

## Participant Brochure

Information about the PASSPORT clinical trial

PASSPORT

# The PASSPORT clinical trial is recruiting study participants with Progressive Supranuclear Palsy (PSP)

PSP affects **5-6** out of every **100,000** people.

Although some medications may help relieve some symptoms associated with PSP, none have been proven to slow or stop the progression of the disease itself. Researchers are working hard to develop new investigational treatments for PSP through clinical research trials.

The goal of the PASSPORT clinical trial is to see if our investigational study drug can help to slow the progression of the disease.

## What is a clinical trial?

A clinical trial is a type of research that tests an investigational study drug to see how well it works and how safe it is to use for different kinds of study participants. An investigational study drug must be tested in clinical trials before it may be approved for use by study participants. Clinical trials play an important role in developing new medications and treatments for people with illnesses.

## How does a clinical trial work?

Clinical trials follow specific research plans called 'protocols'. Research plans are designed to help us better understand diseases and existing and new investigational treatments.

## How are study participants protected?

There are rules and regulations in place to protect clinical trial participants. All clinical trials have their own specific research plan that is required to be strictly followed.

Before a clinical trial begins, the research plan is reviewed for approval by an Ethics Committee (EC) or Institutional Review Board (IRB). An EC or IRB is a group of doctors, researchers, and community members, who are independent from the team running the clinical trial and who have policies in place to protect the rights and welfare of clinical trial participants.

These reviews weigh the risks and benefits of participating, and ensure that study participants' rights and well-being are protected. The clinical trial can only move forward if the research plan is approved.

## Who can participate in the PASSPORT clinical trial?

Anyone interested in joining the PASSPORT clinical trial will be assessed to ensure that all requirements are met and that the clinical trial is right for them. You may be able to participate if you:

- Have PSP
- Are between the ages of 41 and 86
- Are able to walk at least 10 steps either independently or with assistance
- Have someone who sees you regularly for at least 3 hours each week and who can be relied on to accompany you to all clinical trial visits (this will be your 'clinical trial caregiver')
- Are not living in a nursing facility or dementia care facility

## What happens during the PASSPORT clinical trial?

The main clinical trial lasts just over a year. It is divided into a 6-week screening period (when all the necessary assessments will be carried out to check that you are eligible to participate), and a 52-week double-blind\* dosing period, (when either the investigational study drug or inactive substance (placebo) is given), with clinic visits approximately every 4 weeks. Once this portion of the clinical trial concludes, there will also be an opportunity to participate in an open-label dosing period



Study participants will receive their dose (investigational study drug or inactive substance (placebo)) through an intravenous (into the vein) infusion (also known as a drip), which will take about an hour to administer. You will need to stay at the clinical trial clinic for a further 2 hours for monitoring.

\*Neither study participants, clinical trial caregivers, nor the staff at the clinical trial clinic will know what group study participants have been assigned to or whether you are receiving active investigational study drug or inactive substance (placebo).

# What is a placebo and why is it used?

A placebo is an inactive substance given to a control group. We use a placebo so that we can make sure that any changes seen in the health of study participants are due solely to the investigational study drug, and not some other factor (such as increased monitoring).

# What to expect at clinical trial visits?

During the clinical trial visits, we will carry out a series of tests and health checks. Usually these include:



Physical examinations (e.g., height and weight)



Assessment of any side effects



Vital signs checks (e.g., temperature, breathing rate and pulse)



Scans (to assess any changes in the brain)



Neurological examinations (to assess the status of PSP)



Electrocardiograms (a painless way to look at the heart's electrical activity)



Blood tests



Questionnaires for you and your caregiver (to assess general well-being)

A few study participants may be asked to take part in a sub-study, which includes a lumbar puncture procedure (also known as a 'spinal tap'). You do not have to be in this sub-study to participate in this clinical trial and all tests and procedures will be fully explained to you by the clinical trial team. Please feel free to ask questions at any time.

# What is a lumbar puncture?

A lumbar puncture is a procedure where a needle is inserted into the lower part of your back to test for conditions affecting the brain, spinal cord or other parts of the nervous system.

First you will be given a local anesthetic to numb the area, before the doctor (or investigator) gently inserts a hollow needle in between two of the bones in your lower back. This should not cause any pain as you will have had an anesthetic but you may feel some pressure. Once the needle is inserted, fluid will be collected. After this, the needle will be removed and a dressing put on your skin.

