The Art of Ethics in Blockchain for Life Sciences

Ingrid Vasiliu-Feltes

Abstract Blockchain is one of the emerging technologies with profound societal and economic disruptive potential. It can also act as a catalyst for a new era where boundaries between physical, biological, and digital worlds become increasingly blended. This impact will likely trigger a complex cascade of adaptive changes in how we live, work, and educate future generations. Although ethics and moral values have been in existence for centuries, the digital era and rapid large-scale adoption of emerging technologies such as blockchain are posing novel digital ethics challenges that need to be addressed from a philosophical, legal, and self-sovereignty perspective. This chapter highlights how we can design proactive digital ethics programs in life sciences that mitigate potential negative consequences of blockchain deployments. Further, design thinking methodology combined with ethics principles can assist with building a human-centered blockchain ecosystem in the life sciences industry that will protect human rights. Specific digital ethics nuances related to various domains within life sciences as well as cultural or socioeconomic differences that can impact our blockchain ethical design frameworks will be addressed, and topics for future research will be suggested.

Keywords Ethics · Life sciences · Blockchain · Data governance · Identity · Research

1 Introduction

Ethics has been a very important discipline for centuries. After decades of marginalization, we are currently witnessing a resurgence within the scientific and business community due to the complex ethical issues we face while deploying emerging technologies at a larger scale. The scientific and business communities, as well as numerous not-for-profit and government agencies, are appropriately concerned

I. Vasiliu-Feltes (✉)
Detect Genomix, Sunrise, FL, USA
e-mail: ivfeltes@miami.edu

Government Blockchain Association, Washington, DC, USA

W. Charles (ed.), *Blockchain in Life Sciences*, Blockchain Technologies,
https://doi.org/10.1007/978-981-19-2976-2_12

about ethical issues that impact all industries. Topics such as bias, discrimination, data privacy, data ownership, transparency, and trust are making the headlines daily.

Industry leaders wish to be prepared for entering the next industrial revolution. Successful management of emerging technologies, such as distributed ledger technologies (DLTs, most notably blockchain), on all domains within the life sciences ecosystem will be required to display a complex armamentarium of novel skills, such as technology literacy and environmental, social, and governance (ESG) consciousness, as well as mastery of digital and applied ethics [1]. Furthermore, it has become evident that novel technologies like blockchain will also demand versatility in foundational ethical concepts. It is recommended to design proactive ethics programs to avoid negative consequences, and leaders that understand this imperative are poised to be successful. Ethical leaders of our digital era will be defined by upholding moral values, complementing state-of-the-art strategic planning, revising our education system, and embarking on an arduous, complex digital transformation journey.

Blending boundaries between physical, digital, and biological worlds will likely continue at an exponential pace. Emerging technologies such as DLTs, artificial intelligence (AI), Internet of Things (IoT), or next-generation computing have the potential to make a profound disruptive global impact. Many experts consider DLTs—and specifically blockchain technologies—to have a transformative impact across multiple industry sectors (e.g., [2, 3]). The life sciences industry is one of the most significantly affected post-pandemic and will demand unique ethics, business, and leadership challenges.

Deloitte's latest global life sciences outlook report highlights accelerated digitization, a new remote workforce, new customer-centric solutions, shortening of the research and development cycles, cross-border reliance via supply chain optimization [4]. One of the most significant challenges leaders face is the ethical and mindful deployment of emerging technologies. The life sciences industry is represented by a broad business ecosystem. Life sciences are also at the top of the agenda for most digital ethics experts concerned about potential negative consequences during deployments of emerging technologies (e.g., [5, 6]). Blockchain technologies have sparked numerous passionate debates among experts that emphasize the numerous opportunities they bring to the life sciences industry and experts who caution about all potential risks associated with their deployment.

The life sciences industry is undoubtedly experiencing tremendous growth. Several trends demand attention from key stakeholders: a rise in genomics-powered personalized and precision medicine, a rise of in silico trials, a reinvigorated focus on specific specialties such as immunology, pathology, imaging, as well as a remarkable increase in funding for some of the disinclines such as oncology or neurosciences [7].

The ethical aspects of blockchain deployment are complex for any industry. However, there are additional unique challenges related to the life sciences industry that must be addressed proactively. There are essential nuances in the ethical deployment of blockchain, which include societal and individual perspectives.

Among all domains that represent the life sciences, research is one of the most important to emphasize when considering blockchain deployments due to the exponential and long-term impact on all other sciences, healthcare, and the global business ecosystem.

At a basic level, we must ensure that blockchain deployments in life sciences uphold the basic ethical principles such as justice, beneficence, non-maleficence, confidentiality, integrity, and autonomy. A well-planned application of blockchain in life sciences must meet the impartiality and equality conditions, as well as ensure equal access and safeguard ownership of all data generated. The cryptography-based security offered by blockchain technology can contribute to our quest to offer maximum protection for the data stored and protect against unintended breaches, as well as malicious cyber-attacks. The life sciences industry generates massive datasets, numerous products, and solutions that are extremely difficult to safeguard. However, in some situations, a blockchain's attributes can offer a better solution for confidentiality, fidelity, and integrity than traditional technology architectures [8].

