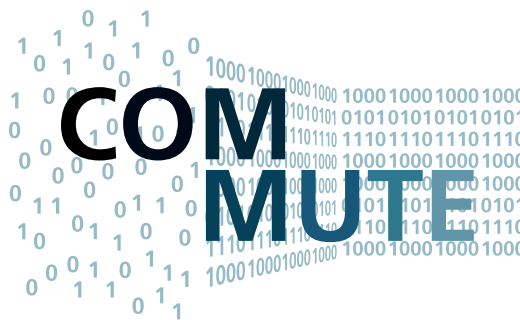# COMMUTE
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Introducing Work Package 5 – Steering the ethical, legal, and patient engagement discourse

COMMUTE is a collaborative European research project that unites multidisciplinary experts to ethically and responsibly investigate how SARS-CoV-2 infection and the broader effects of the COVID-19 pandemic may influence the onset, progression, or outcomes of neurodegenerative diseases (NDDs).

At the core of the COMMUTE project lies a strong commitment to ethical integrity and legal compliance. As the project advances research at the intersection of healthcare and data-driven innovation, COMMUTE aims to establish a robust ethical and legal framework that fosters responsible collaboration, ensures transparency, and promotes trust among all partners and stakeholders.

Work Package 5 (WP5): Ethical & Legal Framework & Patient Engagement lead by Nikolaus Forgó and his team at the University of Vienna

WP5 focuses on setting up a strong legal and ethical foundation that supports the development of a transparent and trustworthy recommender AI system.

Fostering Ethical Awareness

WP5 plays a vital role in facilitating open ethical discussions within COMMUTE. While the consortium brings together leading expertise in biology, clinical research, and data science, integrating ethical and legal perspectives into discussions is essential for **responsible research and innovation.** A key responsibility of WP5 is to **raise awareness of the ethical implications associated with everyday research conducted** within COMMUTE.

Legal Framework and Regulatory Compliance

WP5 plays a central role in ensuring regulatory compliance of COMMUTE. WP5 has conducted comprehensive regulatory mapping across key EU digital regulations to create a clear compliance roadmap to pave the way for the future exploitation of COMMUTE recommender system.

A Data Protection Impact Assessment (DPIA) has been conducted to identify risks and propose mitigation measures by analyzing how health data is managed within COMMUTE and ensuring that safeguards (e.g., data minimization, pseudonymization, and anonymization) and security controls are in place to protect individuals' rights and support compliance with data protection regulations.

Legal Acts

At the core of the project lies respect for **fundamental rights and human dignity**, as enshrined in the Charter of Fundamental Rights of the European Union (CFREU), European Convention on Human Rights (ECHR), the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Oviedo Convention) and its protocols.

A special focus is placed on the **right to the protection of personal data.** COMMUTE processes health data in full compliance with the **GDPR**, following its rules on identifying a lawful basis for data processing, purpose limitation, and security by design and by default.

Regulations relevant to AI-powered recommender systems, in particular the **EU Artificial Intelligence Act (AI Act)** and the **Medical Device Regulation (MDR)**, are also taken into account. These frameworks set out obligations for developers and providers of AI tools intended for use in healthcare. The **EU Product Liability Directive** applicable to AI-based software is another important regulation for the deployment of such systems.

WP5 continuously monitors legal developments to ensure that partners in the project stay informed and are able to address all relevant regulatory measures.

COMMUTE Legal and Ethical Advisory Board

To ensure continuous dialogue between the COMMUTE consortium and future end-users of the COMMUTE recommender system, a **Legal and Ethical Advisory Board (LEAB)** has been established at the onset of the project. The board was formed with **experts in health law, data protection, AI ethics, clinical governance, and patient advocacy**, creating a balanced body of oversight and strategic insight. This ensures the project can effectively address concerns arising throughout the project and uphold the highest legal and ethical standards.

Over the past two years, the Legal & Ethical Advisory Board has played an essential role in advancing the **project's commitment to responsible digital health innovation.** The LEAB has become an active partner in shaping the COMMUTE's emerging standards for ethical AI in healthcare.

