



Together, we're weaving new possibilities in Alzheimer's disease research

**Your guide to study visits
in the CELIA clinical trial**

For volunteers and their care partners



Welcome to the CELIA clinical trial

Thank you for your courage and commitment

The CELIA clinical trial is researching a potential treatment for people with mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's disease dementia by focusing on a protein called **tau**. Abnormal tangles of built-up tau protein can be considered a key sign of the disease. **We want to understand if different doses of a study drug called BIIB080 could be safe and have an effect on the progression of Alzheimer's disease. This could potentially slow down symptoms of the disease.**

Trial timeline

Reviewing the key time commitments to the CELIA trial

Screening period

3 visits



(About 9 weeks, but may be longer for some people)

Now that you have decided to take part in the trial, you will complete some tests and assessments in the screening period.

Placebo-controlled treatment period

14 visits



(About 18 months)

During the placebo-controlled treatment period, you will receive either the different doses of the study drug or placebo once every three months. You and your care partner will also receive scheduled follow-up phone calls.

72% of volunteers will receive a dose of the study drug

28% of volunteers will receive a placebo

Follow-up period

2 visits



(About 5 months)

The follow-up period includes one clinic visit and one phone call to check on your health.

Remember, you will be assigned to one of four different study groups. Neither you, your care partner, nor the study team will know which group you are in.

Study assessments

Summarizing the various tests and assessments that you can expect during study visits



Blood tests

We will collect a sample of your blood.



Changes in your health

We will review the status of your health since your last study visit.



Electrocardiogram (ECG) test

An ECG is a test that measures the electrical pulses from your heart. It helps us monitor your heart rate, rhythm, and health.



Follow-up phone call

You will receive follow-up phone calls one day and two days after each dose of the study drug and once during the follow-up period to check on your health.



Informed consent

Before you join the trial, we will ask you to read and sign an informed consent form (ICF). The ICF explains what will happen during the trial as well as all known risks and benefits of taking part.



Lumbar puncture/study drug administration



A lumbar puncture is a standard medical procedure where a needle is inserted into your lower back (between the bones of your spine). During a lumbar puncture, a trained clinician will administer anesthesia to numb your lower back. Once the area is numb, the clinician will insert a thin needle into the fluid-filled space below the end of your spinal cord. This needle will be used to collect cerebrospinal fluid (CSF) and to administer the study drug or placebo by intrathecal injection. The CSF will be used to gather information on the study drug and the disease.

An intrathecal injection is used so the study drug can be delivered directly into the fluid in your spinal cord and around your brain where it is designed to work. You will receive an intrathecal injection via a lumbar puncture seven times over the course of your two years in the trial.

Magnetic resonance imaging (MRI) scan



MRI scans monitor brain volume, which can change in people with Alzheimer's disease, and eliminate other reasons why memory may be impaired other than Alzheimer's disease.

Neurological exam



We will evaluate certain areas of your nervous system. This may include evaluating your movement skills, balance and coordination, and reflexes.

Other medications



We'll ask you about any new medications you may be taking. This includes any changes to your current prescription or non-prescription medications and herbal supplements.

Physical exam



We will conduct a full check of your physical health.

Pregnancy test (if applicable)



We will take a sample of your blood or urine to see if you are pregnant.

Questionnaires



We will ask you or your care partner a few questions to better understand how you are feeling, your condition, and your quality of life.

Questions about your health



We will ask you or your care partner a few questions to better understand your current health status and symptom progression.

Randomization



During the first study visit, you will be randomly (by chance) assigned to a study group in which you will receive either the study drug (72% of volunteers) or placebo (28% of volunteers). Neither you, your care partner, nor the study team will know which group you are in.

Review eligibility criteria



We will review the eligibility criteria to see if the CELIA clinical trial could be a good fit for you.

Review medical history



We will review your medical history during the screening period and your first study visit.

