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# Playing God: Human Digital Twin. A Legal Approach

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**Abstract**: Human Digital Twins (HDTs) seem futuristic, but the technology behind them is already a reality. Two elements make up HDTs technology: the real person and his or her digital counterpart/twin, as well as two-way communication between them. Furthermore, the actual surroundings and people that the twin interacts with in real life are transferred into cyberspace. A complete HDT does not exist, yet. In most cases, only certain aspects of human attributes are used in a particular context for specific purposes. But the technology will be able, sooner or later, to „create” a “full” HDT. This endeavour could be equated with a God creation, if we admit that God exists. To prepare to face the future, which is already here, everybody should be at least well informed. Therefore, in this article we will try to depict a comprehensible portrait of the HDTs. We will start by making a brief presentation of what Digital Twins (DTs) and HDTs technologies mean, their functioning, and their practical applications. We will focus afterwards on the legal issues concerning HDTs in an EU legal context. We will try to clarify the applicable rules and the HDTs ownership and other possible proprietary rights, such as intellectual property ones. Last, we will name a few legal and other concerns connected with HDTs.

**Keywords**: digital twin, human digital twin, artificial intelligence, personal data.

## Introduction

Human Digital Twins systems, along with innovative technologies such as Self-aware AI, could be considered the peak of the advancement of the digital age, long characterized as disruptive, emerging or cutting-edge technologies[3]. In this

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[3] See, Gartner website, *30 Emerging Technologies That Will Guide Your Business Decisions*, [Online] at https://www.gartner.com/en/articles/30-emerging-technologies-that-will-guide-your-business-decisions, accessed July 14th, 2024; McKinsey Digital, *Tech at the edge: Trends reshaping the future of IT and business,* 21 october 2022, [Online] at https://www.mckinsey.com/capabilities/mckinsey-digital/our-insights/tech-at-the-edge-trends-reshaping-the-future-of-it-and-business, accessed July 14th, 2024; KPMG website, *The Chaning landscape of disruptive technologies – Part 2: Innovation convergence unlocks new paradigms*, 2017, [Online] at https://assets.kpmg.com/content/dam/kpmg/br/pdf/2017/07/disruptive-tech-2017.pdf, accessed July 14th, 2024; V.D. Păvăloaia, S.C. Necula,

era, the concept of Human Digital Twins (HDTs) is redefining the way we understand and interact with technology and the way we relate to the human being.

The idea of Digital Twins (DTs) and HDTs is not new. The novelty consists, above all, in its practical application rather than in the idea itself. For example, as early as 2008, in the movie Iron Man the protagonist, Tony Stark, creates a digital model of his equipment that, during actual use, gives him updates on the performance of the various systems built into the suit. Iron Man thus incorporated both DTs (which gave him real-time information and predictions about the suit's performance) and HDTs technology (which helped in collecting information about the human user, analyzing it and generating predictions about his health). Systems such as DTs or HDTs are based on Artificial Intelligence, and in Iron Man movie this is easily noticeable through the presence of Jarvis - the interactive AI system that assists and alerts the protagonist.

In a broad sense, the HDT or Personal Digital Twin[4] is a digital representation of a person that integrates biological, behavioral, and contextual data to create a holistic and dynamic picture of the individual[5]. This concept transcends the simple idea of a digital profile or virtual avatar, moving beyond static representation to capture human complexity and dynamics in real time. Through the continuous analysis of data and patterns, HDTs can provide relevant information and predictions about the health status, behavior and performance of the individual, bringing with it a potentially transformative effect in fields such as personalized medicine or the sports industry[6].

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*Artificial Intelligence as a Disruptive Technology—A Systematic Literature Review* in Electronics 2023, 12, 1102, https:// doi.org/10.3390/electronics12051102, pp. 1-2.

[4] M. Teller, *Legal aspects related to digital twin*, in Philosophical Transactions of the Royal Society A, 4 October 2021, volume 379, Issue 2207, https://doi.org/10.1098/ rsta.2021.0023; R. Saracco, *Personal Digital Twins. A third evolution step for humankind?*, eBook, 2022, p. 23, [Online] at https://digitalreality.ieee.org/images/ files/pdf/4-2022personal-digital-twins-ebook-final.pdf, accessed on April 4th, 2024.

[5] See also: Y. Naudet, A. Baudet, M. Risse, *Human Digital Twin in Industry 4.0: Concept and Preliminary Model*, in IN4PL - Proceedings of the International Conference on Innovative Intelligent Industrial Production and Logistics, 2021, https://doi.org/ 10.5220/0010709000003062, pp. 138-140; Miller M.E., Spatz E., *A unified view of a human digital twin*, in Human-Intelligent Systems Integration, (2022) 4, https://doi.org/ 10.1007/s42454-022-00041-x, pp. 24, 28, 31; M. Miller, *Human Digital Twin and Modeling Guidebook*, in Air Force Institute of Technology - Technical Report, December 19, 2022, [Online] at https://apps.dtic.mil/sti/trecms/pdf/AD1188552.pdf, accessed on April 4th, 2024, pp. 7-8; W. Shengli, *Is Human Digital Twin possible?*, in Computer Methods and Programs in Biomedicine Update, volume 1, 2021, https://doi.org/10.1016/ j.cmpbup.2021.100014, pp. 2-4.

