# PLATYPUS Participant Information Sheet for Analysis Stage 2 – Parts 1 and 2

## This is information to help you decide if you would like to join a study called PLATYPUS.

- Please take time to read the following information carefully. Discuss it with friends and relatives if you wish. Take time to decide whether you wish to take part.
- You are free to decide whether to take part in this study. If you choose not to take part, this will not affect the care you get from your own doctors in any way.
- You can stop taking part in the study at any time, without giving a reason.
- Ask us if there is anything that is not clear or if you would like more information.
- This leaflet is in 3 parts:

**Part 1: I am considering taking part**
**Part 2: I would like to know more about PLATYPUS**
**Part 3: General information on PLATYPUS**

- We suggest you read these in order and move through the parts if you would like to know more.
- Thank you for reading this information. If you decide to take part, you will be given a copy of this information sheet and asked to sign a consent form, which you can keep a copy.

## Important things that you need to know

- In PLATYPUS, we want to find out if we can find new treatments that may slow down the progression of disability in people with Progressive Multiple Sclerosis (PMS) between 25 and 70 years old.
- Like all medicines used to treat PMS, the treatments used in this study can have unwanted side-effects.
- On top of your usual appointments, this study will require you to visit the hospital every 6 months for up to 5 years.

## Contents



## How to contact us

If you have any questions about this study, please talk to your study doctor or study coordinator/ nurse.

## Part 1: I am considering taking part

## 1 What is PLATYPUS?

- PLATYPUS is an extension of the OCTOPUS trial which opened to recruitment in the United Kingdom (UK) in 2023.
- The sponsor of the OCTOPUS trial is the University College London (UCL).
- Australia is the second region to be added to the OCTOPUS trial and will be known as PLATYPUS in Australia.
- Griffith University will be the Australian national sponsor and will oversee the running of PLATYPUS alongside UCL.
- PLATYPUS stands for Platform Adaptive Trial for remYelination and neuroProtection in mUltiple Sclerosis.
- PLATYPUS aims to find new treatments for people with progressive multiple sclerosis (PMS) that will slow down the rate of disability worsening.
- PLATYPUS is a randomised controlled study for people with PMS.
- It uses a study design called "MAMS" (multi-arm multi-stage) where different treatments can be tested at the same time against standard care.
- This study design also allows us to add new arms to compare new drugs whilst the trial is ongoing, rather than setting up a new trial.
- This is the 2nd part of the study called Analysis Stage 2. In around 2 years, an analysis will be done on all the data including the MRI scans collected in the 1st part of the study. This will allow the study investigators to decide whether any treatment(s) will be stopped if it shows no promise of being better than standard care.
- If a treatment shows promise, then further people with PMS will be able to join and further data collected.

## 2 Why are we doing is study?

Multiple sclerosis (MS) affects more than 33,000 people in Australia, over 2.5 million people worldwide and is one of the most common causes of disability in young adults. MS often begins with a relapsing-remitting phase (RRMS).

Over time, many people with RRMS start to find that they no longer recover after a flare-up and get steadily worse, resulting in increased disability. This is known as Secondary Progressive MS (SPMS). A smaller number of people will find that they experience gradual decline from the beginning, known as Primary Progressive MS (PPMS). SPMS and PPMS together are known as progressive MS (PMS).

There are only a few treatments for people with PMS and they may not be suitable for all. So, PLATYPUS is going to test different treatments added to standard of care against standard of care alone. The aim is to see if we can find treatments that can slow down the progression of disability in people with PMS. The best way of knowing if these treatments work is by carrying out a randomised controlled study.

A randomised controlled study compares two or more groups of people: A research group who receive the new 'research' treatment

(plus or minus standard care, depending on the trial) and a control group who just receive the existing standard care. If you take part in the study, a computer will randomly allocate you to a treatment group. This allows a fair comparison between the new treatment and the existing treatment group to see which one works best.

## 3 Why am I being asked to take part?

You are being asked to take part in PLATYPUS because you are between 25 and 70 years old and have PMS. Your neurologist may be recommending you for this study, or you may have expressed an interest in this study.

This may be through the link to the MS Clinical Trial Pre-screening Platform, MS Trial Screen, or the Registration of Interest Form on the MS Australia website.

Participation in the research is entirely voluntary. If, after considering it you decide not to participate, this will not affect your care in any way and your neurologist will continue to find the best standard treatment available for you.

