Ethics Framework of the UNCAN-CONNECT Project

The UNCAN-CONNECT project is guided by a comprehensive ethical framework aimed at supporting responsible research practices, transparency, and respect for fundamental rights throughout all project activities. Given the project's cross-border collaboration, the use of advanced digital infrastructures, and the handling of sensitive health and research data, ethical considerations are treated as an ongoing process that accompanies the entire project lifecycle. The framework combines guiding principles with practical procedures intended to align project activities with European Union regulations, national legislation, and internationally recognised ethical standards.

A core element of the project is its commitment to operating in accordance with relevant legal and ethical requirements at both EU and national levels. Ethical governance is supported through structured internal procedures together with the involvement of an independent external Ethics Advisory Board. The Board provides expert advice and independent oversight during the course of the project. Its role includes reviewing ethical practices, offering guidance on emerging issues, monitoring alignment with approved standards, and recommending corrective measures where appropriate. This dual governance structure contributes to accountability and transparency while supporting public confidence in the project's objectives and methods.

Ethical aspects are considered across all work areas of the project. The early identification and discussion of potential ethical questions is secured through engagement with stakeholders, such as researchers, clinicians, technical developers, patient representatives, and policy experts. Governance frameworks and data-processing activities are designed with attention to transparency, accountability, and legal compliance. Technical platform development follows privacy-by-design and security-by-design principles aiming to incorporate safeguards into the system architecture from the outset. Research-oriented activities, particularly those connected to cancer-related use cases, receive particular scrutiny due to the sensitivity of the data involved and their potential societal implications.

A distinguishing feature of the project's technical and ethical approach is the adoption of a federated, decentralised model for data utilisation. Within this model, data generally remain under the stewardship of their originating institutions while still enabling collaborative analysis across borders. This approach is intended to reduce risks associated with centralised

storage and to reinforce institutional responsibility for data management. Data processing activities are designed to operate in accordance with European and national data protection laws. In particular, the principles of the General Data Protection Regulation (GDPR), such as accountability, transparency, confidentiality, integrity and data minimisation, are taken into consideration and incorporated into the data-handling practices. Measures such as anonymisation, pseudonymisation, encryption, and controlled access mechanisms are applied where feasible. Participants retain rights regarding their personal data, including rights of access, rectification, and erasure, in line with applicable legislation.

Research involving human biological materials, such as tissues and cell samples, is approached with particular ethical attention. The consortium recognises that the use of such materials raises considerations related to consent, privacy, traceability, and the potential for misuse. Informed consent is sought prior to the collection or use of biological materials, and samples are handled using secure and traceable procedures and used solely for ethically approved research purposes. The origin of tissues and cells is documented to support transparency and accountability, and required accreditations and authorisations are obtained before their use. Collaboration with institutional and national ethics committees contributes to maintaining appropriate standards throughout research activities.

The informed consent process is designed to be clear, inclusive, and respectful of participant autonomy. Consent forms and information materials are prepared in accessible language and made available in relevant local languages to accommodate diverse participant groups. Participants are informed about the nature and purpose of the research, the intended use of their data or biological materials, and their rights, including the possibility to withdraw at any time without negative consequences. Particular care is taken when involving vulnerable populations, such as minors. In such cases, consent is obtained from parents or legally authorised representatives who receive sufficient information to make decisions on behalf of the child. Individuals who are unable to provide valid informed consent are not enrolled in research activities.

All clinical and research activities involving human participants are subject to formal ethics approval procedures. Each participating clinical institution seeks approval from its relevant local or national ethics committees prior to initiating studies. These procedures are aligned with European regulatory frameworks, including the Clinical Trials Regulation, as well as corresponding national laws. Monitoring and auditing mechanisms are established to support continued compliance over time. Periodic reporting to the Ethics Advisory Board contributes to oversight, and corrective actions may be implemented if deviations from ethical or legal expectations are identified.

The project’s ethical orientation is also informed by internationally recognised declarations and conventions that provide widely accepted benchmarks for responsible research conduct. These include the Declaration of Helsinki of the World Medical Association, the International

Ethical Guidelines for Health-Related Research Involving Humans developed by the Council for International Organizations of Medical Sciences in collaboration with the World Health Organization, and the Council of Europe Convention on Human Rights and Biomedicine. These reference documents emphasise respect for human dignity, privacy, fairness, and scientific responsibility.

In summary, the UNCAN-CONNECT project adopts a structured and reflective approach to ethics that integrates governance mechanisms, stakeholder engagement, data-protection practices, responsible handling of biological materials, and transparent informed-consent procedures. This framework is intended to support responsible innovation in cancer research while recognising the importance of individual rights, societal expectations, and evolving regulatory environments.