The SCOUT-015 Study

FOR CHILDREN, ADOLESCENTS, AND ADULTS WITH PRADER-WILLI SYNDROME

INTRODUCTION

- You/your child are being invited to take part in the SCOUT-015 Study because you/they have Prader-Willi Syndrome (PWS).
- Before deciding whether or not to take part in the SCOUT-015 Study, it is important to understand why the study is being done and what it will involve.
- We are going to review some key points to help you better understand the study.
- It is your choice if you want to be a part of this study, so please ask any questions you may have.

DISCUSSION QUESTION

Before we continue, what questions might you have about PWS or about why you/your child have been invited to take part in the SCOUT-015 Study?

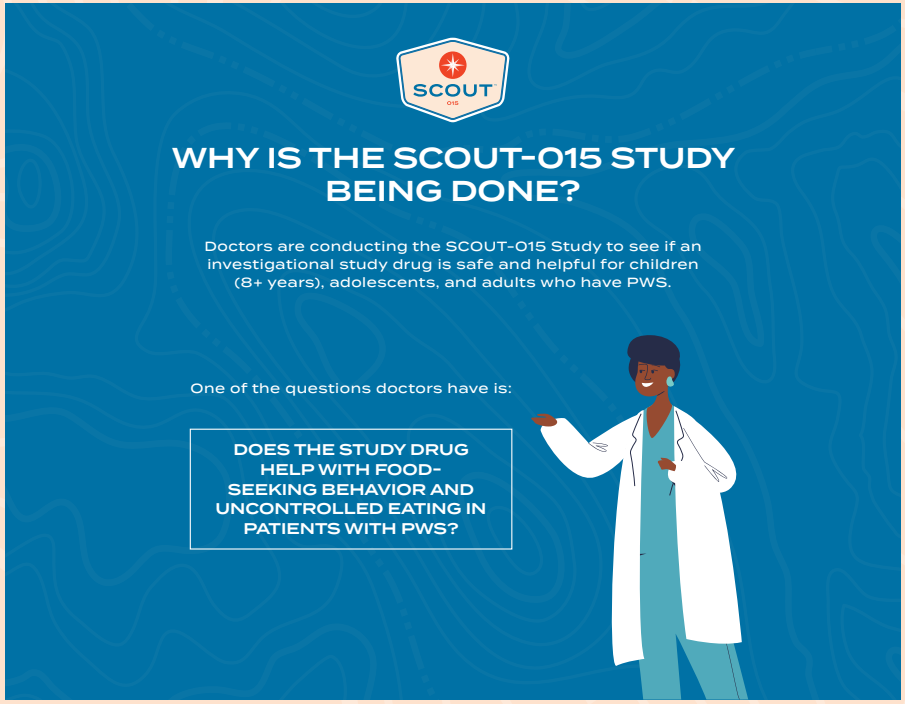
WELCOME TO THE SCOUT-015 STUDY!

The SCOUT-015 Study is a clinical study in children, adolescents, and adults with Prader-Willi Syndrome (PWS).

Before deciding whether or not to take part in the SCOUT-015 Study, it is important to understand:

WHY THE STUDY IS BEING DONE	WHAT IT WILL INVOLVE

STUDY OVERVIEW



- A clinical study is a research study to learn more about what a specific treatment does in people with a specific health condition.
- In this study, doctors want to see if an investigational study drug is safe and helpful for children 8 years and older, adolescents, and adults who have PWS.
- One of the questions doctors have is: *Does the study drug help with food-seeking behavior and uncontrolled eating in patients with PWS?*
- As part of the study, doctors will also assess how safe the study drug is and whether it may help control behavior around food and other behaviors.

WHY IS THE SCOUT-015 STUDY BEING DONE?

Doctors are conducting the SCOUT-015 Study to see if an investigational study drug is safe and helpful for children (8+ years), adolescents, and adults who have PWS.

One of the questions doctors have is:

DOES THE STUDY DRUG HELP WITH FOOD-SEEKING BEHAVIOR AND UNCONTROLLED EATING IN PATIENTS WITH PWS?

STUDY DURATION AND VISITS

- The study lasts about 40 weeks (or about 10 months).
- There will be about 16 visits for the study—10 of them will be at the study clinic and 6 will be remote, by phone or video call.
  - → Visits will be less frequent as the study progresses.
- During screening, there is 1 clinic visit that happens within 3 weeks before starting the study treatment to see if the study is right for you/ your child.
- Then there is a study treatment period that lasts 33 weeks.
- At the end of the study, there is a 4-week period for dose decrease and follow-up. There is one final clinic visit for a checkup, followed by a final phone call.

HOW LONG IS THE STUDY?

