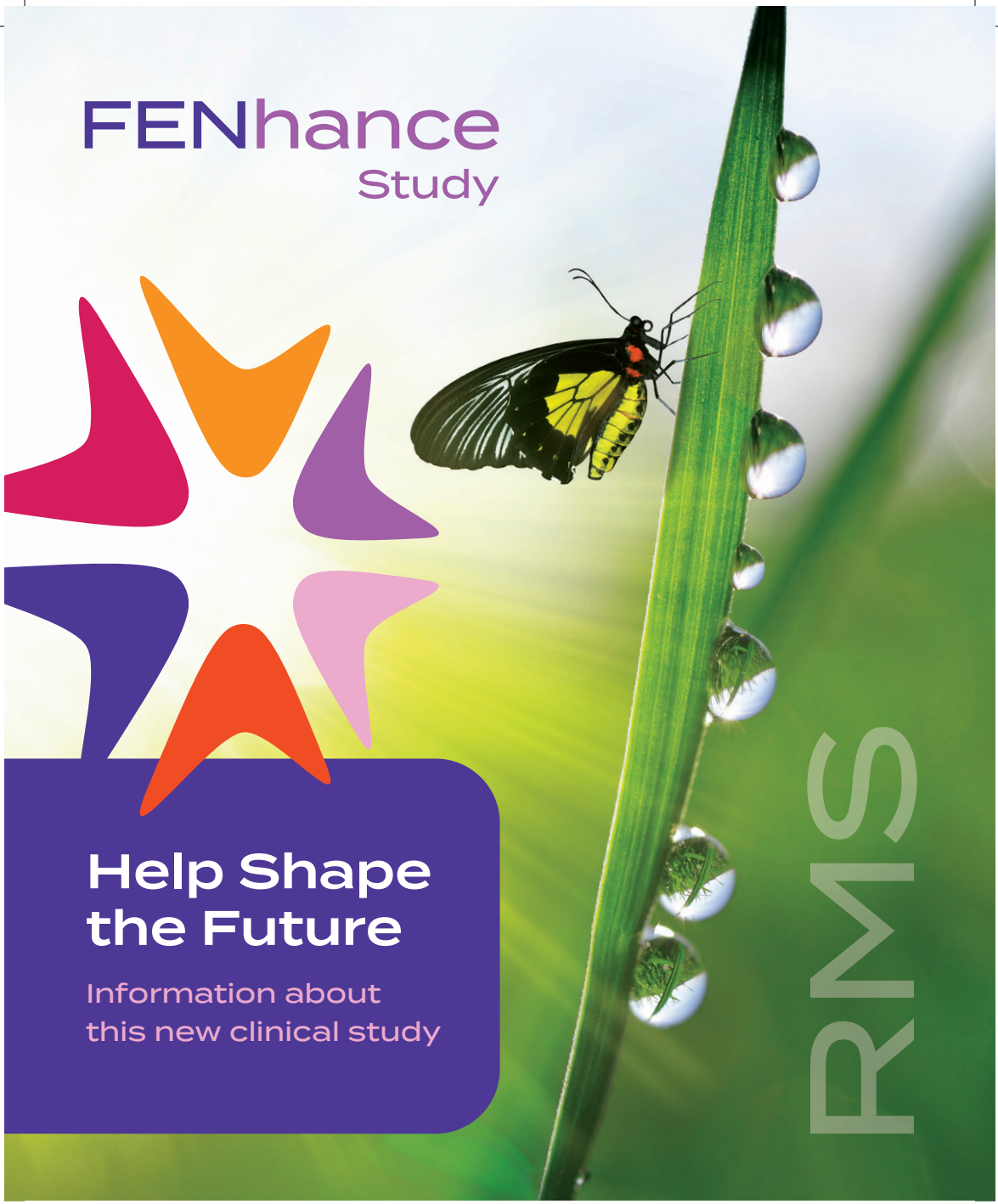
FENhance Study



Help Shape the Future

Information about this new clinical study

RMS

Genentech
A Member of the Roche Group

Roche

Help shape the future of RMS treatment!

