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AI-driven Healthcare and Contracts

Assistenza sanitaria e contratti fondati sull'IA

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Abstract

Remote monitoring technologies, wearables, IoT, applications, have accelerated a transformation in healthcare in the post-pandemic era. Proactive care models facilitate the management of illnesses outside hospital settings and empower individuals to monitor and influence their health trajectories, thereby enabling informed decision-making. However, technological advancements have not addressed the poverty experienced by millions of Italians, who often forgo treatment due to waiting times and costs. Consequently, new insurance products are being developed to cover medical expenses in cases where the NHS doesn't provide coverage, or where public medical treatment is delayed. The mentioned technologies have been than implemented to insurance contract, refiguring them into parametric contracts. This reconfiguration appears to reinforce datafication, surveillance capitalism, and existing inequalities, particularly to the detriment of patients. This essay analyses InsurTech strategies, focusing on insurance contracts for medical expenses that are driven by data, to assess their feasibility according to Private and data protection laws.

Abstract
Le tecnologie per il monitoraggio remoto, i dispositivi indossabili, l'IoT e le applicazioni digitali hanno accelerato la trasformazione dell'assistenza sanitaria nel periodo post-pandemico. I modelli di cura proattiva favoriscono la gestione delle patologie fuori dalle strutture ospedaliere e consentono agli individui di controllare e orientare i propri percorsi di salute, migliorando la capacità decisionale. Tuttavia, tali progressi non hanno inciso sulla povertà sanitaria che colpisce milioni di italiani, i quali rinunciano alle cure a causa di tempi d'attesa e costi. Ne conseguono nuovi prodotti assicurativi destinati a coprire spese mediche non coperte dal SSN o soggette a ritardi. Le tecnologie menzionate sono integrate nei contratti assicurativi, riconfigurati in forma parametrica. Questa evoluzione intensifica dataficazione, capitalism della sorveglianza e disuguaglianze, incidendo sui pazienti. Il saggio analizza le strategie InsurTech e la sostenibilità dei contratti sanitari data-driven alla luce del diritto privato e della normativa sulla protezione dei dati.

Keywords: health; health insurance; InsurTech.

Summary: 1. Health and post-pandemic Healthcare in the Italian context. – 1.1. Medical Poverty. – 1.2. Insurance contracts and new technologies at the rescue. – 2. A taxonomy attempt for AI-driven healthcare and insurance. – 2.1. AI in Healthcare delivery. – 2.2. From clinical IoTs to consumer wearables. – 2.3. From eHealth to InsurTech: when data exit the therapeutic sphere. – 3. Health Insurance. – 4. IoTs and HI. – 4.1. AI-driven contracts implications. – 4.2. The premium narrative. – 5. AI-driven HI and Data Protection. – 6. Conclusion.

1. Health and post-pandemic Healthcare in the Italian context.

The Italian Constitution enshrines the right to health as a fundamental guarantee, explicitly recognised in Article 32, which protects individual wellbeing and proclaims the duty of the Republic to safeguard health as both a collective interest and an individual right. This constitutional protection has traditionally been interpreted in two complementary senses.[1] On the one hand, within a positive dimension, it imposes on the public authorities the duty to provide access to healthcare services and to structure a health system that enables people to obtain necessary treatments across the national territory. On the other hand, on a negative declination, it protects individuals against involuntary medical interventions, limiting compulsory treatments to circumstances expressly provided for by law and typically justified only by extraordinary public-health needs.

The right to health, therefore, operates together with the related right of self-determination in healthcare, which recognises patients' decisional autonomy while situating that autonomy within the therapeutic relationship, clinicians, hospital institutions, and patients are expected to cultivate.[2]

[1] On the different meaning of health, si veda F MINNI-A MORRONE, 'Il diritto alla salute nella giurisprudenza della Corte costituzionale italiana' (2019) Rivista AIC 3, 9 ff.
[2] S Rodotà, *La vita e le regole* (3rd ed., Feltrinelli 2018); G Alpa, 'Il diritto all'autodeterminazione e le direttive anticipate sulle cure mediche' (2006) Riv. crit. dir. priv., 83; G Alpa-G Resta, *Le persone fisiche e i diritti della personalità* (Utet Giuridica 2005); A Santosuosso, 'Dalla salute pubblica

Despite the robust constitutional framing, the reality of accessing healthcare in Italy reveals a persistent tension between formal entitlements and practical availability. In practice, the foundational and absolute nature of the rights invoked collides with structural obstacles that hamper timely access to the National Health Service. Those obstacles, including shortages of personnel, regional disparities in service provision, and, most of all lengthy, waiting times for diagnostic and specialist procedures, effectively dilute the meaningfulness of the constitutional guarantee.

The gap [3] between guaranteed rights and realised access to healthcare produces what may be termed a devaluation of the fundamental right to health, one that has concrete social and economic consequences for individuals and communities. Therefore, only those who have the financial resources to access treatment at private facilities or who have the time to wait for treatment under the public or affiliated system can effectively exercise their right to health.

One of the most worrying consequences is the emergence of a form of "medical poverty". [4] Large segments of the population defer or forgo care because of economic constraints or because public provision is inaccessible in a timely fashion.

Recent official reports indicate that roughly one person in ten renounced visits or treatments in the prior year because of excessive waiting lists, prohibitive costs, or logistical difficulties. Hence, medical poverty affects a large amount of people: a share equivalent of 5.8 million people in 2024, in the Italian context.[5]

1.1. Medical Poverty.

The phenomenon of medical or health poverty in Italy denotes the systematic inability of individuals or households to obtain essential healthcare services, including access to medicines, primary care and diagnostic procedures. The condition is determined by economic, organisational or social

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all'autodeterminazione: il percorso del diritto alla salute', in M Barni-A Santosuosso (eds.), *Medicina e diritto* (Giuffrè Editore 1995), 95; R Pucella, *Autodeterminazione e responsabilità nella relazione di cura*, (Giuffrè Editore 2010), 69; C Castronovo, 'Autodeterminazione e diritto privato' (2010) Eur. dir. priv., 1037; T Pasquino, 'Autodeterminazione', in Aa.Vv., *Le parole del diritto. Studi in onore di Carlo Castronovo* (Jovene 2018), 119; B Salvatore, *Informazione e consenso nella relazione terapeutica*, (ESI 2012), 164; G Facci, 'Brevi osservazioni in tema di funzione riparatoria della responsabilità civile e violazione del sanitario del dovere di informazione' (2008) Resp. civ. prev., 408; E Palmerini, 'Il danno patrimoniale da violazione del consenso informato', in E Navarretta (ed.), *Il danno non patrimoniale. Principi, regole e tabelle per la liquidazione*, (Giuffrè 2010) 532.

[3] A Luciano, '*Dalle società di mutuo soccorso alla mutualità. Risposte alla crisi del welfare'* (2012) Euricse Working Paper 32, 16.

[4] S Sarti-M Terraneo-M Tognetti Bordogna, 'Poverty and private health expenditures in Italian households during the recent crisis' (2017) Health Policy 3, 307-314; L Pesenti, 'Healthcare Poverty and Access to Healthcare Services in Italy: The Challenge of Public-Third sector Integration' (2025) Riv. trim. Scienza dell'Amministrazione, 1-22.

[5] A Petrelli-A Rosano-A Rossi, 'The geography and economics of forgoing medical examinations or therapeutic treatments in Italy during the economic crisis', (2019) Public Health, 12.

barriers, resulting in unmet health needs and increased vulnerability for already vulnerable people affected by diseases. It is a multidimensional form of exclusion in which financial hardship, gaps in service provision and social determinants converge to prevent access to necessary care. It encompasses direct costs, such as out-of-pocket payments for drugs and visits, or indirect costs, such as transport to go in other Italian regions or abroad and even lost earnings, as well as structural barriers, like long waiting lists and regional disparities between structures and personnel, that force people to forgo or delay treatment.

Between the listed factors, the principal drivers of forgone care are long waiting times and economic barriers, with the proportion of the population refraining from care which has increased over the years.

The situation creates a paradox, because the lack of prevention and the postponement of treatment lead to the hospitalisation of cases that become more serious, with the risk of higher costs for the national health service.

Waiting lists[6] themselves are emblematic of systemic strain and regional divergence.[7] Independent health research institutes[8] and national platforms[9] monitoring appointment backlogs report that only about half of scheduled services meet the established maximum waiting times; for the remainder, the situation is critical, with a substantial share of procedures subject to delays measured in months rather than days.

According to CENSIS report,[10] very few patients secure specialist appointments within days of booking, while a non-trivial share face waits more than six months, especially women, foreigners and low-income household members.[11] These delays undermine preventive care, worsen prognoses, and push users towards private alternatives that entail out-of-pocket expenditure.

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[6] On the matter, it is worth mentioning that the Ministry of Health recently adopted guidelines on waiting lists: D.M. 17 february 2025, *Linee guida della Piattaforma nazionale delle liste di attesa e criteri di interoperabilità con le piattaforme regionali*, available at: https://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?anno=2025&codLeg=105773&parte=1%20&serie=null. In literature, E Rogai, 'La crisi delle prenotazioni e delle liste d'attesa nella sanità italiana: situazione attuale e spunti di miglioramento, in Italian Journal of Prevention, (2022) Diagnostic and Therapeutic Medicine', 5, 17-23.

[7] It is worth mentioning that health is a subject which obeys to the concurrent competence of Regional and State level legislator, according to art. 117 Cost., and this affects the way healthcare is managed and provided on the Italian territory.

[8] Report Osservatorio GIMBE, *La mobilità sanitaria interregionale nel 2018*, Bologna, 2020, 2, available at: www.gimbe.org/mobilita2018.

[9] The National Waiting List Platform (PNLA), established by Article 1 of Law No. 107 of 29 July 2024, has recently become available on the AGENAS Transparency Portal. The Platform, created by AGENAS, aims to monitor, on a national scale, waiting times for outpatient services, with particular attention to compliance with the timelines set for the different priority classes. The platform is available at: https://www.portaletrasparenzaservizisanitari.it/pnla/

[10] Fondazione CENSIS-Intesa San Paolo RBM Salute, *IX Rapporto sulla sanità pubblica, privata e intermediata - annualità 2019-2020*, 2021, 74-93.

[11] A Petrelli-A Rosano-A Rossi-C Mirisola-C Cislaghi, 'The geography and economics of forgoing medical examinations or therapeutic treatments in Italy during the economic crisis' (2019) Public Health, 19, 10 ff.

1.2. Insurance contracts and new technologies at the rescue.

The interaction between financial pressure and service delays fuels the penetration of private expenditure into the healthcare landscape, especially after Covid-19 spread.[12] When public provision fails to deliver timely care, patients and households increasingly turn to private providers or purchase health insurance to secure access to high-cost interventions, faster diagnostics, or continuity of care.[13]

Private medical insurance, therefore, acquires new functions and dimensions, while raises new concerns. First, health insurance (in the following sections, HI) broadens its social security function; second, it becomes both a safety valve, that enables those who can afford it to circumvent public-sector bottlenecks, and a tool, to preserve the substantive enjoyment of the constitutional right to health in practice. Third, the growing relevance of private HI for access to essential and high-cost care thus raises pressing questions about privacy, surveillance capitalism and most of all the risk of stratified access to health services.[14]

Concurrently, the healthcare and insurance spheres are being reshaped by a technological revolution driven by artificial intelligence (in the following parts, AI). AI's incursion into healthcare operates on several fronts.

The first concerns the reconfiguration of healthcare delivery itself: diagnostic algorithms, predictive analytics, automated triage systems, and AI-augmented clinical decision support have the potential to modify workflows, redistribute tasks within clinical teams, and alter the therapeutic relationship between institutions, clinicians, and patients. These innovations promise gains in efficiency, diagnostic accuracy, and personalised treatment pathways. Yet, they also introduce new profiles of risk: as often recalled, these new

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[12] R Santagata, 'Polizze assicurative parametriche (o index-based) e principio indennitario' (2022) Rivista di Diritto Civile, 134-172; S Landini, 'Data sharing and innovation in the insurance industry. First thoughts' (2025) European Journal of Privacy Law and Technologies, 12; MC Gaeta-DS D'Aloia, InsurTech in Italy: opportunity, risks and applicable regulation (2021) European Journal of Privacy Law and Technology, 2, 10-23; E Battelli, 'Insurtech ed evoluzione dell'offerta di polizze sanitarie: tra innovazione tecnologica e i nuovi servizi assicurativi in campo medico' (2022) Contratto e impresa, 52-91, in particular 52; M Hazan, 'Gli effetti della pandemia sulle polizze di responsabilità sanitaria ma non solo: una riflessione sulle conseguenze per il mercato assicurativo', in R Caminiti-M Frigessi di Rattalma-P Mariotti (eds.), *Gli effetti della pandemia sulla responsabilità sanitaria e sulla sua assicurazione tra norme, giurisprudenza di legittimità et etica* (Maggioli Editore 2021) 73-85. The A. highlights how impactful is this new insurtech approach in Italy, as a new pillar that stands alone and counterparts the public national and regional sector. On the matter, see also B Nayak-SS Batthacharyya, 'The Changing Narrative in the Health Insurance Industry: Wearables Technology in Health Insurance Products and Services for the COVID-19 World' (2021) Journal of Medical Management, 4, 550-558.

