



## PLATYPUS Participant Information Sheet – Visit information leaflet

This information is extra to the PLATYPUS (the Australian extension of Octopus) Participant Information Leaflet. It will provide you further information on the visits that are needed for PLATYPUS, including what assessments will take place, when they will occur and approximately how long they will take. If you would like further information about the PLATYPUS study, please discuss any queries with your study doctor or nurse.

| Name and Timing of Visit | What will happen?  | Where will it happen?  | How much time will it take? (approx.) |
|--------------------------|--|--|---------------------------------------|
| Screening                | <ul style="list-style-type: none"> <li>Information on PLATYPUS and Consent form signing</li> <li>Physical Examination and measurements</li> <li>Assessment of MS disability (EDSS)</li> <li>Information collected on <ul style="list-style-type: none"> <li>Medical and MS history</li> <li>Medications being taken – bring a list and any health supplements including vitamins</li> <li>Demographic data including for Equality, diversity, and inclusion</li> </ul> </li> <li>Blood tests</li> <li>Urine tests</li> <li>Pregnancy test (if required)</li> </ul>   | Hospital Clinic  | 1 hour                                |
| Randomisation – Month 0  | <ul style="list-style-type: none"> <li>Information about your general wellbeing</li> <li>Physical assessments to assess your neurological system including strength, co-ordination, walking and tests on arm function.</li> <li>Assessment of MS disability (EDSS)</li> <li>Questionnaires about your pain, fatigue, and quality of life</li> <li>Information collected on: <ul style="list-style-type: none"> <li>Medications being taken</li> </ul> </li> <li>Pregnancy test (if required)</li> <li>Blood draw for extra sample collection (optional and only at selected sites)</li> <li>Final check to confirm it is safe and participant can take part in the trial</li> <li>Randomisation and allocation of treatment</li> </ul> | Hospital Clinic<br><br><i>Please note some assessments may be done at the screening visit and the research team may call you to confirm you are happy to take in the trial before you are allocated your treatment</i> | 1-2 hours                             |

| Name and Timing of Visit | What will happen?  | Where will it happen? | How much time will it take? (approx.) |
|--------------------------|--|-----------------------|---------------------------------------|
|                          | <ul style="list-style-type: none"> <li>Prescribe PLATYPUS treatment (you should start taking your treatment within 2 weeks of being randomised)</li> </ul> |                       |                                       |

| Name and Timing of Visit  | What will happen?  | Where will it happen?  | How much time will it take? (approx.) |
|---|--|--|---------------------------------------|
| One Month (Week 4)  | <ul style="list-style-type: none"> <li>Information about your general wellbeing and health check</li> <li>Information collected on: <ul style="list-style-type: none"> <li>Number of capsules taken</li> <li>Medications being taken</li> <li>Any side affects you may be having</li> </ul> </li> <li>Blood tests</li> <li>Urine tests</li> <li>Weight (if required)</li> <li>Pregnancy test (if required)</li> <li>Prescription of PLATYPUS treatment and adjustment of number of capsules (if required)</li> </ul>   | Hospital Clinic  | One hour                              |
| For 4 weeks after each hospital visit                                   | <ul style="list-style-type: none"> <li>Complete Diary card to record number of capsules taken</li> </ul>   | At home  | Up to 5 minutes each day              |
| At 3 months (Week 12)   | <ul style="list-style-type: none"> <li>Information collected on: <ul style="list-style-type: none"> <li>General wellbeing</li> <li>Number of capsules taken</li> <li>Medications being taken</li> <li>Any side affects you may be having</li> </ul> </li> <li>Blood tests at GP or hospital clinic</li> <li>Weight at GP or hospital clinic (if required)</li> <li>Pregnancy test at GP or hospital clinic (if required)</li> <li>Urine tests at home or hospital clinic</li> <li>Prescription of PLATYPUS treatment and adjustment of number of capsules to take (if required)</li> </ul> | Telephone call (at home) with visit to GP or hospital clinic for blood tests | Up to 30 minutes                      |
| 6 months (Week 26) onwards and every 6 months afterwards, up to 5 years | <ul style="list-style-type: none"> <li>Information about your general wellbeing</li> <li>Information collected on: <ul style="list-style-type: none"> <li>General wellbeing</li> <li>Number capsules taken</li> <li>Medications being taken</li> <li>Any side affects you may be having</li> </ul> </li> <li>Blood and urine tests</li> <li>Physical assessments to assess your neurological system including strength, co-ordination, walking and tests on arm function.</li> </ul>   | Hospital clinic  | 1-2 hours                             |

| Name and Timing of Visit                                     | What will happen?  | Where will it happen?      | How much time will it take? (approx.) |
|--|--|----------------------------|---------------------------------------|
|  | <ul style="list-style-type: none"> <li>Assessment of MS disability (EDSS)</li> <li>Questionnaires about your pain, fatigue, and quality of life</li> <li>Weight (if required)</li> <li>Pregnancy test (if required)</li> <li>Blood draw for sample collection (optional and only at selected sites)</li> <li>Prescription and adjustment of number of capsules if required</li> </ul>  |                            |                                       |
| Halfway between 6 monthly hospital visits (e.g. at 9 months) | <ul style="list-style-type: none"> <li>Urine test at home</li> <li>Reporting results to research team via agreed telephone call</li> <li>Provide further urine samples to hospital (if required).</li> </ul>   | At home and telephone call | Up to 15 minutes (more if required)   |
| When finished treatment – 6 monthly up to the 5 years        | <ul style="list-style-type: none"> <li>Information collected on: <ul style="list-style-type: none"> <li>General wellbeing</li> <li>Medications being taken</li> </ul> </li> <li>Physical assessments to assess your neurological system including strength, co-ordination, walking and tests on arm function.</li> <li>Assessment of MS Disability (EDSS)</li> <li>Questionnaires about your pain, fatigue, and quality of life</li> <li>Blood draw for sample collection (optional and only at selected sites)</li> </ul> | Hospital Clinic            | Up to one hour                        |

This information should be used with the PLATYPUS Participant Information Sheet. If you would like further information about the PLATYPUS study, information, please discuss any queries with your study doctor or nurse.

Name of doctor or nurse

Hospital Department

Hospital

Address; Address

Tel: xxx XXX XXX

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.