iCaReMe Registry

International Diabetes Federation (IDF)
AstraZeneca

www.idf.org
iCaReMe Registry
Overall Plan and Phases

Global coverage
- Large cohort
- Heterogeneous population
- Standardized data collection form

Availability of the data for different publications
- Long follow-up
- Wide range of data

From DISCOVER to iCaReMe Registry: from T2D to a complete Cardio-Renal-Metabolism comprehension

- 2014-2019
  - 38 Countries
  - 16,000 people

- 2015-2025
  - First Global T2D Registry

- 2020-2025
  - iCaReMe 2020-2025: First Global Cardio-Renal Metabolic Registry

- 2022-2025
  - Towards a More Comprehensive Understanding
Background and Rational of iCaReMe Registry

Cardiovascular & Renal diseases remain the number one cause of death globally and constitute an enormous burden on patients, society and health care systems.

Type 2 diabetes (T2D) and hypertension (HTN) are the most common risk factors for heart and kidney-related complications, increasing the future risk of heart failure (HF) and chronic kidney diseases (CKD) which are associated with an increased cardiovascular death.

Real world Data on the prevalence, quality of care and outcomes of patients with these inter-related conditions are scarce on the global scale.

The iCaReMe Registry will address the unmet needs by providing data on:

- Characteristics of patients with T2D, HF, CKD and HTN from clinical practice across multiple care settings and multiple geographic regions – including those with limited availability of real-world data

- Quality of care, including management of risk factors and use of guideline directed therapies

- Long-term outcomes, including incidence of complications
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Study Design

The iCaReMe Registry (NCT03549754) prospective, investigator-led, multicentric, multinational, observational registry: Determining Management and Quality of Care of Patients With Type 2 Diabetes, Hypertension, Heart Failure and/or Chronic Kidney Disease

iCaReMe Registry collects standardized real-world patient data on a worldwide scale through HCPs, who will be the registry’s investigators.

Open globally to all HCPs/institutes with the following abilities:
- Availability of medical records
- Ability to conduct high quality real-world evidence studies and the ability to manage all regulations related to the site with this study

Key inclusion criteria:
- 18 years or older
- T2D, HTN, HF, CKD
- Provides written informed consent

Key exclusion criteria:
- Type 1 diabetes as primary condition
- Life-threatening co-morbidity with life expectancy shorter than 1 year
- Participation in an interventional trial

Primary objective:
To describe in patients with T2D and/or HTN and/or HF and/or CKD in real-world settings:
- Socio-demographic and clinical characteristics
- Disease management patterns for primary disease and comorbidities including screening, diagnosis and treatment approach
- Healthcare resource utilization
- Clinical outcomes

Secondary objectives:
- Determinants of disease HF & CKD Progression
- Determinants of uncontrolled T2D and HTN
- Determinant of microvascular and macrovascular complications
- Quality of care

The enrolment had started in February 2018 and will continue under iCaReMe Registry until December 2025
iCaReMe Registry

Governance

- Decision-making body
- Leadership and development of global publication plan
  - Analysis plans
  - Results interpretation
  - Data package sign-off
- Review of global publication proposal submissions
- Support regional and local priority activities as necessary

- Advisory role to the SC
  - Presentation of globally relevant publication proposals
- Contact point for NCs
- Accountability for approval of local publications
- Leadership and development of regional publication plan

- Receive country-level data packages
  - Advisory role to the RCs
  - Contact point for PPs
  - Accountability for local publications
  - Planning
  - Oversight
  - Proposal submissions to RCs
  - Authorship

- Access to clinic-level data
  - Benchmarking
- Submit proposal analyses through NCs
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Operational Model

iCaReMe Registry uses real-world evidence (RWE) box, a central cloud-based interface:
- Collects standardized real-world patient data
- Allows participating physicians to retrieve and analyze their own patient data

User-friendly data dashboard
Overview of patient data
Quality of care indicators

Real Time View & Assessment Of KPIs

- Web-based system as a primary point to input data via the eForm
- Visualization of data through user-friendly dashboard
  - Provides the means to perform descriptive analyses
  - Allows for assessment of feasibility and analyses to answer research questions
  - Provides data for site-specific benchmarking

Data Management Operating Model

Independent
Academic analytical centres
Data report development

Executive
Scientific Committee

Publications