## 4 What will I need to do if I take part?

After filling out the MS Trial Screen survey (the information provided for this is stored by University of Tasmania on behalf of the Australian Sponsor, Griffith University) and/or an initial telephone conversation with your hospital or study doctor, you will be asked to attend one of the PLATYPUS study centres to discuss this information sheet in more detail. If you would still like to take part, are happy to have some tests and provide more information on yourself, we will ask you to sign a consent form. Not everyone will be able to take part in this study.

You will be asked to:

- have some physical assessments to assess your neurological system including strength, co-ordination, walking and tests of arm function.
- have a general physical examination.
- have your medical history checked.
- complete some assessments that ask about your pain, fatigue, and your quality of life.

If these tests show you can take part, your study doctor will contact you or ask you back to the hospital site and ask if you are happy to continue.

You will then be allocated randomly (by a computer) to one of the treatments. Two of these treatments are repurposed treatments and one is the control group. You will receive these in addition to your usual standard of care. You will then have your study visits planned.

## 5 How often will I need to go to hospital?

You will be asked to visit your study doctor at one month; have a telephone call at three months, and then another visit at six months. After this you will be asked to visit the hospital every 6 months for up to 5 years. Between the 6 monthly visits you will be asked to do a urine test and have a telephone call with the study

coordinator or nurse to report the result. The study coordinator or nurse will provide you with instructions and an at-home testing kit that will enable you to carry out this urine test. If your urine dipstick test is positive for protein, as per the instructions provided, you will have to come into the clinic and give further urine samples. These samples will have further tests performed on them and based on the results, appropriate action if required, can be taken.

At each visit to the hospital, you will have the same physical assessments to test your neurological system, and fill in questionnaires on pain, fatigue, mobility, and quality of life. Further tests will be done to check your progress and if you have any problems with the treatment. Treatment can be reduced or stopped, or you can choose to stop PLATYPUS treatment or the trial at any time.

## 6 What do I need to know about the treatments in this study?

PLATYPUS uses some treatments that are already used for other conditions. These are called "repurposed" treatments. A team of experts have looked into a number of treatments and decided that these are most likely to help slow down disability with people with MS. The first PLATYPUS treatments are:

- R/S-Alpha Lipoic Acid (R/S ALA)
- Immediate release metformin

By using repurposed treatments, there is an understanding of their safety and possible side effects. R/S ALA is a health supplement. Metformin is used to treat a type of diabetes. You will be asked to take 2 capsules a day in the evening shortly after a meal (called the low dose) for 4 weeks. This time will help us to check if you have any problems with the treatment.

If you have no problems and you are happy to do so, you will then be asked to take 2 capsules twice a day shortly after meals (a total of 4 capsules) – this is called the high dose. You will also be asked to record the capsules you take when you take them.

If you would like to know more about the treatments and this study, more detail is given in **Part 2** of this information sheet.

## 7 What are the possible benefits of taking part in this study?

We hope that you will be helped by having any of the treatments in this study, but this cannot be guaranteed. Please remember that the treatments tested will not make you better**.** We hope that they will help slow down the progression of disability in people with PMS. However, we do not know this for sure which is why they are being tested.

It is possible that the results may not help you, but the information we get from this study will help us to improve treatment for future patients with PMS.

## 8 What are the possible disadvantages and risks of taking part?

If you take part, you will need to visit the hospital more often. You will be asked to have blood tests, and urine tests before joining the study. You will then have additional blood and urine tests during the study. You will also be asked to complete several assessments and questionnaires each visit to assess pain, fatigue, and your quality of life.

You might experience different or extra side-effects from the treatments that you take in this study.

The most common unwanted side effects are described in **Part 2** of this information sheet.

The effects of the PLATYPUS treatment on babies are unknown and information on how they affect fertility are limited. Therefore, women of childbearing age must not breastfeed, be pregnant or become pregnant while on this study. This is also important for men with a partner who could become pregnant. Therefore, if this applies to you, you must use an acceptable method of contraception (at least a condom and ideally another method) during the study, and for 12 weeks after your last dose of any PLATYPUS treatment. You may also need a pregnancy test before you join the study prior to any prescriptions being provided. Male participants must not donate sperm during the study or for 12 weeks after the last dose of PLATYPUS treatment.

## 9 Can I stop taking part after I have joined the study?

You can stop taking part in all of this study, or in any part of it, at any time. You do not need to give a reason. You must talk to your study doctor or study coordinator or nurse first. They can advise you about any concerns you may have.

