

ETHICAL CONSIDERATIONS IN THE VIRTUAL HUMAN TWINS DEVELOPMENT



Michele Barbier, PhD

European Project manager – Human Digital Twins, Inria
Ethics expert for the European Commission

Michele.barbier@inria.fr

A Virtual Human Twin, definition



Funded by
the European Union

A Virtual Human Twin is a patient-specific virtual representation of real-world systems or processes, that is built on data-driven or knowledge-driven - most often a combination of both - predictive computer models, and that can be used as a clinical decision-support system, a personal health forecasting tool or as a tool for the development and personalization of medical products.

@Michele Barbier, Inria

Virtual Twin of the Heart

Virtual Patients

Drug Testing

Device Design

Therapy

Diagnosis

Training

Healthcare Innovation

Clinical Applications

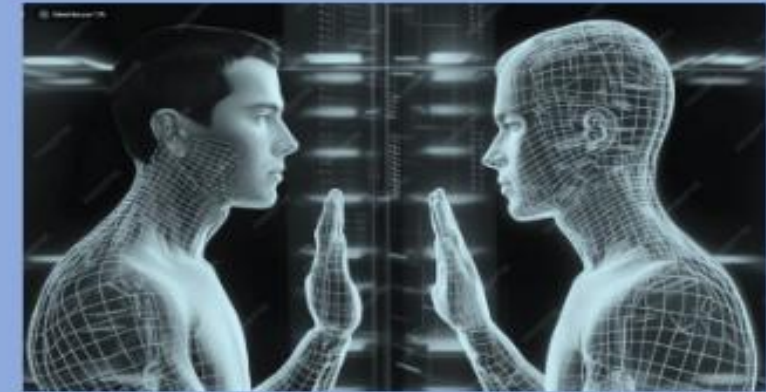
PROFESSIONAL RESPONSIBILITY

Cardiac modeling



Ethics

Reflection on human behaviour and the values that underpin it, with a view to establishing a doctrine or science of morality.