About 40 weeks

SCREENING

1 visit

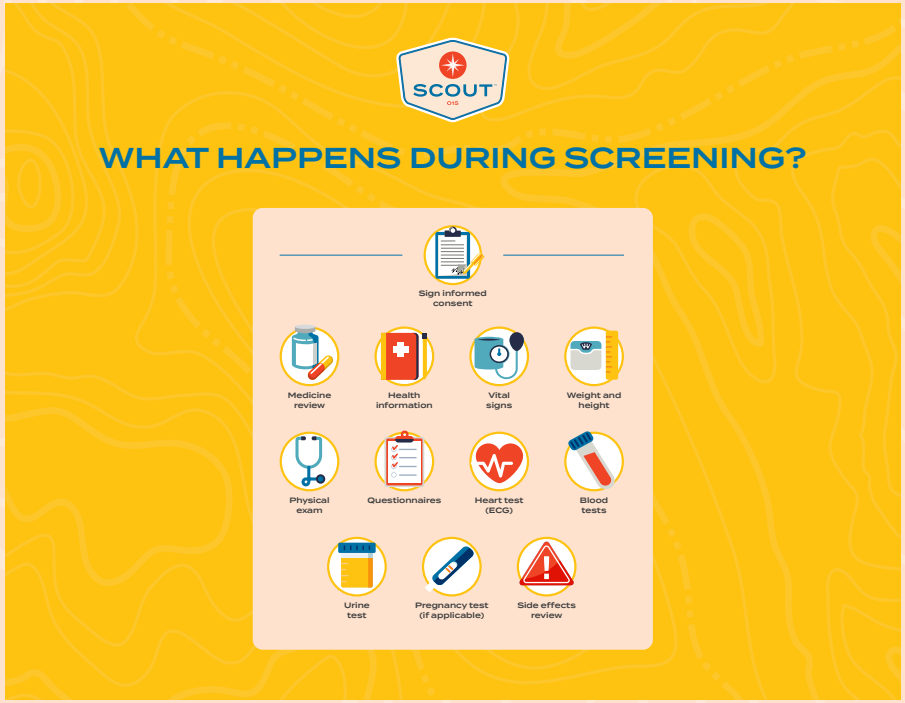
STUDY TREATMENT

33 weeks
13 visits

DOSE DECREASE AND FOLLOW-UP

4 weeks
2 visits

SCREENING



DISCUSSION QUESTION

Some of these tests might not be familiar to you. Which tests would you like to know more about?

- The first part of the study is screening. Screening helps to make sure you/your child meet the requirements needed to continue in the study.
- You will need to review and sign the Informed Consent Form before the screening process can take place. Your child will sign an Informed Assent Form.
- Health checks and tests at screening may include:
  - → Questions about health and medications now and in the past.
  - → A physical exam.
  - → Measuring your height, weight and vital signs such as blood pressure, heart rate, temperature, breathing rate, and blood oxygen levels.
  - → Completing questionnaires about food-seeking behaviors, irritability, other behaviors, daytime sleepiness, skin picking, suicide risk, and seizure history.
    - If a parent or caregiver completes the questionnaires, that same person must complete the questionnaires throughout the study.
  - → Blood and urine tests, which will be done about 6 times during the study.
  - → A heart test called an electrocardiogram, or ECG.
  - → A DEXA scan, which is a painless, open-air, full body scan to check your bone, muscle, and fat.
  - → Note, you/your child may not have all of these tests. The study doctor will also check for side effects from any of the tests and procedures.
- If you/your child are eligible to continue the study, the next part is a 6-week tolerability period to see if you/your child can tolerate the liquid. This time is also for you/your child to get used to the study procedures and taking the study medicine every day.

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WHAT HAPPENS DURING SCREENING?

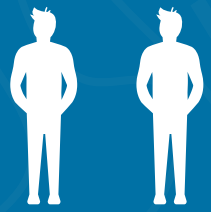
STUDY TREATMENT

- The active study drug is called RAD011, which is a man-made cannabidiol oral solution. It is a liquid that is taken by mouth with food, twice a day about 12 hours apart.
- It is being compared to placebo. Placebo looks and tastes the same as the active study drug but has no active medicine in it. The placebo is important to show what results are due to the active study treatment and not happening by chance.
- You/your child will be randomly assigned by chance to receive active study drug or placebo.
- There is a 2 to 1 chance of being placed into the active study drug group compared to the placebo group. Neither you nor the study doctor will know which study treatment group you/your child are in.

WHAT IS THE STUDY TREATMENT?

A liquid that is taken by mouth with food, twice a day about 12 hours apart.

