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TECHNOLOGY TRANSFER MODELS IN E-HEALTH: HELIX MODELS AND INNOVATIVE PATHWAYS*

di
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1. *Elevating healthcare: e-health and patient empowerment*

This paper offers an in-depth exploration of technology transfer models in e-health, focusing on digital therapeutics, i.e. digital technologies revolutionizing medical therapies. The surge in patent applications for MedTech, pharmaceuticals, and biotechnologies across Europe in 2022 underscores the presence of dynamic e-health innovation ecosystems. These environments see collaboration among universities, industry, public entities, and patients[1]. MedTech comprises 8.1% of the total applications, ranking second among European patent filings at 15,683[2]. While the United States led digital health investments in 2022, European e-health investments halved compared to 2021. Nevertheless, nations like Germany, France, and Italy exhibit commendable models of technology transfer in healthcare.

According to data from the Ministry of Business and Made in Italy (2022), Italy's medical device sector generates a market worth €16.2 billion through exports and the domestic market. The sector comprises 4,546 companies, employing 112,534 individuals, including 134 startups and 164 innovative SMEs, totaling 298 entities[3]. Within this landscape, e-health significantly en-

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[1] D. Scarrà, A. Piccaluga, *The impact of technology transfer and knowledge spillover from Big Science: a literature review*, in «Technovation», 116 (2022), 102165.

[2] European Commission, Public Health (2023), <https://ec.europa.eu/health/ehealth/home_en>; European Patent Office, <https://www.epo.org/en/news-events/press-centre/press-release/2023/403558>.

[3] Ministero delle Imprese e del Made in Italy, <https://www.mimit.gov.it/it>. ISTAT, <https://www.istat.it/it/files//2023/03/CommissioneAttivita-produttive6marzo2023.pdf>.

hances medical care efficiency and accessibility. It achieves this by enabling remote access to medical records and fostering more inclusive health services for citizens. Introduced by the World Health Organization (WHO), e-health denotes ICT utilization in healthcare for enhancing patient care[4]. Also termed Digital Health, e-health encompasses wearable devices, medical informatics, and personalized medicine[5]. Its specific goals include improving patient health, enhancing healthcare quality and accessibility, and ensuring efficient, inclusive, widespread, safe, and accessible tools and services.

E-health centers on the seamless flow of data – from patients to devices, healthcare providers, systems, and back[6]. Key features include connectivity, fostering communication among different systems[7], efficient care processes, quality healthcare, and wearable devices for continuous health monitoring (like smartwatches and heart rate trackers). It involves regulated intra-company health data management, ensuring standardized communication protocols[8] and equitable access to digital networks and infrastructures[9]. Moreover, it transforms clinical studies by improving patient experience, accelerating data collection and making more reliable data analysis.

Implementing the patient empowerment model shifts the healthcare provider-patient relationship. This model places patients at the center, actively engaging them in managing their healthcare journey. Patient empowerment encourages proactive patient involvement in health decisions[10]. Patients

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[4] Parlamento Europeo (2023), L'agenda digitale europea, <https://www.europarl.europa.eu/factsheets/it/sheet/64/un-agenda-digitale-europea>. European Commission (2012). Le tecnologie abilitanti fondamentali: un ponte per la crescita e per l'occupazione, <https://ec.europa.eu/commission/presscorner/detail/it/MEMO_12_484>. European Commission (2018). Shaping Europe's digital future. <https://ec.europa.eu/health/ehealth/home_en>.

[5] G. Eysenbach, *What is e-health?*, in «Journal of medical Internet research», 3, 2 (2001), e833; E. Vayena, T. Haeusermann, A. Adjekum, A. Blasimme, *Digital health: meeting the ethical and policy challenges*, in «Swiss medical weekly», 148 (2018), w14571.

[6] S.K. Bell, T. Delbanco, J.G. Elmore, P.S. Fitzgerald, A. Fossa, K. Harcourt, C.M. DesRoches, *Frequency and types of patient-reported errors in electronic health record ambulatory care notes*, in «JAMA network open», 3, 6 (2020). e205867-e205867.

[7] D. Kiel, J.M., Müller, C. Arnold, K.I. Voigt, *Sustainable industrial value creation: Benefits and challenges of industry 4.0*, in «*International Journal of Innovation Management*», 21, 08 (2017), 1740015.

[8] S. Vaidya, P. Ambad, S. Bhosle, *Industry 4.0-a glimpse*, in «Procedia Manufacturing», 20 (2018), pp. 233-238.

[9] T.D. Oesterreich, F. Teuteberg, *Understanding the implications of digitization and automation in the context of Industry 4.0: A triangulation approach and elements of a research agenda for the construction industry*, in «Computers in industry», 83 (2016), pp. 121-139.

[10] L. Náfrádi, K. Nakamoto, M. Csabai, O. Papp-Zipernovszky, P.J. Schulz, *An empirical test of the Health Empowerment Model: Does patient empowerment moderate the effect of health literacy on health status?*, in «Patient Education and Counseling», 101, 3 (2018), pp. 511-

leverage digital solutions and mobile communications to monitor vital signs and track progress towards health goals. Healthcare professionals act as facilitators, working alongside patients to define therapy. The patient-doctor relationship evolves into a partnership, with patients actively contributing to treatment decisions. Digital tools like telemedicine, teleassistance and online appointment bookings enhance this relationship.

The profound impact of e-health technologies on healthcare quality and diagnostic and therapeutic processes motivates advanced countries to reinforce health-related technological transfer processes. This includes fostering collaborations between research and companies in MedTech, pharmaceuticals, and biotech.

Beginning with the patient empowerment model, subsequent sections delve into various aspects: e-health innovations and digital therapeutics range, actors involved in technology transfer programs, health innovation patterns following the quadruple helix model, and technology transfer models in e-health based on licenses and patents. Additionally, a brief analysis of patent data in Medical Technologies is presented.