Perhaps one of the most convincing arguments for blockchain can be made for upholding the principle of autonomy. Self-sovereign identity has the potential to solve one of the major power dynamics and allow an optimal solution by offering individuals the right to their own digital identity and digital footprint [9]. Blockchain is the technology that can offer the necessary infrastructure to achieve a scalable, secure, decentralized model. In a recently published article about the use of blockchain in e-health, [9] provides a detailed overview of a centralized user-centric self-sovereignty model. The authors illustrate how the model gives users full control and provides the necessary steps for a successful implementation, such as decentralized identifiers, decentralized identifier documentation, and verifiable claims.

In addition to upholding the fundamental ethical principles, experts have called for the creation of a new Code of Ethics and Code of Conduct for Blockchain. Neitz [10] emphasizes the pros and cons of decentralization, as well as the dangers of human bias and conflict of interest for blockchain developers and other agents of interest. The author posits that while having a code of conduct would not eliminate challenges and ethical dilemmas for blockchain deployments, it could provide basic guidance to key stakeholders in the blockchain ecosystem [10].

Australia has taken the lead by drafting a Blockchain Code of Conduct that can serve as a blueprint for other countries. While it certainly offers opportunities for improvement, its content focuses on reputation, respect for rules, honesty, confidentiality, privacy, fairness, competence, self-improvement, conflicts of interest, and responsibility to others [11].

2 Digital Ethics Programs Design for Blockchain in Life Sciences

Digital ethics is a discipline that describes and addresses how we can translate classical ethics principles into the digital and virtual realms, such as beneficence, maleficence, autonomy, justice, and the values we desire to uphold as a society. Furthermore, applied ethics also aims to provide ethical guardrails that can assist us in maintaining trust, respect, responsibility, fairness, and citizenship.

Business ethics include governance, social and fiduciary responsibilities, as well as discrimination, fraud, abuse, or bribery [12]. Ethical life sciences leaders are expected to display a high regard for moral values such as honesty, fairness, respect for others. By striving to demonstrate ethical leadership in this digital era, leaders can greatly improve a Global Life Sciences Ethics Culture [13]. This section provides the overviews of digital ethics codes and summarizes the relevant literature.

2.1 General Application of Digital Ethics Across the Life Sciences Continuum

When evaluating the key elements that constitute a state-of-the-art proactive digital ethics program, we identify a need for a new code of digital ethics, a new code of digital conduct, new digital data governance, and a new digital bill of rights in addition to the traditional components. Gloria [14] forecasts a different future for digital rights, and Neitz [10] has questioned if we need a blockchain-specific code of ethics given "the libertarian origins of blockchain." Neitz expresses concerns about a potential backlash from blockchain developers "who embrace the libertarian ideal" and foresees that they would likely argue that implementation of a common standard goes against the very freedoms that make blockchain a revolutionary technology.

A recent systematic review of the blockchain literature reveals that most research had initially focused on cryptocurrencies. Only lately, a transition has been observed towards the ethical deployment of blockchain and the need for practical tools that can be utilized by industry experts, practitioners, and scholars [15]. The authors note that the spectrum of blockchain ethics research covers sustainability, greater societal good versus the needs of individual citizens, impact on law and democracy, the potential for digital twins and converging technologies, and the transformative power of blockchain for all industries in the digital era. Several publications call for the creation of international frameworks that can address the ethical considerations of blockchain technology infrastructure development and blockchain applications [15].

2.2 Research

Digital ethics has application for all types of research and all stages within the research lifecycle. There are numerous benefits of blockchain technologies in any research enterprise spanning across all domains: IRB review, audits, compliance, reporting, waste reduction, fraud prevention, informed consent, staff certification, patient recruitment, data privacy, addressing conflicts of interest, and advanced financial management [5, 6].

Enhancing the quality and safety in research is paramount to upholding the principles of beneficence and non-maleficence. Deploying blockchain for pharma research could not only reduce errors, reduce adverse events, improve outcomes but also aid with drug traceability, which has led to expanded use of blockchain in pharmaceutical supply chain management [16, 17]. A blockchain-powered pharma industry ecosystem could leverage smart contracts in a secure private permissioned distributed network of stakeholders and could lead to enhanced safety, improved integrity, and efficiency by reducing intermediaries.

Whether we aim to enhance study design, study implementation, study tracking, preparation for audits, or monitoring long-term impact, some of the unique benefits of blockchain can prove to be highly beneficial when deployed mindfully and with a strong data governance program [18]. Furthermore, the enhanced access, decentralized features, automation, and scalability can optimize efficiencies for all types of studies such as analysis of data and specimens, observational studies, interventional studies, case-control studies, cohort studies, cross-sectional studies, or qualitative studies [5]. Randomized controlled studies are often more complex and can serve as s excellent illustrative example of how blockchain technology can be deployed ethically by embedding guardrails and checkpoints during every process that ensures efficiency and compliance.

A comprehensive blockchain-powered digital ethics program can facilitate internal and external audit preparation. Additionally, many of blockchain's characteristics, such as proof of ownership and authority or its practical immutability, can reduce the overhead burden for staff, reduce waste, minimize or eliminate fraud [19].

A proactive robust data governance program requires transparency regarding data controls. The transparency afforded by blockchain technology ensures that all decisions and processes are auditable and confirms adequate data stewardship. Through blockchain's cryptographically backed-up infrastructure, we also achieve improved accountability, and its consent-based features allow seamless cross-disciplinary and inter-organizational collaboration without jeopardizing data sharing standards [20, 21].

