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Ensuring the Continuity of Data Collection in a Focal Epilepsy Clinical Trial During the COVID-19 Pandemic

Lilly Frohlich, Laura Whitmore, Stephanie Pfister, Rachel Gurrell, Ann Dandurand, Pamela Perry, Matthew Leoni

Cerevel Therapeutics, Cambridge, MA

CONCLUSION

- To ensure the continuity of care for trial participants, collection of quality data, and prevention of trial data loss due to COVID-19 restrictions, modifications to allow for remote data capture were successfully implemented in an ongoing phase 2 trial of darigabat in participants with focal epilepsy

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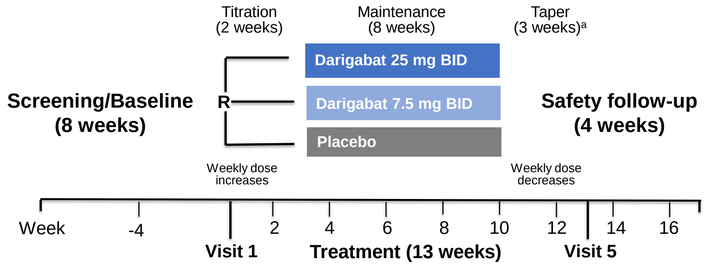
INTRODUCTION

- The COVID-19 pandemic introduced unprecedented complexities in conducting clinical trial assessments at required time points via traditional participant visits to clinical sites
  - It was necessary to implement novel approaches to maintain continuity of care for trial participants and satisfy the objectives of the protocol
- Darigabat (formerly known as CVL-865), an investigational α-2,3,5–selective, γ-aminobutyric acid (GABA) type A receptor positive allosteric modulator, has shown utility across several preclinical models of epilepsy, and has demonstrated efficacy in a phase 2 clinical trial in participants with photosensitive epilepsy
- In an ongoing, global, phase 2 trial of darigabat in participants with focal epilepsy (ClinicalTrials.gov identifier, NCT04244175), mitigations allowing for remote data collection were implemented due to restrictions related to COVID-19
- Here, we describe measures that ensure participant safety and continuity of quality data collection by implementing novel data capture procedures while conducting a clinical trial during the COVID-19 pandemic

METHODS

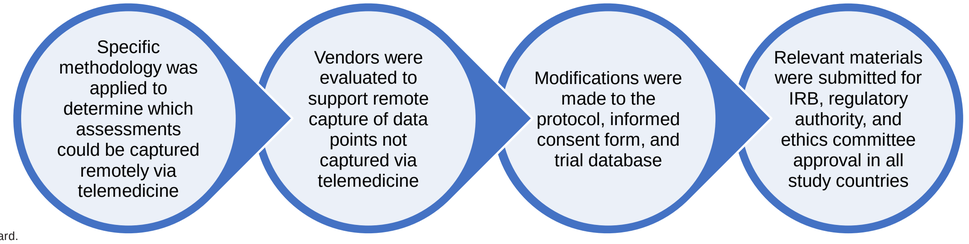
- The REALIZE trial is an ongoing, global, randomized, double-blind, placebo-controlled, phase 2 trial of the efficacy, safety, and tolerability of darigabat as an adjunctive treatment in focal epilepsy (**Figure 1**)
  - Estimated enrollment is 150 participants
  - This proof-of-concept trial will assess the efficacy of darigabat compared with placebo, as measured by a decrease in seizure frequency in participants with drug-resistant focal epilepsy
- Based on trial objectives and key data collection time points, a protocol assessment determined which visits could be performed remotely (**Figure 2**)

Figure 1. Study design.



BID, twice daily; R, randomized. At week 10, eligible participants may enroll in an open-label extension. [a]The three-week taper period only applies to participants not continuing treatment in the open-label extension trial.

Figure 2. Process for protocol assessment and modification of the REALIZE trial.



IRB, institutional review board.

