

VIRTUAL HUMAN TWINS

A Statement of Intent on Development, Evidence, and Adoption in Healthcare Systems

Final Version

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Virtual Human Twins (VHTs), digital representations of human physiology and pathology, have considerable potential for medical research and healthcare delivery, enhancing our understanding of human physiology, pathology, and disease aetiology, enabling personalised, patient-centred medicine.

In healthcare, VHTs can enable enhanced diagnosis and personalised interventions of higher efficacy and safety across the continuum of prevention, treatment and follow-up. In clinical research, VHTs can also dramatically accelerate development of new medicines and medical devices. Development, validation, and adoption of VHTs will thus advance and promote better healthcare services, improved patient outcomes and efficiency gains for healthcare systems.

However, realising the vision for VHTs in health requires prudence vis-à-vis several scientific, technical, ethical, legal, and cultural aspects. Delivering the benefits of VHTs for human health requires a robust ecosystem approach enabling researchers, innovators, healthcare practitioners and patients to build on solid foundational research within well-defined frameworks, based on good practices and successful international collaborations.

We welcome the initiative by the European Commission announced at *[high level event & format in progress]* towards the development of an active ecosystem for VHTs in health across Europe. We support the ecosystem growth and consolidation; the ongoing work to build a VHT repository of existing practices, data and model resources; a European collaborative model development and simulation platform including links to the appropriate computing, data and research infrastructures; and the evolution of the regulatory, legal and ethical basis for use.

Addressing this vision will initially focus on foundational research and the integration of digital and medical technologies towards a shared VHT framework. Respect for citizens' and patients' fundamental rights, and alignment of contributions from stakeholders, will be ensured. Work on the European VHT ecosystem now will contribute to delivering future innovations required to handle the growing pressures within our healthcare systems.

VHT research and innovation, building upon current achievements, must be oriented towards establishing VHTs as a platform technology, generating evidence and value for healthcare and society as a whole. An ecosystem ensuring incentives for excellence, regulatory certainty and trust will be instrumental in unleashing investment supporting innovation.

We are ready to be part of these advanced solutions led and facilitated by the European Commission. Working with all stakeholders across the ecosystem, we intend to further the development of VHT technologies and its ecosystem in Europe by actively contributing to the following actions:

- **Attaining excellence in European research and innovation** in the development, testing, validation, and verification of advanced VHT technologies including AI and other in silico technologies, making use of digital services and capabilities available at European level, e.g. EuroHPC, SIMPL, and others where appropriate.

- **Identifying high-impact clinical and scientific use cases** that stand to benefit from the adoption and use of VHT technologies, products and services, including diagnostics, medical education, training, decision support, treatment development and intervention planning.
- **Enhancing the EU VHT data and models repository** with expertise and resources in full compliance with applicable laws and regulations in Europe.
- **Developing common ground, trust, agreement and certainty on intellectual property management**, as a basis from where partner collaborations among stakeholders in developing VHT technologies ensue.
- **Identifying opportunities, approaches, standards, tools, and techniques that enhance clarity of the regulatory landscape** and support its evolution towards enabling more robust VHT technologies in terms of efficacy, safety, trustworthiness, performance and risk management.
- **Generating clinical, experimental, and digital evidence** for the future development of VHT solutions, methods, and tools that serves to grow VHT maturity, confirm patient benefit, and increase their adoption in healthcare.
- **Contributing to the development, testing and implementation of advanced IT platform architectures** combining, *inter alia*, advanced computing methods and tools, state of the art cybersecurity, cloud services and edge infrastructure supporting the use of advanced VHT models by the citizen, patients, healthcare professionals, researchers and innovators.
- **Advancing the availability of and access to high quality, annotated and interoperable digital health data** that are standardized, while safeguarding patients' privacy, personal data, health and safety.
- **Advancing the understanding of how VHT solutions, products, and services can be used across the disease continuum** in prevention, treatment and follow-up, in different healthcare settings and care modes e.g. diagnosis, remote care and self-care, in non-clinical and clinical research including treatment development, as a basis for their validation and adoption.
- **Ensuring the contributions, feedback, priorities, requirements, views, concerns and interests of citizens, patients, healthcare professionals, and scientists** are proactively captured and addressed as part of the development, testing, verification, and validation of VHT technologies.
- **Ensuring that VHT technology benefits people of all ages, genders, ethnicities, disabilities socioeconomic statuses, fostering equitable and universal access** to high-quality healthcare.

The signatories will work with the European Commission and other parties relevant to the actions above to advance Virtual Human Twin science, technology, and Virtual Human Twin-based solutions, for the benefit of all stakeholders.

THIS STATEMENT HAS BEEN ENDORSED BY