[6] W. Shengli, *op. cit.*, p. 2; M.E. Miller, E. Spatz, *op. cit.*, pp. 28-31; E.O. Popa, M. van Hilten, E. Oosterkamp, M.-J. Bogaardt, *The use of digital twins in healthcare: socio-ethical benefits and socio-ethical risks*, in Life Sciences, Society and Policy, issue 17, 2021, https://doi.org/10.1186/s40504-021-00113-x, p. 2; T. Liu, C. Weng, Q. Jiang, L. Jiao, Z. Ni, *Modelling Human Digital Twins Based on Physical and Mental Fusion*, in NSFC-RGC

Fortunately, a "full"/complete HDT does not exist, yet. In most cases, only certain aspects of human attributes are used in a particular context for specific purposes. The human being is too complex to be „captured" in its entirety in a HDT[7]. But, the technology will be able, sooner or later, to „create" a complete HDT. This endeavour could be equated with a God creation, if we admit that God exists.

To prepare to face the future, which is already here, everybody should be at least well informed. We will make a brief presentation of what DTs and HDTs technologies mean, their functioning, and their practical applications. We will focus afterwards on the legal issues concerning HDTs in an EU legal context. We will try to clarify the applicable rules and the HDTs ownership and other possible proprietary rights, such as intellectual property ones. Last, we will name a few legal and other concerns connected with HDTs.

## 1. From digital twins to human digital twins

Despite appearing to be something out of the future, DTs technology has been present and in use for a while. However, these new technologies are only „adopted" by sectors of the economy that have the resources to invest significantly in the creation of new goods or services, such as the life sciences and health care sector, the military sector, the medical field, or the automotive sector, until they are ready for widespread adoption.

Since the ideas behind DTs, and particularly HDTs, are controversial, new technologies require advertising campaigns that highlight their advantages and pique consumers' interest in using them. Disruptive technologies like HDTs are incorporated into society gradually and with a focus on opportunities and benefits rather than by means that incite distrust or anxiety.

### 1.1. What is a digital twin?

The DT is a virtual replica of a physical system, process or product that is periodically updated with data collected from the real-world twin and the environment in which it is located[8]. By replicating the behavior of the real-world twin under different conditions and analyzing the results, DTs technologies can be used to optimize performance, prevent hardware failures, anticipate maintenance

Conference 2023, 10.13140/RG.2.2.23742.77121, [Online] at: https://www.researchgate.net/publication/370230449_Modelling_Human_Digital_Twins_Based_on_Physical_and_Mental_Fusion, accessed on April 4th, 2024.

[7] Y. Song, *Human Digital Twin, the Development and Impact on Design,* in Journal of Computing and Information Science in Engineering, vol. 23, issue 6, 2023, Paper No: JCISE-23-1076, pp. 4-5, https://doi.org/10.1115/1.4063132.

[8] B. Tekinerdogan, *On the Notion of Digital Twins: A Modeling Perspective,* in Systems 11, issue 1, 2023, https://doi.org/10.3390/systems11010015; E.O. Popa, M. van Hilten, E. Oosterkamp, M.-J. Bogaardt, *op. cit.*, p. 2; W. Shengli, *op. cit.*, p. 2; M. Miller, *op. cit.,* p. 2.

needs and streamline processes by sending reports and suggestions to the real-world twin[9].

In the specialized literature[10], the concept of DTs has been extended to what is called Augmented Digital Twins, a complex system that interacts not only with its real-world twin but also with its environment and with other digital twins. The Augmented Digital Twins system includes, on the one hand, the physical object or system, its surroundings and the relationship with other physical entities, and on the other hand the digital twin, the environment and other digital twins corresponding to those in the real environment. The two dimensions within the Augmented Digital Twins system communicate, change concurrently, interact, and mutually influence each other.

The rationale behind the concept of Augmented Digital Twins is the desire to extend the applicability of DTs technology to humans, living beings, who come into contact with different goods and equipment and are influenced by their environment and interaction with their fellow beings.

### 1.2. What is meant by Human Digital Twin (HDT)?

The HDT is based on the Augmented Digital Twin model. The system comprises two components: the actual person and his/her digital counterpart, as well as two-way communication between them. Additionally, the real environment and people that the real-life twin interacts with are also included and transposed into cyberspace. The effects of situations, human contact, and environmental influences on persons justify the development of the HDT system by including these components[11].

HDT is a copy or a counterpart in cyberspace of a real person in the physical world, being a model based in principle on personal data such as age, height, weight, gender, medical data etc. [12].

The conceptual model of the DT primarily consists of three main components[13]: the real-world twin, located in the physical space; the digital twin, in cyberspace; the data and information communication interface between the twins, which ensures a two-way data transfer between physical and cyber space.

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[9] H. Pascual, X. Masip-Bruin, A. Alonso, J. Cerdá, *A Systematic Review on Human Modeling: Digging into Human Digital Twin Implementations*, 2023, arxiv Publisher, https://doi.org/10.48550/arxiv.2302.03593; M. Miller, *op. cit.*, p. 2.

[10] W. Shengli, *op. cit.*, pp. 1-2.

[11] *Ibidem*, p. 4.

[12] See also the definitions provided by the specialized literature: M.E. Miller, E. Spatz, *op. cit.*, p. 28;

[13] W. Shengli, *op. cit.,* p. 2; M.E. Miller, E. Spatz, *op. cit.*, p. 25; B.R. Barricelli, E. Casiraghi, J. Gliozzo, A. Petrini, S. Valtolina, *Human digital twin for fitness management*, in IEEE Access, volume 8, 2020, pp. 26637–26664, https://doi.org/ 10.1109/ACCESS.2020.2971576; M. Grieves, *Digital twin: manufacturing excellence through virtual factory replication*, in White paper, 2015, [Online] at: https://www.researchgate.net/ publication/ 275211047_Digital_Twin_Manufacturing_Excellence_through_Virtual_Factory_Replication, accessed on April 4th, 2024.