Some of the most promising benefits of blockchain in data governance are highly desirable for any research enterprise. However, when deploying blockchain technologies for research, we must also mitigate some potentially negative aspects such as cost, limited lifespan of encryption, or network maintenance breakdowns [5, 9].

In life sciences research, multiple key stakeholders from a variety of public or private organizations are involved, and a reliance on private keys is often required. Therefore, a careful feasibility analysis of the specific type of blockchain technology to be deployed is essential. Furthermore, deciding what data need to be stored on and off-chain is also crucial and needs to occur early in the design phase [22]. For most life sciences projects, a hybrid design that enhances privacy by storing specific data elements on the chain and preserves some off-chain may prove to be an optimal solution.

Another potential barrier that needs to be overcome for life sciences research is the "zero state challenge." Specifically, the provenance of many records used for a specific research trial will require validation [23]. As described eloquently by La Pointe and Fishbane in the Blockchain Ethical Design Framework [23], an intentional design is essential to achieve optimal results. Specifically, the rules that govern human interaction must be prioritized and decided early in the process. Decision-makers will need to make tradeoffs that ensure the highest effectiveness of blockchain deployment. These tradeoffs can also impact inclusion, diversity, and enterprise return on investment [23].

As described above, the successful deployment of blockchain technologies applies to all domains within the life sciences continuum [16, 17]. However, several nuances are worth highlighting for a few high-impact domains that require a higher degree of customization for successful implementations, such as Genomics, Precision Medicine, Pharma, Biopharma, Biotech, or Biomed. The customization would ensure operational effectiveness and efficiency, as well as uphold ethical principles.

2.3 Genomics and Precision Medicine

Advanced genomic sequencing has opened a new world of opportunities in life sciences, from direct to consumer testing to novel scientific discoveries and the development of new personalized genomics-informed medical solutions. These solutions can include new molecules, new pharmaceutical agents, new medical devices, and new therapeutic pathways. All will require a safe, trusted method to access, store, share, and analyze the massive genomic data sets generated globally. Several publications are highlighting the numerous benefits of blockchain platforms in genomics-powered precision medicine. Most of them emphasize participatory access and distributed data stewardship (e.g., [7, 21, 24, 25]), while others highlight the enhanced security and self-sovereignty characteristics [9].

While there are clear opportunities for blockchain in genomics medicine, we must also overcome several challenges. Thiebes [24] determined that there are 17 technological advantages. The author also outlined the opportunities blockchain brings for increased flexibility, allowing dynamic access to various stakeholders and interdependent privacy. This dynamic consent process enables blood relatives to give data sharing permissions via smart contracts [24].

2.4 *Digital Identity*

Digital identity is a foundational element to successful ethical blockchain deployments in any industry and is crucial for life sciences. Digital identity can be represented by a person, organization, application, or device and includes electronic signatures, seals, website authentication, and registered delivery [9]. From an ethical perspective, we must reflect on all expressions and understand the impact of digital identity categorizations when deploying blockchain across the life science spectrum. Cameron's landmark publication [26] outlined identity principles, and blockchain is conducive to attaining all of them: user control and consent, minimal disclosure for a constrained use, justifiable parties, directed identity, pluralism of operators and technologies, human integration, and consistent experience across contexts.

Another essential article by Allen [27] describes four models of online identity, and each requires different digital ethics guardrails: centralized identity, federated identity, user-centric identity, and self-sovereign identity. He also drafted novel principles of self-sovereign identity, which should be foundational to those developing digital ethics blockchain playbooks: user-centricity, control, access, transparency, longevity, portability, interoperability, consent, minimized data disclosure, and protection.

Bouras et al. [9] provide a comprehensive review and overview of the impact of identity management and its importance in e-healthcare. The seven criteria of identity management they outline fully apply to life sciences research; autonomy, authority, availability, approval, confidentiality, tenacity, and interoperability. They also represent crucial elements of success in life sciences research and can be delivered via blockchain technology. The authors provide a helpful comparison of identity management models and how each type impacts the seven identity management criteria. Their findings suggest that decentralized models are the only ones offering autonomy, as well as the highest authority, availability, and confidentiality. They also highlight challenges with using centralized, federated, or user-centric identity models, such as lack of autonomy and interoperability in centralized models or lack of the approval feature in either centered or federated identity models [9].

3 Cultural, Legal, and Socioeconomic Influences

There is a complex and dynamic interplay between cultural factors, the legal landscape, and socioeconomic factors in each country or region that deeply influences the adoption of emerging technologies and their ethical deployment. There are marked differences in digital literacy and fluency that impact key stakeholders' ability to assess, design, develop, deploy, and monitor the deployment of all emerging technologies. However, blockchain has caused a marked cultural, legal, and socioeconomic divide that must be addressed globally. For research in the life sciences industry to thrive from leveraging blockchain technologies, we must develop new regulatory frameworks and legislative clarity.