Digital Twins in Health Issues, Definitions and Ethical Challenges

BRIEFING NOTE FOR THE FUTURE WORKING
GROUP GT15 OF THE FRENCH DIGITAL HEALTH
ETHICS UNIT

SEPTEMBER 2025

@Michele Barbier, Inria

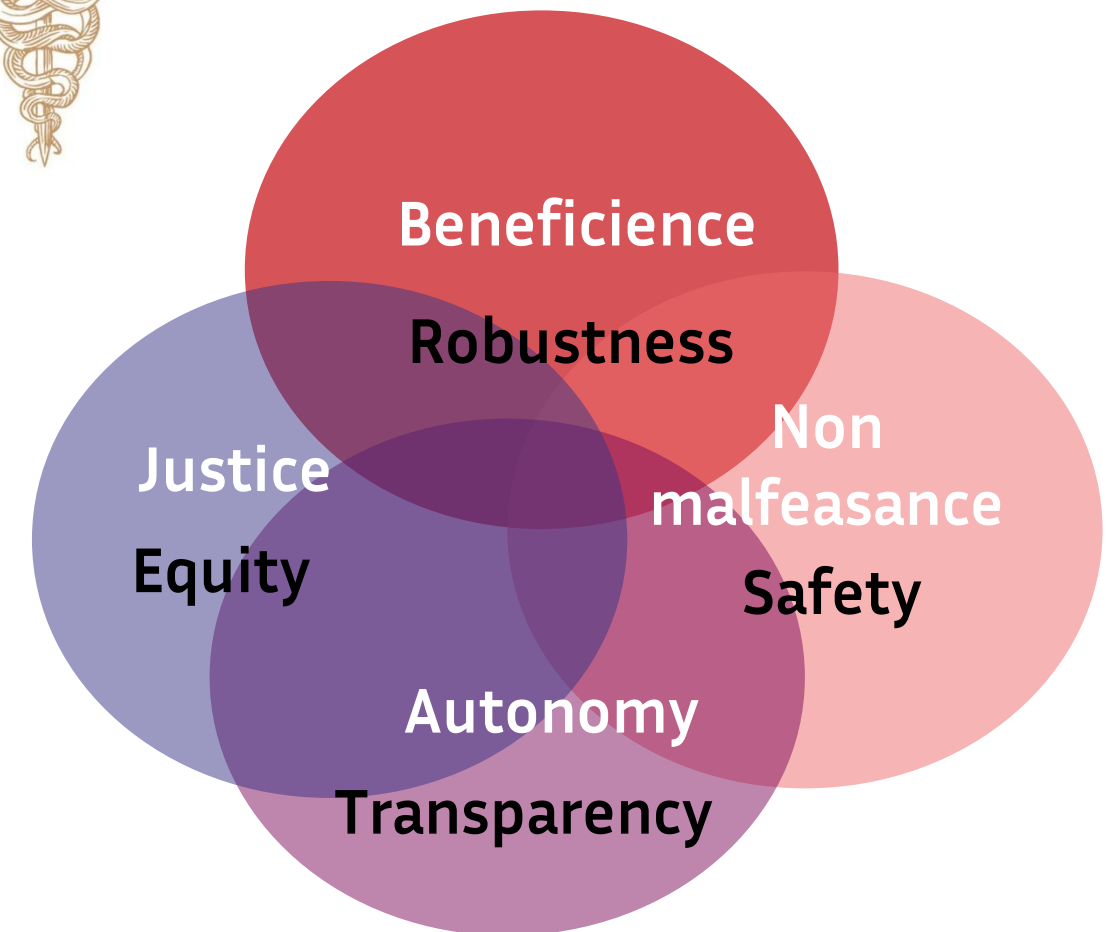
└ A Virtual Human Twin

*A Virtual Human Twin is a patient-specific virtual representation of real-world systems or processes, that is built on data-driven or knowledge-driven - most often a combination of both - predictive computer models, and that can be used as a **clinical** decision-support system, a personal **health** forecasting tool or as a tool for the development and personalization **of medical products.***

@Michele Barbier, Inria



Clinical ethics – Hippocratic Oath



Funded by
the European Union

A Virtual Human Twin

A Virtual Human Twin **is a patient-specific** virtual representation of real-world systems or processes, that is built on data-driven or knowledge-driven - most often a combination of both - predictive computer models, and that can be used as a clinical decision-support system, a personal health forecasting tool or as a tool for the development and personalization of medical products.



@Michele Barbier, Inria



The Nuremberg Code (1946-1947)
Declaration of Geneva, 1948
Helsinki Declaration, 1964
Convention Oyeido, 1999
...

Consent
proportionnality
necessity
right to withdrawal

┐ *A Virtual Human Twin*



Privacy rules, security rules, transaction and code sets, unique modifier rule and enforcement rule



@Michele Barbier, Inria

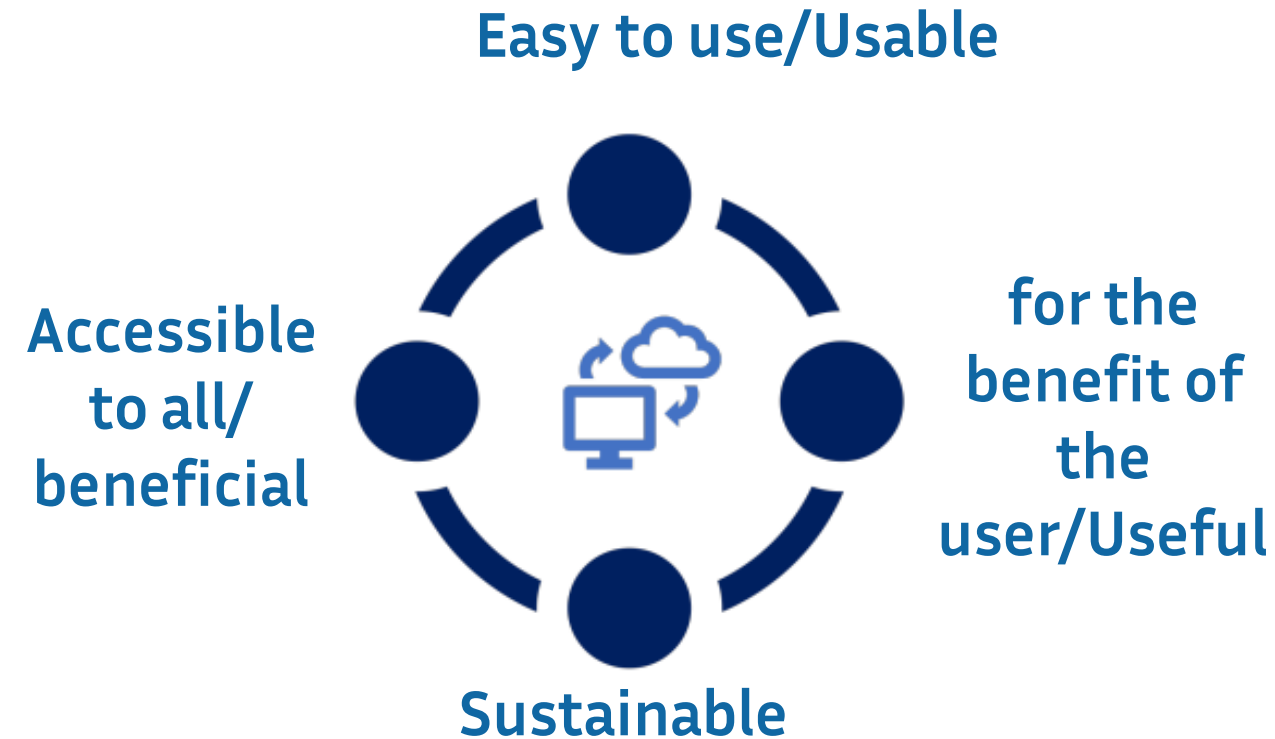
What is the Five Safes framework? - UK Data Service

