

# GILENYA<sup>™</sup> Pregnancy Registry

---

## **Patient Frequently Asked Questions**

### **How do I know if I am eligible to participate in the Registry?**

You are eligible to participate in the registry if:

- You are currently pregnant and you have used fingolimod during pregnancy or up to 8 weeks before your last menstrual period.

AND

- You are willing to allow your health care professionals to provide medical information about you and your baby to the registry.

### **Who do I contact if I have a question or a concern about participating in the Registry?**

Contact IQVIA by calling 1-877-598-7237 or by sending an e-mail to [gpr@quintiles.com](mailto:gpr@quintiles.com) / [gpr@IQVIA.com](mailto:gpr@IQVIA.com).

### **How do I report an adverse event?**

If you need to report an adverse event, please contact your health care professionals. In addition, you may report negative side effects to FDA by calling 1-800-FDA-1088 or visiting [www.fda.gov/medwatch](http://www.fda.gov/medwatch)

### **Is compensation provided for participants?**

Compensation is not provided for registry participants.

### **How do I update my contact information?**

Contact IQVIA by calling 1-877-598-7237 or by sending an e-mail to [gpr@quintiles.com](mailto:gpr@quintiles.com) / [gpr@IQVIA.com](mailto:gpr@IQVIA.com).

### **Where do I find more information about fingolimod?**

Please visit [www.gilenya.com](http://www.gilenya.com)

## **Physician Frequently Asked Questions**

### **Who is IQVIA?**

IQVIA is a leading research provider for patient registries who will manage the registry on behalf of Novartis Pharmaceuticals Corporation. They will collect information related to fingolimod exposure and maternal, fetal, and infant outcomes.

### **Who do I contact if I have a question or a concern about the Registry?**

Contact IQVIA by calling 1-877-598-7237 or by sending an e-mail to [gpr@quintiles.com](mailto:gpr@quintiles.com) / [gpr@IQVIA.com](mailto:gpr@IQVIA.com).

### **How is patient data being collected?**

IQVIA will provide you with more information on how patient data are being collected in the registry, as well as the procedure to follow in order to become involved. Physicians are encouraged to enroll pregnant patients or pregnant women may enroll themselves in the GILENYA Pregnancy Registry by calling 1-877-598-7237 or by sending an e-mail to [gpr@quintiles.com](mailto:gpr@quintiles.com) / [gpr@IQVIA.com](mailto:gpr@IQVIA.com).

### **How many patients will be enrolled and what is the enrollment period?**

The Registry plans to enroll approximately 500 pregnant women.

**Are controls included in the Registry?**

The current protocol does not include a control group.

The frequency of birth defects will be compared to external comparison groups and if available data collected by external investigators including data made available from other registries that include pregnancy exposure and IQVIA information.

GILENYA is a registered trademark of Novartis AG.



Novartis Pharmaceuticals Corporation  
East Hanover, New Jersey 07936-1080

© 2020 Novartis

2/20 GYA-1385864