Information about clinical trials

It's not positive. It's not negative.

It's cognitive.

TALLY

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What is a

clinical trial?

Clinical trials are research trials that explore whether a potential new or known drug is safe and effective for humans. They are designed to help us find:

- Potential new treatments
- Potential new versions of existing treatments
- Potential new uses for existing treatments

Clinical trials are important because they may help us discover more about diseases, how to potentially treat them and ways to keep people healthy in the future. Without clinical trials, it would be almost impossible to develop any potential new medications.

The TALLY clinical trial aims to understand if an investigational drug could be safe and potentially effective in impacting attention and memory in people with schizophrenia.

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Some terms

you may hear

Trial design

The trial design is simply the schedule of dosing and clinic visits. Careful and thoughtful planning goes into the design of a clinical trial. Everything from the length of the research to how often clinic visits will happen is designed specifically to make sure the questions being asked are relevant to the people living with the disease. This plan is checked by the regulatory authority and ethics boards before patients are ever invited to take part.

Trial groups

In a clinical trial, participants are assigned randomly (by chance) to different groups. Participants in different groups may receive different investigational drugs, different doses or a placebo in order to determine and compare the effects of each. In some clinical trials, neither the participant nor their trial team knows which group they have been assigned. In other clinical trials, the participant does not know which group they have been assigned, but the trial team does.

Placebo

A placebo looks exactly like the investigational drug but does not contain any active ingredients. In some clinical trials a placebo is given to a group of people instead of the active (real) investigational drug. Participants often do not know whether they are taking the investigational drug or the placebo. This helps scientists know if any changes in health are due to the investigational drug and not something else.

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Trial

phases

Clinical trials typically go through three phases before authorities approve the investigational drug as safe and effective.

The TALLY clinical trial is a Phase II trial.

Phase I

In Phase I clinical trials the investigational drug is tested in people and will usually involve a small group of healthy volunteers (around 20–100 people).

Phase II

Phase II tests how safe and potentially effective an investigational drug may be for people with the condition the investigational drug hopes to impact. This phase often compares the investigational drug to a placebo. It usually involves 100–300 participants.

Phase III

Phase III trials test the investigational drug in an even larger number of people to study its effectiveness, side-effects and safety. This phase also often compares the investigational drug to a placebo. These clinical trials usually involve 300–3000 participants.

Phase IV

Phase IV trials study the use of the drug in the "real world," rather than at a study site like Phase I–III clinical trials. Phase IV trials happen after the drug has been approved and made available to the public to research its long-term effects.

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What happens

during a clinical trial?

Informed consent

Before we begin any part of the trial, participants or their guardians must carefully read and sign an informed consent form (ICF). This outlines exactly what will happen during the trial and all known risks and potential benefits.

Screening

After the ICF is signed, we check potential participants' health status and medical history to see if they qualify to participate in the trial.

Dosing period

If participants qualify for the trial and agree to take part, they are randomized to a group and enter the dosing period. At this point, they begin taking either the investigational drug or placebo and complete various assessments and health checks.

End of trial

To make sure participants leave the trial safely, we complete a final clinic visit for a last check of their health.

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What else should I know?

Once they decide to join the trial, can participants change their mind?

Taking part in any clinical trial is completely voluntary. If someone joins the trial but then changes his or her mind, he or she can leave at any time for any reason. This will have no impact on their usual healthcare.

What does taking part mean?

- Participants' health may be monitored more closely at frequent health checks
- Participants may provide information that might help grow our knowledge of the condition we are studying
- There is no guaranteed impact on the participant's disease. Their health may get better, worse or stay the same
- Participants may experience unwanted side effects, which are outlined in the ICF that participants must carefully read and sign before they can take part

Do participants have to pay to take part?

No. All investigational drugs are provided to participants at no cost – health insurance is not required to participate. Certain additional costs (like transportation and parking) may also be covered.

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Questions?

Contact the TALLY clinical trial team.

EDITABLE CONTACT INFO

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