

## WHO CAN BE IN THE STUDY?

You may be able to join this study if you:

**Are age 8 to 65 years and have a documented diagnosis of PWS.**

About 200 participants are being asked to join the study.

If you are interested in the study, you will be given an Informed Consent Form (for adult participants and parents/caregivers) or an Informed Assent Form (for children and adolescent participants) to read.

Ask the study team to explain anything you do not understand. Signing this form means you give your permission for you or your child to be part of the study.



## THANK YOU FOR CONSIDERING THE SCOUT-O15 STUDY

This clinical study is being done to see if a new study drug is safe and helpful for children, adolescents, and adults who have Prader-Willi Syndrome (PWS). One of the questions doctors have is, *does the study drug help with food-seeking behavior in patients with PWS?*

This brochure will help you understand what to expect if you decide to join the study. When we say “you,” we mean the study participant.

There are risks and benefits to any research study. The study drug may or may not help you. You could have side effects from the study drug or study tests. With your participation, other children and adults who have PWS may be helped in the future.

You do not have to be in the study if you do not want to. You can also decide to join the study now and then stop being in it at any time. Your regular doctor will still take care of you. Please ask any questions you may have.

### The SCOUT-O15 Study Team

PrintCode

Radius Pharmaceuticals - The SCOUT-O15 Study - Trifold - 23-Mar-2022 - English (Master) - V1.1



## The SCOUT-O15 Study

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



# WHAT HAPPENS DURING THE STUDY?

You will be in the main study for up to 40 weeks (about 10 months). There will be about 16 study visits—10 visits will be in person at the study clinic and 6 visits will be remote by phone or video call.

## 40 weeks (about 10 months)

### Screening

3 weeks



First, you will have health checks and tests at the study clinic to see if the study is right for you.

### Study Treatment

33 weeks



You will take the study drug every day and have study visits for health checks and tests.

### Dose Decrease and Follow-up

4 weeks



Your dose of study medicine will be decreased over 2 weeks. Then there will be one final study visit for a checkup, followed by a final phone or video call.

SCOUT 015  
SCREENING

SCOUT 015  
TREATMENT

SCOUT 015  
COMPLETE

You may be invited to join the long-term SCOUT-016 study during this study.

# WHAT TESTS WILL I HAVE?



Medicine review



Health information



Vital signs



Weight and height



Questionnaires



Physical exam



Blood tests



Urine test



Heart test



Pregnancy test (if applicable)



DEXA scan (if available at your study clinic)



Side effects review

You will not have every test at every visit. The study team will monitor you for side effects from the study drug or study tests.

At some study visits, you will be given a food diary to bring to your next visit. You will need to write down the times you took the study treatment and what you had to eat the night before and the morning of your next visit.

# WHAT TREATMENT WILL I GET?



The active study drug is called RADO11 (synthetic cannabidiol oral solution). It is a liquid that you take twice a day by mouth with food.

You are twice as likely to be in the active study drug group as to be in the placebo group. Neither you nor the study doctor will know which treatment group you are in.

Active study drug



Placebo



Placebo looks and tastes the same as the study drug but contains no active medicine. The placebo is important to show which results (both safety and efficacy) are a result of the actual treatment and not happening by chance.

The SCOUT-015 Study Team is happy to answer any questions you may have.