If you decide to stop taking your study treatment, we ask for you to still attend hospital visits every 6 months so we can continue collecting information about you for up to 5 years. This is important, because it helps us to ensure that the results of the study are reliable. Your study doctor or study coordinator/ nurse will discuss any treatment stops with you.

If you stop taking part in this study, you will continue to receive the treatment you would receive outside the trial (standard of care). This will be discussed with your neurologist.

## 10 Do I have to take part in PLATYPUS?

No, it is up to you to decide whether to take part. If you decide not to take part in this study, you will continue to receive the standard treatment. This is provided to you by your neurologist. A decision to not take part at any time will not affect the standard of care you receive.

If you have private medical insurance, you should consult with your insurer before agreeing to take part.

If you think you might be interested in taking part in PLATYPUS or this aspect of the study, please see **Part 2** for more information.

## 11 Contacts for further information

As well as **Part 2**, you can look at the following websites: www.msaustralia.org.au/platypus and www.ms-octopus.info. Please also contact your study doctor or study coordinator/nurse:

**Thank you for taking the time to consider taking part in this study.**

## Part 2: I would like to know more about PLATYPUS.

## 12 Can I definitely take part?

As stated in **section 4 of Part 1**, after your initial contact with the study and discussion at a clinic visit at a hospital, if you are suitable to take part, we will ask you to sign a consent form. If you decide to consent, we will then ask you to do the following tests:

- A physical examination to check your general health.
- Your medical history. You will also be asked what medications you are taking.
- Blood tests – we will take a small amount of blood (up to 10 ml or 2 teaspoons) from the vein in your arm to check if it is safe to receive the treatments.
- Urine sample to check if you have protein in your urine and if it is safe to receive the treatments. If you are a woman of childbearing age, you will also be asked for a urine sample for a pregnancy test (see section 16 for more information).

These tests will find out if you will be able to take part in PLATYPUS. You will also be asked to perform 6 neurological assessments to assess your strength, co-ordination, walking arm and hand function, vision, and memory. These include:

- EDSS assessment (4.0 – 8.0).
- Timed 9-hole peg test.
- A timed 25-foot walk assessment.

In addition to this there will be about 7 other questionnaires which will ask about your pain, memory, fatigue, and your overall health.

## 13 What if the tests show I can take part?

If the tests show you can take part, you will be asked to confirm if you would like to take part (either by phone or at clinic). If you are happy to proceed, a treatment will be allocated randomly, and we will plan your clinic visits.

## 14 Which group will I be in?

It is important that the groups receiving each treatment are as similar as possible at the start of the study. To ensure that this happens, a process called randomisation is used to allocate people to each group. This allows a fair comparison between the new treatment and the existing treatment group to see which one works best.

In all groups, you will continue to receive your standard treatment for PMS. In addition to your standard treatment you are already receiving, the 3 possible treatments that you may be allocated to are:

- Arm A: a placebo (or dummy drug)
- Arm B: R/S-Alpha Lipoic Acid (R/S ALA)
- Arm C: Immediate release metformin

Everyone who takes part will be in one of these groups.

In PLATYPUS, the people with PMS who receive standard of care treatment are called Arm A (control group). This group acts as comparison for the research groups and is the way PLATYPUS can assess the research treatment. This is a very important part of randomised controlled studies and ensures the results are reliable.

To make sure the results of this study are as reliable as possible, neither you nor any of

your doctors will know which treatment you will get. In an emergency if any doctor needs to find out which treatment you are taking, they will be able to do so.

We will also inform your GP and your neurologist that you have entered this study and your possible treatments.

## 15 Why does PLATYPUS have a placebo (dummy drug)?

One third of participants will be allocated to Arm A. This is the group receiving dummy or placebo capsules, in addition to their normal standard of care.

The placebo capsules will look and taste the same as the other treatments but will contain no active ingredient. Everyone in Arm A will have all the same visits, assessments, and tests as those on in the other groups.

This is the fairest way of comparing the new drug treatment with the current standard care (in the control group) without anyone knowing which treatment the participants are receiving.

When the data has been analysed, the treatment for each participant will be revealed and we will see if one treatment is better than the other. At this point, you will be able to find out what treatment you have been receiving too.

If your arm is stopped after an analysis, you will be able to find out what treatment you have been taking too.

## 16 What will happen to me during the study?

### How will I take my PLATYPUS Treatment?

Whichever treatment group you are in, please start your treatment as soon as possible. If you are not able to start taking your PLATYPUS treatment within 2 weeks of being randomised, please tell your study doctor or nurse.

