MES-CoBraD

Multidisciplinary Expert System for the Assessment & Management of Complex Brain Disorders

LET THE AI ASSISTED MEDICINE REMAIN HUMAN

Developing a care centered model of ethical decision making in AI based healthcare

ITAL- AI 2023nConference

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The MES-CoBraD project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under grant agreement No 965422

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THE MES-COBRAD PROJECT

The Mes-CoBraD platform supports **multiple-type data sharing by the creation, sanitisation, anonymisation, harmonisation and upload of complex brain diseases** (COBRAD) RWD datasets

It provides tools for harmonized data collection and analysis through a **single common data-lake environment**. Clinical history, questionnaires and scales, neurophysiology and neuroimaging data can be used.

The platform integrates several general statistical functions and machine learning algorithms, based on the acquired data, and used in a workflow management system, **forming an expert system to support research and diagnostic processes.**

Users without significant technical experience or available computational resources will be able to **share, review and analyze their data in a unified ecosystem**.

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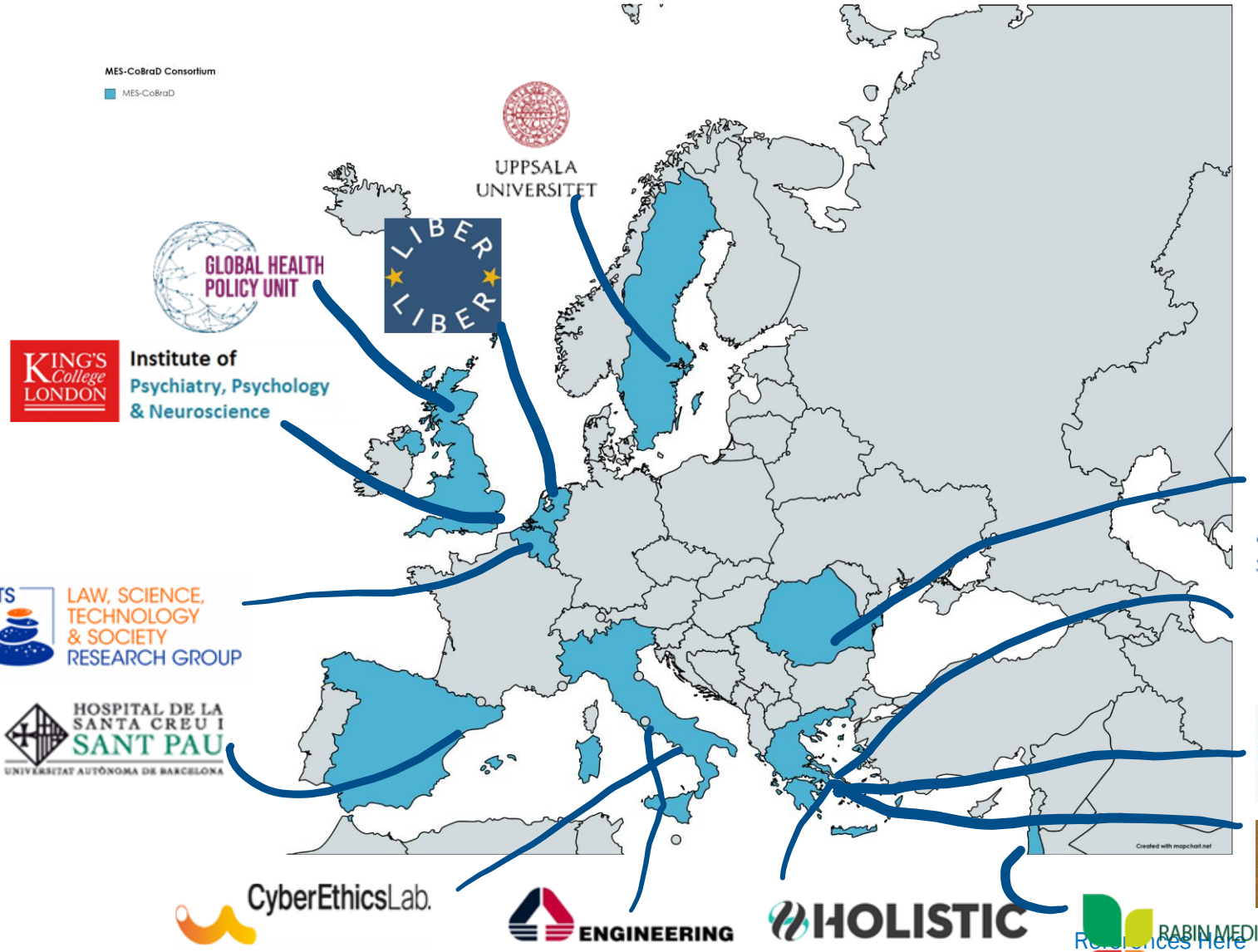
PROJECT CONSORTIUM



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- **Vision**
  - Improved quality of life for patients, their caregivers, and the society at large

- **Mission**
  - Improve early diagnosis, more accurate prognosis, and therapeutic outcomes in Complex Brain Disorders (CoBraD)