The communication of information within the HDT system is bidirectional and in real-time so that a change in the real-world twin produces changes in the digital twin and vice versa[14].

A HDTs system could include the digital representation of an individual or of a human class, where this class represents a group of people with various traits, characteristics, behaviours etc. [15].

Therefore, we could define a HDT as an integrated model that facilitates the description, prediction or visualization of one or more characteristics of a person or class of persons, over time and in a real environment. A HDT system is an association between the real-world twin and the human digital twin; it consists of a model of the real world twin's physical, physiological, psychological, perceptual, cognitive, emotional, and ethical aspects. The two components are integrated so that any changes made to the real world person or his digital representation also affect the other[16].

To put it in another way, as Roberto Saracco (the vice president of the *IEEE-Institute of Electrical and Electronics Engineers - Digital Reality Initiative)* said: "*The Personal Digital Twin can act as a butler (assisting the physical entity) as an avatar (impersonating the physical entity) as an agent (like harvesting information on behalf of its physical entity). In certain situations, it can act as the digital placeholder (like in storing the person's health record).*"[17]

### 1.3. How does the Human Digital Twin work?

The use of advanced data collection and analysis technologies such as biometric sensors, wearable devices, 3D scanning techniques or machine learning algorithms is essential for the creation and operation of HDTs. These technologies enable the continuous collection and processing of data about the functioning of the human body and mind, thus creating a comprehensive digital counterpart to the real-world twin. Sensors are used to provide real-time information about the real twin and its environment. The data provided by the sensors can be supplemented with other categories of data such as: information obtained directly from medical personnel or medical equipment[18]; information of a subjective nature,

[14] M.E. Miller, E. Spatz, *op. cit.*, p. 29.

[15] M. Miller, *op.cit.*, p. 7-8; M.N. Kamel Boulos, P. Zhang, *Digital Twins: From Personalised Medicine to Precision Public Health*, in Journal of Personalized Medicine, volume 11, issue 8, 2021, https://doi.org/10.3390/jpm11080745, p. 4.

[16] *Ibidem*, p. 8.

[17] R. Saracco, *op. cit.*, p. 23.

[18] J. Corral-Acero, F. Margara, M. Marciniak, C. Rodero, F. Loncaric, Y. Feng, A. Gilbert, J.F. Fernandes, H. Bukhari, A. Wajdan, M.V. Martinez, M.S. Santos, M. Shamohammdi, H. Luo, P. Westphal, P. Leeson, P. DiAchille, V. Gurev, M. Mayr, L. Geris, P. Pathmanathan, T. Morrison, R. Cornelussen, F. Prinzen, T. Delhaas, A. Doltra, M. Sitges, E.J. Vigmond, E. Zacur, V. Grau, B. Rodriguez, E.W. Remme, S. Niederer, P. Mortier, K. McLeod, M. Potse, E. Pueyo, A. Bueno-Orovio, P. Lamata, *The 'Digital Twin' to enable the vision of precision cardiology*, in European Heart Journal, Volume 41, Issue 48, 21 December 2020, https://doi.org/10.1093/eurheartj/ehaa159, pp. 4556–4564.

entered directly by the real-world twin (manual data logging), such as mood, emotions or sensations; information that is difficult to track and often requires manual data entry, for example, nutrition information[19].

To develop the digital model, multiple categories of characteristics of the real twin can be collected and processed, including at least one of the following categories: physical characteristics (e.g., anthropometric or biomechanical specifications); physiological characteristics (e.g., heart rate, blood oxygen level); perceptual performance data (e.g., auditory sensitivity, visual acuity); cognitive performance data (e.g., knowledge, skills, or abilities); personality traits; emotional state (e.g., depression, anxiety); behaviour[20].

The bidirectional exchange between the digital and real-world twins provides the digital twin with the ability to sense the real world, create an understanding of the world, and act upon it through the information and predictions transmitted to the real-world twin. More specifically, communication within the HDT system involves a repetitive process with the following seven steps[21]:

- The sensors used by the real-world twin collect data on his/her state, actions and performance, as well as relevant information on the environment in which he/she operates.

- The data communication interface transmits the collected information to the digital twin.

- The data is analyzed to determine if the digital twin accurately matches the real-world twin. If inconsistencies are identified in the digital representation or in the forecasts previously made by HDT then, as appropriate, the data is updated or adjusted and the differences are explained.

- The digital twin generates and tests scenarios of future behaviour in a virtual environment.

- Predictions of future behaviour are compared to a desired state determined by the proposed objective.

- Based on this analysis, the system determines whether a modification in the structure or behavior of the system is likely to lead it towards a desired state and, if so, formulates proposals for modifications to the real twin or his/her behavior to achieve the objective.

- The proposed change is forwarded to the real-world twin and, depending on the latter's decision, is implemented or not.

This series of steps is repeated, with the real-world twin able to make decisions based on the information and predictions generated by the digital twin, in order to achieve the initial goal[22].

[19] B.R. Barricelli, E. Casiraghi, J. Gliozzo, A. Petrini, S. Valtolina, *op. cit.*, pp. 2, 8-9.
[20] M. Miller, *op. cit.*, 8; M.E. Miller, · E. Spatz, *op. cit.*, p. 28.
[21] M.E. Miller, E. Spatz, *op. cit.*, p. 25.
[22] *Ibidem.*

## 2. Applications of the Human Digital Twin Technology

HDTs has been implemented in various fields, such as personalized medicine, performance sports, military, industry, smart cities, or product design[23]. We will briefly present several aspects of each of these fields.

***a. Personalized medicine***

In the medical field, the HDT creates digital replicas of the entire human body, of a single body system or function, or of a single organ[24]. To develop a digital model, it is necessary to collect data from various sources, such as sensors, wearables, medical devices, medical records or information entered by the real-world twin[25].