Urine test

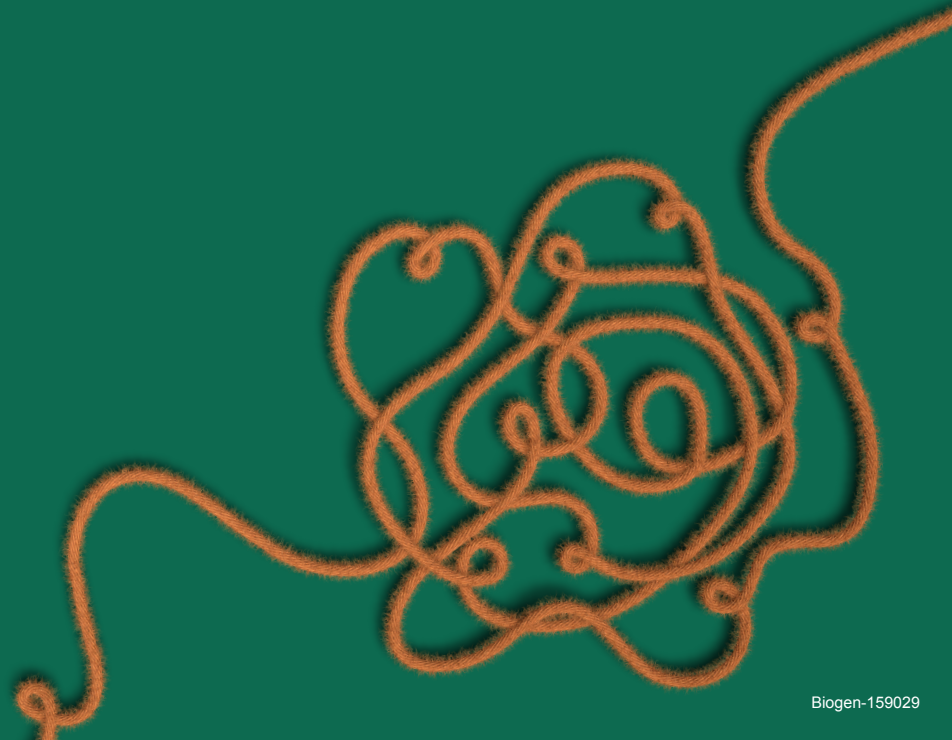


We will collect a sample of your urine.

Vital signs



















We will examine your blood pressure, body temperature, heart rate, and respiratory rate.



Screening visit 1

Date:	Time:
Notes:	

Visit assessments

-  Informed consent
-  Review eligibility criteria
-  Review medical history
-  Weight
-  Height
-  Pregnancy test (if applicable)
-  Blood test
-  Physical exam
-  Neurological exam
-  Questions about your health
-  ECG test
-  Vital signs
-  Urine test
-  Questionnaires
-  Changes in your health
-  Other medications

If you cannot make your appointment, please call your study team. They will help you reschedule.

Screening visit 2

Date:	Time:
Notes:	

Visit assessments

-  Review eligibility criteria
-  Review medical history
-  Vital signs
-  Lumbar puncture
-  MRI scan
-  Questions about your health
-  Changes in your health
-  Other medications

You will have a lumbar puncture during this visit.

Screening visit 3

Date:	Time:
Notes:	

Visit assessments

-  Review eligibility criteria
-  Questionnaires
-  Review medical history
-  Changes in your health
-  Vital signs
-  Other medications
-  Questions about your health















If you cannot make your appointment, please call your study team. They will help you reschedule.

Study visit 1

(Week 1) – Clinic visit

Date:	Time:
Notes:	

Visit assessments

-  Randomization
-  ECG test
-  Review eligibility criteria
-  Vital signs
-  Review medical history
-  Urine test
-  Weight
-  Lumbar puncture/study drug administration
-  Pregnancy test (if applicable)
-  Questionnaires
-  Blood test
-  Changes in your health
-  Physical exam
-  Other medications
-  Neurological exam
-  Follow-up phone call

Three days before randomization, you will need to take a polymerase chain reaction (PCR) test for COVID-19.

Study visit 2

(Week 6) – Clinic visit

Date:	Time:
Notes:	

Visit assessments



Blood test



Urine test



Physical exam



Changes in your health



Neurological exam



Other medications



Vital signs

Study visit 3

(Week 12) – Clinic visit

Date:	Time:
Notes:	

Visit assessments



Weight



Urine test



Pregnancy test
(if applicable)



Lumbar puncture/study
drug administration



Blood test



Questionnaires



Physical exam



Changes in your health



Neurological exam



Other medications



Vital signs



Follow-up phone call

If you cannot make your appointment, please call your study team. They will help you reschedule.

Study visit 4

(Week 18) – Clinic visit

Date:	Time:
Notes:	

Visit assessments



Blood test



Urine test



Physical exam



Changes in your health



Neurological exam



Other medications



Vital signs

If you cannot make your appointment, please call your study team. They will help you reschedule.

Study visit 5

(Week 24) – Clinic visit

Date:	Time:
Notes:	

Visit assessments



Weight



MRI scan



Pregnancy test
(if applicable)



Lumbar puncture/study
drug administration



Blood test



Questions about
your health



Physical exam



Questionnaires



Neurological exam



Changes in your health



ECG test



Other medications



Vital signs



Follow-up phone call



Urine test

Study visit 6

(Week 30) – Clinic visit

Date:	Time:
Notes:	

Visit assessments



Blood test



Urine test



Physical exam



Changes in your health



Neurological exam



Other medications



Vital signs

Study visit 7

(Week 36) – Clinic visit

Date:	Time:
Notes:	

Visit assessments



Weight



Urine test



Pregnancy test
(if applicable)



Lumbar puncture/study
drug administration



Blood test



Questionnaires



Physical exam



Changes in your health



Neurological exam



Other medications



Vital signs



Follow-up phone call

If you cannot make your appointment, please call your study team. They will help you reschedule.

Study visit 8

(Week 42) – Clinic visit

Date:	Time:
Notes:	

Visit assessments



Blood test



Urine test



Physical exam



Changes in your health



Neurological exam



Other medications



Vital signs

If you cannot make your appointment, please call your study team. They will help you reschedule.