└ A Virtual Human Twin

A Virtual Human Twin is a patient-specific virtual representation of real-world systems or processes, that is built on data-driven or knowledge-driven - most often a combination of both - predictive computer models, and that can be used as a clinical decision-support system, a personal health forecasting tool or as a tool for the development and personalization of medical products.

@Michele Barbier, Inria

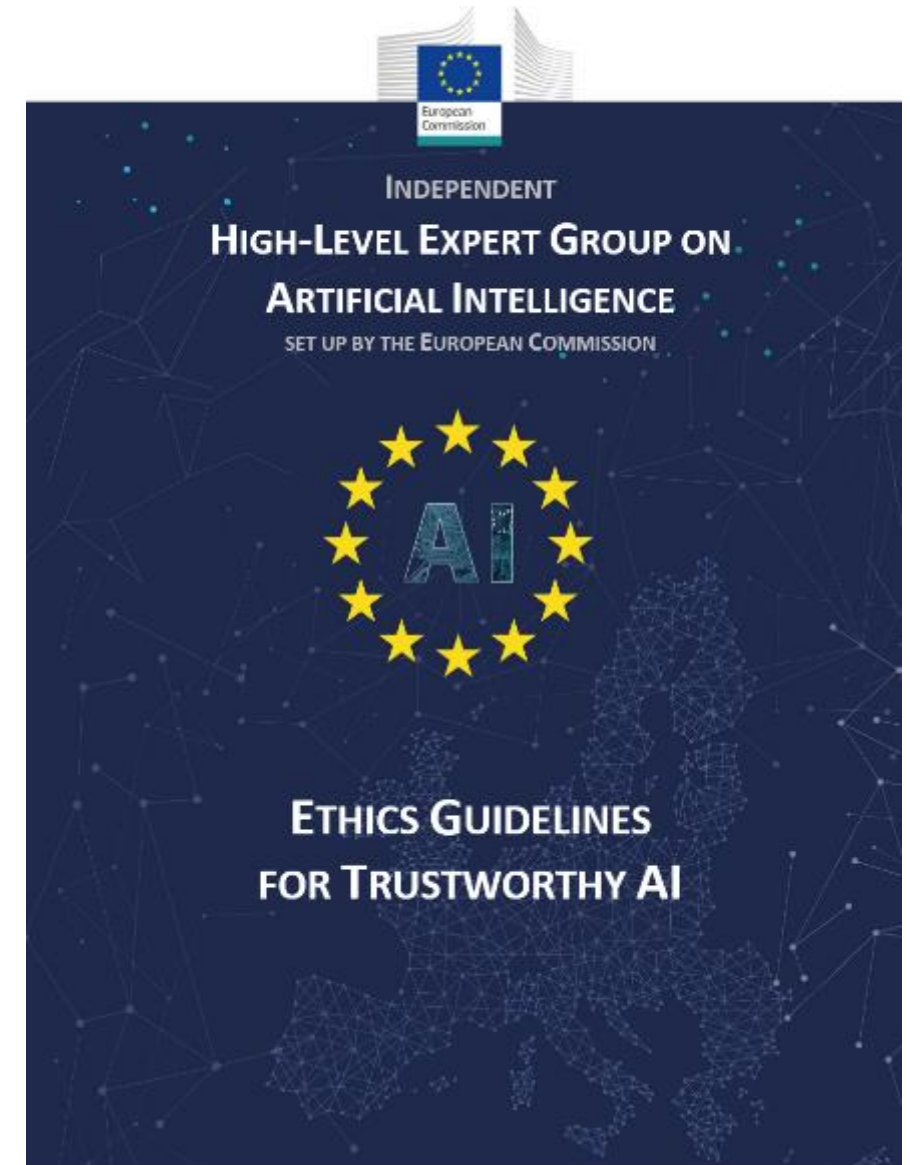
Digital ethics



Funded by
the European Union

A Virtual Human Twin

