

Answers to Questions Submitted During the Frequency Therapeutics National HLA Webinars Held on January 20, 2022

Has FX-322 worked for Meniere's Disease patients?

We have not tested to-date whether FX-322 works for Meniere's Disease patients.

My hearing loss fluctuates due to late-stage Meniere's Disease so I wouldn't qualify for this study. Are there other trials you are involved in that will involve Meniere's?

We cannot comment on future trials.

During the speech perception tests, were the candidates able to SEE the words being spoken, or were the words audio only?

No, trial participants cannot see the words.

It doesn't appear that those with hereditary hearing loss is included in the study, correct?

Correct, genetic hearing loss is exclusionary.

Any details/timing on future studies that may capture other groups again (i.e., premature genetic loss, etc.)?

We cannot comment on future trials.

Is an individual aged 86 eligible for the study?

No, unfortunately not. Current age range for the study is 18-65.

Why are you cutting it off at age 65?

Sixty-five is a traditional cut off for non-aged adult studies.

Can individuals based outside the United States participate in this trial?

No, unfortunately not. The current trial is only accepting U.S. based patients.

What medical conditions would prevent someone from participating in the trial?

We are testing adult onset with specific exclusions. The exclusions are listed on clinicaltrials.gov.

Are you taking single-sided deafness?

An individual that has hearing loss in one ear can be a candidate as long as they meet the criteria described on clinicaltrials.gov.

What impact will hearing assist devices used by participants have on the study?

If a participant uses hearing assistive devices but can do the test unaided, they may qualify.

I applied to participate in this most recent trial but was disqualified because of one-week prednisone treatment in November 2021. At that same time a tube was removed that had been inserted to help with pressure. Is there a way to be reconsidered for this clinical trial?

Unfortunately, no. There is no rescreening for the study.

Are you interested in people with severe loss that was sudden?

Yes.

What do you think the pathology of sudden Sensory Neural Hearing Loss is?

It is idiopathic so no one knows what the ideology is.

What are the environment patients are in during the test? Are they in a noisy environment like the everyday world rather than a clinical setting?

For speech perception measures, we test in quiet and noisy environments.

Are subjects HL aided or not?

When we test them, they are not aided; but aided patients can qualify.

If a sensorineural hearing loss individual is gradually losing more hearing, can he/she possibly be a candidate?

You must have consistent test measures during the lead in period.

What percent of the patients did not receive a change and what would you attribute that to?

Across our studies, we have seen 25% respond with improvement in speech perception. We cannot comment on why that is the case.

Are subjects tested in real world settings?

Participants are tested in controlled, clinical conditions.

Is there any chance this could be used for those younger than 18?

Not currently, because we are testing adult-acquired hearing loss. We are interested in testing a younger population at some point.

I have a hearing loss possibly caused by medication - could it be helped with FX-322?

It's possible FX-322 could be a treatment.

Are there plans to test FX-322 in both ears?

We cannot comment on future trials.