At first, we will ask you to take 2 capsules once a day in the evening shortly after a meal (called the low dose) for up to 4 weeks. You will then come to clinic, where you will have the same tests and assessments you completed when you were finding out if you could join the study. Please see the visit information leaflet for a summary of what tests and checks are performed at each visit.

If there are no problems and you are happy to do so, you will be asked to take 4 capsules (2 capsules twice a day shortly after meals, called the high dose) for up to 5 years. You will have tests and checks at least every 6 months to check how the treatment is affecting you and if it is still safe to take.

At any time, if it is needed, the study doctor may ask you to reduce the number of capsules you are taking or stop them entirely.

We recommend taking the capsules at the same time each day. This is usually easier to remember. If you are taking 2 capsules (called the low dose), it is recommended the capsules should be taken in the evening. Please swallow the capsules whole with plenty of water and shortly after a meal.

If you are unable to swallow the capsules for any reason, do not break up the capsules. Please contact your study doctor or nurse.

You will be given a diary card to help you keep track of what capsules you have taken and provide you with guidance on how to take the

capsules. If you forget to take your capsules or several capsules on a day, do not take extra capsules to catch up. You should only take up to 4 capsules a day. Please note any missed capsules on your diary card and let your study coordinator or nurse know if you missed any capsules when you see them. Please bring completed diary cards to each visit. If you would like to, you can also add a summary of your diary card online, 29 days after each visit. A link can be emailed or texted to you if you would like to do this.

Please keep your capsules away from children and do not let them become mixed up with anyone's medications. They should be stored at room temperature (not in the fridge) and not in direct sunlight.

## What about taking other medications?

If you are on regular medications or supplements (including health supplements and multi vitamins), please make sure your study doctor and study coordinator or nurse know about them before you start your treatment. This includes those for your MS.

It would be helpful if you brought a list of medications (which you can get from your GP). Please bring any supplements (including health supplements and multi vitamins) when you are seen by the study doctor or nurse.

After starting your PLATYPUS treatment, if any new medication is required - including for your MS - it is important that you tell the doctor prescribing the new medication that you are in a clinical study. You will be given a card (same size as a credit card) that states you are on a clinical study and states the possible treatments you are taking.

If you go to hospital or see a doctor during the study, please show them this card.

It is also important that you tell the study doctor if you have been asked to start taking any new medications including for your MS, over the counter or health supplements (including multi vitamins). It is particularly important to tell the study doctor about any of the following:

- Excessive alcohol consumption.
- Any treatment for cancer.
- Treatment with Insulin.
- Any medication or health supplement (including multi vitamins) that contains Alpha Lipoic acid or metformin.
- If you are being planned for any scans (such as CT) that use an **iodine dye.**

If you need to have one of these scans, you will need to stop your PLATYPUS treatment 24 hours before.

You cannot restart trial treatment for at least 48 hours after the scan. You must also have a blood test called Estimated Glomerular Filtration Rate or eGFR.

It is extremely important that you do not take any other medication that contains Alpha Lipoic Acid or metformin.

**You must not buy Alpha Lipoic Acid from any chemist, shop, or other supplier. Please ensure you check any health supplements including multi vitamins. This will affect the study and its findings and might potentially be harmful.**

There are also other medications that must be checked by your study doctor. Therefore, it is very important to please remember to inform your study doctor and study coordinator or

nurse about which medications or supplements that you currently take.

## Can I take part in other research or studies?

If you are already taking part in research or would like to join other studies while participating in PLATYPUS, it is important that these other studies do not involve other drugs. If this applies to you, you should discuss this with the local site team prior to joining PLATYPUS.

## Are there any other precautions I need to know?

It is important that **women of child-bearing age must not breastfeed, be pregnant or become pregnant while on this study.** This is because the effects of the treatment on the baby are unknown. There is also limited knowledge on the effects on fertility. Therefore, you must use an acceptable method of contraception during the study (such as a condom plus ideally 1 other method), and for 12 weeks after your last dose of any PLATYPUS treatment. Please discuss this further with your study doctor. They will be able to advise you if you are unsure whether you are currently using acceptable methods of contraception.

You will also need a pregnancy test before you join the study and prior to any prescriptions provided if considered necessary.

It is also important for men with a partner who is or could become pregnant to use condoms or other acceptable method of contraception during the study.

This is as well as up to 12 weeks after the last dose of any PLATYPUS treatment.