- **Goals**
  - Identify and assess real-world clinical and social information from patients and their caregivers, leveraging scientific research in CoBraD and technical innovation in secure data-sharing platforms, AI, and Expert Systems towards precision and personalized care

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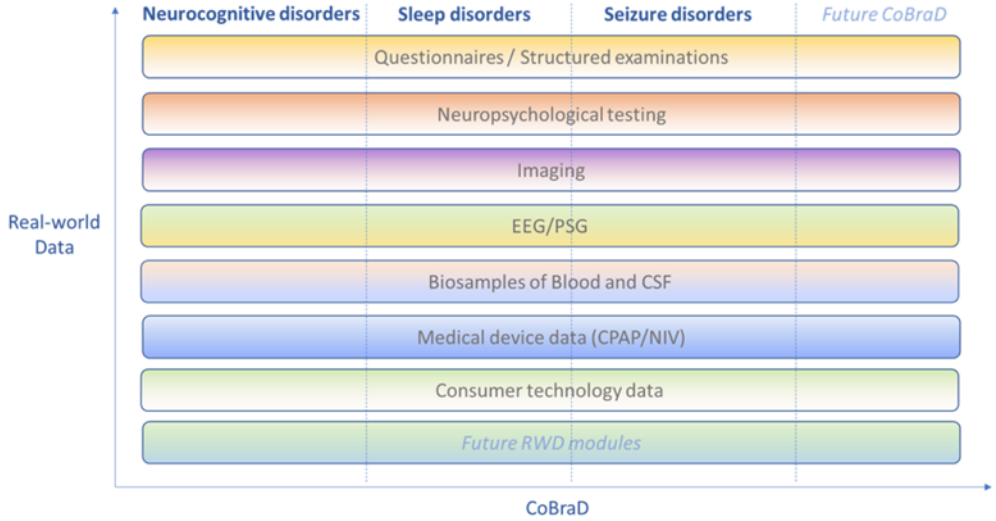
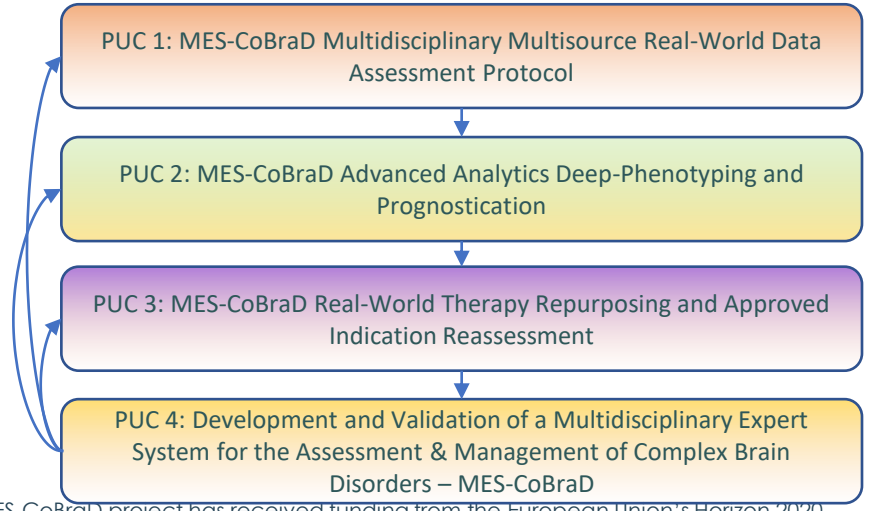
RESEARCH & INNOVATION THROUGH THE MES-COBRAD PROJECT

