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CONTACT US

Journal of Applied Interdisciplinary Research (JAIR)
Technische Hochschule Deggendorf
Dieter-Görlitz-Platz 1
94469 Deggendorf, Germany
Phone: ++49 (0) 991 3615-0
Fax: ++49 (0) 991 3615-297
E-Mail: jair@th-deg.de
Web: https://jas.bayern

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Foreword

Dear readers,

We are proud to present the third special issue of the JAIR, dedicated to the primary field of digital health. As in the last issues, the contributions are the result of the discussions at the International Congress DigiHealthDayS-2024, which took place on November 14th and 15th, 2024. The hosting institution of the DigiHealthDayS at the Deggendorf Institute of Technology was the European Campus Rottal-Inn (ECRI). After the successful issues in the last years, the DIT and the Shupyk National Healthcare University of Ukraine (Shupyk NHU of Ukraine) decided again to realize a joint publication. The guest editors for this issue are Prof. Dr. Dipak Kalra (The European Institute for Innovation through Health Data [i~HD]), Prof. Dr. biol. hum. Horst Kunhardt (DIT), Prof. Dr. Georgi V. Chaltikyan (DIT), Prof. Ozar P. Mintser (Shupyk NHU) and Fara Aninha Fernandes (DIT). For special issues, the guest editors take the sole responsibility of selecting the articles and ensuring the quality process. In this issue we are featuring 9 short communiqué-style articles. Unlike regular articles, these are opinion pieces and do not undergo the regular peer review process.

The Journal of Applied Interdisciplinary Research, short JAIR, is an academic journal that aims to provide a current and international overview of interdisciplinary research which is also undertaken in an applied manner. The combination of these two types of research is a niche that has so far found little attention in academic journals and we are happy to close a previously existing gap by combining these two types of research in its own new journal. As this type of research is a growing field, it warrants a journal of its own type. Various areas of academia are overlapping more and more, so we want to provide an opportunity for researchers to publish their interdisciplinary research in a journal dedicated to advancing this particular field, and committed to the exchange of ideas across academic disciplines.

Your JAIR editors,

Michelle J. Cummings-Koether   Kristin Seffer

CONTENT

Guest Editorial

The **International Congress DigiHealthDayS-2024**, held at the European Campus Rottal-Inn (ECRI), Deggendorf Institute of Technology, once again served as a Global Forum for Education, Research, Innovation, and Networking in Digital Health. Under the overarching theme *"Global Digital Health – today, tomorrow, and beyond,"* this 5th Jubilee Edition brought together around 500 leaders, experts, and students from across the world. Participants engaged in a unique convergence of perspectives with keynote addresses from eminent speakers, thought-provoking student presentations, and lively dialogue sessions. Previous issues of the Proceedings are available in the *JAIR archives.*

Featured Papers

The five selected papers in this year's collection span the breadth of Digital Health education, health systems innovation, and scientific exploration.

The concept paper on a globally harmonized Master of Digital Health (MDH) degree proposes the establishment of an MDH Alliance. The authors argue for harmonized curricula, accreditation systems, and a clear professional identity for Digital Health Specialists, highlighting the urgent workforce needs of the ongoing Digital Transformation.

From Austria, a study of an electronic documentation application for Helicopter Emergency Medical Services highlights the importance of a transition from paper to electronic medical records in high-stress environments. With a usability score and qualitative feedback emphasizing automation and integration, the study underscores the necessity of user-centered design in emergency medicine.

Expanding into pharmacovigilance, a comparative study of Germany and Egypt investigates the use of electronic health records (EHRs) and artificial intelligence (AI) for detecting adverse drug reactions. The authors highlight strong professional support for such tools and the opportunities they offer for pharmacovigilance systems.

The business models of Digital Health start-ups in Europe are analyzed in a framework-based study, identifying archetypes of innovation strategies. The findings stress the importance of stakeholder collaboration, strong value propositions, and sustainability in a highly competitive market, while also recognizing the high attrition rate of Digital Health ventures.

Finally, a theoretical exploration of bioelectronic medicine presents a frontier approach to non-communicable diseases. Building on the magnetoelectrochemical theory of metabolism, the authors propose integrating nanolevel biophysics into medical knowledge, positioning bioelectronic medicine as a promising but still nascent paradigm requiring further research and educational initiatives.

Together, these papers reflect the diversity of Digital Health research and innovation: from educational harmonization and clinical usability to systemic adoption of AI and entrepreneurial innovation, extending even into emerging scientific paradigms.

Communiqués

The nine communiqués capture the rich discussions, dialogues, and reflections from DigiHealthDayS-2024, illustrating the event's role as a global forum for exchange.

The Alumni Voice session highlighted the career trajectories of graduates of the Master of Digital Health, reinforcing the importance of Digital Health literacy and mentorship networks. Complementing this, the Scientific Session showcased applications of AI and digital tools in areas ranging from pharmacovigilance and cancer to mobile screening, genomics, and medical education.

Patient engagement was the focus of a communiqué emphasizing co-creation, real-world evidence, and ethical compensation, while another explored the philosophical and practical divide between informatics as science and digitalization as practice, advocating for interdisciplinary collaboration and contextual adaptation of solutions.

Innovation emerged strongly in the session "El Futuro Es Nuestro", where students presented healthcare solutions with global relevance, supported by a keynote from HIMSS leadership. A complementary session on digital maturity, health data and global policy examined frameworks such as the European Health Data Space and WHO strategies in emphasizing alignment of governance, workforce, and technology.

Further perspectives included a discussion on scaling Digital Health at national and international levels. A critical panel on the EHDS and its capacity to deliver high-quality datasets for AI was presented. Another dialogue concluded with a high-level debate on the future of AI in healthcare, balancing its transformative promise with ethical, regulatory, and global competitiveness concerns.

Together, these communiqués illustrate a Digital Health community deeply engaged with the educational, clinical, systemic, and ethical dimensions of transformation. They remind us that progress in Digital Health requires not only technological advances, but also collaborative networks, regulatory foresight, and patient-centered innovation.

As this special issue illustrates, DigiHealthDayS-2024 was not only a celebration of ideas but also a platform for action. The five featured papers and nine communiqués reflect the richness of discussions that spanned education, workforce development, usability, innovation, policy, patient engagement, and the ethical integration of AI. We extend our sincere gratitude to our sponsors, partners, and the vibrant DigiHealthDay community for their support. Looking ahead, we remain inspired by the vision that drives DigiHealthDay, that is, to create a Digital Health future that is smarter, fairer, and more human-centered.

Prof. Dr. Dipak Kalra, International Chair of DigiHealthDay
Prof. Dr. Horst Kunhardt, Scientific Chair of DigiHealthDay
Prof. Dr. Georgi Chaltikyan, Organizing Committee Chair of DigiHealthDay
Prof. Dr. Ozar Mintser, Editor-in-Chief of Ukrainian Journal of Medical Informatics and Engineering
Dr. Fara Aninha Fernandes, Associate Guest Editor

Towards a Globally Recognized and Harmonized Degree of Master of Digital Health (MDH): The Case for an MDH Alliance

Georgi V. Chaltikyan,[a] Dmitry Etin,[a] Eugenia Lvova,[a] Fara Aninha Fernandes,[a] Jishen Pfeiffer[a]

[a]Deggendorf Institute of Technology (DIT)/European Campus Rottal-Inn (ECRI), Pfarrkirchen, Germany

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ABSTRACT

The digital transformation of healthcare is advancing at an unprecedented pace, reshaping systems, providers, and societies worldwide. While technological development accelerates, the education and training of the health workforce lag behind, producing critical gaps in digital competencies and undermining the adoption of innovation. Biomedical and Health Informatics (BMHI) has historically provided the academic foundations for this field, but the emergence of Digital Health as a broader, interdisciplinary paradigm demands new approaches to education. This paper explores the rationale for a globally harmonized Master of Digital Health (MDH) degree, modeled after the success of the Master of Public Health (MPH), and presents a call for the establishment of an MDH Alliance. We review the history of BMHI education, the evolution towards Digital Health, the development of knowledge, skills, and competences (KSCs), and the role of the workforce in digital transformation. We highlight recent calls for an MDH degree by global thought leaders, drawing inspiration from the MPH, and building on our institutional experience transitioning from a Master of Medical Informatics to a Master of Digital Health. We argue that a coordinated international initiative is essential to ensure quality, comparability, and professional mobility in Digital Health education, and to provide the workforce required for equitable and sustainable digital transformation of health systems.

KEYWORDS

Digital health, health informatics, information technology, MDH, education

1. Background

The academic field now referred to as Biomedical and Health Informatics (BMHI) has roots extending back to the early days of computing in the mid-20th century. The first generation of pioneers envisioned the potential of information technology to support medical practice, research, and education. In Europe, François Grémy, a French physician and biostatistician, was among the earliest advocates, promoting the systematic application of computing to medicine in the 1960s [1]. In the United States, Donald A.B. Lindberg, later Director of the U.S. National Library of Medicine, championed medical computing, advancing the idea that electronic systems could support medical knowledge organization and retrieval [2]. In Germany, Peter Reichertz played a key role in integrating clinical information systems into university hospitals [3]. These early contributions laid the foundation for BMHI as an interdisciplinary field bridging medicine, computer science, and information science.

By the 1970s and 1980s, BMHI had grown into a recognized academic community. This period saw the establishment of professional associations such as the International Medical Informatics Association (IMIA) in 1967 and, later, the European Federation for Medical Informatics (EFMI) in 1976 [4, 5]. These organizations were instrumental in convening researchers and practitioners, promoting standards, and initiating international conferences such as MEDINFO and MIE (Medical Informatics Europe), which became flagship scientific gatherings. Importantly, they also encouraged the emergence of formal educational pathways in BMHI. Early programs were mostly research-focused, often embedded in computer science or biomedical faculties, but gradually evolved into specialized master's degrees and doctoral programs.

The 1990s and 2000s marked a period of expansion in both the field and its educational offerings, reflecting the digitalization of healthcare systems. Electronic health records (EHRs) were increasingly implemented, requiring professionals capable of designing, managing, and evaluating such systems. Health information exchange, computerized provider order entry, and clinical decision support became mainstream topics. BMHI curricula expanded to cover system design, interoperability, data quality, usability, and change management. By the early 21st century, dozens of universities worldwide offered structured BMHI or health informatics programs. A landmark in this process was the publication of the IMIA Recommendations on Education in Biomedical and Health Informatics, which provided the first globally accepted guidance on competencies, curricula, and learning outcomes [5].

However, as the 2010s unfolded, it became clear that the concept of BMHI, while robust, might no longer reflect the full and rapidly expanding breadth of digital innovations transforming healthcare. The more and more frequent usage of the term Digital Health represented a paradigm shift. Digital Health was defined as an umbrella term encompassing the broad spectrum of Information and Communication Technologies (ICT) including mobile health (mHealth), wearable technologies, big data analytics, genomics, artificial intelligence, robotics, telemedicine, virtual and augmented reality, and patient engagement tools [6, 7]. This broader framing reflects the increasing interdisciplinarity of the field, integrating not only informatics and medicine but also engineering, behavioral science, ethics, law, and public health.

The transition from the scientific discipline of BMHI to the domain of knowledge and practice Digital Health had implications for education and workforce development. The WHO Global Strategy on Digital Health 2020–2025 explicitly identifies "strengthening digital health workforce capacity" as a pillar of national digital health ecosystems [7]. Similarly, the European Health Data Space (EHDS) initiative underlines that interoperability, secondary use of data, and digital innovation cannot succeed without appropriately skilled professionals [8].

At the same time, empirical research highlights significant workforce gaps. A systematic review demonstrated that Digital Health technologies can enhance health worker competencies and workplace performance, yet lack of training remains a critical barrier to implementation [9]. In Finland, a national project (MEDigi) identified core eHealth competencies for medical and nursing curricula but concluded that integration remained patchy [10]. In Catalonia, the COMPDIG-Salut project evaluated over 800 health professionals and found that more than 60% failed to reach an intermediate level of digital competence, particularly in data governance and digital collaboration [11]. Similarly, Estonia developed national digital competence profiles for health professionals and identified fragmentation of digital competences across existing education and training programs [12].

To address these challenges, multiple competency frameworks have emerged:

- HITCOMP (EU–US eHealth Work Project) catalogued over 1,000 competencies across domains and proficiency levels, providing a comprehensive repository for education and workforce planning [13].
- The European Commission's DigComp framework, initially developed for citizens, has been adapted to health professionals, emphasizing digital literacy, safety, and collaboration [14].
- The BeWell Skills Strategy (2023) emphasizes not only digital but also green and soft skills for the health workforce, recognizing sustainability and well-being as integral to digital transformation [15].

These frameworks converge on the idea that Knowledge, Skills and Competencies (KSCs) in Digital Health go far beyond technical literacy. They include ethical reasoning, critical appraisal of technology, understanding of interoperability standards (HL7 FHIR, SNOMED CT, LOINC), data protection, cybersecurity, communication, and leadership for change [5].

The role of the workforce in digital transformation is now recognized as decisive. As our own work has demonstrated, health system digitalization projects often fail when human capacity is neglected, even if technology and infrastructure are well funded [16]. Conversely, where training and workforce development are prioritized, adoption accelerates and sustainability improves.

Taken together, the history of BMHI education, the evolution towards Digital Health, and the emergence of workforce competency frameworks highlight a pressing need: a globally harmonized educational standard that can provide assurance of quality, comparability, and professional mobility. Just as the IMIA recommendations shaped BMHI, and accreditation frameworks shaped public health education, Digital Health now requires a similar step forward. The proposal for a globally recognized and accredited Master of Digital Health (MDH) degree, supported by an international Alliance, emerges as the logical next phase in this historical trajectory.

2. Inspiration: The Story of the MPH

The Master of Digital Health (MPH) stands as one of the most influential and successful professional master's degrees in modern history. Its development illustrates how an emergent interdisciplinary field can move from fragmented beginnings to a globally harmonized, accredited, and professionally recognized qualification. The story of the MPH is thus directly relevant to the current efforts to establish the MDH.

Early Origins of Public Health Education
Public health emerged as a distinct discipline in the late 19th and early 20th centuries, spurred by the need to address sanitation, infectious disease control, and later the growing burden of chronic illnesses. Academic programs initially developed in response to pressing health crises, such as urban sanitation in Europe or the spread of tuberculosis in the United States. The first formal schools of public health were established in the early 20th century, including the Johns Hopkins School of Hygiene and Public Health (founded 1916) and the Harvard School of Public Health (founded 1922). These institutions defined curricula around epidemiology, biostatistics, environmental health, and health administration [17].

Although the early MPH programs varied in content and approach, they shared a focus on practical, applied skills to address population health needs. Unlike research-oriented PhD degrees, the MPH was designed to produce professionals capable of working in government agencies, community organizations, and international health bodies. This orientation towards practice, interdisciplinarity, and policy relevance has remained a hallmark of MPH education.

Evolution into a Global Standard
By the mid-20th century, the MPH had spread internationally, with programs established in Europe, Latin America, Asia, and Africa, often with support from international organizations such as the World Health Organization (WHO). The WHO played a crucial role in promoting public health education globally, including the training of professionals in epidemiology and health systems management [18]. As programs multiplied, the need for standardization and quality assurance became evident. In the United States, the Council on Education for Public Health (CEPH) was founded in 1974 to accredit schools and programs of public health. CEPH accreditation established clear competency-based criteria, covering domains such as epidemiology, biostatistics, environmental health, health policy and management, and social and behavioral sciences [19]. Accreditation became a key driver of comparability and credibility, ensuring that MPH graduates possessed a consistent set of core competencies.

In Europe, similar efforts were launched later. The Agency for Public Health Education Accreditation (APHEA), established in 2011 through a collaboration of the Association of Schools of Public Health in the European Region (ASPHER) and other bodies, developed accreditation criteria tailored to European educational contexts [20]. APHEA's model drew heavily on CEPH but emphasized European priorities such as health systems, equity, and cross-border health challenges.

Through these accreditation efforts, the MPH became the gold standard qualification for public health professionals worldwide. Graduates could demonstrate comparable competencies, employers gained confidence in qualifications, and universities aligned curricula with international expectations. The MPH degree thus exemplifies how a new interdisciplinary domain can institutionalize itself through competency frameworks, harmonized curricula, and accreditation systems.

Impact of the MPH Model
The impact of the MPH has been profound. First, it has provided a globally mobile workforce. Public health professionals trained in accredited programs are able to work across borders, as their qualifications are recognized and trusted internationally. Second, the MPH has influenced policy and workforce planning: many national health systems explicitly integrate MPH-trained professionals into leadership and managerial roles. Third, the MPH has fostered a sense of professional identity and legitimacy for public health, enabling the field to stand alongside medicine, nursing, and other established health professions.

From an academic perspective, the MPH has also provided a platform for continuous evolution. Curricula have been updated to reflect emerging challenges such as HIV/AIDS, health inequities, global health, and more recently, planetary health and climate change. Importantly, accreditation frameworks like those of CEPH and APHEA have demonstrated flexibility in adapting to new knowledge while maintaining consistency in core competencies.

Lessons for Digital Health
The trajectory of the MPH offers several critical lessons for the MDH initiative.

1. **Fragmentation to Harmonization:** Just as early public health programs were fragmented, today's Digital Health education landscape is diverse and inconsistent. Universities offer programs in medical informatics, eHealth, biomedical informatics, digital health policy, and related areas, but without harmonization or mutual recognition [5]. The MPH shows that coordinated efforts can overcome fragmentation and create a global standard.
2. **Competency-Based Education:** The MPH model demonstrates the power of competency-based education, ensuring graduates achieve specific knowledge, skills, and attitudes. For Digital Health,

multiple competency frameworks already exist (HITCOMP, DigComp, BeWell, COMPDIG), but a unified, globally endorsed framework is needed to anchor the MDH [8].

3. **Accreditation as a Driver of Quality:** CEPH and APHEA accreditation made the MPH credible and globally recognized. Similarly, a global accreditation mechanism for MDH would ensure comparability, mobility, and trust. Without accreditation, programs risk remaining local and unrecognized.
4. **Professional Identity:** The MPH gave public health professionals a clear identity and career trajectory. For Digital Health, the establishment of MDH can play a similar role, legitimizing the profession and integrating it into workforce planning.
5. **Flexibility and Adaptation:** The MPH has evolved over time, expanding to include new challenges. Digital Health education must likewise remain dynamic, updating curricula to incorporate emerging technologies such as artificial intelligence, blockchain, and virtual reality.

3. Evolution of Digital Health Education at DIT-ECRI: From MMI to MDH

Our institutional journey provides a microcosm of the broader evolution of the field.
In 2015, Deggendorf Institute of Technology – European Campus Rottal-Inn (DIT-ECRI) launched the Master of Medical Informatics (MMI), building on decades of tradition in BMHI education. The evolution of the program to the Master of Digital Health (MDH) rebranded and restructured in 2019 and consolidated in 2021, illustrates both the shifting boundaries of the field and the growing recognition that Digital Health requires a new, globally harmonized qualification.

Origins and Transition: The Master of Medical Informatics (2015-2019)
The establishment of the MMI program at DIT-ECRI in 2015 was rooted in the long-standing traditions of BMHI. At that time, medical informatics was still the dominant terminology, reflecting a focus on information systems in healthcare, data management, and clinical decision support [5]. The MMI program was designed to equip students with skills in electronic health records (EHRs), interoperability, data standards, software development, and health system analysis. The program quickly attracted an international student body, reflecting the growing global demand for professionals with informatics expertise.

By 2017–2018, it had become clear that the field was expanding beyond the remit of “medical informatics.” The concept of “Digital Health” was rapidly gaining traction in global policy documents [6, 7] and industry discourse. At DIT-ECRI, the leadership recognized that the academic program had to evolve in tandem with the field itself.
Discussions among faculty highlighted two key insights. First, Digital Health is inherently interdisciplinary, requiring contributions not only from informaticians but also from clinicians, public health specialists, engineers, social scientists, and ethicists. Second, education must be future-oriented, preparing graduates not only for the technologies of today but for those on the horizon — from precision medicine to immersive simulation. These insights provided the rationale for a strategic reorientation of the program.

Rebranding and Reformation: The Master of Digital Health (2019-2024)
In 2019, the faculty began reforming the program towards MDH. This was not simply a name change but a fundamental restructuring of the curriculum to reflect the expanded domain of Digital Health. The MDH integrated new courses on AI in healthcare, data science and big data analytics, digital health entrepreneurship, and regulatory aspects of digital technologies. At the same time, traditional BMHI subjects such as interoperability standards (HL7, SNOMED CT, LOINC, ICD) and health information systems remained foundational.

The rebranding was also accompanied by a new pedagogical model. The MDH adopted the “I3 (I-cube)” principles: Interdisciplinary, International, and Innovative. Students were recruited from across the globe, creating a diverse classroom that mirrored the international nature of Digital Health challenges. They represented multiple disciplines, emphasizing collaboration between medicine, computer science, engineering, public health, and management. The landmark innovation has been the adoption of Project-Based Learning (PBL) in interdisciplinary small teams simulating real-world innovation.

This reformation positioned DIT-ECRI's MDH among the well-known structured Master of Digital Health programs in Europe, serving as a model for other institutions exploring similar transitions.

Scale and Global Reach: 2024–2025

In 2024, the MDH program had received more than 1,800 applications, with students from all continents, and had graduated more than 220 professionals. Alumni pursued careers in academia, industry, government, and international organizations, often serving as pioneers of Digital Health in their home countries or institutions. The program's popularity demonstrated the global demand for structured, high-quality Digital Health education.

At the same time, the program strengthened its links with international organizations and policy agendas. Since the very establishment of MMI in 2015, DIT-ECRI has been involved in European, international, and global collaboration and networking reflected by its institutional partnership with, and membership in such major non-profits and think-tanks as HIMSS, IMIA, ISfTeH, EFMI, and CHIME. In 2020, a series of online events was launched that developed into the DigiHealthDay – Global Forum for Education, Research, Innovation and Networking in Digital Health attracting more than 1,700 followers including top-tier academics and experts from around the globe [22]. DIT-ECRI became increasingly involved in European projects, and due to its long-lasting collaboration with Data and Digital Health Unit at the WHO Regional Center for Europe, in 2025 was designated a WHO Collaborating Centre for Digital Health Education, Research, and Development — the first in Germany [23]. These developments underscored the program's role as both an educational and research hub, situated at the intersection of academia, policy, and practice.