[13] It is possible to confirm this affirmation in the data gathered by Accenture in 2020, available at: www.iotiassicuro.it

[14] S Zuboff, 'Big Other: Surveillance Capitalism and the Prospects of an Information Civilization' (2015) Journal of Information Technology, 30, 75-89; C Gidaris, 'Surveillance Capitalism, Datafication and Unwaged Labour: The Rise of Wearable Fitness Devices and Interactive Life Insurance' (2019) Surveillance and Society, 17, 132-138; K De Blasio, 'Il marketing algoritmico tra tutela della privacy e pratiche commerciali scorrette' (2025) Riv. it. Informazione e informatica, 3, 379 ff.

technologies may affect healthcare with algorithmic bias, opacity in decision-making, liability uncertainties, and threats to patient privacy.

To strike a balance between the two sides of the coin, the European Community first and the European Union later committed to regulate the phenomenon to protect citizens' rights. In fact, it is possible to detect a progressive regulatory layering in eHealth and mHealth,[15] since European instruments sought to capture rapidly evolving technologies and uses. Foundational device directives such as the Active Implantable Medical Devices Directive 90/385/EEC, the Medical Devices Directive 93/42/EEC and the In Vitro Diagnostic Directive 98/79/EC established early safety, conformity and market access principles for implants, general medical devices and diagnostics, respectively. Later, Regulation 2017/745/EU for medical devices and Regulation 2017/746/EU for in vitro diagnostics were adopted and, in parallel, data protection developed along a distinct but intersecting path, with the Data Protection Directive 95/46/EC and the General Data Protection Regulation 2016/679/EU.[16] Recently, new European initiatives,[17] such as the European Health Data Space Regulation (in the following paragraphs, EHDS), aim at enabling cross-border health data exchange and interoperability with MyHealth@EU infrastructure and related policy instruments. Moreover, the

[15] For the different notion of eHealth and mHealth, see T Mulder, 'The impact of the European Medical Device Regulations on the development and use of mhealth apps in Europe', in J Madir (ed.), *HealthTech: Law and Regulation* (Edwar Elgar Publishing 2020) 329-353; I Rapisarda, 'La privacy sanitaria alla prova del mobile ecosystem. Il caso delle app mediche' (2023) *Nuove Leggi Civili Comm*, 184-213. On telemedicine, see M Faccioli, 'La responsabilità sanitaria in telemedicina' (2021) Resp. civ. prev., 3, 740 ss.; RY Cheng-B. Robin, 'Telemedicine: Opportunities and Challenges – A US Perspective', in J. Madir (ed.), *HealthTech: Law and Regulation* (Edwar Elgar Publishing 2020) 354-373. The "telemedicine" concept emerged in the 1960s due to the need for medical services in space for the National Aeronautics and Space Administration (NASA) and the military. While "telehealth", which is often used as a synonim, refers to a broader application of devices and services for health and self-health without clinicians and medical services involved: more information are provided by NASA, A Brief History of NASA's Contributions to Telemedicine, 2013, https://www.nasa.gov/wp-content/uploads/2024/03/nasatelemedicine-briefhistory.pdf; WHO, *Telemedicine – Opportunities and Developments in Member States,* 2010, https://www.google.com/url?sa=t&source=web&rct=j&opi=89978449&url=https://www.afro.who.int/publications/telemedicine-opportunities-and-developments-member-state&ved=2ahUKEwi039PLjJKRAxV3xQIHHQfXFOkQFnoECBsQAQ&usg=AOvVaw3pjxr8V-3NszsEgJFyc-ni; E Giusti, 'La sanità elettronica: dati personali relativi alla salute, applicazioni e rischi (e-Health: personal health data, applications and risks)' (2023) Riv. it. Med. legale, 85 ss.

[16] Persistent tensions remain where regulatory scopes diverge. For example, consumer wearables may fall outside medical device classification while the personal data they produce nonetheless qualify as health data under the GDPR. Such mismatches underscore the continuing need for interpretative guidance, coordinated enforcement and adaptive governance to ensure coherent protection, innovation and patient safety across overlapping legal regimes.

[17] A Morace Pinelli (ed.), *Dalla Data Protection alla Data Governance: il Regolamento (UE) 2022/868,* (Pacini Giuridica 2024); id., Data Act. Introduzione interdisciplinare e commentario al regolamento (UE) 2023/2854, (Pacini Giuridica 2025); id., la circolazione dei dati personali: persona, contratto e mercato (Pacini Giuridica 2022).

sector is impacted by Digital Services Act, [18] Digital Markets Act, [19] Data Governance Act,[20] Data Act,[21] and AI Act.[22]

The second front, which will be the principal focus of this paper, is the reconfiguration of HI policies. AI-enabled tools and the clinical and consumer-level Internet of Things (IoTs), including wearable devices, allow real-time monitoring of health metrics.[23] These devices allow the generation of highly granular risk profiles and better and broader insurance coverage. In the US,[24] India, [25] China, [26] Japan, [27] and Germany, [28] insurer policymakers are already experimenting with data-driven underwriting,[29] personalised premiums, and contract terms conditioned by the use of sensors and telemonitoring devices,

[18] Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market for Digital Services and amending Directive 2000/31/EC (Official Journal L 277, 27 october 2022).

[19] Regulation (EU) 2022/1925 of the European Parliament and of the Council of 14 September 2022 on contestable and fair markets in the digital sector (Official Journal L 265, 12 october 2022).

[20] 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 (Official Journal L 152, 03 june 2022).

[21] 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 (Official Journal L, 22 december 2023).

[22] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence (Official Journal L, 12 july 2024). It is worth mentioning that, on the matter, Italy adopted the first regulation on AI applications in Europe: law 23 September 2025, no. 132, which provides *Disposizioni e deleghe al Governo in materia di intelligenza artificiale* (Provisions and delegations to the Government on artificial intelligence), published G.U. 25 September 2025, no. 223, which recently entered into force, on 10 October 2025.

[23] P Poletti, 'Data Act ed equa condivisione dei dati generati dagli apparati IoT: di quali dati si tratta?', in A. Morace Pinelli (ed.), *Data Act*, 153-174.

[24] A Troiano, 'Wearables and Personal Health Data: Putting a Premium on Your Privacy' (2017) Brooklin Law Review, 1715-1753; M Antona-C Stephanidis (eds.), *Universal Access in Human-Computer Interaction. Access to Learning, Health and Well-Being* (Springer 2015) 288-299; ME Maccarini, *L'assicurazione sanitaria negli Stati Uniti d'America*, (Consorzio Pavese per gli Studi postuniversitari 1994).

[25] P Kaur-M Singh, 'Exploring the impact of InsurTech adoption in Indian life insurance industry: a customer satisfaction perspective' (2025) TQM Journal, 2, 457-483.

[26] S Cao-H Lyu-X Xu, 'InsurTech development: Evidence from Chinese media reports' (2020) Technological Forecasting and Social Change, 161.

[27] Y Luen Ma-Y Ren, 'InsurTech. Promise, threat or hype? Insights from stock market reaction to InsurTech innovation' (2023) Pacific-Basin Finance Journal, 80, https://doi.org/10.1016/j.pacfin.2023.102059.

[28] T Oletzky, 'InsurTech in the United States and Germany – What are the Drivers behind the Different Business Models' (2023) Risk Management and Insurance Review, 26, 485-511.

[29] A Spender-C Bullen-L Altmann Richer-J Cripps-R Duffy-C Falkous-M Farrell-T Horn-J Wigzell-W Yeap, 'Wearables and the internet of things: considerations for the life and health insurance industry' 2019) British Actuarial Journal, 24, 1-31; D. Neumann-V. Tiberius-F. Biendarra, 'Adopting wearables to customize health insurance contributions: a ranking-type Delphi' (2022) Medical Informatics and Decision Making, 22, 112.

to promote a better policy-holder profiling.[30] This shift[31] is affecting or making its way even in Italy as well,[32] and raises crucial questions about how AI-driven technologies influence individual choices regarding care-seeking, how contractual coverage mediates access to services, and how the diffusion of such technologies may mitigate or exacerbate existing inequalities in healthcare access.

This essay therefore undertakes a taxonomy of AI-driven evolutions in healthcare and insurance markets, in order to examine how AI influences patient/consumer/insured behaviors, and at the same time how insurance contracts are reconfigured whenever they are driven by data gathered through IoTs and wearables, as well as whether these contractual forms are lawful and protective of policyholders' rights. Special attention will be given to data protection frameworks, notably the GDPR and following legislations, and to sector-specific initiatives like the 2025 EHDS Regulation, assessing the compatibility of conditional insurance models with privacy and non-discrimination.

After laying out technological and market developments, the paper will move to a legal assessment of HI that factor in continuous monitoring (and profiling), behavioral incentives, and most of all algorithmic underwriting. The analysis will assess the level of user protection, interrogating whether existing regulatory instruments adequately address asymmetries of information, algorithmic opacity, and the potential for indirect exclusion from coverage. The ultimate objective is to delineate pathways by which innovation can be harnessed to enhance access to care while safeguarding the constitutional right to health and the autonomy of patients, thereby preventing a deepening of medical poverty through technological and market distortions.

2. A taxonomy attempt for AI-driven healthcare and insurance

The application of robotic and artificial intelligence to medicine has become a pervasive and recurrent theme in the scientific literature, even within Italian scholarship, where debates increasingly mirror international conversations. As

[30] On profiling, see A Spangaro, 'Il concetto di profilazione tra "direttiva madre" e GDPR' (2022) Giur. it., 1579-1587; O Sesso Sarti, 'Profilazione e trattamento dei dati personali', in L Califano - C Colapietro (eds.), *Innovazione tecnologica e valore della persona. Il diritto alla protezione dei dati personali nel Regolamento UE 2016/679*, (ESI 2017), 573-626.

[31] I Cimbru-J Wagner-AZ Röschmann, 'On IoT-enabled risk prevention and insurance: A systematic literature review' (2025) Risk Management and Insurance Review, 1-52.

[32] On the matter, see the analysis provided by ANIA, The Italian insurance market and new investment trends under Solvency II, 2017, available at: *https://www.ania.it/documents/35135/126704/Italian-Insurance-in-figures-2017.pdf/684a880f-8919-83d2-7f11-503dfea85f16?version=1.0&t=1575555161527*; also see FinTech & InsurTech Observatory of the School of Management of the Politecnico di Milano, 'Cresce il Fintech in Italia: quali sono le startup e i numeri e della rivoluzione', 15 December 2021 available at: *https://blog.osservatori.net/it_it/FinTech-in-italia*.

habitually stressed by existing literature,[33] the new technologies allow faster, and more accurate diagnostic processes intended to prevent disease progression, reduce hospital admissions, particularly among patients with chronic conditions.

It is worth mentioning, that many of the innovations ascribed to AI in medicine are already tangible rather than merely speculative. The problem is that to achieve these goals of evolution by innovation a vast set of data is required, as well as its proper management and compatibility with the rights guaranteed by supranational and internal sources. Furthermore, these technologies are not yet within everyone's reach. Differently, autonomous tracking mechanisms, by consumer-level IoTs or wearables, are within the reach of everyone or, at least, a large amount of people worldwide.[34]

2.1. AI in Healthcare delivery.

Artificial Intelligence is to be understood as the branch of computer science and engineering that imitates human cognitive functions by means of algorithms, employing sequences of elementary instructions in the form of lines of code to create artefacts that exhibit behaviour commonly regarded as intelligent. These systems are software, that could be embedded in hardware: when these systems are tasked with a complex objective, they acquire data and provide their interpretation, by reasoning on prior knowledge and processing information derived from those data, later they select the best action to achieve the specified goal. AI systems may operate using symbolic rules or by learning numerical models and adapting behaviour by analysing how the environment has been affected by prior actions.