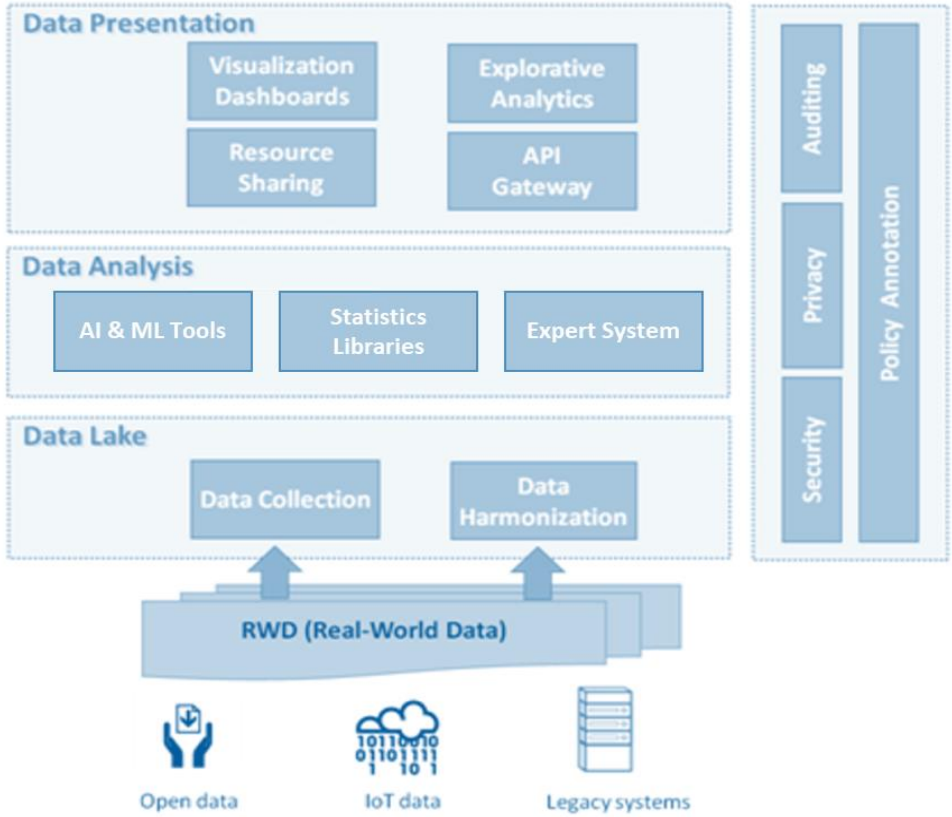
RWD Modular Structure across CoBraD



Pilot Use Cases of Research & Innovation



MES-CoBraD Modular Platform & Data Analytics



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CHALLENGES IN COBRAD – RESEARCH

- **Incomplete assessment of multidimensional CoBraD pathophysiology**
  - Focus on specific processes that are not integrated into more complex CoBraD processes
  - Limited effort to harmonize and integrate RWD or of stand-alone analytic modules into larger platforms
- **Multiple failed costly CoBraD clinical trials**
  - Late treatment initiation, inappropriate medication dosing, erroneous selection of treatment targets, and an incomplete understanding of complex pathophysiology
  - Lack of combination therapies
- **Lack of integration and limited exploitation of research expertise and resources**
  - Comparatively few projects of multisite collaboration
  - Even fewer mechanisms allowing integration of small single-researcher projects into larger collaborative projects
  - AI deliverables within research-oriented institutions and not in clinically-oriented institutions
  - Limited research in low socioeconomic background institutions and, by extension, populations

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CHALLENGES IN COBRAD – TECHNOLOGICAL

- Multisource RWD and consumer technology data resides in isolation across systems and databases
  - Multisource real-world clinical information access and integration
- Low interpretability of complex information stored in large databases
  - User-friendly interface and practical visualization of complex information
- Top-down rigidly structured existing platforms without flexibility and up-to-date potential
  - Dynamic modular updateable platforms
- AI exploitable by experienced scientists with increased resources and not integrated as tools in most platforms
  - Implementation of Advanced Analytics and Artificial Intelligence to optimize diagnostic and therapeutic algorithms
- Lack of access to expert opinion for the known-unknowns and the unknown-unknowns
  - Expert System algorithms to assist in clinical decision making

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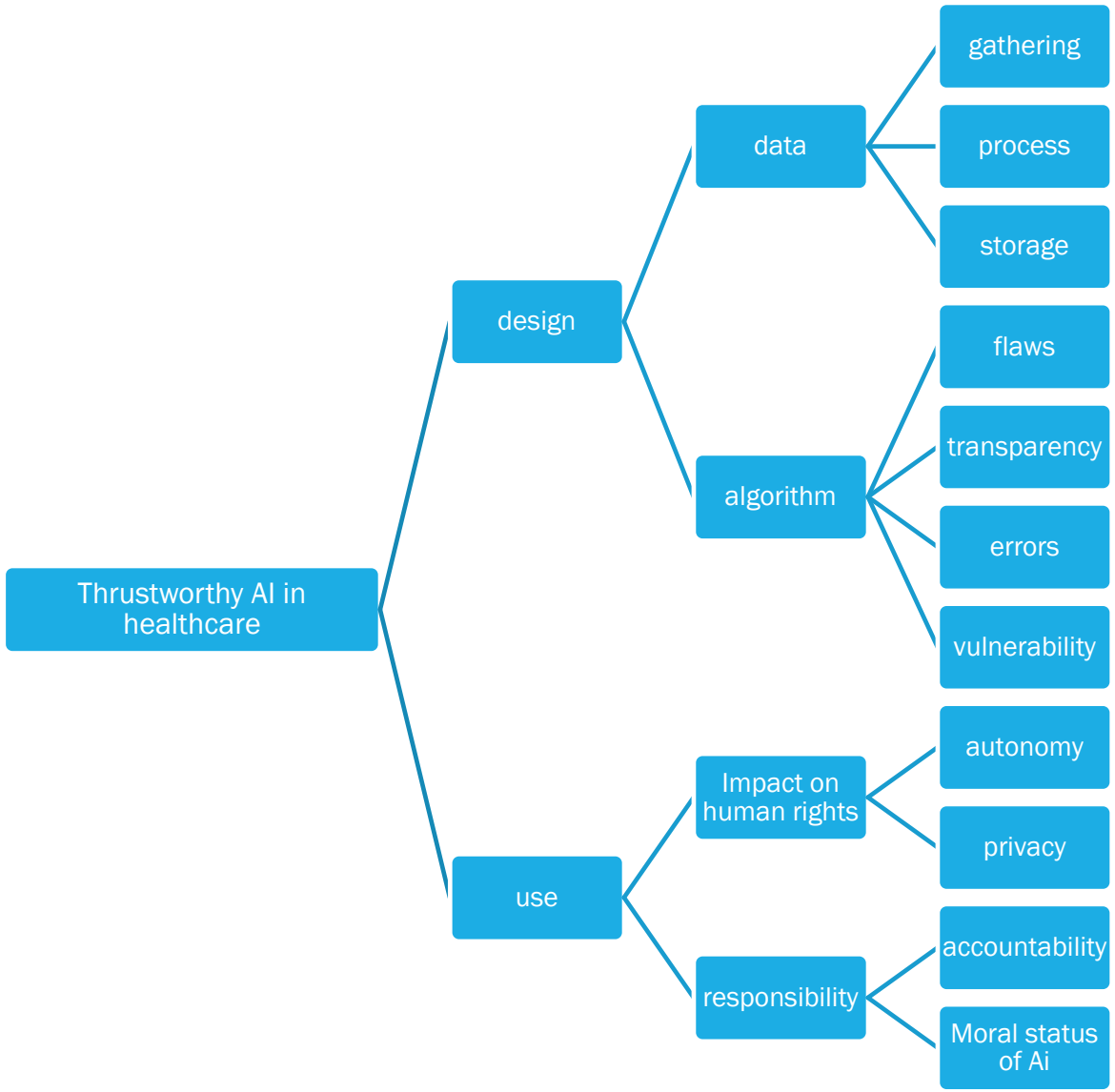

