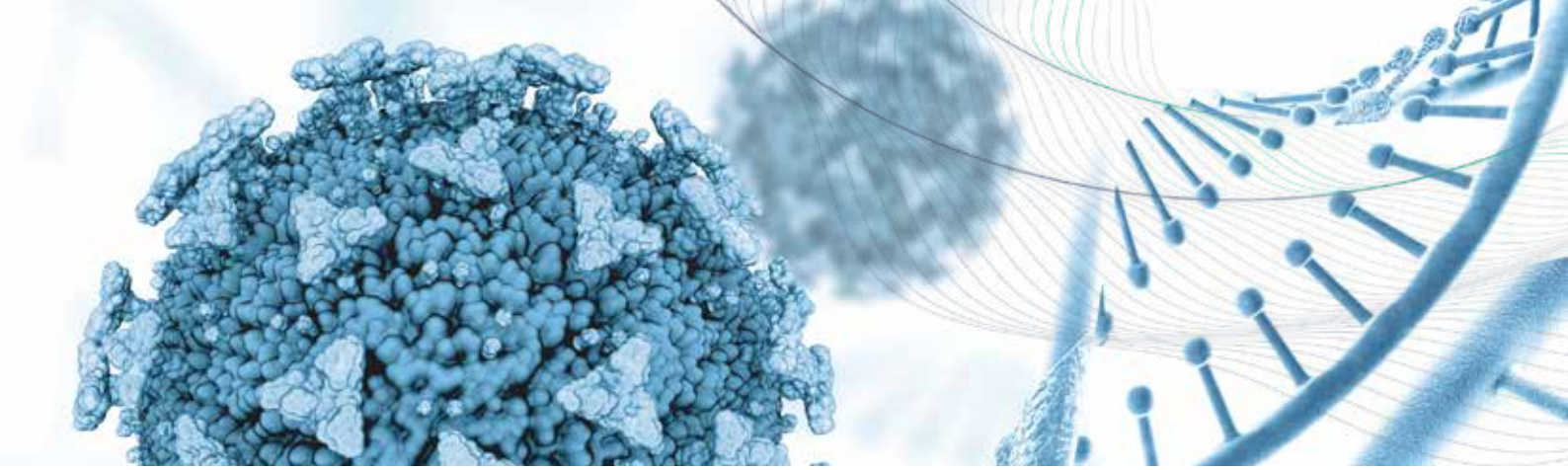
In regions with high rates of full vaccination, infection rates are slowing significantly, and many pandemic restrictions are now being lifted.

This is not the case in other underserved regions, however, and there is still much work to be done to distribute vaccines to these areas and restore normalcy worldwide.

At the recent G7 meeting in Cornwall, the member nations announced the donation of 1 billion vaccine doses to kickstart this effort.

AN EXTRAORDINARY ACHIEVEMENT

The successful rapid development and distribution of COVID-19 vaccines is arguably one of the more extraordinary achievements of the modern era. The pandemic has created a global effort and a focus of scientific expertise and resources on developing preventive vaccines and effective therapeutics.



A typical research and development timeline for vaccines is 10-15 years prior to manufacture and distribution. The first COVID-19 vaccine completed this process and was being distributed in approximately 11 months.

What has contributed most to this unprecedented success?

LESSONS LEARNED

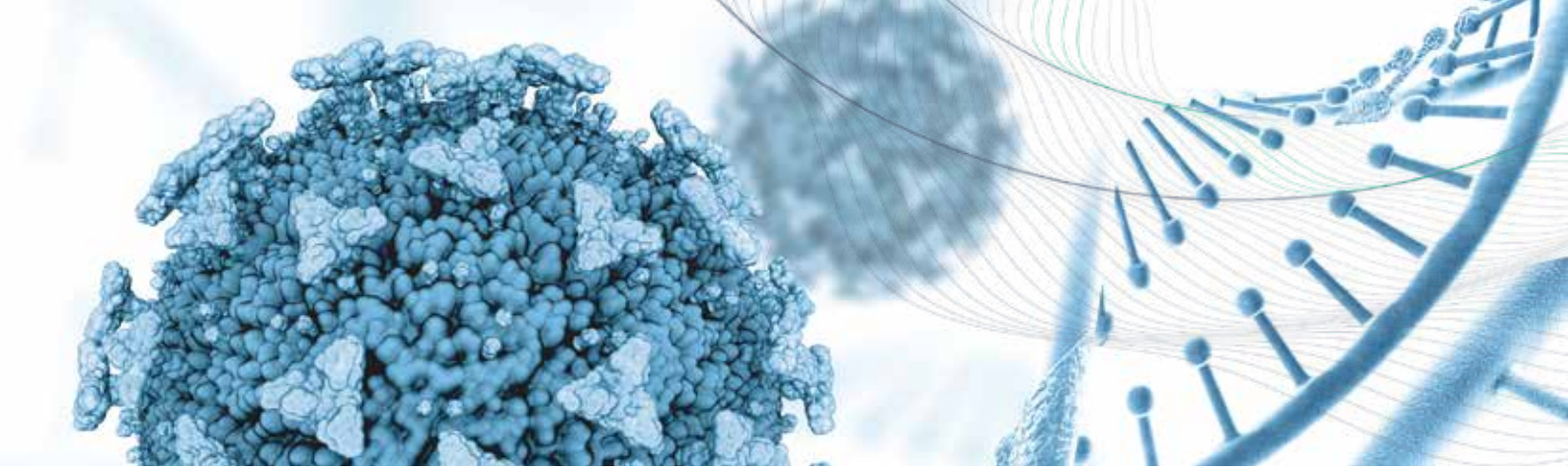
While these vaccines were created much quicker than any in history, the development and testing processes were the same as for other vaccines, utilizing clinical testing of thousands of participants from differing ages and ethnicities.

