PRESS RELEASE: GREG launch

Launch of the GREG initiative to Impact Real-World Evidence practices in Europe

Key messages

- GREG is a five-year, 26.2 million euros initiative that unites 29 partner organizations to advance Real-World Evidence (RWE) practices for the development and evaluation of medicines and medical devices in Europe.

- GREG will provide evidence-based guidance and tools to help generate and use RWE to inform regulatory and Health Technology Assessment (HTA) decision-making.

- GREG will carry out Regulatory and HTA use case studies to map relevant topics, needs, and barriers, supporting the development of practical guidance and tools.

Rotterdam, 12th of May 2025

The GREG project — **Testing, improving, and co-creating Guidance and Tools for Real World Evidence Generation and Use for Decision-Making in Europe** — has been officially launched.

GREG is a public-private partnership supported by the Innovative Health Initiative Joint Undertaking (IHI JU), set to **impact Real-World Evidence practices in Europe**. The **GREG initiative aims** to create, test, and share practical, evidence-based guidance and tools to help generate and use RWE. By improving how RWE informs the development and evaluation of medicines, medical devices, and drug-device combinations, we will support better decision-making for regulators and HTA bodies.

Starting May 1, 2025, the **five-year project** has a **budget of €26.2 million,** of which €13.2 million is requested to be funded by IHI, and €13.0 million is committed by industry.

Bringing together **twenty-nine (29) partner organizations from fifteen (15) countries**, the GREG consortium is uniquely positioned to make an impact on European RWE practices. The consortium is led by the Erasmus University Medical Center (The Netherlands) as the Coordinator, Novo Nordisk (Denmark) as the Project Lead and Sanofi (France) as the co-lead and is supported by the University of Oxford (United Kingdom). This project gathers fifteen (15) public entities, where eight (8) are top-tier academic institutions, two (2) small- and medium-sized enterprises, two (2) Health technology assessment bodies (HTA), two (2) non-profit organizations, one (1) Healthcare professional organization, and one (1) multistakeholder forum; and fourteen (14) industry leaders representing the (bio) pharmaceutical and the medical devices fields.

RWE is evidence derived from the analysis of Real-World Data (RWD), which is data relating to patient health status or the delivery of health care from sources other than clinical trials. Examples of RWD include hospital data and electronic health records. GREG will support better decision-making using RWE, leading

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to faster market entry of medical products and improved access to healthcare technologies and innovations, meeting both patient needs and the needs of diverse European healthcare systems.

Emel Mashaki Ceyhan, Industry Lead, Novo Nordisk: "The field of Real-World Evidence has been gathering much deserved attention in recent years as RWE has the potential to generate valuable and high-quality evidence which could complement clinical trials and inform decision making in clinical development, regulatory review as well as health technology assessments. This potential has not been fully reached despite the recent significant efforts and advancements in this field. Therefore, we strongly believe and remain confident that the outcomes of the GREG project will transform the way RWE is utilized in decision making and enable its use and implementation with confidence by sponsors, to bring innovative treatments to patients faster."

In order to respond in an agile way to needs for guidance and tools throughout the project, **an iterative approach** will be followed to develop, test, and disseminate the GREG guidance and tools. We will use the Observational Medical Outcomes Partnership (OMOP) Common Data Model and leverage the European Health Data and Evidence Network (EHDEN) Foundation and other datasets to engage key European data partners for the testing of our proposed methods, tools, and guidance.

Daniel Prieto Alhambra, Project Coordinator, Erasmus University Medical Center: "As RWE needs increase, there is a clear need for alignment on the best methods, data, and tools for the generation and use of this evidence to inform the development and evaluation of medicines and devices. GREG will deploy a dedicated team of experts to review existing guidelines, fill the gaps in the literature, and generate and pilot-test evidence-based guidance and tools for better RWE generation in Europe."

A selection of **Regulatory and HTA use cases** will be reviewed to map relevant topics, needs, and barriers, facilitating consistent learnings, and the development of the above-mentioned guidance and tools. Followed by a review of existing RWE guidelines and discussions with dedicated regulatory and HTA expert fora, a living library of use cases will be developed, highlighting scenarios where RWE plays a crucial role in the regulatory and HTA process. This effort will involve engagement with key ongoing and upcoming RWE initiatives focused on regulatory action, as well as collaboration with the European Medicines Agency, National Competent Authorities, Notified Bodies, and relevant industry stakeholders.

Stay informed about the latest advancements from the GREG initiative as we commence on an exciting journey to revolutionize Real-World Evidence practices across Europe.

For more information and updates about the GREG initiative, please contact info@ihi-greg.eu, visit our website: https://ihi-greg.eu/ and follow us on LinkedIn.

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