At the same time, this growth highlighted the limitations of a single-institution model. While DIT-ECRI's MDH program was thriving, other universities were launching their own initiatives — sometimes under the name "Digital Health", sometimes under related labels such as "Health Informatics", "Digital Medicine", or "eHealth". The lack of harmonization risked leading to fragmentation, where graduates of different programs possessed highly variable competencies, and employers lacked confidence in their qualifications.

From Institutional Success to Global Vision: The MDH Alliance

By 2024–2025, it had become clear that the next step was to move beyond institutional success to collective global action. The analogy with the MPH became increasingly compelling. Just as the MPH had, over the 20th century, evolved from disparate programs into a globally harmonized degree supported by accreditation bodies such as CEPH and APHEA, [17, 19], so too could the MDH become the benchmark qualification for Digital Health professionals.

This realization led to the decision to convene a Master of Digital Health (MDH) Alliance. The Alliance would bring together universities, professional associations, policymakers, industry, and students to co-create a Global MDH Competency Framework, harmonize curricula, and establish an international accreditation and quality assurance mechanism. In this way, the institutional journey of DIT-ECRI from MMI to MDH became the prototype for a global movement, illustrating both the necessity and feasibility of establishing the MDH as a recognized and accredited global standard.

A similar approach has also been highlighted by thought leaders in the field. In 2025, Car and Topol published a viewpoint paper in JAMA explicitly calling for the creation of a globally recognized MDH degree. They argued that the rapid digitalization of health systems requires a new generation of professionals trained not only in informatics but also in data science, artificial intelligence, ethics, regulation, and patient-centered innovation. Importantly, they emphasized that the MDH should follow the model of the MPH, which successfully established a global benchmark for public health education in the 20th century. Their call underscored both the urgency and feasibility of harmonizing Digital Health education into a coherent, internationally recognized qualification — a vision strongly aligned with the concept of an MDHAlliance [21].

4. Motivation: Why an MDH alliance?

The proposal to establish an MDH Alliance arises from both structural challenges in current education and the strategic opportunities provided by global health system transformation. The rationale is anchored in three interrelated observations: the fragmentation of existing programs, the absence of accreditation and quality assurance mechanisms, and the pressing workforce demand driven by digitalization policies at national and international levels.

Fragmentation of Programs

At present, Digital Health education exists in multiple forms across the globe: health informatics, biomedical informatics, eHealth, digital medicine, and digital health master's programs. While these share overlapping content, their scope, depth, and competencies vary significantly [5]. Some focus on technical informatics, others on health systems management, and others on entrepreneurship or regulatory aspects. Without harmonization, graduates leave with heterogeneous skill sets, creating uncertainty for employers and limiting professional mobility. This fragmentation is further compounded by the absence of a unifying professional identity. Unlike medicine, nursing, or public health, which are anchored by widely recognized qualifications, Digital Health professionals cannot point to a globally standardized degree. The consequence is a lack of clarity in career trajectories and workforce planning.

Absence of Accreditation and Quality Assurance Mechanisms

The second motivation arises from the lack of accreditation or quality assurance systems for Digital Health education. In contrast, the MPH achieved global recognition precisely because of the establishment of accreditation bodies such as CEPH in the United States and APHEA in Europe [19]. Accreditation provides quality control, comparability, and trust. It ensures that programs adhere to defined competency frameworks and that graduates achieve measurable learning outcomes. Digital Health currently lacks such a framework. Although efforts such as COMPDIG, HITCOMP, DigComp, and BeWell have produced important competency models [11, 13–15], these have not yet been consolidated into a globally recognized accreditation process. Without accreditation, programs risk remaining localized, undermining global professional mobility and legitimacy.

Workforce Demand and Policy Drivers

The third motivation is the growing workforce demand created by national and international digitalization strategies. The WHO Global Strategy on Digital Health 2020–2025 identifies workforce capacity-building as a key pillar of Digital Health ecosystems [7]. The European Commission's EHDS emphasizes that interoperability, secondary use of data, and digital innovation require a digitally skilled workforce [8]. Projects such as BeWell further demonstrate the recognition that digital competencies are not optional but essential for Europe's 15 million health workers [15]. At the same time, empirical evidence confirms that workforce readiness remains insufficient [9–11].

Essential Activities of an Alliance

The MDH Alliance can respond to these challenges through a set of essential activities. First, it can develop a Global MDH Competency Framework, synthesizing existing models into a harmonized standard endorsed by universities, professional bodies, and policymakers. Second, it can facilitate curriculum harmonization, ensuring that MDH programs worldwide share a common foundation while allowing for elective specialization. Third, it can establish a pathway for international accreditation, modeled after CEPH and APHEA, to ensure quality and comparability. Fourth, it can promote advocacy and visibility, elevating Digital Health to the same level of professional recognition as Public Health. Finally, it can serve as a platform for mobility and collaboration, enabling student and faculty exchanges, joint degrees, and collaborative research.

A Call for Collective Action
The establishment of the MDH Alliance is not merely an academic exercise but a call for collective global action. The analogy with the MPH is instructive: just as public health professionals once faced fragmented training and uncertain identity, today's Digital Health professionals need a unifying qualification to anchor their field. As Car and Topol argue in their JAMA paper, the time has come for a Master of Digital Health that parallels the MPH in scope and legitimacy [21].

In this context, the MDH Alliance is envisioned as the central coordinating body driving the initiative forward. By convening universities, policymakers, industry, and professional associations, it can provide the governance and momentum needed to turn vision into reality. Its success will ensure that future Digital Health professionals are not only technically competent, but also ethically grounded, policy-aware, and globally mobile — the leaders needed for the safe and equitable digital transformation of health systems.

5. Conclusions

The past half-century of academic development in Biomedical and Health Informatics demonstrates how an emergent field can institutionalize itself through education, research, and professional identity. Yet as the landscape of healthcare has expanded to encompass Digital Health — with its integration of mobile technologies, artificial intelligence, genomics, extended reality, and patient-centered innovation — it has become evident that traditional BMHI frameworks are no longer sufficient. Education must adapt to reflect the breadth and complexity of Digital Health, and the workforce must be equipped not only with technical knowledge but also with ethical, regulatory, and leadership competencies.
The experience of the MPH offers a compelling precedent. Emerging in the early 20th century from disparate programs, the MPH achieved global recognition by establishing shared competencies, harmonized curricula, and formal accreditation systems [19, 20]. The MPH today anchors professional identity in public health, supports international workforce mobility, and provides governments and employers with a trusted standard of training. This trajectory demonstrates that new interdisciplinary domains can move from fragmentation to harmonization, provided that educational leaders act collectively.

Our own institutional journey — from the MMI launched at Deggendorf Institute of Technology in 2015, through the rebranding and reformation as the MDH in 2019, to the program's consolidation and global reach by 2024 — illustrates both the necessity and feasibility of this evolution. The transition was not cosmetic but reflected the real expansion of the field and the demands of students, employers, and health systems. With more than 1,800 applications annually from over 120 countries, the MDH at DIT-ECRI has proven the significant global demand for structured Digital Health education. At the same time, the emergence of parallel programs in other universities has underscored the risks of fragmentation if harmonization is not pursued.

The evidence is compelling: Digital Health technologies can enhance care and professional competence, but without adequate training, their impact is blunted [9]. WHO's Global Strategy on Digital Health (2020–2025) calls for workforce capacity-building as a prerequisite for national Digital Health ecosystems. European initiatives such as the BeWell Skills Strategy and COMPDIG-Salut in Catalonia have demonstrated both the urgency and feasibility of defining competencies and creating accreditation pilots [11, 15]. Yet these remain regional and fragmented. What is missing is a globally recognized qualification that can anchor Digital Health education with the same authority that the MPH achieved for public health.

The MDH Alliance is proposed as the platform to achieve this goal. By uniting universities, professional bodies, policymakers, and industry, the Alliance can define a Global MDH Competency Framework, harmonize curricula, and create an international accreditation and quality assurance system. Such an initiative will not only ensure quality and comparability but also provide graduates with professional mobility, employers with confidence, and governments with a workforce capable of leading digital transformation.

In this sense, the MDH Alliance is more than an academic collaboration: it is a strategic response to a global health challenge. Without harmonization, Digital Health education risks fragmentation and inequity, with some regions advancing rapidly while others are left behind. With harmonization, the MDH can become the gold standard for Digital Health professionals worldwide, equipping a new generation of leaders to guide health systems safely, effectively, and equitably into the digital era.
The time to act is now. Just as the MPH catalyzed public health education in the 20th century, the MDH must catalyze Digital Health education in the 21st century. This concept paper calls on universities, policymakers, professional associations, and industry partners to join in the establishment of the MDH Alliance — to seize this historic opportunity, to prevent fragmentation, and to ensure that Digital Health education serves as a cornerstone of sustainable, equitable, and resilient health systems for decades to come.

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Conflicts of Interest

None declared

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Transitioning from Paper to Electronic Medical Records in Austrian Helicopter Emergency Medical Services: A Usability Evaluation

Magdalena Druml,[a] Eva Turk[a]

[a]St. Pölten University of Applied Sciences, St. Pölten, Austria

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ABSTRACT

Introduction: This study examines the development and usability evaluation of an electronic documentation application specifically designed for the Austrian Helicopter Emergency Medical Service (HEMS). The primary objective is to assess how HEMS crew members, accustomed to paper-based documentation, perceive the usability of the electronic system.

Method: The application was developed using React Native and tailored to the unique demands of the high-stress environment characteristic of HEMS. No existing digital documentation solutions were analyzed or incorporated; instead, the design was grounded entirely in evidence-based practices. The development process underwent iterative refinement based on user feedback in collaboration with a HEMS crew member. A total of thirty healthcare professionals were recruited through convenience and purposive sampling methods. Usability was evaluated using the System Usability Scale (SUS), complemented by qualitative insights obtained from open-ended questions.

Results: The findings indicate an average SUS score of 79.92. Notably, older and more experienced users, as well as those possessing advanced digital skills, provided favorable ratings for the application. Conversely, younger and less experienced users exhibited lower levels of satisfaction. The qualitative analysis revealed four primary themes: automation and integration, the need for improvement and adaptation, a positive disposition towards the application, and prioritization of simplification and efficiency despite existing concerns.

Conclusion: This study underscores the necessity for ongoing optimization within digital healthcare applications, highlighting the critical alignment with user needs. Future developments should prioritize not only technical enhancements but also the optimization of the overall user experience.

KEYWORDS

Digital health, electronic health records, emergency medical services, air rescue, user-centered design

1. Introduction

The swift evolution of digital technologies has catalyzed a profound transformation across virtually all sectors of healthcare in recent years. This technological revolution offers a compelling opportunity to transition from traditional paper-based methodologies to electronic systems, thereby significantly enhancing the efficiency, accuracy, and accessibility of patient data [1]. Electronic health records (EHR) and mobile applications have become pivotal instruments in optimizing the documentation and management of medical information [2].

The accurate and prompt documentation of patient data is particularly critical in the field of emergency medicine. Emergency physicians and medical personnel frequently operate under time-sensitive and high-stress conditions, necessitating rapid decision-making and meticulous record-keeping. Electronic documentation systems possess the capacity to exceed the capabilities of conventional paper-based approaches, not only by augmenting operational efficiency but also by elevating the quality of data, which in turn supports more informed clinical decision-making [2, 3].

However, despite the myriad benefits associated with electronic documentation systems, numerous healthcare providers face substantial challenges during their implementation. These challenges encompass issues related to user acceptance and the seamless integration of new technologies into established workflows [2, 4]. Empirical studies reveal that initial acceptance of these systems is often inadequate, underscoring a pronounced need for targeted training initiatives to ensure their effective and sustained utilization [1–3, 5, 6].

A notable application of these technological innovations is found within the Helicopter Emergency Medical Service (HEMS) sector. HEMS plays a pivotal role in the swift provision of medical care and transportation for patients in emergency scenarios. The implementation of an electronic documentation application presents an opportunity to enhance documentation processes while concurrently alleviating the workload of emergency personnel [5].

In Austria, HEMS is primarily operated by the *Austrian Automobile, Motorbike and Touring Club (ÖAMTC)* through the Christophorus Flugrettungsverein (CFV) [7]. As the largest private air rescue organization in the country, the CFV has significantly contributed to the evolution of air rescue services in Austria since the introduction of the inaugural Christophorus helicopter in 1983 [8]. Annually, HEMS conducts approximately 37,000 missions across Austria, with the CFV ensuring comprehensive national coverage through 17 strategically positioned bases [7, 8].

The operational challenges and stringent safety requirements inherent in air rescue underscore the importance of introducing an electronic documentation system. Such a system has the potential to streamline documentation processes, enhance accuracy, and reduce the cognitive burden on medical personnel during high-stress situations. This study seeks to analyze the development and usability of an electronic documentation application within the context of Austrian air rescue.

The primary objective of this study is to develop and evaluate the usability of an electronic documentation application specifically tailored for use in Austrian HEMS. A particular emphasis will be placed on the app's user-friendly design, as intuitive operation is critical in the high-pressure environment of emergency situations [6]. Furthermore, the application will be designed to accommodate the specific requirements and workflows of healthcare professionals operating within HEMS.

The research is guided by the following question: How do healthcare professionals accustomed to paper-based documentation assess the usability of an electronic emergency documentation application for the Austrian Helicopter Emergency Medical Service?

2. Methods

A comprehensive literature search served as a foundational basis for the app's design and the theoretical framework of the study. Scientific articles from databases such as PubMed, the Cochrane Database, and Google Scholar, focusing on usability, digital applications in healthcare, and emergency medicine were considered. Studies addressing design principles for mobile applications, particularly within pre-hospital emergency medicine, were also incorporated. Evidence-based approaches identified informed both the app's development and the methodological framework of the study.

The methodological approach for evaluating usability is grounded in the study conducted by Martins [9]. This study employed a Delphi survey to establish a consensus on the planning, implementation, and reporting of usability evaluations for digital solutions within the healthcare sector. The resulting checklist provides a methodological framework for this study. The subsequent sections detail the steps and procedures involved in the usability evaluation of the documentation application.

Sampling
Participants were recruited using a combination of convenience and purposive sampling methods. Convenience sampling facilitated the recruitment of participants based on their accessibility and availability within the target population [10]. Conversely, purposive sampling ensured that participants fulfilled specific, predefined criteria pertinent to the research question [11].

This dual approach to sampling enabled the efficient recruitment of qualified participants for the usability evaluation of the documentation application. The objective was to achieve a representative sample of 30 to 40 participants. As this was the inaugural survey of its kind conducted in this context across Austria, a power calculation was not feasible. The sample size was estimated based on findings from prior studies concerning usability evaluation in the healthcare sector, thereby aiming to generate representative data [12, 13].

To ensure the representativeness of the sample, the inclusion and exclusion criteria for the target group of the usability evaluation were explicitly defined:

Inclusion criteria:
- Active HEMS crew members and emergency physicians within the Austrian air rescue service
- Provision of informed consent to participate
- Proficiency in the German language at a minimum of level B2

Exclusion criteria:
- HEMS crew members and emergency physicians involved in the development of the application
- Pilots of the Austrian air rescue service
- Healthcare professionals who were unavailable during the evaluation period

Recruitment was conducted in several phases. Initially, close collaboration was established with stakeholders from CFV to clarify the study objectives and secure recruitment support. In this consultation, geographically proximate bases were identified, including C11 in Klagenfurt am Wörthersee and C7 in Lienz, East Tyrol. Furthermore, the opportunity to conduct the evaluation as part of a supra-regional air rescue training program was established to ensure a diverse sample.

Potential participants were informed about the usability evaluation in advance via email. This communication included a project description, details regarding the procedure and duration, as well as information on data protection. The consent declaration was attached to the email. Prior to the evaluation, Wi-Fi and appropriate facilities were arranged on-site. The strategic recruitment at specific bases, combined with the integration of supra-regional training, minimized potential selection bias and enhanced the generalizability of the results [14].

Application Development
The primary objective was to create an intuitive and user-friendly application tailored to the specific needs of pre-hospital emergency medicine [15, 16]. Color schemes and typography were selected based on existing research to optimize readability. Dominant shades of blue were incorporated into the color palette, as they are known to evoke a calming effect and enhance concentration [17–19]. The font was chosen according to established recommendations for readability in digital applications [20]. The user interface was designed in close collaboration with healthcare professionals to ensure seamless integration with existing workflows [15, 21]. To mitigate the risk of selection bias, these professionals were excluded from the usability testing phase.

The application was developed using React Native and specifically tailored to the high-stress environment of emergency medical services. No existing digital documentation solutions were analyzed or integrated; instead, the design was based entirely on evidence-based practice and the paper documentation in use. The development process followed an iterative, user-centered approach, incorporating feedback from users to refine the application further. This included collaboration with a member of a HEMS crew to ensure the application addressed operational needs effectively. Special emphasis was placed on the ability to record data swiftly and accurately, facilitating efficient use in time-sensitive situations

Data Collection
Data collection was conducted from July 1 to August 1, 2024. Participants were thoroughly informed about the study and its procedures in a quiet setting at their respective bases. They received detailed information regarding the study's objectives, data usage, anonymity, and data protection measures, with an assurance that they could withdraw their participation at any time without facing any disadvantages. Following a 10-minute demonstration of the application, during which its functionalities were elucidated, participants had the opportunity to ask questions. Subsequently, they either independently documented an emergency operation with which they were familiar or engaged with a prepared scenario case within the application. These scenarios were developed in coordination with stakeholders from CFV to ensure their realism.

Participants then evaluated the usability of the application using the System Usability Scale (SUS), a standardized tool for assessing the usability of electronic patient documentation systems [22]. The German translation by Gao [23] was employed due to its methodological validation. The questionnaire was accessible via a QR code, directing participants to a Google Forms document on their personal mobile devices, where they could also digitally confirm their consent. In addition to the ten SUS statements, two open-ended qualitative questions were included to gather deeper insights into the user experience.

Ethics
This research project received approval from the Ethics Board of the St. Pölten University of Applied Sciences. Given that this study was entirely non-interventional in nature, a comprehensive ethics application was not deemed necessary. Participants were informed of the study's objectives in advance and provided their informed consent to participate.

Data Analysis
Data analysis was conducted in August 2024 utilizing Excel and PSPP software. The System Usability Scale (SUS) scores were computed using the established formula [24]:

$$\textbf{SUS-Score} = (\textstyle\sum \textbf{raw value}) \times \textbf{2.5.} \tag{1}$$

Descriptive statistics, including mean, median, minimum, and maximum values, were calculated to assess the distribution of scores. Furthermore, correlations between the SUS scores and baseline characteristics - such as age group, professional experience, and digital competence - were examined using Spearman correlation coefficients.

Qualitative data obtained from open-ended questions were analyzed through thematic analysis as outlined by Schreier [25]. This methodology encompasses several stages, including progressive paraphrasing, streamlining, contrasting, category development, and subsumption. The findings were presented in both qualitative formats (summarized text presentation) and quantitative formats (frequency of categories).

3. Results

As part of the results section, initially, the baseline characteristics of the participating users are detailed. Following this, the quantitative results from the System Usability Scale (SUS) are presented. Subsequently, the qualitative findings, derived from two open-ended questions, are summarized.
A total of 30 healthcare professionals from the Austrian Helicopter Emergency Medical Services participated in the usability evaluation. The demographic characteristics of the participants are summarized in Table 1.

Table 1: Baseline characteristics of the participating healthcare professionals (N = 30).

Baseline	**n**	**%**
male	28	93.3
Age group 25-39 years	7	23.3
Age group 40-59 years	23	76.7
<1 year work experience	3	10
>1 - <=3 years work experience	1	3.3
>3 - <=5 years work experience	3	10
>5 years work experience	23	76.7
“moderate” digital competence	8	26.7
“good” digital competence	12	40
“excellent” digital competence	10	33.3

Among the 30 participants, 28 (93.3 %) were male, which reflects the HEMS employee representation. Participants were categorized into two age groups: seven individuals (23.3 %) fell within the 25–39 age range, while the majority, comprising 23 individuals (76.7 %), were aged between 40 and 59 years.

The participants' work experience was classified into four distinct groups. Three participants (10 %) had less than one year of work experience, while one participant (3.3 %) possessed between one and three years of experience. Additionally, three participants (10 %) had between three and five years of experience, whereas the largest group consisted of 23 participants (76.7 %) who had more than five years of experience.

Regarding digital competence, eight participants (26.7 %) assessed their skills as moderately competent, 12 participants (40 %) rated themselves as 'good,' and ten participants (33.3 %) considered their digital competence to be 'excellent.'

The characteristics gathered indicate a predominantly experienced and male user group with medium to high levels of digital skills.

Quantitative Results
This section presents an analysis of the data obtained from the System Usability Scale (SUS) to provide comprehensive insights into users' perceptions of the application.

Figure 1 illustrates the individual SUS scores of the 30 participants. The average score of 79.92, along with a median of 78.75, reflects a generally high level of satisfaction regarding usability. However, the presence of lower individual scores indicates areas that require optimization. Additionally, the broad range of scores, spanning from 55 to 100, highlights the variability in user experience.

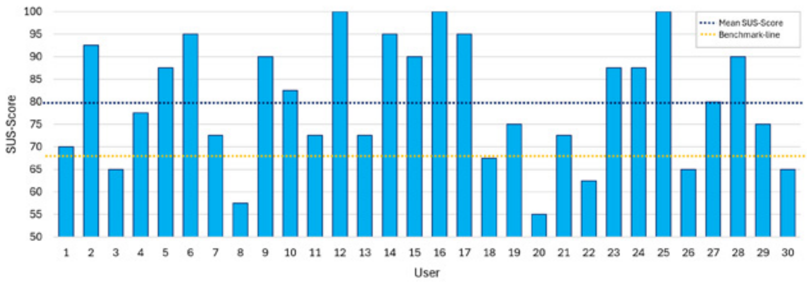

Figure 1: Bar chart illustrating the System Usability Scale (SUS) scores of individual users.

The average SUS rating of 79.92 indicates that the majority of users perceive the usability of the application as good to very good. This is further supported by the frequency of scores ranging from 70 to 95. The median score of 78.75 suggests that most ratings are clustered around the mean, with only a few outliers.

The lowest SUS score recorded is 55, which remains above the critical threshold of 50, below which a system would be deemed clearly inadequate. Users who scored in this range may have encountered specific issues while using the system; however, they do not classify it as entirely unusable.
Additionally, box plots have been generated to illustrate the distribution of user ratings for each of the ten SUS statements. Figure 2 offers in-depth insights into the distribution and trends of individual responses, facilitating a more nuanced interpretation of the usability ratings.

