A whitepaper on
The ethics and governance of sentient AI
Navigating advanced technologies in health data spaces and systems

Contents

Foreword

Digitalization is a transformative, long-term phenomenon that permeates into nearly every aspect of human life, creating an environment where artificial intelligence[1] (AI) can thrive. As digital systems expand, they generate vast amounts of data fueling the rapid deployment of AI across diverse domains, including healthcare, education, mobility, and governance. AI has already begun to influence critical processes and reshape how institutions function. This raises new ethical, policy, legal, and societal challenges.

The emergence of generative AI (GenAI), followed by the recent developments in bio-integrated computing, neural organoids and synthetic cognition, have shifted discussions from possibility to expectation regarding the development of human-level (or beyond) (artificial) intelligence, which also employs sentience. Sentient AI (hereafter SAI) represents intelligent systems/organisms with direct perception of the world, perhaps also capable of subjective experiences, emotional consciousness, and/or autonomous decision-making. While still emerging, these developments push the boundaries of the capabilities of AI, blurring the lines between tool, (moral) agent, and entity. The profound implication of SAI emerges novel ethical challenges, reshaping existing concerns associated with GenAI by giving rise to complex, transdisciplinary, and domain-specific ethical challenges. These issues include questions of rights, responsibility, accountability, agency, and the societal impact of sentient and intelligent machines or (novel) organisms. This gives rise to a need to consider how we might rethink and revise our ethical and regulatory frameworks for the governance[2] of AI.

Health systems are at the forefront of SAI experimentation and integration (e.g., diagnostics, digital therapeutics, mental health applications). These systems carry high ethical sensitivity due to the involvement of patient data, consent, and risk. As scientific progress accelerates toward the possibility of synthetic or even bioengineered sentience and consciousness, there is a critical need to anticipate and responsibly address the moral, legal, and societal implications of SAI systems. This whitepaper examines the profound ethical and governance challenges posed by the emergence of SAI, particularly in relation to advanced technologies such as neural organoids and brains-on-a-chip.

This whitepaper aims to support the International Data Policy Committee (IDPC) of CODATA in its mission to foster global collaboration and research for advancing inclusive, evidence-based, accountable, and equitable data policies and systems. Through the conversations and drafting of this paper, it has reached beyond the IDPC. Responding to the rapid developments in SAI in healthcare and data rich environments, this paper brings together transdisciplinary insights from bioethics, law, computer science, and public health to examine how SAI may emerge and be governed in ways that uphold fundamental values, including those of human rights, dignity, justice, and societal goods. It explores adaptive, human-centered governance frameworks that are co-designed by interdisciplinary stakeholders from science, ethics, law, technology, and civil society. These frameworks must be equipped to anticipate and address the unique risks and responsibilities posed by artificial systems and organisms that simulate or attain sentience and represent intelligence. To guide global policy dialogue in this emerging frontier, this paper grounds governance in responsibility, inclusivity, and transparency by setting out the following objectives:

[1] Artificial intelligence is described by J.J. Brayson as an enhanced version of leftovers from natural intelligence.[20]

[2] Governance is a power of effect and change on societal developments, institutions, organizations and societies.
https://philosophy-science-humanities-controversies.com/listview-list.php?concept=Governance

• To highlight the conceptual ambiguity of SAI and how the lack of definitional clarity complicates ethical and human rights assessment, legal interpretation, regulatory design, and policy development;

• To acknowledge the accelerating role of neural organoids and bioengineered systems in making sentience scientifically plausible possibilities for AI, thereby influencing the urgency and relevance of ethical and governance discussions around SAI;

• To investigate the implications of SAI in healthcare, where core ethical principles, such as patient autonomy, informed consent, transparency, and accountability, face renewed challenges;

• To assess the adequacy of existing legal frameworks, such as the General Data Protection Regulation (GDPR) and other privacy regulations, in addressing the novel dimensions of risk, responsibility, and rights posed by SAI;

• To examine the need for inclusive, transdisciplinary guidance development drawing from the expertise of ethicists, legal scholars, computer scientists, healthcare providers, Non-Governmental Organizations (NGOs), and patient advocates;

• To contribute to the design and scaling of an adaptive, human-centered, and robust governance framework created by interdisciplinary collaboration structures, equipped to align technological innovation with human rights and societal values.

These objectives aim to inform the IDPC and other policy environments in shaping globally relevant, forward-looking data policies that can responsibly navigate the emerging frontiers of SAI. This whitepaper contributes to the growing literature on the ethics and governance of AI in healthcare as well as biomedicine and addresses a gap in the governance of ethical issues presented/ intensified or redefined by SAI. The authors provide a foundation for further research and policy development by raising important questions, building on existing frameworks like FAIR (Findable, Accessible, Interoperable, Reusable) [1], CARE (Collective Benefit, Authority to Control, Responsibility, and Ethics) [2], TRUST (Transparency, Responsibility, User focus, Sustainability, and Technology), and ethical AI guidelines [3], and highlighting key challenges.

A key component in this disruptive technology evolution is the availability of FAIR data, which not only enhances AI's learning potential but also empowers AI to generate cross-domain and synthetic data that closely mirrors real-world information [1]. These advancements have reignited and reshaped longstanding debates, dating back to the Dartmouth Conference, regarding the feasibility of achieving human-level AI [4].

This whitepaper puts forth the ethical and governance challenges associated with the potential for becoming sentient through technological advancements such as neural organoids or brains-on-a-chip. It proposes the creation of adaptive, human-centered governance frameworks developed through interdisciplinary collaboration to address the legal, ethical, and societal implications of emerging technologies.

Introduction

The advancement of AI in healthcare not only reshapes how data is handled but also portrays a novel scene for healthcare services. The disruptive nature of AI enables it to disseminate into all aspects of healthcare practices including physician patient relationship, delivery of healthcare services, diagnosis and treatment plans for health care, and using and reusing health data together with several other data on various virtual platforms that are not conventional or even health data at all, but help AI understand the health profile of the individual [5]. The development of SAI is likely to come about in these two ways: (a) Improvements in AI systems may lead to obtaining sentience, (b) Neural organoids could gain sentience and even connect themselves to some computers to self-actualize [6]. These two possibilities are becoming increasingly viable every day due to advancements in agentic AI [7]. With the obtained sentience, AI systems would be used to improve diagnostic accuracy, personalized treatment, and patient care as long as sentient ones want to be in these processes [8]. On the other hand, the introduction of the SAI may bring out new ethical challenges and/ or complicate the existing ones by changing the context or settings of the dilemmas.

