

FIRST ETHICS AND LEGAL COMPLIANCE REPORT

DigiCare4You aims to improve the early prevention and management of Type 2 Diabetes (T2D) and hypertension (HTN) via a community-based, person-centred solution, integrating both social and healthcare systems, supported by the use of digital tools.

This report is the first of three ethics and legal compliance reports that will be published throughout the DigiCare4You project. This first report outlines the continuous ethics and legal compliance efforts undertaken by the consortium partners during the first 18 months of the project.

LEGAL AND ETHICAL COMPLIANCE

In the first year of the DigiCare4You project, a legal and ethical framework was developed. This serves as a regulatory framework that encompasses relevant international and national laws and regulations relevant to the research activities. This is one of the foundational elements of compliance realisation, as it is the cornerstone for sound and lawful processing of personal data and management of ethics compliance. It outlines principles, rules and general instructions for consortium members to follow when it comes to ethical, legal and security-related aspects. Read more about the Legal and Ethical Framework in deliverable 3.1 [here](#).



An intersectoral innovative solution involving DIGital tools, empowering families and integrating community CARE services for the prevention and management of type 2 diabetes and hypertension

D3.1 DigiCare4You Legal and Ethical Framework

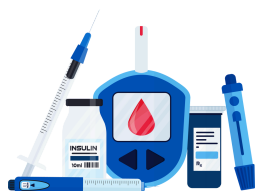
Deliverable No.	D3.1	Due Date	31/12/2021
Description	This deliverable provides the legal and ethical framework for DigiCare4You. It contains a presentation of applicable ethical and legal requirements as well as details how they will be managed. The deliverable confirms the strong dedication of the project consortium to satisfy the highest compliance standards.		
Type	Report	Dissemination Level	Public
Work Package No.	WP3	Work Package Title	Ethics, legal & regulatory compliance
Version	1.0	Status	Final
Lead Beneficiary	Privanova (PN)	Main Contact	Djordje Djokic, djordje@privanova.com

DATA MANAGEMENT PLAN

In addition to the Legal and Ethical Framework, a Data Management Plan (DMP) has also been developed. The DMP is a critical element for the realisation of DigiCare4You, detailing how data will be handled, protected and managed throughout the project. It outlines the principles for data generation, exploitation, accessibility, reuse, curation and preservation. The DMP ensures that all data processing activities comply with ethical standards and the rules of the Horizon2020 programme. It covers the entire data lifecycle, from planning and collection to processing, analysis, sharing, and preservation. Read more about the Data Management Plan [here](#).

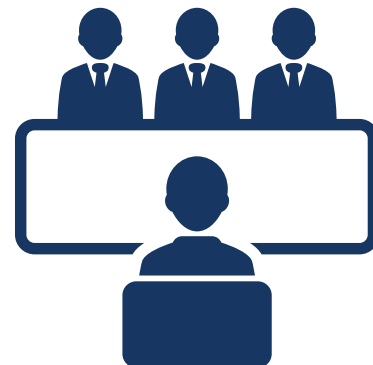


This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement N° 945246



ETHICS APPRAISAL SCHEME

Following the successful scientific evaluation of the proposal, DigiCare4You was evaluated by a panel of ethics experts. This is part of the European Commission's Ethics Appraisal Scheme. The panel conclusions were outlined in the Ethics Summary Report and included as additional requirements in the project Grant Agreement. Therefore, action plans were created to address the requirements and consequently, ethics deliverables were developed and successfully submitted.



PROTECTION OF PERSONAL DATA



To uphold the highest standard and commitment to data protection, the project partners have agreed on technical and organisational measures to avoid unforeseen usage or disclosure of data. Measures to protect data include access controls via secure logins, installation of up-to-date security software on devices, regular data backups, etc. Project partners also committed to the minimum threshold for ensuring data security. Consortium partners, METEDA and CERTH, implemented specific security measures to provide additional layers of data security due to their involvement in the development of the digital tools.

ETHICS ADVISORY BOARD

An Ethics Advisory Board (EAB) was established to supervise the project activities and ensure compliance with ethics requirements. The EAB is composed of three external independent ethics experts. They have contributed to the ethics dimension of the project implementation by providing opinions on the identified ethics issues. The EAB also reviewed project deliverables and publications for the purpose of identifying potential ethics and data protection issues.