Among the many learning techniques that populate the broad field of AI, two are particularly salient for this analysis: Machine Learning (in the following parts, ML)[35] and Deep Learning (in the following parts, DL).[36]

ML denotes a set of methods whereby computer systems improve performance on tasks by identifying patterns in data and making predictions or decisions without being explicitly programmed for each instance. These models typically require feature engineering and can be trained with comparatively

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[33] G Comandé, 'Tecnologie e metamorfosi del danno e della responsabilità sanitaria' (2024) Danno resp., 2, 153-160; F. Cerea, 'Intelligenza artificiale al servizio dei pazienti per il contrasto a CoVid-19' (2020) Nuova Giur. Civ. Comm., III, 45-49.

[34] According to recent studies, IoT spread is likely to reach 31 billion installed units by 2025, each equipped with sensors collecting data from a vast array of physical objects, such as automobiles. On the matter, see M. Hung (ed.), *Leading the IoT. Gartner Insights on How to Lead in a Connected World*, available at *https://www.gartner.com/imagesrv/books/iot/iotEbook_digital.pdf*. This great availability of IoT and wearable has an immediate consequence: as technology costs decrease, the market share of tech-based firms increases, leading to a shift in market structure where low-risk individuals are more likely to select tech insurers. On the matter, see M Soleymanian-CB Weinberg-T Zhu, 'Insurtech, sensor data, and changes in customers' coverage choices: Evidence from usage-based automobile insurance' (2025) Journal of Risk and Assurance, 92, 227-256.

[35] The Royal Society, *Machine learning: the power and promise of computers that learn by example,* 2017, 15.

[36] F Cerea, 'Intelligenza artificiale al servizio dei pazienti per il contrasto a CoViD-19', (2020) Nuova Giur. Civ. Comm 47.

modest datasets, and they often permit greater interpretability of decision logic.

Differently, DL is a subset of ML, that utilises multilayered artificial neural networks to learn hierarchical representations of data. It is defined as deep, since it has multiple processing layers, enabling the automatic extraction of complex features from large volumes of data and supporting supervised, semi-supervised or unsupervised training regimes.

The medical sector[37] is among the most permeated by intelligent systems, a phenomenon driven by the digitalisation of imaging diagnostics, the adoption of digital reporting systems supplanting paper records, advances in molecular biology technologies and the proliferation of Internet of Things devices that continuously generate clinical and physiological data. In practice, AI in medicine spans a range of applications: automated image analysis for radiology and pathology that assists detection, segmentation and classification of lesions; predictive analytics for patient risk stratification and prognosis; natural language processing tools that extract structured information from clinical notes and generate draft reports; personalised medicine platforms that integrate genomic, proteomic and clinical data to suggest tailored therapies; remote monitoring and decision support enabled by wearable sensors and IoT devices; and robotic systems that augment surgical precision or automate routine laboratory workflows.

As described in the examples, the use of artificial intelligence in medicine is heterogeneous in its applications. To exemplify the applications, it has been noted that AI can function as an integrative adjunct to clinical teams or as a substitute for tasks performed by doctors and hospital staff.[38]

In substitutive applications, AI may carry out, wholly or partly, the actions identified as necessary for a patient's condition, yet this does not remove the clinician's and the institution's duty of care and supervisory responsibility, since physicians and healthcare organisations remain legally accountable for overseeing the AI's performance and intervening when outputs are inappropriate or uncertain. For example, AI may perform diagnostics, which will be assessed by the personnel to address the appropriate therapeutic path or alternatively AI may suggest how to treat the patient for the diagnosed pathology.[39]

In integrative roles AI supports clinicians and personnel by enhancing diagnostic accuracy with Clinicians Decision Support Systems (CDSS),

[37] For detailed analysis of the application of AI in medicine, see U Ruffolo, 'Le "mobili frontiere" della responsabilità medica' (2021) Giur. It., 2, 456-516; G Comandé, 'Tecnologie e metamorfosi del danno e della responsabilità sanitaria', 156 ff.; G Votano, 'Intelligenza artificiale in ambito sanitario: il problema della responsabilità civile' (2022) Danno resp., 6, 669-679, in particular 670-671; O Venier, 'Intelligenza Artificiale, Blockchain e mondo IoT: l'esperienza degli operatori' (2020) Dir. Industrale, 2, 166-171; E Verona, 'Errore diagnostico e intelligenza artificiale: profili di responsabilità nell'imaging medico' (2025) Nuova Giur. Civ. Comm., 4, 1075-1084.

[38] G Comandé, '*Tecnologie e metamorfosi del danno e della responsabilità sanitaria*', 158 ff.

[39] A Fiorentini, 'Machine Learning e dispositivi medici: riflessioni in materia di responsabilità civile' (2021) Corr. Giur., 10, 1258-1268.

stratifying risk, offering decision aids, suggesting relevant clinical guidelines[40] and flagging exceptional factors that fall outside guideline-designated cases, thereby augmenting rather than replacing human judgement.

2.2. From clinical IoTs to consumer wearables.

IoT in healthcare gather a network of connected devices and sensors that collect, transmit and sometimes process data across local or internet-based networks to support monitoring, automation and analytics.[41] This category is quite broad and spans environmental sensors, bedside monitors, infusion pumps and implantable devices. [42] These devices are characterized by connectivity and the capacity to feed continuous or periodic data into centralised platforms or distributed analytic engines.[43]

The integration of AI with IoT ecosystems is set to support continuous care in and most of all outside hospital walls, allowing earlier detection of deterioration and more confident early discharge strategies. This outcome has been stressed even by the World Health Organization (WHO): eHealth and mHealth applications can help the EU Member States ensure that «national health systems meet the demand for the delivery of high quality, readily available services in spite of zero-growth or decreasing health budgets».[44]

Wearables are a subset of IoT devices designed to be worn on the body or incorporated into jewellery, clothing, sunglasses, sensors, and other kind of accessories. They capture physiological or behavioural signals, namely heart rate, movement, sleep, glucose levels or respiratory metrics, either continuously or intermittently. These devices can provide immediate feedback to the wearer or stream data for clinical review or to other parties.

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[40] M Faccioli, 'Intelligenza sanitaria e responsabilità sanitaria' (2023) Nuova Giur. Civ. Comm., 3, 732-743; AG Grasso, 'Diagnosi algoritmica errata e responsabilità medica' (2023) Riv. dir. civ., 2, 334-360.

[41] O Venier, 'Intelligenza Artificiale, Blockchain e mondo IoT', 167. On IoT, see also V Zeno Zencovich, 'Ten Legal Perspectives on the "Big Data" Revolution' (2016) Concorrenza e Mercato, 29 ss.

[42] M Ferrari, 'Il rischio putativo e le nuove frontiere "assicurative" degli ecosistemi digitali' (2024) Danno resp., 2, 181-187, in particular 185-186.

[43] On wearables, see E Germani-L Ferola, 'Il wearable computing e gli orizzonti futuri della privacy' (2024) Diritto dell'Informazione e dell'Informatica, 75 ss.

[44] WHO Europe, Health Topics, Health Systems, E-Health, 2019, available at: http://www.euro.who.int/en/health-topics/Health-systems/e-health/e-health-readmore. On the matter, see European Commission, Final report – Benchmarking Deployment of eHealth among. General Practitioners, Brussel, 2013, available at http://ec.europa.eu/newsroom/dae/document.cfm?doc_id=4897; id., Green paper on mobile health, Brussel, 2014, available at http://ec.europa.eu/information_society/newsroom/cf/dae/document.cfm?doc_id=518. The literature on the matter is already vast: for an overview, see G Eysenbach, 'What is eHealth?' (2001) Journal Med. Internet Res., 2, 20 ff.; id., EHEALTH: Improving and Standardizing Evaluation Reports of Web-based and Mobile Health Interventions, (2011) Journal Med. Internet Res., 4, 126 ff.; id., 'Towards ethical guidelines for e-health: JMIR Theme Issue on eHealth Ethics' (2000) Journal Med. Internet Res., 7 ff.; T Mulder, The impact of the European Medical Device Regulations on the development and use of mhealth apps in Europe', 330.

As stated for other AI applications, IoT devices and wearables enable earlier detection of deterioration, more precise therapies, and improved self-management by sane, sick and chronic patients.[45] For healthy individuals, consumer-grade fitness trackers and smartwatches monitor activity, sleep and resting heart rate, providing behavioural feedback that supports primary prevention and healthier lifestyles. In acutely ill patients, hospital-grade IoT sensors and connected monitoring systems stream real-time vital signs into early-warning algorithms that can detect deterioration ahead of routine nursing observations, prompting rapid clinical review. For patients with chronic conditions, the impact is especially pronounced.[46]

2.3. From eHealth to InsurTech: when data exit the therapeutic sphere

The value of the above-mentioned different devices and, above all, the data they collect is not only appreciated in the medical field, to facilitate or speed up the provision of healthcare services or, broadly speaking, administrative services carried out in a public or private hospital. Instead, devices and data enable a wide range of value-adding services and benefits to users, consumers and after all policyholders, before entering a healthcare facility. Mobile apps and wearables allow users and consumers to track their biometric data on a day-to-day basis, with smartwatches,[47] smart fridges, mirrors, scales. There is no doctor supervising the collection and processing of this data: the data is collected because the person wants to know how many steps they have taken or their water or vitamins intake, what their body mass index is, what their eating habits are, what their stress level is, their cycle and their fertility peaks, their exercise rhythm and intensity, their physical improvements, and so on.

Consumers' willingness to collect data through these devices and software can enable physician to understand better the patient condition but it can as well serve other functions such as economic exploitation. The possibility of exploiting this data economically paves the way for new contractual arrangements. Thus, we move from reactive to proactive negotiation, from customership to membership, from a transactional to a more social view of the contract, from an approximation of the contractor's condition to a tailor-made contractual solution for the individual, and from analogue and local negotiation to digital and, at the same time, global negotiation that transcends territorial boundaries.[48]

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[45] P Thottempudi-R Madhavi Konduru-H Bindu Valiveti-S Kuraparthi-V Kumar, 'Digital health resilience: IoT solutions in pandemic response and future healthcare scenarios' (2025) Discover Sustainability, 6, 144.

[46] B Keller, *Big Data and Insurance: Implications for Innovation, Competition and Privacy,* Geneva Association - International Association for the Study of Insurance Economics, Geneva, 2018, 3.

[47] K De Blasio, 'Il marketing algoritmico tra tutela della privacy e pratiche commerciali scorrette', 379 ff.

[48] S Møllegaard, 'Six Mega-trends that will take Insurance back to the Future', in SLB Vanderlinden-SM Millie-N Anderson-SChishti (eds.), *The InsurTech Book. The insurance Technology handbook for Investors, Entrepreneurs and Fintech Visionaries* (Wiley 2018) 57-60.

The potential described above is also valued in contracts covering medical expenses: a field now referred with the neologism InsurTech.[49] InsurTech is an ecosystem,[50] comprehensive of a series of contracts and services, which are either stipulated as an addendum to an employment contract or stipulated directly by the person who intends to better allocate healthcare costs. These solutions are innovating the market and have already received the attention of many international studies. These contracts integrate innovation, technologies and automation into contracts, following the principle of "digital by default".

The phenomenon addresses specifically insurance policies to better frame the risk pool, to provide more coverage and transparency, to optimize value creation, to improve customer experience by adopting a user-centric approach and to overcome the insurance market systemic failure.[51] The contract is established between a policymaker and a policyholder: the latter is a consumer and the weaker party in the relationship, in a particularly vulnerable position because they are or will soon be a patient undergoing medical treatment. Therefore, person's data (a consumer's data and then a patient's data) are used to draw up a B2C contract; consequently, their behaviour, in the therapeutic context, will also be shaped or at least influenced.

As it is possible to understand from the premise, there are several benefits, but there are also multiple risks and most of all areas of interest for scholars who are attentive to these different contractual configurations, if not hybridisations. This is why it is essential to first understand the nature, purpose, structure and function of health insurance contracts and then assess how these policies are changing, or even evolving, within the phenomenon of Insurance of Things (INSoT) in InsurTech.