*A Virtual Human Twin is a patient-specific virtual representation of real-world systems or processes, that is built on data-driven or knowledge-driven - most often a combination of both - **predictive computer models**, and that can be used as a clinical decision-support system, a personal health forecasting tool or as a tool for the development and personalization of medical products.*

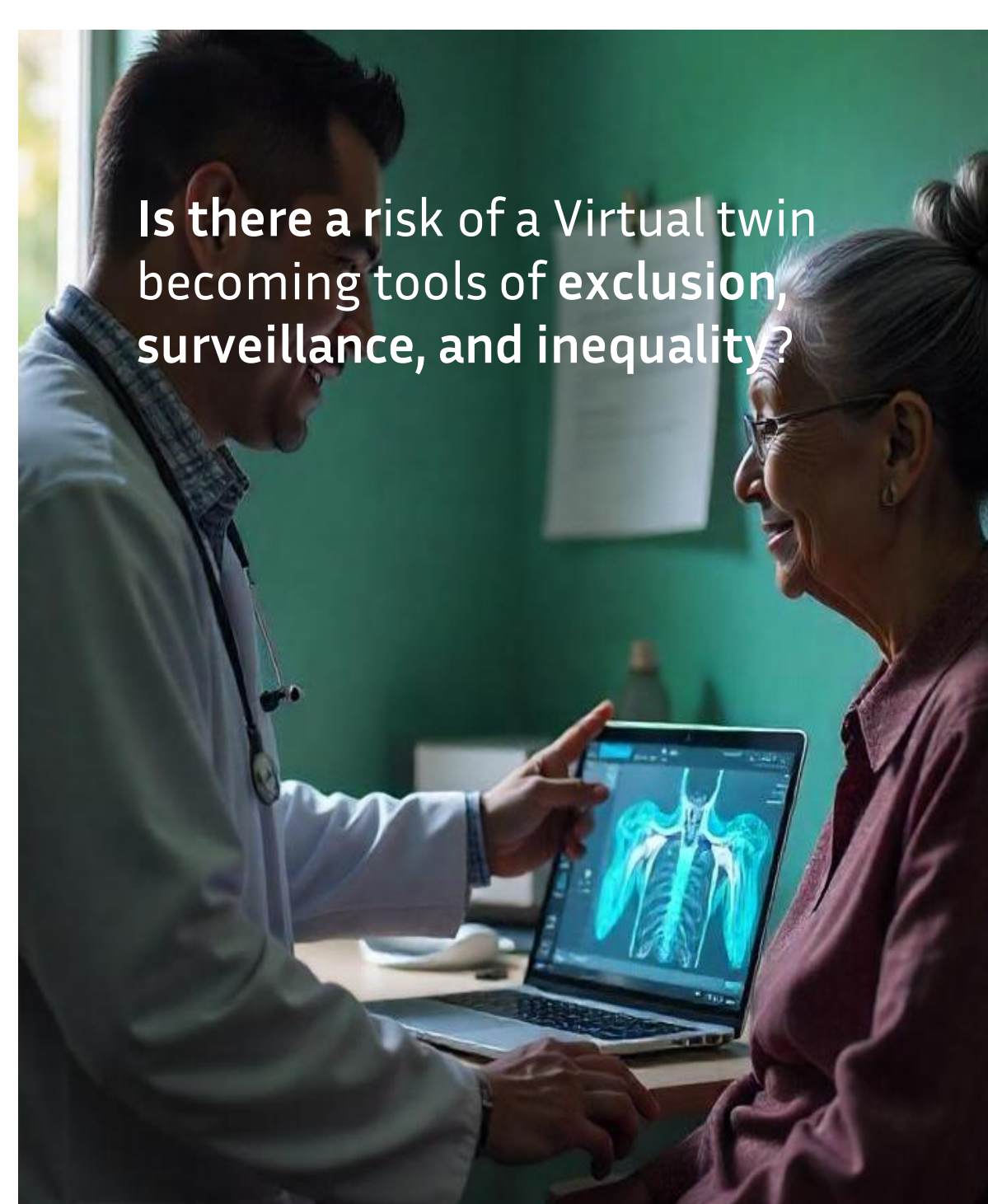


 Funded by
the European Union

@Michele Barbier, Inria

<https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai>

https://assets.ctfassets.net/7s4afyr9pmov/4AXIWGllcrjWDaW2ueTaRS/f98e5cb2528187635895cce6ba5ec309/Blueprint_for_Trustworthy_AI.pdf



