

# FINE-REAL: Non-interventional study to collect real-world data and providing insights into the use of finerenone in routine clinical practice

**First published:** 05/04/2022

**Last updated:** 06/11/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS46493

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### Study ID

50075

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### DARWIN EU® study

No

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### Study countries

 Argentina

 Belgium

 Brazil

-  Canada
  -  China
  -  Denmark
  -  Germany
  -  Greece
  -  Korea, Republic of
  -  Mexico
  -  Netherlands
  -  Portugal
  -  Saudi Arabia
  -  Singapore
  -  Slovenia
  -  Switzerland
  -  Taiwan
  -  Thailand
  -  United States
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## **Study description**

The main purpose of the study is to learn more about treatment patterns in people with CKD and T2D who will start finerenone treatment as decided and prescribed by their doctor as part of their routine medical care. To answer this question, the researchers will collect data on:

- Clinical characteristics (e.g., history of CKD and T2D, blood pressure, heart health) of the participants
- Reasons for starting finerenone
- Reasons for stopping finerenone early
- How long participants have been taking finerenone (planned by their doctor compared to actual time it was taken)
- Dosing of finerenone
- Other medications used while taking finerenone

The researchers will also collect data on medical problems (called adverse events) that the participants may have during the study. All adverse events are collected, even if they might not be related to the study treatment. Hyperkalemia, a medical term used to describe

a potassium level in the blood that is higher than normal, is of special interest when finerenone is combined with some medications commonly taken to control blood pressure. Researchers want to know how often higher potassium levels occur, and when it leads to:

- Stopping finerenone treatment too early
- Dialysis (a medical procedure to filter the blood of extra water and waste)
- Care in a hospital

All data will come from medical records or from interviews study doctors will have with the participants during visits that take place during routine medical care. Participants in the US will be invited to provide voluntary blood and urine samples that could be analyzed later to better understand possible changes in protein or nucleic acid levels over time. Each participant will be in the study for 12 months. This time participating in the study may be shorter if their finerenone treatment is stopped early or the study comes to an end as planned in November 2025.

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### Study status

Ongoing

## Research institutions and networks

### Institutions

**Bayer AG**

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

**Last updated:** 01/02/2024

**Institution**

### Contact details

### **Study institution contact**

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

Study contact

[clinical-trials-contact@bayer.com](mailto:clinical-trials-contact@bayer.com)

### **Primary lead investigator**

Bayer Clinical Trials Contact BAYER AG

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 09/02/2022

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### **Study start date**

Planned: 08/06/2022

Actual: 13/06/2022

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### **Date of final study report**

Planned: 30/06/2028

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Bayer AG

## Study protocol

[21785 FINE-REAL\\_Protocol\\_V1.0\\_09 FEB 2022\\_Redacted.pdf](#) (716.86 KB)

[21785 FINE-REAL Protocol\\_V5.0\\_8Jul2024.pdf](#) (866.95 KB)

## Regulatory

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

No

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

Not applicable

## Other study registration identification numbers and links

NCT05348733

[NCT05348733](#)

## Methodological aspects

Study type

Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Main study objective:**

The primary objective in this study is to describe treatment patterns in participants with CKD and T2D treated with finerenone in routine clinical practice.

## 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**

Diabetic nephropathy

## 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**

4500

# Study design details

## **Outcomes**

1.Descriptive analysis of clinical characteristics of participants with CKD and T2D. 2.Descriptive summary of reasons for introducing & discontinuation of finerenone 3.Planned and actual duration of treatment with finerenone 4.Descriptive summary of dose & frequency of finerenone treatment. 5.Descriptive summary of secondary therapies used in participants with CKD and T2D, 1.Occurrence of adverse events (AEs) and serious adverse events (SAEs) 2.Occurrence of hyperkalemia, - leading to permanent study drug discontinuation. - leading to dialysis - leading to hospitalization

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## **Data analysis plan**

Statistical analyses will be of explorative and descriptive nature. The study is not intended to test pre-defined statistical hypotheses. All variables will be analyzed descriptively with appropriate statistical methods. All analyses will be

performed for the total study population (overall population) and separately for each participating country if patient numbers are sufficient and if required for local reasons. All analyses will be performed for the total study population (overall population) and separately for each participating country if patient numbers are sufficient and if required for local reasons. Interim analysis will consist of demographic and baseline data of patients enrolled as well as available safety data.

## 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 sources (types)

[Other](#)

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### Data sources (types), other

Prospective patient-based data collection

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No