2. *E-health innovations in patient-centric services*

As per the European Commission (2012), enabling technologies or next-generation technologies are solutions characterized by their high knowledge and R&D intensity, rapid innovation cycles requiring substantial investment, and the creation of highly skilled jobs. The advent of Industry 4.0 has ushered in a transformation in healthcare services through the integration of cutting-edge digital technologies, such as artificial intelligence and the Internet of Things (IoT), to produce smart and integrated medical devices, data-driven healthcare systems, and innovative patient-centric applications. Integration primarily focuses on interconnecting devices and machines using standard technologies. The deployment of next-generation technologies like artificial intelligence (AI), Internet of Things (IoT), robotics, among others, in e-health – spanning digital therapy, telemedicine, electronic medical records, blockchain, big data, cloud, and 3D printing – heralds significant shifts in healthcare service delivery[11].

517; M. Marimuthu, S.K. Taghizadeh, J. Kandampully, *Understanding the process of patient empowerment and their well-being in the context of outpatient services*, in «The TQM Journal», 34, 6 (2022), pp. 1713-1731.

[11] D. Kiel, J.M. Müller, C. Arnold, K.I. Voigt, *Sustainable industrial value creation: Benefits and challenges of industry 4.0*, in «International Journal of Innovation Management», 21, 08

The integration and interconnection of these technologies throughout the service phases foster improvements in care efficiency, treatment accessibility, real-time monitoring, information management, and bolster internal and external communication realms. However, the advent of next-generation technologies also raises relevant ethical concerns regarding the responsible handling of sensitive patient information, privacy protection, and regulation of patient-physician relationships through technology[12].

Artificial Intelligence (AI) has gained widespread traction in the healthcare sector due to its precision in specific clinical contexts, diagnostic accuracy achieved through deep learning, and the enhanced productivity of machine learning-based systems. AI finds extensive application in analyzing radiological images to identify tumors, detect diabetic retinopathy, predict cardiovascular diseases using dedicated algorithms, and expedite drug discovery. Furthermore, AI significantly impacts chronic patient care and aids diagnoses and decisions in genomics, imaging, precision medicine, among others[13]. *Machine Learning*, a subset of AI employing data-based algorithms and techniques, initially presented as clinical decision support tools. Recently, the availability of biomedical big data and digital phenotyping processes has facilitated expert systems providing rapid, relevant information to physicians. *Deep learning*, a specialized branch of Machine Learning, tackles intricate issues using artificial neural networks.

Robotics involves AI-driven machine systems proficient in executing precise, repetitive, and programmable activities, making autonomous decisions within predefined sequences. Advanced surgical robots enable intricate procedures with minimal invasiveness, reducing patient risks and enhancing clinical outcomes.

Telemedicine facilitates healthcare provision through digital systems, connecting patients, doctors, and healthcare professionals irrespective of geographical boundaries[14]. Patients' health status and subsequent stages of diag-

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(2017), 1740015; S. Vaidya, P. Ambad, S. Bhosle, *Industry 4.0-a glimpse*, in «Procedia Manufacturing», 20 (2018), pp. 233-238; T. D. Oesterreich, F. Teuteberg, *Understanding the implications of digitization and automation in the context of Industry 4.0: A triangulation approach and elements of a research agenda for the construction industry*, in «Computers in Industry», 83 (2016), pp. 121-139.

[12] C. Innocente, L. Ulrich, S. Moos, E. Vezzetti, *Augmented Reality: Mapping Methods and Tools for Enhancing the Human Role in Healthcare HMI*, in «Applied Sciences», 12, 9 (2022), 4295.

[13] A.S. Ahuja, *The impact of artificial intelligence in medicine on the future role of the physician*, in «PeerJ», 7 (2019), e7702.

[14] J. Aguirre-Sosa, J.A. Vargas-Merino, *Telemedicine Management: Approaches and Perspectives - A Review of the Scientific Literature of the Last 10 Years*, in «Behavioral Sci-

nosis, treatment, and monitoring are transmitted in the form of images, texts, and sounds. Telemedicine fosters ongoing patient-doctor relationships, particularly valuable in secondary prevention, disease diagnosis based on symptoms, patient care and therapy monitoring, rehabilitation at home, and vital signs monitoring. Specialist telemedicine tailors specific digital services within particular medical fields for physician-patient interactions (tele-visits), remote consultations between physicians (tele-consultations), and collaboration among healthcare professionals (tele-cooperation). Tele-health addresses primary care concerning chronic disease diagnosis, monitoring, and management. Tele-assistance encompasses emergency services and support for elderly and vulnerable individuals at home.

The *Electronic Medical Record* (EMR) is an electronic repository containing a patient's clinical and health data, facilitating real-time access and sharing among healthcare professionals to comprehend patient health status and treatment progress[15]. Notably, the Electronic Health Record (EHR), established by Regions or Autonomous Provinces with patient approval, encompasses a broader array of clinical data from hospitals, clinics, and medical practices. It includes identifying information, tests, reports, emergency room data, and patient health management details. The EHR allows authorized facilities under the National Health System to access patient information. The EHR and EMR act as supportive tools for defining clinical pathways or in emergency interventions when direct patient information isn't accessible. They facilitate therapy monitoring and support organizational activities, including outpatient bookings and prescriptions. At an aggregated level, this data aids preventive medicine, health education, service evaluations, expenditure planning, healthcare personnel scheduling, and causal relationship hypothesis testing. *Blockchain*, leveraging cryptography and peer-to-peer control, ensures secure data collection and tracking, notably in verifying digital patient identity, decentralized medical prescription tracking, and monitoring therapy compliance and medical device functionality.

Big Data in e-health refers to the systematic collection and automatic processing of vast data volumes for analysis, sharing, and management in the

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ences», 13, 3 (2023), p. 255; J. Portnoy, M. Waller, T. Elliott, *Telemedicine in the era of COVID-19*, in «The Journal of Allergy and Clinical Immunology: In Practice», 8, 5 (2020), pp. 1489-1491.