Is there a risk of a Virtual twin becoming tools of exclusion, surveillance, and inequality?

Patient's expectations and *needs*

- better health : help improve quality of life ,
Increase individual autonomy
- Optimise the use of healthcare resources: faster access, lower costs
- Assist with diagnosis
- Assist with prognosis
- Assist with planning medical intervention
- Continue to be respected as a human being

@Michele Barbier, Inria



The integration of digital twins into healthcare represents a paradigm shift in how we collect, analyze, and act on personal health data. Immense promise for personalized and predictive medicine, how to resolve legal ambiguities, ethical risks, and governance gaps it introduces. Robust frameworks that prioritize privacy, consent, and patient rights. Digital twins

We must ensure that innovation aligns with the fundamental principles of dignity, freedoms, autonomy, and justice.

@Michele Barbier, Inria

9 KEY CONSIDERATIONS

Privacy, Consent, and Data Governance: Challenges for dynamic, adaptive c individuals

Credibility, Trust, and Agency: Verification, Validation, and Uncertainty Qua that algorithms are accurate, reliable, and transparent

Statistical Normality & the Risk of Determinism: Deterministic thinking st change, resilience, and human agency

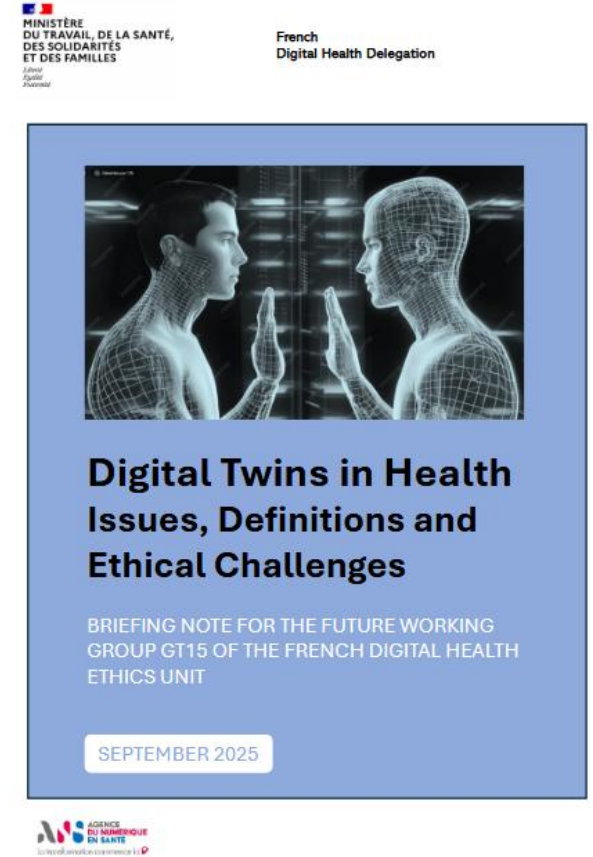
Decision-Making: Share or Algorithmic? Balancing Human Judgment and

Accountability and Liability: Who bears responsibility when things go wro

Human Dignity & the Art of Care: Preserving What Algorithms Cannot Capture, Medicine is a practice of discernment, responsibility, and embodiment.

Social Justice and Accessibility: principles of fairness.

Frugality and sustainability: Digital medicine must align with ecological transition goals, avoiding energy-intensive infrastructures that contradict sustainability objectives.



 **Privacy, Consent, and Data Governance:** Challenges for continuous, dynamic, evolving adaptive digital replicas of individuals, Bias, own control, autonomy

Credibility, Trust, and Agency: Verification, Validation, and Uncertainty Quantification (VVUQ) to ensure that algorithms are accurate, reliable, and transparent

Statistical Normality & the Risk of Determinism: Deterministic thinking strips away the possibility of change, resilience, and human agency

Decision-Making: Shared or Algorithmic? Balancing Human Judgment and Machine Insight

Accountability and Liability: Who bears responsibility when things go wrong?