RESULTS

- Modifications to allow for remote clinical trial data collection are summarized in **Figure 3**

Figure 3. Approaches implemented in the REALIZE trial during the COVID-19 pandemic to ensure participant safety and validity of data capture.

ECG, electrocardiogram.

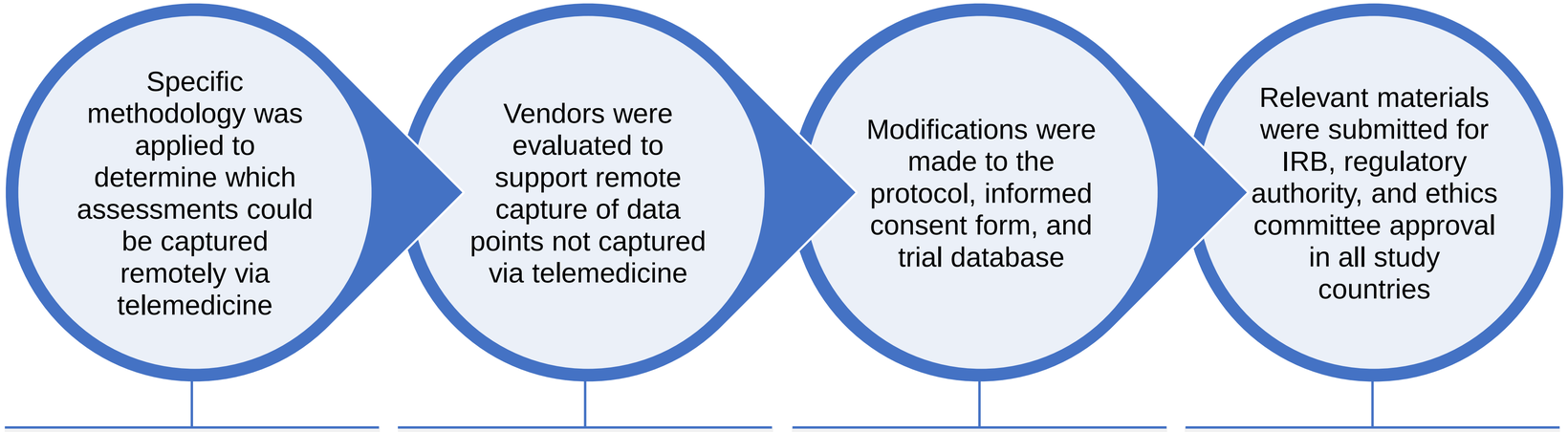
Modifications to the data collection process were made to ensure participant safety and the validity of the trial data, including

- Introduction of home healthcare providers to collect lab draws and vital signs at participants' homes
- Direct shipment of study drug to participants
- Remote ECG collection via the use of a pocket-sized, mobile, single-lead ECG was permitted
- Reporting of scales via telemedicine

Participants consented to the modified data collection procedures at their screening visit

Mitigations were successfully implemented across trial sites

Figure 2. Process for protocol assessment and modification of the REALIZE trial.



- Methodology included
  - Thorough review of protocol assessments
  - Cross-functional alignment regarding which visits/assessments could be performed off-site (ie, remotely or by a third party)
  - Evaluation of whether telemedicine could be used for remote visits/assessments

- Assessments that could be performed remotely but not via telemedicine were evaluated to determine whether a third-party vendor could perform the activity
  - If use of a third-party vendor was determined to be suitable, vendors were formally evaluated for capabilities

- After assessment methods were determined (on-site, remotely via telemedicine, or remotely via third-party vendor), the protocol and informed consent forms were modified to describe these methods
- The trial database was updated to include methods for data collection, which will be reflected in the final data analysis and the clinical study report

- Updated patient-facing study documents and new vendor documents were submitted for institutional review board, regulatory authority, and ethics committee approval
- Approaches were tailored to country-specific allowances regarding remote data capture

IRB, institutional review board.