[15] W.K. Yang, J.S. Chen, Y.S. Chen, *An electronic medical record management system based on smart contracts*, in IEEE, *2019 Twelfth International Conference on Ubi-Media Computing (Ubi-Media)*, (2019), pp. 220-223; N. Mathai, M.F. Shiratudin, F. Sohel, *Electronic health record management: expectations, issues, and challenges*, in «Journal of Health & Medical Informatics», 8, 3 (2017), pp. 1-5.

healthcare sector. It encompasses clinical data, reports from analysis laboratories, check-ups, and monitoring equipment, providing critical insights to support decision-making. It also drives healthcare system enhancements through data-driven innovations, precise treatment definition, accurate diagnoses, and proactive interventions. Big data is instrumental in understanding disease evolution, timely interventions, pathology management, and predictive modeling. At an aggregate level, it aids in identifying healthcare service value and disvalue areas, optimizing resource allocation, and facilitating the shift from reactive to preventive medicine within the National Health System. Dematerialized data from EHRs and ESFs enable value creation through personalized care, decision-making models based on comprehensive patient life information and connectivity between EHR databases for prevention strategies, and planning[16]. *Cloud Computing* in e-health centralizes healthcare company data and information within digitalized systems and infrastructures provided by select service providers. It primarily encompasses network-based data storage, transmission, front-end interaction architecture, and back-end assistance and operational services.

3D printing technology finds extensive usage in the healthcare sector, spanning dental, orthopedic, and acoustic device production, printing surgical instruments (e.g., hemostatic forceps, scissors), and even 3D printing tissues, organs, and bones. Recognized by hospitals, life science companies, and scientific societies for its potential, 3D printing significantly aids treatment personalization, accelerates product development, and establishes public hubs dedicated to shared 3D printing between healthcare facilities. It transforms healthcare organization and delivery models through product and process innovations[17]. The innovation model varies from accelerating device development and prototyping by medical device manufacturers using 3D technology to producing goods/services at the point of use, thereby reducing production costs and delivery times. Hospitals and medical device companies leverage private 3D printing hubs to produce certain devices in-house. Moreover, 3D printing drives product development or service quality enhancement, such as reproducing 3D systems and organs for complex surgical interventions. Finally, the disruptive model redefines the business model by combining product and process innovation, focusing on mass customization at

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[17] Deloitte, *Il futuro dell'Health care: Potenzialità, impatti e modelli del 3D printing in ambito sanitario*, 2019. <https://www2.deloitte.com/content/dam/Deloitte/it/Documents/life-sciences-healthcare/Il_futuro_dell_Health_Care_Deloitte_Deloitte%20Italia.pdf>.

the point of use for personalized products close to the place of use, like implantable prostheses[18].

3. *Technology transfer and innovative pathways in e-health*

Transfer (TT) in e-Health involves the conversion of research outcomes and scientific breakthroughs in the medical and diagnostic realms into innovative solutions to enhance individuals' health, care, and well-being. It's a process bridging scientific research conducted at universities and research centers with industry to capitalize on and commercially exploit research outcomes[19]. Technology transfer occurs through licensing agreements for patents, know-how, or copyrights, encompassing provisions for product sales, licensing of intangible assets, or transfer of ownership rights (EEC regulation 772/2004)[20].

Within the health and medical sector, technology transfer engages universities, public research bodies (EPR), and scientific institutes for hospitalization and treatment (IRCCS). Its focus spans the development of new medical devices, the introduction of innovative therapies, and the marketing of advanced diagnostic tools and digital solutions that augment healthcare services and patient care.

Early investigations into TT in the medical sphere underscored the significance of collaborations among research institutions, companies, and healthcare facilities for transitioning research into clinical practice. TT has been defined as the process through which scientific research outcomes are transferred to businesses, marketed as innovative health-related goods and services, and employed by healthcare professionals in clinical settings[21]. Some

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[18] C. Christensen, M. E. Raynor, R. McDonald, *Disruptive innovation*, in «Harvard Business Review», December (2015), pp. 1-11, <https://www.innosight.com/wp-content/uploads/2018/01/Innosight_HBR_What-is-Disruptive-Innovation.pdf>; C. Christensen, A. Waldeck, R. Fogg, *How disruptive innovation can finally revolutionize healthcare. A Plan for Incumbents and Start-Ups to Build a Future of Better Health and Lower Costs*, in «Industry Horizons» (2017), <https://www.christenseninstitute.org/wp-content/uploads/2017/05/How-Disruption-Can-Finally-Revolutionize-Healthcare-final.pdf>; V. Sounderajah, V. Patel, L. Varatharajan, L. Harling, P. Normahani, J. Symons, H. Ashrafian, *Are disruptive innovations recognised in the healthcare literature? A systematic review*, in «BMJ innovations», 7, 1 (2021).

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[20] European Commission, Competence Centre on Technology Transfer, 2023 <https://ec.europa.eu/knowledge4policy/technology-transfer_en>.

[21] L. Fitzgerald, E. Ferlie, M. Wood, C. Hawkins, *Interlocking interactions, the diffusion of innovations in health care*, in «Human Relations», 55, 12 (2002), pp. 1429-1449.

scholars[22] emphasize the role of the organizational context – where scientific knowledge develops and clinical practices apply – in driving technological transfer in medicine. These studies expand the scope of stakeholders involved in TT to encompass patients, investors, and healthcare providers within the e-health ecosystem.

More recently, literature on health management has provided nuanced definitions of technology transfer to capture the complexity and dynamism of the phenomenon, particularly with the spread of next-generation digital technologies. Technology transfer is now seen as the strategic process that translates scientific discoveries and technological innovations into tangible benefits for patients[23].

It represents a dynamic process integrating scientific discoveries and new technologies into clinical practice, enhancing patient care, and fostering the overall advancement of the healthcare sector. TT serves as a strategic link connecting academic research to practical healthcare applications, aiming to refine patient diagnoses, treatments, and clinical outcomes. Specifically, TT embodies a connected continuum marked by collaboration among researchers, industry, and health professionals, facilitating the flow of innovations from experimental to clinical phases, hastening the progression of medicine and health[24]. In TT, the focus lies in the process of adopting, diffusing, and integrating new medical technologies into clinical practices and healthcare systems to enhance care quality, efficiency, and patient accessibility. Key aspects include the interdisciplinary nature between research and clinical practice, the multidimensional innovation in medical applications, and the patient's well-being – centered on health enhancement and improved care quality, stemming from new drugs, therapies, and equipment derived from the economic exploitation of biomedical research outcomes[25].