1.Contextualizing the Ethical and Governance Challenges of SAI in Healthcare

In order to understand and contextualize the ethical and governance challenges posed by the emergence of SAI in healthcare, this whitepaper begins by tracing the evolution of AI from the early visions articulated at the Dartmouth Conference, 1956, to 2025, renewed interest in "thinking machines" capable of subjective experiences, self-awareness, and autonomy. While discussions surrounding AI ethics are not new, the prospect of AI that is not primarily machine-based but rather organic, based in living organisms, and (eventually) less or not reliant on machines or even data, introduces novel complexities that may require a renewed approach to how we govern AI.

The advent of SAI introduces profound novel ethical challenges, building on and reshaping existing concerns associated with GenAI. While questions of bias, transparency, and accountability have long been central to AI ethics, SAI raises additional domain-specific challenges. These include evolving debates around moral agencies, autonomy, responsibility, and the potential societal impacts of machines that stimulate or attain forms of sentience. As AI continues its rapid evolution, the possibilities of SAI underscore the urgent need for ethical governance[3] frameworks that are proactive, inclusive, and anticipatory, while also offering both transdisciplinary and domain-specific mechanisms, particularly in fields like healthcare where stakes are high and trust is critical.

To elucidate these emerging dilemmas renewed with the potential complexities of SAI, and their implications to governance, this paper begins by defining core concepts of sentience and SAI, distinguishing them from GenAI. It situates the discussion within the historical trajectory of AI development and AI ethics that balance technological innovation with human rights, privacy, and accountability. Although a working definition of sentience is provided, the paper acknowledges that sentience remains somewhat abstract and philosophical, which presents difficulties in establishing concrete criteria for identifying or measuring sentience in AI systems. This conceptual ambiguity complicates the assessment of practical and legal implications of SAI.

[3] Governance is a power of effect and change on societal developments, institutions, organizations and societies.
https://philosophy-science-humanities-controversies.com/listview-list.php?concept=Governance

While AI-focused narratives and literature already touch on ethical, legal, and social challenges posed by SAI, there remains a gap in specific risks, particularly in healthcare settings [9]. Although the primary focus of this whitepaper is on ethical and governance issues, rather than technical aspects, it recognizes the relevance of adjacent developments and mechanisms, such as the use of explainable AI (XAI) techniques to improve the transparency of SAI systems or the development of privacy-preserving and privacy-enhancing technologies to protect patient data in health data spaces (HDSs).

At the regional level, within the European context, the GDPR is recognized as the primary legal framework for addressing data protection and transparency concerns, while acknowledging its limitations in the context of SAI [10]. Similarly, in the United States, the Health Insurance Portability and Accountability Act (HIPAA) [11] governs the privacy and security of health data. However, these were not designed with AI-driven and bio-integrated systems in mind and so exclude many emerging sources of health-related data, including their analysis and impact. To ensure a globally inclusive approach, this paper highlights the need to integrate diverse policy trends, global perspectives and governance experiences into a broader dialogue that addresses the complex challenges of GenAI and SAI, such as source and algorithmic bias [12, 13].

By examining SAI in a broader technological and societal context, the paper aims to provide an overview of the current state of the field, identifying and articulating key ethical challenges arising from its application. Additionally, we contextualize its application in the healthcare domain. The focus on integrating SAI into HDSs addresses a critical area newly developing within Europe and beyond. HDSs have the potential to facilitate the development and deployment of SAI systems, particularly in the area of research. They further raise questions regarding agency, responsibility, accountability, privacy and confidentiality, data protection, security, and access [10]. Insofar as this paper calls for the development of robust, adaptive governance structures, with a better understanding of the distinction between SAI and GenAI in context, it also contributes to the development of a framework for assessing the ethical impact of SAI systems in healthcare. This framework is designed to inform and guide the design, development, and deployment of SAI systems in a way that minimizes risks while maximizing the benefits by requiring attention to rights, sovereignty, and transparency as well as openness and the capacity to share.

Central to this effort is the role of co-creation and stakeholder engagement in shaping the ethical governance of SAI. Addressing the ethical and governance challenges posed by SAI will require interdisciplinary collaboration between ethicists, computer scientists, healthcare professionals, NGOs representing patients, policymakers, and other stakeholders. The interdisciplinary collaboration enables reflection on the use of AI ethics tools and methodologies, such as ethical impact assessments, value-sensitive participatory design that promotes the human-centered development and deployment of SAI systems while considering the limitations in existing information systems and pointing to subjective and context specificity characteristics of the emerging narrative in this space.

1.1 Synopsis of Ethical Discussions on AI from the Dartmouth College Conference (1956) to Today

HDSs, with their attempt to develop secure, digital environments designed for the collection, curation, analysis, and sharing of health information, are becoming central to the evolution and dissemination of AI in healthcare. These spaces enable the integration of large datasets that include medical records, imaging results, and other patient information, allowing AI systems to provide deeper insights into disease patterns and treatment outcomes. The production of synthetic data from the Electronic Healthcare Documentation system (EHD) by AI presents a broader set of opportunities for AI in healthcare services as well as scientific research [14, 15]. With these high prospects, AI systems have proven effective in both clinical settings and as decision support systems in healthcare. Although ethical challenges emerging from the extensive use of AI in decision-support systems in medicine have been widely discussed, these concerns have recently been amplified by the introduction and rapid incorporation of GenAI, along with its potential to create new data in decision-making procedures [16]. As deep learning improves based on faster and more comprehensive and reliable quick access to how people see the world and respond, supported by the diminishing need for human coding for personalized real-time interactions due to cognitive computing and self-learning algorithms, the possibility for AI to develop a deeper comprehension of how the human brain and mind operate, how intelligence itself works, grows exponentially. Popular GenAI tools such as OpenAI GPT, and Google's Gemini as well as several others on the market, accelerate this potential.

