

Pediatric Type 2 Diabetes

STUDY SPOTLIGHT

PEDIATRIC TYPE 2 DIABETES STUDY

Information for Parents and Guardians of Children with Type 2 Diabetes

What is Involved in this Study?

Parents/guardians and children who are interested in being in the study will first visit the study clinic for a screening visit. During this visit, evaluations such as blood tests and vital signs will be done to see if your child is a good fit for the study.

Those who qualify will be placed by chance like the flip of a coin into one of two groups. One group will take the study medication every day and the other group will take a placebo every day. The placebo looks just like the study medication but contains no active ingredient. You, your child, the study doctor, and the study staff will not know which group your child has been placed into.

If your child has been placed into the study medication group and certain requirements are met, he or she may receive a higher dose of the study medication.

Your child will continue his/her current diabetes treatment regimen while participating in the study. Your child will also receive counseling about diet and exercise.

During the visits, medical assessments such as physical exams, blood tests, and urine tests will be performed. You and your child will also be contacted by telephone by the study doctor or a member of the study staff at least four times throughout the duration of your participation in the study.

About Clinical Research Studies

A clinical trial is a research study that tries to answer questions about how medicines work in the body, what is safe, how best to use them, and how well they are working. These studies usually have a specific objective. These studies may help doctors find new ways to help prevent, detect or treat, such as diabetes. Some studies are to see if a new medicine that has already been approved or a new grade to see if it is more effective than a different drug group.

What is the Study Drug?

The study medication and the matching placebo look like the study medication but contain no active ingredient. It is taken every morning, with or without food. The study medication or any help control blood sugar in children with type 2 diabetes, but this is not for certain.

What is Informed Consent?

Informed consent is the process of learning the key facts about a clinical research study. Before you let your child take part in the study, you should know all the risks and benefits of the study. At the study doctor's office, you will sign an informed consent form. You will also receive a copy of the study information sheet.

APPOINTMENT REMINDER

Your next appointment is scheduled for:

MON TUE WED THU FRI SAT SUN

at _____ at _____

Please make every effort to keep this appointment. If you must reschedule, please call: _____ at _____ as soon as possible.

See reminders on back

PEDIATRIC TYPE 2 DIABETES STUDY

DOES YOUR CHILD HAVE TYPE 2 DIABETES? Learn about a clinical research study.

The pediatric type 2 diabetes clinical research study is testing the safety and effectiveness of a study medication in children who have type 2 diabetes.

The study medication is approved for use in adults with type 2 diabetes, but it has not been tested or approved for use in children.

Your child may qualify to take part in the pediatric type 2 diabetes study if he or she:

- Is diagnosed with type 2 diabetes.
- Is taking insulin to treat type 2 diabetes.
- Has a parent, guardian, or other adult who will be closely involved in his/her daily activities and assist with study requirements.

Additional requirements apply. Participants in the study will continue to take their current diabetes medication(s). The study medication and all study-related evaluations and tests will be provided at no cost.

For more information, including possible risks and benefits of participation, please contact:

Creative Process

Imperial created printed materials and digital tools for a pediatric type 2 diabetes study for participants 10-17 years old. Pediatric studies require special attention to ensure appeal to youngsters as well as parents and guardians.

Imperial team members met with the sponsor’s study team to get their unique perspective on the study, including the indication, study details, and any expected patient recruitment challenges. Working with that information plus, studying the protocol and ICFs, and conducting in-depth research of the indication and the patient population and demographics, we wrote protocol-compliant text for the patient and professional materials.

Study branding was developed to create the look and feel that would carry across all the materials. Drawings were used to appeal to the patient 10-17-year-old age group, parents and caregivers. The colors and graphic elements selected were all strategic decisions to complement the study, stand out, and capture the attention of the patients, their parents/guardians, and referring physicians.

This design concept was then applied through the development of print and digital tools to promote the study, garner referrals, enhance engagement, and support research sites with their recruitment and retention efforts.



Patient-Facing Materials

Participant Video

The study video is an engaging educational recruitment tool for potential participants and their parents/guardians. The video presents a general overview of clinical studies, specific details about the type 2 diabetes study, and what the participants and parents/guardians can expect. Imperial provided all facets of scripting, design, and production.

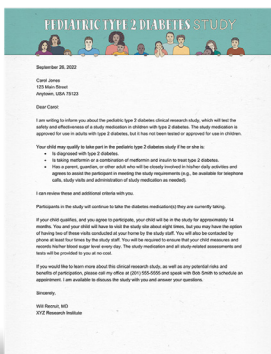


Appointment Reminder Card, Poster, Brochure, Visit Procedure Guide

These pieces bring the study to the attention of potential participants and their parents/guardians.

The poster is designed to alert parents/guardians about the study. It is placed in health care environments such as hospitals and physician offices.

The brochure is also a take-home tool that contains additional information, including types of medical tests, number of visits, the study drug, and the informed consent process.



Web Assets

Banner and social media ads allow sites and advocacy groups to use the power of their websites and social media sites to create study awareness across the patient population.

Patient Letter

This letter contains study information and an invitation for the parent/guardian to discuss the study directly with the study physician. It is formatted to be customized with the physician and parent mailing information.

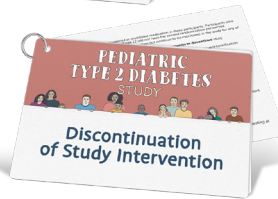
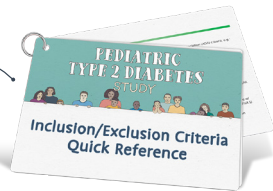
Study Site Materials

Physician Referral Letter

Physician Referral PowerPoint Presentation

This customizable letter allows the investigator to request referrals from physicians treating participants that might qualify for the study.

This PowerPoint presentation is an effective communication tool for sites and study physicians to inform potential referring physicians about the study. This presentation features high-level study information, including key inclusion and exclusion criteria. This tool can be used for in-person or virtual meetings.

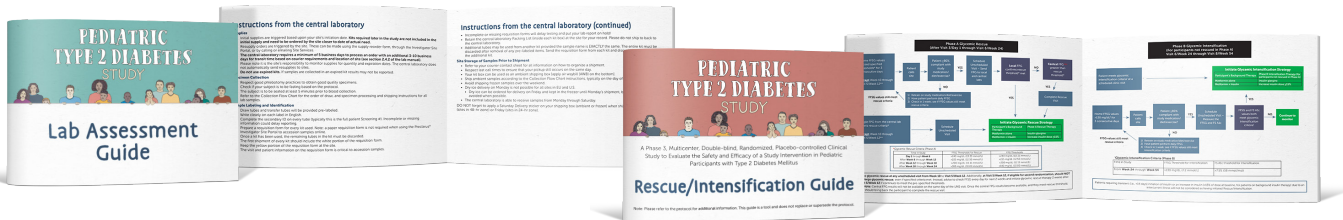


Inclusion-Exclusion Cards

Full inclusion and exclusion criteria are featured in a convenient card-size format to simplify the patient screening process.

Discontinuation Cards

These convenient-size cards provide site staff with the criteria and procedures required for discontinuing the study medication due to adverse events.



Lab Assessment Guide, Rescue/Intensification Guide

This guide contains visit-by-visit lab sampling instructions, including protocol-driven requirements for sample collection, labeling, identification, storage, and shipping.

The criteria and strategies for participants requiring glycemic rescue therapy or intensification at different study visits are presented in a convenient format.

Let's discuss strategies to connect your study with patients, physicians, and sites.

Imperial has the expertise and tools to make your study a success.

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