

# FAQ: What is the Process for Obtaining Remdesivir for Compassionate Use?

Remdesivir is an investigational nucleotide analog with broad-spectrum antiviral activity. It has *in vivo* and *in vitro* activity against Ebola, Marburg, Middle East Respiratory Syndrome (MERS), and Severe Acute Respiratory Syndrome (SARS) viruses. This medication has been studied in patients with Ebola and healthy volunteers. Remdesivir's clinical safety and efficacy for treating COVID-19 is still being determined through prospective clinical trials; however, the drug is currently available for compassionate use in patients who meet criteria (Criteria available here: <https://rdvcu.gilead.com/>).<sup>1</sup>

When obtaining remdesivir for compassionate use, other sites have completed the steps listed in **Figure 1**. Please note that these steps are subject to change; however, this diagram should give you an idea of the general process involved in obtaining remdesivir for compassionate use.

## **Below are a few tips and tricks to help make the process go more smoothly:**

- Expect the process to take a few days. Compassionate use requests were taking 5-6 days as of March 20th and this will probably continue to increase as the number of COVID-19 cases around the world grows.
- Collect contact information (names and phone numbers) for the representative that you speak with on the phone so that you maintain a clear path of communication with Gilead if the patient you are trying to start on remdesivir is transferred to another facility or experiences a change in clinical status.
- The phone number to the medication information line at Gilead is 1-866-633-4474.

**Reviewed on 3/24/2020.**

### References:

1. Press Release. Gilead Science Initiates Two Phase 3 Studies of Investigational Antiviral Remdesivir for the Treatment of COVID-19. 26 February 2020. <https://www.gilead.com/news-and-press/press-room/press-releases/2020/2/gilead-sciences-initiates-two-phase-3-studies-of-investigational-antiviral-remdesivir-for-the-treatment-of-covid-19>

## Figure 1. Steps for Obtaining Remdesivir for Compassionate Use

### Step 1

- Go to <https://rdvcu.gilead.com/> and review compassionate use criteria.
- If your patient meets criteria, click "Next" to submit the request to obtain remdesivir to Gilead (online).
- **Note:** You will not receive a confirmation email after you submit this information.

### Step 2

- Gilead will send an email letting you know that the request was approved.
- Inform your local IRB and clinical trials department and complete any necessary work to meet their requirements for study drug approval. Keep them informed throughout the process.

### Step 3

- Gilead will request patient data. Complete Gilead's expanded clinical data entry online.
- They will send a prescriber agreement, consent form template, and drug information (e.g. investigator brochure, protocol, pharmacy manual, clinical baseline form, and clinical update form).
- Return prescriber agreement to Gilead via email.
- Request eIND from the FDA by phone. **Website for FDA contact information and instructions:** <https://www.fda.gov/drugs/investigational-new-drug-ind-application/emergency-investigational-new-drug-eind-applications-antiviral-products>
- Obtain patient or family consent.

### Step 4

- The FDA will send Form 3926 via email for you to complete. Return Form 3926, CV, medical license, Gilead letter of authorization to FDA via email and mail. **Note:** Do not fax this form since employees are working from home.

### Step 5

- Gilead will send a letter of agreement via email.
- The FDA will issue eIND via email that you should send to Gilead via email
- Work with IT to get the drug entered into your electronic health record / order entry.

### Step 6

- Drug arrives at facility
- Fill out clinical baseline form and send to Gilead prior to starting remdesivir.
- Prescribe drug, order safety labs
- Send clinical update forms to Gilead daily while the patient is on remdesivir.