A recent book, Future Law, eloquently highlights the challenges we encounter when developing legislation for emerging technologies, as well as some of the main regulatory and ethical intricacies lawmakers need to consider [28]. The authors also emphasize that arts and culture play a mediating role between technology and law. Mittelstadt and Floridi [29] also identify key societal issues and approaches that rule the debate on the ethical deployment of new and emerging technologies while calling for international collaboration to develop information governance policies. The authors caution against exceptionalism, parochialism, and adventitious ethics in life sciences research. While written to address ethical issues in big data management, the fundamental problems, main conclusions, and recommendations can be easily extrapolated and applied to blockchain technologies.

Another intriguing opinion highlights the convergence of ethics, law, and governance and the impact technology deployments in life sciences on significant decisions in the healthcare, military, defense, and space industries [18]. The authors also highlight how traditions and values in various global communities that share religious beliefs markedly impact the ability to draft laws for emerging technologies. They also point to the significant governmental bias, outdated regulations, and bureaucratic burdens existent in many geographic markets that preclude the development of legislation or policies that can assist with deploying emerging technologies such as blockchain [18]. The book calls out the tension between promoting innovation and entrepreneurship that stimulates economic growth and the regulatory hurdles. Examples are provided from various countries where the political process interferes with appropriate assessment of the benefits and risks associated with emerging technologies such as blockchain. Safety, privacy, responsibility, and public health are often crucial topics in the passionate debates, and key stakeholders within the life sciences and blockchain industries often find themselves caught in the middle of the polemic.

Carnevale and Occhipinti [30] pose several questions to all digital ethics advocates: Who is authorized to make decisions in a decentralized system? What about the mechanism for deciding? Authorized by whom? With what kind of consensus? To which principles must the decision-making mechanism respond? Answering these initial questions to optimize all aspects of the life sciences research industry is only the beginning of the digital ethics odyssey. It constitutes a moral imperative for all decision-makers [30].

Dierksmeier and Steel [12] forecast some of the moral dilemmas business leaders will have to solve before and during blockchain technology deployments. The authors share their views on the application of Habermasian corporate social responsibility theory in blockchain applications. The life sciences research industries are particularly amenable to data transparency to authorized stakeholders. State-of-the-art ethics programs will be required to navigate the numerous sources of ambivalence caused by those who endorse a utilitarianist, contractarianist, deontological, or virtue ethics approach [12].

The impact of ethical deployment of blockchain in life sciences research will inevitably also cause a recalibration of the educational and business processes within life sciences and, therefore, a novel emphasis on blockchain business ethics and educational ethics-related aspects. Other authors (e.g., [10]) caution about the ethical challenges with decision-making in all types of blockchain technologies that influence state and governing regulatory bodies.

Zatti [31] calls attention to how the pandemic has highlighted the need to share relevant biobank data and the benefits blockchain technologies offer while safeguarding intellectual property rights. The authors also echo other experts' calls to enhance legislation and more explicit regulatory guidelines that can facilitate large-scale adoption of blockchain.

Several governments worldwide have acknowledged the need for new laws and regulatory guidelines and already adopted blockchain. Europe and Asia are leading the way. However, there are promising efforts in North America, South America, Australia, and Africa. Lawmakers, policymakers, and ethicists will have to collaborate closely to align their new bodies of work with the global digital ethics frameworks. At a global level, we have a few universal opportunities that can drive successful blockchain deployments in life sciences and other industries, such as increased digital ethics advocacy, sustainability, and inclusion.

4 Blockchain Ethics and Purpose in Life Sciences

Life sciences leaders have the opportunity to shape the future by fostering a culture of digital ethics and contribute to the development of a Global Digital Ethics Framework for the life sciences research industry. This global framework can facilitate the attainment of the United Nations Sustainable Development Goals (SDGs) and further validate the existing sense of purpose in life sciences research.

While the deployment of blockchain technologies can have a large-scale impact on all United Nations SDGs, a few SDGs are more directly impacted by blockchain solutions where a lack of ethical deployment can have devastating circumstances on society. Blockchain technologies can augment and amplify sustainability efforts related to reducing poverty, reducing hunger, improving access to quality education, optimizing gender equality, promoting decent work and economic growth, building a robust infrastructure, reducing inequality, and creating sustainable cities [1]. Undoubtedly, blockchain technologies deeply influence the health and wellness ecosystem and specifically the life sciences industry through enhanced capabilities across various essential domains such as clinical trials, supply chain management, contract management, financial transactions, credentialing, and safety. At a global level, blockchain deployments can also accelerate research and development efforts, as well as act as an enabler for the large-scale adoption of other emerging technologies [6].

Perhaps one of the most important ethical aspects is blockchain's impact in ensuring appropriate assent, prosent, and consent in human research, as it transcends ethics and elicits legal, social, and philosophical considerations. Blockchain-enabled platforms also have a crucial potential to facilitate corporate ESG consciousness by becoming a foundational technology for data standardization, asset performance assessments, and compliance with ESG mandates or standards [1].

Ethical deployment of blockchain can only be successful with strong ethical leadership. We currently live in a globalized society that has become hyperconnected, with a high degree of automation and digitization embedded in our daily lives. Business leaders that wish to be successful in this new world must add a whole set of novel skills to their portfolio, such as ability to translate ethical concepts into daily practice, understand the basic methodologies defined by design thinking, enhance their digital acumen and become global digital citizens [13]. When we develop a state of the art enterprise digital ethics roadmap, it is recommended to align it with other key strategic initiatives and to embed all elements that are included in an ethics portfolio: social consciousness, concerns about climate impact, ethical use of cybersecurity software, as well as a customized digital code of conduct for the organization and its employees.