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[49] V Ricciardi, 'InsurTech Definition as its Own Manifesto', in S Christi-J Barberis (eds.*), The InsurTech Book: The Insurance Technology Handbook*, 6-8; S Cruz Rambaud- J Lopez, 'Insurtech, Proptech, and Fintech Environment: Sustainability, Global Trends and Opportunities' (2023) Sustainability, 15, 9574; A Gramegna-P Giudici, 'Why to buy insurance? An explainable artificial intelligence approach' (2020) Risks, 8, 137; A Vigil Iduate, 'InsurTech' (2019) Rev. Ibero-Latinoam. Seguros, 53, 173-180; Ö Gürses, 'Insurance Law and AI. Demystifing InsurTech', in E. Lim-P. Morgan (eds.), *Private Law and Artificial Intelligence* (Cambridge University Press 2024) 534-556. According to these Aa., the neologism InsurTech is used to frame the application of AI methods to (big) data retrieved from users' engagement via smartphones or other media, in order to close the gap between non-life insurance providers and consumers, thereby improving the protection provided and better allocate overheads, which are quite high in this sector, as premiums for insured well-behaved customers. In the Italian literature, on the matter, see E. Battelli, 'Insurtech ed evoluzione dell'offerta di polizze sanitarie', 59-91; A Luberti-C Tabarrini, 'Insurtech. Una ricognizione empirica e giuridica' (2018) Consumers' Forum. Il cittadino nell'era dell'algoritmo, 93 ff.; D Porrini, 'Big Data, personalizzazione delle polizze ed effetti nel mercato assicurativo', in V Falce-G Ghidini-G Olivieri (eds.) *Informazione e big data tra innovazione e concorrenza* (Giuffrè 2018) 319 ff.; MC Gaeta-DS D'Aloia, 'InsurTech in Italy: opportunity, risks and applicable regulation' (2021) European Journal of Privatcy Law and Technology, 2, 10-23.

[50] V Ricciardi, 'InsurTech Definition as its Own Manifesto', 6.

[51] S Tunstall, 'Why is Insurance Failing?', in SLB Vanderlinden-SM Millie-N Anderson-S Chishti (eds.), *The InsurTech Book*, 9-12.

3. Health Insurance.

Health insurance (HI) evolved into novel, [52] usage-based, contractual schemes that aim at transferring[53] the costs connected to the risks depending on future pathological conditions and any other connected conditions of the insured person.

The risks are allocated whenever they are not due to violent external causes and the contract does not cover for permanent disability.

Although in the Italian legal system the right to health is a fundamental and absolute right, which gives rise to the possibility of access to free healthcare for the poor, art. 38 Cost. allows for the supplementary fulfilment of the social security function and to supplement the social rights of individuals through the exercise of negotiating autonomy.[54]

These pacts tend to challenge and drift from traditional insurance dichotomy, which is usually based – at least in Italy, under art. 1882 c.c. and reflected on art. 38 of IVASS Regulation – on the main difference between the types of risks covered, considering the so-called damages branch and life branch.[55] While accident insurance, which qualifies as part of the damages' insurance branch , usually includes insurance for healthcare costs, the reverse cannot be said to be true. HI covers for the losses which impact on the patient's patrimony[56] and not (or at least, not exclusively) for the body integrity.[57] However, the loss for the patrimony is linked to the body integrity infringement, so this makes HI part of the non-life damages-branch.[58]

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[52] On the matter, see F Schiavon, *Le spese per cure mediche nella legislazione fiscale e nella riforma sanitaria. Deducibilità Irpef e successioni; Assicurazione privata malattie; Cure all'estero; L'Assistenza pubblica: prestazioni ed oneri contributivi; Normativa fiscale dei prodotti farmaceutici* (Roma 1982) 44-54.

[53] On the transfer technique, see S Landini, 'Data sharing and innovation in the insurance industry. First thoughts' (2025) European Journal of Privacy Law and Technologies, 2 ff.; I Partenza-RV Nucci, *L'assicurazione della responsabilità sanitaria. Professionisti e strutture sanitarie, rischi assicurati, profili giurisprudenziali, ipotesi di riforma* (Pacini Giuridica 2022) 19. In the Italian case law, Cass. Civ., Sez. Un., 22 may 2018, no. 12564, in Foro it., 2018, 6, 1900 ff.

[54] S Pardini, 'L'assicurazione contro i danni alla persona: sulla vita e sulla salute', in M. Gorgoni-F. Greco (eds.), *Diritto delle Assicurazioni*, 320-321.

[55] TV Russo, 'Vigilanza sulle imprese di assicurazione e riassicurazione', in M Gorgoni-F Greco (eds.), *Diritto delle Assicurazioni,* 65-92.

[56] G Iorio, 'L'assicurazione del patrimonio e di cose', in M Gorgoni-F Greco (eds.), *Diritto delle Assicurazioni*, 337-353; S Pardini, 'L'assicurazione contro i danni alla persona: sulla vita e sulla salute', 330.

[57] On the *summa divisio*, see G Fanelli,' La "summa divisio" delle assicurazioni private: riflessioni su un vecchio problema' (1962) Foro it., IV, 51 ff.; S Pardini, 'L'assicurazione contro i danni alla persona: sulla vita e sulla salute', 319-335, in particular 330. On the difference, see S Landini, 'Polizze sanitarie nelle dinamiche contemporanee della longevità' (2019) Riv. it. Med. Leg, 2, 511 ff.; F. Schiavon, 'Le spese per le cure mediche', 46.

[58] I Partenza-RV Nucci, 'L'assicurazione della responsabilità sanitaria', 18 ff.

HI may cover individual risk or that of family and non-family groups. These contracts recall the instruments for integrative[59] supplementary[60] coverage connected to the work contract and from payment protection insurance,[61] and on a certain level the issues that will be considered for private law insurance pacts could be extended to integrative coverage as well.

HI pacts bind an insurer (the policymaker) and the insured (the policyholder), and these contracts are designed specifically for medical expenses coverage or second medical opinion[62] or hospital stays[63] or recovery periods or even direct access to the health facilities to have access to benefit from a medical treatment, which has a previous pact with the insurance (indirect reimbursement). [64] The direct reimbursement may be complete or may integrate the difference with the national social healthcare assistance. So, HI typically perform a health-security function by reimbursing medical expenses and such reimbursements (or direct payment to the medical facility) may respond as a reaction or mitigation measure to an acute, newly occurring illness or to ongoing needs arising in daily life, for example the chronic care requirements of an elderly person.[65]

Usually, this contract allows for reimbursement considering the insured risks, however they pose maximum limits and deductibles.

This type of contract can also be entered into to overcome the limitations of national healthcare systems, with international insurance contracts, and/or to guarantee access to treatments that comply with a broader concept of health, understood as a condition of general psychological and physical well-being,[66] aimed at including cosmetic surgery, treatments for physical defects or pre-existing conditions, dental expenses, home care for the elderly and people with disabilities, and nutritional consultations.

These non-life damage-branch insurance policies are aleatory contracts,[67] subject to the principle of indemnity,[68] therefore determining reimbursement of the amount equal to the damage suffered, without determining enrichment

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[59] E Piras, 'Fondi sanitari integrativi e società di mutuo soccorso: le nuove frontiere della sanità integrativa' (2016) Resp. Civ. Prev., 1870 ff.; id. (ed.), *Le attuali prospettive della previdenza complementare e della sanità integrativa*, (ESI 2022), 69. These pacts are regulated by l. 23 ottobre 1992, n. 421, which was implemented with d.lgs. 30 dicembre 1992, n. 502.

[60] M Lippi Bruni-S. Rago-C. Ugolini, *Il ruolo delle mutue sanitarie interattive* (Il Mulino 2012); G. Rocco, Sanità integrativa: ruolo centrale nel welfare aziendale' (2018) Dir. prat. lav., 1048.

[61] E Battelli, 'Insurtech ed evoluzione dell'offerta di polizze sanitarie', 80 ff.

[62] S Landini, 'Polizze sanitarie nelle dinamiche contemporanee della longevità', 511 ff.

[63] F Schiavon, 'Le spese per le cure mediche', 47.

[64] E Battelli, 'Insurtech ed evoluzione dell'offerta di polizze sanitarie', 52.

[65] S Landini, 'Polizze sanitarie nelle dinamiche contemporanee della longevità', 521.

[66] See the new notion in the Preamble at the Constitution of the WHO, as adopted by the International Conference of Health, New York, 19-22 june 1946, available at: https://apps.who.int/gb/bd/pdf/bd47/en/constitution-en.pdf. On the matter, see N Vettori, 'Il diritto alla salute alla fine della vita: obblighi e responsabilità dell'amministrazione sanitaria' (2016) Riv. it. med. leg., 1463 ff.; A Guarnieri, 'Profili giuridici della fine della vita umana' (2009) Resp. civ., 1707 ff.; V Rotondo, *Responsabilità medica e autodeterminazione della persona* (ESI 2020) 31 ff.

[67] On the different scholarly opinions on the risk-based nature of the contract, see I Partenza- RV Nucci, 'L'assicurazione della responsabilità sanitaria', 21.

[68] On the function of the contract, see F Bosetti, *La causa del contratto,* in M Gorgoni-F Greco (eds.), *Diritto delle Assicurazioni*, cit., 173 ff.

to the benefit of the injured party, despite the existence of risk. Therefore, there is no speculative function of risk. Furthermore, they are subject to the rescue obligation, which encourages the insured to prevent and mitigate risk, and to the rule of no-coverage for intentionally caused risks and damages: for example, the HI doesn't provide any coverage for damages and costs related to alcohol, narcotics, psychotropic medication abuse.

HI are offered under private law, structured as premium-paying arrangements in which the premium and the scope of benefits are dynamically linked to individual behaviour and physiological indicators.[69] The insurer is usually tasked with identifying the risk profile of the person seeking cover. To do this, it is necessary to mitigate the information gap and gather data about the individual and their habits. Underwriters use demographic and statistical data,[70] personal questionnaires and the applicant's available clinical records: these factors allow the 'fixed active component' defined ex ante and statically for the insurance premium to be determined.[71] Once the risk picture is assembled, the insurer allocates a risk category and proposes insurance cover. At this point the element of alea becomes clear: the policyholders may behave responsibly, or their condition may deteriorate, or fall ill, or even adopt unhealthy habits or present a condition different from that detected in the pre-contractual phase. The insurer therefore prices[72] and structures the policy to reflect that uncertainty, often applying exclusions, waiting periods or premium adjustments. This makes these pacts, as other insurance schemes, "contract(s) upon chance":[73] an effective risk assessment needs to manage unpredictable future health developments.

The nature and object of the contract in question also determine its duration,[74] which may depend on a fixed end date or on exposure to risk. In contracts based on a static risk assessment, the contract duration is usually one year, with the possibility of activating the clause that provides for the continuation of the contractual relationship for another year.

Since the HI design is explicitly user-centric,[75] the new trend (or quest) for policymakers is to base the risk analysis on the continuous profiling of the

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[69] A Troiano, 'Wearables and Personal Health Data: Putting a Premium on Your Privacy' (2017) Brooklin Law Review, 1715-1753; I Cimbru-J Wagner-A.Z. Röschmann, 'On IoT-enabled risk prevention and insurance', 13-14.

[70] The use of statistics for insurance and risk pooling has been regulated under the Solvency II Directive: Directive 2009/138/EC of the European Parliament and of the Council of 25 November 2009 on the taking-up and pursuit of the business of Insurance and Reinsurance.

[71] P Manes, 'Credit scoring assicurativo, machine learning e profilo di rischio: nuove prospettive' (2021) Contratto e Impresa, 2, 469-489, in particular 474.

[72] It is worh mentioning that Big data already impacted on negotiations by allowing the application of personalized prices of which consumers are not aware of, using "group pricing" or "geoblocking" but also "first degree discrimination" considering the single consumer data gathered. On the matter, see M Maggiolino, 'Big data e prezzi personalizzati' (2016) Concorrenza e mercato, 95 ff. On Big data, see V Zeno Zencovich, 'Ten Legal Perspectives on the "Big Data" Revolution' (2016) Concorrenza e Mercato, 29 ff.

[73] This expression as been used in anglosaxon case law: Seaman v Fonereau (1742) 2 Str. 1183, 93 E.R. 1115; Carter v Boehm (1766) 3 Burr. 1905.

[74] M Chironi, 'L'accordo, la forma e la durata del contratto', in M Gorgoni-F Greco (eds.), *Diritto delle Assicurazioni. Attività, Contratti, Responsabilità e Mercato* (Pacini Giuridica 2024) 137.

