

VALIDATE Framework

Deliverable

D3.2 Ethical Plan

Project Acronym: **VALIDATE**

Project Title: **Continuous stratification for improved prevention, treatment, and rehabilitation of stroke patients using digital twins and AI**

Grant Agreement Number: **101080875**

This project has received funding from the European Union's Horizon 2022 programme under Grant Agreement No. 101080875

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	Work Package	3	Deliverable D3.2 Ethical Plan
Work package information			
	Dissemination Level		Public

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1 Introduction to VALIDATE framework

2 How Requirements are Organized

Requirements are structured to provide a clear view of their definitions and parameters. Below is an outline detailing how these are organized, articulated through an example of a standard requirement.

2.1 Requirement YZ-N-AAA

Description: Each requirement bears a unique ID, constructed as follows:

- **YZ:** Sub-chapter numbers reflecting the requirement's area
- **N:** Sequential number within the sub-chapter
- **AAA:** The first three letters of the chapter topic

For instance, the requirement for implementing confidence intervals in predictive modeling might state: "X of [example parameter] for measuring model uncertainty are implemented to provide a confidence interval for predictions in the app available at [time point]".

2.2 Parameters

- **[Example parameter]:** Parameters listed in brackets are adjustable by the WP 1 team during the project period.
- **[time point]:** This refers to the deadline by which a requirement should be met, typically specifying some due date.

2.3 Phases

Each requirement is mapped to a specific project phase:

- **Development:** Focuses on developing the tool's prototype until month 18.
- **Testing:** The prototype undergoes testing until month 18.
- **Validation:** Begins in month 18, marking the start of validating the developed and tested prototype.

2.4 Stakeholders and Owner

Stakeholders: Includes project staff and other relevant groups affected by or necessary for fulfilling the requirement.

Owner: Each requirement is assigned an Owner, usually a WP lead relevant to existing tasks. The Owner is responsible for task delegation and execution to meet the requirement.

2.5 Requirement Categorization

Based on the parameterized statements, requirements are classified into three categories:

- **TOLERABLE:** The minimum achievement threshold for a requirement.
- **GOAL:** Represents the objective aimed to be reached by the project. If both Tolerable and Goal are defined, the project's likely outcome will be between these two.
- **WISH:** Desirable outcomes that are aimed for but likely only partially achieved.

3 Human Agency and Oversight (HUM)

AI systems should support human autonomy and decision-making, as prescribed by the principle of respect for human autonomy. This requires that AI systems should both act as enablers to a democratic, flourishing and equitable society by supporting the user's agency and foster fundamental rights and allow for human oversight.

3.1 Fundamental rights

Like many technologies, AI systems can equally enable and hamper fundamental rights. They can benefit people for instance by helping them track their personal data, or by increasing the accessibility of education, hence supporting their right to education. However, given the reach and capacity of AI systems, they can also negatively affect fundamental rights. In situations where such risks exist, a fundamental rights impact assessment should be undertaken. This should be done prior to the system's development and include an evaluation of whether those risks can be reduced or justified as necessary in a democratic society in order to respect the rights and freedoms of others. Moreover, mechanisms should be put into place to receive external feedback regarding AI systems that potentially infringe on fundamental rights.

None of the identified requirements could be mapped to this category. Other than the requirements addressed in related sections such as privacy, we believe that our tool does not influence fundamental rights.

3.2 Human Agency

Users should be able to make informed autonomous decisions regarding AI systems. They should be given the knowledge and tools to comprehend and interact with AI systems to a satisfactory degree and, where possible, be enabled to reasonably self-assess or challenge the system. AI systems should support individuals in making better, more informed choices in accordance with their goals. AI systems can sometimes be deployed to shape and influence human behaviour through mechanisms that may be difficult to detect, since they may harness sub-conscious processes, including various forms of unfair manipulation, deception, herding and conditioning, all of which may threaten individual autonomy. The overall principle of user autonomy must be central to the system's functionality. Key to this is the right not to be subject to a decision based solely on automated processing when this produces legal effects on users or similarly significantly affects them.

3.2.1 Requirement 12-1-HUM

Description: In the events where there is a clear conflict between the predictions of the tool and the medical opinion of the doctor, a process protocol for epistemic authority dilemmas customized for **physician expertise level** can be followed. Available by **time point**.

physician expertise level: beginner; intermediate; expert

time point: project end

Owner

- WP1

Stakeholders

- WP 1 (ethics)

- WP 3 (design)

- WP 4 (clinical validation)

- Other: medical staff

Tolerable

In the events where there is a clear conflict between the predictions of the tool and the medical opinion of the doctor, a process protocol for epistemic authority dilemmas customized for **beginner; intermediate; expert** can be followed. Available by **project end**.