The exponential adoption of blockchain in life sciences will require a robust, sustainable digital ethics culture to avoid potential data breaches, optimize privacy and ensure ownership in this highly virtualized and digitized era. Digital ethics conscious leaders should be appropriately concerned about upholding core foundational ethical values, as well as those unique to the life sciences research ecosystem.

5 Future Directions: Disruption, Innovation, Evolution

The life sciences research industry has faced perhaps one of the highest pressures for digital transformation and disruption during and in the current post-pandemic era. The research enterprise has been disrupted by the global pandemic demands and has continued to evolve to meet the demand of a highly volatile, high-risk environment. From meeting novel regulatory and legislative guidelines, revising pricing structures in the face of economic downturn, and increasing efficiency, effectiveness, and safety while deploying the latest emerging technologies are just a few of the items life sciences leaders have to consider. Blockchain technologies have proven themselves feasible during the pandemic crisis and are now adopted at an accelerated pace within the life sciences disciplines and particularly in research [6]. However, enterprises must embark on a journey of continuous improvement, innovation, and disruption to remain competitive and ensure sustainability. Having a contours improvement mindset can facilitate the long-term success of digital ethics programs even in this highly volatile and high-risk post-pandemic era.

Industry experts forecast that blockchain technologies will continue to promote innovation and entrepreneurship while driving a new digital economy. For life sciences research, a few potential trends are emerging that can all benefit from blockchain deployments. These include novel use cases in various disciplines such as Psychology and Behavioral Sciences, Endocrinology, Immunology, Embryology, Neurobiology, as well as the emergence of new disciplines such as those that study the medical applications of brain–computer interfaces, human cloning, and bionic humans [32].

These disciplines pose unique ethics challenges that require innovative ethics approaches and a state of the art ethics governance. Organizations would be well advised to seek ethics counsel and create a robust ethics governance model to avoid or mitigate potential ethical breaches [33].

For all new use cases of blockchain technology deployment in life sciences, we have also noticed an exponential increase of converging technologies to optimize their impacts, such as the smart use of blockchain with AI, IoT, advanced computing methodologies such as quantum computing to create new concepts that can enhance development, quality, and safety such as digital health [34]. Designing state-of-the-art digital ethics programs that can accommodate the exponential ethical challenges brought upon by deploying multiple emerging technologies will become a moral imperative for leaders in this digital era.

For example, the combined deployment of AI & DLTs leverages the benefits of both technologies to optimize public health efforts, as well as facilitate the prevention, treatment and management of diseases. Large-scale adoption of converging emergent technologies such as blockchain AI, nanotechnology, and IoT can disrupt the current health care ecosystem and lead to improve global population health. To achieve long-term success, we must encourage and attain inter-and cross-disciplinary collaboration. There is a need to redesign the current life-sciences and healthcare delivery ecosystems to allow never paradigms such as precision and personalized medicine to fully develop. A completely redesigned AI and DLT-powered global health and life sciences ecosystem would be characterized by enhanced access to precision medicine solutions for patients worldwide. Last but not least, it would be essential to wisely and ethically deploy genomics-based precision medicine and further stimulate life-sciences research.

Evangelatos et al. [20] described how the unique combination of open source code software and blockchain technology could prove to be a viable solution for public biobanks' data governance. Building research ecosystems using decentralized blockchain technology that addresses the free-riding problem in the research community can lead to sustainability and aligns with free-market models.

By creating a virtual environment embodied as a digital twin, we can significantly enhance our ability to exchange valuable information with other stakeholders, enhance safety testing and optimize our data processing capabilities. Digital twins are designed and deployed to enable virtual collaboration, absorb and process big data, and assist us with managing the physical world more efficiently and safely [35]. The pandemic impact and disruption caused to the global economy have accelerated the pace and adoption of digital twins globally [35]. The design and deployment of digital twins are complex and intimately connected to other digital technologies such as blockchain, cloud computing, AI, IoT, 5G networks, virtual, augmented, or mixed reality. By maximizing the use of digital virtual replicas, we can exponentially accelerate our efforts in research and development, optimize quality assurance and safety testing, reduce waste, decrease operational inefficiencies and increase the return on our investments [35].

Life sciences and healthcare are examples where digital health twins could potentially solve several of the major challenges we are facing globally and have a profound disruptive effect. A global blockchain-powered precision medicine data exchange supporting research enterprises would allow us to derive meaningful and actionable insights exponentially and shorten the research and development lifecycle for novel drugs, devices, and treatment pathways [34].

Futurists and emerging technologies' advocacy groups are also envisioning blockchain technologies as a gateway technology for smart cities due to their ability to enable safer, more reliable, and transparent transactions among multiple stakeholders involved in the governance of smart cities. Smart research, smart health care, smart hospitals, smart research will hopefully become a golden standard for upcoming generations.

Overall, industry experts estimate that we will witness the increased incorporation of blockchain in the life sciences strategic planning process within the next few years [6]. To be successful, leaders ready to embark on this journey must address all stages from redesigning research processes, developing proofs of concept, deploying pilots, demonstrating the ability to scale, and creating an ethics culture mindset for the enterprise [15, 23].

