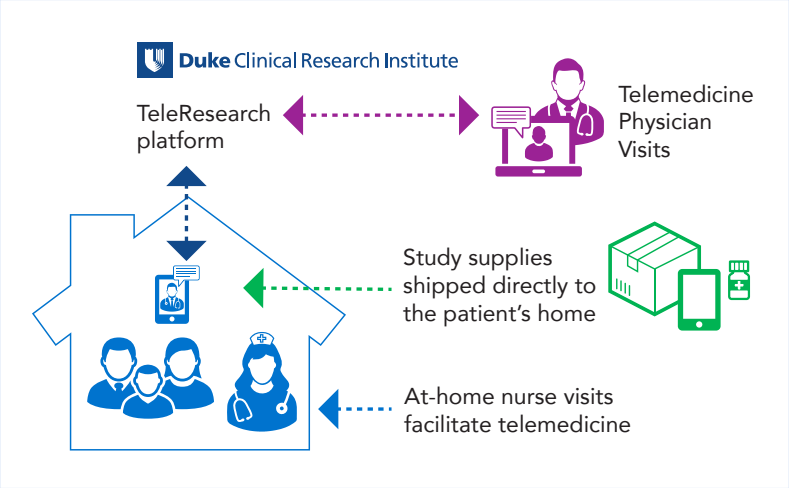
Direct-to-Family Pediatric Lupus Trial

iPERSONAL
Individual Patient Exposure and Response in Pediatric Lupus

WHY IS THIS STUDY NEEDED?

Bringing clinical trials directly to participants in their homes can remove significant barriers, increase diversity, and reduce costs. For children and teens, this approach can make it easier for them to participate in trials without significant disruptions to their daily lives. Despite these advantages, there is not much information on how to design or lead direct-to-family clinical trials for children and teens with chronic diseases like lupus. One major goal of the iPERSONAL Trial is to learn what works well, and what doesn't work well, in direct-to-family clinical trials for pediatric lupus.



In addition, for children and teens managing lupus, consistent treatment with hydroxychloroquine (Plaquenil®) reduces symptoms and improves health. However, many patients struggle with their treatment schedules. The iPERSONAL Trial is testing whether an electronic pill bottle with automated reminders can help children and teens with lupus remember to take their medicine. The study will also collect data to find the best dose of hydroxychloroquine for children and teens with lupus.

WHAT KIND OF STUDY IS THIS?

The iPERSONAL Trial is a direct-to-family trial, a type of study also called a "Virtual" or "Fully Decentralized" clinical trial. In this approach, the trial's home-based design combines on-site nursing visits and mobile technology, including the electronic pill bottle, to make participating in research easier and more convenient.

The study enrolled 26 children and teens ranging from 10-17 years old with lupus who were also part of the Childhood Arthritis and Rheumatology Research Alliance (CARRA).

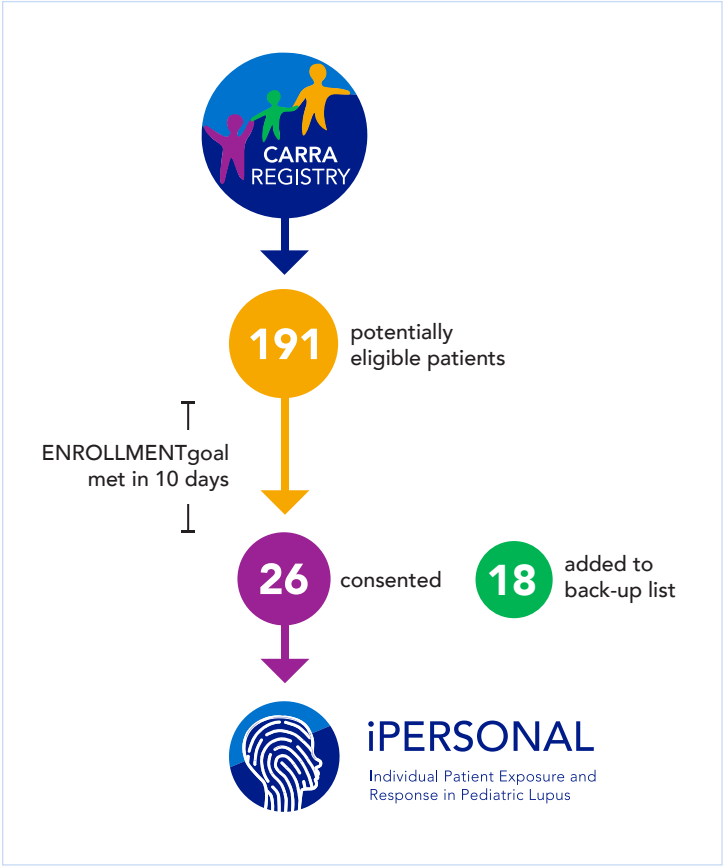
CARRA REGISTRY

WHAT ARE LESSONS LEARNED FROM STUDY PLANNING & START-UP?

We learned that involving patients and families during the early stages of the iPERSONAL trial design resulted in several important changes. We created an advisory group made up of lupus patients, families, and advocacy group leaders, who helped name the study, put together branding and recruitment materials, review the ethics of the study, and make important changes to the design, such as involving the participant's pediatric rheumatologist to receive laboratory results and manage safety issues.

We learned that recruiting participants from a registry sped up the recruitment process. In fact, we met our initial enrollment goal in just ten days! Participants expressed interest in joining the study for access to new technology tools, like the electronic pill bottle, to help them better manage their treatment for lupus.

We also learned that integrating multiple technologies with trial data was highly complicated. We required several different suppliers and a dedicated data integration team to collect all of the information needed for this study.



Additional lessons learned are described in the scientific paper, "Delivering clinical trials at home: protocol, design and implementation of a direct-to-family paediatric lupus trial" in Lupus Science & Medicine at https://lupus.bmj.com/content/lupusscimed/8/1/e000494.full.pdf.

WHAT HAPPENS NEXT?

Already, this study has revealed the importance of directly engaging patients and their family members in the research process. Additional results from this trial will help determine if an electronic pill bottle can help with treatment adherence. Our results will also be used to make dosing recommendations for hydroxychloroquine in children and teens with lupus. We hope our findings will improve care for adolescents with lupus and provide important information for researchers planning direct-to-family clinical trials for many other diseases. Participants can expect to see final study results by Winter 2021.

QUESTIONS?

Visit our website at https://sci37.in/LupusTeen, or reach out to the study investigator:

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