ACTIVE STUDY DRUG



PLACEBO

STUDY TREATMENT VISITS

- During study treatment, you/your child will have 8 study clinic visits for health checks and tests.
- There will also be 5 remote visits by phone or video call to review your/your child's health and medicines.

Food diary

- There will be 4 times when you/your child will need to complete a food diary before you arrive for the next clinic visit. If a parent or caregiver completes the food diary, that same person must complete the food diaries throughout the study.

DISCUSSION QUESTION

Can you explain why it would be important for you to come in for clinic visits and tests and complete the food diary?

WHAT HAPPENS AT STUDY TREATMENT VISITS?


Medicine review


Health information


Vital signs


Weight and height


Physical exam


Questionnaires


Heart test (ECG)


Blood tests


Urine test


Pregnancy test (if applicable)


DEXA scan (if available at your study clinic)


Side effects review

Food diary
The same person will need to complete the food diaries throughout the study.

FOLLOW-UP

- Before completing the study, you may be asked if you want to continue to the long-term open-label extension study, SCOUT-016.
- If you/your child do not want to continue, the study treatment dose will be gradually decreased and you/your child will stop taking the study drug.
- There will be 2 final visits to check you/your child's health. One will be at the study clinic and one will be remote by phone or video call.

WHAT HAPPENS AT THE END OF THE STUDY?

CONTINUE TO SCOUT-016 STUDY

OR

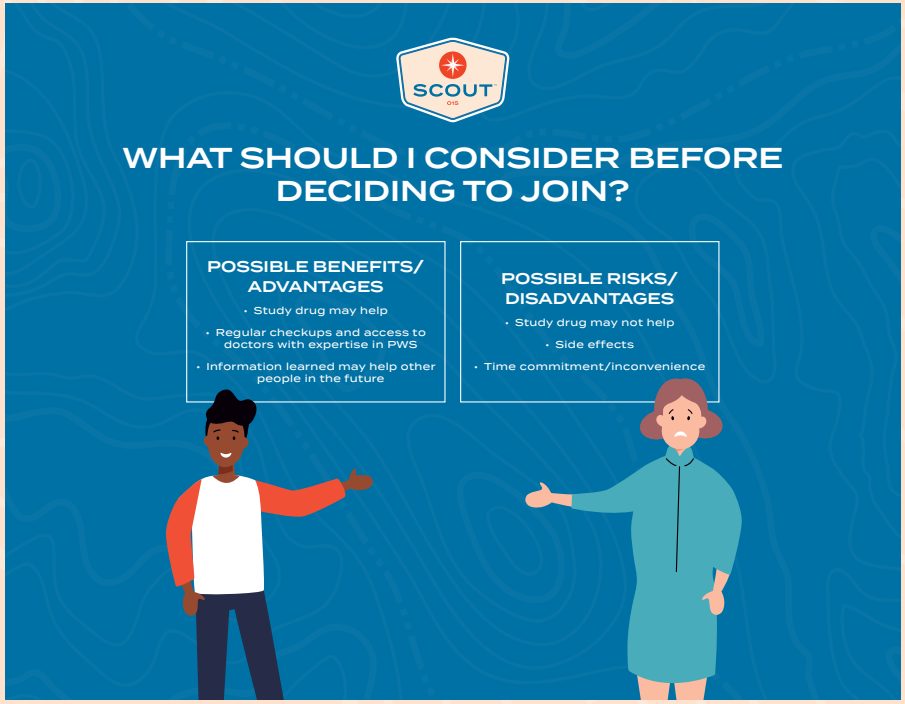
END YOUR PARTICIPATION, DECREASE YOUR DOSE, AND STOP TAKING THE STUDY DRUG

Medicine review

Health information

Physical exam *(only at study clinic)*

Side effects review



DISCUSSION QUESTION

Can you tell me what you understand about possible risks and benefits to taking part in the study?

There are risks and benefits to any research study.

Possible Benefits/Advantages

- The study drug may help with PWS-related food-seeking behavior and other behaviors.
- You'll have regular checkups and access to doctors with expertise in PWS.
- Information learned from the study may help other people in the future.

Possible Risks/Disadvantages

- The study drug may not help.
- There may be side effects from the study drug or study tests. Read the informed Consent Form for the list of possible side effects.
- There is also the time commitment and potential inconvenience of taking part in the study.

Remember:

- Participation in the study is voluntary and you/your child can decide to leave the study at any time.
- We may ask you/your child to come for one final follow-up visit if you do decide to leave early.