The digital twin makes it possible to gain a detailed understanding of the "replicated" patient, predict the evolution of the patient's health, anticipate ineffective or potentially dangerous treatments, test the human body's reactions to different stimuli and medications. This use of digital twins is in line with researchers' desire to develop "4P medicine" – personalized, predictive, preventive and participatory[26].

Based on data released by the US Food and Drug Administration (FDA)[27], patients with diseases ranging from depression to cancer have between 38% and 75% of their prescriptions being unsuccessful. Variability amongst people taking identical medications is the cause of this. Personalized medicine aims to develop and prescribe the right drug, in the right dose, at the right time for each unique patient. With the capability to analyze in detail the characteristics and conditions of each person individually, digital twins can contribute to the implementation of personalized medicine[28].

Moreover, the medical databases collected by HDTs can be used in the development and streamlining of clinical trials, thus minimizing the participation of human subjects and their exposure to experimental treatments.

In light of the potential for gathering and keeping human digital twins in HDTs banks – which function as structured data warehouses complete with audit trail systems[29] – performing clinical research in the digital setting using data from these banks may one day become a possibility.

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[23] See M.E. Miller, E. Spatz, *op. cit.*, p. 23; M. Miller, *op. cit.* pp. 8-10; H. Pascual, X. Masip-Bruin, A. Alonso, J. Cerdá, *op. cit.*, pp. 1-2.

[24] M.N. Kamel Boulos, P. Zhang, *op. cit.*, p. 4.

[25] C. Tang, W. Yi, E. Occhipinti, Y. Dai, S. Gao, L.G. Occhipinti, *Human Body Digital Twin: A Master Plan*, 18 July 2023, last revised 12 September 2023, https://doi.org/10.48550/arXiv.2307.09225, [Online] at https://arxiv.org/abs/2307.09225, accessed on July 14th, 2024, pp. 5-10; H. Pascual, X. Masip-Bruin, A. Alonso, J. Cerdá, *op. cit.*, p. 2.

[26] M. Teller, *op. cit.*, p. 2.

[27] M.N. Kamel Boulos, P. Zhang, *op. cit.*, p. 2.

[28] See W. Shengli, *op. cit.*, pp. 1, 3.

[29] According to European Medicines Agency, "*an audit trail is a secure, computer generated, time-stamped electronic record that allows reconstruction of the events relating to*

***b. Performance sports***

HDT could bring added value to the sports industry and performance sports by monitoring, analyzing and developing programs to improve athletes' performance, as well as assisting coaches in optimizing the behaviour and development of athletes or teams[30].

The data generated by HDT models, developed to understand human performance in the medical or high-performance sports fields, can also be utilized for product design innovation. For example, data collected from high-performance athletes and processed through the HDT system can contribute to the development of equipment that optimizes athletic performance (*product design*).

At the Olympic Games in 2024 nine of the American swimmers were guided by their digital twins[31], within a project started in 2015 by teams of researchers at Emory University and the University of Virginia.

***c. Military field***

HDTs also find applicability in the military field, contributing to the monitoring of troops, the development of their performances, and also to their "synchronization" with advanced military technology. For instance, a project funded by the US Air Force seeks to employ HDTs technology for aircraft pilots, aiming to develop personalized training models that enhance pilot performance, reduce injury risk, improve physiological predictions, and optimize cockpit and equipment ergonomics[32].

***d. Manufacturing industry***

In industry, HDTs aim to enhance productivity, ensure worker safety, and minimize manufacturing errors. For example, a digital twin system in a manufacturing environment consists of an operator handling various materials and multiple data collection systems. In this system, the model can be used to identify material handling steps that induce substantial fatigue, allowing these steps to be evaluated and redesigned. In this example, the real-world twin includes the

*the creation, modification, or deletion of an electronic record.*" See, European Medicines Agency, *Guideline on computerised systems and electronic data in clinical trials*, March 9th, 2023, [Online] at https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-computerised-systems-and-electronic-data-clinical-trials_en.pdf, accessed on April 4th, 2024.

[30] Also, see H. Pascual, X. Masip-Bruin, A. Alonso, J. Cerdá, *op. cit.*, p. 8.

[31] K. Douglass, A. Lamb, J. Lu, K. Ono, W. Tenpas, The Mathematical Intellinger, *'Digital Twins' Give Olympic Swimmers a Boost*, July 8, 2024, [Online] at https:// www.scientificamerican.com/article/training-with-digital-twins-could-boost-olympic-swimmer-speeds/, accessed on July 14th, 2024.

[32] Z. Cheng, Z., *Human digital twin with applications*, in Proceedings of the 7th International Digital Human Modeling Symposium 7(1): 41, 2022, https:// doi.org/ 10.17077/dhm.31783; H. Pascual, X. Masip-Bruin, A. Alonso, J. Cerdá, *op.cit.*, p. 7.

production environment, the operator and data collection subsystems, and the digital twin[33].

***e. Smart cities***

DT technology can play a crucial role in urban development and public health decision-making by being used in various applications, such as road traffic management and flood and emergency monitoring services, in the context of smart and healthy cities. These digital twin cities go beyond traditional 3D city models, enabling smart cities to dynamically integrate key factors like time and human behaviour to better monitor indicators of interest, test different intervention scenarios, and predict how the city's system will react to changes and how its population will be affected[34].

For example, with the help of AI, DTs and HDTs technologies, the digital twin of the city of Boston helps architects and developers to visualize proposed buildings, especially very tall ones, and anticipate their impact on healthy living and working conditions in the neighboring districts[35].