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[22] L.S. Welch, D. Russell, D. Weinstock, E. Betit, *Best practices for health and safety technology transfer in construction*, in «American journal of industrial medicine», 58, 8 (2015), pp. 849-857.

[23] R.S. Eisenberg, R. Cook-Deegan, *Universities: the fallen angels of Bayh-Dole?*, in «*Daedalus*», 147, 4 (2018), pp. 76-89.

[24] K. Chen, C. Zhang, Z. Feng, Y. Zhang, L. Ning, *Technology transfer systems and modes of national research institutes: Evidence from the Chinese academy of sciences*, in «Research Policy», 51, 3 (2022), 104471.

[25] J.D. Miller, M.S. Ackerman, B. Laspra, J. Huffaker, *The acquisition of health and science information in the 21st century*, in «The Information Society», 37, 2 (2020), pp. 82-98.

4. *Actors and structures involved in the e-health technology transfer*

Technology transfer involves two distinct legal entities and encompasses preliminary phases including technology assessment, validation of strategic information for industrial activity, acquisition, and application of validated information within production processes. The aim of technology transfer is linked to economic exploitation and operates within a specific timeframe. Research institutions such as universities and research centers contribute research outcomes, while the e-health industry engages in pre-competitive development through established or new companies, including start-ups, academic ventures, and entrepreneurial spin-offs. Various actors participate in technology transfer, classified into three primary groups: donors, recipients, and interface structures.

Donors, such as universities, R&D laboratories, and the national research council (CNR), are the holders of technology, while recipients, encompassing spin-offs, start-ups, SMEs, and large enterprises[26], are the technology users. Relationships between donors and Technology Transfer Offices (TTOs) are shaped by collaborations involving universities, corporations, and public bodies (top-down) as well as independent collaborations initiated by researchers and their affiliated universities (bottom-up), often facilitated through networks and EU programs.

Interface structures acting between donors and recipients include Technology Transfer Offices (TTOs), Industrial Liaison Offices (ILOs), technological incubators, accelerators, Science and Technology Parks (STPs), Engineering Research Centers (ERCs), and Digital Business Points (DBPs). These structures serve as conduits between universities and the external ecosystem, fostering skill development, knowledge exchange, engaging local businesses, gaining insights from production systems, and promoting TTO-related collaborations while organizing public engagement activities within the community.

Incubators foster new business creation, supporting start-ups in developing innovative technologies and products through strategic and welfare initiatives[27]. They vary in support nature, incubation type (full-time or part-

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[26] D. Iacobucci, A. Micozzi, A. Piccaluga, *An empirical analysis of the relationship between university investments in Technology Transfer Offices and academic spin-offs*, in «R&D Management», 51, 1 (2021), pp. 3-23; M. Muhos, M. Saarela, D. Foit, L. Rasochova, *Management priorities of digital health service start-ups in California*, in «International Entrepreneurship and Management Journal», 15 (2019), pp. 43-62.

[27] S.M. Hackett, D.M. Dilts, *A systematic review of business incubation research*, in «The Journal of Technology Transfer» 29, 1 (2004), pp. 55-82; H. Al-Mubaraki, M. Busler, *Business*

time), location (urban/suburban or rural areas), sector specialization, program specifics, facility size, and participant composition (universities, nonprofits, public entities). Accelerators target companies with a minimum viable product (MVP), offering participation in company equity in exchange. These entities provide selective screening and intensive acceleration programs in addition to services typical of incubators, including seed funding.

Science and Technology Parks (STPs) comprise clusters of small and medium-sized enterprises (SMEs) concentrated within specific territorial zones, fostering strong ties with universities. Leveraging human capital, shared regulations, intellectual property rights, and collaboration with research centers, these parks enable hosted companies to compete with technologically advanced corporations. Engineering Research Centers (ERCs) operate as interdisciplinary units addressing transient crises and enhancing competitiveness in global markets through industry-university partnerships. Digital Enterprise Points (DEPs) are established within Italian Chambers of Commerce as part of the national Enterprise 4.0 Network, offering orientation services on enabling technologies, training, information on 4.0 technologies, digitalization processes, and vouchers to SMEs.

5. *Helix models and health tech innovations*

The synergy among research, industry, and public entities is seen as pivotal for fostering innovation in the medical field, aligning with the quadruple helix model. Building upon the triple helix model[28], innovation policies introduced the public sector as a vital third actor supporting collaborative inno-

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Incubators models of the USA and UK: a SWOT analysis, in «World Journal of Enterprenuership, Management and Sustainable Development» (2010), pp. 335-354; S. Mian, W. Lamine, A. Fayolle, *Technology Business Incubation: An overview of the state of knowledge*, in «Technovation», 50 (2016), pp. 1-12; M. Lukeš, M.C. Longo, J. Zouhar, *Do business incubators really enhance entrepreneurial growth? Evidence from a large sample of innovative Italian start-ups*, in «Technovation», 82 (2019), pp. 25-34; K. Sohail, M. Belitski, L.C. Christiansen, *Developing business incubation process frameworks: A systematic literature review*, in «Journal of Business Research», 162 (2023), 113902.

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vative strategies between universities and industries. At the core of the Triple Helix model lie the interactions and reciprocal influences among the University, Industry, and Public Sector. The university serves as the primary catalyst for fostering entrepreneurship and managerial skill development, closely intertwined with the other actors to establish shared organizational objectives and synergies. The industry, as the second helix, is tasked with identifying and funding promising ideas from their inception, translating them into innovations, and fostering internal research. The public sector, representing the third helix, shapes regulatory conditions and infrastructure to facilitate the convergence of research and industry. Within this model, technology transfer enables universities and research centers to access human resources and capital, particularly when faced with cuts in public funding. Technology transfer, via patents and research collaborations, complements basic research. The university assumes a hybrid role between research and its societal mission, cultivating an environment conducive to innovation and entrepreneurship[29], providing incubators and technology transfer offices (TTOs) to support the creation of university spin-offs, innovative start-ups, and entrepreneurship training programs.