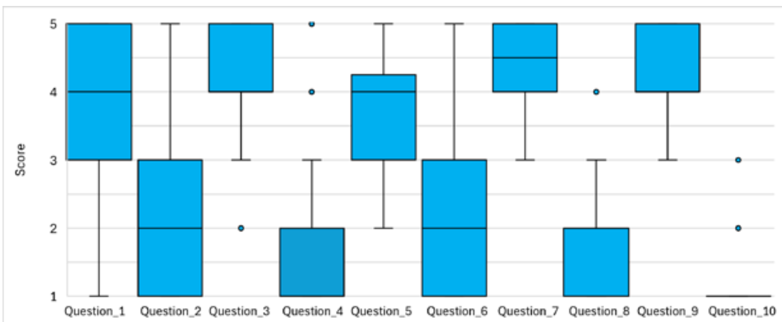

Figure 2: Boxplot of SUS Scores by Question.

Overall, the box plots indicate a predominantly positive user perception of the app. The medians for the questions (1, 3, 5, 7, and 9) fall within a high range, reflecting a strong level of user satisfaction. Conversely, the questions addressing potential negative aspects of usability (2, 4, 6, 8, and 10) show low medians, suggesting that the majority of users did not encounter these issues.

A correlation analysis was conducted to explore the relationships among various variables associated with the usability of the electronic documentation application. The analysis revealed a moderate positive correlation between users' digital competence and their usability ratings ($r = 0.19$, $p = 0.31$), suggesting that individuals with higher digital competence tend to perceive the application as more user-friendly. Conversely, a very weak negative correlation was observed between participants' work experience and their perceived usability ($r = -0.10$, $p = 0.58$), indicating that more experienced users tend to provide lower ratings for the application. Additionally, no significant correlation was identified between participants' age and their usability ratings ($r = 0.11$, $p = 0.53$). These findings imply that digital competence and work experience are more influential factors in shaping users' perceptions of the application than age.

Qualitative Results
While the System Usability Scale (SUS) scores offer a general overview of usability from the user's perspective, the qualitative data provides more profound insights into specific user experiences, challenges, and suggestions for improvement. The qualitative findings are summarized below to present a nuanced understanding of user perspectives regarding the application. Two open-ended questions were posed to capture users' attitudes and opinions on electronic documentation utilizing the app:

- “What additional comments do you have about this app?”
- “If the app were to be launched tomorrow, what are your feelings about it?”

The responses were paraphrased, compared, and organized into meaningful categories. The developed coding framework resulted in the following four categories:

1. **Automation and Integration:** The necessity for automated data transfer and integration with existing systems.
2. **Need for Improvement and Adaptation:** Specific suggestions for optimizing the application and the ongoing need for improvement and adaptation.
3. **Positive Attitude Towards the Application:** General acceptance and a favorable attitude towards the application.
4. **Simplification and Efficiency vs. Concerns:** The desire for straightforward and efficient operation, coupled with certain concerns.

These categories were systematically applied to the responses to provide a comprehensive overview of user opinions. The most significant results of the qualitative analysis are presented below.

1. Automation and Integration (13 of 43 responses, approximately 30 % of all statements)
A considerable proportion of users underscored the importance of automated data transfer from medical devices and integration with existing systems, such as ‘Leonardo’. This technical integration is deemed essential for the effective utilization of the application. One user articulated this need as follows: “[…] *Übertragung des Protokolls ins Leonardo oder eine automatisierte Aufzeichnung der Daten aller unserer medizinischen Geräte in dieses System […]* ([…] transfer of the protocol into Leonardo or automated recording of data from all our medical devices into this system […])” (Statement 2.1). Other comments highlighted the necessity for all relevant data to be automatically transferred to the application without requiring manual input: *“Alle Daten sollten automatisch übernommen werden, ohne sie selber eintragen zu müssen, […] es sollte wirklich nicht viel Zeit in Anspruch nehmen, so dass man sich immer an den Patienten widmen kann* (All data should be automatically transferred without having to enter it yourself, […] it really shouldn't take much time so that you can always focus on the patient)” (Statement 1.20). These technical requirements are considered central to the efficient use of the application, as they could significantly reduce the documentation effort.

2. Need for Improvement and Adaptation (15 of 43 responses, approximately 35 % of all statements)
A significant number of users provided specific suggestions for enhancing the application, encompassing both technical and functional aspects. Notable recommendations include the incorporation of additional drop-down menus for medication dosages (statement 1.7) and the addition of a 'Now' button for time entries (statement 1.5). These insights indicate that users possess clear expectations regarding the app's functionality and are inclined to utilize it if it undergoes continuous enhancements. Furthermore, several respondents underscored the importance of allowing for improvements post-launch to better align the app with practical needs: *'[...] es sollte die Möglichkeit bestehen, weiterhin Verbesserungen nachträglich zu implementieren* ([…] it should be possible to continue to implement improvements at a later date)' (statement 2.11).

3. Positive Attitude Towards the Application (23 of 43 responses, approximately 54 % of all statements)
The majority of users conveyed a generally favorable attitude toward the application. Comments such as *'Gute Umsetzung, intuitiv zu bedienen* (Good implementation, intuitive to use)' (statement 1.9) and '[...] *optisch ansprechend und autodidaktisch gut gelöst!* ([…] visually engaging and autodidactically well solved)' (statement 2.2) reflect a high level of satisfaction with its development. Although many users acknowledge the challenges associated with the app's implementation, they perceive the transition toward digitalization as a positive and necessary step: *'Grundsätzlich ist so eine Umstellung [...] mit einem höheren Zeitaufwand verbunden, [...] aber der Weg "vorwärts in Richtung Digitalisierung" wäre zu begrüßen!* (Basically, such a change [...] is associated with a higher time expenditure, [...] but the path "forward towards digitalization" would be welcomed!)' (statement 2.1).

4. Simplification and Efficiency vs. Concerns (8 of 43 responses, approximately 19 % of all statements)
Despite the overall positive feedback, some users expressed concerns regarding the app's practicality, particularly in time-sensitive situations. One user remarked: *'Sie darf nicht komplexer und langwieriger sein als eine analoge Dokumentation. Meist am Rückflug ausgefüllt mit wenig Zeit [...]* (It should not be more complex and time-consuming than analogue documentation. Usually filled in on the return flight with little time [...]' (statement 1.8). These concerns highlight that the app's efficiency and usability are critical to its acceptance. Additionally, some users feared that the application might be implemented too hastily or could prove impractical in certain circumstances.

The qualitative analysis indicates that users view the introduction of a digital documentation application as a promising tool for the digitalization of medical records. The high level of acceptance is evident in the predominantly positive feedback. Users have distinct expectations regarding the app's functionality, usability, and integration. Automation and seamless integration with existing systems are perceived as essential for the success of such applications. The successful implementation will largely hinge on meeting these expectations and continuously adapting the application to the evolving needs of users.

4. Discussion

This study aimed to assess the usability of an electronic documentation application utilized by the air rescue service, focusing on the perspectives of healthcare professionals. The research employed a comprehensive data collection approach, encompassing both quantitative and qualitative methods, to achieve an in-depth understanding of user experiences and to inform future developments of such systems.

The results from the quantitative assessment, utilizing the System Usability Scale (SUS), were correlated with qualitative feedback. The evaluation of the electronic documentation application yielded an average SUS score of 79.92 from 30 participants, with a median score of 78.75. This score significantly exceeds the commonly referenced benchmark of 68, which is regarded as the threshold for above-average usability [26].

In contrast, a cross-sectional study conducted in the United States reported an average SUS score of only 45.9 (SD ± 21.9) for electronic health records. In that study, higher SUS scores were linked to lower levels of emotional exhaustion and depersonalization, as well as a reduced frequency of work-related burnout [27]. The elevated SUS score in the current study suggests that the application is user-friendly, even though it may not fully satisfy the requirements of all user groups.

It is important to note that the interpretation of SUS scores can vary across different contexts. A more recent interpretation, based on the Curved Grading Scale (CGS) proposed by Sauro & Lewis [28], assigns a more favorable classification to the same score, categorizing it as "A-," which corresponds to a percentage score of 85–89 %. This variation illustrates that identical SUS scores can be perceived differently depending on the scoring system employed. In this recent interpretation, the high score indicates a user-friendly application; however, it should not be regarded as definitive proof of optimal usability across all dimensions.

A critical aspect of the analysis is the variation in SUS scores relative to individual user characteristics. Participants with greater experience and higher digital competence tended to provide more favorable usability ratings. This contrasts with findings from another study, which indicated that older physicians rated electronic health records as less user-friendly compared to their younger counterparts [27]. The specific involvement of Austrian HEMS crew members in the app's development may have resulted in a tailored application primarily suited for experienced and digitally adept users. It may be beneficial to create specific adaptations of the app for users with less experience or digital proficiency.

An examination of the 7 participants (23.33 % of 30) whose SUS scores fell below the benchmark of 68 revealed that individuals in the 25–39 age group (23.57 % of the 7 participants) provided a less favorable evaluation of the application. This finding supports the notion that the app may not adequately address the needs of younger users.

Interestingly, some experienced users with strong digital skills also rated usability poorly, indicating possible inconsistencies in the feedback. Such discrepancies may stem from misunderstandings in interpreting the SUS statements, a concern echoed by participants who reported difficulties in comprehending the statements.

Qualitative data analysis indicates that while the majority of users generally rate the application positively, they express clear requirements for technical integration and process automation. Notably, 30 % of the comments highlighted the necessity for seamless integration with existing systems, such as Leonardo, as well as the automation of data collection. These requirements are deemed essential for the application's acceptance and usability. Literature supports the notion that inadequate software integration and insufficient automation can lead to low acceptance rates [29], as the application may otherwise be perceived as an additional burden.
Furthermore, qualitative analysis reveals that users expect the application to be both easy and intuitive to use while simultaneously demanding a robust and well-integrated solution. This expectation presents a challenge for future development, necessitating a balance between the required technical complexity and usability. This critical issue warrants further investigation, particularly concerning implementation in high-stakes environments such as air rescue services.

The high acceptance of the application, coupled with the favorable SUS score, reflects a generally positive attitude among users towards digital documentation systems. However, the findings from both qualitative and quantitative evaluations underscore the ongoing need to enhance the application and adapt it to the evolving needs of users, thereby facilitating its full integration into daily workflows and further increasing acceptance.

Strengths and Limitations
The methodological approach of this study presents several strengths and limitations, which are elaborated upon below.

A notable strength of this study is the utilization of a QR code for distributing the questionnaire and conducting data collection on participants' mobile devices. This approach enhances accessibility to the survey and increases the likelihood that participants can complete the questionnaire in its entirety without encountering technical barriers.

The combination of convenience and purposive sampling allows for efficient participant recruitment and the fulfilment of specific inclusion criteria. However, this sampling strategy introduces potential bias. Convenience sampling may lead to an overrepresentation of certain demographic groups while underrepresenting others that are relevant. Additionally, purposive sampling carries the risk that the sample may not fully represent the target population, which could limit the generalizability of the findings, particularly concerning the experiences and perspectives of Austrian HEMS professionals.

The absence of a power calculation and the reliance on previous studies for sample size estimation raise concerns that the sample may be insufficiently sized to yield statistically significant results. This limitation may impact the power of the findings and diminish the ability to detect differences or associations, especially when analyzing subgroups.

Participant recruitment was primarily focused on two HEMS bases (Klagenfurt am Wörthersee and Lienz in East Tyrol) and individuals participating in one supra-regional air rescue training program. Despite efforts to enhance sample diversity through supra-regional training, this regional concentration may have constrained the variety within the sample. Consequently, regional differences in working conditions, culture, or technical access may not be adequately represented, potentially affecting the transferability of the findings to other regions in Austria.

While the use of the System Usability Scale (SUS) for assessing usability is advantageous due to its widespread recognition, it also has limitations. The SUS is relatively general and may not fully capture the specific aspects of usability pertinent to highly specialized applications such as emergency medicine. The careful selection and implementation of a systematically validated German translation of the SUS reflect the author's commitment to ensuring methodological rigor and scientific integrity. However, the "unnatural choice of words" in the German version may have influenced participants' interpretations of the statements, thereby affecting the validity of the results.

The inclusion of a qualitative component through open-ended questions complements the quantitative SUS results, offering deeper insights into user experience. This approach enhances the understanding of the nuances and complexities of user perceptions, thereby improving the quality and validity of the findings. However, the intended supplementary qualitative method, the think-aloud, could not be executed due to the inability to recruit participants. This represents a significant limitation, as this method would have yielded valuable insights into users' cognitive processes during their interaction with the application. The absence of this qualitative component limits the study's ability to provide a deeper, contextualized understanding of the user experience, which is challenging to capture through quantitative methods alone.

Theoretical and Practical Implications
Based on the findings of this study, several recommendations can be proposed for future research and practical applications.

The results indicate that usability assessments vary according to users' digital competence and work experience. It is advisable to tailor the user interface of the electronic documentation application to meet the specific needs of diverse user groups. A significant barrier to the acceptance of the application is its lack of integration with existing systems, such as Leonardo. Therefore, prioritizing seamless integration and automation of documentation processes is essential to reduce user workload and enhance the application's usability.

The observed discrepancies in usability ratings among different age and experience groups warrant further investigation. Future research should focus on systematically analyzing these variations and identifying their underlying causes.

The inconsistencies in the System Usability Scale (SUS) ratings suggest possible misunderstandings in interpreting the statements. Future studies should explore the extent to which these discrepancies arise from cultural or linguistic differences. Given that the SUS may be interpreted differently across languages and cultural contexts, comparative studies on its international application would be beneficial. Such research could enhance our understanding of the SUS's validity in various contexts and, if necessary, lead to the development of adapted versions of the instrument.

Considering the specific circumstances of the Austrian air rescue service, it is recommended that pilot tests of the electronic documentation application be conducted at regional CFV bases. This approach would facilitate the collection of site-specific feedback, ensuring that the application is tailored to the varying operational conditions across Austria. Acknowledging regional differences in work processes will help optimize the application's usability in diverse operational scenarios.

5. Conclusion

This study examined the usability of an electronic documentation application for Austrian Helicopter Emergency Medical Services from the perspective of healthcare professionals. The findings indicate that the application demonstrates good overall usability, as evidenced by an average SUS score of 79.92, reflecting a high level of user acceptance and satisfaction.

However, the detailed analysis reveals variations in usability perception: experienced and digitally competent users tended to provide more favorable ratings, while less experienced and younger users exhibited lower satisfaction levels. This discrepancy suggests that the application may not be equally effective for all user groups.

Qualitative analysis indicates that users desire improved integration of the application with existing IT systems and enhanced process automation. Users' willingness to adopt the application is closely linked to their perceptions of its efficiency and usability.

Overall, the results of this study emphasize the importance of continuously adapting and enhancing digital health applications to align closely with the needs of end users. The high acceptance level of the application, combined with the identified areas for improvement, suggests that it can offer valuable support to HEMS, provided that the noted shortcomings are addressed. Consequently, future developments should focus not only on enhancing technical functionalities but also on optimizing the user experience to ensure sustained acceptance.

Addressing the research question provides insights into how digital systems can be optimized to enhance user acceptance and satisfaction, ultimately contributing to improved patient care in high-stress emergency situations.

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Conflicts of Interest Statement

The authors declare that there is no conflict of interests regarding the publication of this paper.

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AI Integration in EHR-Based Pharmacovigilance: A Comparative Study of Germany and Egypt

David Naguib,[a] Georgi Chaltikyan,[b] Ahmed Adel[c]

[a]VigiPRO GmbH, Deggendorf Institute of Technology (DIT), Deggendorf, Germany
[b]Deggendorf Institute of Technology (DIT)/European Campus Rottal-Inn (ECRI), Pfarrkirchen, Germany
[c]Cur-is Life Sciences Solutions®, The University of Utah, Salt Lake City, Utah, USA

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ABSTRACT

Introduction: **Pharmacovigilance (PV) depends mainly on traditional reporting as a main source of data. This research will focus on another source, namely EHRs (electronic healthcare records). As we deal with big data from EHRs, AI (artificial intelligence) tools will be indispensable for the processing, and analysis of data and the early detection of ADRs (adverse drug reactions) from EHRs. In this research, we will explore the knowledge, attitudes and practices (KAPs) of the experts regarding the current application of AI in EHR-based PV, the potential benefits of implementing these technologies in PV, and the challenges toward their implementation in Germany and Egypt.**

Methodology: **A semi-structured survey of 30 questions that targeted the attitudes, knowledge and experience from PV experts (172 responses) was conducted.**

Results: **The results revealed that most PV companies in Egypt or Germany do not use EHRs as a main data source. This can be attributed to the lack of the application of EHRs in Germany and Egypt (e.g. EHRs in Germany is in a very early phase). Most of the PV organizations in both companies do not use AI as well in their PV activities. There is also a lack of proper adherence to data protection regulations in Egypt. However, the participants in both countries show a very positive attitude toward the adoption of AI and EHRs in the PV.**

Conclusion: **AI technologies and EHRS in the domain of PV are very rarely applied either separately or collectively in both countries, there is also a lack of knowledge among PV specialists about digital health but there are positive attitudes toward its adoption.**

KEYWORDS

Pharmacovigilance, electronic healthcare records, electronic healthcare records-based pharmacovigilance, adverse drug reactions, artificial intelligence

1. Introduction

One of the leading causes of death and a significant contributor to the expenses in public health (PH) are adverse drug reactions (ADRs) [1]. According to the Centers for Disease Control and Prevention (CDC), adverse medication events result every year in over 1.5 million visits to emergency rooms. About 500,000 individuals annually require hospitalization for further care following emergency room visits due to adverse medication reactions [2]. This accounts for the importance of pharmacovigilance (PV) which focuses on drug safety.
Pharmacovigilance can be defined as the science and process of monitoring the safety of medications and implementing actions to reduce the risks and increase the safety and benefits of medicines. This very task of the PV is one of the key roles of public health [3].

PV depends on a variety of data sources to monitor the safety of medications. Pharmaceutical companies, patients, and healthcare professionals voluntarily report ADRs through individual case safety reports (ICSRs) to spontaneous reporting systems (SRS) for compilation [4]. Furthermore, patient health data is recorded in EHRs during clinical practice and can be used to identify safety signals. Medical services are also tracked by healthcare claims databases, which helps with ADRs identification [5]. In addition, clinical trials, registries, and observational studies all shed light on drug use and safety in the real world and serve as potential and good supplemental sources of data for PV activities. Further viewpoints on adverse events and medication use can be found in patient surveys, pharmaceutical sales data, and social media conversations, in addition to the literature reviews (sometimes called medical literature) [6]. Collaborative networks (e. g. the European Network of Centers for Pharmacoepidemiology and Pharmacovigilance [ENCePP]) emphasize a complete strategy to guarantee patient well-being and drug efficacy, which adds to our understanding of medication safety [7]. So, there are a lot of sources of data that are utilized in the domain of PV.
In this research, the focus will be on EHRs (electronic healthcare records) as a promising source of data. The use of EHRs in pharmacovigilance is a good example of the secondary use of data [8, 9]. In the past ten years, there has been a rise in interest in pharmacovigilance using EHRs [10, 11]. And as we deal with the big data of the EHRs, we need advanced tools for data processing and analysis. So, the use of AI is crucial.

There is great interest in the topic of artificial intelligence (AI) and its application in the domain of PV. For instance, from 2010 to 2020 alone, the publication rate on the topic of machine learning (ML; a subcategory of AI) in PV has increased approximately sixfold [12].

EHRs are already utilized independently as a source of information for pharmacovigilance activities in some countries (e. g. South Korea). For example, the Korea Institute of Drug Safety and Risk Management (KIDS) transformed 9 million records into a certain common data model (CDM) to standardize the data in EHRs between different healthcare systems in order to facilitate the detection of drug safety signals [13]. Other European countries have already established EHR systems (Italy, Great Britain, Norway, Sweden, Finland, Denmark) [14]. Other countries like the U.S., Japan, Canada, and Australia have also already implemented EHRs and associated activities to the PV. The WHO also uses EHRs in the PV process [11, 15]. The use of EHRs in pharmacovigilance activities will be adopted as well by other international organizations (e. g. the Food and Drug Administration [FDA]) despite some challenges like the problem of heterogeneity and the integration between the drug safety data [16]. The FDA's Adverse Event Reporting System (FAERS) is working on getting Real-world Evidence (RWE) from real-world data (RWD) through a collaborative project called FDA's Sentinel Initiative. This project which is adopted by FAERS aims to use all the new technological advancements (big data, AI, EHRS, etc.) to enhance the monitoring of drug safety and this will be done through collaboration with different stakeholders (e. g institutes, hospitals, AWS, Epic developers, etc.) [16–18].

A comprehensive literature review of the existing literature on the use of AI in EHR-based pharmacovigilance in Germany and Egypt was implemented and there were no specific papers identified that discuss the use of AI or EHRs in Germany and Egypt separately or collectively. Almost all the papers that address the pharmacovigilance situation in both countries are about common problems like the poor quality of the reports or the underreporting, [19] or German physician's lack of awareness about pharmacovigilance [20], or about the practices and attitudes of physicians and pharmacists in Egypt toward PV [21, 22]. Moreover, we identified case studies on some medications discussing the pharmacovigilance of homeopathic products or veterinary medicine or about the hierarchy and the organization of pharmacovigilance in Germany [23].

The research questions were aimed at detecting the attitudes, the knowledge and the behavior (KAPs) of the experts regarding the reality of AI application in EHR-based PV. Reality means the real applicability, namely: How is AI already being applied to EHR-based pharmacovigilance (EHRs as the mean source of data)? What are the advantages or benefits and opportunities of the future application of AI in EHR-based PV? And what are the challenges to such implementation of AI in EHR-based PV? For a better understanding of these dimensions, we need a real context, we therefore examined the reality, challenges, advantages, and opportunities of the applicability of EHR-based PV in both Germany and Egypt. Finally, we will pose some suggestions and recommendations that will help increase AI adoption in EHR-based PV in general, and in Egypt and Germany specifically.

To achieve these goals, an Internet-based survey was conducted by specialists in Germany and Egypt. Then all the results (either qualitative or quantitative data) were collected and analyzed to discover the common trends, opportunities, and challenges based on the expert opinions. Interviews with experts (8 experts) as a validation method for the semi-structured survey were also conducted.

The scope of this research is on the role of pharmacovigilance in post-market analysis. In this phase of post-market analysis, our focus will be on the detection of ADRs rather than the other functions of pharmacovigilance which are concerned with quality issues, adulteration, misuse…etc.
The survey followed this logical sequence, which is based on the research question. First, we examine the knowledge and practices regarding the reality and then the attitudes and the expectations of the experts regarding the potential opportunities, and the challenges toward the application, and finally the suggested solutions.

