

**PRIVACY POLICY/NOTICE
FOR SCIENTIFIC RESEARCH
EU General Data Protection Regulation
Art. 13 and 14
Date: 5/07/2024**

1. Data Controllers

Findata

Real World Genetics Oy, Y-tunnus: 3389814-4
Karjalankatu 10 B 27,
00520, Helsinki, Finland

Contact person in matters concerning the project:

Andrea Ganna
Karjalankatu 10 B 27, 00520, Helsinki
ag@realworldgenetics.com

2. Description of the study and the purposes of processing personal data

This research project aims to investigate the efficacy of SGLT2i and GLP1-RA medications in patients with and without chronic kidney disease (CKD) by analyzing real-world data from Finnish healthcare registries. The study will examine how various factors, such as demographic characteristics and pre-existing conditions, influence the effectiveness of treatments like SGLT2i and GLP1-RA on renal outcomes. By linking drug purchase records to clinical laboratory values and healthcare utilization data, we aim to quantify the response to these medications by changes in kidney function markers and to identify key risk factors that predict non-optimal treatment response. Other glucose-lowering agents will be used to understand how much the effects are specific to SGLT2i and GLP1-RA. The findings are expected to inform more personalized treatment strategies for managing patients with CKD or kidney function in patients with type 2 diabetes.

3. Parties and their responsibilities in research collaboration

Real World Genetics Oy is responsible for the study design, analysis and is the main applicant for data access. Real World Genetics Oy will be responsible for the data management and fulfillment of data controller's duties. Maze therapeutic sponsors the study and will help with study design, but will not have access to the data.

4. Principal investigator

Andrea Ganna
Karjalankatu 10 B 27, 00520, Helsinki

5. Contact details of the Data Protection Officer

Andrea Ganna
Karjalankatu 10 B 27, 00520, Helsinki
ag@realworldgenetics.com

6. Persons processing personal data in the study

Personal data will be processed by Andrea Ganna. Real Word Genetics might hire external individuals to carry out the analyses. These individuals will seek approval from FinData and their names will be added to the privacy notice and DPIA.

7. Name, nature and duration of the study

Name of the study: Predictors of poor response to blood glucose-lowering drugs in patients with and without chronic kidney disease

☒ One-time research ☐ Monitoring study/longitudinal study

Duration of the processing of personal data: The project duration is from the acquisition of registry data until 31.12.2028

8. Lawful basis of processing

Personal data is processed on the following basis, which is based on Article 6(1) of the General Data Protection Regulation:

- ☐ participant's consent
- ☐ compliance with a legal obligation to which the controller is subject
- ☐ performance of a task carried out in the public interest or in the exercise of official authority vested in the controller:
 - ☒ scientific or historical research purposes or statistical purposes
 - ☐ archiving of research materials or cultural heritage materials
- ☐ legitimate interests pursued by the controller or by a third party
 - description of the legitimate interest:

9. Personal data included in the research materials

The data from various registers will be linked using personal identity codes and then pseudonymized with a random key. Pseudonymization key will be stored by FinData.

In this study, we will use nationwide registries to identify all individuals who have ever purchased a blood glucose-lowering drug, excl. insulins (ATC code: A10B*) as well as those individuals who have purchased an agent acting on the renin-angiotensin system (ATC code: C09*) and aldosterone

antagonists and other potassium-sparing agents (ATC code: C03D*) at a pharmacy in Finland between 2013 and 2024 (or the last time the drug purchase register is updated at the time of data extraction). The population is around 1M individuals.

The research data includes information available from different data holders:

- Finnish Institute for Health and Welfare (THL)
 - Care Register for Health care (HILMO)
 - Register of Primary Health Care Visits (AvoHilmo)
- Statistics Finland (Tilastokeskus)
 - Cause of Death Register
- Social Insurance Institution of Finland (KELA)
 - Drug Purchases Register
 - Laboratoriovastaukset
- Helsinki University Hospital
 - HUS Potilaiden pituus, paino ja BMI
 - Database with blood pressure

10. Sensitive personal data

The following sensitive personal data will be processed in the study:

- ☐ Racial or ethnic origin
- ☐ Political opinions
- ☐ Religious or philosophical beliefs
- ☐ Trade union membership
- ☐ Genetic data
- ☐ Biometric data for the purpose of uniquely identifying a natural person
- ☒ Health
- ☐ A natural person's sex life or sexual orientation

Sensitive data is processed on the following basis, which is based on Article 9(2) of the General Data Protection Regulation:

- ☐ Consent of the participant
- ☒ Scientific or historical research purposes or statistical purposes
- ☐ The sensitive data has been made public by the participant
- ☐ Other: *Please clarify*

☐ Personal data relating to criminal convictions and offences or related security measures will be processed in the study.

