

Why are **clinical studies** important?

Clinical research studies are scientific evaluations in people, led by researchers and physicians. They play an important part in efforts to improve healthcare. They can help us to understand a disease better and learn how best to treat it and can lead to new treatments being made available.

Clinical studies are very important for developing new treatments. Indeed, an investigational drug cannot be approved for use until it has been tested in clinical studies to confirm its safety profile, how it acts in the body and how it affects certain medical conditions.

People decide to participate in clinical studies for a variety of reasons. Some wish to contribute to medical research, potentially to help others with the same condition as them. Others may wish to try a new approach to therapy or want to receive a medication that they would otherwise not have access to.

How do I join?

If you are interested in joining the **APN-002 Study**, you must:

- Be between 25 and 65 years old
- Have obstructive sleep apnea

There are other joining criteria and checks to complete before you join the study. These are to determine if you are right for the study, and whether the study is right for you.

If you would like to learn more about the **APN-002 Study**, please contact us as follows:

Contact Name: *Giulia Alexandru*

Contact Number: *847-674-3600*

Contact Site: *Northshore Sleep Medicine*

If you contact us, it does not mean you have to join the study.

Are you interested in a new and different treatment for your **obstructive sleep apnea**?

The **APN-002 Study** – a clinical research study for people with obstructive sleep apnea

Patient Information Brochure



Your diagnosis

Obstructive sleep apnea (OSA) is a condition which causes your breathing to stop and start repeatedly during sleep. While asleep the walls of your throat relax and narrow, briefly blocking your airway and interrupting normal breathing. This means your sleep is regularly interrupted.

OSA can leave you feeling excessively tired during the day, and experience headaches and dry mouth particularly in the mornings. Some of the daily symptoms you experience may include difficulty concentrating, forgetfulness, depression, or irritability. It can lead to poor quality of life for you and those close to you.

Your doctor may already have discussed your diagnosis with you and talked about the treatment options available to you. You may have tried a Continuous Positive Airway Pressure (CPAP) device at night-time to help keep your airway open. Another possible option for you is to join a clinical research study.

Would you consider a clinical research study for the treatment of your obstructive sleep apnea?

Introducing the APN-002 Study

The **APN-002 Study** is a new clinical research study in obstructive sleep apnea and we are looking for people who would like to join.

The purpose of the **APN-002 Study** is to see how well an investigational* drug, called AD036, works as a treatment for people with obstructive sleep apnea, and what is the most effective dose.

*'Investigational' means that the study drug is not yet approved for sale, but it is authorized for use in clinical studies like this one.

What will the study involve?

- The **APN-002 Study** will last for about 8 weeks.
- You will be randomized into 1 of 4 treatment groups – 3 groups will receive different doses of AD036, and 1 group will receive a placebo. A placebo looks exactly like the investigational drug, but it contains no active ingredients.
- Randomization is when something is assigned by chance, like drawing straws, so you will not know which group you are in.

- The study team will also not know which group you are in, but this can be found out if medically necessary.
- During the study you will stay overnight at the study clinic on two occasions. While you are asleep you will have a polysomnography (PSG) test.
- You will attend a number of appointments at the study clinic, where you will be given the study medication (either AD036 or placebo) to take at home.
- The study medication is a capsule. You will swallow 2 capsules with a glass of water about 30 minutes before bedtime.
- You will also have several routine tests during the study. These tests include blood pressure, pulse and temperature measurement, an ECG, and blood and urine samples.
- You will also be asked to read and fill out questionnaires about your OSA symptoms and your quality of life.