The scientific process was guided in part by prior success with anti-viral platforms already used successfully for humans and by over a decade of mRNA vaccine research that was reaching maturity. Data was also employed from clinical trials for vaccine candidates developed after the severe acute respiratory syndrome (SARS) outbreak of 2003 and Middle East respiratory syndrome (MERS) outbreak of 2012, giving researchers a head start in developing multiple vaccines to fight this novel coronavirus.

Highly collaborative global efforts by private industry, governments, and non-governmental organizations resulted in several SARS-CoV-2 vaccine candidates moving to Phase III trials in a period of only months from the start of the pandemic. Regulators networked to share information and identify acceptable clinical trial endpoints. High levels of funding were offered from public and private entities to assist with these efforts and to mitigate the risk of concurrent clinical trial phases and manufacturing in anticipation of approval.

Multiple post-mortem analyses show these critical components:

- Overlapping clinical trial phases were used where safe and practical to save time
- Factories were built and vaccine production commenced while clinical trials were still underway
- Large scale cold chain storage and logistics were rapidly deployed to safeguard new mRNA vaccines requiring sub-zero temperatures
- Regulators streamlined processes for Emergency Use Authorization once trials were completed



- Phased vaccine delivery was implemented at the start of distribution to reach the most vulnerable first

This is a success story born of collaboration, risk mitigation and accelerated innovation. Ultimately, the rapid development of COVID-19 vaccines represents the alignment of an urgent global need, regulatory flexibility, and the sheer force of political will.

What will the next chapter of this story reveal?

FUTURE STATE

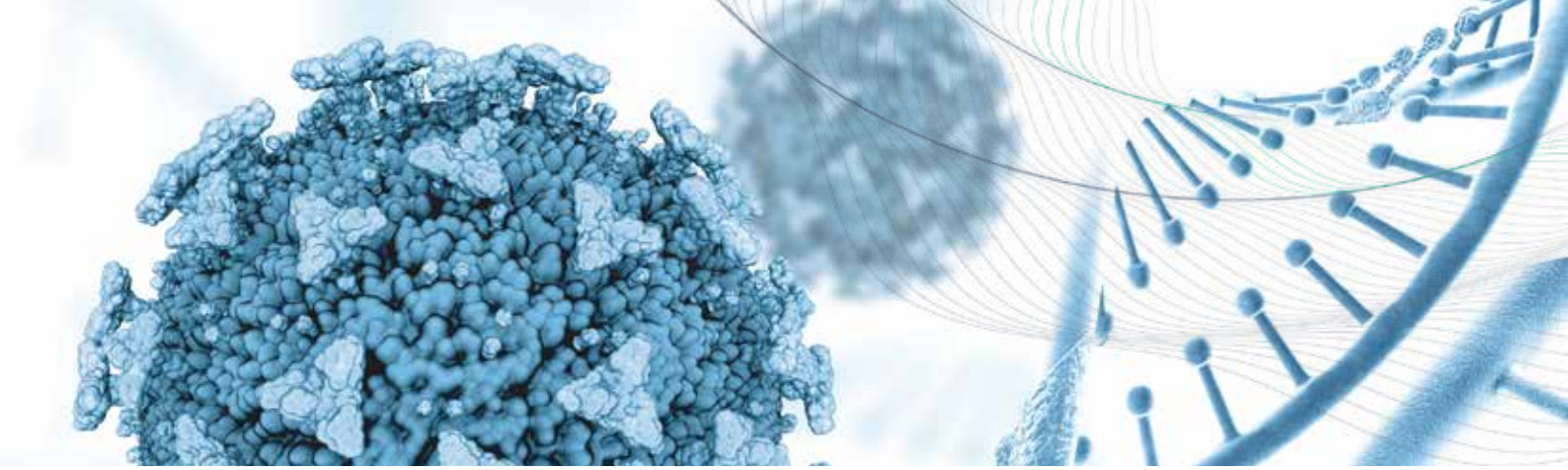
As the world continues to grapple with the ongoing effects of the pandemic, every day seems to bring news of advancements in research and potential treatments.