## 3. Legal issues on HDTs in a European Union Law context

At the heart of the HDTs are data and AI systems. This means that the legal issues revolve around data and AI. Next, we will only address broadly the legal concerns, as each application of HDTs involves a specific approach.

### 3.1. What data needs a HDTs technology?

The symbiosis[36] between the real twin and the digital twin involves a constant supply of data, which circulates on a two-way path. The vast majority of data are personal data, hence the name Personal Digital Twin, as an alternative to HDT. The real twin, as a rule, does not have the necessary technology to take the initiative of creating the digital twin. Therefore, the "creator" is a third party, a company/organization, which pursues a specific purpose; the purpose differs depending on the field where the digital twin is used. The "creator" has the technology or has the necessary resources to get it. This technology requires data to be able to work.

What kind of data? The diversity and volume of data collected, generated and processed may vary depending on the complexity of the digital twin to be created, but in most cases at least four categories of data can be identified[37]:

- data that contributes to the creation of the model of the real twin in the digital space (for example, the model of the heart);

[33] For more examples of HDT implemented in the manufacturing industry, see: H. Pascual, X. Masip-Bruin, A. Alonso, J. Cerdá, *op. cit.*, p. 4.

[34] M. N. Kamel Boulos, P. Zhang, *op. cit.*, p. 8.

[35] *Ibidem.*

[36] M. Teller, *op. cit.*, p. 2.

[37] R. Saracco, *op. cit.*, p. 28.

- data obtained from monitoring (shadowing) of the real twin (for example, the heart rate in real time, by using trackers/wearables);

- metadata derived from the analysis of several data streams (for example, establishing the physical state of the real twin, using data such as age, weight, health, environmental, etc.); metadata is what gives "meaning" to the first two categories of data: no one is interested in what pulse a person has at any given time, but rather in whether or not that pulse is normal. This information can be obtained by analyzing various personal and ambiental data, such as, for example, the route that the real twin jogs on (at the gym, on a straight or inclined plane, outside, on mountain paths, etc.)[38];

- synthetic data; „*synthetic data is data generated through machine learning algorithms from original real-world data (i.e. data relating to existing individuals or events*)"[39]; the synthetic data is an abstract model inspired by the data of the digital twin together with the data of several other people, to establish, for example, how a person, who has a certain physical state, would react in certain circumstances[40].

What is the source of this data? The question concerns the first two categories of data, since metadata comes from their analysis/processing, and synthetic data is generated by AI, so its provenance is known.

A small part of this data is the data provided directly by the real twin, through various devices, wearables, such as smart watches, fitness trackers, smart tattoos, etc.[41]. We consider that these data are the most truthful and relevant in the digital model development process. However, most data is collected by interested third parties with whom the real twin interacts online in his/her daily activities: online shopping, payments using digital banking applications, online video games, online entertainment activities such as listening to music, watching a movie on a platform, booking a hotel using short term rentals platforms, buying a plane ticket, accessing a public service, making an appointment with a doctor online for a routine medical check-up and so on.

This information, or raw data, is worthless in its raw state. However, all the real digital twin actions leave a *digital footprint*, and the interested parties collect and process that data using AI; this way, the data becomes valuable, has a meaning and contributes to the creation of the digital twin[42].

What is the legal basis for the collection and processing of (personal) data that the algorithms making HDTs work are fed on?

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[38] *Ibidem,* p. 29.

[39] A. Beduschi, *Synthetic data protection: Towards a paradigm change in data regulation?*, in Big Data & Society, 11(1), 2024, https://doi.org/10.1177/ 20539517241231277.

[40] R. Saracco, *op. cit.*, p. 29.

[41] Also, see: H. Pascual, X. Masip-Bruin, A. Alonso, J. Cerdá, *op.cit.*, p. 2; Y. Dai, J. Wang, S. Gao, *Advanced Electronics and Artificial Intelligence: Must-Have Technologies Toward Human Body Digital Twins*, in Advanced Intelligent Systems, Influence Series, vol. 4, issues 2, 2022, 2100263 (1-11), https://doi.org/10.1002/aisy.202100263.

[42] R. Saracco, *op. cit.*, pp. 28-29.

### 3.2. Data & applicable rules: GDPR and beyond

It is indisputable that for personal data the applicable rules are those of the GDPR[43]. HDTs technology, though, is not limited only to personal data. As we have already shown, the collected and processed data concern the status, the actions, the performance of the real twin, as well as relevant information regarding the environment in which the real person acts and interacts, including with other people. Therefore, the data cannot only be personal data, but can also be mixed data and non-personal data[44].

In EU there are a few regulations which could be useful to HDTs in certain circumstances among which: Data Act[45], Data Governance Act (DGA)[46], Artificial Intelligence Act[47], Medical Device Regulation[48], Regulation proposal on the European Health Data Space[49].

As to GDPR, this piece of transnational European legislation is applicable to both personal data and mixed data. Indirect references to mixed data exist only in the Regulation 2018/1807[50], according to which when a data set is composed of both personal data and non-personal data, Regulation 2018/1807 applies to non-

[43] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119, 4.5.2016.

[44] C.T. Ungureanu, *Proprietatea asupra datelor digitale: realități, neliniști și posibile soluții*, in Revista Română de Drept Privat no. 2/2023, pp. 75-90.

[45] Regulation (EU) 2023/2854 of the European Parliament and of the Council of 13 December 2023 on harmonised rules on fair access to and use of data and amending Regulation (EU) 2017/2394 and Directive (EU) 2020/1828 (Data Act), OJ L, 2023/2854, 22.12.2023.

[46] Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act), OJ L 152, 3.6.2022.

