

ARCADE Study

**for Children with
CDKL5 Deficiency Disorder
or Duplication 15q Syndrome**

WHAT IS THE ARCADE STUDY?

ARCADE is a Phase 2 open-label pilot study that will evaluate how the investigational medicine OV935 affects the frequency of seizures in participants with **CDKL5 deficiency disorder (CDD)** or **duplication 15q syndrome (Dup15q)**. The study will also examine the safety and tolerability of OV935 and how it works within the body.

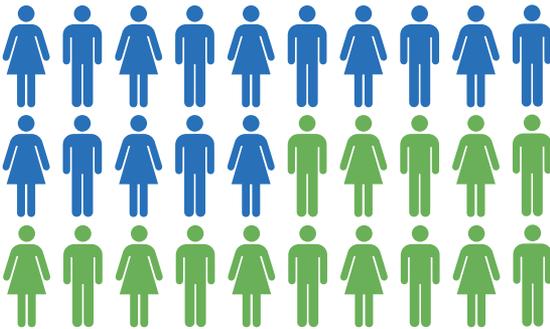
The ARCADE study will enroll approximately **30 participants** between the **ages of 2 and 17**, including **15 children with CDD** and **15 children with Dup15q**. A parent or primary caregiver for the child will need to provide consent and assent, attend scheduled visits and participate in study assessments.

Participation in the ARCADE study will last approximately 22 weeks and include eight visits to the study medical center. During these visits, you and your child will meet with the study team, which will include a doctor, nurse and other healthcare professionals. Your team will explain the study, answer all your questions and closely monitor your child's health. At the end of ARCADE, you and your child may choose to **enroll in a two-year extension** of this study.

30

PARTICIPANTS

2 ← AGE → 17



CDD

Dup15q



22
WEEKS
8 VISITS



DOES MY CHILD QUALIFY FOR THE ARCADE STUDY?

Your child may qualify to participate in the ARCADE study if he or she meets the following criteria:

- ☑ Has a documented diagnosis of CDD or Dup15q
- ☑ Has a parent or caregiver who can provide consent and assent, attend scheduled visits and participate in study assessments
- ☑ Is between the ages of 2 and 17
- ☑ Has an average of at least three motor seizures a month

ARCADE also has other requirements that help ensure the safety of all participants. If your child qualifies to participate in the study, these additional conditions will be reviewed with you by the team at your study medical center.

If you are interested in learning more about the ARCADE study for your child with CDD or Dup15q, please visit www.arcadestudy.com or talk with your doctor.

HOW TO DECIDE TO PARTICIPATE IN A CLINICAL STUDY?

A clinical research study is a scientific test that helps determine if and how a potential medicine or treatment may work. Clinical research studies, like the ARCADE study, are conducted in four different phases that involve increasing numbers of study doctors and participants and longer periods of time. The U.S. Food and Drug Administration monitors clinical research studies, and independent ethics committees review research studies to safeguard the rights and welfare of research participants.

Participating in a study is voluntary, and people agree to participate in studies for many reasons. These can include the chance to help others who may be or become affected by certain conditions, to give back to the scientific community, to play an active role in their health, and to gain access to new potential medicines.

Deciding to volunteer in a clinical research study is an important choice. If your child qualifies to participate in ARCADE, your study team will ensure that both of you understand the study and its possible risks and benefits. **You or your child can decide to withdraw from the ARCADE study at any time.**

HELPFUL RESOURCES

The following organizations are dedicated to CDD and Dup15q research and support for patients and families:



Information about clinical research studies and what it means to be a study participant can be found on the following websites:

www.ciscrp.org

Includes important information to consider before joining a clinical trial
Informational videos on how to be a good clinical trial participant

www.clinicaltrials.gov

A comprehensive list of all clinical studies currently underway in the United States

www.nih.gov

Information for parents and children who are interested in joining a clinical trial



**ARCADE
Study**