A state-of-the-art digital ethics program for life sciences would have to start with infusing core ethics values at all levels within the organization. Such a program would require building an ethics mindset at the board level, including the C-suite, as well as middle management, employees, and patients. This program would also require developing a new vision and mission statement that emphasizes digital ethics, new policies and guidelines, new operating procedures, and embedding digital ethics guardrails into all relevant daily processes [36].

6 Conclusions

Beasley [37] questions if ethical leadership is an art. This author agrees and adds that implementing digital ethics programs in any organization requires ethical leadership and a proactive approach. Moral identity and moral imagination are not often included in a leadership skills list, yet they are crucial in successfully navigating some of the significant challenges leaders face, such as conflict management, ethical dilemmas, and uncertainty. Emerging technologies such as blockchain are perfect examples that showcase the complexity and need for inter-disciplinary collaboration of key stakeholders to be successful. Another key takeaway from this chapter is the need to develop and nurture a culture of digital ethics, encourage a continuous improvement mindset, and develop key digital ethics performance indicators to measure the impact of blockchain deployments in life sciences. Lastly, this author hopes that increased attention will be given to ethical deployments of blockchain as a sizable blockchain divide must first be overcome [38].

Digital ethics could and should become an integral part of our global education ecosystem and deeply embedded into the DNA of any life sciences research enterprise. Ideally, we would like to live and work in a world where we have designed, adopted a new Hippocratic Oath customized for the Digital Era and a New Code of Blockchain Ethics.

Key Terminology and Definitions

Applied ethics: Applied ethics is a branch of ethics devoted to treating moral problems, practices, and policies in personal life, professions, technology, and government.

Biobank: An extensive collection of biological or medical data and tissue samples amassed for research purposes.

Bionic humans: A human being whose body has been taken over in whole or in part by electromechanical devices.

Brain-computer interface (BCI): A system that measures the activity of the central nervous system (CNS) and converts it into artificial output that replaces, restores, enhances, supplements, or improves natural CNS output, and thereby changes the ongoing interactions between the CNS and its external or internal environment.

Contractarianism: A theory stemming from the Hobbesian line of social contract thought specifying that persons are primarily self-interested and that a rational assessment of the best strategy for attaining the maximization of their self-interest will lead them to act morally.

Cyberethics: The study of ethics pertaining to computers, covering user behavior and what computers are programmed to do, and how this affects individuals and society.

Digital ethics: The branch of ethics that applies to digital media, for example, in online contexts, how users interact with each other, both in representing themselves and controlling data about themselves in the platforms and technologies that they use and in their respect for other users and other users' rights to self-determination and privacy.

Digital twin: A digital representation of a real-world entity or system.

DLT: Distributed ledger technologies.

Environmental, social, and governance (ESG): Criteria are a set of standards for a company's operations that socially conscious investors use to screen potential investments.

Genomics: The branch of molecular biology concerned with the structure, function, evolution, and mapping of genomes.

Habermasianism: The theory by Jurgen Habermas, Sociologist, and Philosopher.

Human cloning: The creation of a genetically identical copy (or clone) of a human.

Open source code: Software for which the original source code is made freely available and may be redistributed and modified according to the requirement of the user.

Neurobiology: The branch of the life sciences that deals with the anatomy, physiology, and pathology of the nervous system.

Self-sovereignty: A feature of an ID or identity system, whereby individual users control when, to whom, and how they assert their identity.

Smart city: A smart city uses information and communication technology (ICT) to improve operational efficiency, share information with the public and provide a better quality of government service and citizen welfare.

Sustainable development goals (SDGs): A set of goals adopted by the United Nations in 2015 as a universal call to action to end poverty, protect the planet, and ensure that by 2030 all people enjoy peace and prosperity.

Utilitarianism: The doctrine that an action is right insofar as it promotes happiness, and that the greatest happiness of the greatest number should be the guiding principle of conduct.

Virtue ethics: Currently, one of three major approaches in normative ethics.

References

1. Singh R, Dwivedi AD, Srivastava G (2021) Blockchain for united nations sustainable development goals (SDGs). Front blockchain. https://www.frontiersin.org/research-topics/18154/blockchain-for-united-nations-sustainable-development-goals-sdgs
2. Heister S, Yuthas K (2021) How blockchain and AI enable personal data privacy and support cybersecurity. In: Blockchain potential in AI [Online First]. IntechOpen. https://doi.org/10.5772/intechopen.96999
3. Tan E (2021) A conceptual model of the use of AI and blockchain for open government data governance in the public sector (No. B2/191/P3/DIGI4FED). DIGI4FED. https://soc.kuleuven.be/io/digi4fed/doc/d-3-2-1-a-conceptual-model-of-the-use-of-ai-and.pdf
4. Levy V (2021) Global life sciences sector outlook. Deloitte. https://www2.deloitte.com/global/en/pages/life-sciences-and-healthcare/articles/global-life-sciences-sector-outlook.html
5. Benchoufi M, Ravaud P (2017) Blockchain technology for improving clinical research quality. Trials 18(1):1–5. https://doi.org/10.1186/s13063-017-2035-z
6. Charles WM (2021) Accelerating life sciences research with blockchain. In: Namasudra S, Deka GC (eds) Applications of blockchain in healthcare. Springer Singapore, pp 221–252. https://doi.org/10.1007/978-981-15-9547-9_9
7. Scott M (2019) Feature interview with David Koepsell, CEO of EncrypGen. Blockchain Healthc Rev. https://blockchainhealthcarereview.com/charting-the-blockchain-of-dna-feature-interview-with-david-koepsell-of-encrypgen/
8. Lo SK, Staples M, Xu X (2021) Modelling schemes for multi-party blockchain-based systems to support integrity analysis. Blockchain Res Appl 100024:100024. https://doi.org/10.1016/j.bcra.2021.100024

