## **Participant Journey**

This tool is to help you understand what to expect during the OTO-313-201 study.

### 1. Review & sign the **Informed Consent Form**

You must sign the Informed Consent Form (ICF) before you receive any study assessments.

2. Confirm study requirements

At the Screening visit, you will receive study assessments and complete questionnaires to confirm you qualify for the study.

#### 4. Be randomly assigned to receive study drug or placebo

You will be assigned to receive the study drug or placebo (no active ingredients).



#### 3. Complete a daily diary

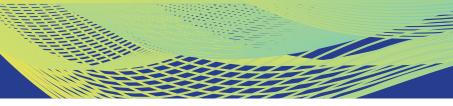
You will complete a daily diary during the study, for a total of 18 weeks.

#### **5.** Receive injection

A member of the study team will inject the study drug or placebo into your ear.

6. Complete Follow-up visits After you receive your injection, you will visit the study clinic monthly (for 4 months) for tests

and assessments.



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# **Participant Journey**



### 1. Review & sign the Informed Consent Form

The Informed Consent Form (ICF) explains the study and what you can expect in more detail. The study team will help review the information in the ICF and answer any questions about the study. You can discuss the information in the ICF with friends and family before you decide to participate. Your decision is your choice, but you must sign the ICF to give your consent before you receive any study assessments.



#### 2. Confirm study requirements

**3. Complete a daily diary** 

your smartphone or tablet.

During Screening, the study team will ask you questions about your tinnitus and perform several tests and assessments, including a physical examination of your ears and a hearing test.

You will rate your tinnitus loudness and annoyance each day in your diary

by ranking it along a scale. You will access this diary using an application on



#### 4. Be randomly assigned to receive study drug or placebo

Once you have met the Screening requirements, you will be randomly assigned (like the flip of a coin) to receive an injection of the study drug or placebo. You have an equal chance of receiving each assignment.

#### **5. Receive injection**

You will be asked to lie down and stay very still. A trained medical professional will numb a part of your ear drum, insert a small needle into your middle ear, and inject the study drug or placebo. Afterward, you will be asked to rest. The procedure will take about 20 minutes to complete.

### 6. Complete Follow-up visits





**Clinical Trial** for Tinnitus

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You will visit the study clinic 4 additional times at monthly intervals so the study team can check your health, ask you questions about your tinnitus symptoms, and perform physical ear examinations and hearing tests.