Real world data supports the growing realization that the vaccine development process can be accelerated significantly without negative impacts on patient safety.

While it may be impractical to maintain the current scale of the COVID-19 effort, there is hope that accelerated vaccine development can offer new treatments for cancer, HIV, and other serious diseases such as malaria, tuberculosis, and pneumonia that affect millions of people every year. For example, the mRNA technology used in some the vaccines can be chemically synthesized in days and can be manufactured for different diseases in the same facility, lowering costs and making it well-suited for fighting future pandemics as well.

The regulatory world is also in the process of re-evaluation. National regulators continue to exchange information on vaccine trials through a global body called the International Coalition of Medicines Regulatory Authorities (ICMRA). There are ongoing efforts to reach consensus on critical criteria such as the best endpoints for vaccine trials and harmonizing how to monitor side effects during new vaccine rollouts.

Enormous amounts of data have been generated from clinical trials conducted around the world to test COVID-19 vaccines, offering hope of a quantum leap in human vaccinology. At a minimum, there is growing consensus that this data must be used to stay ahead of future pandemics through ongoing research and development.

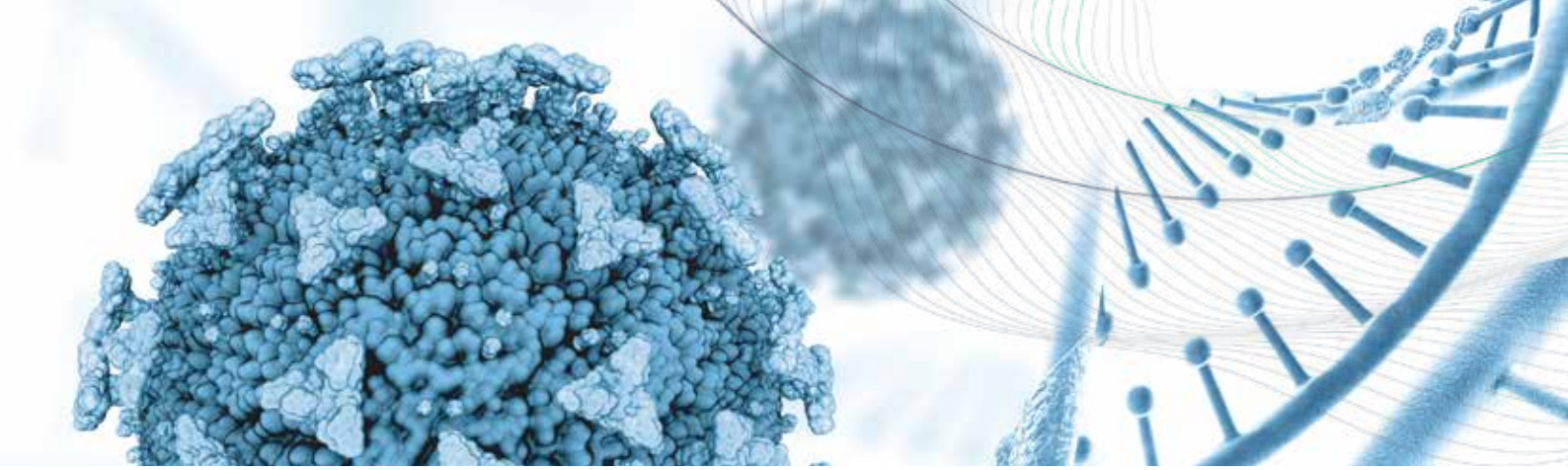


Several organizations, such as the Coalition for Epidemic Preparedness Innovations (CEPI), are actively working to create the infrastructure required for rapid development of vaccines against viruses like MERS, Ebola, and Zika, which are viewed as having pandemic potential. Additionally, the Global Preparedness Monitoring Board (GPMB) is offering guidance and monitoring of pandemic preparedness and response for future emergencies.