11. Sources of personal data

The research data specified in section 9 of this notice are collected from registries that are part of 3 different data holders:

- Finnish Institute for Health and Welfare (THL)
- Statistics Finland (Tilastokeskus)
- Social Insurance Institution of Finland (KELA)
- Helsinki University Hospital (HUS)

12. Transfer and disclosure of the personal data to third parties

Personal data will not be transferred or disclosed to third parties. Only individuals approved by both Real World Genetics Oy and FinData have access to the research data.

13. Transfer or disclosure of personal data to countries outside the EU/European Economic Area

Personal data is only accessible remotely via FinData compliant system and cannot be transferred outside the computational system. Researchers will remotely access the data only if they are located within the EU/EEA or a country with adequate personal data protection based on the European Commission adequacy decision (Article 45 of the GDPR).

14. Automated decisions

No automated decisions will be made.

15. Safeguards to protect the personal data

☒ The data is confidential.

Protection of manual material:

Personal data processed in IT systems:

☒ username ☒ password ☒ logging ☒ access control
☐ other: (please specify)

Processing of direct identifiers:

☒ Direct identifiers will be removed in the analysis phase
☐ The material to be analysed includes direct identifiers. Reason: (reason for retention of direct identifiers)

16. Processing of personal data after the completion of the study

- ☒ The research material will be deleted
☐ The research material will be archived:
☐ without identifiers ☐ with identifiers

17. Your rights as a data subject and deviations from the rights

The contact person in matters concerning the rights of the participant is the person mentioned in section 1 of this notice.

Withdrawing your consent (Article 7 of the General Data Protection Regulation)

If the processing of your personal data is based on your consent, you have the right to withdraw your consent. The withdrawal of consent does not affect the lawfulness of processing based on consent before its withdrawal.

Right of access (Article 15 of the General Data Protection Regulation)

You have the right to obtain confirmation as to whether or not personal data concerning you is processed, and, where that is the case, what data is processed. You may also request a copy of the personal data undergoing processing.

Right to rectification (Article 16 of the General Data Protection Regulation)

You have the right to obtain rectification of inaccurate personal data.

Right to erasure (Article 17 of the General Data Protection Regulation)

You have the right to obtain erasure of your personal data where one of the following grounds applies:

- a) the personal data are no longer necessary in relation to the purposes for which they were collected or otherwise processed
- b) you withdraw consent on which the processing is based
- c) you object to the processing pursuant to (please see 'Right to object' below) and there are no overriding legitimate grounds for the processing
- d) the personal data have been unlawfully processed
- e) the personal data have to be erased for compliance with a legal obligation in Union or Member State law to which the University is subject

However, you have no right of erasure if such erasure is likely to render impossible or seriously impair the achievement of the objectives of the processing.

Right to restriction of processing (Article 18 of the General Data Protection Regulation)

You have the right to obtain restriction of processing where one of the following applies:

- a) the accuracy of the personal data is contested by you, for a period enabling the controller to verify the accuracy of the personal data
- b) the processing is unlawful and you oppose the erasure of the personal data and request the restriction of their use instead
- c) the controller no longer needs the personal data for the purposes of the processing, but they are required by you for the establishment, exercise or defence of legal claims
- d) you have objected to processing pending the verification whether the legitimate grounds of the controller override those of the data subject.

Right to data portability (Article 20 of the General Data Protection Regulation)

Where the lawful basis of your personal data is your consent or performance of a contract to which you are party, and the processing of personal data is carried out by automated means, you have the right to receive the personal data concerning you, which you have provided to the University, in a structured, commonly used and machine-readable format and have the right to transmit those data to another controller.

In exercising this right, you have the right to have the personal data transmitted directly from one controller to another, where technically feasible.

Right to object (Article 21 of the General Data Protection Regulation)

You have the right to object to processing of personal data concerning you if the lawful basis of processing is the performance of a task carried out in the public interest or in the exercise of official authority or the legitimate interests pursued by the controller or by a third party. In that case, the University may no longer process the personal data unless it demonstrates compelling legitimate grounds for the processing which override the interests, rights and freedoms of the data subject or for the establishment, exercise or defence of legal claims. The University may also continue the processing of your personal data where processing is necessary for the performance of a task carried out for reasons of public interest.

Deviation from the rights

The rights described in this section may be deviated from in certain situations to the extent the rights would render impossible or seriously impair the achievement of the objectives of processing personal data for scientific or historical research purposes or statistical purposes. The grounds for deviation are set forth in the General Data Protection Regulation and the Finnish Data Protection Act. The necessity of deviating from the rights will always be evaluated on a case by case basis.

Right to lodge a complaint

You have the right to lodge a complaint with the Data Protection Ombudsman's Office if you think your personal data has been processed in violation of applicable data protection laws.

Contact details:

Data Protection Ombudsman's Office (Tietosuojavaltuutetun toimisto)

Address: Ratapihantie 9, 6th floor, 00520 Helsinki

Postal address: B.O. Box 800, 00521 Helsinki

Tel. (switchboard): 029 56 66700

Fax: 029 56 66735

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