Datasets quality and representativness

Opacity/autonomy

Algorithmic biases

Safety/security

Respect of human rights

Responsibility attribution/rights to redress

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CHALLENGES IN COBRAD – SOCIETAL AND ETHICAL

- The system could infringe human autonomy and dignity
  - The “black box” nature of many ML algorithms and their complexity questions the explainability of the system’s outputs. Do patients really have means of giving a true “informed” consent?
- The system could be perceived as some sort of “authority”, absence of biases not granted
  - System not fully trustable, frailty in case of application to different contexts, datasets not fully representative of social contexts, under-represented groups or low-income countries not included, presence of “authority” biases
- Responsibility and accountability
  - Who is responsible in case of errors and damages and who is accountable? Are we going towards a deresponsabilization of clinicians? On what basis the decision about the validity of a certain system’s output is taken if the system is not transparent?
- Depersonalization of care
  - Medicine is going towards an extensive presence of AI tools and techniques. Are we going towards a knowledge-based medicine as opposed to an experience based one? What about the relationship doctor/patient? Is it important in the context of healthcare?
- Effects at scale, risks of misuses and of social scoring
  - The effects on health systems of the introduction of any AI healthcare system should be attentively meditated. Risks of misuses and social scoring (e.g. people denied insurance or a job)
- Strong ethical uncertainty: how to behave in ethically complex situations?
  - Need of supporting both healthcare professionals and developers in the process of building and interactig with an expert system dedicated to healthcare

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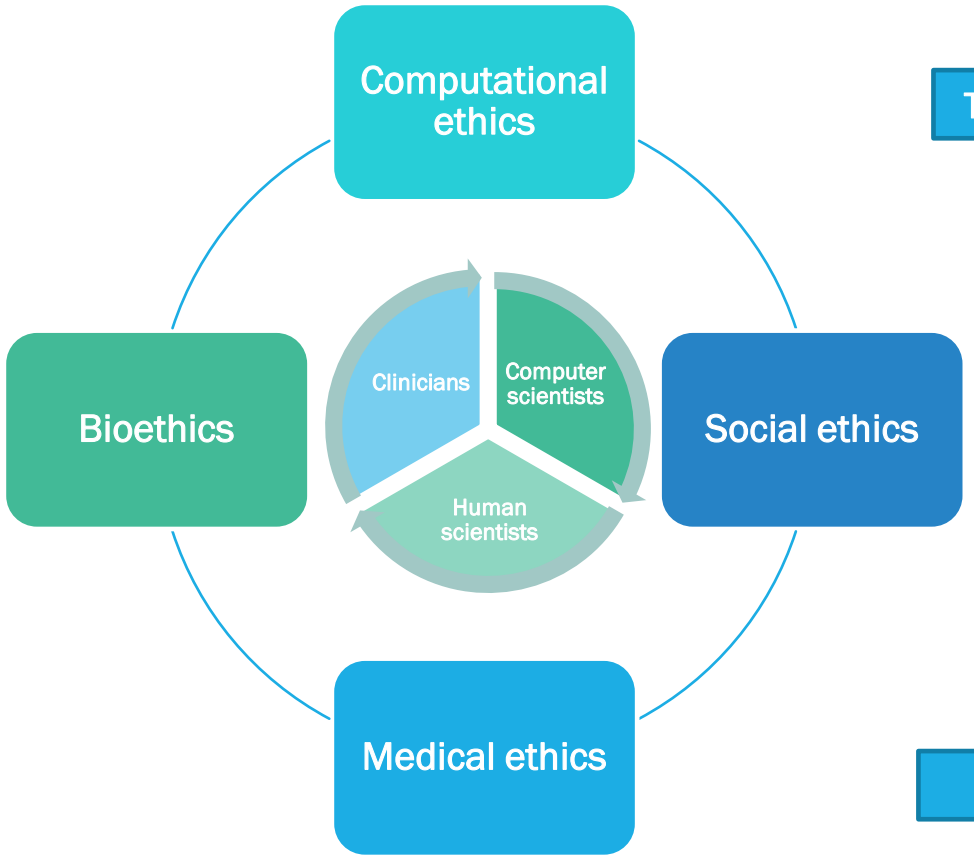
ETHAI MODEL: APPROACH AND OBJECTIVES



