

INTEREST AREA/TRACK

Clinical Development and Operations

KEYWORDS

Decentralized Clinical Trials, DCT, Mobile Nurses, Adherence, Pediatric Study, Patient Experience

OBJECTIVE

To illustrate the **positive impact on enrollment, retention, and patient burden** of deploying a decentralized clinical trial (DCT) and a well-trained team of mobile nurses to a phase 2 exploratory study of hydroxychloroquine dosing and adherence among children with lupus.

METHOD

The fully-DCT study was done in the U.S, Sept. 2020 to June 2021. Participants, aged 5 to 17.5, were identified via a lupus registry. **Each was given a Fitbit, an iPhone, and a Pillsy** electronic bottle cap alert, so all data would be collected remotely. Home nurses would make 4 visits per patient.



RESULTS

- The **initial target of enrolling 20 participants** was achieved just 10 days after activation, so the study was increased to accommodate 26 participants in total.
- Note, the study **targeted only patients already taking hydroxychloroquine** under the guidance of their physician as the standard of care, so no medications were prescribed or altered as part of the research.
- **Remote data were collected in a number of ways**, including in-home visits, telemedicine exams, blood and urine sample collection, surveys, and connected devices of the electronic pill bottle cap with reminders and FitBits. A total of 96 mobile nurse visits were administered throughout the study.
- The electronic pill bottle cap and its accompanying software application **reminded participants to take a scheduled dosage of medication** via electronic pill bottle cap alerts and smartphone push notifications, text messages, and/or automated phone calls. The app recorded the dosing dispense date and time.
- A **unified, end-to-end DCT technology platform** orchestrated the study workflow between patients, nurses, investigators, coordinators, and connected devices which harmonized all of this data.
- The **primary outcome of medication adherence** was evaluated using electronic medication event-monitoring, plasma drug levels, patient questionnaires, and pill counts.
- At the close of the study, **just two of the 26 participants had dropped out** prematurely.

CONCLUSION

- While a DCT approach may not always be appropriate for every clinical trial, this exploratory lupus study demonstrates the **vast potential of DCT to remove geographical barriers and make clinical research accessible to all** patients (and providers). Traditional studies generally pose a greater burden on participants, who must visit brick-and-mortar sites, and the inconvenience is amplified in pediatric studies, because the logistical burden affects the whole family, not just the participant. Yet, by taking the trial directly to the families, this study was able to achieve the enrollment target in just 10 days, recruiting participants in all parts of the U.S., from the Pacific Northwest to Southeast of Florida.
- **Technology was the enabler** of this study, both in terms of the devices used to collect data remotely (iPhone, Fitbit, and Pillsy) and the unified, end-to-end DCT technology platform that orchestrated the study workflow and harmonized all of this data.
- **The training and mobilization of the home nurses were also critical** to the success of this study, which relied wholly on remote data collection. The majority of nurses participating in this study had more than 10 years of experience, including hospital, home health, and clinical trials. Providing a fast, accurate nurse experience is important to building trust with participants, reducing their burden, and therefore ensuring high retention rates — and with just two dropouts, this study was a testament to that.