2. Methodology

2.1 Data collection

The **online-based survey** (quantitative/qualitative data collection techniques) is the research method which was used to collect the primary data, namely the attitudes, the knowledge and the opinions of the digital health specialists and healthcare professionals (HCP) who are involved in the process of pharmacovigilance in Germany and Egypt (target audience).
The Internet-based survey was conducted through a Microsoft Forms survey. The survey was started on 16th January 2024 and ended on the 22nd February 2024, and it was available in English and German.

2.2 Calculating the Sample of the Survey

To ensure the accuracy and representativeness of the data within the respective contexts of Germany and Egypt in this comparative study, distinct sample sizes were computed of each population separately. The study attempted to attain strong statistical power and precision within each group by calculating sample sizes appropriately, which would allow for relevant comparisons between Egypt and Germany.
Sampling tactics ensured the inclusion of pharmacovigilance specialists as a crucial demographic to ensure proper representation, taking into consideration their smaller population when compared to other healthcare professionals.
A simple formula for determining sample size based on the population size and a desired confidence level was used.

The formula is:

$$\textbf{Sample size} = Z2 \times p \times (1-p)/E2 \qquad (1)$$

Where:
Z is the Z-score associated with the desired confidence level
p is the estimated proportion of the population that has the characteristic we were interested in (if unknown, we used 0.5 for maximum variability)
E is the margin of error

The desired sample sizes for Germany and Egypt were 60 and 90 participants, respectively. The difficulty in collecting bigger sample sizes was exacerbated by a scarcity of pharmacovigilance specialists in Egypt and Germany. The number of participants needed remained relatively constant despite the smaller population sizes (approximately 3,000) because the computation is mostly based on the acceptable margin of error and confidence level.

So, the confidence level was changed to roughly 90 % for **Germany**, where a smaller target sample size of 60 was established. Based on the assumption of 3,000 participants in pharmacovigilance, a proportion (p) of 0.5, and a margin of error (E) of 10.55 %, the revised sample size computation produced a result of around 60. Similarly, a comparable adjustment to almost 90 % for the confidence level was made for **Egypt**, with a target of 90 participants. Recalculating the sample size, we found that it was 90 with a population of 3,000 people participating in pharmacovigilance, a proportion (p) of 0.5, and a margin of error (E) of 8.57 %. These modifications made it possible to obtain more manageable sample sizes without sacrificing a respectable degree of accuracy and confidence in the survey results. These calculations were done with the help of online calculators [24] and ChatGPT.

In addition, the power of the experiment/statistical power was calculated for some of the data points (questions number 8, 10, 18). The one-sample z-test for proportions is the statistical test that is being applied in these situations for the validation or the confirmation of the hypothesis/claim for each of the questions of the survey. The mathematical formula for the z-statistic in a one-sample z-test for proportions is:

$$z = \frac{\hat{p} - p_0}{\sqrt{\frac{p_0(1-p_0)}{n}}} \qquad (2)$$

One-sample Z test

$\hat{p}$ is the sample proportion.
p^0 is the hypothesized population proportion.
n is the sample size.

The above-mentioned equation was quoted from ChatGPT. The one-sample z-test for these questions was calculated for the general sample (total number of participants, Germany and Egypt) and each country separately. The Z for these experiments was conducted with the help of Python under the supervision and guidance of a data analyst.

The survey was designed to obtain the two main types of data, namely structured (labeled) and unstructured data (unlabeled), taking into consideration that our focus was on structured data [25].
To get this structured data, multiple-choice close-ended questions were used. Dichotomous or trichotomous (i. e., “yes” or “no”, “not sure”) questions were also employed in the survey to the same end. Rating or Likert scales were used as well [25].

2.3 Validation of the survey

Different ways were used to validate the survey [26].

Interviews: The opinions of the experts were collected through 8 interviews which ensured the validity of the content. The interviews were conducted as a validation method for the survey questions and to determine the best questions which serve the purpose of the survey. Interviews were conducted with different audiences working in different settings in PV fields (target audience), with different job descriptions. The interview was conducted within a time interval of 40–60 minutes. The interviews were conducted in English and German, recorded, and finally transcribed. Participants were asked to sign consent for the sake of data privacy and protection. The following table depicts the demographics of the 8 interviewees:

Table: Demographic information.

Age Categories
25–34: 2 interviewees
35–44: 5 interviewee
45–54: 1 interviewee
Over 65: no interviewees in this category
Gender
Male: 4 interviewees
Female: 4 interviewees
Workplace Categories
Pharmaceutical company: 5 interviewees
Contract research organization: 1 interviewee
Digital Pharmaceutical Company: 1 interviewee
Insurance company: 1 interviewee
Years of Experience
2–3 years: 3 interviewees
4-7 years: 3 interviewees
8+ years: 2 interviewees

PV role categories
Quality and PV manager: 2 interviewees
Senior pharmacovigilance specialist: 2 interviewees
Pharmacometrician: 1 interviewee
Pharmacist Product Owner and Manager: 1 interviewee
Pharmacovigilance physician	medical affairs: 1 interviewee
Patient tele-education: 1 interviewee
Country of Work
Egypt: 4 interviewees
Germany: 4 interviewees

Pilot test: a survey was done on a small scale (a sample of a similar target group of 10 people) before sending the survey to the whole target group to check the technical issues, the comprehensibility of the survey's questions, and the duration of the survey.

The questions of the surveys will be presented in the Results section together with the answers.
A list of 789 experts in Germany and Egypt that were to receive the survey was made (199 in Egypt, 590 in Germany).
The survey was sent through e-mails, social media platforms (e. g., specialized Facebook groups), and recruiters' platforms (LinkedIn), and it was further forwarded to personal contacts through colleagues.

3. Data Analysis

The data derived from the survey were divided into two categories: structured categorical, and unstructured data.

3.1 Analysis of the Structured Data

Regarding the structured categorical data, it was first saved in tabular format and rendered into quantitative form. The process of conversion of structured categorical data to structured quantitative data was done by using the measures of center (i. e., frequency or mood). These conversions were done by Microsoft Forms Analytics itself, and the data was collected in xlsx format and saved in One Drive. **Descriptive analytics** were conducted from Microsoft Forms data analytics and the data was also visualized using graphics (histogram, pie chart, dot plot).

The tabular data in the Microsoft Excel sheet format (xlsx) was imported to be analyzed by the Python programming language for further significant analytics to draw a comparison between Germany and Egypt. The comparison was only implemented for the questions which may show significant insights because of the comparison between Egypt and Germany. **These were the questions 9, 10, 13, 16, 18, 28, 29.**

The validation of this comparative analysis was conducted using **the two-sample z-test.** In our specific case, null hypothesis (H0): The percentages of affirmative answers from Egypt and Germany are the

same while the alternative hypothesis (H1) represents the percentages of favorable answers from Germany and Egypt differ.
The following mathematical formula of the two-sample z-test was employed:

$$z = \frac{(p_1 - p_2)}{\sqrt{\frac{p(1-p)}{n_1} + \frac{p(1-p)}{n_2}}} \quad (3)$$

Two-sample z-test

Where:
The sample proportions of the two groups under comparison are denoted by p1 and p2.
The sample sizes for the two groups are n1 and n2.
The total proportion combined from the two groups is denoted by p.
The two-sample z-test equation was quoted from ChatGPT.
The comparison and the validation were done using **Python** and the results were incorporated in the Results section.

All the graphs which were generated by Microsoft Forms or by Python. They were subsequently refined and modified (only for the better appearance) using ChatGPT.

3.2 Analysis of the Unstructured Data

The unstructured data from the survey was collected carefully to be analyzed by **thematic analysis** and incorporated into the Conclusion part.

4. Results

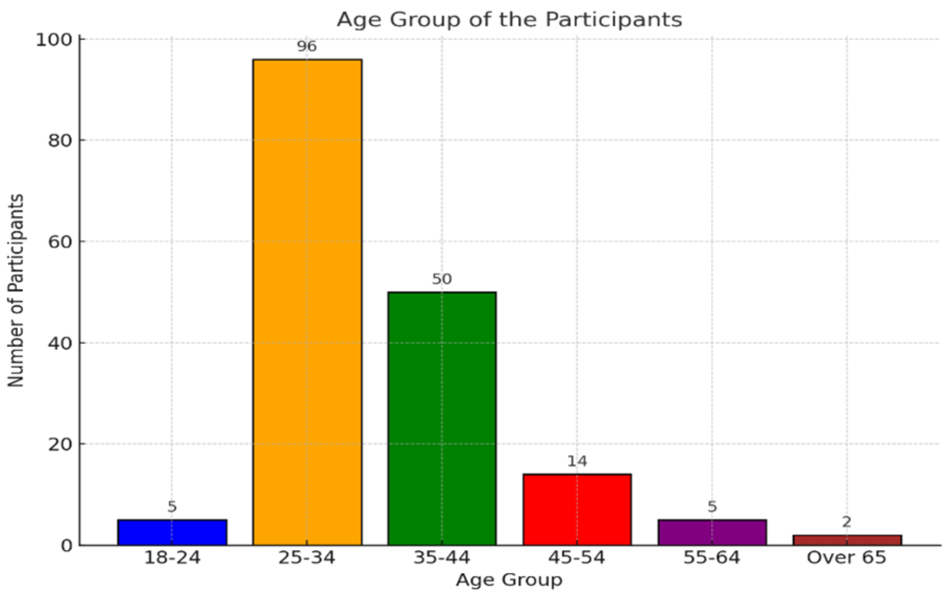
In total, **172 responses** to the survey were collected (63 in Germany, 93 in Egypt, and 16 other countries). The survey consisted of **30 questions which** were classified into 4 categories: q1–q7 consent of participation and demographics, q8–q19 Reality and application, q20–q23 (opportunities), and q24–q30 (challenges and suggestions).
The graphs represent the total number of participants including those who were not from Germany or Egypt to get a holistic overview of the topic of interest and because some of those who answered with "other" had already worked in Egypt or Germany
In addition, in certain questions where the statistical comparisons were deemed to be proper between Germany and Egypt, only data from both countries (excluding other participants) were utilized to conduct statistical analysis.
The results of one-sample z-test and the two-sample z-test were represented in association with corresponding questions.

4.1 Consent and Basic Demographics.

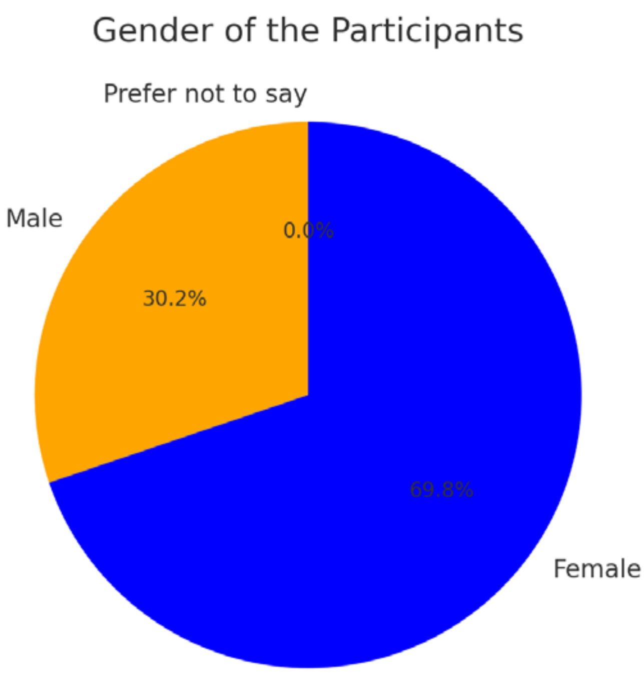
1. I have read and understood the information provided and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost.

I agree to participate: 172 I don't agree: 5

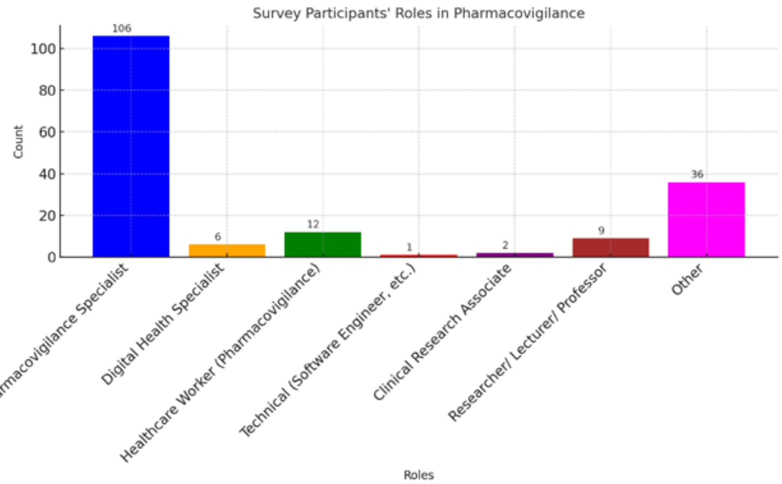
2. What is your age?



3. What is your gender?

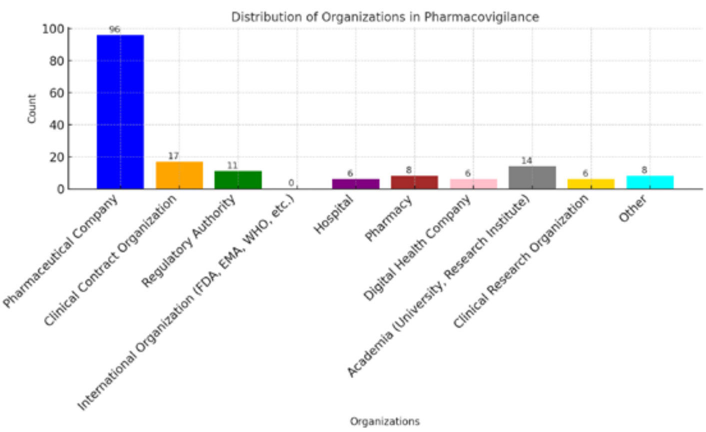


4. What is your current role and area of expertise in healthcare?

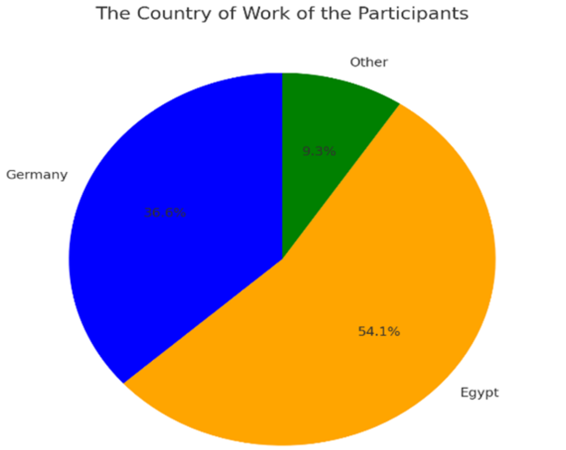


5. How many years of experience do you have in your current role?

6. Where is your workplace?

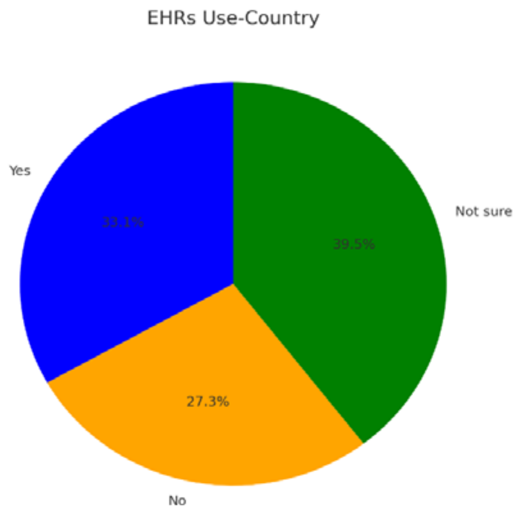


7. In which country are you currently working?



4.2 Reality and Application

8. Does your country of residence use electronic healthcare records (EHRs) in its healthcare system?



The one-sample z-test was conducted on this question and the results were the following:

For the total sample (Germany and Egypt)

The power of the experiment was 1.0; the z-statistic was 6.44704865098455, while the p-value was 1.140491864235056e–10. The p-value was 1.140491864235056e-10 less than the chosen significance level of 0.05. Therefore, we rejected the null hypothesis. There was sufficient evidence to suggest that the observed proportion of 0.3314 is significantly different from the expected proportion of 0.1.

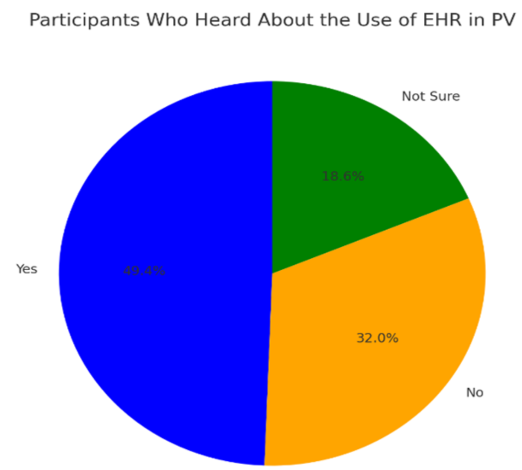
For Germany only

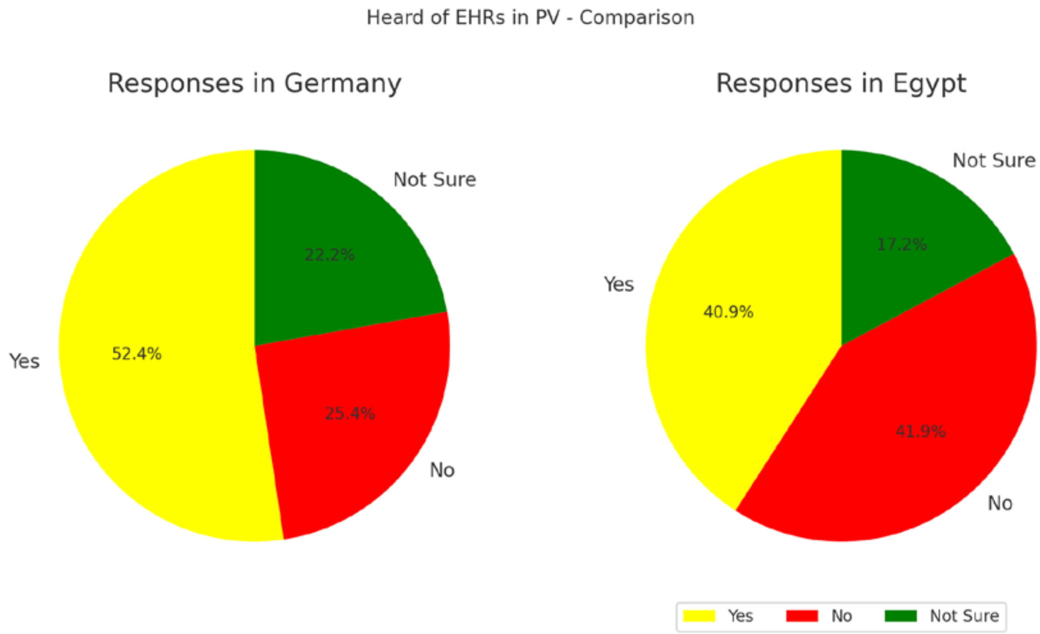
The power of the experiment was 1.0, the z-statistic 7.561249896677136, while the p-value was 3.992144237751295e–14. The p-value was 3.992144237751295e–14 less than the chosen significance level of 0.05. Therefore, we rejected the null hypothesis. There was sufficient evidence to suggest that the observed proportion of 0.5714 is significantly different from the expected proportion of 0.1.

For Egypt only

The power of the experiment was 0.21639975207702283, while the p-value was approximately 0.269; it exceeds our chosen significance level of 0.05. Hence, we had no grounds to reject the null hypothesis. In other words, there was not enough statistical evidence to support the claim that the observed proportion of 0.1398 deviated significantly from its hypothesized value of 0.1.

9. Have you ever heard about the use of electronic healthcare records (EHRs) of patients in the pharmacovigilance process?

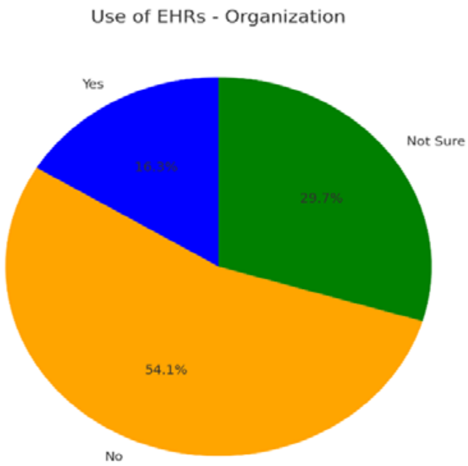


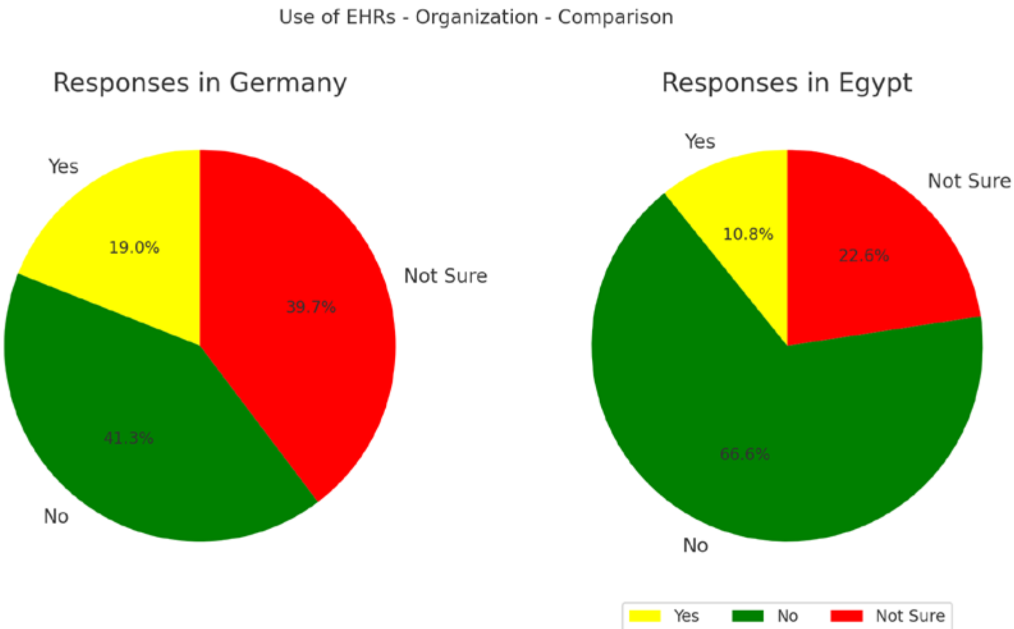


The **two-sample z-test** was conducted for this question.