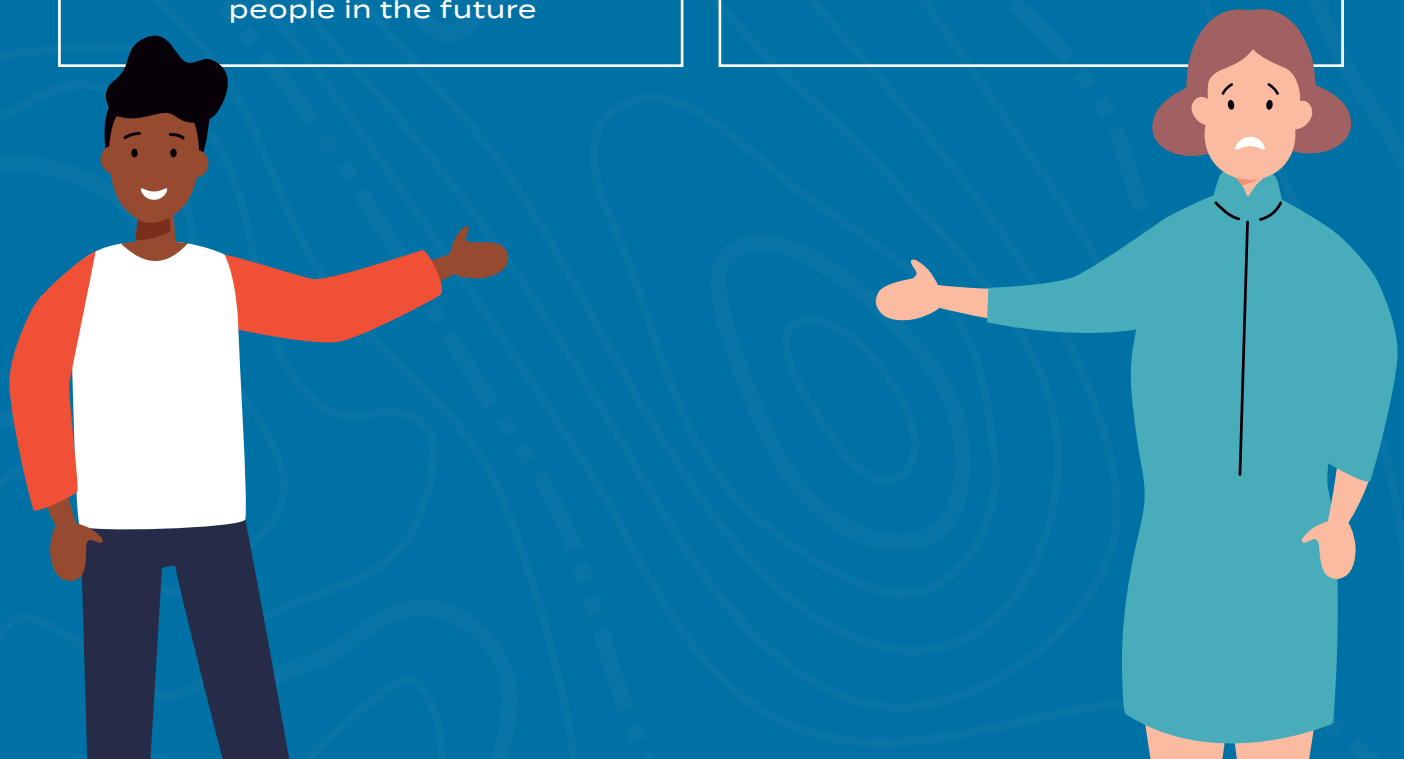
WHAT SHOULD I CONSIDER BEFORE DECIDING TO JOIN?

POSSIBLE BENEFITS/ ADVANTAGES

- Study drug may help
- Regular checkups and access to doctors with expertise in PWS
- Information learned may help other people in the future

POSSIBLE RISKS/ DISADVANTAGES

- Study drug may not help
- Side effects
- Time commitment/inconvenience



EXPECTATIONS

- Come to the study visits and do your best to follow directions.
- Take the study medicine as instructed.
- Complete all questionnaires and food diaries to the best of your ability.
  - → If a parent/caregiver completes the questionnaires and food diaries, that same person must complete the questionnaires throughout the study.
- Be open and honest with the study team.

What Happens Next?

- Please carefully read and review the Informed Consent Form.
- Take time to decide if you would like to take part in the SCOUT-015 Study.
- Talk it over with your family and friends.
- Ask the study doctor any questions you may have.
- If you decide to join, you will give your permission by signing the Informed Consent Form.

WHAT IS EXPECTED DURING THE STUDY?

- Come to all study visits
- Follow instructions
- Take the study medicine as instructed
- Complete the questionnaires and food diaries as instructed
- Be open and honest with the study team

WHAT HAPPENS NEXT?

1	2
Please carefully read and review the Informed Consent Form.	Take time to decide if you would like to participate in the SCOUT-015 Study.

The SCOUT-015 Study