WP5 spearheads and coordinates the functions of LEAB as an external oversight. The LEAB is periodically invited to participate in legal and ethical discussions, participate in patient engagement workshops, and provide guidance to ensure responsible and transparent project outcomes.

COMMUTE Legal, Ethical, and Patient Engagement Workshops

Stakeholder engagement

One of the key tasks within WP5 is to foster regular engagement between the consortium and patients, healthcare professionals, policymakers, and other key stakeholders. To ensure that the project's results effectively meet user needs, WP5 engages various stakeholder groups to ensure a **human-centered approach** is effectively incorporated in the development and design considerations of the COMMUTE recommender system. A key part of this effort is the organization of **annual patient engagement workshops** that bring together patient-interest representatives and other key stakeholders.

These workshops serve the following purposes:
- **Sharing insights** into current challenges identified within the project and discussing potential solutions.
- **Encouraging dialogue** and exchange of ideas to better understand user expectations, experiences, and perspectives.
- **Build strong relationships with clinicians, researchers, and patient groups** to ensure diverse perspectives in ethical decision-making.

The workshops of the LEAB and patient representatives aim to bring the **viewpoint of patients to the ethical and legal discussions** within the project. The insights gathered from the workshops are shared with all partners to be realized as ethical considerations within the respective WPs. WP5 coordinates this endeavor by developing public panel discussions and interactive workshops that aim to address emerging legal and ethical issues, along with possible solutions.

To date, WP5 has organized the following events to tackle legal and ethical dimensions relevant to COMMUTE:

- 1st COMMUTE panel and workshop held at the University of Vienna in Nov 2024: **Predictive Medicine and Patient Rights: Balancing Risks and Benefits for Individuals and Society.**[1]

- 2nd COMMUTE panel and workshop held at the University of Luxembourg on Nov 2025: **AI-driven Predictive Medicine in Alzheimer's and Parkinson's: Ethical and Legal Challenges to the Future of Clinical Authority.**

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1 The recording can be accessed on the following link: https://youtu.be/cAS4AgMb3jg

Collaboration with peer projects

COMMUTE is not the only project funded in the respective EU call. Towards the end of the project, WP5 will organize a **joint symposium on ethics and legal aspects** of similar projects to exchange arguments and strategies with other legal professionals and to investigate, **to what extent the legal and ethical guidance in WP5 can be generalized.**

Legal and ethical discourse concerning AI-predictive tools

WP5 has systematically conducted a review of the current **ethical and legal discourse concerning comorbidities** (COVID-19 and NDDs), with a particular focus on medical interventions and their long-term impacts on both vulnerable and resilient populations.

As a major outcome, a set of recommendations will be developed by WP5 to guide the development of the COMMUTE recommender system prototype.

Transparent, Trustworthy, and Ethical AI system

COMMUTE aims to **enable ethical innovation** by allowing the project to scale without compromising patient rights or regulatory expectations. Building on the European Commission's ethics guidelines for trustworthy AI, WP5 plays a leading role in ensuring an **'ethics-by-design' approach** is utilized in the development of the COMMUTE recommendation system.

A review of the state of discussion in the healthcare ethics community on diagnostics that indicate high-risk socio-psychological impact on patients, and prospective safeguards and limitations needed in relation to these diagnostics, have been conducted by WP5 in the first two years of the project.

- Systematic analysis of existing guidelines and legal / health / ethics experts' opinions.
- Review of legislation and regulatory aspects of digital health apps in the neurological and brain-health research.
- Ethics assessment that indicates issues with the deployment of risk models predicting Alzheimer's and Parkinson's.
- Careful evaluation and discussion on the ethical, legal, and societal implications of our prototypical recommendation system.

WP5 is focused on assessing **clinicians' awareness requirements** related to the future use of digital health applications in the neurological brain-health domain, in particular, how this will affect the nature of clinical diagnosis and societal implications of AI-based predictions. In addition, WP5 continuously evaluates the risks associated with deploying inadequately validated predictive models and aims to deliver recommendations for the field regarding the level of confidence and evidence necessary prior to introducing such an application to patients, general practitioners, and the wider market.