The introduction of the new GenAI systems revitalized a relatively "old" discussion that dates back to Alan Turing and the Dartmouth College Conference back in the 1950's [17, 18]. This discussion began with a query into the possibility of creating "*thinking machines*" indicating "artificial minds" that operate *like the human mind* by exhibiting complex cognitive-like functions [19]. These cognitive-like functions extend beyond computational skills, which have been considered as *an* indicator of *intelligence* that can be measured by objective criteria, such as the ability to process a set of data faster and more accurately than one's competitors [20]. The cognitive functions are now being extended from *thinking machines* to systems or organisms that *perceive* the world, either through data or directly, and give rise to what may be considered subjective experiences, self-awareness, personal memory, autonomy, feelings, and/or even consciousness[4], functions that have been largely ascribed only to *human* beings and therefore have been considered as an indication of our singular *humanness*.

When intelligence[5], emotions[6] and their relationship with sentiency are considered, they appear to be directly and informed and shaped by perception (e.g., *evidence* in science). Their understanding (intelligence) results from an evaluation or analysis of the stimuli, defining their behavior and their decisions. However, sentiency itself may not necessarily be accompanied by rationality, emotions, consciousness, conscience, or other attributes we have come to use to define intelligence. Because humanity has proof that some people can easily be considered as sentient while not having or feeling of any emotion and while suffering from intellectual disabilities.

Thanks to what are described as complex mental functions, humans can make autonomous decisions that are situation-specific, reflecting their understanding and their character, while also providing rational explanations of their decisions (why this or that was decided), while

[4] Consciousness is being able to differentiate stimuli, control instincts and reactions, and fulfill necessities according to the conditions. (https://dictionary.apa.org/consciousness)

[5] Intelligence has been defined in many different ways throughout history; however, the meaning of the term is handled as a capability of understanding intentions behind actions and having or associating knowledge obtained from one's own experiences [59] or others, according to the conditions, motivations, and perceptions of one's own and those obtained by others. [54, 60, 61]

[6] Emotion is the obscure design of reaction determined by situations and feedback and includes psychological, empirical, and behavioral components. (https://dictionary.apa.org/emotion)

also allowing those decisions to be shaped by values or emotions. These qualities appear to be what we normally take to define humans as ethical agents, providing them with a separate, special, and (according to the anthropocentric approach – perhaps the only approach an anthropoid is capable of) a distinct position in the known universe. The essence of this complex, ongoing process can be distilled into feelings, consciousness, and self-awareness. However, at the same time, despite the fact that the improvements in science and technology appear to have advanced our understanding of the world and ourselves, even bringing us very close to human-like artificial systems, the workings of the human mind are still largely shroud in mystery. We still do not know exactly how the human mind works. Said otherwise, our intelligence continues to escape our understanding. *The mind is nowhere to be found*.

Returning to earlier discussions about the possibility of SAI, we recall the Chinese room test that was an attempt to prove that artificial minds do not really *understand* the context, but learn how to process data so accurately as to produce human-like outputs, outputs that create a falsely understood anthropomorphic perception in the people with whom they communicate, giving (as least) the impression that they are interacting with another human. In parallel with the development of these *intelligent* technologies, the discussions on *machine intelligence* danced around terms such as human-like AI, strong AI, GenAI, and artificial superintelligence, discussions largely considered embedded in theoretical philosophical dimensions [20], either due to our limited knowledge of the human mind or the failure of technologies to actually satisfy such a curiosity.

The current acceleration of new technologies, such as laboratory-grown brain-like structures that reproduce aspects of human cognition and perhaps sentience (e.g., neural organoids orportable neuroimaging technologies) complicates this once more philosophical discussion by increasing the probability of producing SAI, giving rise to discussions in ethics and science that SAI may add to the complexity of, as well as our resolution of, already existing questions of understanding, rationality, agency, and morality.

Building on this evolving discussion, this paper investigates adaptive governance structures that might balance technological innovation with our fastly held values of human rights, privacy, security, and accountability. It does so by examining the emerging technologies, their applications, and the governance frameworks necessary to ensure their ethical use in a human-centered world. To achieve this goal, the ethical issues raised by SAI are first listed, followed by a brief description of the additional specific problems introduced by SAI in the health field. This is followed by a specific focus on the reality of the emergence of neural organoids that can provide a limited framework into what SAI may come to mean for us. Finally, the ethical issues are merged with the presence of a new reality to explore governance and policy options for an evaluation framework that can help us address the possibilities and the concerns.

1.2 Definition of Sentience; Main approaches and Discussions

What does sentience mean? How do different philosophical traditions conceptualize sentience, and what are the methodological implications for defining sentience in AI systems?

In general, sentiency is defined as perceiving the external world, often accompanied by the internal processing of the data received through the senses to subconsciously or consciously develop emotions and thoughts, and using them for decision-making or generating more thoughts or emotions together with various data inputs to form complex archives of memory.[7] The conceptualization of sentience varies significantly across disciplines and philosophical

[7] https://www.sciencedirect.com/topics/neuroscience/sentience

approaches by comparative analysis of biological and artificial systems and human and AI cognition, interdisciplinary analysis of (inter)subjectivity and theoretical analysis of sociopolitical implications.

The Cartesian dualism defines sentience in connection with consciousness and self-awareness as in "*cogito ergo sum*," while Hobbesian approaches frame sentience as a sociopolitical issue rather than metaphysical. Empiricist approach identifies sentience via sensory experience and subjective perception while phenomenological approaches narrow the focus to lived experiences and inner subjectivity that require a physical and contextual existence in the world. A pragmatist approach might distinguish between sapient and sentient beings thereby stressing the inferential nature of the seemingly exceptional way of human communication. In contrast, a practical perspective to sentience is provided by distinguishing between strong sentience and simulated sentience. Strong sentience refers to having human-like qualia that enables the being to feel subjective experiences that include emotions, sensations, and self-awareness. Simulated sentience on the other hand, stands for mimicking behaviors or emotional reactions of a being with strong sentiency. The conceptualization of SAI has been these two practical approaches.

