



# COVID-19 ADVANCED MRNA TECHNOLOGY TO MEET UNMET MEDICAL NEED

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## ABSTRACT

*The Covid-19 pandemic, responsible for over 6 million worldwide deaths, there was an urgent need for preventative measures to mitigate its effects. Conventional vaccines, which typically prevent or reduce disease severity, usually require more than a decade for development and commercialization. The pressing nature of the pandemic led to the pursuit of novel solutions like mRNA-based vaccines, playing a critical role in saving lives. This article highlights the potential of mRNA technology to go beyond infectious diseases, offering the possibility to change the treatment landscape of future malignant diseases and address unmet medical needs.*

**Keywords:** Vaccines, mRNA, Pandemic, Covid

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## INTRODUCTION

Vaccines have long been used for the prevention of infectious diseases, but in recent times, their scope has expanded beyond prevention to include the treatment of malignant diseases, with the potential to impact further in the future. The advent of the novel Covid-19 pandemic, which resulted in over 6 million<sup>(1)</sup> deaths worldwide, presented an urgent need for biopharmaceutical companies and regulators alike to find ways to protect against the deadly virus.

One of the technologies that was leveraged to combat the pandemic was mRNA technology, which was novel at the time, with no commercially available product using this technology until the authorization was received for the mRNA based Covid-19 vaccine in late 2020. Although technology had existed and been developed over time since 1960<sup>(2)</sup>, it was only when an imminent need arose that this technology gave new hope to protect people and subsequently commercialized in less than a year, saving billions of lives.

Health authorities and biopharmaceutical companies played a pivotal role in the progress of mRNA technology, paving the way for exploration of new technologies and leveraging existing technologies to prevent, provide alternatives or cure other diseases or disorders.

The success of the mRNA-based Covid-19 vaccines has demonstrated the potential of this technology to transform the healthcare industry, leading to a renewed focus on research and development of vaccines and personalized treatments for a wide range of diseases.

As we move forward, it is clear that the future of medicine lies in the hands of innovative technologies such as mRNA and it is only through continued investment and collaboration that we can unlock its full potential to save human lives.

Currently, there are several mRNA vaccines in development but, for understanding purposes, they are broken down below as mRNA personalized vaccines and mRNA generalized vaccines.

### **mRNA Personalized Vaccines**

Below are examples of personalized mRNA vaccines that have in recent times demonstrated groundbreaking results to combat cancer

1. BioNTech, a biotechnology company, has made significant progress in the development of personalized mRNA vaccines. The promising results from the phase 1 trials of their pancreatic cancer vaccine have shown that the vaccine has been able to prevent the return of cancer for up to 18 months after treatment for 50% of enrolled patients. This breakthrough is significant in the medical field as it highlights the potential of mRNA vaccines to address previously unmet medical needs. Although the drug development lifecycle is still in its early stages, this development is a tremendous leap forward technologically. The success of BioNTech's personalized mRNA vaccine in clinical trials offers hope for the future of cancer treatment and could pave the way for other mRNA vaccines to be developed, commercialized, and made widely available, significantly improving the lives of patients around the world. <sup>(3)</sup>
2. In late 2022, Moderna and Merck announced the findings from their collaborative Phase 2b trials. The trials evaluated the efficacy of Moderna's personalized mRNA vaccine candidate, mRNA-4157/V940, in combination with Merck's Keytruda immunotherapy drug in patients with melanoma. The results were statistically significant, demonstrating that the combination therapy was more effective than Keytruda alone. Patients who received both treatments experienced a 44% reduction in the risk of recurrence or death compared to those who received Keytruda alone. This is an exciting development in the field of oncology as it highlights the potential of mRNA technology to enhance the effectiveness of existing treatments. The success of this trial offers hope for improved outcomes for melanoma patients and could pave the way for further research and development of mRNA vaccines for other types of cancer. With continued investment and innovation, personalized mRNA vaccines have the potential to revolutionize cancer treatment and improve the lives of millions of people around the world. <sup>(4)</sup>

### **mRNA Generalized Vaccines**

Numerous mRNA vaccines are currently in development, spanning from the initial stages of research to those already in the market. These vaccines, like the Covid mRNA vaccine, are designed to have a broad impact on large populations rather than being personalized for individual use.