Study visit 9

(Week 48) – Clinic visit

Date:	Time:
Notes:	

Visit assessments



Weight



MRI scan



Pregnancy test
(if applicable)



Lumbar puncture/study
drug administration



Blood test



Questions about
your health



Physical exam



Questionnaires



Neurological exam



Changes in your health



ECG test



Other medications



Vital signs



Follow-up phone call










Urine test

Study visit 10

(Week 54) – Clinic visit

Date:	Time:
Notes:	

Visit assessments













-  Blood test
-  Urine test
-  Physical exam
-  Changes in your health
-  Neurological exam
-  Other medications
-  Vital signs

Study visit 11

(Week 60) – Clinic visit

Date:	Time:
Notes:	

Visit assessments

-  Weight
-  Urine test
-  Pregnancy test (if applicable)
-  Lumbar puncture/study drug administration
-  Blood test
-  Questionnaires
-  Physical exam
-  Changes in your health
-  Neurological exam
-  Other medications
-  Vital signs
-  Follow-up phone call








If you cannot make your appointment, please call your study team. They will help you reschedule.

Study visit 12

(Week 66) – Clinic visit

Date:	Time:
Notes:	

Visit assessments

-  Blood test
-  Urine test
-  Physical exam
-  Changes in your health
-  Neurological exam
-  Other medications
-  Vital signs













If you cannot make your appointment, please call your study team. They will help you reschedule.

Study visit 13

(Week 72) – End of treatment (EOT) visit

Date:	Time:
Notes:	

Visit assessments











-  Weight
-  Urine test
-  Pregnancy test (if applicable)
-  Lumbar puncture/study drug administration
-  Blood test (if applicable)
-  Questionnaires
-  Physical exam
-  Changes in your health
-  Neurological exam
-  Other medications
-  Vital signs
-  Follow-up phone call

Depending on your study site, you may have a urine or blood test during this visit. Your study team will let you know if these assessments apply to you.

End of study/early termination visit

Date:	Time:
Notes:	

Visit assessments

-  Pregnancy test (if applicable)
-  MRI scan
-  Physical exam
-  Questions about your health
-  Neurological exam
-  Questionnaires
-  ECG test
-  Changes in your health
-  Vital signs
-  Other medications





If you cannot make your appointment, please call your study team. They will help you reschedule.

Unscheduled visit

(For change in Alzheimer’s disease medication)

Date:	Time:
Notes:	

Visit assessments

-  Questions about your health
-  Questionnaires
-  Changes in your health
-  Other medications








You will have an unscheduled visit before you start, change, or discontinue any of your Alzheimer’s disease medication. During this visit, we may check for changes in your health and ask you questions about your health.

Follow-up visit 1

Clinic visit

Date:	Time:
Notes:	

Visit assessments

-  Blood test
-  Questionnaires
-  Physical exam
-  Changes in your health
-  Neurological exam
-  Other medications
-  Vital signs



If you cannot make your appointment, please call your study team. They will help you reschedule.

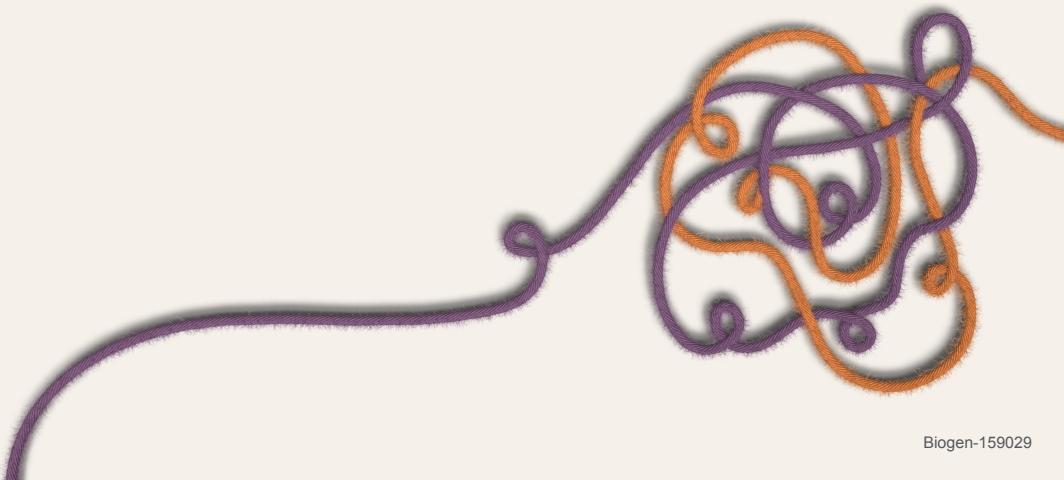
Follow-up visit 2

Telephone call

Date:	Time:
Notes:	

Visit assessments

-  Changes in your health
-  Other medications



Notes:

Notes:

Thank you for your continued participation in the CELIA clinical trial

Because of you, we will continue weaving new possibilities in Alzheimer's disease research. Please contact your study team for any additional information or questions about study visits.

[STUDY TEAM CONTACT DETAILS]

For more information about clinical trials and Biogen's research in Alzheimer's disease, visit [**BiogenTrialLink.com**](https://www.biogen.com/clinicaltrials).