The Quadruple Helix model identifies four key stakeholders in the innovation system: University, Industry, Public Sector, and Society[30]. Acknowledging the significance of active citizen participation in driving innovation and value co-creation processes, especially in the realm of smart technologies facilitating bidirectional knowledge exchanges and open collaboration systems is crucial for regional innovation policies[31]. Relationships in the

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[29] L. Compagnucci, F. Spigarelli, *The Third Mission of the university: A systematic literature review on potentials and constraints*, in «Technological Forecasting and Social Change», 161 (2020), 120284; C. Gunasekara, *Reframing the role of universities in the development of regional innovation systems*, in «The Journal of technology transfer», 31 (2006), pp. 101-113; M. Guerrero, D. Urbano, *Academics' start-up intentions and knowledge filters: An individual perspective of the knowledge spillover theory of entrepreneurship*, in «Small Business Economics», 43 (2014), pp. 57-74.

[30] E.G. Carayannis, D.F. Campbell, *Triple Helix, Quadruple Helix and Quintuple Helix and how do knowledge, innovation and the environment relate to each other?: a proposed framework for a trans-disciplinary analysis of sustainable development and social ecology*, in «International Journal of Social Ecology and Sustainable Development (IJSESD)», 1, 1 (2010), pp. 41-69; E. G. Carayannis, E. Grigoroudis, D.F. Campbell, D. Meissner, D. Stamati, *The ecosystem as helix: an exploratory theory-building study of regional co-opetitive entrepreneurial ecosystems as quadruple/quintuple helix innovation models*, in «R&D Management», 48, 1 (2018), pp. 148-162.

[31] H.W. Chesbrough, *Open innovation: The new imperative for creating and profiting from technology*, Boston, Harvard Business Press, 2006; A. Pundziene, R. Sermontyte-Baniule, J. Rialp-Criado, H. Chesbrough, *Indirect effect of open innovation on clinical and economic value*

Quadruple Helix model are bidirectional, multi-level, and involve roles that interchange between holders and recipients.

Within the healthcare sector, institutions not only promote innovation but also regulate and evaluate advanced technologies for effective patient care, ensuring prompt, safe, and compliant integration within technical and economic constraints of the healthcare system. E-health technologies must deliver tangible health benefits, ensure safety, and meet efficiency criteria. The path of innovation in the medical field involves three simultaneous processes: the innovation process leading to technological solutions, the regulatory process, and the evaluation process influenced by social, economic, and ethical factors[32].

In these processes, three key actor categories – patients, doctors, and technology producers – play pivotal roles. The innovation process generates e-health technology by amalgamating intellectual, relational, and economic capital, fostering strong interactions among physicians (researchers), patients, and technology producers, within the confines of time and research methodology. The cyclical nature of this process involves continuous interaction among patients, doctors, and manufacturers across basic research, clinical trials, and scientific dissemination channels. However, the project faces financial risks due to technical, regulatory, social, and ethical challenges.

The regulatory process addresses safety concerns and incremental healthcare benefits compared to existing options. It follows codified procedures and culminates in regulatory decisions on the methods for marketing innovative products and determining sales prices. Evaluation in industrialized nations is delegated to agencies that adhere to Health Technology Assessment (HTA) principles. HTA encompasses multidisciplinary evaluations focusing on clinical, economic, social, and ethical aspects of health technology use in a systematic, impartial, and transparent manner[33].

Its aim is to shape safe, effective, patient-centered health policies for higher-value benefits. Evaluation elements include clinical aspects (health problems, technology use, safety, effectiveness) and non-clinical facets (costs, ethics, organization, social and legal aspects). HTA reports offer pre-

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creation in digital healthcare: A comparative study of European countries, in «Journal of Business Research», 159 (2023), 113701.

[32] *Ricerca scientifica e trasferimento tecnologico. Generazione, valorizzazione e sfruttamento della conoscenza nel settore biomedico*, cur. A. Cicchetti, F.E. Leone, D. Mascia, 28, Milano, Franco Angeli, 2007.

[33] Ministero della Salute, (2023). Il processo di Health Technology Assessment (HTA), <https://www.salute.gov.it/portale/dispositiviMedici/dettaglioContenutiDispositiviMedici.jsp?lingua=italiano&id=5199&area=dispositivi-medici&menu=tecnologie>.

liminary recommendations - use or non-use, conditional use, or use in research - for National Health Service (NHS).

Furthermore, the Control Room may propose:

- Non-adoption of technology due to unproven effectiveness or unassessed safety.
- Benefits of integrating technology into healthcare processes.
- Conditional use subject to further research to generate scientific evidence.
- Possible introduction into the NHS, contingent on the collection of real effectiveness and cost data, and subsequent approval.

As part of health technology assessment, Horizon Scanning aims to proactively identify potentially impactful health technologies in early development. The evaluation outcome determines the extent of health technology diffusion within clinical practice.

6. *Licensing and patents models in e-health tech transfer*

Technology transfer (TT) within the e-health sector follows standard phases of innovation, akin to large-scale production[34]. These typical phases include invention disclosure, IP protection, IP evaluation, and license agreement.

Invention disclosure involves assessing intellectual property (IP) domains. Absent technology disclosure, research findings can be utilized through scientific publications, research contracts, and collaborations. Otherwise, IP protection research results via legal protection encompassing industrial inventions, trademarks, designs, and intellectual works. IP spans copyrights for artistic and literary works, trademarks for distinct signs and industrial design, and patents for industrial inventions. Patent exclusions cover surgical or therapeutic methods for humans or animals and diagnostic methods applied to them. It's essential to differentiate between physical (products, devices) and intangible (methods or specific uses) inventions. The former might be patentable (e.g., a substance for treating a condition or a diagnostic device using X-rays), while the latter (e.g., a diagnostic method or therapeutic approach) might not be patentable.

