

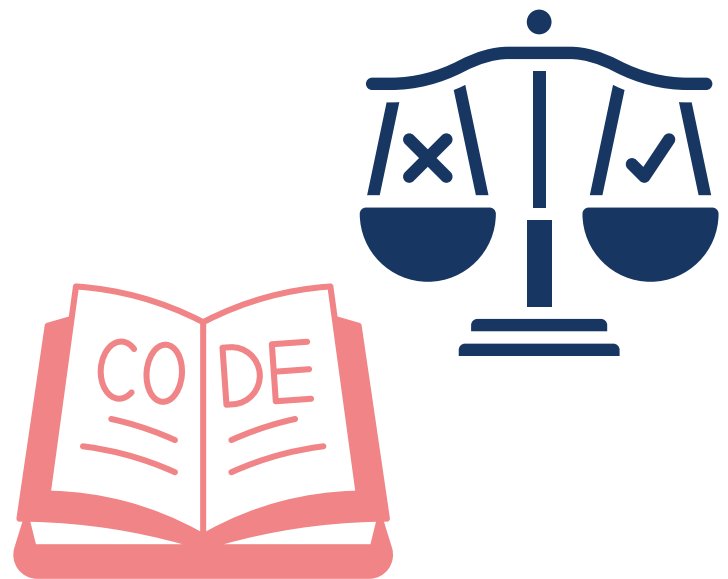
## DIGICARE4YOU LEGAL AND ETHICAL FRAMEWORK

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

As part of the project, a legal and ethical framework has been developed which outlines the consortium's strategy for managing research activities in accordance with national, international, and supranational ethical and legal standards. The legal and ethical framework outlines considerations and actions for the consortium in the domains of ethics compliance, artificial intelligence (AI) and ethics, data protection, clinical trial regulations, and relevant national and international regulatory frameworks.

### ETHICS COMPLIANCE

The **DigiCare4You** research project has **ethical implications**. It is, therefore, of the outmost importance for the consortium to adhere to, and manage, potential ethical issues. The **DigiCare4You Legal and Ethical Framework** highlights the dedication of the consortium to uphold the highest standards of ethical principles, regulatory requirements, and rules of the **Horizon 2020 programme**. All partners conduct research in accordance with the fundamental principles of research integrity.



As part of the European Commission Ethics Appraisal Scheme, the DigiCare4You project was evaluated by a panel of experts. The panel conclusions were outlined in the Ethics Summary Report and the project was conditionally cleared. The project consortium had to satisfy ethical requirements regarding the participation of humans (development and enforcement of procedures and criteria used to identify and recruit the different types of research participants in the DigiCare4you project), data protection (DPO assignment in host institutions, the ethics risk assessment, and opinion on the Data Protection Impact Assessment (DPIA), as well as the technical, organisational measures and security measures implemented within DigiCare4you for safeguarding the rights and freedoms of the data subjects/research participants) and establishment of an independent Ethics Advisory Board (EAB). An action plan was developed to address the ethics compliance of the project. Details of the action plan can be found in deliverable 3.1 [here](#).



# ARTIFICIAL INTELLIGENCE AND ETHICS

One of the project outcomes is the contribution to mHealth through the development of a personalised digital platform for the management of T2D and HTN. For this purpose, the AI-based Education Virtual Assistant (EVA) was enhanced to educate and support end users. In consideration of the plan to develop the AI assistant, DigiCare4You paid particular attention to the European Commission Ethics Guidelines for Trustworthy AI and the WHO Guide on Ethics and Government of Artificial Intelligence for Health. These frameworks provide guidance on how AI should be developed, deployed, and used, in line with ethical principles such as the respect of human autonomy, the prevention of harm and the promotion of well-being, and the fostering of fairness, equity, responsibility and accountability.

Data protection principles highlight that processing and collection of personal data should be:

- lawful, fair, and transparent in providing information about the collection and use of the data
- limited to what is relevant and necessary
- not kept longer than needed
- processed in a manner that ensures security and confidentiality

## DATA PROTECTION

As the project is collecting and processing data, data protection principles is an important consideration for the consortium. Data protection principles highlight that any processing of personal data should be lawful, fair, and transparent in providing relevant information about the collection and use of the data. The collection of personal data should also be limited to what is relevant and necessary for the purpose, not kept longer than necessary, and processed in a manner that ensures appropriate security and confidentiality. When collecting personal data, individuals must be informed in an easily accessible way about their rights concerning the use of their data and elements listed in the General Data Protection Regulation (GDPR). The processing of personal data must be done lawfully and based on informed consent by the participants.

Each consortium partner has to implement appropriate technical and organisational measures to ensure the security of personal data processing. The Legal and Ethical Framework provides various recommendations to consortium partners on what to consider to effectively protect personal data.

## CLINICAL TRIALS REGULATION

The new Clinical Trials Regulation (CTR) was enacted in January 2022. The ambition of the CTR is to create an environment that is favourable to conducting clinical trials in the EU and provide a greater level of harmonisation and streamlining of rules for conducting clinical trials throughout the EU.



With the CTR entering into force during the time of the DigiCare4You project, it was anticipated that the CTR might apply to some of the research activities, but exceptions from the CTR were also relevant. It was decided that project partners would decide whether they would conduct the research in accordance with the CTR rules or opt for the old system of regulation. Regardless of the decision of the application of the CTR, the consortium is dedicated to respecting the requirements concerning the informed consent regulated by the CTR, which differ from those under GDPR. CTR informed consent aligns with the Helsinki Declaration, protecting human dignity and integrity, while GDPR informed consent is one legal ground for lawful data processing. Informed consent of participants adheres to both GDPR and CTR requirements.

## SPECIFIC NATIONAL REGULATORY FRAMEWORKS

The Legal and Ethical Framework also highlights national sector-specific regulations concerning T2D and HTN screening, prevention and management in the four implementation countries – Albania, Bulgaria, Greece and Spain. The various national regulatory frameworks identified as relevant for the DigiCare4You project are outlined in the table overleaf.

Albania	Bulgaria	Greece	Spain
<ol style="list-style-type: none"> <li>1. Protocol for managing patients with T2D</li> <li>2. Guideline for the screening, diagnosis, prevention, and treatment of diabetes and its complications</li> <li>3. National plan for control and prevention of non-communicable diseases</li> </ol>	<ol style="list-style-type: none"> <li>1. National program for the prevention of non-communicable diseases</li> <li>2. National framework agreement N° RD-NS-01-4/23 December 2019 for medical activities between the National Health Insurance Fund and the Bulgarian Medical Union</li> </ol>	<ol style="list-style-type: none"> <li>1. Guidelines for the management of people living with diabetes</li> <li>2. Individual student health record (ISHR)</li> <li>3. National action plan for the prevention and treatment of diabetes and its complications</li> <li>4. European Society of Cardiology (ESC)- European Society of Hypertension (ESH) 2018 guidelines for the management of hypertension</li> <li>5. Arterial hypertension: committee on the monitoring of pharmaceutical expenditure, the completion of diagnostic therapeutic protocols and the creation of patients' clinical file/databse</li> </ol>	<ol style="list-style-type: none"> <li>1. Diabetes strategy of the national system of health</li> <li>2. Comprehensive diabetes care programme in the region of Aragon</li> <li>3. Nursing care plan in the patient with diabetes in the region of Aragon</li> </ol>