Functionalists display another practical approach by arguing that mental capabilities are defined by their functions rather than what they are made of. In this perspective there is no difference between a human brain and an artificial "brain" as long as they exhibit the same functions [9]. According to the functionalist perspective, it is irrelevant if the "brain" consists of organic neurons or inorganic neural networks, as long as it is functional. This line of reasoning indicates that if the functions are the same, the ethical status and the moral value of the entities are identical. This thought process is refined by the Principle of Substrate Non-Discrimination that states "If two entities have the same functionality, and differ only in the substrate of their implementation, then they have the same moral status." and Principle of Ontogeny Non-Discrimination that states "If two beings have the same functionality and the same consciousness experience, and differ only in how they came into existence, then they have the same moral status."[21]

Discussions about the possibility of AI having strong sentience capacity are densified with the developments in neural organoids and the increasing potential of GenAI or agentic AI. The prospect of AI having strong sentience capacity necessitates the redefinition of the concepts of personhood and agency, in addition to the ethical problems inherent in the functionalist approach. This situation creates the need to open a new chapter not only in AI ethics but also in AI laws.

The current meta consensus on SAI is that it is a realistic possibility that AI may have sentiency in the near future and that it would be irresponsible to ignore this possibility or neglect the for considering policy based on insights into such a reality and its possibilities alongside the identification of risks and an assessment of measures that might be needed for precautionary approaches [22].

1.3 What are the different and similar characteristics of SAI from generative artificial intelligence (GenAI)?

Gen AI and SAI are based on the data shared with them. While Gen AI may just produce something new via transforming the data according to the algorithms of it, SAI may prioritize the elements in data, reject the task given to it, or develop new algorithms for it according to self-necessities. Because SAI, besides using the data shared with it, may understand, make some comments on the data, and produce some future plans about it. While Gen AI can produce new data from the data, it cannot think on the data or results according to its perspective out of its software.

2. SAI: Ethical Challenges

The emergence of SAI brings a range of ethical questions that demand both philosophical and epistemological grounding and practical governance considerations. These questions are not merely theoretical, they challenge the foundations of legal personhood, moral agency, rights, and responsibility attribution toward to non-human actors. Key ethical dilemmas include:

1. What is the legal and ethical status of AI once/if it attains or is perceived to attain sentience? How should the existing frameworks evolve to accommodate this shift?
2. If sentient beings can form intimate, meaningful relationships with each other, what ethical frameworks should guide this new form of relationship between artificial and non-artificial actors– or between multiple (sentient) artificial agents [19]?
3. What is the relationship between sentience and rights? Given that many legal systems recognize rights for sentient beings, under what conditions (if any), should similar rights be extended to artificial agents? Who defines the ethical boundaries for this new form of being framed [23]?
4. Is it ethically appropriate to create and destroy artificial sentient beings as we like? (Not only from the perspective of rights, but from the lens of wisdom and compassion.)
5. Can the creation of sentient beings be justified solely for the prospect of providing benefit for human beings [24]? What are the ethical implications of instrumentalizing sentience as a tool for human goals?
6. How does the AI alignment problem–the challenge of ensuring value aligned AI goals– alter these ethical debates [25]?

When SAI is used in healthcare, these general ethical questions regarding SAI are complicated by another set of ethical questions that revolve around consent, respect for autonomy and individual sovereignty, transparency, accountability, data ownership, and privacy [26]. These questions signal the need for proactive, ethical governance, before SAI systems become widely deployed.

2.1 Patient Consent and Respect for Autonomy

In traditional healthcare models, decisions are made by human healthcare providers based on clinical judgment, often in consultation with the patient. SAI systems, however, may bypass human decision-making processes altogether or at least supplement them in complex ways that confound the human decision-making processes [27, 28]. If patients are not fully informed about how their data is collected and analyzed, used in intricate HDS with other patients' data and/or public (health) data, or how AI systems are involved in their care, this could compromise the ability of patients to provide meaningful consent [28, 29]. Although it is argued that this problem is overcome with the principle of disclosure obliged by the EU GDPR [10] and HIPAA [30] that the service providers (including healthcare service) to disclose if and to what extent AI is used in a given service, SAI brings in a more complex clinical setting that is fundamentally different than the conventional physician-patient relationship. This may significantly impact patient autonomy in the decision-making process, because of its capacity to assess patients' data in a breadth and depth that a normal physician cannot and/or does not access, even if she has the means to do so, because some of this data is personal and may be considered irrelevant for clinical decision-making. Using this data, which is considered less important or even irrelevant in traditional medicine, SAI can meticulously profile the patient's personality characteristics and manipulate a patient's autonomous decision-making process [31]. This deep and unnatural empathy/understanding may prevent the patient from making rational and independent decisions by making him open to suggestions from SAI.

2.2 Transparency and Accountability

AI systems, particularly those that use machine learning algorithms, are often described as ‘black boxes', meaning that their decision-making processes are not always transparent or easily understood by humans [9]. This lack of transparency raises questions about accountability [32-34]. These concerns raise questions such as “If an SAI system makes a decision that leads to a negative patient outcome, who is responsible?” [31] This becomes all the more complex when the decisions incorporate data not collected (or perhaps even capable of being collected) and analyzed by humans. What is the relationship between the healthcare provider and SAI? How are responsibility and accountability defined with regard to the use of SAI in healthcare decision making? And how are these different from an AI system that is not sentient, if so?

The contemporary approach to black box problem is "the user does not need to know how the AI system works/ the user can not know how the AI system works, all the user needs to know that AI is used in the process, and have a general understanding about what risks/benefits AI usage may bring in" [32]. This approach argues that if the user is informed about the usage of AI, then transparency is achieved. However, this approach is quite limited considering the unique features of the physician-patient relationship and the complexity of the dynamics induced by the vulnerability and emotional stress of the patient and potential information imbalance between parties. Another problem with this approach is the identification of “user” in medical settings. Is the “user” the physician or the patient? Should the principles of transparency and trustworthiness apply to developers of SAI systems and provide them to healthcare facilities, or should it apply to the healthcare facility administration to disclose the information to the physicians, or does it apply to physicians who use the SAI system on the bedside [26]?

Accountability, on the other hand, is more complex than transparency as it has concrete legal consequences. The contemporary approach is to recommend human supervision as a main prescription to transparency and accountability problems. In this respect, if human oversight is provided by “humans in the loop”, the responsibility shifts to those humans who oversee the process, and the problem is *solved [9]*. However, this is a very simplistic approach because human beings would be reluctant to decide against what AI suggests, especially in diagnostic procedures, since underdiagnoses may have devastating consequences. While overdiagnosis can be more acceptable legally, it raises some ethical problems, such as resource allocation [16].