The experiment had a power of 0.294467363572484. There were 93 samples in total from Egypt, which had a "yes" response in 38 cases and a "no or not sure" response in 55. There were 63 samples from Germany. Of them, only 33 provided "yes" responses, while the rest registered negative responses. The p-value for this research was calculated as approximately 0.156248483680624, with the z-statistic being approximately equal to that value at around 1.4178023301850076. As such, the null hypothesis remained unrefuted by the data used. There is no significant difference between the two countries.

10. Does your organization use Electronic Health Records (EHRs) in the pharmacovigilance process?





The **one-sample z-test** was conducted on this question and the results were the following:

Total sample (Germany and Egypt)

The experiment's power was 0.8063293867124136, the z-statistic was -3.0980984951602624, while the p-value was 0.0019476668523687802. Therefore, the null hypothesis was rejected since there was enough evidence to demonstrate that the observed proportion of 0.1628 differed significantly from the expected one of 0.25.

Germany Only

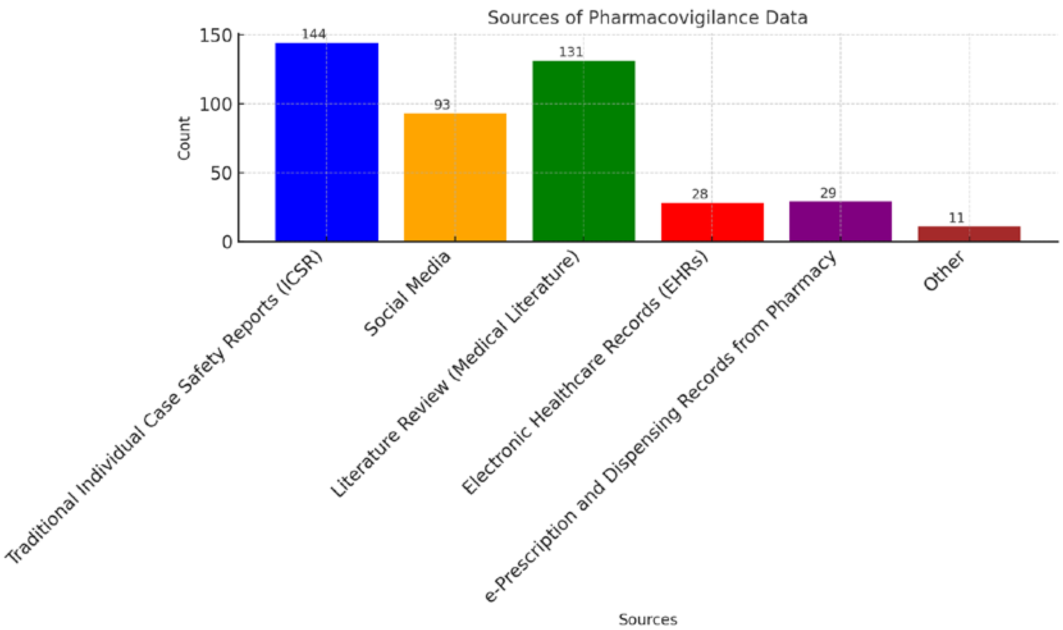
The experiment's power was 0.2028228819391893, the z-statistic was -1.2031667773495276, while the p-value was 3.992144237751295e-14. Therefore, we did not reject the null hypothesis since there was not enough evidence to show that the observed rate of (19 %) was different from the expected (25 %).

Egypt Only

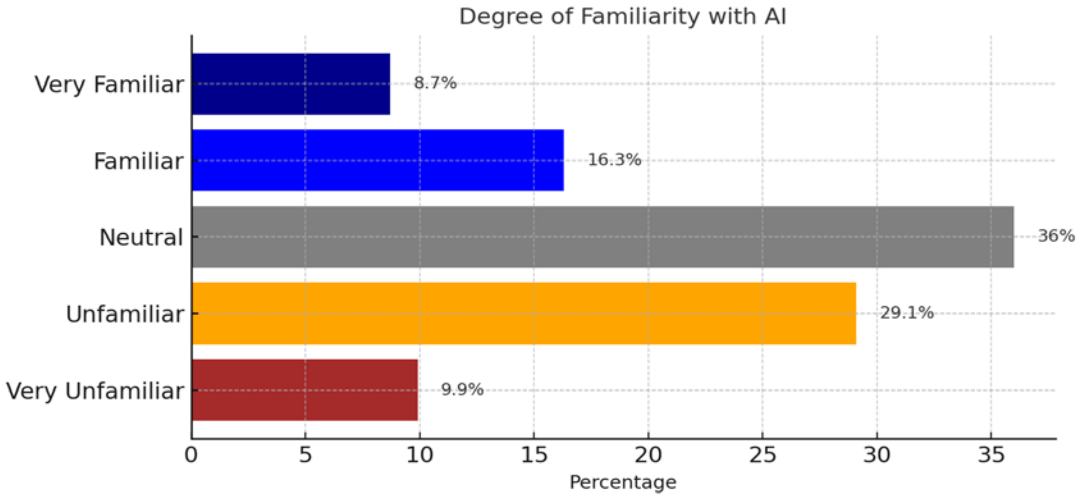
The power of the experiment was 0.9512066280912967 whereas the p-value was approximated as equal or greater than or equal to 0.05. Therefore, the null hypothesis should be rejected. There was enough evidence that demonstrated a significant difference between an observed proportion of 0.1075 and an expected one equaling 0.25

This question was subjected to a **two-sample z-test**. The power of the experiment was 0.3021145262608525. The z-statistic value was equal to 1.4605723670157307; while p = 0.14413283425964837.
The p-value equals approximately 0.144. This value was greater than or highly close enough to the pre-chosen significance level of α = 0.05; therefore, we could not reject the null hypothesis here. There seemed to be no compelling evidence that the proportion of positive responses differed significantly between Germany (0.19) and Egypt (0.108).

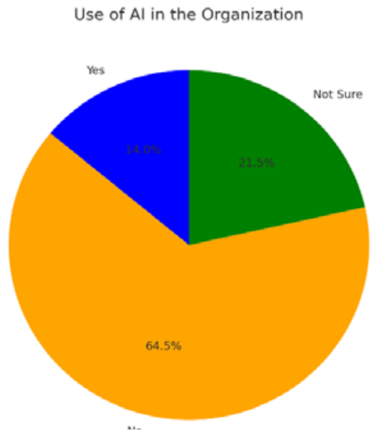
11. Which type of/source of information is used in the pharmacovigilance process in your workplace (select all that apply)?

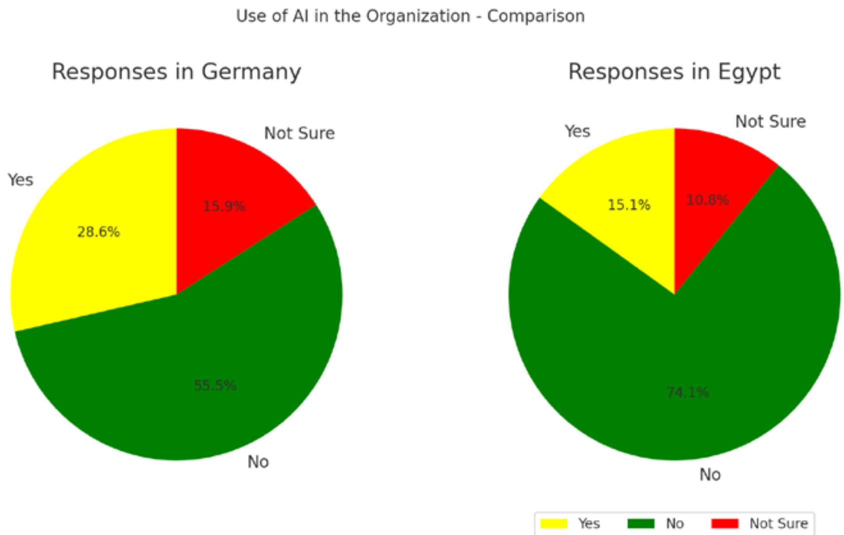


12. How familiar are you with the concept of AI (artificial intelligence) in pharmacovigilance?



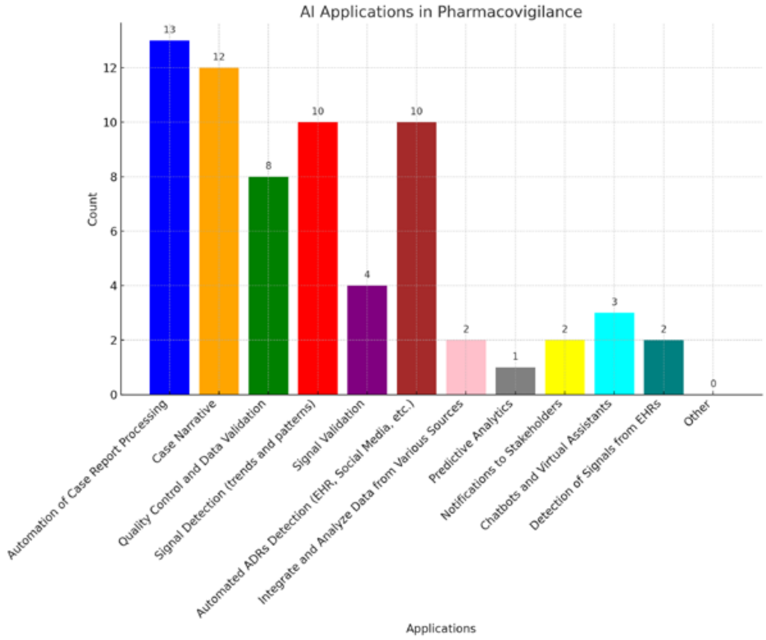
13. Does your organization currently use AI (artificial intelligence) in the process of pharmacovigilance?



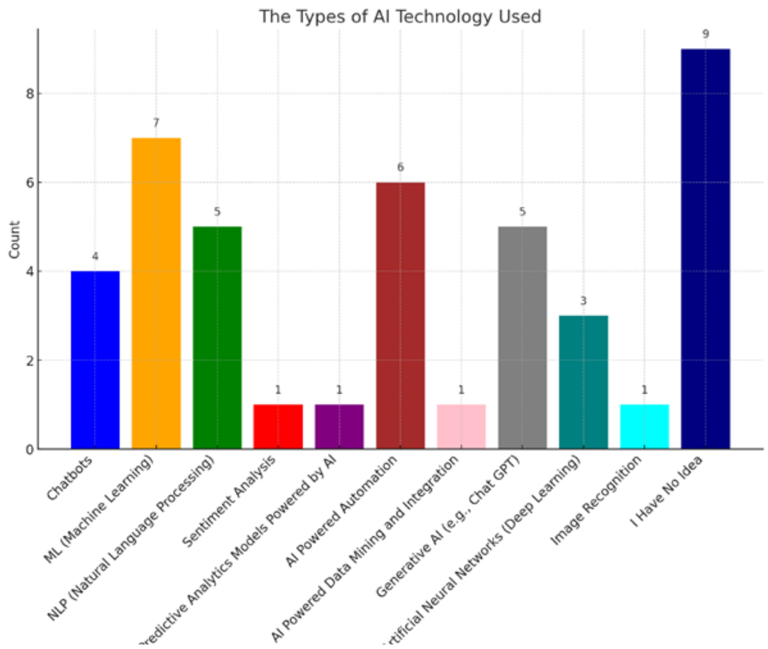


For this question, the two-sample z-test was conducted. The power of the experiment was 0.1529. The z-statistics were 0.9386 while the p-value was 0.348. The p-value was approximately 0.348, therefore, we failed to reject the null hypothesis. There was not sufficient evidence to suggest that there was a significant difference between the proportion of positive responses from Germany (0.159) and Egypt (0.108).

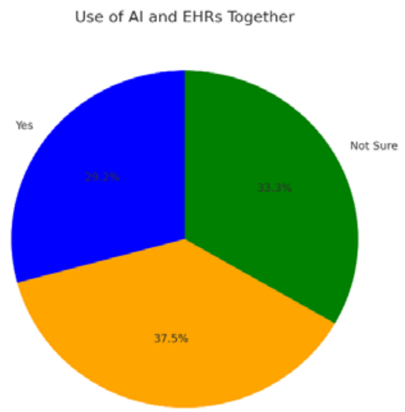
14. In which field does your organization use AI (artificial intelligence) in the pharmacovigilance process (select all that apply)?

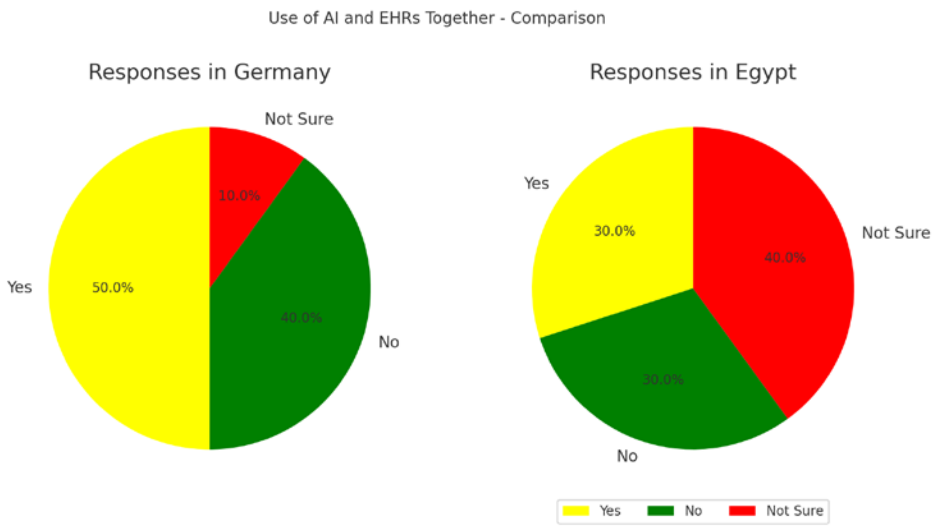


15. What specific AI (artificial intelligence) technologies or tools does your organization use for pharmacovigilance (select all that apply)?



16. Does your organization have any previous experience with the use of AI (artificial intelligence) and EHRs (electronic healthcare records) together, in other words, the use of AI technology in the detection of adverse drug reactions from the electronic healthcare records of the patients?



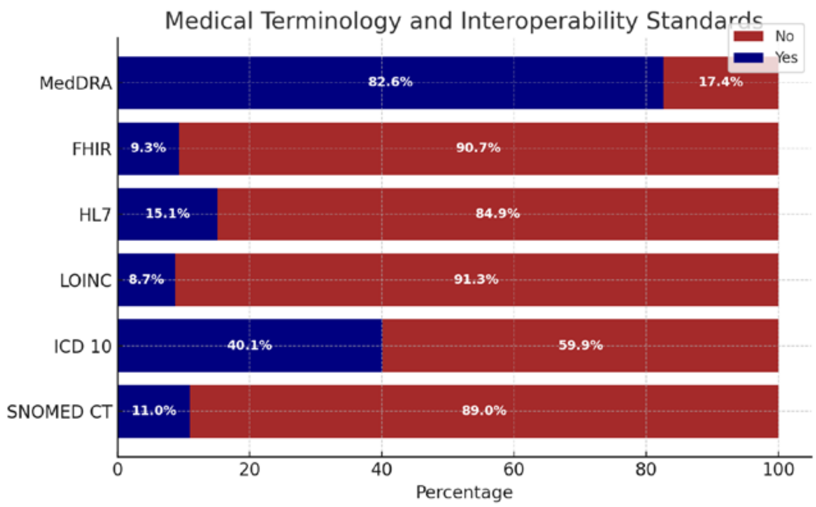


For this question, **the two-sample z-test** was conducted.

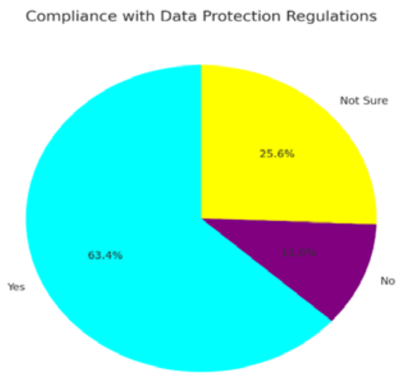
The power of the experiment was 0.21085961971387923. The z-statistic was -1.1180339887498947, while the p-value was 0.2635524772829728.

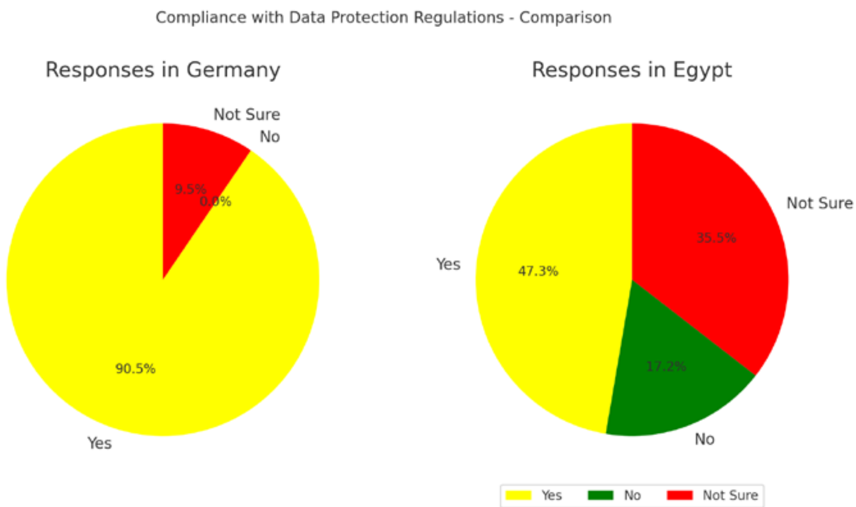
The p-value was approximately 0.264, therefore, we could not reject the null hypothesis.
There was not sufficient evidence to suggest that there was a significant difference between the positive responses from Germany (0.1) and Egypt (0.3).

17. Do you have any knowledge about the following concepts of medical terminology, ontology, data exchange, and interoperability?



18. Does your organization ensure compliance with the German DSGVO/GDPR (General Data Protection Regulations) or Egypt's data protection law?





The **one-sample z-test** was conducted on this question and the results were the following:

For the Total Sample (Germany and Egypt)

The power of the experiment was 0.9094870575812052. The z-statistic was -3.1652695177265 and the p-value was 0.0015493935939829518. The p-value is 0.0015493935939829518, therefore, we rejected the null hypothesis. There was sufficient evidence to suggest that the observed proportion of 0.6337 is significantly different from the expected proportion of 0.75.

For Germany Only

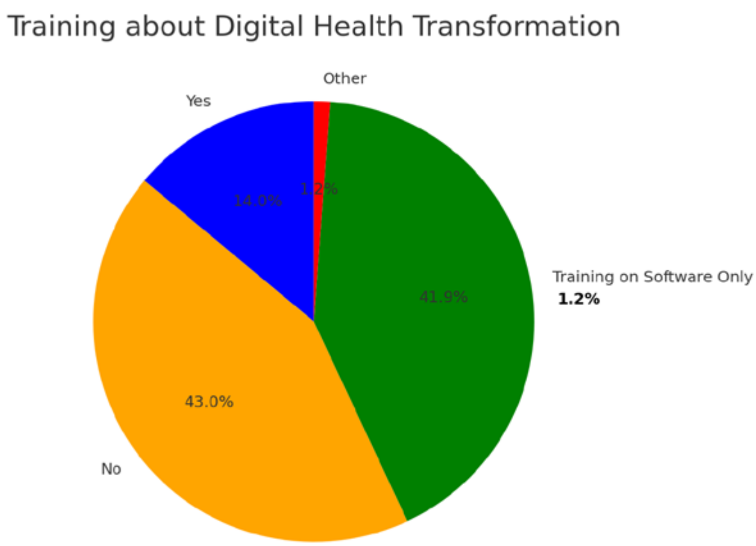
The power of the experiment was 0.9065155381549374. The z-statistic was 4.184675991984893, while the p-value was 2.8557312958510958e-05. Alternative: As the p-value was above the threshold of 0.05, we rejected the null hypothesis. There was sufficient evidence to suggest that the observed proportion of 0.9048 was significantly different from the expected proportion of 0.75.

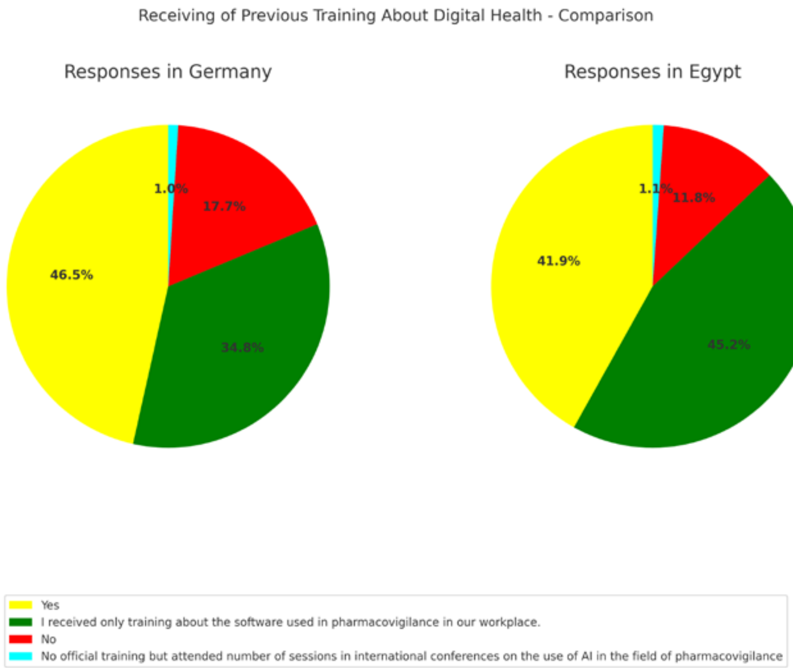
For Egypt Only

The power of the experiment was 0.9998068220766971, the p-value was approximately 0.0. Therefore, we rejected the null hypothesis. There was sufficient evidence to suggest that the observed proportion of 0.4731 was significantly different from the expected proportion of 0.75.