9. Bouras MA, Lu Q, Zhang F, Wan Y, Zhang T, Ning H (2020) Distributed ledger technology for ehealth identity privacy: state of the art and future perspective. Sensors 20(2). https://doi.org/10.3390/s20020483
10. Neitz MB (2020) Ethical considerations of blockchain: Do we need a blockchain code of conduct? The FinReg Blog. https://sites.law.duke.edu/thefinregblog/2020/01/21/ethical-considerations-of-blockchain-do-we-need-a-blockchain-code-of-conduct/
11. Blockchain Australia Code of Conduct (2021). https://blockchainaustralia.org/codeofconduct/
12. Dierksmeier C, Seele P (2019) Blockchain and business ethics. Bus Ethics 29(2):348–359. https://doi.org/10.1111/beer.12259
13. Vasiliu-Feltes I (2020a) Ethical leadership in the fintech era. Xpertsleague. https://www.xpertsleague.com/ethical-leadership-in-the-fintech-era/
14. Gloria K (2021) Power and progress in algorithmic bias. Aspen Inst. https://www.aspeninstitute.org/publications/power-progress-in-algorithmic-bias/
15. Hyrynsalmi S, Hyrynsalmi SM, Kimppa KK (2020) Blockchain ethics: A systematic literature review of blockchain research. In: Cacace M, Halonen R, Li H, Phuong T, Chenglong O, Widén L, Suomi R (eds) Well-being in the information society. Fruits of respect. Springer, Cham, pp 145–155. https://doi.org/10.1007/978-3-030-57847-3_10
16. Uddin M (2021) Blockchain Medledger: hyperledger fabric enabled drug traceability system for counterfeit drugs in the pharmaceutical industry. Int J Pharm 597:120235. https://doi.org/10.1016/j.ijpharm.2021.120235
17. Uddin M, Salah K, Jayaraman R, Pesic S, Ellahham S (2021) Blockchain for drug traceability: architectures and open challenges. Health Inform J 27(2). https://doi.org/10.1177/14604582211011228
18. Marchant GE, Wallach W (eds) (2017) Emerging technologies: Ethics, law and governance. Taylor and Francis. https://www.routledge.com/Emerging-Technologies-Ethics-Law-and-Governance/Marchant-Wallach/p/book/9781472428448
19. Ingraham A, St. Clair J (2020) The fourth industrial revolution of healthcare information technology: key business components to unlock the value of a blockchain-enabled solution. Blockchain Healthc Today 3(139). https://doi.org/10.30953/bhty.v3.139
20. Evangelatos N, Upadya SP, Venne J, Satyamoorthy K, Brand H, Ramashesha CS, Brand A (2020) Digital transformation and governance innovation for public biobanks and free/libre open source software using a blockchain technology. OMICS 24(5):278–285. https://doi.org/10.1089/omi.2019.0178
21. Shabani M (2018) Blockchain-based platforms for genomic data sharing: a decentralized approach in response to the governance problems? J Am Med Inform Assoc 26(1):76–80. https://doi.org/10.1093/jamia/ocy149
22. Miyachi K, Mackey TK (2021) hOCBS: a privacy-preserving blockchain framework for healthcare data leveraging an on-chain and off-chain system design. Inf Process Manag 58(3):102535. https://doi.org/10.1016/j.ipm.2021.102535
23. LaPointe C, Fishbane L (2018) The blockchain ethical design framework. Beeck center for social impact + innovation, Georgetown University. https://beeckcenter.georgetown.edu/wp-content/uploads/2018/06/The-Blockchain-Ethical-Design-Framework.pdf
24. Thiebes S, Kannengießer N, Schmidt-Kraepelin M, Sunyaev A (2020) Beyond data markets: opportunities and challenges for distributed ledger technology in genomics. In: Bui TX (ed) Proceedings of the 52nd Hawaii international conference on system sciences, pp 3275–3284. https://hdl.handle.net/10125/64142
25. Thiebes S, Schlesner M, Brors B, Sunyaev A (2019) Distributed ledger technology in genomics: a call for Europe. Eur J Hum Genet 28(2):139–140. https://doi.org/10.1038/s41431-019-0512-4
26. Cameron K (2005) The laws of identity. Microsoft corporation. http://myinstantid.com/laws.pdf
27. Allen C (2016) The path to self-sovereign identity. Life with alacrity. http://www.lifewithalacrity.com/2016/04/the-path-to-self-sovereign-identity.html
28. Edwards L, Schafer B, Harbinja E (eds) (2021) Future law: emerging technology, ethics and regulation. Edinburgh University Press. https://books.google.com/books/about/Future_Law.html?hl=&id=JheztAEACAAJ

