

DATA PROTECTION IN THE CONTEXT OF THE DIABETES DATA CELL PROJECT

This document aims to inform you about the linkage and use of pseudonymized data in the context of the Diabetes Data Cell project, a project of the Belgian Diabetes Forum (**BEDF**), **Sciensano**, the Academisch Centrum Voor Huisartsgeneeskunde (**ACHG-KUL**) and the Internutualistic Agency (**IMA**) that aims to create a data cell allowing to study the epidemiology of diabetes, and to monitor and improve the quality of care for people living with diabetes at all levels of the Belgian health care system.

This message concerns:

- All persons being treated within the “Overeenkomst inzake zelfregulatie van diabetes mellitus patiënten - Convention en matière d'autogestion de patients atteints de diabète sucré.”, and therefore eligible for inclusion in the data collection of the IQED (Initiative for Quality improvement and Epidemiology in Diabetes) project. More information on the IQED project is available via <https://www.sciensano.be/en/projects/initiative-quality-improvement-and-epidemiology-diabetes>
- All persons being treated within the “Overeenkomst inzake zelfregulatie van diabetes mellitus bij kinderen en adolescenten - Convention en matière d'autogestion du diabète sucré chez les enfants et les adolescents.” and having signed the informed consent form for inclusion in the data collection of the IQECAD (Initiative for Quality Improvement and Epidemiology in Children and Adolescents with Diabetes) project. More information on the IQECAD project is available via <https://www.sciensano.be/en/projects/initiative-quality-improvement-and-epidemiology-children-and-adolescents-diabetes>
- All persons living with diabetes, followed by a general practitioner enrolled in the Intego network of the ACHG-KUL. More information on the Intego network is available via <https://www.intego.be/>.

Why collecting data in the context of the Diabetes Data Cell project?

Diabetes is one of the leading non-communicable diseases (NCDs), with a rapidly increasing burden of disease. By 2021, about 537 million adults worldwide were living with diabetes. The associated healthcare costs are high and expected to increase due to ageing and multimorbidity, unhealthy lifestyles and reduced mortality due to better medical treatments. It is therefore crucial to accurately track the prevalence, risk factors, course and treatment of diabetes in order to adapt daily care and care organization at all levels to this increasing burden.

Diabetes care is however complex. It concerns many patients with various symptoms due to different types of diabetes and complications. Their treatment is multifaceted and complex, and distributed over several disciplines of healthcare professionals, including both medical and paramedical caregivers in primary and secondary line. In addition, the daily life of the patients is highly impacted by their condition (lifestyle changes, self-monitoring, frequent medical checkups, etc.). Collecting data in these circumstances by different health care professionals at different levels of healthcare and with patient input is a major challenge.

Today, there is no diabetes registry (or combination of registries or data collections) that covers all people with diabetes in Belgium. Health data are collected by different actors or for different purposes, cover only subpopulations or regions, or lack exact diagnoses. Combination of the individual data sources is mandatory in order:

- To be able to identify unique persons living with diabetes (albeit pseudonymized), and to more accurately determine diabetes prevalence in Belgium.
- To form an exhaustive picture of the quality of diabetes care provided across different levels of the health care system, and the related health care costs.
- To evaluate diabetes care.
- To longitudinally follow up persons throughout the health care system (“patient journey”).
- To identify populations at increased risk of developing diabetes complications.

How will this data collection take place?

To answer these research questions, Sciensano, in collaboration with the BEDF, the ACHG-KUL and IMA, launched the Diabetes Data Cell project. The Diabetes Data Cell project will also be elaborated as a pilot project within the Joint Action on Cardiovascular Disease and Diabetes (JACARDI).

For the purpose of this project, no new data are collected, but existing databases are linked.

It is crucial to note that only pseudonymized data will be linked. This means that the involved researchers will not be able to identify you. Your name, national register number, date of birth and address are not available to the researchers. Only a selection of data necessary for this project will be used from the existing databases.

The following data will be used from the, already existing, databases mentioned below:

- Database of IQED and IQECAD: identification number of the Belgian social security system (NISS, pseudonymized), demographical data (sex, date of birth, region and date of death), date of onset diabetes, date of onset treatment, anthropometric data, lab results, treatment, results of care and complications.
- Database of Intego: identification number of the Belgian social security system (NISS, pseudonymized), demographical data (sex, date of birth, region and date of death), date of onset treatment, anthropometric data, lab results, treatment, results of care and complications.
- Database of IMA: identification number of the Belgian social security system (NISS, pseudonymized), data on healthcare use and reimbursement status of the Belgian citizens selected in the clinical databases IQED, IQECAD and Intego.

The registration of data in each of the above mentioned databases has been previously approved by the competent authorities.

Who is responsible for the processing of the data?

Sciensano, ACHG-KUL and IMA are jointly 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 (art. 9.2 (i), of the GDPR).

Concerning the legal framework of the data processing, we refer you to:

- Article 4 of the “Wet van 25 februari 2018 tot oprichting van Sciensano / 25 FEVRIER 2018. – Loi de 25 février 2018 portant création de 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 the Intego data is required for scientific research and is done according to Article 9.2(i) of the General Data Protection Regulation (GDPR).
- Articles 278 till 281 of the “Programmawet van 24/12/2002”, and articles 3a and b of the “Wet van 6 augustus 1990” concerning the legal tasks and obligations of the IMA.

The processing of data is done by authorized persons, under supervision of a medical doctor of Sciensano (Dr. Karin De Ridder), ACHG-KUL (Prof. Dr. Bert Vaes) and IMA (Dr. Ann Ceuppens). The processing is technically supported by the HealthData.be platform. The linked pseudonymized data will be stored in the IMA data warehouse.

Who has access to these data?

The involved researchers at Sciensano, ACHG-KUL and IMA have access to the linked pseudonymized data. Strict user access control has been implemented through procedural and technical measures.

Sciensano, ACHG-KUL and IMA can share anonymized or pseudonymized data with other scientists in the framework of national, European and international collaborations. Where applicable, such reuse will

require approval from the Information Security Committee. The persons/institutions with whom information will be shared, will also not be able to identify you.

Reports and scientific publications with the results of the Diabetes Data Cell project will be made publicly available and will be shared with partners. These reports will only contain aggregated data (in text, tables and graphs), meaning that included persons will not be identifiable.

How long will the data be stored?

The pseudonymized data will be stored 10 years, in accordance with the requested approval of the Information Security Committee.

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, ACHG-KUL and IMA will only be able to respond to such requests if it is possible to link the data to the requesting individual. Since this project links pseudonymized data, it is not possible to know which data belongs to which person, and Sciensano, ACHG-KUL and IMA would therefore need additional information from the applicant.

The project is requesting the approval of the Information Security Committee to use these personal and medical data within a clearly defined framework.

If you believe your 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
- the responsible of ACHG-KUL: intego@kuleuven.be
- the Data Protection Officer of IMA: dpo@intermut.be

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

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

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

For more information regarding the functioning and the services of the IMA, please visit: www.aim-ima.be.