

# 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.



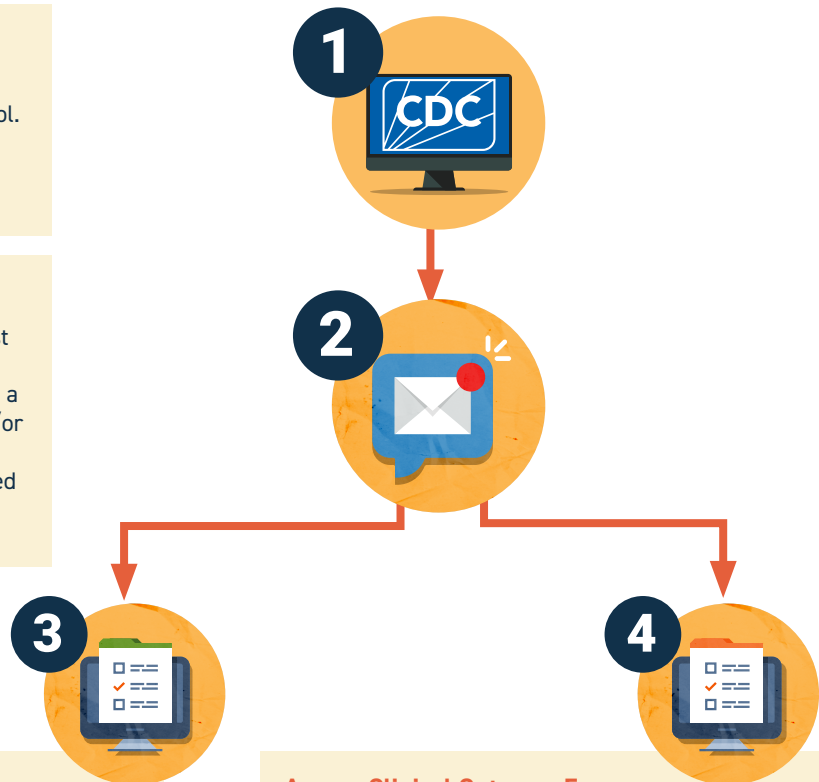
## Steps to Register and Access Electronic Patient Intake and Clinical Outcome Forms

### 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 registry 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 should submit this form to CDC within 3-7 calendar days of completing tecovirimat treatment.

### 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 are requested to submit the form to CDC within 7 days of the last patient follow up.

**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 should re-register to receive 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).