Theoretical — Set up a tailored ethics standard on AI in healthcare

Clinical — Framework that can be used as a reference for decision making processes in AI technologies for health research

Ethical — Analyse the reasons that could lead to an ethical misalignment and generate risks or cause negative impacts on patients

Societal — Make the Platform exploitable by the wider community of stakeholders while securing legal ethical medical and social standards and practices for artificial intelligence

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ETHAI MODEL: WHY WE NEED IT

To facilitate collaborative (AI+human) decision making in healthcare AI

To guide developers in the design and deployment of the system

To bridge the gap between the ethical principles, the regulation, and the development of the system(s)

To assist users in their decision making process, mantaining it human centered

To reassure stakeholders that the tool is not going to cause ethical concerns

To scientifically contribute towards the process to safely (ethically) integrate AI into healthcare

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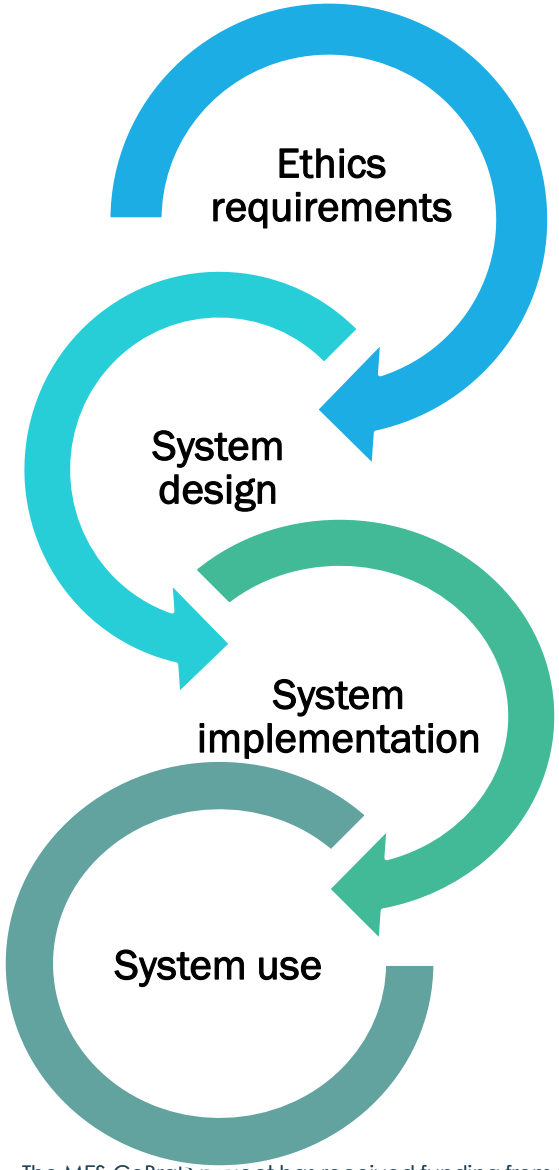
ETHICS AS A PROCESS



Ethics by design

Ethical requirements may not be understood

No feasible translation «into practice» of ethical requirements

Even if the system is «designed ethically» there may be ethical doubts or dilemmas

Ethics not only during the assessment phase.
Should not be an assessment but a process, entering all the project phases and including all the teams