You must not donate sperm during the study or for 12 weeks after the last dose of PLATYPUS treatment.

If you do become pregnant, you will need stop the PLATYPUS treatment. We will continue to follow you within the trial and provide additional information to you and ask for your consent to collect information on the outcome of your pregnancy. If you are male, and your partner becomes pregnant within 3 months of your last PLATYPUS treatment, we will provide information for them and ask them to come to speak to your study doctor. If they agree, the study doctor or study coordinator/ nurse will obtain their consent for us to collect information about the outcome of the pregnancy.

## How often will I have to come to hospital and what will I have to do?

You will be asked to visit the hospital 4 weeks after starting your treatment. At this visit your study doctor or study coordinator/ nurse will check your health and perform a physical examination. They will check if you are on other medications or if you have had any side effects.

You will also need to have the tests to check if it is safe for you to continue the treatment and increase the number of capsules you take.

Following the week 4 visit, you will have a telephone call at three months and a visit to the hospital at six months. After this you will be asked to visit the hospital every 6 months for to up to 5 years. Please see the Visit Information leaflet that summarises what tests and checks are performed when.

Between the 6 monthly visits, you will be asked to perform a urine dipstick test on a

urine sample at home. All the collection pots and tests will be provided to you for these tests. You will then have a telephone call with the nurse to report the result.

If there is protein found, you will be asked to repeat it the next day. If protein is found again, you will be asked to take 2 more urine samples to the hospital to check for infection and kidney function.

The nurse will phone you after testing to tell you whether you need to change your PLATYPUS treatment or if you have an infection.

## When should I stop taking PLATYPUS Treatment?

Your treatment will be offered for as long as it is safe for you to take it. The PLATYPUS treatment will continue for up to 5 years.

At 5 years, if the treatment you were allocated has shown benefit or is still being assessed, you will have a conversation with your study doctor about continuing PLATYPUS treatment and how it is provided. If your treatment does not show benefit, you will revert to best standard of care only and you will have this conversation with your Study doctor or neurologist.

If a treatment shows benefit following analysis, the PLATYPUS study team will work with the required organisations to apply for the approvals for the treatment to be part of standard of care for people with PMS.

You may stop taking treatment before you reach 5 years because:

- Tests and checks show it is best for your study doctor to reduce or stop the capsules being taken.
- You decide you would like to stop PLATYPUS treatment.
- the treatment or arm you are part of is stopped early after analysis (see next section).

In all these instances you must discuss this decision with your study doctor or nurse. This will ensure that you are fully informed prior to any decision. The study team can advise you on any concerns you may have and what is required after stopping.

If you or your study doctor decide for you to stop taking your study treatment, we will need to continue collecting information about you every 6 months for up to 5 years. This is important, because it helps us to ensure that the results of the study are reliable. If this occurs, your study doctor and nurse will discuss this with you.

If you stop taking part in this study, you will continue to receive standard care, and this should be discussed with your neurologist.

A decision to stop taking part at any time will not affect the standard of care you receive.

## What happens if my PLATYPUS study arm stops early?

As part of PLATYPUS study design, if a treatment does not appear to be of benefit, this will be discussed by the independent oversight committees of the study. The committees may then suggest that the treatment or arm should be stopped. If this happens participants who are on that treatment will have a final visit with their study doctor.

They will arrange for your standard care to continue outside the study.

These participants, if they would like to and are still suitable for the study, may be offered the opportunity to join the study again, after a suitable period of time (around 6 months). If this is the case for you, your study doctor will discuss this with you. This is not available to you if your study arm has not stopped early, or you are on Arm A (placebo or dummy).

### What happens if the PLATYPUS study stops early?

Very occasionally a study is stopped early. If it happens, the reasons will be explained to you and your doctor will arrange for your care to continue outside of the study.

## 17 What are the possible side-effects?

### What are the most common side-effects?

The PLATYPUS treatments, Alpha Lipoic Acid and metformin, may cause some side effects. You may experience none, some, or all the side effects listed below. The most common side-effects of these treatments are:

- Taste disturbance
- Nausea (feeling sick) *
- Vomiting*
- Abdominal pain*
- Loss of appetite*
- Dehydration

** These tend to be more obvious at the beginning but do ease off with time.*

If you become concerned about any side-effects, please tell the study doctor or nurse as soon as possible.