Accountability becomes a particularly thorny issue when SAI systems generate data, analyze data according to their ‘experiences,’ and make decisions affecting patients. If an AI system recommends incorrect treatment or misdiagnoses a patient based on the data it (partially) generated and analyzed, who is responsible [32]? Traditional legal frameworks typically hold healthcare providers or institutions accountable for medical errors, but SAI introduces new complexities. Should the developers of AI technology be held responsible, or is the healthcare provider ultimately accountable for implementing the AI system [23]? These are crucial questions also for the development of health data spaces. Moreover, if an AI system is deemed sentient, there is the theoretical possibility that it could bear responsibility for its actions. Governance frameworks must address these questions by defining, identifying, and establishing epistemic criteria and clear lines of accountability, ensuring that patients and healthcare providers have avenues for recourse if AI-driven decisions result in harm.

To address these concerns, governance frameworks must prioritize the reliability and transparency of SAI alongside considerations for patient autonomy within intricate health data spaces used for both research and clinical care. The challenge will be to fully inform patients

about how AI systems are involved in their care as well as how they are able to consent to the use of SAI as well as the data and analyses it generates [29]. Of course, one would argue that healthcare providers should retain ultimate responsibility for patient outcomes, but when SAI systems are used to inform clinical decisions that go beyond the understanding of the healthcare provider, how do we assign accountability within these health data spaces?

2.3 Data derived from SAI: ownership and privacy

Data ownership and privacy are central ethical and legal concerns when it comes to the use of SAI in health data spaces. SAI systems are designed to autonomously process vast amounts of data, including (also highly) sensitive patient information, and derive insights that can inform clinical and non-clinical decisions. The sheer volume and complexity of data that these systems handle pose significant challenges regarding who owns the data, how it is used, and who is accountable when things go wrong [35].

2.4 Data ownership

One of the most pressing questions in the governance of SAI is who owns the data that the AI processes and generates. Typically, patient health data is considered the property of the patient or, in some cases, the healthcare provider [10]. However, with SAI systems that continuously analyze and derive new insights from this data [36], the boundaries of ownership become blurred. Should the patient maintain ownership of the data once it has been processed by an AI system, or do the insights generated by the AI system belong to the developers of the technology, or should there be a neutral intermediary and moderator between the different roles in play? There is also the question of whether AI systems that demonstrate autonomy or sentience should be granted ownership rights to the data they generate.

2.5 Privacy and security concerns

SAI systems often access and analyze patient data beyond the scope of the original purpose for which it was collected, leading to significant privacy concerns. For instance, an AI system analyzing a patient's genetic data might uncover a predisposition to certain diseases, even though the patient only consented to an analysis for a specific health condition. This kind of overreach raises ethical questions about whether patients are adequately informed about the full extent of how their data will be used and whether they have given meaningful consent. It also poses legal challenges related to data protection laws like the European Union General Data Protection Regulation (GDPR) and its AI Act, which requires explicit consent for data processing as well as transparency in data analysis [10]. Governance frameworks must establish stringent privacy protections alongside transparency requirements, ensuring AI systems do not exceed the boundaries of (patient) consent [37, 38].

3. The role of data policies in SAI

Four questions for further development of this section

1. How can existing data protection laws, such as GDPR and HIPAA, be adapted to address the unique challenges posed by data generated and analyzed by SAI?
2. What specific guidelines should be included in data policies to manage consent dynamically, especially as SAI applications evolve over time?
3. Should data policies (hard and soft law plus recommendations) explicitly address the potential for SAI systems to hold rights or ownership over the data they autonomously generate, and what implications would this have for healthcare governance?
4. Does SAI require or is it strongly useful to establish special data institutions such as data trustees to constantly offer neutral contact points and services for stakeholders of SAI ecosystems and infrastructure?

The role of data policies in SAI is crucial given the transformative nature and complexity of emerging health technologies. As SAI systems process, generate, and manage vast amounts of sensitive patient and health-related data, robust and clear data policies become essential [39]. Effective data policies must define boundaries around the ownership, privacy, and ethical utilization of data. Ownership concerns become particularly complex with SAI, where traditionally understood notions of patient or institutional data ownership blur as AI generates new insights autonomously. Clearly articulated data policies are necessary to assign ownership and rights to data generated by SAI, whether it remains with the patient, the health institution, the developers of the AI, or potentially even the sentient system itself [38].

Moreover, privacy concerns escalate significantly as SAI technologies can analyze patient data beyond the initial scope for which consent was given. This creates critical ethical and legal risks, notably within the context of existing frameworks, such as explicit consent, transparency, accountability, equity and non-discrimination, and fairness in data processing. These frameworks include China's detailed regulations on algorithm transparency[40], India's comprehensive National Strategy for AI emphasizing inclusive growth [41], the European Union's GDPR and AI Act, the US HIPAA, Brazil's General Data Protection Law [42], Bill on the Development and Utilization of Artificial Intelligence Technologies [43] and the African Union's initiatives on ethical AI development and digital sovereignty [44], providing valuable global lessons.

Data policies in different legal areas need to set strict rules so that patients can keep control of their personal information and clearly understand how their data is used, especially when it involves sensitive or predictive data [45] that could show unexpected health issues or risks. In this context, adaptive data policy frameworks play a critical role in enabling flexible governance that evolves alongside technological advancement. Besides research, other ethics committees could play a concomitant role here. Dynamic consent mechanisms, transparency obligations, and clear accountability structures must be integral parts of these adaptive data policies. Policies should set up frameworks and procedures for ongoing review and public input, making sure that they can adapt to new technologies and changing needs in society. Collaboration across disciplines and sectors in policy development will prioritize ethical issues, hence boost public trust, and protect individual rights in SAI implementation within current and future health data spaces and infrastructure.

4. Neural Organoids as a manifestation of SAI and Ethical questions

Four questions for further development of this section

1. What are the factual and normative connections between neural organoids and potential for SAI?
2. At what developmental stage should neural organoids be accorded ethical or legal protections, if any?
3. How do we ethically balance research advancement and potential future developments with potential sentience in neural organoids?
4. What international guidelines or governance mechanisms are necessary to prepare and manage ethical consistency across neural organoid research?