Human Dignity & the Art of Care: Preserving What Algorithms Cannot Capture, Medicine, is a practice of discernment, responsibility, and encounter.

Social Justice and Accessibility: principles of fairness.

Frugality and sustainability: Digital medicine must align with ecological transition goals, avoiding energy-intensive infrastructures that contradict sustainability objectives.

 **Privacy, Consent, and Data Governance:** Challenges for dynamic, adaptive digital replicas of individuals

Credibility, Trust, and Agency: Verification, Validation, and Uncertainty Quantification (VVUQ) to ensure that algorithms are accurate, reliable, reproducible, and transparent. Dataset assessment, Monitoring

Transparency and explainability are democratic imperatives.

Statistical Normality & the Risk of Determinism: Deterministic thinking strips away the possibility of change, resilience, and human agency

Decision-Making: Shared or Algorithmic? Balancing Human Judgment and Machine Insight

Accountability and Liability: Who bears responsibility when things go wrong?

Human Dignity & the Art of Care: Preserving What Algorithms Cannot Capture, Medicine, is a practice of discernment, responsibility, and encounter.

Social Justice and Accessibility: principles of fairness.

Frugality and sustainability: Digital medicine must align with ecological transition goals, avoiding energy-intensive infrastructures that contradict sustainability objectives.

 **Privacy, Consent, and Data Governance:** Challenges for dynamic, adaptive digital replicas of individuals

Credibility, Trust, and Agency: Verification, Validation, and Uncertainty Quantification (VVUQ) to ensure that algorithms are accurate, reliable, and transparent

Statistical Normality & the Risk of Determinism: comparing individuals against statistical norms, overlooks the uniqueness of individual experiences, Deterministic thinking strips away the possibility of change, resilience, and human agency,

Decision-Making: Shared or Algorithmic? Balancing Human Judgment and Machine Insight

Accountability and Liability: Who bears responsibility when things go wrong?

Human Dignity & the Art of Care: Preserving What Algorithms Cannot Capture, Medicine, is a practice of discernment, responsibility, and encounter.

Social Justice and Accessibility: principles of fairness.

Frugality and sustainability: Digital medicine must align with ecological transition goals, avoiding energy-intensive infrastructures that contradict sustainability objectives.

 **Privacy, Consent, and Data Governance:** Challenges for dynamic, adaptive digital replicas of individuals

Credibility, Trust, and Agency: Verification, Validation, and Uncertainty Quantification (VVUQ) to ensure that algorithms are accurate, reliable, and transparent

Statistical Normality & the Risk of Determinism: Deterministic thinking strips away the possibility of change, resilience, and human agency

Decision-Making: Shared or Algorithmic? Balancing Human Judgment and Machine Insight. Shifting authority from dialogue to data, **Marginalized clinical judgment and diminished patient autonomy**, as decisions become acts of **adjusting to predictions** rather than deliberative choices. **Algorithmic heteronomy**

Accountability and Liability: Who bears responsibility when things go wrong?

Human Dignity & the Art of Care: Preserving What Algorithms Cannot Capture, Medicine, is a practice of discernment, responsibility, and encounter.

Social Justice and Accessibility: principles of fairness.

Frugality and sustainability: Digital medicine must align with ecological transition goals, avoiding energy-intensive infrastructures that contradict sustainability objectives.



Privacy, Consent, and Data Governance: Challenges for dynamic, adaptive digital replicas of individuals

Credibility, Trust, and Agency: Verification, Validation, and Uncertainty Quantification (VVUQ) to ensure that algorithms are accurate, reliable, and transparent

Statistical Normality & the Risk of Determinism: Deterministic thinking strips away the possibility of change, resilience, and human agency

Decision-Making: Shared or Algorithmic? Balancing Human Judgment and Machine Insight

Accountability and Liability: Who bears responsibility when things go wrong? accountability becomes fragmented, dilution of responsibility, multiple layers of decision-making

Human Dignity & the Art of Care: Preserving What Algorithms Cannot Capture, Medicine, is a practice of discernment, responsibility, and encounter.

Social Justice and Accessibility: principles of fairness.

Frugality and sustainability: Digital medicine must align with ecological transition goals, avoiding energy-intensive infrastructures that contradict sustainability objectives.

