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Leverage synthetic data to propel personalized medicine to new heights: Launching SYNTHIA, a pioneering public-private partnership funded by the Innovative Health Initiative

The SYNTHIA project, a groundbreaking public-private partnership funded by the Innovative Health Initiative (IHI), is set to revolutionize the field of personalized medicine by harnessing the power of synthetic data. As the first IHI project to tackle the critical need for privacy-preserving data solutions in healthcare, SYNTHIA aims to propel research and innovation to new heights, ensuring that patients receive the best possible care while safeguarding their personal information.

Hamburg. We are excited to announce the launch of SYNTHIA, an IHI funded project, which has been kicked-off in Valencia Spain. Over the next five years, three Fraunhofer institutes participating in SYTHIA, Fraunhofer Institute for Algorithms and Scientific Computing SCAI, Fraunhofer Institute for Translational Medicine and Pharmacology ITMP and Fraunhofer Institute for Digital Medicine MEVIS will collaborate closely with leading academic and industry partners to develop a cutting-edge platform for generating, evaluating, and applying synthetic patient data. SYNTHIA stands out by offering a comprehensive 360° approach to synthetic data generation, addressing various data types, fidelity, privacy assessment, as well as regulatory and practical considerations. The project also incorporates highly innovative concepts such as digital twins, clinical trial emulation, and federated machine learning.

Prof. Dr. Carsten Claussen concludes that "The attractiveness of the Fraunhofer-Gesellschaft as a partner in IHI-funded public-private partnership projects is strengthened by the cross-institute pooling of individual expertise." The co-lead of SYNTHIA, Prof. Dr. Holger Fröhlich from Fraunhofer SCAI, states: "In our view, generative AI methods for synthesizing patient data have enormous potential for tackling a whole range of relevant challenges in medicine. As we have been researching in this field for years, we are delighted to be able to contribute, further develop and apply these methodologies in a project with top-class international partners from industry and academia."

Unlocking new possibilities in health research

Synthetic data, which are artificially generated to mimic real patient data, present a solution to many of the challenges faced in health research today. These data allow researchers to overcome the limitations of access to high-quality, real-world datasets and address growing concerns about patient privacy. However, questions have lingered

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about the quality and applicability of synthetic datasets, especially in diverse and complex scenarios. SYNTHIA is addressing these challenges head-on by developing validated tools and methods for synthetic data generation (SDG) across various data types, including laboratory results, clinical notes, genomics and imaging. By focusing on six specific diseases the project will demonstrate the utility of synthetic data in advancing personalized medicine:

- Two solid tumors: Lung cancer, Breast cancer
- Two blood cancers: Multiple myeloma, Diffuse large B-cell lymphoma
- Alzheimer's disease
- Type 2 diabetes

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Fostering trust through innovation

A key component of the SYNTHIA project is its dedicated federated platform, which will serve as a central resource for the research community. This platform will provide synthetic data generation workflows tailored to specific needs, along with robust frameworks to assess data privacy, quality, and applicability. Each dataset will be clearly labelled with its suitability for various research applications, building trust among stakeholders and promoting the responsible use of synthetic data.

Collaborative efforts driving success

The SYNTHIA consortium partners from Medtech, Pharma, Academia, Medical research and Healthcare institutions are committed to advancing the use of synthetic data in healthcare. The project's outputs will be made accessible to researchers worldwide, fostering a collaborative environment where innovation can thrive.

SYNTHIA is a multidisciplinary collaboration of 32 consortium partners - SDG developers, FAIR data experts, clinical researchers, developers of therapies and data-based tools, legal experts, socio-economic analysts, regulatory, policy advocacy, and communication experts - that will provide a 360° vision on how to advance healthcare applications through SD use. SYNTHIA invites researchers, healthcare providers, and innovators to join in pioneering a new era of healthcare research. With synthetic data as a catalyst, SYNTHIA is ready to accelerate discoveries in medicine, making personalized healthcare more accessible and effective for all.

FRAUNHOFER INSTITUTE FOR TRANSLATIONAL MEDICINE AND PHARMACOLOGY ITMP**About the Fraunhofer-Gesellschaft**

The Fraunhofer-Gesellschaft based in Germany is the world's leading applied research organization. Prioritizing key future-relevant technologies and commercializing its findings in business and industry, it plays a major role in the innovation process. Founded in 1949, the Fraunhofer-Gesellschaft currently operates 76 institutes and research units throughout Germany.

Three Fraunhofer institutes are participating in SYTHIA:

Fraunhofer Institute for Algorithms and Scientific Computing SCAI is co-leading the project, contributing advanced generative AI approaches for clinical studies in the field of Alzheimer's disease. Fraunhofer SCAI is also co-leading this specific use case in collaboration with Gates Ventures.

Fraunhofer Institute for Translational Medicine and Pharmacology ITMP is co-leading the application of generative AI approaches in the field of type 2 diabetes, in partnership with Novo Nordisk.

Fraunhofer Institute for Digital Medicine MEVIS will provide its long-lasting expertise with generative AI techniques in the field of medical imaging, specifically in the Alzheimer's Disease field.

About the Innovative Health Initiative (IHI)

The Innovative Health Initiative (IHI) aims to translate health research and innovation into real benefits for patients and society, and ensure that Europe remains at the cutting edge of interdisciplinary, sustainable, patient-centric health research. Health research and care increasingly involve diverse sectors. By supporting projects that bring these sectors together, IHI will pave the way for a more integrated approach to health care, covering prevention, diagnosis, treatment, and disease management.

IHI is a partnership between the European Union and European industry associations representing the pharmaceutical, medical technology, biotechnology, digital health and vaccine industries, namely COCIR, EFPIA, EuropaBio, MedTech Europe and Vaccines Europe. IHI's total budget is EUR 2.4 billion. Half of this comes from Horizon Europe, the EU's research and innovation program. The IHI industry partners have committed EUR 1 billion to IHI, and a further EUR 200 million can be committed by other organizations that decide to become Contributing Partners. IHI builds on the successes of the Innovative Medicines Initiative (IMI), and the IHI Program Office continues to manage the IMI project portfolio.

About SYTHIA: Synthetic Data Generation framework for integrated validation of use cases and AI healthcare applications

SYTHIA is a pioneering public-private partnership leveraging synthetic data to propel personalized medicine to new heights. This project is funded by the Innovative Health Initiative Joint Undertaking (IHI JU) under grant agreement No 101172872. The JU receives support from the European Union's Horizon Europe research and innovation program and COCIR, EFPIA, EuropaBio, MedTech Europe, and Vaccines Europe and DNV. Supported by the European Union's Horizon Europe research and innovation program and industry leaders such as COCIR, EFPIA, EuropaBio, MedTech Europe, Vaccines Europe, and DNV, SYTHIA is dedicated to advancing synthetic data generation for healthcare applications, ensuring that data-driven innovations can safely and effectively transform patient care.

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