4.1 Moral Status Concerns

New concerns are arising with regard to neural organoids with potential cognitive and sentient functions that present both exciting possibilities and ethical challenges [20]. These organoids are small, three-dimensional clusters of neural cells grown in the laboratory, which mimic certain aspects of brain development and function [29]. Organoids are in-vitro grown masses of cells that resemble organs. This indicates that a neural organoid is a complex cell cluster

compared to any other organoids because of the potential for higher brain activities performed by neurons [46]. Researchers use neural organoids to study brain diseases, test potential therapies, and investigate neurological processes that are difficult to observe in living patients [6, 47]. However, as these organoids become more advanced, the possibility arises that they could exhibit neural activity resembling attributes of animals and humans such as cognition or even sentience. On their own, or in combination with biological computers or other sentient organisms, these neural organoids may begin to generate data and experiences derived from their own independent activities [48]. Additionally, neural organoids may reveal specific features of the donor's mental state during the research [49].

The potential sentience of neural organoids raises profound ethical questions. If these organoids develop neural networks capable of higher-order brain functions, should they be granted a moral status [6, 20, 29]? Some ethicists argue that as neural organoids continue to advance, we must reassess our ethical frameworks to determine whether these biological entities deserve rights or protections similar to those afforded to animals used in research [50]. Additionally, the use of neural organoids in conjunction with biocomputing systems or other sentient life complicates the ethical landscape [51]. Lastly, the possibility of carrying mental features of a donor by neural organoids emerges as a neuroprivacy issue that requires further reflections. We intentionally did not include the neuroprivacy issue because of the frame of this paper.

The transplantation of neural organoids into non-human animals (or eventually into humans) also raises ethical concerns [48]. If organoids are integrated into the brains of non-human hosts and contribute to their cognitive functions, we are confronted with the possibility of creating chimeric organisms that blur the lines [29, 51] between species or create new ‘intelligent species’ that might rival human intelligence. Further, we might consider the possibility of ‘trained neural organoids that enhance human intelligence by being transplanted into humans or connected to the human brain through machines. Should these chimeric entities be afforded special protection [6]? What ethical considerations must be in place to ensure that neural organoids and the life forms (including humans) they are integrated into are treated humanely? What would be the possible consequences of this enhancement in terms of evaluation, society, and economy? Would we find an ethical basis for this type of enhancement [52]?

Governance frameworks for sentient organoids must take into account the ethical implications of using neural organoids in research and healthcare. This includes establishing ethical guidance and regulation for the acceptable use (or limits of use) as well as the moral status of organoids or those life forms to which they have been enjoined, especially if they exhibit signs of sentience.[46] Ethics guidance and regulations should address the use of neural organoids in creating chimeric organisms, ensuring that these experiments are conducted responsibly and with due consideration for the moral implications.[20, 51]

5. Legal and ethical considerations for SAI, neural organoids, and data management

Four questions for further development of this section

1. How might existing legal definitions of personhood need to change to accommodate SAI entities or neural organoids?
2. How can legal frameworks clearly assign accountability when harm results from decisions made by SAI?
3. What ethical and legal implications arise when integrating large-scale SAI-generated insights into public health policy?
4. What would be the socio-cultural consequences of granting personhood to AI?

The integration of SAI, neural organoids, and advanced data management systems into healthcare requires a rethinking of existing legal and ethical frameworks which might apply to

SAI: technical norms and standards, professional codes of conduct, fundamental human rights, (inter- and supra)national legislation for individual and social groups as well as policies regarding – as they are sentient beings too – animal welfare and environmental law [51]. To be clear: Traditional healthcare models are governed by well-established principles, such as patient autonomy, beneficence, and justice. However, these principles must be reinterpreted to address the unique challenges posed by emerging technologies such as SAI. Legal frameworks, in particular, must evolve to provide adequate protection for patients while ensuring that technological innovation is not stifled, and effective human rights impact assessments are at hand [51].

5.1 Legal recognition of SAI

One of the key legal questions surrounding SAI is whether these systems should be granted legal recognition as autonomous entities. If AI systems demonstrate self-awareness or cognitive functions similar to those of humans, they may challenge existing notions of legal personhood [23]. Should SAI systems have rights and responsibilities, similar to legal entities like corporations? This question has profound implications for healthcare, where SAI systems could be tasked with making life-and-death decisions. Governance frameworks must carefully consider the legal recognition of AI systems and determine whether they should be granted rights or be held accountable for their actions [23].

Research involving neural organoids, which aspires to model aspects of human brain activity, can pose significant ethical and legal challenges [46]. If it is possible that these organoids could develop cognitive functions that are capable of sentience, they may require legal protections to ensure they are not subjected to unethical experimentation or use. If these concerns materialize, which would be evident through researchers working with neural organoids, they must navigate the delicate balance between advancing scientific knowledge and respecting the potential moral status of these biological models [6]. Governance frameworks must address the possibility that neural organoids could achieve a level of sentience, and regulations should be in place to ensure that their use in research and healthcare aligns with ethical principles [50].

5.2 Data management and SAI in health data spaces

The sheer volume of data generated by SAI and neuroimaging technologies requires robust data management systems along the whole research data lifecycle. These should entail ethical considerations regarding data. However, data management in health data spaces presents unique ethical challenges, particularly around consent and data sharing. Patients must be informed about how their data will be used, and they should have the ability to control who can access their information [39]. Furthermore, data governance frameworks must ensure that health data is used equitably and that AI systems do not exacerbate existing inequalities in research, clinical trials, health technology prototyping, and healthcare [53]. For instance, if AI systems are trained on biased datasets, they may provide inaccurate or harmful recommendations for certain demographic groups [12, 13, 15, 31]. Addressing these challenges requires an intersectional approach to data governance, ensuring that the needs of all patients are considered.