For this question, **the two-sample z-test** was conducted:
The power of the experiment was 0.9999834400364302.
The z-statistic was 5.536781025086471, while the p-value was 3.080813360109637e-08.
The p-value was approximately 0.0, which is below the chosen significance level of 0.05.
Therefore, we rejected the null hypothesis. There was sufficient evidence to suggest that there is a significant difference between the proportion of positive responses from Germany (0.905) and Egypt (0.473). The proportion of "yes" responses from Germany was higher.

19. Did you receive any formal training in digital health transformation?
Digital Health Transformation means briefly: the application of information and communication technologies in the healthcare and medical fields. It is also about the implementation of AI, big data, mobile apps, data-sharing principles, virtual and augmented reality, etc. in the healthcare sector.

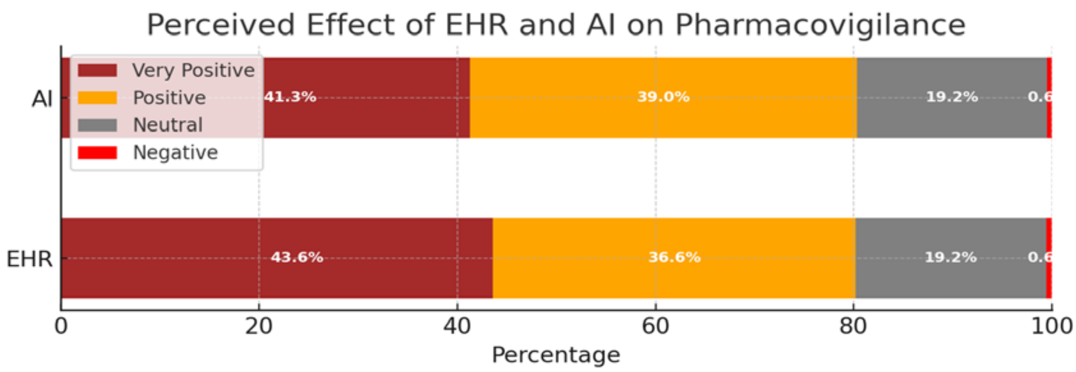




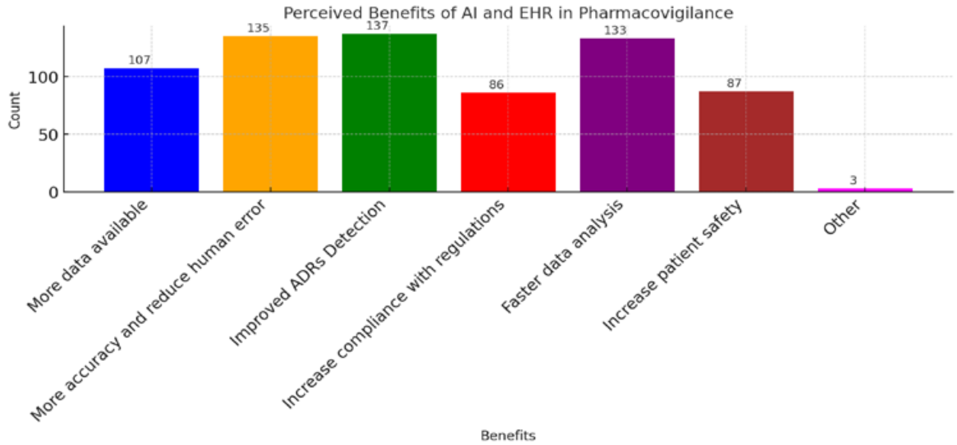
The two-sample z-test was conducted for this question.
The power of the experiment was 0.1653179334753394. The z-statistics were 0.9917466689612985, while the p-value was 0.3213211190920956.
The p-value was approximately 0.321. Therefore, we failed to reject the null hypothesis. There is not sufficient evidence to suggest that there is a significant difference between the proportion of positive responses from Germany (0.175) and Egypt (0.118).

4.3 Section: Opportunities

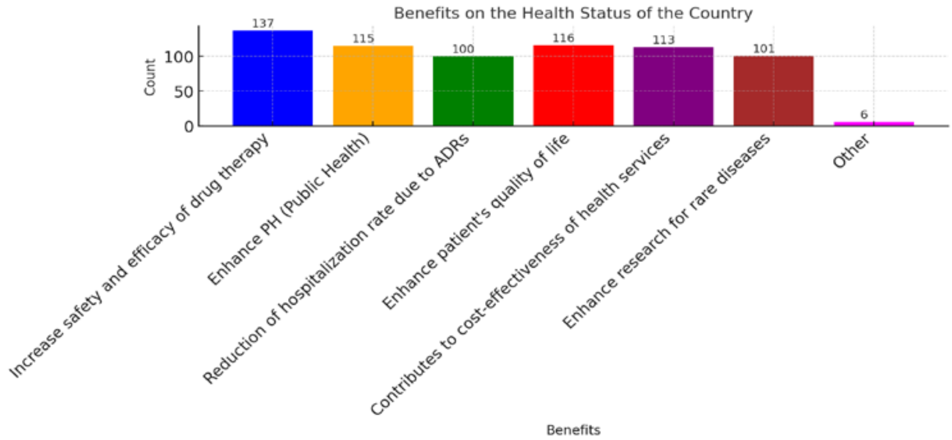
20. How do you see the effect of the following concepts, if they were applied, on pharmacovigilance:



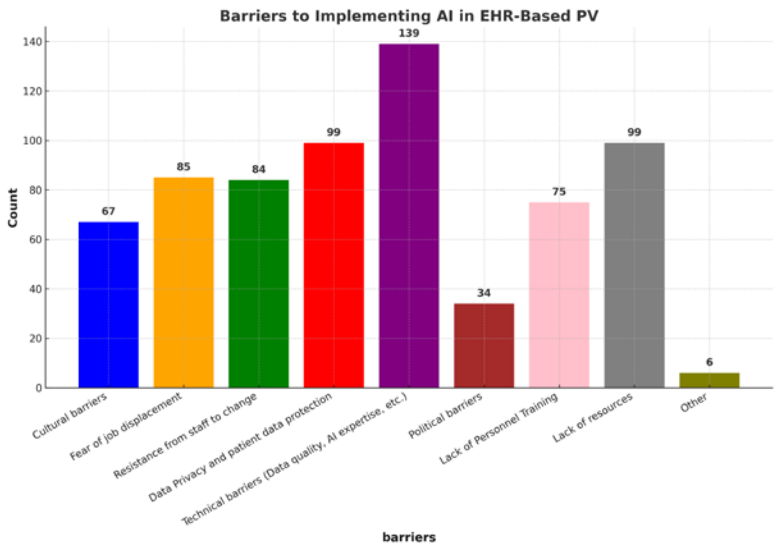
21. What are the expected benefits of using AI and EHR together in PV (select the most significant answers)?



22. What are the expected benefits of using AI in EHR-based pharmacovigilance on the health status of the country (select the most significant answers)?

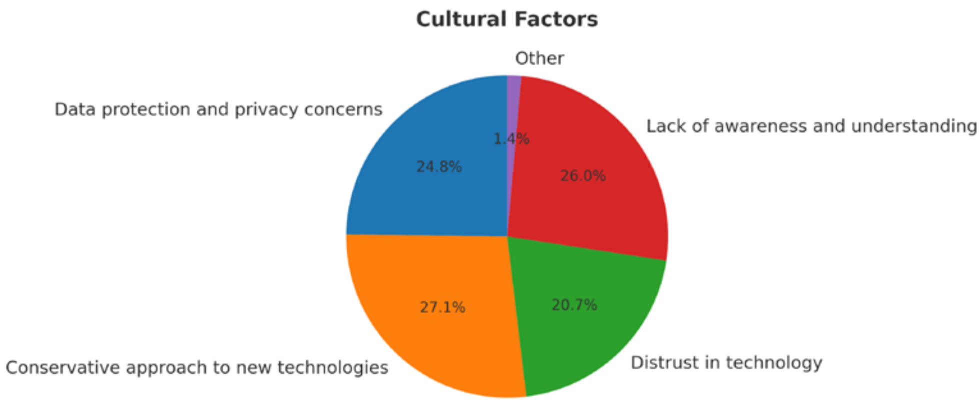


23. In your opinion, what are the main barriers to the application of AI (artificial intelligence) in EHRs (electronic healthcare records) based pharmacovigilance in your country of residence (please select the most significant answers)?

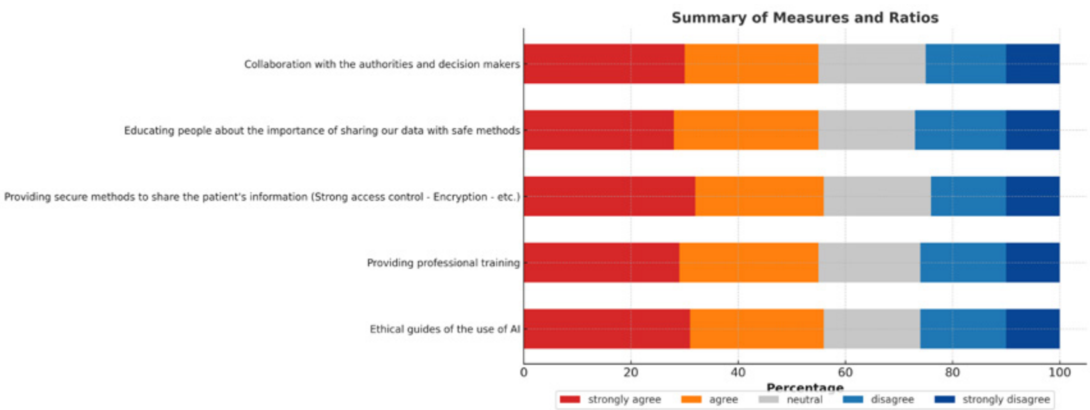


4.4 Challenges and Suggestions

24. Which of these cultural factors are considered barriers to the implementation of AI in EHR-based pharmacovigilance (select the most significant answers)?



25. How will these measures help to increase the implementation of AI and EHR in pharmacovigilance?



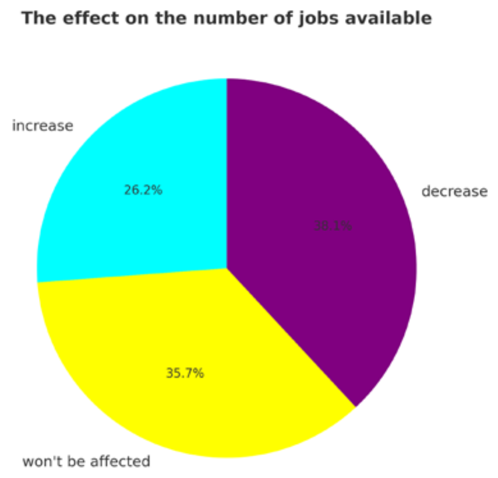
Summary of Measures and Ratios

Measure	Strongly Agree (%)	Agree (%)	Neutral (%)	Disagree (%)	Strongly Disagree (%)
Collaboration with authorities and decision-makers	53.5	35.5	10.5	0.0	0.6
Educating people about sharing data (safe methods)	45.9	37.2	14.5	1.7	0.6
Providing secure methods to share patient information	55.2	33.7	10.5	0.0	0.6
Providing professional training	54.1	32.6	12.8	0.6	0.0
Ethical guides for the use of AI	52.3	30.2	15.7	1.2	0.6

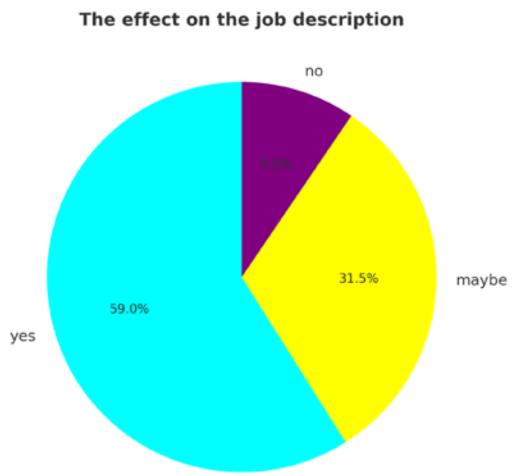
26. Do you have any further suggestions/solutions to enhance the application of AI and EHR in Pharmacovigilance?

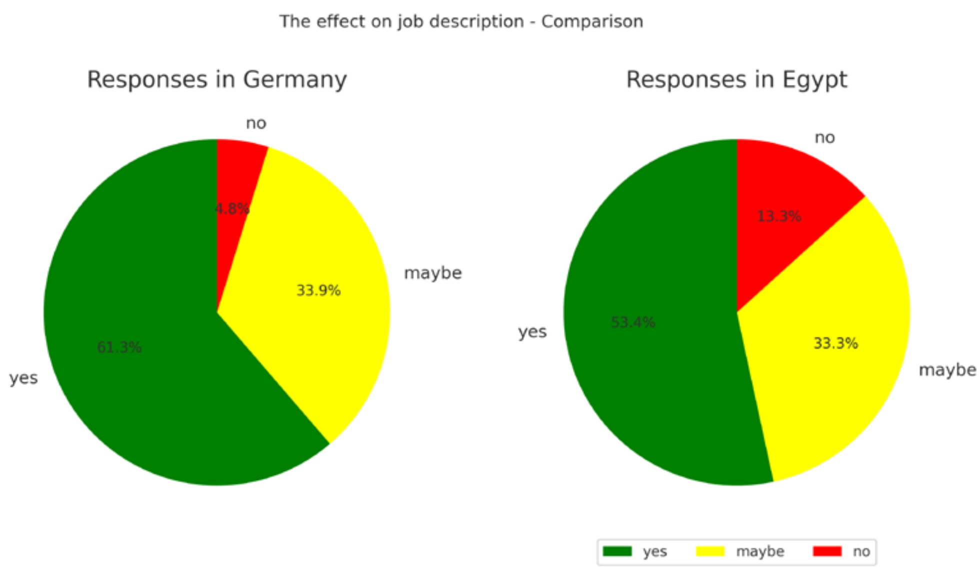
It was an optional question, and we received 62 responses. The significant responses will be added to the Conclusion part.

27. How do you expect the number of jobs available in the PV market to change in the case of the application of EHR and AI in PV?



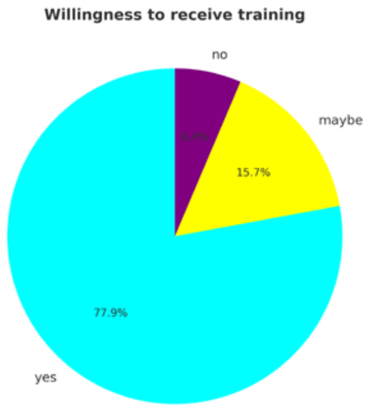
28. Do you expect the role/ job description of a PV specialist to change in the case of the application of AI and EHR in PV in the future?

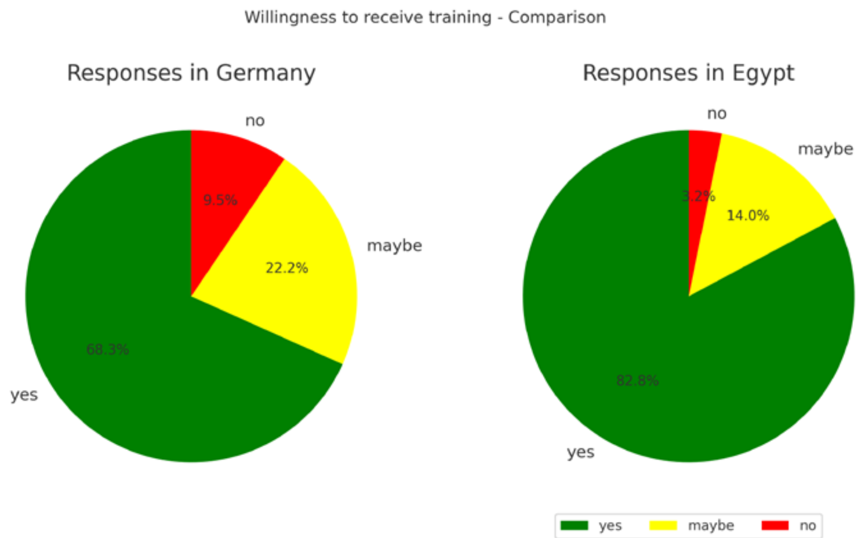




For this question, the two-sample z-test was conducted.
The power of the experiment was 0.164185261766375.
The z-statistic was 0.9726721278116287, while the p-value was 0.33071628210080184
The p-value was approximately 0.331, which was greater than or equal to the prechosen significance level of 0.05. Therefore, we failed to reject the null hypothesis.
There is not sufficient evidence to suggest that there is a significant difference between the proportion of positive responses from Germany (0.613) and Egypt (0.533).

29. Are you interested in receiving training about the use of AI in EHR-based pharmacovigilance?

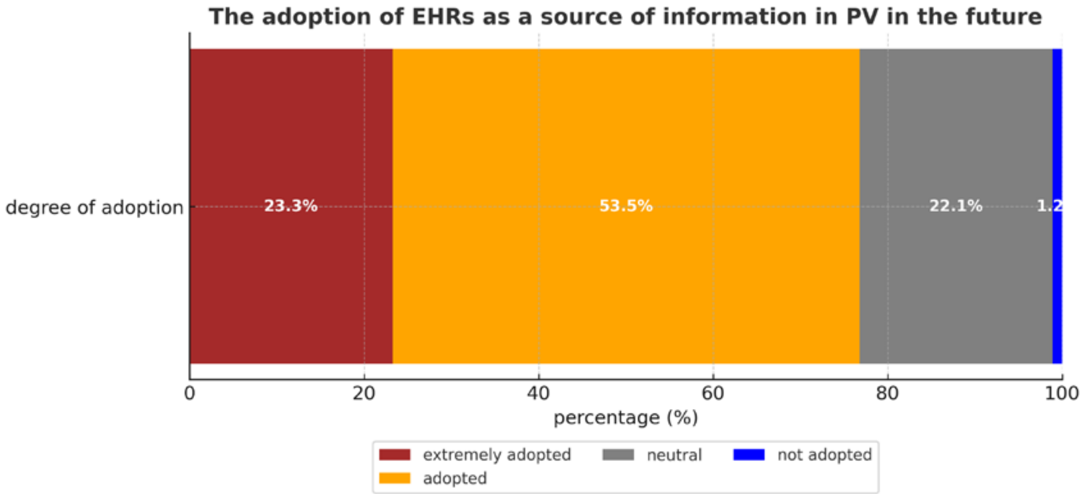




The two-sample z-test was conducted for this question.

The power of the experiment was 0.5533108329740837.
The z-statistic was -2.115184578952405, while the p-value amounted to 0.034414218753534384.
The p-value was approximately 0.034, which was less than the prechosen significance level of 0.05. Therefore, we rejected the null hypothesis. There was sufficient evidence to suggest that there was a significant difference between the proportion of positive responses from Germany (0.683) and Egypt (0.828). The proportion of "yes" responses from Egypt was higher.

30. How do you see the adoption of EHR as a source of information for PV in the next 10 years?



5. Conclusion

5.1 Summary of results

5.1.1 Reality and Application in Germany and Egypt

There are generally positive attitudes toward the adoption of AI and EHRs in the domain of pharmacovigilance **(questions 20 and 29)**. This attitude is not a special phenomenon because of the young age of most participants **(question 2)**.
Most of the participants are PV experts **(question 4)** who have different job descriptions and work in different settings. The result of this question indicates how the use of AI can enrich the PV industry because of the diversity of the tasks and roles in this domain.
Most of the participants are a mix of early-career (1–5 years) and mid-career professionals (6–10 years). The percentages of these two groups were 49.4 % and 26.74 %, respectively (see **question 5**). Most of the participants work in pharmaceutical companies (55.81 %), but there is a diversity in their workplaces as well **(question 6)**. This diversity provides different perspectives and points of view on how AI can be used in PV.

As far as the **8th question** is concerned, EHRs started to be implemented in Germany (still in the initial phase), but not yet in Egypt.
Only 49 % of the participants (in both countries) have heard about the use of EHRs in PV before (question 9).

Regarding the organizations (question 10), most of the organizations in Germany and Egypt are not utilizing EHRs in pharmacovigilance.
When it comes to the resources of information in the domain of PV in both countries, ICSR (individual case safety reports) remain the most important source of data in PV. The literature is still a valid source of information (2nd place), but the local literature review in Egypt is of poor quality. There is a rise in the usage of digital portals and social media, but EHRs are rarely used (question 11).
PV specialists lack knowledge and awareness of the use of AI in PV (question 12). These results indicate the importance of further education and efforts to understand the role of AI in improving PV. In addition, AI is not yet widely applied in the organizations involved in PV activities neither in Germany nor Egypt, and there is no significant difference between the two countries (question 13).

This indicates a generally similar attitude towards the acceptance of AI in PV in both countries.

The most common uses of AI in PV (very few participants answered to this question) are case reporting processing and narrative writing (14 responses). Automated ADR detection (from structured and unstructured data, e.g. EHR, social media, medical literature) and signal detection (by detecting trends and patterns) are some other uses of AI in PV.
AI can be used in the domain of PV to facilitate and accelerate the reporting of side effects on the national pharmacovigilance platforms (e.g. in Germany www.nebenwirkungen.bund.de). AI-supported input assistance could improve the quality of the data by using plausibility checks to directly correct input errors for that reporting, therefore, fewer questions will be required later. Context-dependent additional information can be requested depending on patients' characteristics such as age, gender, or pregnancy, as well as specific symptoms and progression [12].

The most used AI technologies in PV are ML, AI-powered automation, NLP, generative AI, and chatbots, respectively, taking into consideration that very few participants responded to this question (question 15).
There is very little simultaneous use of AI and EHRs in PV organizations in both Germany and Egypt, and there is no significant difference in the adoption between Germany and Egypt in this regard (question 16). There were also very few participants.

In Germany as well as in Egypt, MedDRA is the most known and used coding language in PV **(question 17)**. The ICD10 comes in second place. Although few PV experts are familiar with other concepts of medical terminology and the standards of data share and interoperability, there is still a lack of knowledge of these domains among PV experts. The WHO Drug Dictionary is also used.