[75] E Battelli, 'Insurtech ed evoluzione dell'offerta di polizze sanitarie', 52 ff.

policyholder via IoTs devices and wearables enable far more granular identification of risk, widening the pool of potential customers by matching bespoke offers to heterogeneous risk profiles. These technologies may be developed and integrated in their systems by the insurance policymakers, or they could resort to externalization and partner with tech companies to gather data.[76] These peculiar new dynamic features make these contract known as open insurances[77] and recalls the legal institution already known to the Italian legal system of the so-called estimated policy, as regulated under art. 1908 co. 2 c.c.[78]

Moreover, a distinctive legal and operational feature of many HI products is their embodiment as computable or computational contract, [79] which are generally referred to as "smart contracts".[80] The locution is comprehensive not so much of actual contracts, but consists in contractual terms encoded in a software, which follows a programmable logic, according to which automatically activates, suspends or modifies contractual effects when specified conditions are met. Moreover, streams of biometric and behavioural data feed machine learning models that continuously recalibrate the contract's parameters, producing real-time adjustments to coverage, premiums or benefits. This automation yields efficiency and actuarial refinement, but it also relocates essential decisions from human agents to algorithmic processes whose internal functioning is often opaque to the insured.

The heavy reliance on profiling and adaptive algorithms impacts on autonomy considering several levels. The monitoring is relevant so the user can impact in a positive and negative way on the outcomes.

Since the monitoring is so relevant, one must consider that the insured frequently lacks meaningful understanding of which factors will influence the contractual balance, or how the machine learning system synthesises these signals into risk scores and consequent contractual effects.

As considered, monitoring and algorithmic processing constitutes a precondition for concluding the analysed insurance contract, for this reason the policymakers may be compromised in their agency: consent (to contract and data protection first, and to medical treatment later) risks being formal rather than real, and contractual agreement may reflect a disturbed policyholders' determination insofar as they cannot foresee or evaluate the probabilistic and adaptive consequences of their data being continuously processed.

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[76] Ö Gürses, 'Insurance Law and AI. Demystifing InsurTech', 535.

[77] S Landini, 'Data sharing and innovation in the insurance industry. First thoughts' (2025) European Journal of Privacy Law and Technologies, 2025, 8 ff.: A Camedda, 'La rivoluzione tecnologica nel settore assicurativo: l'avvento dei big data (Big Data & insurance: potential benefits and issues)' (2016) RTDE, 4, 5 ff.; B Keller, 'Big Data and Insurance', 2018, 10.

[78] On the estimated policy and its compatibility with the principle of indemnity, see S Pardini, 'L'assicurazione contro i danni alla persona: sulla vita e sulla salute', 331.

[79] C Scognamiglio, 'Lo smart contract in ambito bancario', in M. Proto (ed.), *Intelligenza artificiale e rapporti bancari* (Pacini Giuridica 2024) 29-40.

[80] U Salanitro, 'Smart contract tra accordo e rapporto patrimoniale giuridico' (2025) Pactum, 2 141-146; E Battelli, 'Le nuove frontiere dell'automatizzazione contrattuale tra codici algoritmici e big data: gli smart contract in ambito assicurativo, bancario e finanziario' (2020) Giust. civ., 4, 681 ff.; R Santagata, 'Polizze assicurative parametriche (o index-based) e principio indennitario' 156.

4. IoTs and HI.

In contexts of poverty, where time and money are scarce and public healthcare services are patchy, the deployment of IoT devices and wearable technologies is often presented as a promising and apparently practical solution. Such technologies can be framed as low friction means to encourage healthier lifestyles, to monitor early signs of disease progression and to maintain surveillance of chronic conditions to avoid costly and disruptive hospital admissions.

For populations who cannot afford frequent medical treatments or who are constrained by work and territorial barriers, the idea that a low-cost wearable or a remotely managed sensor network might substitute for parts of face-to-face care has considerable intuitive appeal. The literature and industry discourse increasingly depict IoT and wearables as instruments that extend the reach of health services into daily life, allowing preventive interventions and earlier, less invasive treatments to be delivered at scale. They are, but to a certain extent.

Across healthcare systems, both private and public, these technological affordances have catalysed new models of interaction between patients, clinicians and hospitals, especially where health is not a universal right (i.e. United States). In fact, wearables that measure activity, heart rate, glucose or respiratory parameters enable continuous or repeated observations that were previously only attainable in clinical settings. IoT-enabled home devices can monitor environmental triggers and adherence to therapies. When combined with analytics, these streams can support risk stratification algorithms that identify deterioration earlier than sporadic clinic encounters and that prioritise interventions to avert acute episodes. In principle, for low-income populations the downstream effects are attractive: fewer emergency admissions, fewer invasive procedures, and reduced catastrophic out-of-pocket expenditure tied to hospitalisation. This is why these technologies can perform both as clinical aids and socioeconomic equalisers.

However, the promise of IoTs and wearables becomes complex and open to contest when the data they generate are folded into contractual relations with insurers, creating a new sector named INSoT, the Insurance of Things.

The pandemic [81] accelerated public awareness of health risks and contributed to growth in consumer demand for protection against health-related expenditures. [82] So, insurers, responding to market dynamics, have deepened their engagement with digital health tools integrated in the policies: they started proposing schemes that explicitly leverage behavioural and biometric data to shape cover and price. In the depicted scenario, insurance companies have introduced a range of IoT/wearables integration into policy models: discounts on premiums conditional on engagement with wellness

[81] P Thottempudi-R Madhavi Konduru-H Bindu Valiveti-S Kuraparthi-V Kumar, 'Digital health resilience: IoT solutions in pandemic response and future healthcare scenarios' (2025) Discover Sustainability, 6, 144.
[82] E Battelli, 'Insurtech ed evoluzione dell'offerta di polizze sanitarie', 83.

programmes, subscription or membership benefits tied to device use, provision of devices or services for free or at subsidised cost in exchange for data sharing, vouchers or rewards for sustained healthy behaviours, and tiered products that adjust underwriting rules based on continuous monitoring.[83]
This integration produces a perturbative effect on the mentioned HI contract. Traditionally, insurance underwriting begins with an assessment of the applicant: a one-off evaluation of personal, medical and behavioural factors used to classify risk through a questionnaire and set a fixed premium, like a photograph of the policyholder. That model assumes a relatively stable risk profile that can reasonably be summarised at inception and adjudicated through defined policy terms. By contrast, embedding IoT devices and wearables into the insured relationship replaces or combines that initial, static mapping with a continuously evolving dataset generated by real-time monitoring. Consequently, risk assessment shifts from a point estimate to a dynamic process. Premiums, coverage conditions and incentives may be recalibrated in response to live data streams rather than remaining anchored to the original underwriting file. Insurers can observe behavioural and physiological signals on an ongoing basis and adjust their view of exposure accordingly. This creates a contractual regime where obligations and benefits are contingent on future measurement, producing novel uncertainties for both parties.

4.1. AI-driven contracts implications.

The mentioned perturbation of the private law contract has multiple direct and indirect implications.

This reconfiguration challenges the traditional actuarial framework by introducing temporal volatility and potential feedback loops between monitoring, behaviour and underwriting.

Precisely, the above-mentioned integration of automation and monitoring in contracts impacts on bilateral informational asymmetry.[84] Policymakers may not fully understand the risks, but most of all policyholders may not fully understand how continuous data will affect their terms. Policyholders may not realise the impact of poor maintenance, poor device monitoring, inaction during periods when they are working or have other commitments, and the extent of the data set that is collected.

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[83] A Spender-C Bullen-L Altmann Richer-J Cripps-R Duffy-C Falkous-M Farrell-T Horn-J Wigzell-W Yeap, 'Wearables and the internet of things: considerations for the life and health insurance industry' (2019) British Actuarial Journal, 24, 1-31.

[84] F Greco, 'Trasparenza e obblighi comportamentali', in M Gorgoni-F Greco (eds.), *Diritto delle Assicurazioni*, 395-414; M Soleymanian-CB Weinberg-T Zhu, 'Insurtech, sensor data, and changes in customers' coverage choices', 231. It is worth mentioning that the informational (and bilateral) asymmetry is also a issue in traditional insurance policies, as considered by E Battelli, 'Insurtech ed evoluzione dell'offerta di polizze sanitarie', 83; A Zurlo, 'L'oggetto del contratto di assicurazione', in M Gorgoni-F Greco (eds.), *Diritto delle Assicurazioni*, cit., 157 ff.; D Porrini, 'Asimmetrie informative e concorrenzialità nel mercato assicurativo: che cosa cambia con i Big data?' (2016) Concorrenza e mercato, 139 ff.; M Chironi, 'L'accordo, la forma e la durata del contratto', 128.

A second innovative profile emerging from the integration of IoTs and wearables into HI is the temporalisation of underwriting and contract duration. Rather than treating risks as a static attribute measured at inception, insurers are now able to observe continuous behavioural and physiological streams and to make coverage contingent on trajectories over time. Devices that record activity patterns, sleep quality, heart-rate variability, glucose excursions or medication adherence enable insurers to define eligibility and benefit levels not only at the point of sale but throughout the lifetime of the policy. This produces contract forms in which renewal, premium adjustment and scope of cover are functions of longitudinal metrics: a sustained period of "healthy" readings may trigger discounted renewal offers, whereas an unfavourable trend could provoke premium increases, additional co-payments or conditional cover windows. Such arrangements, known as "pay as you live" or "cover as you need" models,[85] are "usage-based insurance" schemes (UBI)[86] which nominally tailor financial exposure to actual behaviour and health status. This appears to be a contract configuration method compatible with the so-called best execution rule,[87] according to which the insurer must take steps to provide the customer with the best possible contract, tailored to their specific needs. In practice, however, they transform the contract from a stable social instrument into a continuously negotiated bargain mediated by data flows, shifting risk assessment into an operational, ongoing activity.

A third innovative profile is the emergence of surveillance-driven exclusion and pre-emptive contract termination. Continuous monitoring can reveal early, subtle signs of disease that the user may not understand or appreciate because of informational asymmetry; insurers, by contrast, possess analytic capacity to detect and act on these signals. When contractual terms permit, such inferences may be used to restrict or withdraw coverage before clinical diagnosis or before the patient has had an opportunity to seek appropriate care. The consequences can be listed as follows: denied or limited cover increases out-of-pocket exposure precisely for those entering a trajectory of increasing need, thereby impeding access to costly but necessary interventions. This dynamic disproportionately affects socioeconomically vulnerable individuals who rely on insurance to manage catastrophic costs.

Moreover, the spectre of surveillance-based penalties fosters risk-averse behaviour and may undermine therapeutic self-determination: patients may avoid seeking diagnostic care, clarity, or even decline beneficial interventions since they fear of incurring adverse contractual consequences. In both profiles,

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[85] These schemes mimic the the plethora of contracts that have emerged for motor insurance: "pay as you drive" or "pay how you drive". On the matter see, M Infantino-D Porrini, 'Portabilità dei dati e scatole nere. un commento a margine di una recente riforma'(2025) Resp. civ. prev., 2, 672.

[86] M Soleymanian-CB Weinberg-T. Zhu, 'Insurtech, sensor data, and changes in customers' coverage choices', 229 ff.; E Battelli, 'Big data e algoritmi predittivi nel settore assicurativo: vantaggi e nuovi rischi' (2019) Corr. Giur., 12, 1517-1518; MC Gaeta-D.S. D'Aloia, 'InsurTech in Italy: opportunity, risks and applicable regulation' (2021) European Journal of Privacy Law and Technology, 2, 19.

[87] M Rossetti, *Il diritto delle assicurazioni. Vol. I. L'impresa di assicurazione. Il contratto di assicurazione in generale* (Pacini Giuridica 2011), 854 ff.; A Zurlo, 'L'oggetto del contratto di assicurazione', 166.

the promise of personalised, adaptive coverage is shadowed by new forms of conditionality and exclusion. To prevent it, the surveillance should be converted as a new configuration for the "rescue burden" (onere di salvataggio), according to art. 1914, co. 1, c.c., to prevent damages and limit the negative externalities.[88]

This reconfiguration of the rescue burden can have a decisive impact on the market: statically estimated insurance costs lead to the selection of only high-risk individuals, while those who fall into a low-risk cluster usually decide not to take out insurance because of the cost, causing a phenomenon known as the Akerlof adverse selection. [89] In addition, policyholders engage in riskier behaviour, known as moral hazard. In contrast, parametric insurance is structured to cover low-risk individuals and prevents moral hazard, although the literature[90] emphasises the innovative scope of these measures to include even the most serious and chronic patients in the market.

