

# Clinician Role in Observational Carvedilol Study

## Pre-Study Preparation

- Attend optional virtual meeting
- Access information about study and study forms on KCNT1 Epilepsy Foundation website

The Caregiver/Parent will bring printed forms to all clinic visits for completion similar to that of a routine physical form. (Or you can print from website.)

### Study Website:

<https://kcnt1epilepsy.org/carvedilol>

## Visit 1

Parent will bring a 7- or 14-day **Screening Diary** to this visit (see Key Fact #4 below)

- Through your screening and assessment process, you will determine whether carvedilol will be prescribed off-label

Parent will bring **(2)** additional printed forms **for clinician or clinic staff to complete at this appt:**

- Clinic Intake Form**
- CCSA-Clinician Form**
- Return completed forms to the Caregiver/Parent. They will share forms with a Study Coordinator to enter data into study dataset

## Follow Up Visits

Parent will bring a completed **Daily Tracker Diary** completed for one week after every change in dose

- Through your assessment process, determine whether dose will be changed

Parent will bring **(1)** additional printed form **for clinician or clinic staff to complete:**

- Clinic Intake Form**
- Return completed forms to the Caregiver/Parent who will enter data or share with a Study Coordinator to enter data into study dataset

## Final Visit

Final Visit is triggered when any of the following are true:

- Patient has reached the maximum tolerated dose (are no longer increasing the dose), OR;
- Decision is made to discontinue carvedilol, OR;
- Month 6 is reached.

Parent will bring a completed **Daily Tracker Diary** completed for one week

Parent will bring **(3)** additional printed forms **for clinician or clinic staff to complete at “final” follow-up visit:**

- Clinic Intake Form**
- CCSA Clinician**
- Clinician Global Impression**
- Return completed forms to the Caregiver/Parent who will enter data or share with a Study Coordinator to enter data into study dataset

## Key Facts

1. The Clinician is neither a PI, nor a participant in this study. The study is observational and will simply follow your patient forward in time, monitoring for changes.
2. The Caregiver/Parent brings the clinician-reported forms and surveys to their clinician appointments. Clinicians will complete forms in the clinic. Forms will be shared with Study Coordinators for entry into the study dataset. See #4-6 for further information.
3. Caregivers/Parents should consent to the study prior to their first appointment.
4. To the first appointment, the Caregiver/Parent should bring a printed, completed Screening Diary including daily seizure and heart rate for 7-14 days. If you prescribe carvedilol, this will become a study document, collecting screening data at baseline. They will also bring **(2) forms** found in **Doctor Launch Packet A: Clinic Intake Form + CCSA-Clinician Form**. These forms should be completed in the clinic.
5. To all follow up appointments, Caregivers/Parents will bring **(1) form** in **Doctor Follow Up Packet B: Clinic Intake Form**. This form should be completed in the clinic.
6. To the final appointment (either at Month 6, at the maximally tolerated dose, or upon discontinuation of medication, Caregivers/Parents will bring **(3) forms** in **Doctor Follow Up Packet C: Clinic Intake Form, CCSA-Clinician Form, and Clinician Global Impression**. These forms should be completed in the clinic.
7. Every 30 days Caregivers/Parents will complete a Parent Global Scale to document any perceived changes in numerous domains.
8. IRB Protocol # substudy to: **KCNT001**
9. If you have questions, please contact **KaitlynE@KCNT1epilepsy.org**