Frequently Asked Questions for Members of the Public

I am already several months pregnant. Can I still enroll in the Registry?
Yes, you can enroll in the Registry at any time during your pregnancy.
Ideally, the Registry would like to enroll women before they reach the 16th week of their pregnancies. You can enroll in the Registry if you had taken fingolimod up to 8 weeks before your last menstrual period or for anytime during your pregnancy.

What do I do if I have a question or a concern about participating in the Registry?
For more information about the Gilenya Pregnancy Registry, please contact your health care provider. In case your health care provider is not participating in the registry, they can contact Quintiles Outcome group, the research organization managing this registry, which can provide them with more information. Contact information is provided in this document.

I am a participant in the Gilenya Pregnancy Registry, but I've recently moved address. Can I still participate?
Yes, you can still participate. Please inform your health care provider of your move at your earliest convenience.
If you have a new healthcare professional as a result of this move, please also provide their contact details to Quintiles Outcome, the Contract Research Organization which is running this registry. Quintiles Outcome, will contact them, in order to follow-up your participation into the registry.

I am not participating in the registry, but I would like to report a possible side effect, what should I do?
In case of any side effects, please contact your health care provider directly, they will advise you what to do and will be responsible for reporting the event.

Frequently Asked Questions for Healthcare Professionals

What do I do if I have a question or a concern about participating in the Registry?

To learn more about the registry, to register a patient or to participate as a site please contact Quintiles Outcome, the research organization managing this registry. Contact details including local toll free numbers can be found in the 'Contact Us' section on the website or send an e- mail to gpr@quintiles.com/gpr@IQVIA.com.

Who is the registry sponsor?
The Gilenya Pregnancy Registry is sponsored by Novartis Pharma AG.

How many patients will be enrolled?
The Gilenya Pregnancy Registry plans to enroll up to 500 patients worldwide.

Are you recruiting controls? How?
The registry does not include a control group.
The frequency of adverse outcomes for mother and child will be compared to external comparison groups i.e. EUROCAT for European data, MACDP (CDC) for US data.

What does the Scientific Advisory / Steering Committee do?
The Advisory Committee of the registry has been involved in protocol and CRF (Case Report Form) development. The Steering Committee is actively supporting the registry team to ensure the scientific integrity and is overseeing the progress of the registry.

Is the registry approved by an ethics committee?
Depending on local regulations, the registry protocol will be submitted to a local ethics committee prior to enrolling patients in a participating country.