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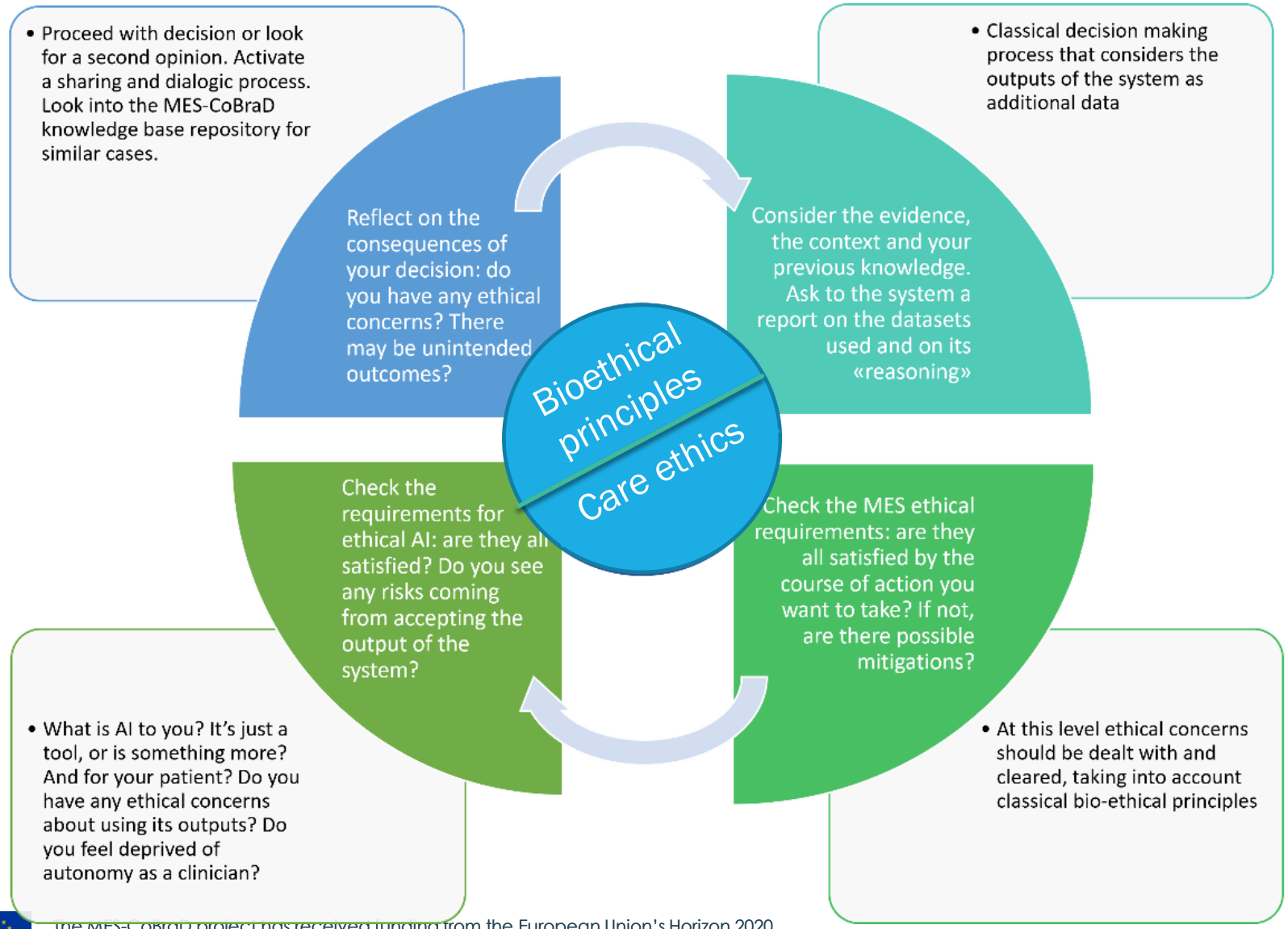
THE ETHAI MODEL



General approach that has been adapted and itemized for the ethical problems of AI applied to health care

Will be applied to case studies provided by the scientific partners to assess it against real word contexts

A comparison with two different approaches at the basis (principalism and care ethics) will be attempted

Should serve as a guideline for both clinicians and developers

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ETHAI MODEL: BASE PRINCIPLES AND MAIN QUESTIONS

Principalism

Bioethics principles

- Beneficence
- Non maleficence
- Justice
- Autonomy

AI HLEG Guidelines

Human Agency and Oversight;
Technical Robustness and Safety;
Privacy and Data Governance;
Transparency;
Diversity, Non-discrimination and Fairness;
Societal and Environmental Well-being;
Accountability

Question: is it sufficient to capture all that is necessary to make an AI system «ethical»?
Ample debate on this

Question: do we risk of leaving something out?
The human characteristics that are so fundamental in healthcare?
If we could obtain a system that always makes perfect diagnoses would that be sufficient for healthcare?

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PURPOSES OF AN ETHAI MODEL

Two kinds of problems:

Lead to a twofold solution

Ensure that the system is designed and developed so as to respect ethical values and requirements and that delivers ethically sound outputs

Design

Outline ethical requirements (and their base values) and ensure (test) that **they are embedded into the design and the development of the system.**

Help clinicians and stakeholders in the decision making process when using the system in clinical practice or in research

Use

Apply the model to real use cases, it should help users to **decide how to act in ethically problematic situations** and to **ethically use the outputs of the system**