[47] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act), OJ, L series, 12.7.2024.

[48] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 5.5.2017.

[49] Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, Strasbourg, 3.5.2022, COM(2022) 197 final, 2022/0140(COD), [Online] at https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:52022PC0197, accessed on April 4th, 2024.

[50] Regulation (EU) 2018/1807 of the European Parliament and of the Council of 14 November 2018 on a framework for the free flow of non-personal data in the European Union, OJ L 303/59, 28.11.2018.

personal data from the data set, and GDPR applies to personal data. If the personal and non-personal data in the set are inextricably linked, the entire data set is subject to the rules of the GDPR [art. 2 (2) of Regulation 2018/1807]. Data can be considered to be inextricably linked when the separation of the two types of data is either impossible or considered by the data controller to be economically inefficient or technically infeasible. The Regulations do not impose any obligation on professionals who collect, process or control data to separate personal data from non-personal data in a mixed data set. Accordingly, a mixed data set will generally be subject to GDPR rules[51].

The creation and operation of HDTs involve, above all, the collection and processing of personal data. Organizations which develop HDTs must ensure transparency about how personal data is collected and processed, respect the data subjects' rights and provide easy ways to exercise them. At the same time, HDTs developers must implement adequate technical and organizational protection measures, considering the risks involved in the use of AI in data processing.

For the lawfulness of the personal data processing, two legal grounds can be used: the *consent* of the person concerned (data subject) [art. 6 (1) a) GDPR], in the form of the standard consent, as provided in art. 7 GDPR or of the *explicit* consent (for sensitive data) [art. 9 GDPR] and the *contract* [art. 6 (1) b) GDPR].

How could data subject consent be obtained? The easiest way is to use specialized platforms. Thus, in the context of HDTs, the controller interested in processing personal data outsources the activity of obtaining the consent of the data subject *to Consent Management Platforms (CMPs)*[52]. There are a lot of CMPs[53], with OneTrust at the top of the list in 2024[54].

HDTs technology also uses a lot of sensitive personal data. According to art. 9, art. 4 (13), (14) and (15) GDPR, the following personal data is considered 'sensitive' and is subject to specific processing conditions: *personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs; trade-union membership; genetic data, biometric data processed solely to identify a human being; health-related data; data concerning a person's sex life or sexual orientation.* For these types of data, the real twin must express an explicit consent, as a mandatory and prior condition to the collection and processing of the data[55].

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[51] C.T. Ungureanu, *Proprietatea asupra datelor digitale…op. cit.*, pp. 80-81.

[52] M.I. Khalid, M. Ahmed, J. Kim, *Enhancing Data Protection in Dynamic Consent Management Systems: Formalizing Privacy and Security Definitions with Differential Privacy, Decentralization, and Zero-Knowledge Proofs*, in Sensors 2023, 23, 7604, https://doi.org/10.3390/s23177604.

[53] C. Santos, M. Nouwens, M. Toth, N. Bielova, V. Roca, *Consent Management Platforms Under the GDPR: Processors and/or Controllers?*, in: N. Gruschka, L.F.C. Antunes, K. Rannenberg, P. Drogkaris(eds), *Privacy Technologies and Policy*, APF 2021, Lecture Notes in Computer Science, vol. 12703. Springer, Cham., https://doi.org/10.1007/978-3-030-76663-4_3.

[54] *Best Consent Management Platforms for 2024*, [Online] at https://www.playwire.com/blog/top-cmp-partners, accessed on April 4th, 2024.

[55] European Data Protection Board, Guidelines 05/2020 on consent under Regulation

The processing of personal data, which does not require an explicit consent, can be carried out on the legal basis of the performace of the contract concluded by the data subject (the real-world twin) with the developer of the HDT system.

The contract, as a legal basis for data processing, is not only provided for in the GDPR, but also in the Data Act, which concerns the data generated by smart devices or related services. In the Data Act (recital 5), it is stated that at the heart of data sharing are the rules of private law and the principle of freedom of contract applies.

According to Data Act at least three contacts should be concluded for the sharing of data (personal, non-personal and mixed). Initially, a contract is made between the smart product/service users and the legal or natural person that sold, rented, or leased the product/service to them (i.e., the data holder). A separate agreement is made between the smart product/service user and the third party (the data recipient) with whom the user wishes to share the data generated by the smart product/service; the purposes of the data sharing are outlined in this agreement (art. 6.1.). The user requests that the data holder make the relevant data available to the recipient rather than giving the recipient immediate access to the data. A contract that complies with the FRAND requirements ('fair, reasonable, and non-discriminatory terms') is also reached between the data holder and the recipient; this contract also includes a reasonable price [and the EC will adopt guidelines on the calculation of reasonable compensation (art. 8 and 9 DA)].

The Data Act clarifies within art. 1(5) how it interacts with other regulations, in particular with the GDPR, stating that Data Act *is without prejudice to Union and national law on the protection of personal data,* and in the event of a conflict between Data Act and the legislation on data protection the latter prevails.

As to DGA and HDTs, the rules in the DGA must be followed when certain data, which may contribute to the creation/operation of the digital twin, are shared by a data subject (who shares his personal data) or by a data holder (which can be a natural or a legal person, a public body, an international organization, which has the right to grant access to personal or non-personal data) to a data user for the purpose of joint or individual use of such data. In order to data sharing, contracts may be concluded, based on the contractual freedom of the parties, directly or through an intermediary, in exchange for a price or free of charge. The data user has the right to use the respective data for commercial or non-commercial purposes [art. 2(8)-2(10) DGA]. The notion of data user in the DGA is similar to that of data recipient in the Data Act (In European regulations there is no uniformity of terms, which can lead to confusion).