 **Privacy, Consent, and Data Governance:** Challenges for dynamic, adaptive digital replicas of individuals

Credibility, Trust, and Agency: Verification, Validation, and Uncertainty Quantification (VVUQ) to ensure that algorithms are accurate, reliable, and transparent

Statistical Normality & the Risk of Determinism: Deterministic thinking strips away the possibility of change, resilience, and human agency

Decision-Making: Shared or Algorithmic? Balancing Human Judgment and Machine Insight

Accountability and Liability: Who bears responsibility when things go wrong?

Human Dignity & the Art of Care: Preserving What Algorithms Cannot Capture, Medicine is a practice of discernment, responsibility, and encounter. True medicine balances data with compassion, prediction with presence, and calculation with connection. Not a business place

Social Justice and Accessibility: principles of fairness.

Frugality and sustainability: Digital medicine must align with ecological transition goals, avoiding energy-intensive infrastructures that contradict sustainability objectives.

 **Privacy, Consent, and Data Governance:** Challenges for dynamic, adaptive digital replicas of individuals

Credibility, Trust, and Agency: Verification, Validation, and Uncertainty Quantification (VVUQ) to ensure that algorithms are accurate, reliable, and transparent

Statistical Normality & the Risk of Determinism: Deterministic thinking strips away the possibility of change, resilience, and human agency

Decision-Making: Shared or Algorithmic? Balancing Human Judgment and Machine Insight

Accountability and Liability: Who bears responsibility when things go wrong?

Human Dignity & the Art of Care: Preserving What Algorithms Cannot Capture, Medicine, is a practice of discernment, responsibility, and encounter.

Social Justice and Accessibility: healthcare divide or healthcare fairness? vulnerable populations, technological frugality, data minimisation, real-world datasets

Frugality and sustainability: Digital medicine must align with ecological transition goals, avoiding energy-intensive infrastructures that contradict sustainability objectives.



Privacy, Consent, and Data Governance: Challenges for dynamic, adaptive digital replicas of individuals

Credibility, Trust, and Agency: Verification, Validation, and Uncertainty Quantification (VVUQ) to ensure that algorithms are accurate, reliable, and transparent

Statistical Normality & the Risk of Determinism: Deterministic thinking strips away the possibility of change, resilience, and human agency

Decision-Making: Shared or Algorithmic? Balancing Human Judgment and Machine Insight

Accountability and Liability: Who bears responsibility when things go wrong?

Human Dignity & the Art of Care: Preserving What Algorithms Cannot Capture, Medicine, is a practice of discernment, responsibility, and encounter.

Social Justice and Accessibility: principles of fairness.

Frugality and sustainability: Digital medicine must align with ecological transition goals, avoiding energy-intensive infrastructures that contradict sustainability objectives.

Practical guidelines

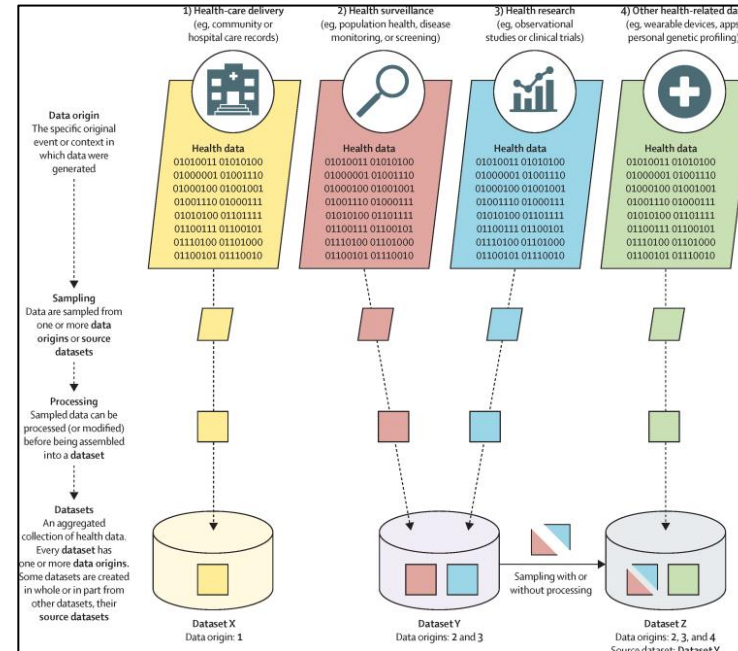


AI evidence pathway for operating trustworthy AI in health (JRC)

