# FINErenone druG Utilization Study and assessment of Temporal changes following availability of different treatment options in patients with chronic kidney disease and type 2 diabetes (FINEGUST)

**First published:** 22/08/2022

**Last updated:** 04/09/2025

Study Finalised

## Administrative details

**EU PAS number**

EUPAS48148

**Study ID**

49285

**DARWIN EU® study**

No

**Study countries**

- ☐ Denmark
- ☐ Japan

- [ ] Netherlands
- [ ] Spain
- [ ] United Kingdom
- [ ] United States

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**Study description**

This is an observational study in people with chronic kidney disease (CKD) and type 2 diabetes (T2D) who have already started or will start one of the following treatments for T2D or CKD: Sodium-glucose cotransporter 2 inhibitors (SGLT2i), Glucagon-like peptide-1 receptor agonists (GLP-1 RA), Steroidal mineralocorticoid receptor antagonists (sMRA), Finerenone a non-steroidal mineralocorticoid receptor antagonist (nsMRA), Other nsMRA (only in Japan).
The main purpose of the study is to collect and describe characteristics of patients in each treatment group before and after finerenone became available.
To do this, the researchers will collect data on:
• Patient characteristics (e.g., age sex) of the participants
• Clinical characteristics (e.g., history of CKD and T2D, heart and liver health, other health problems) of the participants
• Treatments for T2D and CKD
• Other medications used Data will be grouped by type of treatment that is initiated (e.g., SGLT2i, a GLP-1 RA, a sMRA, finerenone, or other nsMRA).
Two time periods will be compared.
Period I is the time until finerenone became available in the respective country, starting from 2012 (2014 for Japan).
Period II will begin when finerenone becomes available in the respective country and will end at the end of the study (planned in September 2024). Researchers will also collect data on treatment patterns and changes in baseline characteristics in both time periods.
Existing health care data will be collected from various sources in six countries (e.g., Denmark, Japan, the Netherlands, Spain, UK, and US). Besides this data

collection, no further tests or examinations are planned in the study. The patients will receive their treatment as prescribed by their doctors during routine practice.

Each patient will be in the study from first use of one of the listed drug classes until:

• End of study

• The data are somehow no longer available

• The patient leaves or has to leave the study

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**Study status**

Finalised

# Research institutions and networks

## Institutions

### RTI Health Solutions (RTI-HS)

- ☐ France
- ☐ Spain
- ☐ Sweden
- ☐ United Kingdom
- ☐ United Kingdom (Northern Ireland)
- ☐ United States

**First published:** 21/04/2010

**Last updated:** 13/03/2025

**Institution** **Not-for-profit** **ENCePP partner**

## Optum

Germany

**First published:** 03/01/2012

**Last updated:** 07/02/2014

Institution | Outdated | Other | ENCePP partner

## Clinical Practice Research Datalink (CPRD)

United Kingdom

**First published:** 15/03/2010

**Last updated:** 17/01/2025

Institution | Laboratory/Research/Testing facility | ENCePP partner

## Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark

**First published:** 20/07/2021

**Last updated:** 02/04/2024

Institution | Educational Institution | ENCePP partner

## The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands

**First published:** 07/01/2022

**Last updated:** 19/12/2025

Institution | Non-Pharmaceutical company | ENCePP partner

## The Foundation for the Promotion of Health and Biomedical Research of Valencia Region (FISABIO)

Spain

**First published:** 01/02/2024

**Last updated:** 31/10/2025

Institution

## FISABIO Spain, The Japan Chronic Kidney Disease Database Extension Japan, Optum Clinformatics® DataMart US

# Contact details

**Study institution contact**

Bayer Clinical Trials BAYER AG clinical-trials-contact@bayer.com

**Study contact**

clinical-trials-contact@bayer.com

**Primary lead investigator**

Catherine Johannes

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 31/05/2022

Actual: 06/05/2022

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**Study start date**

Planned: 01/10/2022

Actual: 01/10/2022

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**Date of final study report**

Planned: 31/12/2024

Actual: 06/03/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Bayer AG

## Study protocol

21956_FINEGUST_Protocol_Redacted_v1.0_2022-05-30.pdf (812.13 KB)

## Regulatory

**Was the study required by a regulatory body?**

No

**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

**Study type:**

Non-interventional study

**Scope of the study:**

Drug utilisation

**Main study objective:**

The primary objective of this study is to describe baseline patient characteristics, comorbidities, and comedication of adult patients with CKD and T2D who initiate an SGLT2i, a GLP-1 RA, a MRA, or finerenone in each of 2 time periods corresponding to the finerenone pre-launch and post-launch dates.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Study drug International non-proprietary name (INN) or common name**

FINERENONE

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**Anatomical Therapeutic Chemical (ATC) code**

(C03DA05) finerenone

finerenone

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**Medical condition to be studied**

Chronic kidney disease

Type 2 diabetes mellitus

## Population studied

**Age groups**

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

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**Special population of interest**

Renal impaired

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**Estimated number of subjects**

50000

## Study design details

**Outcomes**

• Descriptive summary of baseline patient characteristics
• Descriptive summary of patient comorbidities
• Descriptive summary of patient comedications,
• Descriptive summary of changes over time in treatments in the new-user cohorts
• Descriptive summary of temporal changes in the baseline characteristics of medication-specific cohorts

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**Data analysis plan**

Descriptive analyses of patient characteristics and treatment patterns.

## Documents

**Study results**

21956_EU PAS Abstract_Redacted_V1_06_Mar_2025.pdf (187.71 KB)

**Study report**

21956_FINEGUST Final Report_v1.0_06 MAR 2025_for publication.pdf (5.76 MB)

# Data management

## ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

**Data source(s)**

Clinical Practice Research Datalink

PHARMO Data Network

**Data source(s), other**

Danish National Health Registers Denmark,

Valencia Health System Integrated Database Spain,

Japan Chronic Kidney Disease Database Extension Japan,

Optum Clinformatics® DataMart United States

**Data sources (types)**

Administrative healthcare records (e.g., claims)

Disease registry

Electronic healthcare records (EHR)

Other

**Data sources (types), other**

Prescription event monitoring

# Use of a Common Data Model (CDM)

**CDM mapping**

No

# Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

# Data characterisation

## Data characterisation conducted

No