The Artificial Intelligence Act must be considered by the developer/"creator" of HDTs with regard to the use of AI systems in the formation

2016/679, version 1.1, adopted on 4 May 2020, section 4 - Obtaining Explicit Consent, [Online] at https://www.edpb.europa.eu/sites/default/files/files/file1/edpb_guidelines_202005_consent_en.pdf, accessed on April 4th, 2024.

and operation of HDTs, having the obligation to comply with all its provisions (from the date of its application)[56].

In the situation where HDT systems are used for medical purposes or to improve the performance of the real twin, they can be included in the concept of medical devices[57], making the Regulation (EU) 2017/745 on medical devices applicable. Essentially, the application of the Regulation involves ensuring that these HDT technologies are developed in accordance with EU standards for medical devices, thus guaranteeing their safety and effectiveness for patients/users.

In the scenario where the HDTs system is based on AI technologies capable of autonomously making decisions that directly and irreversibly affect the real twin, HDTs technology developers will be required to perform an appropriate assessment of the risks and benefits associated with use in medical practice[58].

### 3.3. Who owns the HDT and who benefits from it?

Data ownership is a long-debated issue in the legal literature[59]. At the EU level, the approach goes beyond the idea of property rights, although data as a resource (perhaps more important than other resources, such as oil, precious stones, mineral deposits) would imply that access to it is based on a property right. European regulations use other rights that allow data sharing, namely, the *right of access* and the *right to control* the data, without making any reference to the data ownership.

Nevertheless, a HDT could be subject of proprietary rights if it is seen as a digital asset. A *digital twin entity* was considered as „*A digital asset* which implements digital representation and digital execution of a certain view of a *target entity*, and achieves *state* synchronization with the *target entity* at an appropriate rate and *credibility* through single direction or bidirectional communication."[60].

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[56] C. Novelli, P. Hacker, J. Morley, J. Trondal, L. Floridi, *A Robust Governance for the AI Act: AI Office, AI Board, Scientific Panel, and National Authorities*, in Centre for Digital Ethics (CEDE) Research Paper Series, May 5, 2024, http://dx.doi.org/ 10.2139/ssrn.4817755.

[57] According to Regulation (EU) 2017/745 - art 2, *'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: i. diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease; ii. diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability; iii. investigation, replacement or modification of the anatomy or of a physiological or pathological process or state; iv. providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations; and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means*. For details on medical devices, see Ș.R. Tataru, *Soluționarea litigiilor referitoare la contractele de comerț internațional cu produse farmaceutice*, Ed. Hamangiu, 2020, p. 28.

[58] See Regulation (EU) 2017/745 - art. 2 (27) and chapters VI-VII.

[59] For a synopsis, see, C.T. Ungureanu, *op. cit.*

[60] H. Duan, S. Gao, X. Yang, Y. Li, *The development of a digital twin concept system*,

According to UNIDROIT Principles on Digital Assets and Private Law, 2023[61], a digital asset *means an electronic record which is capable of being subject to control* [art. 2(2)]. *A digital asset can be the subject of proprietary rights* [art. 3(1)]. It is not clear what kind of proprietary rights, but the authors of the Principles rely on the rule of *nemo dat quod non habet* (one cannot give what one does not have[62]): *a person can transfer only the proprietary rights that it has in a digital asset, if any, and no greater proprietary rights* [art. 9(1)]. While this does not really assist in recognizing the proprietary right on an HDT, it does demonstrate that the ownership dispute over digital assets is still far from resolved.

UK, which seems to be an appealing jurisdiction for technology related cases[63], is prepearing for legislative reforms on personal property issues, the digital assets being accomondated as property[64]. So, under English Law, a HDT could be object of personal property.

Another possible solution related to HDT ownership is that of the intellectual property rights. HDT, as a data collection, could be protected by intellectual property rights: database copyright and a *sui generis* right on the content of the database. According to Directive 96/9 on the legal protection of databases[65] (transposed into the Romanian legislation by inclusion in the Law no. 8/1996 on copyright and related rights[66]), databases which, through the choice or arrangement of elements, constitute the author's own intellectual creation are protected as such by copyright (art. 3.1.). The content of the database is protected by a *sui generis* right, according to art. 7. In order to obtain *sui generis* protection, it must be proven that a substantial qualitative or quantitative investment (financial, material and/or human) has been made either in obtaining the content or in verifying and presenting the content of the database.

Legal protection of the database does not work in all cases, however. For example, according to art. 43 of the Data Act, the *sui generis* right over the content of the database, made up of data obtained or generated by smart products or related services, cannot be recognized. The purpose of this provision is to prevent data holders from invoking the *sui generis* right, thus preventing users of smart

in Digital Twin 2023, 2:10, https://doi.org/10.12688/digitaltwin.17599.2.

[61] UNIDROIT Principles on Digital Assets and Private Law, [Online] at https://www.unidroit.org/wp-content/uploads/2024/01/Principles-on-Digital-Assets-and-Private-Law-linked.pdf, accessed on July 14th, 2024.

[62] This principle is a general one, included also in the Romanian Civil Code – art. 17(1): *Nimeni nu poate transmite sau constitui mai multe drepturi decât are el însuşi/ No one can transfer or constitute more rights than he himself has.*

[63] M. Lehmann, *Seeking an Edge in Judicial Competition: England is Becoming the Leading Crypto Litigation Hub*, 11 July 2024, [Online] at https://eapil.org/2024/07/11/, accessed on July 13th, 2024.

[64] UK Law Commission. Reforming the Law, *Digital Assets*, [Online] at https://lawcom.gov.uk/project/digital-assets/, accessed on July 13th, 2024.

