

DATA PROTECTION IN THE CONTEXT OF THE LINK-VACC PROJECT

This letter is designed to inform you about the linking and the use of pseudonymized data in the context of the LINK-VACC project, a project of Sciensano that aims to ensure the monitoring of COVID-19 vaccines in the phase following their marketing authorization (post-authorization surveillance).

Persons to whom this message concerns:

- All persons having received at least one dose of the COVID-19 vaccine in Belgium.
- All persons tested because of a suspicion of COVID-19 in Belgium.
- All medical doctors administering COVID-19 vaccines.

Why post-authorization surveillance?

All vaccines, including COVID-19 vaccines, are only allowed onto the European market after being evaluated as qualitative, safe and effective by the European Medicines Agency (EMA) in an extensive authorization procedure.

Nonetheless, when rolling-out a vaccination campaign with a newly registered vaccine, it remains very important to monitor a number of indicators in what is called post-authorization surveillance.

This surveillance is a public health priority and is recommended by the World Health Organization.

This post-authorization surveillance includes, amongst others:

- Measurement of uptake and coverage of the vaccination. This allows to estimate the percentage of the population (and of certain target groups) already vaccinated. This way suboptimal uptake in certain target groups can be identified.
- Estimation of vaccine effectiveness. This indicator tells us the degree in which vaccination is capable of preventing illness (infection, severe illness, death...). Pharmaceutical companies measure this as well (it is then called vaccine efficacy) in their clinical trials. However, the vaccine effectiveness measured in real-life circumstances may differ from the vaccine efficacy measured in these clinical trials that are typically run in strictly controlled settings. Moreover, mutations in the virus that emerge also affect the effectiveness of the vaccine.
- Continuous monitoring of the vaccine's safety. This allows to identify breakthrough cases (cases of COVID-19 in fully vaccinated individuals) and possible (rare) adverse events of vaccination.

How will this surveillance take place within Sciensano?

To allow this post-authorization surveillance, Sciensano launched the LINK-VACC project. For the purpose of this project, no new data are collected, but existing databased are linked. All necessary data for this surveillance are indeed already part of existing databases.

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

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

- **Vaccinnet**: demographical data (sex, age, postal code) of all persons to whom a COVID-19 vaccine has been administered in Belgium, data on the vaccinator, the vaccination site, the vaccine administered and the observed side effects.

- **HealthData COVID-19 database (or Database II Contacttracing)**: demographical data (sex, age, postal code) of all persons who had a COVID-19 test done in Belgium, data clarifying the reason for this test and test results, COVID-19 variant (if sequenced) and symptoms reported during contact tracing.
- **HealthData COVID-19 Clinic Database**: demographical data (sex, age, postal code) and clinical data (such as information on medical examinations, treatment, complications, hospital stay, ...) of all persons hospitalized with a confirmed COVID-19 infection in Belgium.
- **STATBEL**: demographical data (such as migration background, household status) and socio-economic data (such as level of education, employment status, income level) of all Belgian citizens who have received at least one COVID-19 vaccine and/or have been tested for COVID-19 in Belgium.
- **Database of the Intermutualistic Agency (IMA)**: data on comorbidities, reimbursed flu vaccination during the last flu season and reimbursement of relevant medication of all persons affiliated to a Belgian health insurance fund, and who have received at least one COVID-19 vaccine and/or have been tested for COVID-19 in Belgium.
- **Common Base Registry for Healthcare Actors (CoBRHA)**: demographical data (sex, age, postal code) of all persons who are registered as a healthcare worker in Belgium, profession, specialty, status (active or not).

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 is 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 the "*Loi de 22 décembre 2020 portant diverses mesures relatives aux tests antigéniques rapides et concernant l'enregistrement et le traitement de données relatives aux vaccinations dans le cadre de la lutte contre la pandémie de COVID-19 - Wet van 22 december 2020 houdende diverse maatregelen met betrekking tot snelle antigeentesten en de registratie en verwerking van gegevens betreffende vaccinaties in het kader van de strijd tegen de COVID-19-pandemie*" and the "*Arrêté royal de 24 décembre 2020 concernant l'enregistrement et le traitement de données relatives aux vaccinations contre la COVID-19 - Koninklijk besluit van 24 december 2020 betreffende de registratie en de verwerking van gegevens met betrekking tot vaccinaties tegen COVID-19*" (both only available in French and Dutch).

The processing of data is done by authorized persons, under supervision by the project coordinator. The processing is technically supported by the HealthData platform. The person responsible for the project coordination is: Dr. Joris van Loenhout.

Who has access to these data?

Researchers at Sciensano involved in the LINK-VACC project have access to the linked pseudonymized data.

Pseudonymized demographical data (only sex and age), data on the vaccinator and data concerning the administered vaccine in breakthrough cases, will also be shared with the Federal Agency for Medicines and Health Products (FAMHP), the competent agency for the monitoring of vaccine safety.

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 will, amongst other, be shared with:

- The European Centre for Disease Prevention and Control (ECDC).
- The World Health Organization (WHO).

Reports with the results of the surveillance will be made public and will be shared with partners and federal and regional ministries of public health. These reports will only contain aggregated data (in tables), so once again you will not be identifiable.

How long will the data be stored?

The pseudonymized data will be stored for 10 years, in accordance with the approval of the Sectoral Committee of Social Security and Health.

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 links pseudonymized data, it is not possible to know which data belongs to which person, and Sciensano would therefore need additional information from the applicant.

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.