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[34] E. Autio, T. Laamanen, *Measurement and evaluation of technology transfer: review of technology transfer mechanisms and indicators*, in «International Journal of Technology Management», 10, 7-8 (1995), pp. 643-664; C. Troise, *Aspetti manageriali del trasferimento tecnologico nelle Università*, Torino, G. Giappichelli Editore, 2020; A. Brantnell, E. Baraldi, *Understanding the roles and involvement of technology transfer offices in the commercialization of university research*, in «Technovation», 115 (2022), 102525.

Technology disclosure involves drafting a document (disclosure form) briefly outlining the invention's aspects eligible for patenting, including identifying the technical problem, recognizing the current state of the art, highlighting innovation elements, originality, industrial applications, and the invention's comparative advantages. This disclosure marks the start of patenting and initiates preliminary assessments of patentability and potential market value. The Technology Transfer Office (TTO) aids researchers in disclosure, identifying suitable licensees based on expertise, resources, partnerships, sales networks, and market definition. Technology summaries and confidential information, protected by agreements, can be used for informational content preparation. University-established committees may assist the TTO in evaluating continuation or abandonment of patent procedures. Following the patent filing phase, the subsequent phase involves patent valorization through assignment or negotiation of the license agreement. The license permits third-party use of patented technology, subject to royalty payments, for a limited duration during the license period.

The license and patent model, widely adopted in health technology transfer (TT), stemmed from the United States with the Bayh Dole Act of 1980. This regulatory act allowed universities and non-profit research institutions to own property rights to federally funded research discoveries. Defining apt licensing strategies is pivotal for research outcome exploitation, scientific progress, and societal impact. This model employs patents for scientific research result dissemination while safeguarding investment, inventor rights, and subsequent licensing agreements to economically exploit technology by Research Institutes. This model faces challenges due to country-specific IP regulations, high patenting costs, and licensing agreements with foreign entities. Licensed technology transfer occurs when the licensor supports research, development, and production activities before economic exploitation.

Technology transfer agreements can be reciprocal, granting each party patent, know-how, rights, or mixed licenses for competitive or product-producing technologies. Licenses can be exclusive, non-exclusive, or co-exclusive. In exclusivity, there's mutual reliance in technology transfer. In non-exclusivity, the licensor retains usage rights and can grant licenses to others. Multiple licenses support varied technology uses, preferred by licensors for extensive health technology dissemination. Co-exclusive licenses grant exclusive rights to the licensee, with the licensor retaining usage rights. For public entities aiming for widespread technology dissemination contributing to scientific advancement and healthcare enhancement, non-exclusive licenses ensure broad market penetration.

7. *A look at patent data in MedTech*

In 2022, the European Patent Office observed a 2.5% increase in patent applications, notably from companies headquartered in the Netherlands (+3.5%), Belgium (+5.0%), Austria (+3.4%), Switzerland (+5.9%), and Ireland (+12.3%). The United States, Germany, Japan, China, and France maintained their positions as the top five countries in terms of total patent applications filed, although Germany and Japan reported a decrease compared to 2021. Notably, South Korea secured a spot in the top ten with 10,367 patent applications, reflecting a significant 10% growth from the previous year[35].

Regarding application scope, medical technology (MedTech) claimed the second position in the top 10 European patent filing applications, totaling 15,683 applications, marking a 1% growth from the prior year. MedTech accounts for 8.1% of the total application volume. Among these applications, 41% originate from EPO countries (including the EU27, the United Kingdom, Norway, and Switzerland), 38% from the United States, and 21% from other nations. Pharmaceutical products (ranking 5th) and biotechnologies (ranking 8th) also displayed positive performance, amassing 9,310 and 8,168 patent applications, respectively, showing increases of +1% and +11% compared to 2021. Topping the list, the digital communication sector led with 16,705 filed applications, exhibiting a growth rate of +11.2%, the second highest among all industrial sectors in Europe. Refer to Figure 1 for a breakdown of patent applications filed by field of application in 2022[36].

Figure 2 depicts the ten-year trend of patent applications by country, affirming the consistent positions of the USA, Japan, China, and South Korea among the top nations with the highest number of patent applications. In Figure 3 a constantly growing trend characterizes medical technologies, digital communications and computer technology both in terms of the number of applications filed and patents granted. Additionally, Figure 4 illustrates the rising utilization of artificial intelligence in smart health.

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[35] European Patent Office, <https://www.epo.org/en/news-events/news/innovation-stays-strong-patent-applications-europe-continue-grow-2022-0#:~:text=Applications%20from%20most%20other%20leading,and%20Austria%20(%2B3.4%25)>.

[36] European Patent Office, <https://report-archive.epo.org/about-us/annual-reports-statistics/statistics/2022.html>.