Regarding the restrictive following of the data protection regulations in Egypt and Germany **(question 18)**, the results show that PV organizations in both countries do follow the rules of data protection. However, a comparative analysis of the survey's data shows that most PV organizations in Egypt do not strictly comply with data protection and privacy regulations in comparison to Germany. There is far greater adherence in the PV organizations in Germany. These findings highlight potential disparities in the implementation of data protection measures between the two countries, which could impact on the handling and processing of sensitive healthcare data, including data used in PV practices involving AI technologies. So, there is a serious problem in the data protection laws in Egypt which demands interventions of the decision-makers.
Most of the participants received training about the software used in pharmacovigilance in our workplace, but a few of them received formal training in digital transformation. There is no significant difference between the two countries in this regard **(question 19)**.

The survey results **(question 20)** show positive attitudes from the participants toward the adoption of **EHRs and AI** in the field of pharmacovigilance. This reflects the specialists' awareness of the potential positive impact of these technologies on the field of PV. These positive attitudes and perceptions should encourage the decision-makers to introduce these technologies and provide financial support for the companies and the required training for pharmacovigilance experts.

5.2 Potential Opportunities in Germany and Egypt

Based on the results of the survey, there are a lot of expected benefits of the simultaneous use of AI and EHRs in PV **(question 21)**. The implementation of these technologies will provide us with more data to be analyzed and will help to solve the eternal problem of **underreporting and the poor quality of reports**. There are other expected benefits like the facilitation of narrative writing, a faster signal detection process, automated case triage, more accuracy, reduced human error, improved ADRs, increased compliance with regulations, faster data analysis, and increased patient safety.
The use of AI in EHR-based pharmacovigilance will have a positive impact on the health status of the country **(question 22)**. Some of these benefits are increased safety and efficacy of drug therapy,

enhanced PH (public health), reduction of the hospitalization rate due to ADRs, improved patients' quality of life, contribution to the cost-effectiveness of health services, and enhanced research for rare diseases.

5.3 Challenges and Barriers in Germany and Egypt

There are a lot of barriers to the implementation of AI in EHR-based PV **(question 23)**. The barriers are the following: cultural barriers, the fear of job displacement, resistance from the staff to change, data privacy and patient data protection (refusal of the use of clinical data), technical barriers (data quality issues – unstructured data in EHRs – lack of AI expertise – reliability of AI algorithms – data exchange problems), political barriers, lack of personnel training and lack of resources. The most significant barriers are the technical barriers, then secondly the lack of resources and data privacy and protection, then the fear of job displacement and the resistance to change from staff.

One of the major technical problems is the low quality of data and unstructured data. This problem can be approached through the standardization of medical terminology and the mapping between different medical languages, in addition to the use of standards of interoperability between different systems to share data [30, 31]. Another approach to deal with this challenge is to develop and to update the medical languages (i.e. MedDRA). Also, sequential labeling of the data in EHRs is crucial, in addition to the definition of the metadata and the use of common data models (CDM).
To enhance the performance of ML, high-quality data should be used. In addition, the effectiveness of existing AI algorithms necessitates a "human-in-the-loop".

Regulatory barriers are crucial barriers as well; to overcome these barriers, we need to have new **PV regulations** that permit the use of AI rather than the traditional regulations that impede its implementation. In addition, **regulations regarding AI use** and regulations regarding the secondary use of data are required. Another suggested solution is to adapt the digitalization plan of the healthcare systems (e.g. Digital Health Act in Germany). Financial support is also crucial to solving the problems of lack of training and the fear of job displacement.

The conservative approach to new technologies (140 responses) is the most significant cultural barrier toward the implementation of AI in EHR-based PW. The lack of awareness and understanding (e.g. lack of patient reporting) comes in second place (134 responses). Pharmacovigilance is only included in the syllabus of pharmaceutical studies, while other medical curricula do not convey any knowledge of drug safety in general, especially in pharmacovigilance [23]. Then comes data protection and privacy concerns (128 responses), and finally the distrust in technology (107 responses; **question 24**).

There are a lot of measures that may increase the implementation of AI and EHRs in PV **(questions 25 and 26)**: One of these measures is a collaboration with the authorities and decision-makers, proposing the road map, and having a long-supported pilot phase. The roadmap for the implementation of the digital health law in Germany can be a role model [32].

Educating people about the importance of sharing our data (with safe methods) is crucial to overcoming misunderstandings and fears. One of the ways to address people's fear is to provide ethical guidelines for the use of AI, while at the same time providing secure methods to share the patient's information, e. g. strong access control – encryption – pseudonymization – anonymization or blockchains [33 ,34]. Providing professional training for PV experts is crucial.

Regarding data privacy and protection, we need to apply the rules correctly, and at the same time, we need to ensure feasible access to health data for the sake of usage in PV and other research purposes. EHDS is a promising project to solve this dilemma [35].

Initiatives that encourage stakeholder collaboration for diverse datasets are crucial. Patient engagement can be increased by leveraging AI-driven tools to engage patients in PV efforts, such as mobile apps for reporting adverse events and monitoring medication adherence. Raising the awareness of the stakeholders and the decision-makers is also crucial.

There was no absolute agreement regarding the number of jobs available in case AI and EHRs are applied in the domain of PV **(question 27)**. Some see that AI will replace conventional human tasks and others see that the implementation of these cutting-edge technologies will create new opportunities. Despite those fears, there are still positive attitudes toward AI and EHRs. The rise of awareness and the motivation to develop will help to reduce such fears.
A majority of the participants expect a change in the role description of PV specialists, and these expectations are similar, with no significant difference between Egypt and Germany **(question 28)**.
There is a great interest in receiving training about the use of AI in EHR-based PV in both countries, and this interest is greater in Egypt than in Germany. Germany may be more conservative toward new technologies, in addition to the competitive nature of the market in Egypt **(question 29)**.
Finally, the participants show a positive attitude toward the adoption of EHRs as the source of information for PV in the next 10 years. This indicates the awareness of the positive impact of EHRs as a source of information on PV **(question 30)**.

5.4 Recommendations

Egypt can profit from the road map of the German government regarding the digitalization of the healthcare system, minimally starting with a good documentation system. In addition, Egypt should issue a comprehensive law on data protection following the steps of the European Union. These two pillars, namely, the digital healthcare system and data protection laws, are indispensable for taking further steps toward the secondary use of data for PV and research purposes.
Digital health specialists also need to raise awareness in the public, towards healthcare professionals and the regulatory authority about the importance of digital tools in the domain of PV.
In addition, the regulatory bodies in both countries need to profit from the positive attitude toward these technologies (AI, EHRs) and accelerate the process of integration of these technologies in healthcare generally and in PV specifically. This includes offering training and providing financial aid to the PV companies.

5.5 Limitations

- One of the limitations of these studies is the sample size. Although the sample size is quite acceptable, if the researcher gets more respondents he will have a sample size calculation with a better confidence interval and margin of error.
- Some of the key stakeholders in the domain of PV refused to participate in the survey for different reasons.
- The difficulty in accessing real-world data in EHRs to test the ability of AI to detect ADRs in EHRs. This difficulty could be attributed to the regulatory and privacy barriers. Both research datasets (which are available for research purposes) and synthetic data were insufficient because they do not fully present the reality.
- In addition, the technical barriers to the possibility of implementation of AI and EHRs would be better discussed with IT specialists with special interviews.

5.6 Suggestions for future research

These are some of the suggested areas for future research:

- The use of AI in community pharmacies: How can AI enhance the role of the pharmacist regarding public health?
- The use of AI in clinical research (clinical trials)
- The use of AI in drug design
- Interoperability standards/mapping for EHR-based PV to synchronize the PV activities with EHRs.
- Security methods for EHR-based pharmacovigilance
- Facilitation of the restricted rules for reporting and the issuing of new legislation for the different types of PV.
- How can the use of EHRS enhance research on rare diseases?
- The use of AI in social media-based PV.
- Systematic reviews of the current state of PV in Egypt and Germany.
- The barriers toward the digitalization of healthcare systems in Germany and Egypt.

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Conflicts of Interest Statement

The authors declare that there is no conflict of interests regarding the publication of this paper.

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The Business Model Framework for Digital Health Start-ups in Europe, based on the Innovation Landscape

Gaurang Thanekar,[a] Georgi V. Chaltikyan[b]

[a]Politecnico di Milano, Milan, Italy
[b]Deggendorf Institute of Technology (DIT)/European Campus Rottal-Inn (ECRI), Pfarrkirchen, Germany

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ABSTRACT

In today's fast-paced world, it is difficult to acquire the same quality level of healthcare efficiently. To achieve a similar quality of service in a shorter time, digital health solutions ranging from applications to online registration play a pivotal role in the lives of healthcare practitioners and more specifically patients.

The new digital health paradigms have shifted to be more patient-centric, preventive, predictive, and personalized to more accurately and precisely cater to the patient's needs. The dawn of novel innovative technologies revolutionizing the digital health sector across the globe has generated multiple value creations and research opportunities. The following research focuses on studying innovation diffusion in the digital health sector and its effect on the success of start-ups via analysis of the business models [1]. It is essential to understand the significant proportionality of innovation to the success of digital health startups in delivering quality care to users/patients without compromising quality or failing to create business value in the current competitive market.

KEYWORDS

Digital health, entrepreneurship, business model innovation, open innovation, accelerators, incubators, success factors

1. Introduction

The success of such digital health-related business models is based on multiple factors including market choice, technology used, value addition, and many more. The innovation landscape is getting wider and measuring its success concerning digital health start-ups in Germany has become highly important to understand the intricate causes of failure of a massive 90% of start-ups in their first 5 years of inception, roughly around 1 in 12 start-ups find it difficult to survive [2].

The creation of archetypes based on various significantly affecting factors would help to categorize current digital health start-ups [1].

In their study, Burström et al. [3] explored AI-enabled business model innovations by analyzing how AI transforms the mechanisms of value creation, delivery, and capture within organizations. They proposed a comprehensive framework illustrating that AI not only enhances existing business models but also enables the development of new, dynamic business models by integrating advanced data analytics and automation capabilities. The authors emphasize that these AI-driven innovations can significantly improve competitive advantage, particularly in sectors such as manufacturing, where digital transformation is still nascent. However, despite this potential, AI-based business models remain underexplored and insufficiently researched, especially regarding their implementation and ecosystem interactions. This gap underscores the urgent need for further investigation into innovative business models that leverage AI to drive digital transformation and sustainable growth in industrial contexts.

Similarly, Huckvale et al. [4] highlighted the critical role of the human factor in the design, development, and implementation of patient-centric digital health interventions. Their research emphasized the importance of a partnership model involving healthcare professionals, patients, and software systems to enhance decision-making processes. This collaborative approach is particularly vital in low- and middle-income countries, where digital health innovations must be tailored to local contexts and resource constraints. Huckvale and colleagues argue that the success of digital health solutions depends not only on technological advancements but also on the active engagement and alignment of all stakeholders involved, ensuring that digital tools effectively meet patient needs and improve health outcomes.

1. Goal and Objectives

Goal – To successfully analyze the implementation of innovative technologies in digital health start-ups and its effect on business models leading to the success of the start-ups in Europe by establishing the relevant knowledge of the success of the digital health start-ups.

Objectives

- **Objective 1** – To perform a scoping review of efforts to support the digital health entrepreneurship landscape until current advancements.
- **Objective 2** – To study the current digital health start-up scene in Europe and cluster the start-ups with similarities as individual archetypes focusing on innovations, with a minimum of three start-ups [1].
- **Objective 3** – To equate the correlating factors and differentiating factors facilitating each archetype that is contributing the most to the success of the start-ups.
- **Objective 4** – To be able to draw clear conclusions by connecting various factors involved in innovation that led to the success of the start-up archetypes via qualitative semi-structured interviews with the subject matter experts and start-up founders/representatives [1].

The research topic and methodology are designed to evaluate the success factors of digital health start-ups concerning the needs and expectations of digital health consumers, market penetration/access, business innovation and technology frameworks, etc.

2. Methodology

2.1 Systematic Literature Search

To gain a comprehensive understanding of both current research and previously established literature, a rigorous systematic structured literature review was conducted across multiple reputable academic databases and search engines. These included Google Scholar, PubMed, ABI Inform/ProQuest, EBSCO/Business Source Premier, JSTOR, MENDELEY, ScienceDirect, Scopus, SpringerLink, and Web of Science.

This systematic approach ensured a thorough review of relevant literature, enabling the synthesis of existing knowledge on the identified topics and contributing to scholarly discourse in the field.

Snowballing Method: Snowballing is an iterative and complementary method to systematic literature research to include articles that may have slipped the attention of the researcher. There are two types of snowballing – forward and backward snowballing [5].

2.2 Primary and Secondary Data Collection Methods

This research employed in-depth semi-structured interviews to gather primary data from subject matter experts within the industry and representatives of digital health start-up companies. The selection criteria for participants included considerations such as geographical location, educational background, professional experience, and affiliation with digital health start-ups or relevant industry entities such as hubs, accelerators, or incubators. Each interview was meticulously recorded and transcribed verbatim using Microsoft Teams, with participant anonymity safeguarded through the use of pseudonyms. Following data collection, a rigorous simultaneous coding process was undertaken to identify and categorize key themes and patterns within the interview transcripts.

Subsequently, these overarching themes were analyzed to develop archetype-specific system dynamic models, such as causal loop diagrams, and archetype-specific business and conceptual frameworks. The thematic analysis facilitated a deeper understanding of the nuances and complexities inherent in the digital health innovation landscape, shedding light on the interplay between various factors and stakeholders within the industry. By synthesizing insights from diverse sources, this study aims to contribute to the development of robust theoretical frameworks and practical strategies to navigate the evolving landscape of digital health innovation [1].

The start-ups examined in this research study were characterized as operational entities with a functional history ranging from 1 to 5 years. Their primary products or service offerings were required to be within the digital health domain, featuring relevant innovations such as artificial intelligence (AI), natural language processing (NLP), or virtual/augmented reality (AR/VR) technologies.

Incubators specialize in nurturing early-stage start-ups that are primarily focused on product development and have yet to establish a fully developed business model. Conversely, accelerators are geared towards expediting the growth of established companies that have already developed a minimum viable product (MVP) and demonstrated traction among early adopters, with a proven product-market fit [6].

This distinction between incubators and accelerators underscores their respective roles in supporting start-ups at different stages of development within the digital health innovation ecosystem. By elucidating these distinctions, this study provides valuable insights into the diverse pathways available to start-ups seeking support and growth opportunities in the dynamic landscape of digital health entrepreneurship.

The criteria for inclusion and exclusion were clearly defined for prospective interview participants in this study:

Inclusion Criteria:

- Residency within the European Union (EU), the United Kingdom (UK), or the European Economic Area (EEA).
- Affiliation with either a digital health start-up for the start-up representative cohort or involvement with an accelerator or incubator for the subject matter experts' cohort.
- Proficiency in English communication, as evidenced by exposure to international environments through prior educational or professional experiences.

Exclusion Criteria:

- Lack of involvement in the digital health innovation landscape for both experts and start-ups.
- Participants residing outside of the European Union, the UK, or the European Economic Area were excluded from participation.

These criteria were established to ensure that interview participants possessed relevant experience and perspectives within the context of digital health innovation in the specified geographical regions.

Stratified Sampling Method

Stratified sampling stands as a method of probability sampling commonly deployed in sample surveys. It entails dividing the elements of the target population into distinct groups or strata, where elements within each stratum share similarities regarding certain key characteristics pertinent to the survey. The stratification process serves not only to enhance the efficiency of sample design in terms of survey costs and estimator accuracy but also to refine the precision of estimations. This article delves into the foundational principles of stratified sampling within the context of simple random sampling. Key areas of discussion encompass the delineation of strata formation and the optimal distribution of samples among these strata. Furthermore, practical considerations in implementing stratified sampling are explored, encompassing methodologies such as systematic sampling, implicit stratification, and the utilization of contemporary software for strata construction. The significance of employing stratified sampling in practical research settings is underscored by its widespread application in five major large-scale health surveys conducted in both the United States and the United Kingdom [7].

There were two cohorts or subgroups in this research first cohort as subject matter experts who were employed or directly associated with digital health innovations carried out in accelerators or incubators based in the European region. The second cohort consisted of founders, co-founders, or active long-term employees of a digital health start-up based in Europe.

While acknowledging that qualitative research, particularly in the form of small-scale interview-based studies, is deliberately conceptual in its approach, the resulting findings inevitably carry an element of speculation as they are not intended to be final but rather suggestive. This characteristic aligns with the exploratory nature of such research, which aims to propose ideas rather than definitively prove them, thus diverging from the reliance on representativeness and large sample sizes typically associated with verification-oriented studies. It is essential to emphasize that rigor in both methodology and argumentation remains paramount in exploratory research, even more so than in verification-focused investigations, as the latter often lacks the familiar markers of assurance. Nevertheless, within a realist framework, the hypothetical nature of concepts emerging from exploratory studies does not fundamentally differ from the results of research aiming for truth-claiming conclusions. In the broader context of science, all knowledge remains contingent on ongoing developments, characterized by provisional designations of symbols, myths, or theories [8].

The study involved a sample size comprising five participants from each cohort, totalling ten interview participants across both cohorts. However, due to time limitations, only eight interviews (3 + 5) were conducted in practice. Pre-designed questionnaires, delineating the allotted time duration for each section, were developed for both cohorts.

Semantic Approach

The method of simultaneous coding involves using multiple coding techniques ranging from a pre-defined coding system, i. e. Priori coding, to descriptive coding. In the analysis of this research question, interview transcripts were coded mainly in two types: 1 In-vivo coding, the codes that emerged from the direct quotes of the interviewee, while Descriptive coding allows the researcher to use their own subject knowledge for describing the terminology or scenario. This combination of codes is complementary and inclusive of two diverse perspectives. As described by Braun and Clarke [9], their research suggested that semantic codes are explicit and grounded in the surface meanings of the data, allowing researchers to stay close to the participants' actual words while still applying analytical interpretation.

Thematic Analysis

Thematic analysis, sometimes referred to as template analysis, offers a broad spectrum of creative possibilities. Researchers have the flexibility to apply coding techniques across multiple levels without rigid constraints. This method allows for the exploration of various layers of meaning within qualitative data, facilitating a nuanced understanding of complex phenomena. By employing thematic analysis, researchers can uncover rich insights and patterns embedded within the data, thereby enhancing the depth and comprehensiveness of their findings. This approach encourages an iterative and exploratory process, empowering researchers to delve deeply into the intricacies of their data and extract meaningful themes and patterns. Ultimately, thematic analysis serves as a versatile and powerful tool for uncovering and interpreting the underlying narratives and structures present in qualitative data. This method of qualitative analysis should be the backbone as it helps to surface known themes and in result novel theories reshaping the newer avenues of research [9, 10].

The depth and breadth of qualitative thematic analysis allow researchers to capture the complexity of the research topic; however, validating such research remains a challenge. In Canada, Nowell et al. [11] conducted mixed methods research aimed at establishing the trustworthiness and rigor of thematic research designs. Building on Koch's [12] assertion, maintaining detailed documentation of the interview process and its nuances provides a systematic approach that enhances the replicability of qualitative studies, allowing subsequent researchers to arrive at similar, though not identical, conclusions. Nowell et al. [11] further demonstrated that audit trails—comprehensive records of qualitative data collection and analysis—contribute significantly to systematizing the research process, thereby enhancing the overall trustworthiness and rigor of qualitative research models [13]. The audit trail of the semi-structured interview process performed in this research is depicted below (Figure 1):

<u>1. Audit Trail</u>

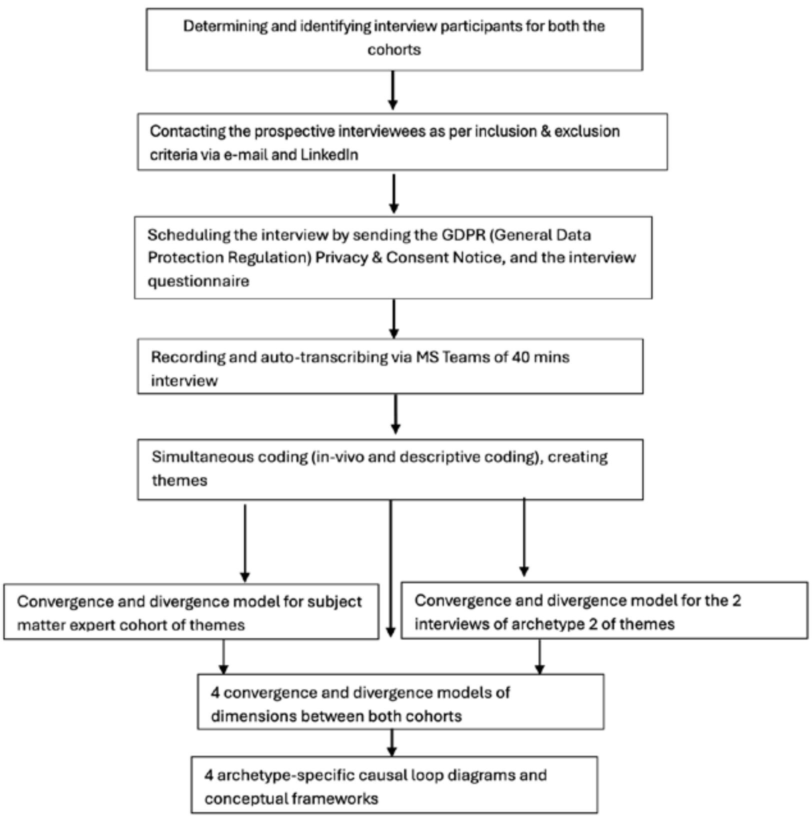

Figure 1: Audit trail.

2. Expert's Validation
An additional approach to validate the study design involves iteratively seeking expert opinions on the conceptual framework or model generation. In the research conducted for this study, three subject matter experts were consulted, and one of them provided iterative advice, resulting in subsequent adjustments to the framework. This iterative process of expert consultation ensured the refinement and enhancement of the conceptual framework, thereby bolstering the robustness and credibility of the study design. The insights gleaned from expert input facilitated a more nuanced understanding of the research context and contributed to the development of a comprehensive and well-founded conceptual model.

Literature Review

The seminal research work functioning as the backbone research for this study is elaborated in Table 1.

The search terms utilized encompassed key concepts related to start-ups, new ventures, small firms, and digital health, among others. Terms such as "start-up", "new venture", "small firm", "digital health", "mhealth", "ehealth", "medtech", "success", "successful", "market", and "factors" were combined using AND and OR conditions across various combinations.