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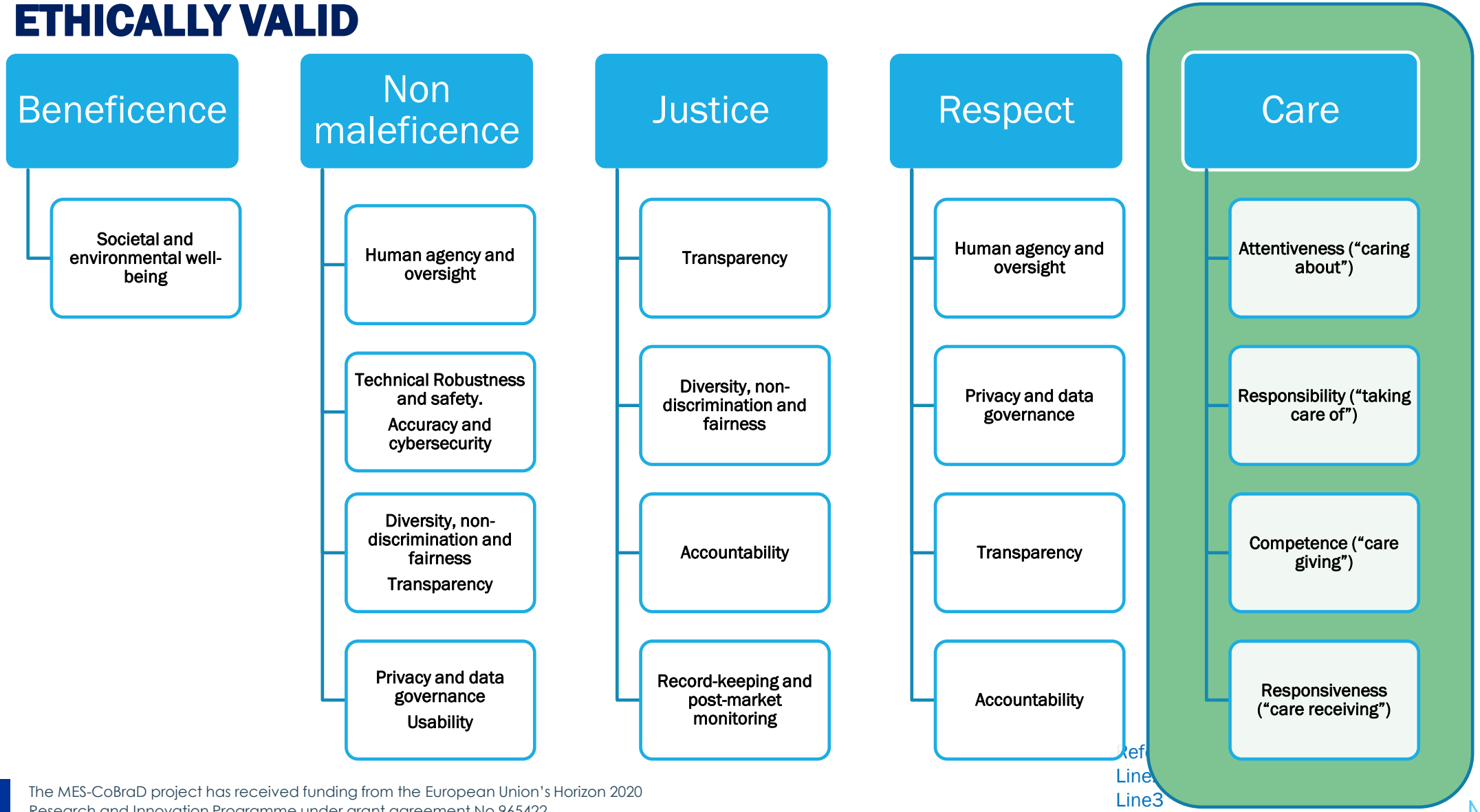
DESIGN THE SYSTEM IN A WAY THAT ENSURES THAT THE OUTPUT IS ETHICALLY VALID



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USE THE OUTPUTS OF THE SYSTEM IN A WAY THAT IS ETHICALLY VALID

Interpretation

- MRI and other data on which system acts to deliver an output are are based on probabilistic covariances and not on causal connections, the system output is the result of an interpretation which in turns depends on the theory behind the system.
- Machine learning algorithms are opaque, the reasons why a certain output is delivered may be not knowable. On what basis the clinician decides to accept a certain result/diagnosis?
- Risk of a reductionist approach to brain diseases. Mental care is not only biological. Consider socio/cultural/psychological determinants

Communication

- Pristine diagnosis: should it be communicated? The burden of knowledge and the possible discriminations caused by being an at-risk patient should be considered
- Have the patient's needs and point of views been considered?
- Doctor/Patient relationship: how should the clinician behave so as to not put at risk his/her trust relashionship with the patient?

Decision

- How can the patient decide on the basis of opaque data and reasoning?
- Is the clinician accountable if he decides on the basis of opaque data and reasoning or of a wrong output?
- What degree of probability would count as sufficient when dealing with the prediction of a disorder? Would the potential harm caused by drugs justified?

Discrimination

- Unwanted biases problem: biases may be present due to diverse factors. How should the clinician behave in order to minimize the risk of discriminating against a single or a group?
- Risk of social scoring: with the progress of brain-scan techniques the neuro privacy and cognitive privacy could be at risk and the results could be exploited for unclear purposes. Risks of patient reidentification using MRIs and biometrics.
- Use at scale: MES-CoBraD could be used do support policy makers in deciding about Government's health policies. But the system outputs are probabilistic in nature. How minimize the risk of wrong conclusions?

