

# Tecovirimat (TPOXX) IND Registry for Providers and Facilities



## Why register?

An online registry is available for providers and affiliated medical facilities providing tecovirimat (TPOXX) under the CDC-held expanded access Investigational New Drug (IND) protocol to register. All providers must register with the TPOXX IND Online Registry.



- The TPOXX IND Online Registry enables compliance with IND regulations.
- Providers must be registered to access electronic TPOXX IND forms that are required for completion and submission to CDC. The secure electronic forms include:
  - Form FDA 1572 (Statement of Investigator)
  - Patient Intake Form
  - Clinical Outcome Form
- The online registry provides an up-to-date list of participating providers and facilities under the TPOXX IND protocol.

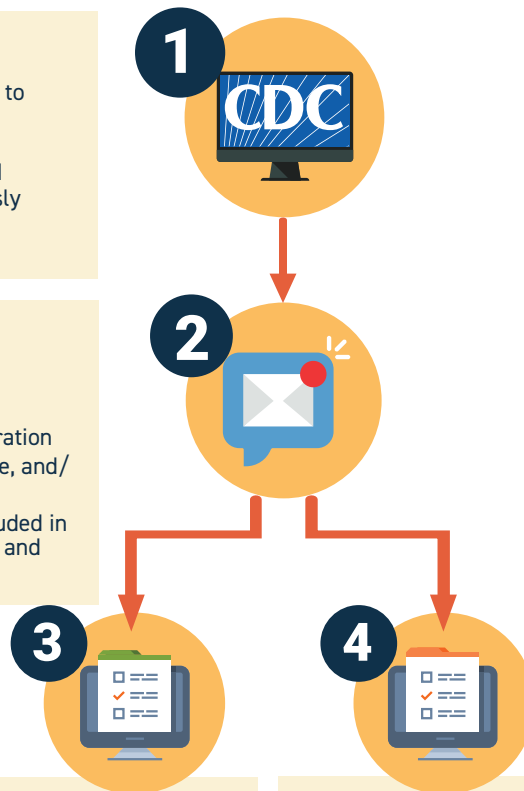
## Steps to Register and Access Electronic Patient Intake and Clinical Outcome Forms

### Register Online

- [Register](#) as participating providers and facilities to be covered under the CDC-held TPOXX IND protocol.
- The electronic Form FDA 1572 can be completed through the online registry if it was not previously submitted to CDC.

### Complete Verification

- Upon registration, the provider will receive the first email from "CDC TPOXX IND <noreply@dcipher.cdc.gov>" confirming registration as a participating provider to prescribe, dispense, and/or administer TPOXX under the CDC-held IND.
- Please complete the brief verification steps included in the email to access the electronic Patient Intake and Clinical Outcome Forms.



### Access Patient Intake Form

- Upon verification, a provider will receive a second email with a secure link to electronically fill out the Patient Intake Form.
- The secure link can be accessed multiple times to complete the form for each patient treated.
- For each patient treated with TPOXX, providers must submit this form to CDC within 7 calendar days of therapy initiation.

### Access Clinical Outcome Form

- Upon verification, a provider will receive a third email with a secure link to electronically fill out the Clinical Outcome Form.
- The secure link can be accessed multiple times to complete the form for each patient treated.
- For each patient treated with TPOXX, providers should submit this form to CDC within 3-7 calendar days of completing tecovirimat treatment.

**Note:** For security reasons, the electronic Patient Intake and Clinical Outcome forms must be completed and submitted in one sitting, and the links to these forms expire **180 days** from issuance. Providers with expired links who need access to these forms can email [regaffairs@cdc.gov](mailto:regaffairs@cdc.gov) to request new secure links.

For any questions regarding the TPOXX IND Online Registry and/or electronic forms, please email [regaffairs@cdc.gov](mailto:regaffairs@cdc.gov).