Furthermore, while it is true that scientific and legal literature[91] asserts that this insurance model, which integrates monitoring with wearables, would make it possible to insure a larger number of people, especially those with chronic conditions or illnesses who have limited access to these contracts, it is also true that data collection can lead to an initial negative assessment that discourages policymakers from insuring the sick person, thus determining a sort of mutation of the insurance contract devoid of its typical mutualistic risk.[92]

Additionally, the data driven nature of the profiling for the risk pooling interferes with the application of the policyholder duty to provide duly information to let the policymaker choose the adequate "bucket" in risk pooling.[93] This reversal generates a disruption of communication flows and of the legal dynamics envisaged by statutory provisions. If so, informational paucity or opacity cannot be imputed to the policyholder, whose informational corpus may have been supplanted by IoT outputs. Attention instead turns to whether reliance on inappropriate datasets can be attributed to the policymaker. That question is especially acute where regulatory frameworks allocate communicative duties between policyholders and policymakers in a

[88] On the rescue burden, see R Santagata, 'Polizze assicurative parametriche (o index-based) e principio indennitario', 167; A Zurlo, 'L'oggetto del contratto di assicurazione', 173 ff.; I Partenza-RV Nucci, 'L'assicurazione della responsabilità sanitaria', 32-34.

[89] M Maggiolino, 'Big data e prezzi personalizzati', 95.

[90] B Keller, 'Big Data and Insurance', 3.

[91] C Poncibò-P Terezkiexcz, 'EU Digital Insurance: Comparative Legal Perspectives' (2025) AIDA Europe Research Series on Insurance Law and Regulation, 14, https://doi.org/10.1007/978-3-031-96496-1_1 ; A Spender-C Bullen-L Altmann Richer-J Cripps-R Duffy-C Falkous-M Farrell-T Horn-J Wigzell-W Yeap, 'Wearables and the internet of things: considerations for the life and health insurance industry' (2019) British Actuarial Journal, 24, 1-31.

[92] E Battelli, 'Insurtech ed evoluzione dell'offerta di polizze sanitarie', 85; P Manes, 'Credit scoring assicurativo, machine learning e profilo di rischio', 485.

[93] P Manes, 'Credit scoring assicurativo, machine learning e profilo di rischio', 474; O Gürses, 'Insurance Law and AI. Demystifing InsurTech', 542: according to the A., the essence of the duty of fair presentation of the risk lies on the tests of materiality and inducement (…). The data that the insurer has taken into account has therefore to be revealed by the insurer who would argue that the assured breached the duty of fair presentation of the risk. The insurer who argues the breach of the duty would have to specifically identify the issues known by the insurer through the data already available to them and the information provided by the assured, as well as the circumstances that the assured failed to present fairly.

way that presumes reciprocal access to reliable information. The problem is compounded when the policymaker exerts only limited control over the dataset, or when a third-party provider curates and governs the datasets.

It is possible to also note that profiling is feasible because insurers rely on large, heterogeneous and regularly updated datasets, which enable risk stratification and predictive modelling. The core issue, however, is that datasets often embed structural biases related to gender, disability and ethnicity. Women, people of colour and individuals with rare diseases or disabilities are frequently under-represented in research, producing sparse and skewed data first and wrong "bucket" risk pooling later.[94] Such gaps distort model outputs, perpetuate discriminatory inferences and undermine the fairness and legality of profiling practices embedded in the insurance contract.

Taking into account the mentioned implications, one must consider the contract is void whenever it covers for a risk that cannot be covered for, like the costs intentionally caused by the insured, according to art. 1900 c.c. Since the insured person has wearables, they can prevent medical expenses by leading a healthy lifestyle: if the person benefiting from a parametric insurance contract has a lifestyle that is not compatible with the goals set or the average standards for their category, then the illness or expense to be reimbursed could be considered as voluntarily created, and therefore not subject to coverage because it is not insurable. This is not true if we only consider that the subject is not always able to understand the consequences of the relationships that arise from that data, because they do not have the wealth of information available to the doctor, clinic or insurance company.

Also, since the contract is based on continuous data monitoring, it does not seem to comply with the principles that govern indemnity insurance. The insured policyholder pays a fixed amount for the medical expenses' coverage upon the occurrence of an eventual triggering event. So, instead inherently data driven insurance policies could recall an "index" based product,[95] where the payment is determined by the degree of covariation between an event and an estimated loss. While the main principle for insurance is that the assured is entitled for indemnity (art. 1882, 1904, 1905, 1907, 1908, co. 1°, 1909 and 1910, c.c.), [96] up to the full amount of the actual loss suffered, whenever the parametric insurance interferes with this principle, the contract cannot be considered insurance, but it is an index-based product, which may obey to other disciplines. If these pacts do fall into the parametric or index-based contract framework, then they need to comply with art. 37 EU Regulation no. 1305/2013 and art. 2-bis d. lgs. 102/2004. Notwithstanding, to apply this framework to a parametric pact, it is required that the payment is subject to an objective exogen index. However, the contract considered in this paper is certainly parametric in the sense that it depends on the tracking of specific data on which the determination of risk depends, but prima facie they do not appear to be either objective or external. They are not objective because they relate to the

[94] K Langenbucher, 'Responsible A.I.-Based Credit Scoring – A Legal Framework' (2020) European Business Law Review, 31, 527-547.
[95] In this sense, Ö Gürses, 'Insurance Law and AI. Demystifing InsurTech', 537. The A. argues that the term insurance is misplaced.
[96] R Santagata, 'Polizze assicurative parametriche (o index-based) e principio indennitario', 138.

person insured by the policymaker; they are not external because they can be controlled through suggestions and tracking by the policymaker and are undoubtedly subject to influence by the policyholder who produces this data. If anything, this index can be assimilated to external and objective indices if we consider the black box effect, the asymmetry and the inability of the insured to understand the implications of the collection of this data. Therefore, the parameter must necessarily be customised for risk pooling, it performs a technical function of verifying that the threshold for coverage has been reached, it is connected to the interest of the insured to be reimbursed, and so it can be inferred that the insurance in question is not subject to the rules laid down for contracts directly linked to index or units of collective investment undertakings referred to in art. 41 Insurance Code.[97] Moreover, this peculiar model of health insurance appears to reconfigure the category of the estimated insurance policies, according to art. 1908 co. 2 c.c.: since the estimated risk is limited by the data collected, and coverage is determined by reference to the expenses actually incurred or to be incurred, or by the cost of the healthcare service requested from the hospital. However, in practice, it will be necessary to verify whether the index is always internal or external and whether the reimbursement serves an indemnity or speculative function, to identify the applicable regulations.

The above-mentioned control intersects and broaden the product oversight and governance (POG):[98] on one end, the policymaker do need to walk through a process for the product approval; on the other, they have the duty to evaluate a coherent and adequate risk profile to the target client and to do it in a transparent way, according to the EU Directive 2016/97 and d. lgs. 68/2018.[99] Finally, the use of monitoring and the anchoring of contractual risk may result in the loss of the aleatory nature of the contract itself.[100] Thus, the loss of intrinsic uncertainty, which determines the need to allocate risk to others, may lead to a void contract, unless the risk assessment is not based exclusively on continuous profiling but is anchored also to an initial static profiling that offers coverage regardless of the data collected.

[97] In questo senso, si veda R Santagata, 'Polizze assicurative parametriche (o index-based) e principio indennitario', 141; *contra* Ö Gurses, , 'Insurance Law and AI. Demystifing InsurTech', 537.
[98] A Camedda, 'La product oversight and governance nel sistema di governo societario dell'impresa di assicurazione' (2021) Banca Borsa Tit. Credito, 2, 234 ff.; M Hazan, 'Effetti della pandemia sulle polizze di responsabilità sanitaria', 75.
[99] S Landini, 'Appropriatezza, adeguatezza e meritevolezza dei contratti di assicurazione' (2017) Assicurazioni, 39-58; R Santagata, 'Polizze assicurative parametriche (o index-based) e principio indennitario', 163. On the broadened application of the suitability rule, see M Hazan, *L'assicurazione "responsabile" e la responsabilità dell'assicuratore: quali prospettive dopo IDD*? (2017) *Danno e resp.,* 630 ff., who states that IDD broadened the concept of suitabily, taking into account not only the specifics of the single contract (and client) but also the specifics of the market in which the product is sold.
[100] E. Battelli, 'Big Data', 1519.

4.2. The premium narrative.

Scientific literature [101] has focused and continues to focus on the consequences of exchanging data for services or money for services. As will be assessed below, data processing regulations do not exclude this possibility and the tying of consent to a contract for the desired service.

Nevertheless, the object of this paper analysis appears to be somewhat different. In the contracts analysed, i.e. AI-driven HI contracts, consent to data processing is not exchanged for access to a free service: the service is paid for, but data are provided to gain a reduced rate or to get access to additional services or even to get exclusive packages. This constitutes a middle ground narrative compared to that studied in the literature on data processing, namely the premium narrative.

Two question then arise: is it the exchange data for cover allowed and within which circumstances? Does the exchange between the premium package and consent have further implications? While the first question will be addressed in the following paragraphs, [102] the second question opens the way to further reflections, because premium narratives can not only contribute to undermining individuals' self-determination in healthcare, data processing and insurance agreements, but can also generate additional problems for consumer protection. In fact, this way of reconfiguring the contracts analysed risks introducing unfair commercial practices, such as gamification.

Gamification[103] is the application of game design elements, such as points, badges, leaderboards and progress bars, to different contexts not linked to recreational functions to motivate and engage people, turning routine tasks into more rewarding experiences. Common examples include loyalty schemes, fitness apps that use streaks and badges to encourage exercise, corporate training platforms that award points for completed modules, and social apps that use leaderboards to increase interaction. Educational platforms add quizzes and levels to improve retention, while some civic initiatives use gamified challenges to boost participation in surveys or recycling programmes.

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[101] C Langhanke-M.Schmidt-Kessel, 'Consumer data as consideration' (2016) Journal of European Consumer and Market Law, 5, 218; A De Franceschi, *La circolazione dei dati* (ESI 2017) 67 ff.; A Metzger, 'Data as Counter-Performance: What Rights and Duties do Parties Have?' (2018) Journal of Intellectual Property, Information Technology and Electronic Commerce Law, 7, 1 ff.; G Resta-V Zeno-Zencovich, 'Volontà e consenso nella fruizione dei servizi in rete' (2018) Riv. trim. dir. e proc. civ., 411, 436 ff.; V Ricciuto, 'La patrimonializzazione dei dati personali. Contratto e mercato nella ricostruzione del fenomeno' (2018) Il diritto dell'informazione e dell'informatica, 4-5, 689; S Thobani, 'Operazioni di tying e libertà del consenso' (2019) Giur. it., 533 ff.; id., Processing Personal Data and the Role of Consent (2020) European Journal of Privacy Law and Technologies, 93-104, in particular 96; id., 'Il mercato dei dati personali: tra tutela dell'interessato e tutela dell'utente' (2019) Media Laws, 147; id., 'Il consenso nella regolazione della circolazione dei dati' (2025) Persona e Mercato, , 2, 469-486; V Bachelet, *Il consenso oltre il consenso. Dati personali, contratto, mercato* (Pacini Giuridica 202), 51 ff.; G Versaci, *La contrattualizzazione dei dati personali dei consumatori* (ESI 2020) 69 ff.; I Rapisarda, 'La privacy sanitaria alla prova del mobile ecosystem', 201.

[102] *Infra* § 5.

[103] A Faust, *The effects of gamification on motivation and performance* (Springer Gabler 2022); V Zambrano, 'We are only scratching the surface: a proposito di ai e sfruttamento economico dei dati sportivi' (2025) Contratto e impresa, 2, 299-332.

This practice does not only apply to recreational contexts, such as the video game or sports industries,[104] instead gamification consists in the application of games and related strategies to various other sectors , including finance[105] and potentially insurance. The phenomenon enables the user to boost participation and learning, especially among younger and first-time users, it can allow providers to build loyalty and trust, but it carries risks. These systems may encourage superficial engagement or "gaming the system", where users chase rewards rather than meaningful outcomes, and can undermine intrinsic motivation, create unhealthy competition, or even foster addiction-like behaviours.

