REGENERON®

More Information on Personal Data Collection as it relates to Adverse Event (AE) Reporting and REGENERON's Pharmacovigilance Activities

What is Pharmacovigilance?

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse events or any other medicine-related problem.

REGENERON collects Personal Data when you or a third party provide us with information in relation to an Adverse Event that affected you or someone else.

REGENERON will only collect the minimum data required for the purposes of fulfilling our pharmacovigilance obligations, as well as our legal requirements. This information is only processed where relevant and necessary. Some of this information is considered by law to be "sensitive personal data."

(a) Patient (Subject of the Adverse Event report)

The personal data that we may collect about you when you are the **Patient (Subject of an Adverse Event report)** includes, but is not limited to, the information below, if permissible under applicable law:

- Patient ID, Initials, and/or First/Last Name
- Contact Details (which may include address, email address, phone number)
- Social Media handle
- Age and/or Age Group
- Full or Partial Date of Birth
- Sex at birth (the sex that a person has or was assigned to at birth)
- Gender, current gender (how the person thinks of themself)
- Weight and Height
- Ethnicity
- Race
- Pregnancy information, when applicable
- Request for authorization to contact your Health Care Professional to obtain their assessment/opinion regarding the Adverse Event.
- Suspect Product, including start/stop dates, duration, dosing, route of administration, lot/batch/serial number, indication, availability of product for return.
- Medical history, including past medication history.
- Concurrent medication: Details of other medicines or remedies you are taking or were taking at the time of the reaction, including the dosage you have been taking or were prescribed, the period of time you were taking that medicine, the

reason you have been taking that medicine and any subsequent change to your regimen.

- Adverse Event information including:
  - Diagnosis including special situations (i.e., medication errors, misuse, occupational exposure, etc.)
  - Symptoms
  - Event onset date, resolution date (if any), and outcome
  - Course and details about the Adverse Event
  - Treatment received
  - Hospitalization details relevant to the Adverse Event
  - Long-term effects the reaction caused to your health
  - Procedures and/or tests results relevant to the Adverse Event (i.e., laboratory / imaging reports).

(b) Reporter(s)

A Reporter is an individual (e.g., patient/healthcare professional) who reports the facts about the Adverse Event.

Pharmacovigilance laws require us to ensure that Adverse Events are traceable and available for follow-up. As a result, we must keep sufficient information to allow us to make contact once we have received the report. The personal data we may collect is outlined below:

- Name
- Contact details (which may include address, email address, phone number)
- Social media handle
- Occupation
- Profession (i.e., Healthcare Professional vs. Non-Healthcare Professional)
- Professional qualifications
- Relationship with the Subject of the Adverse Event Report

How Do We Use and Share This Information?

As part of meeting our pharmacovigilance obligations, we may use and share your Personal Data to:

- Investigate the Adverse Event
- Contact you for further information about the Adverse Event you reported
- Collate the information about the Adverse Event with information about other Adverse Events received by REGENERON to analyze the safety of a batch, REGENERON product or active ingredient as a whole.

- Provide mandatory reports to National and/or Regional Authorities so that they can analyze the safety of a batch, REGENERON product, active ingredient as a whole alongside reports from other sources.

Who Do We Share the Information This Information With?

Personal data collected from you in connection with our Pharmacovigilance obligations may also be shared with other pharmaceutical companies, including those who are our co-marketing, co-distributing, or other Collaborators, where pharmacovigilance obligations for a product require such exchange of safety information.

We share information with National and/or Regional Authorities, such as but not limited to, the European Medicines Agency (EMA) and the Food and Drug Administration (FDA) in accordance with pharmacovigilance laws. We are unable to control their use of shared information, however, note that in these circumstances, we do not share information that directly identifies any individual (such as names or contact information). We only share pseudonymized information. Pseudonymization protects sensitive data by replacing personal identifiers with an alias. One example would be the replacement of a Patient Name (e.g. Jane Doe) with a Patient Identification Number (12345).

Lastly, we may publish information about Adverse Events (such as scientific literature articles, case studies and summaries); in this case, we remove personal identifiers from any publications so that no individual can be identified.