One notable example of a breakthrough in mRNA technology is Moderna's vaccine candidate, mRNA-1345, which aims to prevent respiratory syncytial virus (RSV). This candidate has demonstrated an impressive efficacy rate of 83.7% without raising any safety concerns. Moderna is now preparing to submit the vaccine for regulatory review in 2023. <sup>(5)</sup>

Another promising mRNA vaccine is Pfizer's PF-07252220, which targets influenza and is currently in phase 3 of development. <sup>(6)</sup>

The advancements in mRNA technology showcased by these vaccines highlight the power of this novel approach in revolutionizing the field of medicine and improving public health on a global scale.

## CHALLENGES

### Manufacturing Complexity & Costs

mRNA vaccines have been a game-changer in the field of disease prevention, with the Covid-19 pandemic highlighting their potential for rapid development and deployment on a global scale. While mRNA vaccines for preventive diseases like Covid-19 are relatively easy to manufacture and scalable, the same cannot be said for personalized vaccines such as those used for cancer treatment. Unlike traditional vaccines, personalized mRNA vaccines are tailored to each individual patient's specific cancer, making them complex and expensive to manufacture. <sup>(7)</sup>

The manufacturing process for personalized vaccines involves identifying the specific genetic mutations that are driving the growth of the cancer cells and then designing a vaccine that targets those mutations. This requires significant resources and expertise, which drives up the cost of production.

Despite these challenges, the benefits of personalized mRNA treatments cannot be understated. The potential for customized cancer vaccines to provide targeted and effective treatment has the potential to save countless lives. While cost may be a barrier to access for some patients, the impact on public health could be significant. As seen with mRNA Covid-19 vaccines, the ability to rapidly develop and deploy new treatments can have a massive impact on preventing the spread of disease and saving human lives. The development of personalized mRNA vaccines may be challenging, but the potential rewards are enormous, making continued investment in this field critical for the future of healthcare.

### Logistics

The authorized/approved mRNA based Covid vaccines have brought hope to the world amidst the ongoing pandemic. However, their storage requirements pose significant logistical challenges, particularly in remote areas with poor infrastructure. The ultra-low temperature storage requirements of the Pfizer-BioNTech and Moderna vaccines are a significant hurdle that needs to be overcome to ensure equitable distribution and administration of the vaccines.

The requirement for ultra-low temperature storage is due to the inherent stability of mRNA molecules. These molecules are highly sensitive to external factors, which can cause them to degrade and lose their efficacy. To prevent this, the vaccines must be stored at ultra-low temperatures, which requires specialized equipment and infrastructure. <sup>(8)</sup>

In remote areas, where infrastructure is sparse, the availability of such specialized equipment is a challenge. This poses a significant risk to the efficacy of the vaccines as they may be exposed to temperatures that could lead to their degradation. Furthermore, the cold chain logistics system, which is already under strain due to the unprecedented demand for vaccines, is further burdened by the ultra-low temperature requirements.

Despite the logistical challenges posed by the ultra-low temperature storage requirements of mRNA-based vaccines, the benefits of vaccination far outweigh the challenges. Healthcare providers must continue to explore innovative solutions to ensure that vaccines reach all those who need them, irrespective of their location or infrastructure.

## Future:

Traditionally, the development cycle for vaccines can take anywhere from 10 to 15 years, with multiple phases of clinical trials and regulatory approvals required before they are deemed safe and effective for human use. However, the emergence of mRNA technology during the Covid-19 pandemic has transformed the vaccine development landscape, enabling the expedited development of mRNA-based vaccines in less than a year. Despite the rapid development, these vaccines have undergone rigorous safety and efficacy reviews by several health authorities worldwide and have been authorized for emergency use.

The transformative science of mRNA technology has enormous potential to prevent and treat a variety of diseases beyond Covid-19. The commercial success of Covid-19 mRNA vaccines is a testament to the advancements in science that have led to saving billions of human lives. While manufacturing of these vaccines is relatively easy, as discussed above, there are challenges associated with storage and distribution, particularly in remote areas where infrastructure is sparse. The regulators and manufacturers/sponsors of mRNA-based vaccines will need to identify effective ways to overcome these challenges while also making them cost-effective for patients who may require personalized treatments in the future.

The development of personalized mRNA vaccines could revolutionize the treatment of cancer and other diseases, but their cost is a significant barrier to wider adoption. To make personalized mRNA treatments more accessible, manufacturers will need to find ways to produce them at scale while also reducing the cost of production. With continued investment and innovation in mRNA technology, we can look forward to a future where personalized medicine is affordable and accessible to all those who need it.

## Conflicts of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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