

DATA PROTECTION IN THE CONTEXT OF THE IQED PROJECT

This letter is designed to inform you about the use of pseudonymized data in the context of the IQED project, a project of Sciensano that aims to study the epidemiology of diabetes and monitor and improve the quality of care for people living with diabetes and treated with intensive insulin therapy in Belgium.

Persons to whom this message concerns:

- All persons having signed the “Overeenkomst inzake zelfregulatie van diabetes-mellitus-patiënten - Convention en matière d'autogestion de patients atteints de diabète sucré.”
- All persons living with diabetes on intensive insulin therapy, followed in specialized diabetes centers.

Why collecting data in the context of the IQED project?

Since 1988, a multidisciplinary approach has been put in place to care for people living with diabetes. The Belgian diabetes centers can conclude a rehabilitation agreement (“convention”). Beneficiaries are people living with diabetes on intensive insulin therapy who are followed in the context of the convention.

Since 2001, article 17 of the convention agreement stipulates that each hospital participates in a data collection initiative for epidemiological and quality improvement purposes; the Initiative for Quality improvement and Epidemiology in Diabetes (“IQED”). Sciensano was entrusted with the scientific and practical management of this initiative in collaboration with a multidisciplinary scientific council composed of several Belgian health care professionals (Group of Experts) with specific experience in the field.

The IQED project is studying the quality of diabetes care in the context of the convention. The project has two objectives. The primary aim of the project is to conduct an audit of the quality of care provided to people living with diabetes and to promote quality improvement among health care providers. To achieve this objective, the performance of the hospitals is anonymously compared (“benchmarking”). Based on this comparison, the hospitals can determine their strengths and weaknesses compared to the national average. This project allows the hospitals to evaluate themselves, compare their respective performances and improve the care provided to people living with diabetes through the development of quality circles.

In a second aim, the IQED project analyzes the evolution and impact of diabetes healthcare based on the collected data and studies diabetes from an epidemiological point of view.

How will this data collection take place within Sciensano?

The personal data collected in the context of the IQED project comes from both the National Register and the patient's medical file at the hospital. Each diabetes center registers every 2 years data of a sample of minimum 10% of their total number of patients followed in the convention, in a secure way through the HealthData.be platform.

Only data necessary for the aims of the IQED project will be collected. It is crucial to note here that only pseudonymized data will be stored. This means that the researchers at Sciensano will not be able to identify you. Your name, national register number and address are never available for the researchers.

The following data will be collected and stored in the HealthData data warehouse at Sciensano:

- Data Source National Registry: identification number of the Belgian social security system (NISS, Sciensano only receives the pseudonymized code), demographical data (sex, date of birth, region and date of death).
- Data Source Medical record: identification number of the Belgian social security system (NISS, Sciensano only receives the pseudonymized code), demographical data (sex, date of birth, place of residence and date of death), date of onset diabetes, date of onset of treatment, medical history, smoking status, weight, length, intermediate outcomes and complications, examinations and results, glucose management and treatment.

The registration of the above mentioned data has been previously approved by a) the Sectoral Committee of Social Security and Health and b) the Ministry of Internal Affairs.

Who is responsible for the processing of the data?

Sciensano and RIZIV/INAMI are responsible for the processing of the data. The processing is based on the grounds of public interest (art. 6.1 (e) of the General Data Protection Regulation (GDPR)) and in particular for data concerning health, for reasons of public interest in the areas of public health and scientific research (art. 9.2 (i), of the GDPR).

Concerning the legal framework of the data processing, we refer you to the "Wet van 25 februari 2018 tot oprichting van Sciensano" (only available in French and Dutch). This law states that Sciensano has to process data in order to achieve its activities regarding the creation of knowledge to support healthcare.

The processing of data is done by authorized persons, under supervision of the project coordinator. The processing is technically supported by the HealthData platform.

Who has access to these data?

Researchers at Sciensano involved in the IQED project have access to the pseudonymized data. Strict user access control has been implemented through procedural and technical measures.

Sciensano can share anonymous or pseudonymized data with other scientists in the framework of national, European and international collaborations. The persons/institutions with whom information will be shared, will also not be able to identify you.

The anonymous or pseudonymized data might, amongst other, be shared with:

- The IQED-Foot project (Sciensano)
- The IQECAD project (Sciensano)
- Researchers of scientific projects in Belgium or abroad (after authorization from the Sectoral Committee of Social Security and Health).
- Pharmaceutical companies and health authorities (after authorization from the Sectoral Committee of Social Security and Health).

Reports with the national results of the IQED project will be made public and will be shared with partners and RIZIV/INAMI. These reports will only contain aggregated data (in tables), meaning that included persons will not be identifiable.

How long will the data be stored?

The pseudonymized data will be stored for 30 years after death, in accordance with the approval of the Sectoral Committee of Social Security and Health. After this period of 30 years, the data will be stored in an anonymous way.

What are your rights?

The General Data Protection Regulation (GDPR) gives persons whose data are processed a right of access, rectification, deletion, restriction and objection. Sciensano will only be able to respond to such requests if it is possible to link the data to the requesting individual. Since this project uses pseudonymized data, it is not possible to know which data belongs to which person, and Sciensano would therefore need additional information from the applicant.

Note: Exceptions to the right to data erasure, the right to limit processing and the right to object are possible in the public interest and for scientific research purposes (Article 17 §3 c) and d) GDPR; Article 21 § 1 GDPR and Article 21 § 6 GDPR).

The project obtained the approval of the Sectoral Committee of Social Security and Health to use these personal and medical data within a clearly defined framework.

If you believe you're rights have been violated, you can file a complaint with the Data Protection Authority (www.dataprotectionauthority.be).

More information?

For more information regarding the processing of your data, please contact the Data Protection Officer of Sciensano: dpo@sciensano.be.

For more information regarding the functioning and services of Sciensano, please visit our website: www.sciensano.be.

For more information regarding the functioning and the services of Healthdata, please visit: www.healthdata.be.