### Are there other side-effects?

Other rare and very rare side effects are:

- Lactic acidosis - a condition when the body makes too much lactic acid, and it cannot get rid of it quick enough. This condition can lead to changes in your kidneys
- Decrease in the amount of vitamin B12 absorbed by the body
- Skin reactions such as itchy skin or rash
- Changes to your liver function
- Proteinuria – when there is too much protein in your urine
- Constipation
- Dizziness
- Breathlessness
- Muscle cramps or weakness
- Burning or prickling sensation in hands, legs, feet, or other body parts

It is important that you should tell your study doctor if you think you may be having any of these side effects. The study doctor may decide to change the number of capsules you have to take each day.

There may be risks involved in taking these treatments that have not been found in the so far. Every precaution will be taken, and you must report anything troubling you.

Also, do not forget about the card we will give to you, please always carry it with you. The card will inform doctors that you are on a clinical study and the treatments that you might be being treated with. The card also lists the side effects that you might expect to experience from your allocated treatment.
On the card are the details of the people you should contact if you feel unwell.

## 18 Will I get back any travel costs?

If you take part, you will receive travel costs for coming to the hospital for study visits. This will be repaid **up to a set limit**. The study team will explain this to you.

## 19 Do I need to provide extra samples for future MS research?

As said in **Part 1**, we are also asking if you are happy to donate extra blood samples to help in future MS research. This is in addition to those for the PLATYPUS trial blood tests. It will help find substances in your blood which might help us understand more about MS, potential predictive (protein or genetic) biomarkers and the treatment types that might be more effective for other PMS in the future. It will not help with your own treatment.

This part of the study will only take place in some PLATYPUS hospital sites, so please check with your study doctor or study coordinator or nurse if this is available to you. Your consent form will ask whether you are happy to provide these extra samples for future research. It is voluntary if you wish to take part in this aspect of the study and if you choose not to allow storage of your blood, you can still participate in the study.

If you choose to participate in this part of PLATYPUS, we will ask for 4 extra blood samples when you join PLATYPUS and then 3 extra blood samples at every 6-month visit. This will be approximately 25 – 35ml (equal to 2-3 tablespoons). These will be taken at the same time as your other blood samples.

This is more blood than usually taken but will not require any extra blood tests or visits.

### What will happen to my extra samples if I donate them?

To look for genetic biomarkers, we will extract deoxyribonucleic acid (DNA) from your blood. This allows us to look at whether differences in people's unique genetic code affect the way their MS progresses, or how they respond to treatment. Your blood will be used to analyse inherited material (DNA) or biochemical markers.

Your extra donated samples will be anonymised and then sent and stored within the Australian MS biobank based at Monash University, as the coordinating centre, prior to distribution to various research institutions around Australia. A copy of your anonymised consent form will be sent to the Australian MS biobank who will manage and store the samples. The Australian MS Biobank will hold the following basic information: date of birth, gender, details about your MS (type and length of MS, disability level, relapse and MRI information), ethnic background, any other illnesses. The Australian MS biobank will also hold your PLATYPUS trial ID, Australian MS Longitudinal Study (AMSLS) ID, and your MSBase ID (if you have one and give specific consent for this).

Any projects using these extra samples including genetic or biochemical analysis, will be performed within national or international sites of expertise and may occur during or after the end of the study. They must have ethical approval for any work undertaken and permission for use from Griffith University, and on behalf of the OCTOPUS Trial Management Group.

If there are any residual samples that are not used at the end of the study, we will ask your

permission for these to be stored at Monash University (see address below) and/or distributed to various research institutions around Australia for processing and future use.

Please see **Part 3 section 3.**

## 20 Contacts for further information

If you would like further information, please carry on reading **Part 3.** If you have any questions, please also contact your study doctor or nurse.

**PLATYPUS Participant Information Sheet for Analysis Stage 2 – Part 3**

## This is general information to help you decide if you would like to join PLATYPUS.

- This is **Part 3** of the PLATYPUS Participant Information Sheet. Please also read Parts 1 and 2 if you are interested in this study.
- **Part 3** contains general information you need to know if you would like to take part in this study.
- Please take time to read the following information carefully. Discuss it with friends and relatives if you wish. Take time to decide whether you would like to take part. Ask us if there is anything that is not clear or if you would like more information.
- You are free to decide whether to take part in this study. If you choose not to take part, this will not affect the care you get from your own doctors in any way.
- You can stop taking part in the study at any time, without giving a reason.
- Thank you for reading this information. If you decide to take part, you will be given a copy of this information sheet and asked to sign a consent form. You will get a copy of that as well.

## How to contact us

If you have any questions about this study, please talk to your study doctor or nurse.