In addition, SAI can use previous and current data sets and evaluate them according to its "perception." While SAI gains its own perception, it probably uses all data according to the evaluation of the previous data sets and gathers different perspectives. Therefore, these differences present different ethical challenges than before:

-the span of patients` data disregarded being anonymous (because of the accessibility of varying data by SAI, making anonymization can be just a try),

-the appropriate decisions of SAI in legal and ethical bases,

-accuracy of data sets being used by SAI,

-accessibility of different populations` health data in different ratios and its consequences on the perception and their management by SAI.

-possibility of manipulation of data sets by humans or results of them by SAI.

Despite all the ethical challenges above, SAI probably has fewer weak points than human beings because manipulation of it may be harder than any human due to its access to a wide range of information. In addition, people have some benefits while doing anything, therefore they can try to gain different interests from what is offered to them, or they want to cover some mistakes made by themselves or loved ones [54]. When these points are regarded, SAI can be accepted as more trustworthy for some while holding the health data and managing it.

6. Proposed governance frameworks: an adaptive approach

Four questions for further development of this section

1. How can adaptive governance frameworks be practically implemented in rapidly evolving healthcare environments?
2. What role should public, and stakeholder consultation play in shaping adaptive governance frameworks, especially for SAI?
3. How to establish and maintain resilient data infrastructures involving SAI under an open science ecosystem?
4. What metrics or indicators should be used to evaluate the effectiveness of adaptive governance frameworks over time?

Given the rapid pace of technological advancement in healthcare, governance frameworks for SAI and relevant research and innovation areas like neural organoids, and neurotechnology, digital twin simulations etc. must be flexible and adaptive. Traditional regulatory models, which are often rigid and slow to adapt, may not be sufficient to keep pace with the ethical and legal challenges posed by these emerging technologies [27]. Therefore, governance frameworks should draw onto established rules, and they should be designed to evolve in response to new developments thereby addressing unforeseen ethical challenges. Moreover, the harmonization of existing policies – hard and soft law – would help coming to terms with the governance of relevant convergent technologies such as machine learning, neurotechnology, synthetic tissue printing, and their ethical, social, and cultural implications [12].

The development of scientific literacy among policymakers is a top priority in order to guarantee that the governance of SAI is in accordance with the general welfare of society. This means successfully managing risks while striking a balance between ethical considerations and technological advancement. Policy makers who have a thorough understanding of the complexity of SAI would be better equipped to handle the ethical, legal, and social issues surrounding the technology. Effective legislators with scientific backgrounds can understand the complexities of AI regulations and manage the trade-off between innovation and potential risks and ethical issues [55].

6.1 Dynamic consent models

One of the key features of an adaptive governance framework is the use of dynamic consent models. Dynamic consent allows patients to modify their consent preferences over time, as they become more informed about the technologies being used in their care. For example,

patients might initially consent to having their health data analyzed by an AI system for a specific purpose, but later, as new applications for the AI system are developed, they might want to adjust their consent preferences. Informed consent from patients is reliable for their lifespan [56, 57]. However, the longevity of data owners does not limit its use. How can appropriate consent be taken while developments in technology are so fast and unforeseen? May consent be updated by inheritors of the data owners after the owner's death? Or how can the consent changes be handled in the decreased mental capacity of the owner? Dynamic consent models provide patients with greater control over their data and ensure that their autonomy is respected throughout the data lifecycle.

6.2 Transparency, trust, and public engagement

Transparency is essential for building trust in the use of SAI and related technologies in healthcare [33]. Patients and the public must be informed about how AI systems are being used, what data is being collected, and how decisions are being made. Transparency also requires that AI systems be explainable and interpretable; that is, their decision-making processes should be understandable to both healthcare providers and patients. Governance frameworks should include provisions for public engagement, allowing patients and other stakeholders to participate in the development of ethical guidelines and regulatory policies. Public consultations and deliberate forums can help ensure that the values and concerns of patients are reflected in governance structures.

6.3 Interdisciplinary collaboration

The governance of SAI and neural organoids in healthcare requires interdisciplinary collaboration between ethicists, legal scholars, technologists, social scientists, healthcare providers, and policy makers. Ethical review boards and regulatory bodies must work closely with AI developers, researchers, and potential users to ensure that emerging technologies are used responsibly. Furthermore, international collaboration will be essential for developing harmonized regulatory frameworks that can be applied across borders. AI and neuroimaging technologies are being deployed globally, and consistent ethical and legal standards are necessary to ensure that patients in different regions receive the same level of protection.

6.4 A model of governance of AI in healthcare

Transparency, accountability, and participation are principles rooted in a sustainable, democratic, and ethical mode of governance. Their implementation necessitates both appropriate mechanisms and public institutions to ensure accountability, besides sustaining legal framework. Healthcare, insurance, and AI industries, together with public sector officials and departments should take their decisions with the participation of the community and transparently disclose key decisions with the rationale behind the decisions, particularly if these decisions affect individual rights. Public participation is the most significant mechanism that ensures higher diversity of perspectives and a more balanced approach to issues regarding the positive and negative impacts that decisions may have on citizens' rights and quality of life.

There are already plenty of public organizations with policies to govern differing aspects of AI, but they only may be fully operational if they are accompanied by clear mandates, sufficient funding and resources, and autonomy to avoid interference from other sectors of government and the private sector. Cooperation mechanisms at sectoral interfaces, where diverse policies intersect -such as data systems, AI, and ethics-, are less frequently observed. The rapidity of technological change requires higher levels of agility than is common to public administration to be able to respond both to the concerns of citizens and the needs of industry, and the changing political, social, and economic conditions.

Potential Sections for the Further Development of this Whitepaper

The use of SAI in medical research

- Enhanced research capabilities: SAI systems can significantly advance medical research by autonomously identifying novel biomarkers, disease patterns, and therapeutic pathways.
- Ethical complexities in consent: Traditional consent processes may require adaptation to address the dynamic nature, and unpredictable data uses associated with SAI-driven research.
- Transparency and integrity: Clear policies are essential to maintain transparency in SAI's role in generating research data, protecting participant autonomy, and ensuring research integrity.

The use of SAI in medical care

- Improved clinical outcomes: SAI has potential to substantially enhance clinical decision-making through real-time, personalized diagnostics and treatment recommendations, significantly impacting patient outcomes.
- Patient rights and accountability: Ethical and legal frameworks must address accountability for clinical decisions made or influenced by autonomous SAI systems.
- Preserving patient autonomy: Protocols must clearly define how patients are informed about the use of SAI technologies, preserving autonomy and protecting patient privacy and dignity.

