

# Research & Test Results: Finding a Coronavirus Vaccine

## White Paper

As the number of COVID-19 cases continue to balloon across the globe, scientists and researchers are working tirelessly to find an effective vaccine for COVID-19. Many healthcare institutes, pharma companies, and universities are working towards formulating treatments for COVID-19.

Developing a safe vaccine for a new disease is not an easy task. Thankfully, rapid progress is being made as coronaviruses were already on the health science researchers' radar. Earlier, when SARS and MERS caused by coronaviruses hit the human world, vaccines were developed to contain those outbreaks. Fortunately, those learnings can be applied in defeating the COVID-19 pandemic.

# Researching the Coronavirus Vaccine

Pandemics often remain an enigma for months or even years, thus heightening its fear. COVID-19 is no different. While the lab researchers, pharma companies, and scientists are tapping into developing a vaccine and effective treatments at blazing speed, the pandemic is moving even faster. Yet, it usually takes years to build a new drug treatment or vaccine; authorities are relying on containment measures like travel bans, quarantines, social distancing, and lockdown to contain the spread.

As high-speed research is moving on different fronts, one of the most crucial is to get a vaccine that could provide immunity; thus, allowing human life to return to normalcy. On the other front, scientists are also exploring if existing drugs and treatments might work to combat the coronavirus.

All drug and vaccine research is challenging. In fact, it can take researchers several tries to find one. Again, the [development cycle of new vaccines](#) involves pivotal stages, including exploratory, pre-clinical, clinical development, regulatory review and approval, manufacturing, and quality control. With the completion of each of these stages, researchers and scientists need to submit a ton of documentation. As FDA guidelines, internal compliance requirements, accounting, and more need to be met, there seems an endless list of documents that they need to create. Again, each of these requires to be submitted in full at each step. Until this gets delivered, much of the work comes to a halt. And people can't risk a delay in finding a vaccine amidst a global crisis.

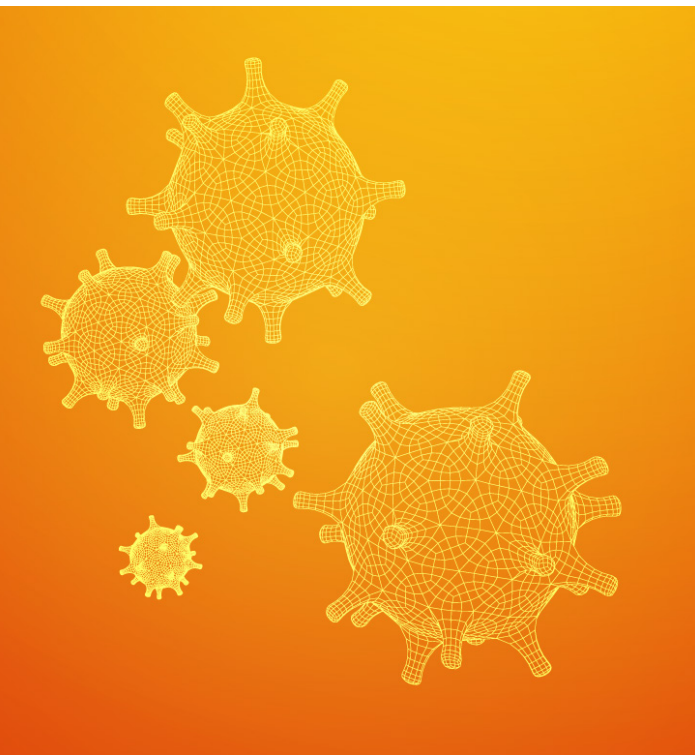


## Documentation Delays: Roadblocks in Finding a Coronavirus Vaccine

A key part of the research is the documentation generated that reports the results. These generated documents are leveraged internally by everyone involved in the process and are also sent to the FDA for the approval process. Right from trained professionals to pharmaceutical companies, a lot of stakeholders are involved in the vaccine research and development cycle. This includes health professionals, individuals, academia, committees, non-governmental organizations, private industries, manufacturers, government agencies, and media.

With that in mind, let's also not forget the fact that documents need to be generated and submitted for approval after each step of the vaccine research and development cycle. Given the meticulous testing and approval processes involved in finding a vaccine, and the sheer number of stakeholders that contribute in the process, it can take years to document, develop, and move a vaccine from lab to public, which is not affordable in the times of crisis.

While taking years to document a coronavirus vaccine is beyond the scope, it should not even take a month, week, or a day. Instead, it should take only a few seconds. So, to



minimize the time spent on document preparation, it is crucial to implement a strong document automation system.

## **Automation: Conquering Documentation Dilemmas**

In the process of bringing new medicines to market (most recently for the COVID-19 vaccine), researchers, scientists, and pharmaceutical companies undergo several R&D phases, which requires them to generate thousands of documents to record, review, and manage the information throughout the process. Thus, they need to spend a lot of time compiling documents, which delays the process further. Again, these have to be sent to the government or international authorities, including FDA, for

review; ensuring that they meet regulatory compliance, as well.

However, an appropriate document automation system plays a significant role in formalizing this process. Right from advanced document generation to ensure that the pharma regulatory compliance standards are met, it automates the end-to-end document creation process.

## **Why Automate?**

As scientists are developing a new drug, they invest a lot of time in finalizing whether they have the right combinations of chemicals. Also, the FDA mandates the consolidation and compilation of information about the drug that is being developed. So, right from the discovery phase, large volumes of documents are generated. To ensure that these documents comply with the FDA regulations and such an ever-increasing amount of documents is handled efficiently, document automation comes into the role.