29. Mittelstadt BD, Floridi L (eds) (2016) The ethics of biomedical big data. Springer International Publishing Switzerland. https://doi.org/10.1007/978-3-319-33525-4
30. Carnevale A, Occhipinti C (2019) Ethics and decisions in distributed technologies: A problem of trust and governance advocating substantive democracy. In: Bucciarelli E, Chen SH, Corchado JM (eds) Decision economics. Complexity of decisions and decisions for complexity. Springer, Cham, pp 300–307. https://doi.org/10.1007/978-3-030-38227-8_34
31. Zatti F (2021) Blockchains and dynamic consent in biobanking. SSRN. https://doi.org/10.2139/ssrn.3853352
32. Bar-Cohen Y (2004) Bionic: bionic humans using EAP as artificial muscles reality and challenges. Int J Adv Robot Syst 50(2):217–223. https://doi.org/10.1097/00002480-200403000-00188
33. Ishmaev G (2019) The ethical limits of blockchain-enabled markets for private IoT data. Philos Technol 33(3):411–432. https://doi.org/10.1007/s13347-019-00361-y
34. Popa EO, van Hilten M, Oosterkamp E, Bogaardt M-J (2021) The use of digital twins in healthcare: socio-ethical benefits and socio-ethical risks. Life Sci Soc Policy 17(1):1–25. https://doi.org/10.1186/s40504-021-00113-x
35. Vasiliu-Feltes I (2020b) Digital health twins—the great enablers of new healthcare ecosystems? LinkedIn. https://www.linkedin.com/pulse/digital-health-twins-great-enablers-new-healthcare-ingrid
36. Tandon A, Dhir A, Islam AKMN, Mäntymäki M (2020) Blockchain in healthcare: a systematic literature review, synthesizing framework and future research agenda. Comput Ind 122:103290. https://doi.org/10.1016/j.compind.2020.103290
37. Beasley B (2021) Is ethical leadership an art? Notre Dame Deloitte center for ethical leadership. https://ethicalleadership.nd.edu/news/is-ethical-leadership-an-art/
38. Tang Y, Xiong J (2019) Blockchain ethics research: a conceptual model. SIGMIS-CPR '19. In: Proceedings of the 2019 computers and people research conference, pp 43–49. https://doi.org/10.1145/3322385.3322397

Further Readings

39. Castellanos S (2021) Quantum computing scientists call for ethical guidelines. Wall Str J. https://www.wsj.com/articles/quantum-computing-scientists-call-for-ethical-guidelines-11612155660
40. Lemieux VL, Hofman D, Hamouda H, Batista D, Kaur R, Pan W, Costanzo I, Regier D, Pollard S, Weymann D, Fraser R (2021) Having our omic cake and eating it too? Evaluating user response to using blockchain technology for private and secure health data management and sharing. Front Blockchain 3:558705. https://doi.org/10.3389/fbloc.2020.558705
41. Parry G, Collomosse J (2021) Perspectives on good in blockchain for good. Front Blockchain 3:609136. https://doi.org/10.3389/fbloc.2020.609136

Dr. Vasiliu-Feltes is a healthcare executive, futurist, and globalist who is highly dedicated to digital and ethics advocacy. She is a passionate educator and entrepreneurship ecosystem builder, an expert speaker, board advisor, and consultant. Throughout her career, she has received several awards for excellence in research, teaching, or leadership. This past year, she has been named one of the Top 25 Leaders in Digital Twins, Top 50 Health Tech Global Thought Leaders, 100 Global Women Leaders, 100 Global Healthcare Leaders, Top 100 Global Finance Leaders, and Top 100 Women in Crypto. Additionally, she received the 2021 Excellence in Education Award, World Women Vision Award for Technology and innovation, serves as an Expert Advisor to the EU Blockchain Observatory Forum, and was appointed to the Board of UN Legal and Economic

Empowerment Network. Most recently, she also received the WBAF World Excellence Award for The Best Businesswoman Role Model Demonstrating Social Entrepreneurship. She is an active supporter of the UN SDGs illustrated in several global collaborations and through her contribution as Global Chairwoman for GCPIT and the Global SDG Summit.

During her academic tenure, she taught several courses while on faculty at the Miller School of Medicine, as well as for the combined MD/Ph.D. and MD/MPH programs. She currently teaches the Business Technology-Digital Transformation Course at the University of Miami Herbert Business School, as well as Innovation and Digital Transformation at the WBAF Business School. Throughout her career, Dr. Vasiliu-Feltes held several leadership positions and is a member of numerous prestigious professional organizations. She holds several certifications, such as Bioethics from Harvard, Artificial Intelligence and Business Strategy from MIT Sloan, Blockchain Technology and Business Innovation from MIT Sloan, Finance from Harvard Business School, Negotiation from Harvard Law School, Innovation and Entrepreneurship from Stanford Graduate School of Business, Certified Professional in Healthcare Risk Management, Fellow of the American College of Healthcare Executives, Patient Safety Officer by the International Board Federation of Safety Managers, Master Black Belt in Lean and Six Sigma Management, Professional in Healthcare Quality by the National Association of Healthcare Quality, Manager for Quality and Organizational Excellence, by the American Society for Quality, and Certified Risk Management Professional by the American Society for Healthcare Risk Management.