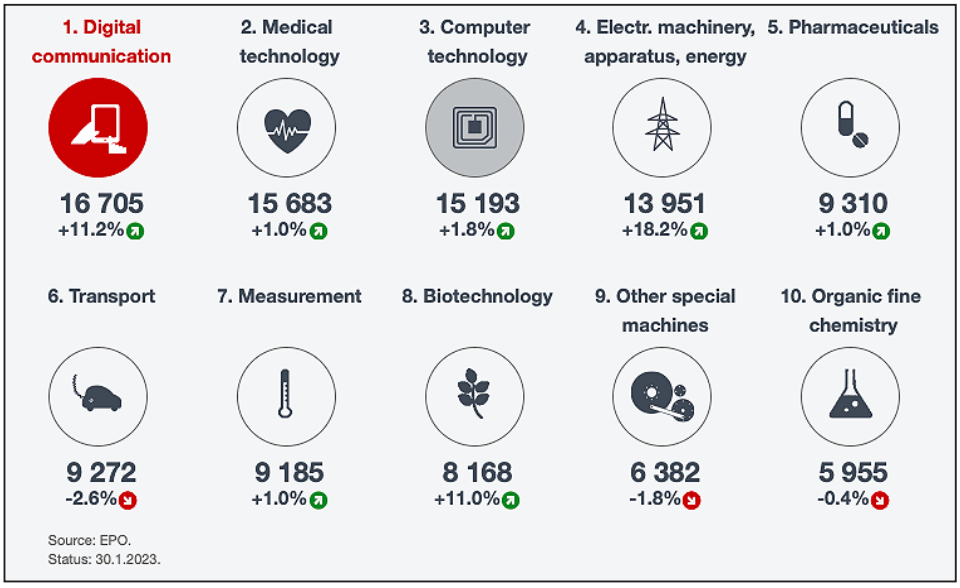

Fig. 1 - *Patent applications by fields of activity in 2022.*

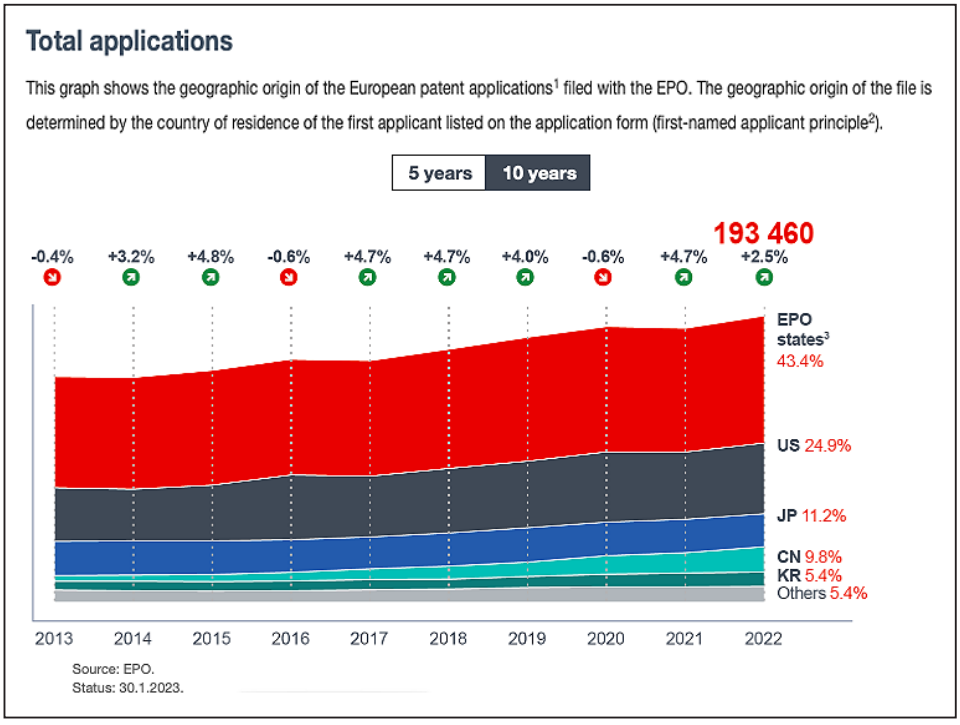

Fig. 2 - *Patent Applications Trend by Field of Activity: 2013-2022.*

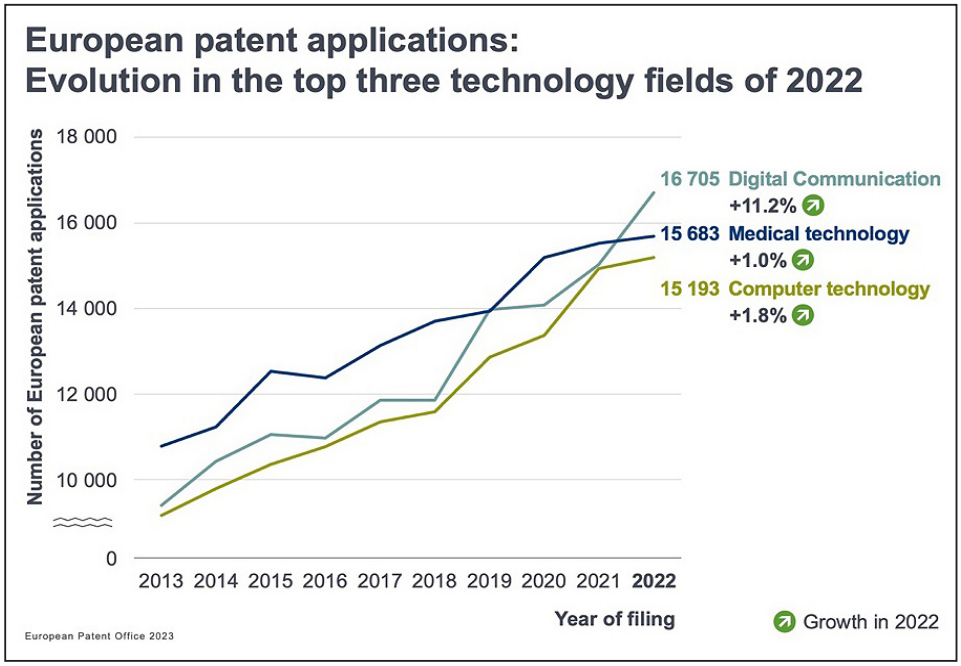

Fig. 3 - *Trends in Medical Technology, Digital Communications, and Computer Technology (2013-2022).*