With document automation, pharmaceutical firms and researchers can ensure better regulatory compliance, fewer errors, and improved efficiency.

### **1. Cut the repetitive parts of document creation**

Employees in the life science industry invest a lot of their time in compiling documents that suffice the demands of regulators. With a document automation solution, they can pull data from [multiple datasources](#) and automatically populate a compliant document without any need for manual entry. As the template documents will always be built with the right data, it helps get rid of process roadblocks that slow down the business. Thus, teams can spend more time working on research and development.

### **2. Take regulatory information management to the next level**

With the centralization of regulatory document templates and connected resources, a great document automation system mitigates the risk of errors and saves time for

everyone involved in the document creation process. Moreover, it enables medical teams to update the required information in real-time across all the templates with the help of certain data points.

### **3. Speed up the approval process & bring drugs to the market quicker**

Inefficient processes cause delays in the approval of new medicines, which can cost a ton. With document automation, clinicians, doctors, and research scientists can access information in a moment to compile the reports for the FDA and ensure that all dots are connected. This keeps visibility and transparency across the proceedings; thus, reducing cost, saving time, and speeding up the approval process and bringing the drug to the market.

## **Ramp Up Your Document Generation With An Efficient DocGen Solution**

An average document generation system can add months to the final approval and release of a coronavirus vaccine. And this is a considerable time for thousands of lives at stake today. So, a system that requires multiple people or makes it difficult to use different data can be a giant roadblock at this time.

The ineffective document automation system in good times can merely be expensive, but in this unprecedented time of the pandemic, the limitations of such a system can cost people's lives. During this time, all that lab researchers, pharmaceutical companies, scientists, and healthcare specialists require is a document generation solution that quickly creates documents through templates and that too, in a fraction of the time.

[Windward comes with this ability.](#)

While researchers worldwide are working non-stop to develop a vaccine for coronavirus, Windward ensures quick documentation of vaccine and testing reports with its document automation software.

### **1. Template Designer**

Template creation is a collaborative effort under most document automation solutions. However, companies must look for a document automation solution that comes with two of these significant advantages. First, template design should be in the template itself. It should require no code, developer, or designer to complete the work. Besides, the system must be designed to help anyone on the teams to create templates. Second, designing templates should be fast. *For instance, a solution that accomplishes template [designing in 1/10th the time](#) that researchers spend on their existing systems, is a good choice to make.*

With simple-to-use templates, scientists and lab researchers can put their crucial vaccine development data and share the findings with their co-researchers and authorities in real-time. Moreover, they don't need to have a team of developers or be technically sound to generate documents or reports. With Windward, everything is so super-friendly and intuitive that even an individual can create a report or document in a few clicks. This is inevitable when all that the researchers need to do is change a few vaccine or data fields on the report, whereas everything else remains constant. Thus, it cuts out





the laborious process of entering data manually into the reports.

## **2. Pharma Regulatory Compliance**

When scientists venture to find a drug or medicine, they require compiling their research data, findings, and reports for approval. With strict regulations in place, it becomes crucial to ensure that all medicines are safe and efficient, i.e., meeting regulatory compliance. A document automation system sees to it that organizations generate documents and reports in compliance with pharma regulations, it assures that the best practice is adhered to.

With DocGen solutions, [pharmaceutical companies](#) can manage, automate, and optimize document generation processes that govern the best document creation practices. Thus, it enables them to address the challenges of regulatory compliance while ensuring improved efficiency, accuracy, and speed to bring the drug to the market.

## **3. eSignature**

To comply with 21 CFR Part 11, pharmaceutical companies need to implement the electronic signature controls. As document automation software promotes effective collaboration with all the stakeholders, it enables teams to forward documents to the right person for review, approval, and eSignature. The reviewers can access the information in these documents, verify it, make amendments, and sign as approval to it irrespective of where they are. With an efficient document generation system like Windward, document delivery and signing can be accomplished at a faster rate.

#### 4. Side by side

While there's no room to replace the existing system in such a crisis or put a strain on the company's finances, [the side-by-side document automation approach](#) can be valid. With the integration of a single piece of software into the existing system, companies can have the document generation processes running swiftly. This approach takes fewer resources, doesn't completely upgrade your current systems, and gives the freedom to transition the data over the new system as and when needed.

Researchers find Windward's side-by-side approach great for their different reporting needs. While they can use it to generate mass reports efficiently, they can continue to use their existing system in place for reports that still need a human involvement to finalize.

#### 5. Integrations

When scientists and researchers indulge in a rigorous study to find a vaccine, they depend on different tools for research and testing results. Switching between applications now and then whenever they need to access data is intimidating and time-consuming. To tide over these hassles, document generation solutions offer [world-class integrations](#) into a suite of tools, products, and software that the pharmaceutical organizations and research labs utilize. It works as a central repository for crucial data; thus, fuelling the docgen and reporting power.



### Windward Can Help Scientists Find A COVID-19 Vaccine

As the world is in dire need of a vaccine that fights COVID-19, every minute counts. While healthcare providers and pharmaceutical companies are contending to help the world tide over the crisis, automating workflows and eliminating paper-based processes can help them deliver better and quicker outcomes. Besides, complying with the ever-shifting healthcare data regulations requires them to handle the data efficiently and securely.

[Windward wants to help the pharmaceutical and healthcare sectors](#) in making their research easier in any way possible. While working on the COVID-19 vaccine, Windward can be a great choice.