AI evidence pathway for operationalising trustworthy AI in health - Publications Office of the EU

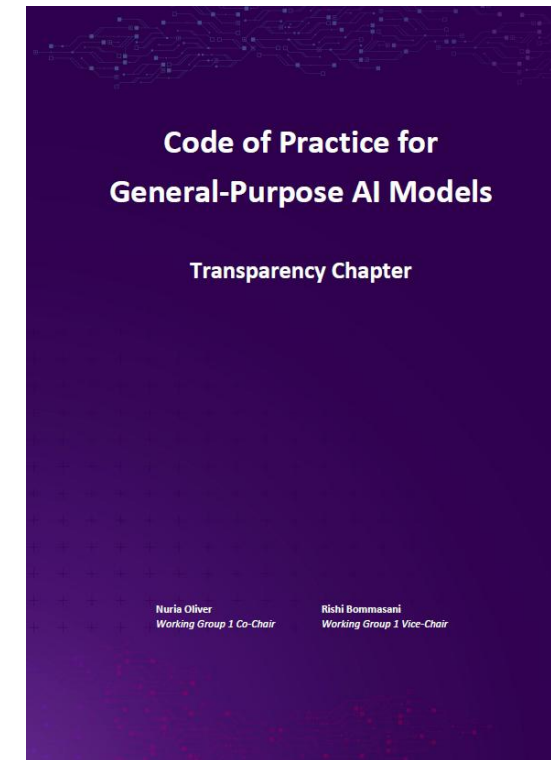
ALTAI - EC

<https://altai.insight-centre.org/>



Health datasets: the STANDING Together consensus recommendations

Alderman JE, et al., Tackling algorithmic bias and promoting transparency in health datasets: the STANDING Together consensus recommendations. Lancet Digit Health. 2025 Jan;7(1):e64-e88.



GPAI / AI ACT

<https://digital-strategy.ec.europa.eu/en/policies/ai-code-practice>



Ethics & algorithms Toolkit

MIT licence

<https://ethicstoolkit.ai/>



**Our social responsibility
for even more diverse impacts
... in a more or less near future**

The main question no longer seems to be, how does the world work?

But how to use, to our benefit, what we observe or measure with our advanced tools?

Hannah Arendt, 1958, 1961

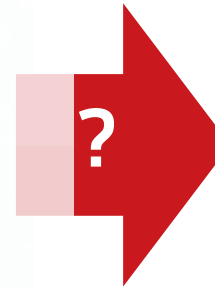
Are we surrounded by this so-called 'doing without understanding'? Baron, 2025

EDUCATION

PLURI-DISCIPLINARITY

Decision-makers, industries and researchers must ensure that the effects of their actions or decisions do not impact the autonomy, dignity, integrity and vulnerability of future humanity.

Hans Jonas, 1979



ELITIST MEDICINE

IMMORTALITY

TRANSHUMANISM

EUGENISM: techno-eugenics

HEDONISTICS IMPERATIVE

SELF-ALIENATION

DEHUMANIZATION

RELATION TO POLITICS



Ashruf, C. Artificial intelligence through the eyes of Hannah Arendt: fear, alienation, and empowerment. *AI & Soc* (2025)

Cooper F.B.K, 1976: The literature of medical ethics: a review of the writings of Hans Jonas, *J. medical ethics*: (2): 39-43

Bazin, D. (2007). *Une introduction au principe responsabilité de Hans Jonas* (No. halshs-00727582).

Baron, Sam (2025). Trust, Explainability and AI. *Philosophy and Technology* 38 (1):1-23.

©Michele Barbier, Inria

1-4 September 2026 - Milan

VPH2026

TOWARDS THE ADOPTION OF
DIGITAL TWINS IN HEALTHCARE



Conference chairs



**FRANCESCO
MIGLIAVACCA**

CHAIR

Politecnico di Milano



**GIULIA
LURAGHI**

CHAIR

Politecnico di Milano



**JOSÉ F.
RODRIGUEZ MATAS**

CHAIR

Politecnico di Milano

Main Topics

- Modelling health and diseased conditions
- Tissue-medical device interaction
- In Silico Trials
- Virtual planning for optimal clinical decision
- **Trusted AI and modeling in Health and Care**
- Knowledge-driven vs data-driven models in healthcare
- Industrial applications of digital twins for healthcare
- Regulatory for digital twins

Info: vph-conference.org



Inria

Thank you

Michele.barbier@inria.fr