# FINTEPLA REMS Cardiovascular Adverse Event Reporting Form

My patient’s most recent echocardiogram observed signs of valvular heart disease (VHD), pulmonary arterial hypertension (PAH), or other cardiac findings in the echocardiogram.

## Instructions

Within 3 business days of receipt, complete this form and submit the completed form online at www.FiniteplaREMS.com, via fax to 1-833-568-6198, or via mail to 1710 N Shelby Oaks Dr, Ste 3, Memphis, TN 38134.

## PATIENT INFORMATION

* indicates required field.

<table>
<thead>
<tr>
<th>Field</th>
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<tbody>
<tr>
<td>First Name*</td>
<td>Yes</td>
</tr>
<tr>
<td>Last Name*</td>
<td>Yes</td>
</tr>
<tr>
<td>Date of Birth (MM/DD/YYYY)*</td>
<td>Yes</td>
</tr>
<tr>
<td>REMS ID*</td>
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## PRESCRIBER INFORMATION

* indicates required field.

<table>
<thead>
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<tbody>
<tr>
<td>First Name*</td>
<td>Yes</td>
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<tr>
<td>Last Name*</td>
<td>Yes</td>
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<tr>
<td>National Provider Identifier (NPI)*</td>
<td>Yes</td>
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<tr>
<td>Phone*</td>
<td>Yes</td>
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<td>Email</td>
<td>Yes</td>
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## CARDIOVASCULAR ADVERSE EVENT INFORMATION

* indicates required field.

**Cardiac findings on echocardiogram (select all that apply):**

- □ Valvular heart disease (VHD)
- □ Mild or greater aortic regurgitation (State degree of aortic regurgitation: )
- □ Moderate or greater mitral regurgitation (State degree of mitral regurgitation: )
- □ Restricted valve motion (aortic and mitral valves) (Which valve(s)?)
- □ Valve thickening (aortic and mitral valves) (Which valve(s)?)

- □ Pulmonary arterial hypertension (PAH)
- □ Interventricular septal flattening
- □ Elevated right heart/pulmonary artery pressure (pulmonary artery systolic pressure >35 mm Hg); PASP reading was mm Hg
- □ Other (please specify):

**Echocardiogram findings of PAH (select all that apply):**

- □ Other cardiac valve abnormalities (select all that apply):
  - □ Mild or greater pulmonic valve regurgitation (State degree of regurgitation: )
  - □ Moderate or greater tricuspid valve regurgitation (State degree of regurgitation: )
  - □ Other (please specify):

- □ Dose of FINTEPLA at the time of the event*: mg/kg/day and mg/day

- □ Is patient on concomitant stiripentol?* Yes No

- □ Duration of treatment with FINTEPLA (provide treatment dates)*:

- □ Was treatment discontinued due to this event?* Yes No

- □ Was the patient symptomatic?* Yes No

If yes, please describe symptoms*:

- □ Were there any signs on physical exam?* Yes No

If yes, please describe signs*:

Did the VHD, PAH, or other cardiac valve abnormalities result in any of the following (check all that apply):

- □ Medication or interventional therapy
- □ Hospitalization
- □ Discontinuation of treatment
- □ Death
- □ No change

If an event of VHD or PAH or other cardiac abnormality is reported, the patient’s prescriber will be contacted for further information regarding the report. Pertinent echocardiogram and laboratory test results will be required to be sent to the FINTEPLA REMS.

Submitted by: Prescriber Designee Prescriber

If the patient has been discontinued from FINTEPLA treatment, the prescriber/prescriber designee must notify the FINTEPLA REMS.

If you have any questions or need additional information, please visit www.FiniteplaREMS.com or call 1-877-964-3649, Monday through Friday, between 7 AM and 7 PM Central Time.

Reference ID: 4631810