

International Diabetes Federation (IDF)

AstraZeneca

Overall Plan and Phases



Rational

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



Study Design

iCaReMe Global Registry Design



The iCaReMe Registry (NCT03549754) prospective, investigator-led, multicentric, multinational, observational registry Determine 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 realworld 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
- Participating in an interventional trial

Adults with T2D, HTN, HF, CKD iCaReMe Registry uses real-world evidence (RWE) box, a central cloud-based interface with a user-friendly electronic form which: - 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

Web-based electronic

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

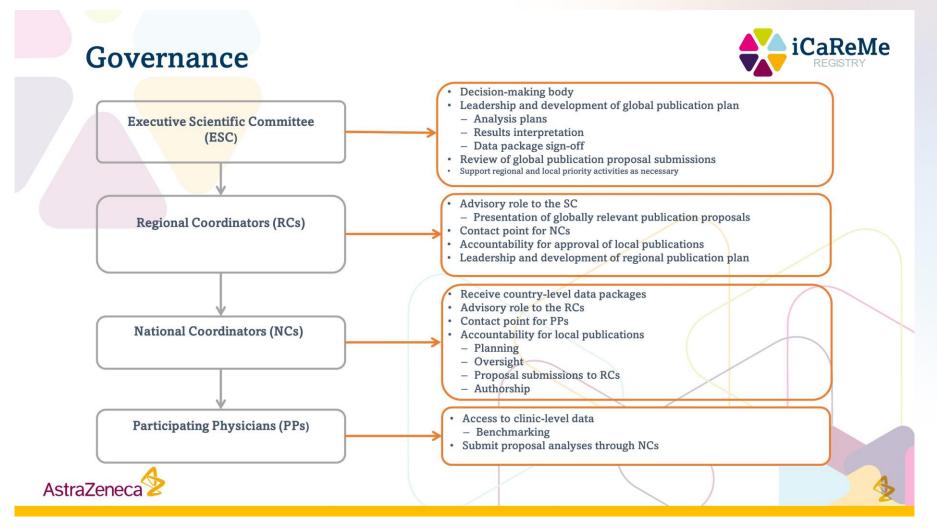
Secondary objectives

- 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

Governance



Operational Model



iCaReMe Registry uses real-world evidence (RWE) box, a central cloud-based interface :

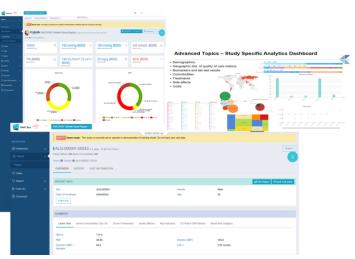
- Collects standardized real-world patient data
- Allows participating physicians to retrieve and analyze their own patient data

User-friendly data dashboard

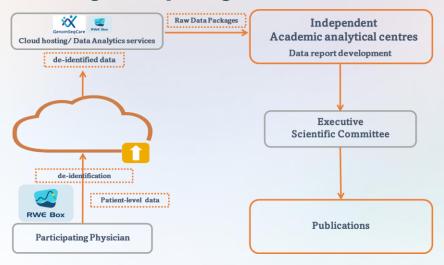
Overview of patient data Quality of care indicators

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





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