Gamification can create a cognitive bias for the user[106] and especially for contractual parties: who concludes the contract does it for its playful nature or accesses the premium version or other accessories and services for its playfulness or remains bound by the contract or decides to continue to sign the contract for its playfulness or underestimates the negative externalities of the contract because they are described to the contractor as a loss in the game and not as an economic loss or downplays the losses.[107] Also, the practice can be linked to social media trends and the proliferation of financial influencers, often referred to as fin-influencers, producing a phenomenon known as behavioural contagion, with uncritical, imitation based, and herd-like adherence by consumers based on informational cascades, i.e. the herd effect. For these reasons, a contract can be signed because it is a viral trend to do so and not because the party (especially the vulnerable and weaker one) understood the severity of the negotiation. It appeals to younger and first-time consumers, also due to emotional or aesthetic reasons.

While in other sector gamification hasn't been assessed by authorities and the national case law, it has been legally assessed and framed into legal categories in the gaming and financial sectors.

In the gaming sector, gamification is referred to be a harmful action in games and videogames, as provided by the European Commission's Consumer Protection Cooperation Network (CPC), [108] and it is considered to be, potentially and according to the specific case scenario, an aggressive or

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[104] On the matter, it is possible to read a first assessment of gamification in the sport and game industries provided by the Italian case law: Trib. Torino, sez. Impresa, 11 october 2023, n. 3872; Trib. Torino, sez. III, 11 october 2021, n. 4523.

[105] C Brescia Morra-D Colonnello-M Gargantini-G Sandrelli-G Trovatore, 'La gamification degli investimenti finanziari' (2025) Quaderni giuridici, 32, 7-98, available at: https://www.consob.it/documents/d/area-pubblica/qg32

[106] C Failla, 'Gamification, dark patterns e cripto-attività. Prospettive di adattabilià della disciplina delle pratiche commerciali scorrette' (2024) Osservatorio del diritto civile e commerciale,, 114; A Mathur-J Mayer-M Kshirsagar, 'What Makes a Dark Pattern... Dark? Design Attributes, Normative Considerations, and Measurement Methods' (2021) Conference on Human Factors in Computing Systems, 3-5; A Mathur-G Acar-MJ Friedman-E Lucherini-J Mayer-M. Chetty-A Narayan, 'Dark Patterns at Scale: Findings from a Crawl of 11K Shopping Websites' (2019) Proceedings of the ACMon Human Computer Interaction, III, 2.

[107] C Brescia Morra-D Colonnello-M Gargantini-G Sandrelli-G Trovatore, 'La gamification degli investimenti finanziari', 10.

[108] European Commission, *Commission and national authorities take action to protect children from harmful practices in video games*, Brussels, 21 march 2025, available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_25_831

deceiving practice against consumer rights, according to AGCM.[109] It is an unfair practice even if the prize or reward is assigned casually to the consumer.

To qualify gamification as unfair practice can lead to different consequences. First, it poses greater attention to pre-contractual disclosure requirements, not so much for reasons related to data protection or the suitability of insurance products, but for the protection of vulnerable consumers. Second, since these activities could be addressed as unfair practices, art. 18 co. 1 lett. m) of the Italian Consumers Code applies: the competent administrative independent authority (AGCM) has a surveillance duty on the sector, can adopt emergency measures, has powers to inhibit the continuation of the activity, also has the power to make the sanction public in order to inform consumers of the nature of the practice and prevent the negative effects of its possible continuation. Furthermore, consumers who have been harmed by unfair commercial practices may also bring proceedings before the Italian competent ordinary courts to obtain compensation for the damage suffered and a reduction in price or termination of the contract, taking into account the seriousness and nature of the unfair commercial practice, the damage suffered and other relevant circumstances, in accordance with Article 27, co. 15-bis of the Italian Consumer code.

In the financial sector, after the notable cases of Gamestop and Trade Republic AG,[110] new regulations have been adopted. Art. 22 co. 1 law no. 21/2024 modified art. 7-*octies* co. 1-*bis* of the Unified Code of Finance (TUF), which now bans internet advertising of financial products, activities and services, even when considered indirectly, whenever the investment is promoted by an unauthorised person. Moreover, this practice could be addressed as market manipulation, with the related administrative and criminal sanctions.

5. AI-driven HI and Data Protection.

The mentioned contractual hybridisation now raises several critical issues, connected to data protection.

Monitoring technologies deployed by insurers capture a wide range of personal information, from daily habits to precise geolocation, yet the accuracy and meaning of such data are contingent on how devices operate, on user maintenance and on technical limitations. Devices frequently lose data, misclassify activities and fail to reflect contextual factors or external influences that shape human behaviour, so continuous profiling premised on seamless surveillance is factually and technically flawed. The reliance on this imperfect data gathering risks entrenching inequality: individuals who already face barriers to traditional cover, such as those with chronic conditions, are pressured to surrender detailed personal information simply to obtain or

[109] AGCM , 19 october 2020, n. 28368, proc. n. PS11593. On the matter, see A Fachechi, Gli orientamenti dell'Autorità Garante della Concorrenza e del Mercato in materia di pratiche commerciali scorrette (2019-*2020*) Conc. merc., 26-27, 543-554.

[110] On the Gamestop and Trade Republic cases, see C Brescia Morra-D Colonnello-M Gargantini-G Sandrelli-G Trovatore, 'La gamification degli investimenti finanziari', 14-22.

afford insurance, producing a commodification and datafication [111] of vulnerability. For those who lack technological literacy or resources, this dynamic effectively creates a "data for cover" market in which the poorest exchange privacy for access to services, [112] while an opaque surveillance-capitalism model operates behind subscription-style premium reductions. In these HI schemes, data can be seen as part of counter-performance, jointly with the payment of the premium price or discounted subscription price. It is a model that fosters a form of participation surveillance [113] where consent is given under asymmetrical power and informational disadvantage, undermining the voluntariness that data protection law presumes.

Moreover, the gamification techniques embedded in some schemes incentivise behavioural modification in ways that may be discriminatory or coercive, and they open pathways to punitive uses of data: adverse adjustments to premiums, denial of renewal, or the generation of risk scores that follow individuals into other domains. This also affect a constitutional right, such as self-determination in medical treatments.

The cross-sectoral effects are several: scoring[114] resulting from insurer-held telemetry can influence access to other insurance products, employment opportunities and credit, amplifying systemic exclusion.

These factors explain why health data collected by mobile applications, [115] Internet of Things devices and wearable technologies, are firmly regulated under the General Data Protection Regulation (EU) 2016/679 [116] and the emerging framework established by Regulation (EU) 2025/327[117] .

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[111] F Gattillo, 'Assicurare l'opera d'arte digitale: rischi emergenti, polizze cyber e nuove tecnologie' (2024) Arte e diritto, 2, 347 ff.

[112] On the use of personal data as a counter-part performance or an exchange, see C Langhanke-M Schmidt-Kessel, 'Consumer data as consideration', 218; A De Franceschi, 'La circolazione dei dati', 67 ff.; G Resta-V Zeno-Zencovich, 'Volontà e consenso nella fruizione dei servizi in rete', 436 ff.; V Ricciuto, 'La patrimonializzazione dei dati personali, 689.

[113] E Germani-L. Ferola, 'Il wearable computing e gli orizzonti futuri', 75.

[114] P Manes, 'Credit scoring assicurativo, machine learning e profilo di rischio: nuove prospettive', 469-471. The A. notes that, in the area of access to credit, the Italian legislator was prompted by the European legislator and has adopted regulations that allow policymakers to map information on policyholders and, where necessary, query the relevant database in order to protect the credit system. This possibility would lead to improve the risk assessment phase and lower risk exposure, but, at the same time, this would also increase the costs that policymakers have to bear for risk assessment, making this reconfiguration unlikely to be adopted on a large scale of contracts. On the high costs of these products, see also R Santagata, 'Polizze assicurative parametriche (o index-based) e principio indennitario', 169.

[115] I Rapisarda, 'La privacy sanitaria alla prova del mobile ecosystem',187 ff.

[116] The literature on the matter is quite extensive, for this reason see G Finocchiaro, 'Introduzione al Regolamento europeo sulla protezione dei dati' (2017) Nuove leg. civ. comm., 1-18.; id. (eds.), *La protezione dei dati personali in Italia, Regolamento UE n. 2016/679 e d.lgs. 10 agosto 2018, n. 101,* (Il Mulino 2019).

[117] A Morace Pinelli, 'Lo spazio europeo dei dati sanitari (reg. UE n. 327/2025)' (2025) Nuova Giurisprudenza Civile Commentata, IV, 1016-1031; M Faccioli, 'La responsabilità civile per violazione della disciplina per l'utilizzo dei dati sanitari elettronici nell'European Health Data Space (art. 100 Reg. 2025/327/UE)' (2025) Resp. civ. prev., 5; S Faillace, 'I diritti dell'interessato nell'uso primario dei dati sanitari elettronici secondo il nuovo regolamento EHDS' (2025) Contratto e Impresa, 2, 379-401; S Corso, 'Lo spazio europeo dei dati sanitari. Prime riflessioni sul regolamento UE 2025/327' (2025) Nuove Leggi Civili Commentate, 3, 563-603; id., 'Il trattamento dei dati personali in ambito sanitario' (2025) Riv. it. informatica e diritto, 2, 2-20; F Cascini-MA

Insurers seeking to employ these data streams for risk management cannot treat them as ordinary telemetry: instead, their processing must rest on a clearly articulated lawful basis, with explicit, freely given and revocable informed consent where that basis is relied upon and must satisfy the GDPR's core principles of purpose limitation, data minimisation, accuracy and storage limitation. These legal constraints are complemented by the governance structures and technical requirements of Regulation 2025/327. This consent also provides an additional level of information pursuant to Article 119-*bis* of the Italian Private Insurance Code.[118]

The General Data Protection Regulation introduced a clear framework to enable a firm personal data protection towards exogenous incursion but also provided a right to data portability under Article 20,[119] to allow individuals to receive their personal data in a structured, commonly used and machine-readable format and to transmit those data to another controller. This right was conceived to facilitate the circulation of personal information across services and borders, thereby supporting contractual engagement while preserving the data subject's autonomy through consent. Portability under the GDPR, however, is anchored firmly to the individual's control: processing for portability relies on a lawful basis such as consent, and where consent is invoked, it must be specific, informed, freely given and revocable. High standards of confidentiality and security accompany this right, reflecting the GDPR's special protection for health-related information as a peculiar category of personal data.

Recent regulatory developments, notably the European Health Data Space Regulation 2025, partially affect and modify this paradigm.[120] Especially after the Covid-19 pandemic, the EU wants to stress and enforce the centrality of individual data control and the growing societal importance of health data for research, planning and the economy, as well. This is why 2025 EHDS introduces a two-track model. The first track preserves primary use under the familiar consent-based and patient-centred regime: personal health data used for direct care or under explicit consent remain subject to individual authorisation and the associated safeguards. The second track creates a regulated pathway for certain secondary uses of health data without requiring individual consent when processing serves clearly defined objectives of public interest. More precisely, art. 53 EHDS[121] enumerates broad categories of such purposes, including scientific research, public health surveillance and health system planning. A similar provision entered into force in Italy, thanks to the new Italian law on AI applications, art. 8 l. 23 settembre 2025, no. 132.[122]

Arcuri, 'Uso secondario dei dati personali relativi alla salute: panoramica della normativa europea e nazionale' (2024) Diritto dell'informazione e dell'informatica, 6, 837 ff.

[118] F Greco, 'Trasparenza e obblighi comportamentali', 398-400.

[119] On the matter, see M Infantino-D Corapi, 'Portabilità dei dati e scatole nere. Un commento a margine di una recente riforma' (2025) Resp. Civ. Prev., 2, 672 ff.; E Battelli, 'Big data', 1520.

[120] A Morace Pinelli, 'Lo spazio europeo dei dati sanitari', 1018-1019; S Faillace, I diritti dell'interessato', 382; S. Corso, 'Lo spazio europeo dei dati sanitari', 586.

[121] A Morace Pinelli, 'Lo spazio europeo dei dati sanitari', 1020; S Faillace, I diritti dell'interessato', 381, fn. 4.

[122] Legge 23 settembre 2025, no. 132 recante le *Disposizioni e deleghe al Governo in materia di intelligenza artificiale*, published in G.U. 25 september 2025, no. 23.

Nevertheless, art. 24 lett. B) Law no. 132/2025 provides for a regulatory framework and delegates powers to the Italian Government to update regulations in the banking, insurance and payment services sectors in accordance with the regulation.

To the purposes of the analysis of this paper, careful consideration must be placed when comparing the different definitions.