At Roche, we recognize it takes courage to live with the unpredictability that is Relapsing Multiple Sclerosis (RMS). While many treatments have been approved for RMS, there is an unmet need for a treatment that may not only reduce MS disability and relapses, but may also slow the progression of the disease. That's why we're conducting the FENhance Study—we want to see if our investigational study drug can be a safe and effective treatment option for RMS. We're looking for approximately 1500 people to actively help advance the treatment of RMS. You may qualify if you:

- **Are between 18 and 55 years old**
- **Have been diagnosed with RMS**

This brochure will tell you about clinical research in general, explain why this study is being conducted and describe what taking part would involve. If you have any questions or would like to learn more please don't hesitate to contact us using the details on the last page.

What is a clinical study?

A clinical study (also known as a clinical trial) is a carefully controlled scientific investigation that helps us answer questions about an investigational drug, such as:

- **Is it safe?**
- **Does it work?**
- **Does it work better than another treatment?**

Hundreds of thousands of people all around the world take part in clinical trials every year.

The results of these studies must be approved by health authorities before a drug can be used by the general public. In fact, every drug that you have ever taken will have been investigated in clinical trials that were only possible because of their participants.

What will this study involve?

The study will last for approximately 2 years*, as outlined below:

Screening period

Up to 1 month

We'll carry out some tests to make sure that the study is right for you.

Double-blind treatment period

*Approximately 2 years**

Participants will be randomly assigned to receive either:

- The investigational study drug *(50% chance)*

or

- The approved comparator drug *(50% chance)*

Safety follow-up period

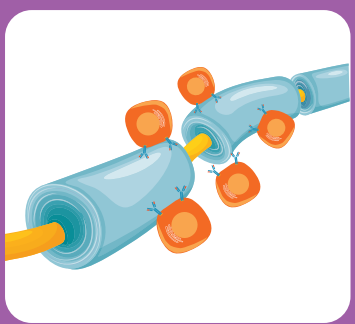
Approximately 8 weeks

We'll continue to monitor participants' health and condition.

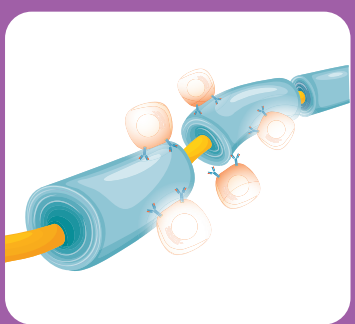
*Unless participants are withdrawn from the study for any reason.

About the investigational drug

The immune system is a complex network of cells that work together to protect the body from harmful substances



B cells are one component of this network. They produce antibodies to help the body fight harmful substances, but in some autoimmune conditions, such as multiple sclerosis (and RMS), B cells can overreact and and cause harm.



The investigational study drug is designed to work by suppressing these B cells

How are the study drugs given?

The investigational drug will be taken by mouth, 2 pills for each dose, twice a day.

The approved comparator drug will be taken by mouth, 1 pill for each dose, once a day.

What does 'double-blind' mean?

This study's treatment period is 'double-blind'. This means that neither participants nor the study doctor will know which drug participants are receiving. This helps us remove any bias and be sure that any differences we see are due to the investigational study drug and not some other factor, such as increased health monitoring.

How will participants' health be monitored?

During the study, participants will need to visit a study clinic at least 15 times, including a screening and follow-up visit (unless for any reason they leave the study early). This is so that we can monitor their general health and see how they are responding to their assigned study drug. Health assessments will vary between visits, but may include:

Blood tests

Urine tests

Physical examinations

Magnetic resonance imaging (MRI)

Neurological examinations

Questionnaires

Multiple sclerosis review tests

For the first 6 months of the study, participants will need to attend the study clinic visits every 4 weeks. Following this they will only need to attend the study clinic every 12 weeks until the end of the double-blind treatment period. Participants may be required to attend more frequent clinic visits for additional blood draws depending on local requirements. They will also have telephone interviews approximately every 6 weeks between study clinic visits so that we can monitor participants' health.

Will participants need to pay for anything?

No. Participants will not have to pay for the study drugs or any study-related assessments. Reimbursement for travel costs may be available as well.

Can participants change their minds?

Yes. As a volunteer, participants can change their mind and leave the study at any time without any impact on their regular healthcare.

How can I learn more?

If you have any questions or would like to find out more, please contact the study team. They will be happy to help.

Study team contact details:

We invite you to contact us with any questions or concerns about our thoughtfully designed FENhance Study. We look forward to speaking with you.

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FENhance Study

Study ID Numbers: GN41851 (FENhance 1), GN42272 (FENhance 2). FENhance_Patient brochure_v2_04Feb21_Master