Further information on data protection

Version 1.0, 21 April 2022

Oriola study number 1121
(Survey)

The purpose of the survey is to map the experiences of persons who use self-injected biological medicines, particularly biosimilars, as well as their views on the use of the medicine and the instructions they have received. The goals of the survey include finding out what kind of views patients have on the quality of and need for instructions and what kind of guidance they want for the use of self-injected medicines. The survey is funded by Viatris Oy and carried out by Oriola Finland Oy.

The survey is anonymous by design, and there will be no personal data or direct personal identifiers available that would allow linking the data to a specific person. Thus, the study does not meet the criteria specified in the EU General Data Protection Regulation. Although no actual privacy statement is needed, this document has been created in order to describe the data processing that takes place in the study. Responding to the survey is voluntary.

1A CONTROLLERS

The controller of the study register is the sponsor of the study:

- Viatris Oy, Vaisalantie 2–8, 02130 Espoo, Finland

Party carrying out the study and processing the register data:

- Oriola Finland Oy, Orionintie 5, 02200 Espoo, Finland

1B PARTIES INVOLVED IN THE STUDY, PERFORMED AS A JOINT INITIATIVE, AND DIVISION OF RESPONSIBILITIES

The study sponsor is the controller of the study register. Both the controller and the party processing the register data are responsible for data management, data analysis and reporting.

The study register is anonymous and contains no direct identifiers or other data that would allow linking the collected data to individual subjects.

The study is carried out mainly in Oriola's research pharmacies using iPads. The Internet link for the survey can also be shared via partner pharmacies which are not part of the research pharmacy network, or via patient organisations.

The party carrying out the study will report any medicine-related adverse effect reports to the study sponsor as required by law.

1C NATIONAL COORDINATOR OF THE STUDY OR PERSON RESPONSIBLE FOR REGISTER-RELATED MATTERS

Tuire Prami, tuire.prami@oriola.com

1D PERSONNEL CONDUCTING THE SURVEY

- Viatris personnel participating in the study
- Oriola personnel participating in the study
- Pharmacy and patient organisation personnel participating in the study

2. CONTACT DETAILS IN MATTERS RELATING TO THE REGISTER

Oriola Finland Oy
Orionintie 5, 02200 ESPOO, Finland
Tel.: +358 10 4398 255
E-mail: tutkimus@oriola.com

3. NAME OF THE STUDY REGISTER

Oriola 1121: Biosimilars survey

4 PURPOSE OF DATA PROCESSING

Purpose of the processing: The purpose of this study is to find out the views and experiences of anonymous persons in Finland who are using a biosimilar or the corresponding originator product concerning instructions they have received for the use of the medicinal product.

Scope of the study: Individuals aged at least 18 years using self-injected biosimilars or the corresponding originator product (adalimumab, etanercept, filgrastim and pegfilgrastim, among others).

Number of subjects: approximately 200 survey respondents

Duration of the study: Data collection for the survey begins in May 2022 and is estimated to end in September 2022. See also section 9.

5 STUDY DATA CONTENT

Data collected from voluntary respondents: Gender, age group, illnesses and medications, the hospital district responsible for the respondent's care, and the opinions and experiences of the respondents in relation to the instructions they have received for the use of the self-injected biosimilar or the corresponding originator product.

6 STUDY DATA SOURCES

Survey: a questionnaire completed electronically by subjects

The survey respondents will be informed about the processing of the data before participating in the study, and they will be told that the survey is completely anonymous.

7 DISCLOSURE AND TRANSFER OF PERSONAL DATA OUTSIDE THE EU AND EEA

The data will not be transferred outside the EU or EEA.

8 PRINCIPLES OF REGISTER PROTECTION

The electronically processed data are protected using firewalls, passwords and other technical measures. The databases and their backups are located in locked premises. Each user has a dedicated username and password for systems that contain study-related electronic material. The data are only processed by persons who have the right to process the data because of their working duties.

9 DURATION OF STUDY REGISTER STORAGE

The survey data collected through questionnaires will be stored as long as necessary for the survey. However, the survey data will be destroyed no later than three years after they have been stored.

10 RIGHTS OF THE DATA SUBJECT

This register does not collect any such data that would identify a person and allow the recognition of an individual respondent. The right to erasure of data, as mentioned in the EU GDPR, thus does not apply in this survey or in the register formed based on it.

Subjects who have any other questions related to the rights of the data subject are invited to contact the party processing the register data, see sections 1A and 2. The subjects also have the right to lodge a complaint with a supervisory authority; see Section 12.

11 DATA PROTECTION OFFICERS AT THE ORGANISATIONS TAKING PART IN THE STUDY

- Viatris: Dataprivacy@viatris.com
- Oriola: GDPR-DPO@oriola.com

12 RIGHT TO LODGE A COMPLAINT WITH A SUPERVISORY AUTHORITY

If the data subject considers that the processing of their personal data infringes the EU GDPR, they have the right to lodge a complaint with a supervisory authority, in particular in the EU member state of their habitual residence, place of work or the place of the alleged infringement.

Details of the supervisory authority: Office of the Data Protection Ombudsman, Lintulahdenkuja 4, 00530 Helsinki, Finland
Telephone exchange: +358 29 566 6700. E-mail: tietosuoja@om.fi