On one end, the GDPR's notion of health data [123] is intentionally broad, covering any data that reveal health status, including derived or inferred indicators. [124] Furthermore, if the provisions of the GDPR are specified considering the DSA, health and wellness products are medical devices regulated according to the functionality of the product, as intended by the manufacturer. The device will be a medical device if the intended functionality of the device has a medical purpose, including, for example: actions such as diagnosis, prevention, monitoring, prediction, prognosis, treatment, mitigation, investigation, replacement or modification relating to a disease, injury or disability, or the anatomy of a physiological or pathological process or condition; the provision of an in vitro examination of samples from the human body; and the control or support of conception.[125]

On the other, the EHDS adopts the terminology of Article 14 to specify the forms of electronic health data that are subject to access and exchange regimes: these are typically records and clinical data held within healthcare systems. Notably, data generated by consumer Internet-of-Things devices, wearables and wellness apps are not automatically encompassed by the EHDS list, unless they are incorporated into clinical records under the secure clinical exchange framework. Interoperability rules permit such an intersection: data from an app or wearable may become part of an electronic health record if accompanied by the regulation's conformity label, if it is integrated through established clinical exchange channels, if a specific consent has been provided.

So, across all applicable instruments, consent for processing data originating from wearables, IoTs and apps still remains central. Although there is marked support within the EU for circulation and secondary use without consent, the use of data for marketing purposes remains unrelated and therefore insurance companies cannot resort to regulatory innovations to justify its processing. Where consent is the lawful basis, it must be explicit, specific, informed and freely revocable; the data subject must be able to withdraw consent at any

[123] I Rapisarda, 'La privacy sanitaria alla prova del mobile ecosystem',195; E. Giusti, 'La sanità elettronica', 85 ff.

[124] Art. 75 of the Italian Privacy code recalls the same notion and the same terms for legal treatment. On the notion provided by art. 75, see D Poletti, 'Commento sub art. 75 D.lgs 196/2003', in CM Bianca - FD Busnelli (eds.), *Commentario al codice privacy 2003* (Cedam 2007) 1205; P Guarda, 'I dati sanitari', in V Cuffaro-R D'Orazio-V Ricciuto (eds.), *I dati personali nel diritto europei* (Giappichelli 2019) 597. Moreover, this notion has been interpreted in a broader sense whenever standard data can have an identification pattern for the user and impact health: on the matter, see Cass. civ., Sez. Un., 27 dicembre 2017, n. 30984, in *Giur. it.*, 2018, 12, c. 263, con nota di A Ricci, 'Protezione dei dati personali-trattamento di dati sensibili e principio di responsabilizzazione'.

[125] A Dennis, 'Healthcare technology regulation in the EU and the UK: from medical devices to intellectual property and advertising', in J. Madir (ed.), *HealthTech: Law and Regulation*, 53-79.

time, and withdrawal must have practical effect, ceasing further tracking or processing.

The above-mentioned centrality of informed consent requires to consider revocability holds even where an individual's insurance coverage or underwriting model relied on continuous data feeds. If consent withdrawal requires to terminate the data flow, the monitoring through IoT and wearable must cease, although the contract is based on a dynamic monitoring of the policyholder.

These regulatory contours produce several consequential implications for insurers and other commercial actors that seek to rely upon app, IoT and wearable-derived health signals in risk management and contractual design.

First, there is an intrinsic restriction on the applicability of a contractual model premised exclusively on continuous tracking. Because individual consent to processing remains protected and revocable, a contract that depends solely on uninterrupted tracking cannot be guaranteed in perpetuity. The policyholder retains the right to withdraw consent, thereby interrupting the data flow upon which the contractual performance may have been predicated. This feature constrains the space for purely tracking-based contractual formulations even where portability and data exchange facilitate initial contractualization. This is why insurance analysis considers legislation and data protection as the first barriers for this new insurance reconfiguration.[126]

Second, if considered viable as a contract depending on the wearable and IoT data processing, withdrawal of consent to monitoring cannot lawfully produce automatic termination of an insurance contract where such termination would coerce the insured into sustaining monitoring against their will. To treat revocation as a ground for contract dissolution would instantiate a de facto compulsion to consent, incompatible with the GDPR's insistence on voluntariness and with fundamental principles of contract law that prohibit unlawful tying of a right to the surrender of autonomy. Accordingly, a tying relationship[127] between consent to tracking and the insurance contract may exist in relation to privileges, discounts or tailored terms, but the exercise of the right to withdraw consent shouldn't extinguish the policyholder insurance coverage. Therefore, ultimately it should be noted that the practice of tying is not prohibited per se but it is permitted only in cases where the service is offered either for a fee or free of charge in exchange for consent to processing. Furthermore, the paid service and the service accessed by consenting to the transfer of data must be equivalent. Finally, it must be possible for the service covered by the contract to be provided by the data controller without the need to consent to further or additional uses of the data.

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[126] D Neumann-V. Tiberius-F. Biendarra, 'Adopting wearables to customize health insurance contributions: a ranking-type Delphi' (2022) Medical Informatics and Decision Making, 22, 112; A. Vigil Iduate, 'InsurTech', 176.

[127] S Thobani, 'Operazioni di tying e libertà del consenso' (2019) Giur. it., 533 ff.; id., 'Processing Personal Data and the Role of Consent' (2020) European Journal of Privacy Law and Technologies, 93-104, in particular 96; id., 'Il mercato dei dati personali: tra tutela dell'interessato e tutela dell'utente', 147; id., 'Il consenso nella regolazione della circolazione dei dati (2025) Persona e Mercato, 2, 469-486; V Bachelet, *Il consenso oltre il consenso,* 51 ff.; G Versaci, *La contrattualizzazione dei dati personali dei consumatori* (ESI 2020) 69 ff.; I Rapisarda, 'La privacy sanitaria alla prova del mobile ecosystem', 201.

Third, if monitoring functions as an index correlating to the level of coverage, premium or additional benefits, the decision for cessation of monitoring legitimately gives rise to contractual adjustments rather than automatic termination. The reasonable legal architecture is one of renegotiation or the application of a default or standard tariff in place of monitoring-linked advantages. Such an approach preserves the insured policyholder's autonomy while allowing insurers and policymakers to recalibrate risk allocation and pricing considering diminished information. Only by taking this path, it is possible to prevent the risk or the predicted risk for diminished protection for individuals who might otherwise be uninsurable or charged prohibitive rates, notably those with chronic conditions, while maintaining the high standards of privacy and data protection demanded by EU law.

It should also be considered that individual scoring is a further cause for concern for European legislators, which in the GDPR has resulted in the obligation to explain creditworthiness decisions when they are based on algorithms that are not comprehensible to the individual.[128] The aim is to prevent the "black box" effects of intelligent predictive systems. This seems to refer exclusively to access to credit and not to insurance coverage; nevertheless, a strengthening of the information obligation in the pre-contractual phase and during the execution of the contract can be recovered with the suitability rule,[129] under MiFID II EU Directive 65/2014, Insurance Distribution Directive 97/2016 and art. 183 co. 2 of the Italian Private Insurance Code.[130]

However, the European Union's efforts to regulate new technologies applications continue. Considering the ongoing drafting of the Digital Fairness Act (DFA), the European Commission recently published the findings of the Digital Fairness Fitness Check. The DFA would aim to fill the regulatory gaps left by earlier landmark digital laws, such as the Digital Services Act and Digital Markets Act, as well as structural consumer protection frameworks and safeguards, including the Unfair Commercial Practices Directive, Consumer Rights Directive, and Unfair Contract Terms Directive. Namely, the DFB would target business-to-consumer (B2C) practices across interface design, subscription management, personalised pricing and marketing strategies, and influencer-led content in digital environments. According to the mentioned Fitness Check, a wide range of harmful online practices has been identified, including "Sneak Into Basket", confirm shaming, forced continuity, hidden costs, unknowingly granting permissions, bait and switch, misdirection, disguised ads, shadow banning, buried data sharing, and most of all subscription with dynamic pricing, particularly when algorithmic or behavioural design methods disproportionately impact vulnerable consumers, including minors, older persons, and individuals with lower education levels. It is worth mentioning that the EU Legislative process is still in the making, and by 2027 AI

[128] P Manes, 'Credit scoring assicurativo, machine learning e profilo di rischio: nuove prospettive' 481.
[129] S Landini, 'Appropriatezza, adeguatezza e meritevolezza dei contratti di assicurazione', 39-58.
[130] A Zurlo, 'L'oggetto del contratto di assicurazione', 166.

driven contracts with subscription with dynamic pricing could be heavily affected and even restricted by new consumer-protective policies.

So, the various European disciplines engaged with algorithmic contracting and parametric insurance increasingly converge on three core priorities: strengthening transparency and information duties, widening the scope of the suitability rule, and recognising informed consent as the decisive authorisation for AI-driven contractual mechanisms.

The recent Italian legislative efforts exemplify this trajectory and add operative detail. Notably, art. 20 Law 16 December 2024, no. 193[131] addresses market competition in automotive insurance by prohibiting contractual clauses that prevent the policyholder from uninstalling electronic mechanisms upon contract expiry. This provision operationalises transparency and consumer autonomy, limiting residual vendor lock-in and supporting post-contract mobility. The policyholder can have access to the gathered data, and the policymaker can use the gathered data to calculate the premium and even to continue or discontinue the insurance coverage. Whenever the insurance company wants to terminate the contract because of the data, then the policymaker needs to compensate the policyholder, with an amount of 20 euros.

6. Conclusion.

In contexts of poverty affecting millions of Italians and shaping medical decision making, the diffusion of eHealth and mHealth represents a potential turning point for access to care and health management. Yet, this technological promise is shadowed by significant risks arising from the convergence of parametric insurance, medical practice and pre-existing vulnerability, therefore «technological progress has merely provided us with more efficient means for going backwards».[132]

At a time when the practical force of informed consent and individual autonomy appears increasingly eroded [133] by automated processes and datafication, normative references nonetheless reassert the centrality of information and consent as legal and ethical anchors. Even where regulatory regimes open avenues for the circulation of data without explicit consent, including data directly related or indirectly related to health, the principles of transparency and self-determination must be actively safeguarded.

The above-mentioned imperative holds irrespective of the technical complexity of intelligent systems, the multilayered and evolving nature of the regulatory framework, and the demonstrable capacity of algorithmic tools to influence individual behaviour. Protecting autonomy cannot be traded away in exchange for convenience, discounts or premium subscriptions embedded in health-insurance contracts. Crucially, such contracts must be preceded by the

[131] On the new relevant legislation for the automotive sector, see M Infantino-D Porrini, op. cit., 672. On the impact of automation in the automotive sector, see S Pellegatta, 'Automazione nel settore automotive: profili di responsabilità civile' (2019) Contratto e impresa, 4, 1418-1446.
[132] A Huxley, *Ends and means: An Inquiry into the Nature of Ideals*, (Harper & Brothers 1937).
[133] S Thobani, 'Processing Personal Data and the Role of Consent', (2020) EJPLT 93-104.

execution of the information obligation, capable of satisfying the suitability rule, the data protection regulation and the consumers' rights policy. Especially considering transparency and informed consent, the short duration of the contract and the new guarantees introduced by Law no 193/2024 for the automotive insurance sector, including the right of access and control of tracked information, as well as the right not to use the device for monitoring, constitute a viable path also in the field of AI-driven health insurance, taking into account the additional impact that such contracts may have on the fundamental right to self-determination in healthcare. Nevertheless, informed consent as a tool for protecting informational self-determination is significantly undermined if we consider that dense information notices are bypassed by consents given for the sole purpose of accessing the service more quickly and if we consider how, even with an awareness of the importance of one's own data, there is a lack of tools to ensure the authenticity of the will expressed.[134]

According to the analysis conducted, HI contracts may respond to current medical poverty and to recent technical developments, but their validity depends on specific structural conditions. Surveillance-enabled features must not eliminate the aleatory element of risk that underpins insurance; parametric instruments must protect the indemnity principle and must not be repurposed into index-based products; parametric coverage must not prevent a static reconstruction of the original risk profile; the continuous surveillance-driven contract could broaden the insurance coverage, especially where the National system does not allow for immediate and effective care; the Premium narrative[135] linked to these products cannot lead to terminate the contract whenever the policyholder does not want to be monitored, since a standard base contract should always be available, except for legally non-insurable risks.

[134] On the consent dilemma, see S Thobani, 'Il consenso nella regolazione sulla circolazione dei dati', (2025) in *Pers. merc.*, 473.
[135] A Troiano, 'Wearables and Personal Health Data', (2017) 82 Brook. L. Rev. 1750-1751.