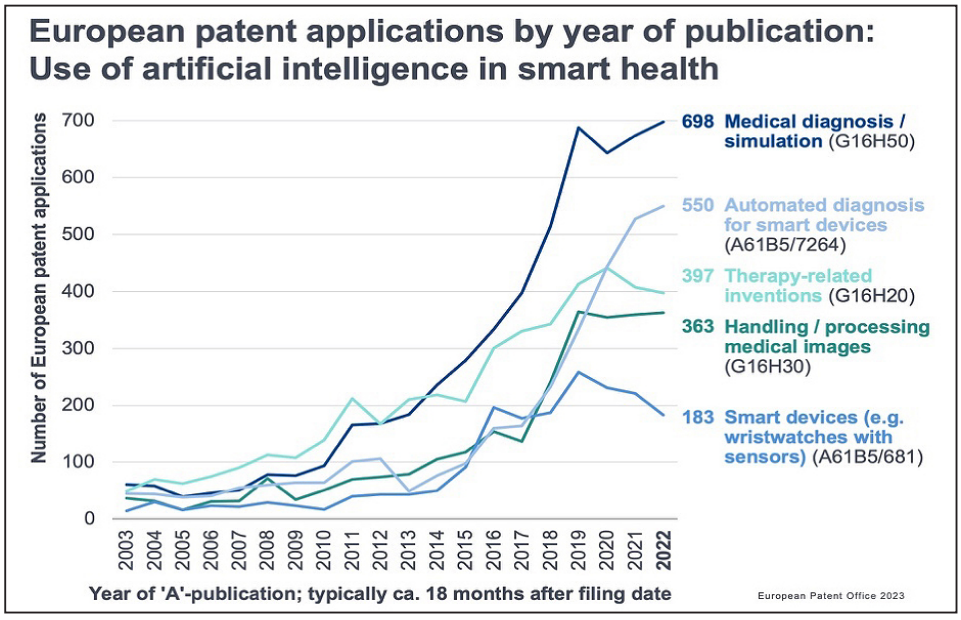

Figure 4 - *2003-2022 Use of AI in smart health.*

8. *Implications and future research*

In Italy, the Technology Transfer Office (TTO) activities related to health and digital health technologies are on the rise. Technology transfer stands as a cornerstone in innovation policies, contributing to bolstering industrial competitiveness and revitalizing key sectors within the country's economy[37]. In the realm of technology transfer within medicine and healthcare, collaborative efforts between universities, research centers, and pharmaceutical companies aim to amplify the outcomes of biomedical research through pioneering therapies and advanced medical devices.

Significant strides have been made, particularly in the domains of cancer and neurodegenerative disease diagnosis and treatment. Innovations span from medical robotics facilitating precise and minimally invasive procedures to telemedicine enabling remote assistance, particularly in underserved areas. Real-time patient monitoring, innovative drug development, and biotechnology targeting complex diseases also mark notable advancements. Italian universities and research centers have forged partnerships with pharmaceutical companies, establishing dedicated research centers and innovation laboratories. Notably, institutions like the Polytechnic of Milan, the Polytechnic of Turin, the Sant'Anna School of Pisa, and La Sapienza University of Rome have made significant contributions to e-health technology transfer. Their efforts revolve around multidisciplinary projects merging engineering, medicine, and materials sciences.

Governmental bodies and economic development agencies in Italy play a crucial role by facilitating funding programs, offering tax incentives, and engaging in collaborative research in the medicine and health sectors. Aligning with recent research[38], findings underscore the pivotal role of technology transfer models based in licensing and patents. These models act as connectors, bridging researchers, industry players, and healthcare professionals, thereby facilitating the seamless flow of innovations from experimental stages to clinical application, accelerating advancements in medicine and healthcare.

From a managerial perspective, these findings underscore the importance of strengthening interdisciplinary collaborations between experimental and

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[37] R. Grimaldi, M. Kenney, A. Piccaluga, *University technology transfer, regional specialization and local dynamics: lessons from Italy*, in «The Journal of Technology Transfer», 46 (2021), pp. 855-865.

[38] K. Chen, C. Zhang, Z. Feng, Y. Zhang, L. Ning, *Technology transfer systems and modes of national research institutes: Evidence from the Chinese academy of sciences*, in «Research Policy», 51, 3 (2022), 104471.

applied research, involving various stakeholders within helix models. Furthermore, the results suggest that managers of healthcare facilities should engage in technology transfer models to facilitate the refinement and dissemination of MedTech. Future research directions involve delving deeper into the networks comprising e-health ecosystems to comprehend the centrality of stakeholders and their roles in the development and diffusion phases of e-health technology. Additionally, mapping the involved facilities is crucial to understand how the localization of centers of excellence contributes to the specialization of an area in specific technological domains. Lastly, further future research focuses on how licensing and patent-based TT models facilitate the interconnection among next-gen technologies and the dissemination of e-health innovations with high degrees of standardization.

ABSTRACT

This research examines technology transfer models in e-health, where digital therapies (MedTech) represent an innovative field. E-health focuses on the circular flow of data between patients and healthcare systems. Enabling technologies or next-generation technologies introduce significant changes in the delivery of healthcare services and treatment outcomes. The development of e-health involves various stakeholders in the healthcare ecosystem (universities, public research institutions, scientific hospitals and care institutes - IRCCS, patients) engaged in technology transfer programs. Building upon the quadruple helix model, this research investigates the technology transfer model based on licenses and patents. Findings contribute to understanding the crucial stages that connect academic research to practical applications in the healthcare sector, thereby enhancing patient diagnosis, treatments, and clinical outcomes.

Questa ricerca esamina i modelli di trasferimento tecnologico nell'e-health, dove le terapie digitali (MedTech) rappresentano un ambito innovativo. L'e-health si concentra sul flusso circolare di dati tra il paziente e i sistemi sanitari. Le tecnologie abilitanti o tecnologie di prossima generazione introducono cambiamenti significativi nell'erogazione dei servizi sanitari e negli esiti delle cure. Lo sviluppo dell'e-health coinvolge diversi attori dell'ecosistema sanitario (università, enti pubblici di ricerca, istituti scientifici di ricovero e cura - IRCCS, pazienti) impegnati in programmi di trasferimento tecnologico. Partendo dal modello della quadrupla elica, la ricerca analizza il modello di TT basato su licenze e brevetti. I risultati contribuiscono a comprendere le fasi cruciali che collegano la ricerca accademica alle applicazioni pratiche nel settore sanitario, migliorando così la diagnosi, i trattamenti e i risultati clinici dei pazienti.