[65] Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases, OJ L 77, 27.3.1996.

[66] Law no. 8/1996 regarding copyright and related rights, OG no. 60, 26.3.1996.

products/services from exercising the *right to access and use data and the right to share data with third parties*[67].

If the HDT has a commercial use, it could be protected as a trade secret. According to the European Directive 2016/943 on the protection of *know-how* and trade secrets[68], to be protected as a trade secret the HDT should consist in information that is secret (not *generally known or easily accessible to people in the circles that normally deal* with the type of information in question); that have commercial value by being secret (having the ability to generate economic benefits to the one who controls it); that have been subject of reasonable measures, under given circumstances, for keeping it secret[69].

Anyway, only the HDTs developer, who collects data, raw or not, processes it, then creates and maintains the two-way operation of the HDTs system can benefit from legal protection. *The real twins have nothing* (unless they have the technology to create their own digital twins). The real twins don`t even have a right to access their digital twins. According to the Data Act the user of smart products/services, who could be the real twin, has the right of access only to the raw data, not to the processed data[70]. The user has the right to access and share with third parties *all raw and pre-processed data generated from the use of a connected product or a related service that is readily available to the data holder. This applies to both personal and non-personal data, including relevant metadata*[71].

Even though the real twin has no rights on his/her own digital twin, the former can benefit from the latter in one way or another.

For instance, such benefits could be related to health and the provision of adequate medical care. In this sense, a European project, launched on December 21, 2023, the *European Initiative Virtual Human Twins*[72], may be relevant. A virtual human twin (VHT) – according to this initiative – „*is a digital representation of a human health or disease state. They refer to different levels of human anatomy (e.g. cells, tissues, organs or organ systems). VHTs are built using software models and data and are designed to mimic and predict behaviour of their physical counterparts, including interaction with additional diseases a person may have. The key potential in health and care of this technology is related to targeted prevention, tailored clinical*

[67] Recital 112 DA.

[68] Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure, OJ L 157, 15.6.2016.

[69] For details, see C.T. Ungureanu, S.R. Tataru, *The legality of reverse engineering or how to legally decipher trade secrets,* SHS Web of Conferences vol. 177/2023, article number 02001, *Legal Perspectives on the Internet. COPEJI 6.0,* http://doi.org/10.1051/ shsconf/202317702001, pp. 2-6.

[70] See Data Act explained, [Online] at https://digital-strategy.ec.europa.eu/ en/ factpages/data-act-explained , accessed on April 4th, 2024.

[71] *Idem.*

[72] European Commission, *Shaping Europe's digital future. European Virtual Human Twins Initiative,* [Online] at https://digital-strategy.ec.europa.eu/en/policies/virtual-human-twins, accessed on July 4th, 2024.

*pathways, and to supporting healthcare professionals in virtual environments. Examples include implementation of clinical trials for medicines and devices, medical training, surgical intervention planning, and several other potential use cases in virtual world environments."*[73].

Connected to VHT project there is a regulation proposal from 2022 on European Health Data Space[74], having as a goal the provision of *rules, common standards and practices, infrastructures and a governance framework for the primary and secondary use of electronic health data* (art. 1.1.).

### 3.4. Legal and other concerns connected with HDTs

HDTs technology raises a few legal challenges which go beyond data privacy (that we have already addressed). We will name just those which seem of great importance to us, without delving into their detailed analysis[75]:

- data security; effective protection systems against cyber threats must be used, so that personal data cannot be accessed or disclosed to unauthorized persons;

- liability for improper operation of HDTs; since HDTs can make predictions, recommendations or even make decisions under certain conditions, which could be erroneous, with more or less serious effects on the real twin or the community, the question of liability arises; tracing the person responsible can be difficult, given the multiple actors involved;

- discrimination in access to HDT technology;

- the psychological impact on the real twin; the real twin can suffer psychological trauma, determined by the permanent surveillance (from the fact that he/she becomes „transparent") and assists his own transformation and the aging process; this awareness can affect *self-esteem, self-perception, and mental health*[76]; therefore, the real twin may need psychological counseling.

## Conclusions

The prospects provided by the HDTs concept are impressive, even though it presents a number of legal and other challenges. HDTs create new avenues for innovation in a wide range of sectors by demonstrating the sophisticated integration of digital technology into the study and understanding of the human body and mind, as well as their interaction with the environment and other people.

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[73] *Idem.*

[74] Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, Strasbourg, 3.5.2022, COM(2022) 197 final, 2022/0140(COD), [Online] at https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:52022PC0197, accessed on April 4th, 2024.

[75] M. Cellina, M. Cè, M. Alì, G. Irmici, S. Ibba, E. Caloro, D. Fazzini, G. Oliva, S. Papa, *Digital Twins: The New Frontier for Personalized Medicine?*, in Applied Sciences 13, no. 13/2023, https://doi.org/10.3390/app13137940, p. 12; M. Teller, *op. cit.*, pp.1-5.

[76] *Ibidem*, p. 12.

New technologies also involve risks. There are situations when the intended outcome is very different from the original aim. *Will your heart's digital twin become a health coach or an agent of the insurance company that refuses your life insurance*? [77] Since the real-world twin does not have a right of control over his/her digital twin, any scenario can be possible. The rules adopted or in the process of being adopted are intended to correct possible deviations from the use of HDTs technology for purposes contrary to good faith and the well-being of the real-world twin and the community he/she is part of.

Despite the negative connotation associated with „playing God," which stems from human manipulation through technology and human limitations in controlling situations beyond their comprehension, we think HDT's technology has potential benefits for humanity. "The beast" could be tamed if the rules are followed.

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