AGILE DOCUMENTATION AND LOCALIZATION

With the potential for continued acceleration of vaccine and therapeutics development, what are the implications for documentation and localization support?
Can fundamental process improvements combined with cutting-edge technology be used to partner with CROs and pharmaceutical companies to expedite the release of vaccines and other life-saving drugs? How can they be applied to keep pace and supply more agile documentation and translation without compromising quality?
Some fundamental changes prior to document creation and translation often bring immediate improvements in speed and accuracy during translation and review:

- Terminology management should ideally occur prior to authoring and translation. The goal is to identify terms that are "common use" and can be reused and to isolate those that are truly specialized, may be of limited use, or are unique to a clinical trial.
- Unique terms should be placed in glossaries for special handling within your process and/or terminology management application for use in appropriate workflows and documents (e.g., ICFs, PROs). Have them scrubbed against core terminology to ensure they cannot be replaced with another validated term. Share this information with your language service provider prior to the start of each clinical trial or project.
- Create standard templates and forms whenever possible that will only need to be translated and validated one time. Allow room in the design for unique content that will be required for new candidate vaccines, etc.
- Reusing source material and placing an emphasis on the reuse of translated information is a good idea, but taking advantage of content management tools to reuse compatible source content whenever possible offers another path to translation cost and time reduction. It will also help to increase overall intelligibility



and consistency in source content, heighten comprehension for translators, and enhance clarity in the final deliverable to patients.

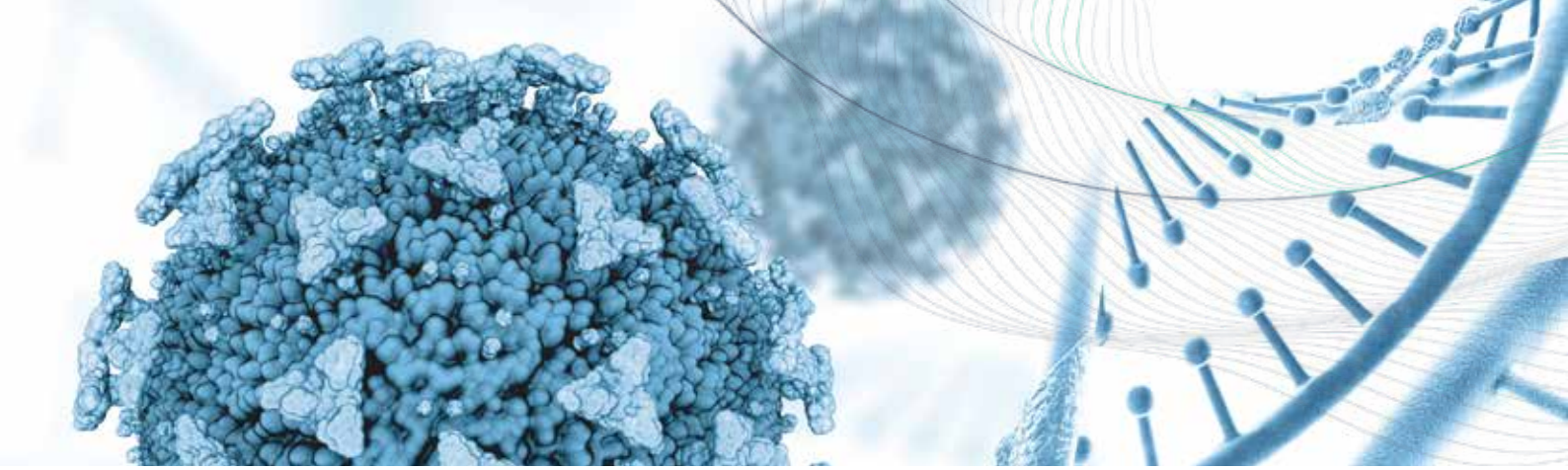
- Standardize and validate all acronyms, date and time displays, numerical formats, and units of measure in source and target languages. Share this information with your language service provider so it can be enforced during translation.

Recent advances in machine translation (MT) offer new possibilities for expediting the translation of critical documents without compromising quality. Some things to consider:

- By leveraging validated terminology and verified translation memory, it is possible to train a custom MT engine to be used with human post editing (MTPE) for one of the forward translation paths in the linguistic validation workflow or for other critical document translation.
- Using a third-party review service can enhance translation quality and make it easy to continue building high-confidence data for the ongoing training of a custom MT engine.

CONCLUSION

The past 19 months have proved once again that even the most challenging circumstances can be overcome through collaboration and innovation. Hopefully, the lessons learned from the COVID-19 pandemic will push us forward into greater scientific achievements and more efficient critical support processes for the benefit of the entire world.



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