Cultural and social considerations for the adoption and integration of SAI in clinical practice

- In certain cases, it may be more practical for SAI to assume diagnostic responsibilities; however, some patients may prioritize the traditional doctor-patient relationship, valuing human empathy and trust over automation.
- Factors such as education level, regional familiarity with AI technologies, and cultural trust in medical professionals play a significant role in the acceptance and effectiveness of SAI.
- In societies where physicians' judgment is highly respected, SAI adoption may be slower or viewed with skepticism, raising the question of how these tools can complement rather than compete with established practices.

Global policy and regulatory context

- A dedicated section on international frameworks, such as UN and UNESCO or OECD guidelines or WHO recommendations, currently influencing or potentially applicable to SAI.
- Discussion on harmonization of regulatory and ethical standards globally, addressing how SAI might require international legal coordination.
- Implications of global, cultural, and local variation in ethical norms and regulatory capacities in implementing uniform governance for SAI [58].

Human rights and SAI

- Privacy, dignity, and autonomy: SAI challenges traditional understandings of personhood and autonomy, raises concerns about privacy, data ownership, and informed consent in healthcare and research [23].

- Equality and non-discrimination: Governance frameworks must address biases in SAI to prevent discrimination and ensure alignment with both international human rights standards and eventually animal protection as well [15].
- Moral and legal recognition of SAI: Ethical debates continue on whether SAI should be granted rights or protections, requiring interdisciplinary dialogue on its moral and legal status.

Data infrastructures for future SAI

- Interoperability: To ensure technical interoperability among systems to ensure appropriate data flow for robust SAI environment development that connects humans and machines.
- Data sovereignty first: "open as possible, as closed as necessary" of open science infrastructures needs to be revised in the light of control regimes and understandability issues underlying legal and geo-political interoperability issues.
- High Performance Computing: scalable, cybersecure and resilient infrastructures to enable and enhance the processing of big data for SAI.
- Understandability: balance between white-box and black-box methods to ensure reliable and reproducible results properly interpreted driven by SAI
- Robustness: Flexible to embrace fast-going ICT revolution to ensure high-quality SAI in addressing complicated physical world challenges, such as for health and long-term sustainability.

Public engagement and societal perspectives

- Exploration of public perceptions and societal acceptance of SAI in healthcare, including potential societal fears or misconceptions.
- Strategies for effectively engaging the public and patients in shaping policies and governance approaches.
- Ethical implications of societal inequities in access and benefits from SAI-driven healthcare technologies.

Economic and commercial implications

- Analysis of economic impacts, such as the costs associated with SAI integration into healthcare systems and equitable distribution of benefits and risks.
- Potential conflicts of interest or ethical issues arising from private sector involvement in developing or deploying SAI.
- Recommendations for ethical procurement, partnerships, and investment frameworks related to SAI.

Risk and obsolescence management frameworks

- A dedicated examination of risk management strategies specifically tailored to the unpredictable nature of SAI, particularly emphasizing liability, error as well as obsolescence management, and contingency planning for unintended harms.
- Proposed standards for monitoring, assessing, reporting, and mitigating unintended consequences or adverse outcomes from SAI use.

Training and education needs

- Recommendations for capacity building in healthcare professionals to ensure proper and ethical use of SAI systems.

- Educational approaches to increasing awareness among healthcare providers and patients about SAI implications and ethical considerations.

Future research directions

- Identification and anticipation of critical areas requiring further investigation, particularly empirical research into ethical, legal, and societal implications of SAI.
- Suggestions for prioritized funding and policy support to guide responsible innovation in SAI technologies and neural organoids.

A Question for future directions

Might any probable harmful effect of a developing technology prevent its development?

Harmful effects of technology can or cannot be predicted throughout the development process by the developers or others. However, the development generally takes place in an environment where, although people have some concerns about it, they generally have some beliefs about the necessity of it or the risks of being developed by other people, or the anticipated effects may become underestimated when they are compared with the factual results.

Limitations

This whitepaper aims to explore the ethical, legal, and governance perspectives surrounding emerging sentient technologies such as neural organoids and SAI with a particular focus on their potential roles, rights, and responsibilities in healthcare. While preparing this document, we encountered several limitations. First, not all perspectives can be addressed equally due to the limited availability of resources that support a comprehensive transition from current systems to potential future frameworks. Second, the rapid pace of AI development, including the emergence of agentic AI and the growing possibility of artificial sentience demands ongoing review. Despite our efforts to stay current, we acknowledge that some developments may have been missed.

Conclusion

Enhancements in artificial intelligence and the emergence of neural organoids bear different ethical, legal, societal, and governance challenges. While the probable use of SAI and neural organoids in patient care can increase the pace and accuracy rate of diagnosis, as well as the compatibility of research materials with human physiology; the integration of synthetic intelligence into health systems has potential problems. The challenges include informed consent, transparency and accountability of SAI, data ownership, responsibility for any mistakes arising from the hybrid system, and the role of humans in the loop.

Effective and trust-enhancing governance must adopt a multi-layered approach that evolves with technological advancements to provide data security and clarity of ownership of the data that will be analyzed or produced by SAI. The regulatory system needs to establish clear frameworks regarding the authority and responsibility of SAI in patient care. When the high development pace of SAI capabilities is considered, informed consents should evolve to have a more dynamic nature.

Interdisciplinary and multi-stakeholder collaboration will be crucial in navigating these challenges. Ethicists, neuroscientists, and AI developers must jointly establish thresholds for organoid complexity that trigger enhanced ethical oversight. Legal systems require modernization to address the ambiguous status of SAI in medical liability frameworks and the ownership rights surrounding organoid-derived discoveries. Public engagement initiatives

should demystify and critically reflect these technologies while gathering diverse perspectives on acceptable innovation boundaries. Ultimately, governance must balance two imperatives: fostering the unprecedented medical potential of these convergent technologies, while implementing safeguards that preserve human dignity, equitable healthcare access, and societal trust in neuro-technological progress. Only through adaptive, ethically anchored frameworks can we ensure these revolutionary tools enhance rather than undermine the core values of medical practice.

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