## Contents: Part 3



## 1 How will my personal information and data be used?

As part of the OCTOPUS trial, PLATYPUS is conducted in Australia by the MRC Clinical Trials Unit at UCL, Griffith University, and members of the Australian MS Clinical Trials Platform.

As such, UCL will be using information from you and your medical records, obtained from hospital and, GP records, to undertake this study and will act as data controller for this study.

UCL will be responsible for looking after your information and using it properly. UCL will keep identifiable information about you for a minimum of 25 years after the study has finished.

Your rights to access, change or move your information are limited. This is because we need to manage your information in specific ways for the research to be reliable and accurate.

If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights,

we will use the minimum personally – identifiable information possible. You can find out more about how we use your information at https://www.ucl.ac.uk/legal-services/privacy/ucl-general-privacy-notice-participants-and-researchers-health-and-care-research-studies

## 2 How will your personal information and data be stored and collected?

Your personal data will be collected and held in compliance with the UK General Data Protection Regulation (GDPR). Some data is stored outside the UK, and so have different data protection laws. It will be stored by the following organisations:

- PLATYPUS hospital where you are treated.
- University College London (UCL) who are the trial sponsor and are coordinating the OCTOPUS study.
- MS Society (anonymous data only).
- OCTOPUS database (names, email addresses and phone numbers only for online questionnaires).

All companies and organisations working with the OCTOPUS trial have contracts in place with UCL and/or Griffith University that make sure that they cannot use your data for any purposes other than those instructed. They will not share your personal information with any other organisation, and they will hold it securely and retain it for the period UCL instructs.

Your hospital will collect information from you and your medical records for this study in accordance with Griffith University and UCL instructions.

Your hospital will use your name, Medical Record Number and contact details (including your email if you agree to this), which are collected from your Registration of Interest, to:

- contact you about PLATYPUS
- make sure that relevant information about the study is recorded for your care
- to oversee the quality of the study.

Your hospital will keep identifiable information about you from this study for at least 25 years after the study has finished. Your hospital will provide personal information such as your initials, date of birth or medical record number to MRC Clinical Trials Unit at UCL along with the information collected from you and your medical records. This information will include health information, which is regarded as a special category of information.

They will use this information to conduct our research. Individuals from UCL, Griffith University and regulatory organisations may look at your medical and research records to check the study accuracy.

In addition, if you provide consent, your email address and/or phone number are provided to allow trial database to send some assessments such as diary cards or questionnaires to you for you to complete online. This information is stored in the UK. However, the information required to send the links to the questionnaires (your name and email address) are processed in the EU and then stored for 30 days. If the links for the questionnaires are through your phone number, then your name and phone number are processed in the US and then stored for

300 days. No other personal or medical information is included in this and held outside the UK or Australia.

For further information consult the University's Privacy Plan at http://www.griffith.edu.au/about-griffith/plans-publications/griffith-university-privacy-plan or telephone (07) 3735 4375.

### What information will be collected to track for long term health status and other reporting?

UCL and Griffith University will collect information about you, for research, from your hospital site, your medical record, your My Health Record, or any applicable national health registers that you are part of, such as MSBase, and the Australian MS Longitudinal Study, if you provide consent for us to do so. This information will include initials, date of birth, and health information. We will use this information to track your long-term health status which may be during or after your participation in the trial.

Where information could identify you, the information will be held securely with strict arrangements about who can access the information. The people who analyse the information will not identify you.

Some information regarded as sensitive information may be collected if you are happy to give it. This includes ethnic origin, sexual orientation, caring responsibilities, and socio-economic status. If you do not want to give this information, you can state you prefer not to say.

This information will only be collected at screening. The MRC Clinical Trials Unit and Griffith University will pass this information onto the UK funder of the trial, the MS Society, and the Australian MS Clinical Trials Platform for statistical analysis. The data provided to these groups will be anonymous, and they will not be able to identify you. This data will help the MS Society and Australian MS Clinical Trials Platform to understand the diversity of participants in MS research. They aim to have a research community that is equal, diverse, and as inclusive as possible to ensure it is best qualified to improve the lives of people affected by MS in the UK and in Australia.

## 3 Will my data or samples be used for future research?

When you agree to take part in PLATYPUS, the information about your health and care may be provided to researchers running other research studies at Griffith University, and in other organisations. This data will be anonymised so we will not share information with others that can identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care.