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CARE ETHICS VS PRINCIPALISM

- For care ethics ethical **problems cannot be solved by means of abstract principles**
- Principalism approaches see the individual as a sovereign being with the right to self defence
- Care ethics focuses on the **fundamental dependence of each individual with respect to other ones** rather than on their sovereignity
- The dependance of each individual towards the other ones is considered normal and paradigmatic for relashionships
- Care ethics puts the ethical problems in context. **Relashionships** are the most important context. They are a fundamental feature of human existence and play a significant role into ethical problems
- Principlism adopts a deductive approach: action is derived and justified from abstract principles
- **Care ethics focuses on understanding the particular nature of the patient and their situation**. Generalisability is replaced by singularity and particularity.

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CARE ETHICS ISSUES IN THE CONTEXT OF AI SYSTEMS

- **How to translate care ethics principles into requirements** that could be adopted in the context of a model for ethical design, evaluation and use of healthcare **AI systems**?
- **Are patients equivalent to the data it's possible to gather and process about them**? Do data tell us all that it's useful to take care of the patient (diagnosis and terapy)? If not, how is it possible to define exactly what the datafication approach misses?
- Ho to take into account into a model for ethical AI in healthcare the fundamental aspect of **human interaction**? Between doctors and the system and between patients and doctors using the system
- **Is it possible to reconcile a care approach to healthcare with an AI based one**?
- Working on the requirements with clinicians and researchers as well as reflecting on how to incorporate the point of view of patients led us to **critically reconsider the ETHAI model, shifting the attention towards and approach that puts the concept of care at its basis**

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REQUIREMENTS – CARE

Req #ID	Identified Risk	MES-CoBraD Requirement
Attentiveness ("caring about")		
CA1	External factors, other than the true patients' needs, guide the development of the system. This results into a system that does not meet patients' needs and that might also be in conflict with them	Take into account, during the design phase, the patients' needs, listening to them in dedicated focus groups and co-creation workshops, in order to design a system that has patients' vision and needs embedded into it from the beginning
CA2		Pay attention that the project research is guided by patients' needs and not by other – external – issues, such as scientific curiosity, advancement of a certain field of research, etc.
Responsibility ("taking care of")		
CR1	A biological deterministic attitude is adopted, not considering factors that are essential to the human beings, especially in the healthcare and even more in brain diseases field	During the data collection phase, insert also variables about how the patients responded emotionally and psychologically to therapies. Use these variables to suggest the best therapy for a specific patient (matching his/her profile with those in the knowledge base), taking into account not only biological but also emotional factors and aiming at the maximum possible grade of personalization of care (the best therapy for that particular patient)
Competence ("care giving")		
CC1	Only technological parameters (e.g. system robustness) are considered during the design and development phase, bringing to neglect fundamental aspects proper of a care relationship	Parameters that assess the quality of care shall be identified and the system shall be assessed against them
Responsiveness ("care receiving")		
CRS1	Patients' feedback and opinions about something (the care plan) that directly concerns them aren't considered, resulting into an arrogant approach	Before and after the release, user acceptance tests that also involve patients shall be executed
CRS2		The patient shall have a way to report their feedback, which shall be taken into consideration by researchers in dedicated and periodical review sessions
CRS3		The consequences and impact on human beings (both at the individual level and at the societal level) of the introduction of the MES-CoBraD ES shall be evaluated and assessed beforehand and continuously monitored in the post-release phase
CRS4		A structured way of monitoring the effects of the introduction of MES-CoBraD on the patient/doctor relationship shall be set

ETHAI MODEL: WHERE WE ARE NOW

Ethical principles defined

Requirements checked, to be refined and furtherly expanded

Model to be completed and validated, use cases to be gathered

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WHERE WE ARE NOW

We examined the requirements with clinicians and engineers to refine and possibly change them

The platform for RWD analysis is almost completed

We are building the knowledge base

We must attach to ethical requirements AI tools and techniques to satisfy them. Problem: detachment between ethical requirements and their implementation, people who should emebed them in the stystm do not understand them and how to translate them into practice

The ES is still under development

We are refining the requirements and the ethical decision model and we are gathering use cases to work on them with the help of the model and see if it delivers sensible results

Gather use cases	• From the clinicians and the researchers (also peculiar to COBRAD) • From literature
Build knowledge base	• Ethically relevant cases • Policy briefs and other relevant documentation
Discuss requirements	• Check if they are sensible and achievable • Are they enough to grant an ethical outcome? • Involve stakeholders
Clarify if the system is a medical device	• In case it is, define the steps for the conformity assessment
Attach tools and techniques to requirements	• Per each requirement attach the technique or tool we are going to use to implement it
Validate the model	• Applying it to real use cases and working with the clinicians

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HOW TO VALIDATE THE MODEL

Apply MES-CoBraD ES to Sample use cases (to be provided by medical partners) OR Reason with medical partners on sample use cases that may pose ethical dilemmas

Consider the output of the system

Identify the ethical questions to be tackled by the clinician

What can we say about the embedding of the requirements? Has it been correctly done?

Does the system return enough evidence to allow to understand its reasoning (for different audicences)?

Reach a conclusion using the ETHAI model: is it satisfactory? Would the conclusion have been different if we changed something (e.g. the base values) in the model? Is the model helpful in supporting decision making?

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THANK YOU FOR YOUR ATTENTION

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