The whole procedure should take around 30 minutes. You may be told to lie flat in bed or with your head slightly raised for 1-4 hours to prevent or reduce the severity of a headache.

## Is there anything else I should know?

In order to participate in the study, you'll need to read and sign an informed consent form. This shows that you understand what the clinical trial involves, and that you agree to participate. Your caregiver accompanying you on this clinical trial will also need to sign an informed consent form.

All clinical trial-related medications, tests and assessments will be given to study participants at no cost. Reimbursement for travel and other clinical trial-related expenses may be available.

Participating in a clinical trial is entirely voluntary. You can leave the clinical trial at any time (even if you have started taking the investigational study drug). Your future healthcare options will not be affected. Please be sure to weigh up the risks and benefits before making your decision to participate.

## Risks and Benefits

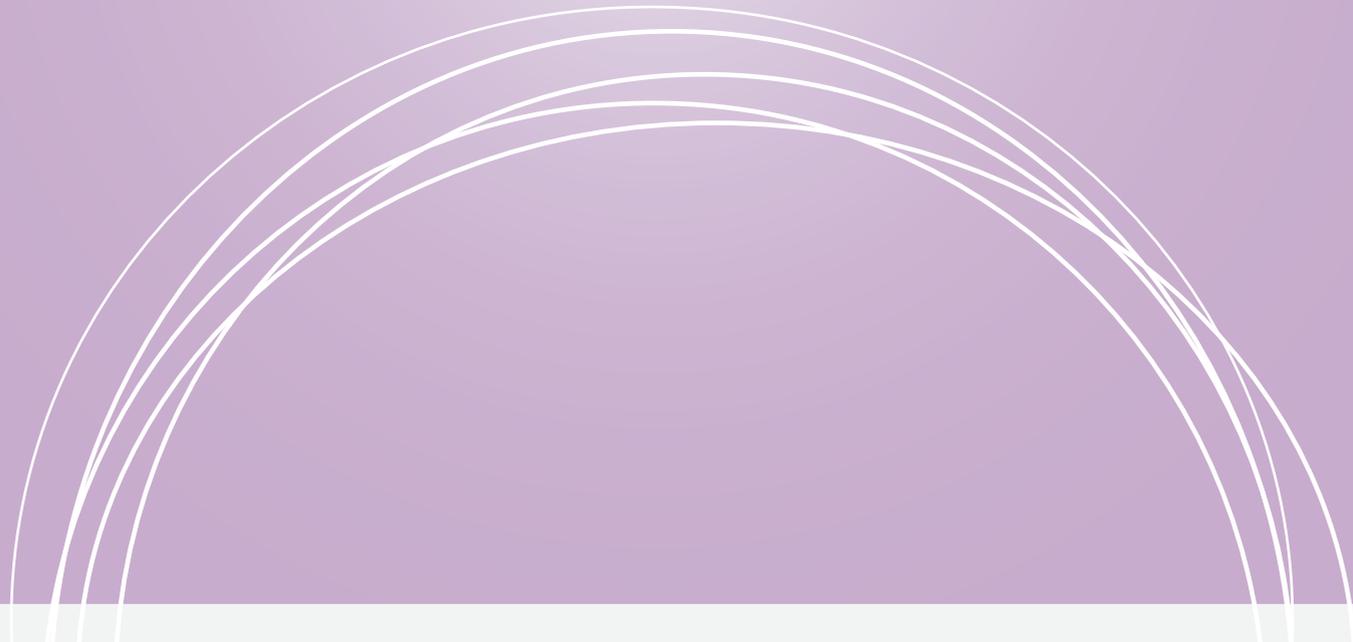
You may wish to consider the following:

### Risks

- Your condition may not change
- Clinical trial assessments may be uncomfortable
- There may be investigational study drug side effects

### Benefits

- Clinical trial-related drugs and health checks are free of charge
- Reimbursement may be provided for time and travel
- Opportunity to help improve the future of PSP treatment





# Thank you for your interest

To learn more about this clinical trial, please go to [passportstudy.com](https://passportstudy.com) or contact the clinical trial team using the details below.

We look forward to  
hearing from you.

Clinical trial team contact details:



## Additional Resources

To learn more about clinical trials, visit the following websites:

[psp.org](https://www.psp.org)

[nih.gov/health/clinicaltrials](https://www.nih.gov/health/clinicaltrials)