A doctor has given you this brochure because you (or someone you care for) may qualify to join a clinical trial that's now enrolling. This brochure will help answer some of the questions you may have about the study and about clinical research, in general. Please talk to your/their doctor to learn more.

What is a clinical trial?

A clinical trial, also called a **clinical research study**, is conducted to learn whether an investigational medication is safe and effective for use in people with the medical condition being studied.

Clinical trials/studies are required to follow strict scientific standards to help ensure the safety of the participants while researchers learn more about the investigational medication.

What about the study participant's private health information?

The study doctor and staff will handle all personal health information in a confidential manner. Personal health information includes both a participant's study data and original medical records. To protect privacy, participant and/or caregiver name and other personal information will not be identified unless necessary for study purposes. Instead, the participant and/or caregiver will be identified only by a code.

The TEMPO study is **enrolling now.**

Santa Monica Clinical Trials
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TEMPO

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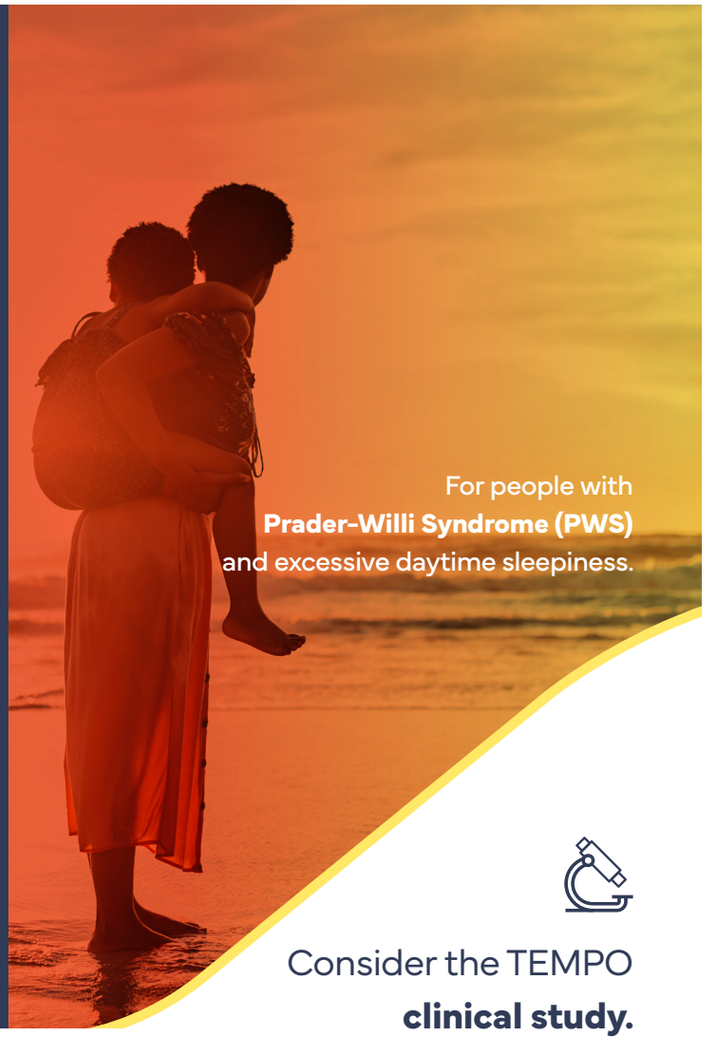

For people with
Prader-Willi Syndrome (PWS)
and excessive daytime sleepiness.

Consider the TEMPO **clinical study.**

The TEMPO clinical study is assessing an investigational medication for **excessive daytime sleepiness (EDS)** in people 6 years of age or older with PWS and is seeking volunteers.

TEMPO

A little about Prader-Willi syndrome

As you likely already know, Prader-Willi syndrome (PWS) is a rare genetic disorder, meaning that people are born with it. So even though there is no "cure," there are some common symptoms – like excessive daytime sleepiness (feeling very sleepy during the day) – that may be able to be managed or even treated. Research studies like this one are key to developing medicines that may help.

Per the National Organization of Rare Disorders, PWS affects males and females in equal numbers and occurs in all ethnic groups and geographic regions around the world.

For this reason, it is important to study the investigational medication in a wide range of people with PWS. We need ALL types of people with PWS to enroll – including children, teens and adults who are of any race, ethnic origin, or gender.

What is this study about?

This study will assess whether an investigational medication is safe and effective compared to placebo (a tablet/pill with no medicine in it). Researchers want to assess its impact on the severity of excessive daytime sleepiness in people 6 years of age or older who have PWS. They also want to assess its impact on the severity of irritable and disruptive behaviors and on hyperphagia (excessive eating).

National Organization for Rare Disorders, last updated 7/12/2023, https://rarediseasesorg/rare-diseases/prader-willi-syndrome/#affected.

The plan is to enroll 134 people in this study, which will consist of:

- A Screening/Baseline Period of up to about 45 days (to make sure volunteers qualify to enroll).
- An 11-week Treatment Period (during which time study participants will take their assigned study drug [i.e., placebo OR the investigational medication, pitolisant]).
- An Open-Label Extension Period during which eligible participants will have the option to continue in the study and all will receive the investigational medication, pitolisant, as their study drug.
- A Follow-Up Period consisting of 2 telehealth video visits within a month after the last study drug dose to see how participants are doing.

Study participation will last up to about 22 weeks (6 months), during which time there will be 5 visits and up to 3 telehealth video visits.

For those who continue on to the Open-Label Extension Period, total participation will last closer to 74 weeks (or about a year and a half).

Who qualifies to join the study?

A person may qualify to participate in the TEMPO study if they:

- Are 6 years of age or older.
- Have a diagnosis of Prader-Willi syndrome.
- Have excessive daytime sleepiness.

Why consider this study?

More medicines are needed to help treat the symptoms of PWS, but they must first be evaluated in clinical studies. This study depends on volunteers to participate to help researchers learn more about the use of this investigational medication in people with PWS to see if it may help their excessive daytime sleepiness.

The study doctor and staff understand that you or the person in your care has special needs and they may be able help with any questions or concerns you have with participating.

The TEMPO study is **enrolling now.**

Talk to your family doctor and/or contact us today to see about enrolling.