These organisations may be universities, medical organisations/hospitals, or companies involved in health and care research in this country or abroad. Your information and samples will only be used by organisations and researchers to conduct research in accordance with relevant legal and ethical research policy requirements.

It will not be used to make decisions about future services available to you, such as insurance.

If there is a risk that you can be identified your data and samples will only be used in research that has been independently reviewed by an ethics committee and with permission from UCL.

For the optional (or extra) samples donated, if there are any unused samples are not used at the end of the trial, we ask your permission for these samples to be stored for use in future projects about MS and other neurological diseases, at the Australian MS biobank (located at Monash University). At this point they will be overseen by the Australian MS biobank procedures.

If you decide you would not like to give this permission, then any unused sample will be destroyed at the end of the study. If you decide to withdraw consent for the use of your samples at any point, please let your study doctor and study coordinator or nurse know.

Please be aware we will not be able to remove your sample(s) from completed analyses or projects but prevent from any further use.

## 4 What will happen to the results of the PLATYPUS study?

When the study is completed, a summary of the results will be available via the MS Australia website:
https://www.msaustralia.org.au/
and UCL website:
https://www.mrcctu.ucl.ac.uk/.

We will also publish the results in medical journals, so that other doctors can see them. You can ask your doctor for a copy of any publication. Your identity and any personal details will be kept confidential. No named information about you will be published in any report of this study.

## 5 Who is organising and funding the study?

The sponsor for the OCTOPUS trial is the University College London (UCL). In Australia, the OCTOPUS trial will be known as PLATYPUS, with Griffith University as the Australian sponsor. PLATYPUS will be conducted by the MRC Clinical Trials Unit at UCL, Griffith University, and members of the Australian MS Clinical Trials Platform. The study coordination within Australia will be provided by Griffith University, and the overarching management, analysis and administration will be provided by UCL.

Your study doctor or neurologist are not receiving any money or other payment for asking you to be part of the study.

As the national sponsor in Australia, Griffith University has responsibility for the conduct of this study in Australia, with UCL having overall responsibility of the study. UCL and Griffith University are responsible for ensuring the study is carried out ethically and in the best interests of the study participants.

The study is funded by the UK MS Society with further supportive funding from UCL. MSWA and MS Australia have funded the extension of the study in Australia.

## 6 Who has reviewed the PLATYPUS study?

The study has been reviewed by international scientists and other doctors and experts in the field of multiple sclerosis and its treatment. It has been approved regulators in

the UK as well as by Gold Coast Hospital and Health Service Health Human Research Ethics Committee (Lead HREC) and Research Governance Office (RGO).

It has been validated by the Therapeutic Goods Administration (TGA) through the Clinical Trial Notification scheme.

## 7 What if new information becomes available during the study?

Sometimes during a study, new information becomes available about the treatments that are being studied.

If this happens, your doctor will tell you about it and discuss with you whether you want to continue the study.

If you decide to stop taking part in the study, your doctor will arrange for your care to continue outside of the study.

Your doctor might also suggest that it is in your best interests to stop taking part in the study. Your doctor will explain the reasons and arrange for your care to continue outside the study.

## 8 What can I do if I have a complaint or a concern?

Griffith University and Gold Coast Hospital and Health Service conduct research in accordance with the National Statement on Ethical Conduct in Human Research (2007, Updated 2018).

If you have any concerns or complaints about the ethical conduct of this research project, you are encouraged to contact any or all of the following:

Manager, Research Ethics
Griffith University
Bray Centre (N54) 0.15
Nathan Campus
Griffith University QLD 4111
Email: research-ethics@griffith.edu.au
Phone: 07 3735 4375

HREC Coordinator
Gold Coast University Hospital
1 Hospital Boulevard
SOUTHPORT QLD 4215
Email: GCHEthics@health.qld.gov.au
Phone: (07) 5687 3879

Research Governance Office
Gold Coast University Hospital
1 Hospital Boulevard
SOUTHPORT QLD 4215
Email: GCHResearch@health.qld.gov.au
Phone: (07) 5687 3880

Any complaint will be investigated promptly, and you will be informed of the outcome.

## 9 Contacts for further information

If you want further information about the PLATYPUS study, information is also available on our website www.msaustralia.org.au/platypus. Please also contact your study doctor or study coordinator/ nurse.

Thank you for taking the time to read this information and for considering taking part in

PLATYPUS. Please feel free to keep this information sheet.

If you decide to take part in PLATYPUS, you will be asked to sign a consent form and you will be given a copy of the signed consent form to take home.