

Has your child been diagnosed with Dravet syndrome?

Ask about the ENVISION study



We need your help to advance the understanding and treatment of SCN1A-positive (SCN1A+) Dravet syndrome.

While diagnosis and management of Dravet syndrome is improving, there is still a lot to learn about the full range of symptoms, their presentation and progression, and the impact Dravet has on the lives of your child and family.

The ENVISION natural history study is now enrolling. This study will collect information that may help with development of potential disease-modifying treatment options for children living with SCN1A+ Dravet syndrome, such as gene therapy.

Why should my child take part in the ENVISION study?

Current treatment options for Dravet syndrome can partially reduce seizure frequency, but they do not treat the root cause of SCN1A+ Dravet syndrome, meaning that the other devastating symptoms are yet to be addressed. Studies like ENVISION are needed for medical advances, which cannot be achieved without the involvement of people like you and your child. Learnings from the ENVISION study will help doctors to better understand Dravet syndrome and inform the development of potential new treatments, including gene therapies.

What is the purpose of the ENVISION study?

The ENVISION study is a natural history study aimed at understanding as much as we can about how living with SCN1A+ Dravet syndrome can impact children and their families. This study is collecting information about the seizure and non-seizure symptoms of SCN1A+ Dravet syndrome over a period of time to learn how these develop and change over time. Specifically, ENVISION is assessing and collecting information on seizure types and frequency, learning and behavioral difficulties, problems eating, sleeping and walking, and day-to-day challenges faced by children and families living with SCN1A+ Dravet syndrome.

The information collected in the ENVISION study will be used to help inform a future clinical study that will test a potential gene therapy aimed at eliminating or significantly reducing seizure and non-seizure symptoms and enhancing the quality of life of children and families living with SCN1A+ Dravet syndrome.

Who can participate in the ENVISION study?

To be eligible to participate in this study, a child must:

- Be 6 months to 5 years of age at time of enrollment
- Have a clinical diagnosis of Dravet Syndrome and a confirmed mutation in the SCN1A gene

This is not a complete list of the study eligibility requirements. The study doctor will review the full list of requirements with you.



What can I expect if my child participates in the ENVISION study?

Over the course of 2 years and 3 months, you and your child will be expected to:

- Attend the 5 scheduled in-person study visits, which may be combined or at the same time as the regular care appointments
- Complete an electronic seizure diary before each visit, as well questionnaires at home
- Provide complete information regarding your child's medical and medication history
- Inform your study doctor or staff if your child experiences any new signs or symptoms or starts taking any new medications

During the scheduled in-person visits, laboratory tests, physical exams, additional assessments, and questionnaires may be conducted. The study doctor will review all assessments with you in detail and answer any questions you may have. Participation in the ENVISION study is voluntary and you have the right to withdraw from the study at any time for any reason.

Where is the ENVISION study being conducted?

The ENVISION study will take place at approximately 15 locations across the United States, Australia, and the United Kingdom.

What are the costs of participating in the ENVISION study?

For the duration of the ENVISION study, you will not be charged for tests and procedures that are outside the scope of the anticipated treatment for your child. Travel and transportation costs may be covered for you and your child to go to and from scheduled study visits, depending on your location.

Natural history studies: The details What is a natural history study and why are they important?

A natural history study, also known as an observational study, collects medical information on a group of people with a given disease or condition to better understand its progression over time. By this information, the ENVISION natural history study will allow doctors to uncover hallmarks of Dravet syndrome, learn when symptoms start and how they progress, identify potential environmental factors that can impact the disorder's progression and outcomes, and characterize the true unmet needs of Dravet syndrome. Natural history studies also help families better understand their child's own unique disease characteristics by collecting information that may not be part of their normal care.

Information obtained from natural history studies play a very important role in drug development, from informing the design of clinical studies to potential use as a control dataset for clinical studies of potential new treatments. Although participating in ENVISION does not guarantee inclusion in a future gene therapy clinical trial, some participants in the natural history study may cross over to interventional trials. In such a case, the natural history information previously collected may be used to understand the effect of a potential gene therapy in specific individuals.

How are natural history studies different from clinical trials?

In a natural history study, medical information is collected from individuals over a period of time without any attempt to change the treatment or course of their disease beyond the routine care that they normally receive from their doctor. A clinical trial is designed to test how safe and effective potential new treatments are in people with a specific disease.

In the ENVISION natural history study, the participating child will not receive treatments beyond what their doctor prescribes as part of their normal care. However, he or she may be asked to attend study visits that are in addition to their normal care appointments.

For more information on ENVISION, please speak with your child's doctor and visit <https://clinicaltrials.gov/ct2/show/NCT04537832>

If you would like to learn more about Encoded or clinical trials, please email patientadvocacy@encoded.com

Encoded 
THERAPEUTICS



**Thank you for your interest in the ENVISION
natural history study for children 6 months to 5 years of age
living with SCN1A+ Dravet syndrome.**