PRESS RELEASE: READI KICK OFF

READI

This This project is supported by the Innovative Health Initiative Joint Undertaking (IHI JU) under grant agreement No 101166227. The JU receives support from the European Union's Horizon Europe research and innovation programme and COCIR, EFPIA, EuropaBio, MedTech Europe, Vaccines Europe, and Medicines and Healthcare Products Regulatory Agency and Breakthrough T1D. This project is also supported by UKRI (UK Research and Innovation).

innovative health initiative

COCIR Advancing Healthcare

efpia

EuropaBio The European Association for Bioindustries

Vaccines Europe

Co-funded by the European Union

UK Research and Innovation

READI Project Launches to Enhance Patient Representativeness and Inclusion in European Clinical Research

January, 16, 2025

The pioneering project READI —Research in Europe and Diversity Inclusion—a public-private partnership funded by the Horizon Europe Innovative Health Initiative (IHI) and driven by meaningful co-leadership with patients, officially launches today.

Its purpose is to promote **a less fragmented and more democratic ecosystem for clinical studies (CS)** by engaging key stakeholders in the process of including underserved and underrepresented populations in CS.

The consortium is coordinated by the Servicio Madrileño de Salud (SERMAS), through Hospital Universitario La Paz, as the Project Coordinator, Novartis as the Project Lead, and supported by The Synergist as the Digital & Sustainability Coordinator. This project brings together a highly multidisciplinary consortium of 73 organizations from 18 different countries. **The six-year project will have a budget of €66.8 million, of which €31.5 million is requested to be funded by IHI, and €34.2 million is committed by industry and contributing partners.**

READI's main objective is **to enhance the representativeness of underserved populations in clinical studies** by fostering a more cohesive and integrated clinical study ecosystem, with the ambition of achieving full inclusion by placing the patient at the center. It will actively connect key stakeholders involved with underserved and underrepresented communities, and equip them with the necessary tools, training programs, and strategies essential for recruiting and retaining underserved and underrepresented patients in clinical studies. To demonstrate READI's capacity to broaden representation in clinical research, the approaches will be tested in real-world pilot clinical and non-clinical use cases, supported by industry partners.

The work will include mapping the characteristics of these populations using Real-World Data (RWD), developing standardized descriptors for their inclusion, collecting insights and informing regulatory and Health Technology Assessment (HTA) policies to enhance representativeness in clinical studies.
READI will help underserved and underrepresented communities overcome barriers to clinical study participation, such as lack of information or awareness, mistrust, poor communication, geographic limitations, and prejudice. In addition, READI will design and implement a patient-centered, open, and innovative digital platform. This platform will improve access to clinical study information and READI tools, while fostering patient connections with established communities.

Ultimately, this initiative will lead to more innovative science and will improve inclusive participation in clinical trial research thereby promoting health equity in Europe.

This This project is supported by the Innovative Health Initiative Joint Undertaking (IHI JU) under grant agreement No 101166227. The JU receives support from the European Union's Horizon Europe research and innovation programme and COCIR, EFPIA, EuropaBio, MedTech Europe, Vaccines Europe, and Medicines and Healthcare Products Regulatory Agency and Breakthrough T1D. This project is also supported by UKRI (UK Research and Innovation).

The expertise behind READI

The READI project is supported by a consortium of 73 organizations, drawing together expertise from clinical research, patient advocacy, digital health, and regulatory affairs. Collectively, they contribute to READI's mission of fostering inclusive clinical studies across Europe, addressing health disparities, and expanding patient access to innovative treatments.

Coordinated by:
SERMAS (Servicio Madrileño de Salud)), through Hospital Universitario La Paz in Spain, **Novartis** in Switzerland, and supported by The Synergist in Belgium.

Consortium include:
AbbVie, Aarhus Universitet (AU) and Aarhus Universitetshospital (AUH), Almirall SA (ALM), AstraZeneca AB (AZ), Boehringer Ingelheim, Breakthrough T1D, (BREAKTHROUGH1D) Bristol-Myers Squibb Company Corp (BMS) , CDISC Europe Foundation Fondation (CDISC) Chiesi Group, Curewiki, Digestive Cancers Europe (DiCE), Eli Lilly and Company (Lilly), Esperity (CT.be), European AIDS Treatment Group (EATG), European University Cyprus (EUC), ECRIN European Clinical Research Infrastructure Network (ECRIN), F. Hoffmann-La Roche AG (Roche), FIBHUG (Fundación para la Investigación Biomédica del Hospital Universitario de Getafe), Fundación para la Investigación Biomédica del Hospital Universitario la Paz (FIBHULP), FISABIO (Fundacion para el Fomento de la Investigación Sanitaria y Biomédica de la Comunitat Valenciana), Forum des Patients Européens (EPF), Fundación 29 de Febrero, Fundació Privada per a la Recerca i la Docència Sant Joan de Déu (FSJD), GlaxoSmithKline Research & Development Limited (GSK), Global Heart Hub (GHH), HL7 International Fondation , Information Technology for Translational Medicine (ITTM) SA, Irish Platform for Patients' Organisations Science and Industry (IPPOSI), Janssen-Cilag Limited, a Johnson & Johnson company, Klinikum der Universität zu Köln (UHC), Medicines and Healthcare Products Regulatory Agency (MHRA), Midtjyllands EU Kontor Forening (CDEU), National Cancer Institute (NCI), National Institute for Health and Care Excellence (NICE), Novo Nordisk A/S, Pagalbos Onkologiniams Ligoniiams Asociacija (POLA), Penta Foundation (PENTA) Pfizer Inc (Pfizer), Sanofi, Shine 2Europe LDA (SHINE), Socialit Software e Consulting Srl (SIT), Stichting EUPATI Foundation (EUPATI) Stichting VU, Synapse Research Management Partners SL (Synapse), Synergist Services (Synerserv), Takeda Pharmaceuticals International AG (TPIZ), The August Pi i Sunyer Biomedical Research Institute (IDIBAPS), Trial Nation (TrialNation), UCB Biopharma (UCB), Universitair Medisch Centrum Utrecht (UMCU), University of Nicosia (UNIC) , University Court of the University of Aberdeen (UoA), Vicomtech, ViiV Healthcare UK LTD , VU University Medical Center (VU), Youth Cancer Europe (YCE), and Zabala Innovation Consulting SA (ZABALA).

Contact:

For more information about the READI project,
Visit our website: https://ihi-readi.org/
Follow us on LinkedIn, X and Subscribe to our YouTube Channel // @IHIREADI

Media contact:

This This project is supported by the Innovative Health Initiative Joint Undertaking (IHI JU) under grant agreement No 101166227. The JU receives support from the European Union's Horizon Europe research and innovation programme and COCIR, EFPIA, EuropaBio, MedTech Europe, Vaccines Europe, and Medicines and Healthcare Products Regulatory Agency and Breakthrough T1D. This project is also supported by UKRI (UK Research and Innovation).

Nora Franco - nfranco@zabala.es – Dissemination & Communication Manager
Bea Quintillá - bquintilla@zabala.es – Dissemination & Communication Manager

This This project is supported by the Innovative Health Initiative Joint Undertaking (IHI JU) under grant agreement No 101166227. The JU receives support from the European Union's Horizon Europe research and innovation programme and COCIR, EFPIA, EuropaBio, MedTech Europe, Vaccines Europe, and Medicines and Healthcare Products Regulatory Agency and Breakthrough T1D. This project is also supported by UKRI (UK Research and Innovation).