Table 1: Collection of seminal work

Title	Author/ reference	Finding	Focus	Summary
Success Factors for Market Entry of Mobile Health Startups	Lux and Kempf [14]	Study concludes that while the success factors identified could aid start-ups in avoiding mistakes and achieving successful market entry, they do not guarantee success.	Success factor for mHealth start-ups in market entry	Although the research focused on identifying success factors, it acknowledged that the diversity of business models makes it difficult to generalize the results.
Health-tech start-ups in healthcare service delivery: A scoping review	Chakraborty et al. [15]	5 out of 76 articles could focus on the status of health tech start-ups	Research gap in business framework	The business model framework in digital health has not been explored.
Critical success factors of startups in the e-health domain	Chakraborty et al. [16]	The study underscores the significance of identifying (critical success factors (CSFs) for health tech start-up success in a rapidly evolving healthcare landscape. Findings offer valuable guidance for stakeholders and suggest avenues for future research to strengthen success trajectories in the health tech sector.	Success factors for health tech start-ups in India	The STOF (Service-Technology-Organization-Finance) framework helps to identify the CSFs for health tech start-up success in a rapidly evolving healthcare landscape.

International aspects of growth management in eHealth service start-ups	Saarela et al. [17]	The results indicate that international factors are integral to growth management. Key areas of management priority associated with internationalization include focus, strategic management, and service development and delivery.	Growth management in the international environment	In summary, incorporating internationalization aspects as fundamental components of business growth management could enhance the stages of growth perspective.
Key components and critical factors for developing a telehealth business framework: a qualitative study.	Velayati et al. [18]	Results revealed four main themes: key components for developing a telehealth business framework, success factors, challenges, and barriers. Key components identified included value creation, resources, activities, partnerships, licenses, pricing, revenue, marketing, support services, and customer feedback. Success factors included support from individuals and organizations, along with economic benefits.	Success factors in telehealth industry	The study underscores the importance of a telehealth business framework in facilitating commercialization and sustainability in a competitive market.
The 4P telehealth business framework for Iran.	Velayati et al. [19]	68 out of 74 components proposed in the initial framework were approved across four major dimensions: prerequisites, production, payments and costs, and post-production services. The developed framework is expected to facilitate the commercialization of telehealth technologies, aid in business planning, and enhance the success of telehealth start-ups in a competitive market.	Framework for telehealth businesses	The research employed a mixed methods approach, combining systematic review, qualitative research, expert panel review, and Delphi method validation. The framework underwent refinement based on the input from a panel of telehealth experts and subsequent validation through the Delphi method across three rounds.

Management priorities of digital health service start-ups in California	Muhos et al. [20]	Meta-analysis, ser vice-based businesses typically have the following manage-ment priority areas: focus, power, HR, marketing, decision making, strategic management and growth management, etc.	Analysis of US-based digital health service industry	Through a multiple case study, qualitative and contextual characteristics of growth are identified, leading to the formation of a management priori-ties framework. Network management emerges as a key priority for start-ups aiming to introduce radical innovations to complex markets, where fundrais-ing plays a crucial role in success.

Due to the geographical limitation of the study, the last research article was excluded.
These six articles collectively offer insights into the success factors, challenges, and frameworks pertinent to start-ups within the health tech and telehealth sectors.

Lux and Kempf [14] emphasize the identification of success factors for market entry of mobile health start-ups, highlighting the significance of avoiding mistakes, but caution that success is not guaranteed. Meanwhile, Velayati et al. [18] and Velayati et al. [19] delve into the development of telehealth business frameworks, identifying key components and critical factors for commercialization and sustainability, with the latter focusing specifically on the Iranian context.

In contrast, Chakraborty et al. [15] and Chakraborty et al. [16] explore critical success factors for start-ups in the healthtech and e-health domains, respectively. While Chakraborty et al. [15] point out a research gap in business frameworks and models within digital health, Chakraborty et al. [16] highlight the significance of identifying success factors and offer guidance for stakeholders in a rapidly evolving healthcare landscape.

Saarela et al. [17] examine international aspects of growth management in e-health service start-ups, stressing the importance of incorporating internationalization aspects into business growth management for enhanced perspectives on growth stages.

In summary, these studies collectively underscore the complexity and significance of success factors, frameworks, and international considerations in fostering the growth and sustainability of start-ups within the health tech and telehealth industries.

Business Model and Value Proposition

The Business Model Canvas (BMC) serves as a comprehensive framework for entrepreneurs and businesses to visually represent and analyze their business models. Developed by Alexander Osterwalder and Yves Pigneur, the BMC provides a structured approach to understanding the fundamental components of a business, including key activities, resources, partners, customer segments, revenue streams, and cost structure. This tool enables stakeholders to gain a holistic view of their venture, facilitating strategic decision-making, innovation, and communication across teams and stakeholders. By condensing complex business concepts into a concise format, the BMC fosters clarity and alignment, empowering organizations to iteratively refine and optimize their business models in response to market dynamics and customer needs [21].

Central to the Business Model Canvas is the concept of value proposition, which encapsulates the unique value that a product or service delivers to its target customers. A compelling value proposition articulates how a company's offering addresses customer needs, solves pain points, or fulfills desires in a distinctive and superior manner compared to alternatives in the market. By focusing on the value created for customers, businesses can differentiate themselves, attract and retain customers, and drive revenue growth. Moreover, the Value Proposition Canvas (VPC), an extension of the BMC, provides a structured framework for systematically designing, testing, and refining value propositions by understanding customer jobs to be done, pains, and gains, thereby enhancing product-market fit and competitiveness in dynamic business environments [22].

In this research study, the questionnaires were segmented into 10 sections, with each section demonstrating direct interconnectivity attributable to its influence on both the BMC and the VPC. Therefore, the ensuing illusion of interlinking is evident.

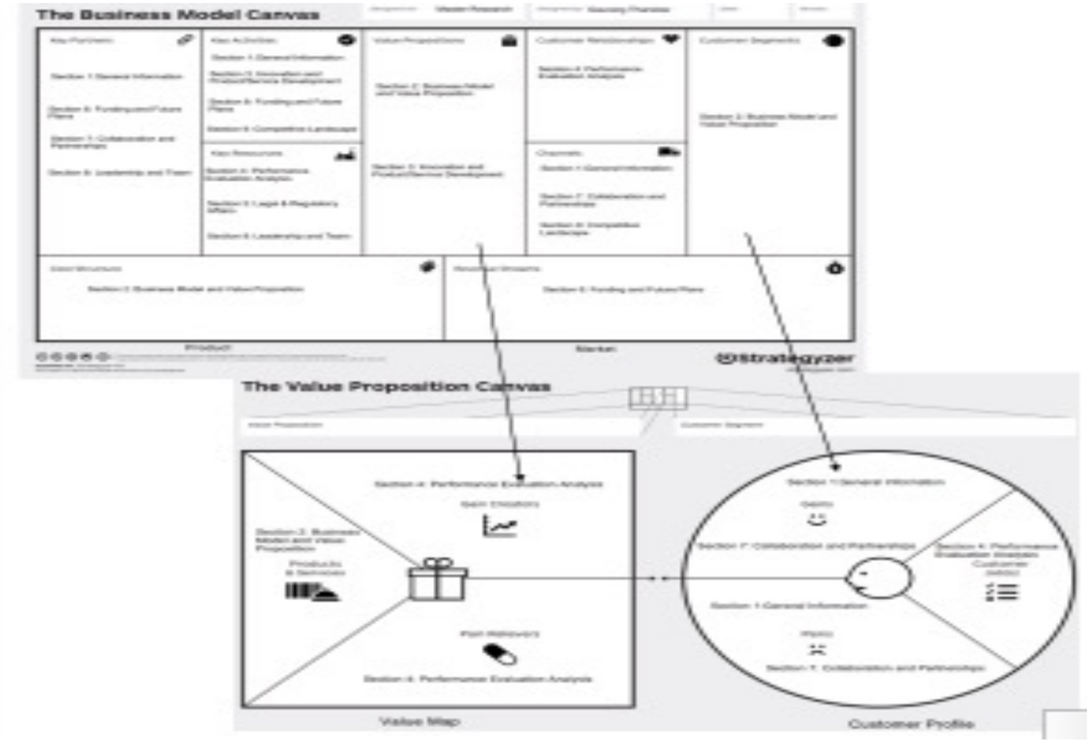

Figure 2: Business Model Canvas – Download the official template. (n. d.). (Source: https://www.strategyzer.com/library/the-business-model-canvas; Creative Commons Attribution-ShareAlike 3.0 Unported License [CC BY-SA 3.0] [23]).

Types of the Business Models

Business models represent the foundational framework upon which businesses operate and generate value. They define how a company creates, delivers, and captures value within its ecosystem. Various types of business models exist, each tailored to suit different industries, markets, and organizational objectives. Traditional business models include the manufacturer model, where products are produced and sold directly to consumers, and the distributor model, where products are sourced from manufacturers and distributed to retailers. Service-based business models focus on delivering intangible services instead of physical products, such as consulting firms or subscription-based services like streaming platforms. Another prevalent model is the platform model, which facilitates transactions or interactions between multiple parties, often leveraging network effects to scale rapidly. Additionally, the subscription model offers recurring revenue streams through periodic payments for access to products or services. More contemporary models include the freemium model, which provides basic services for free while charging for premium features, and the sharing economy model, which connects individuals to share resources or services. These diverse business models highlight the versatility and adaptability required for success in today's dynamic business landscape [24].

3. Results

The results of qualitative and quantitative data were collected and analyzed for emerging codes (first order), sub-themes and overarching themes (second order), and lastly aggregate dimensions and insights. The dimensions of the subject matter expert cohort were compared with each archetype-specific dimension, as a result forming various convergence and divergence models. The secondary quantitative data collated from reputed reports and articles were triangulated for validation of the research.

Thematic Analytical Planning

Table 2: Details about cohort and Interviews

Actual cohorts	Actual interviews conducted	Actual time required	Actual geographical outreach
Subject matter experts	3	Around 40 mins	Western Europe including the UK and Southern Europe
Start-up representatives	5	Around 40 mins	Western Europe and Southern Europe

For the thematic analysis, five interviews for each of the two cohorts, namely subject matter experts and start-up representatives (current employees of the start-up) were planned, in total 10 interviews with a duration of around 40 minutes. The geographical boundaries for the data collection were envisioned to be the EU including the UK and EEA.
The results were found to be that a total of eight interviews were conducted: three of subject matter experts and five of start-up representatives. The duration of the interviews happened to be approximately 40 minutes each. The actual regions that participated in the interviewing process were Western Europe, the UK, and Southern Europe with significant participation from Spain.

Start-up details related to the archetypes:

Table 3: Information of the Start-ups archetypes with commercialization model

Start-up represented by	Archetype	Founding year	Operational year	Commercialization model	Headquarter
SR1	Personalized Chronic Disease Management Platform	2018	2020	Business-to-Customer model	Netherlands
SR 2 & SR 3	Integrated Multi-Omics Imaging Platform	2012	2020	Business-to-Business model	Spain
SR 4	Global Medical Tourism Platform	2023	2023	Business-to-Customer model	Germany
SR5	AI-Powered Biologics Discovery Platform	2022	2023	Business-to-Business model	Germany

Table 3 depicts the diverse nature of each start-up based on its geographical location, founding and operations years, and commercialization model implemented for the European market. The two start-ups were in operation for 1 year while the other two start-ups were operating for 3 years. This data supported the categorization of these start-ups based on their operational maturity levels.

The Outcome of Comparative Thematic Analysis

All three interviews with subject matter experts were conducted, coded, and analyzed resulting in convergence and divergence of the themes.

Thematic Convergence and Divergence Model

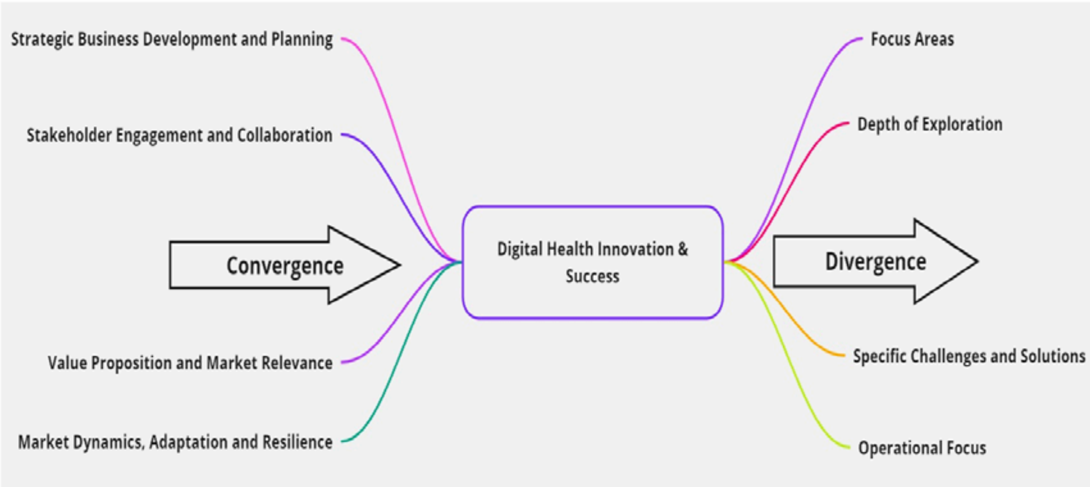

Figure 3: Overall Convergence and Divergence model.

A thorough convergence and divergence model was formulated from the emerged themes. The following is a detailed analysis of the similarities and differences across the three interviews:

Convergence of Themes:

1. Strategic Business Development and Planning:

- All three interviews emphasized strategic planning, development, and resource management as crucial for business success.
- Themes such as strategic planning and development, strategic implementation and customization, and strategic business development aligned across all interviews.
- All three interviews addressed strategic business development, emphasizing the importance of planning, resource management, collaboration, and partnerships for success.

2. Stakeholder Engagement and Collaboration:

- The importance of stakeholder engagement, collaboration, and partnerships was highlighted consistently in all interviews.
- - Themes related to stakeholder engagement, networking, and collaborative growth were common across the interviews.
- - Stakeholder engagement was a recurring theme across all interviews, highlighting the significance of collaborating with stakeholders for innovation, validation, and market penetration.

3. Value Proposition and Market Relevance:

- Recurring themes were understanding market needs, developing a strong value proposition, and ensuring market relevance.
- Themes such as value proposition development, market analysis and segmentation, and value creation aligned across the interviews.
- The importance of developing a strong value proposition and ensuring market relevance was evident in all interviews, focusing on understanding market needs, adapting to market dynamics, and creating value for customers.

4. Market Dynamics, Adaptation and Resilience:

- Adapting to dynamic markets and regulatory environments was emphasized across all interviews.
- Themes related to market dynamics, adaptation, and regulatory challenges converged in all interviews.
- Adaptation and resilience emerged as key themes in all interviews, emphasizing the need for start-ups to adapt to changes in the market, regulatory landscape, and operational challenges.

Divergence of Themes:

1. Focus Areas:

- Each interview had its unique focus areas and sub-themes. For example, while the first interview (SME 1) emphasized ecosystem engagement and entrepreneurial attributes, the second interview (SME 2) focused more on strategic business model innovation and market engagement.

2. Depth of Exploration:

- Some interviews dived deeper into certain topics than others. For instance, the third interview (SME 3) explored strategic team development and value proposition validation more extensively than the other interviews.

3. Specific Challenges and Solutions:

- Different interviews addressed specific challenges and solutions based on the context and perspectives of the interviewees. For example, the second interview (SME 2) discussed regulatory compliance and operational strategy in detail, while the third interview (SME 3) focused on continuous innovation and stakeholder engagement.

4. Operational Focus:

- While all interviews touched upon operational aspects, the depth of coverage varies. Some interviews, like the third one (SME 3), dove deeper into operational challenges and solutions.

Divergence by interviews:

1. Interview of SME 1: Emphasized diverse themes such as social responsibility, trustworthiness organizational dynamics, and inclusion.
2. Interview of SME 2: Focused on holistic market engagement, strategic business model innovation, and operational challenges.
3. Interview of SME 3: Highlighted themes related to team development, dynamic markets, continuous innovation, and resource-intensive market entry.

4. Aggregate Dimensions and Insights

Aggregate Dimensions and Insights of Subject Matter Expert Cohort

The insights from expert interviews were categorized based on overarching themes, sub-themes, and their correlation with the Business Model Canvas (BMC) and Value Proposition Canvas (VPC). Key aggregated dimensions include:

Table 4: Aggregate Dimensions with the Business Model Canvas (BMC) and Value Proposition Canvas (VPC)

Dimension	Key Focus Areas	Impact
Strategic Business Development & Planning	Strategic planning, market segmentation, differentiation	Aligns business strategies with cost structures, refining value propositions and customer focus
Market Ecosystem Engagement & Customer Focus	Market engagement, user-centric customization, stakeholder interactions	Enhances business success through refined value propositions and user engagement
Innovation & Adaptability	Continuous innovation, integration, strategic adaptation	Ensures competitiveness through market feedback-driven innovation
Regulatory Compliance & Risk Management	Regulatory navigation, operational risk mitigation	Ensures sustainability by adhering to compliance standards
Resource Management & Funding	Resource allocation, investment, financial constraints	Secures funding and demonstrates investor value through clear revenue strategies
Collaboration & Networking	Partnerships, networking, ecosystem synergy	Strengthens value propositions through collaborative growth
Team Development & Organizational Culture	Team building, human resources (HR) management, entrepreneurial mindset	Enhances innovation and customer engagement via a strong organizational culture
Value Proposition & Business Model Innovation	Refining value propositions, business models	Ensures market relevance and competitive advantage through customer insights
Performance Evaluation & Metrics	key performance indicators (KPIs), performance monitoring	Aligns value propositions with success metrics for customer satisfaction
Adaptation & Resilience	Start-up challenges, dynamic market navigation	Ensures sustainability by adapting business models to evolving conditions

These dimensions aimed to capture the essence of the interviews while providing a framework for analysing the data in a more aggregated manner. They encompassed a wide range of factors that influence the success and growth of digital health start-ups within accelerator/incubator programs in Europe.

Aggregate Dimensions and Insights of Start-up Representative Cohort

The insights from expert interviews were categorized based on overarching themes, sub-themes, and their correlation with the Business Model Canvas (BMC) and Value Proposition Canvas (VPC). Key aggregated dimensions include:

Given the diverse range of themes and sub-themes across the interviews, the following are the aggregate dimensions and insights into the broader purview:

1. Personalized Chronic Disease Management (B2C) Platform

Table 5: Aggregate Dimensions of the Personalized Chronic Disease Management (B2C)

Dimension	Key Focus Areas	Impact
Regulatory Compliance & Market Expansion	Navigating regulations, ensuring compliance, cost implications	Facilitates market expansion and innovation within legal frameworks
Strategic Resource Management & Innovation	Business model innovation, resource optimization, product development	Enhances efficiency and growth through strategic innovation
Patient-Centric Innovation & Solution Validation	Meeting patient needs, technological advancement, performance validation	Ensures that solutions align with patient requirements and effectiveness
Strategic Planning & Market Entry	Market entry validation, investment acquisition, partnerships	Strengthens market penetration through strategic decision-making
Cost Management & Regulatory Challenges	Financial constraints, regulatory compliance, fostering innovation	Balances cost efficiency with compliance for sustainable growth
Strategic Partnership & Intellectual Property Management	Collaborative partnerships, intellectual property (IP) rights, business model innovation	Leverages partnerships for business development and market advantage
Cultural & Personal Attributes in Entrepreneurship	Diversity, leadership, team dynamics, entrepreneurial mindset	Cultivates a supportive and innovative entrepreneurial culture
Tailored Solutions & Market Alignment	Customization, market fit, unique value proposition	Enhances stakeholder value through aligned product offerings
Understanding Market Needs & Proposition Development	Market analysis, value proposition refinement, business model alignment	Drives business success through targeted market strategies
User Engagement & Satisfaction	User feedback analysis, experience enhancement, performance monitoring	Ensures continuous improvement and customer-centric growth

2. Integrated Multi-Omics Imaging (B2B) Platform

The insights from expert interviews were categorized based on overarching themes, sub-themes, and their correlation with the Business Model Canvas (BMC) and Value Proposition Canvas (VPC). Key aggregated dimensions include:

Table 6: Aggregate Dimensions of the Integrated Multi-Omics Imaging (B2B) Platform

Dimension	Key Focus Areas	Impact
Regulatory Compliance & Market Expansion	Navigating regulatory challenges, compliance, adaptability, market expansion	Ensures adherence to legal requirements while exploring new market opportunities
Strategic Resource Management & Innovation	Business model development, scientific advancement, resource management	Aligns resource allocation with innovative business models for value creation
Patient-Centric Innovation & Solution Validation	Strategic product development, regulatory compliance, technological validation	Meets patient needs while addressing regulatory hurdles

Dimension	Key Focus Areas	Impact
Strategic Planning & Market Entry	Market entry validation, stakeholder engagement, strategic funding	Optimizes value propositions for successful market penetration
Cost Management & Regulatory Challenges	Cost constraints, regulatory landscape, operational efficiency	Balances cost management with compliance in healthcare markets
Strategic Partnership & Intellectual Property Management	Collaboration, IP management, revenue models	Strengthens business sustainability and competitive advantage
Cultural & Personal Attributes in Entrepreneurship	Diversity, entrepreneurial characteristics, innovation culture	Fosters an inclusive entrepreneurial environment for innovation and growth
Tailored Solutions & Market Alignment	Customization, market readiness, stakeholder engagement	Ensures alignment with target customer segments for optimized value delivery
Understanding Market Needs & Proposition Development	Market analysis, competitive positioning, value proposition refinement	Develops compelling value propositions that address customer pain points
User Engagement & Satisfaction	Stakeholder engagement, performance evaluation, customer experience	Drives customer retention and loyalty through enhanced user satisfaction

3. Global Medical Tourism (B2C) Platform

Table 7: Aggregate Dimensions of the Global Medical Tourism (B2C) Platform

Dimension	Key Focus Areas	Impact
Stakeholder Engagement & Collaborative Strategy	Partnerships, collaborations, stakeholder engagement	Drives innovation and ensures start-up success through strong relationships and aligned goals
Financial Management & Resource Allocation	Cost structure optimization, revenue diversification, funding acquisition	Ensures sustainability and supports expansion and innovation efforts
Patient-Centered Innovation & Experience Enhancement	Understanding patient needs, addressing pain points, experience improvement	Enhances healthcare outcomes and patient satisfaction
Operational Excellence & Infrastructure Development	Process optimization, technology investment, continuous improvement	Ensures seamless service delivery and high-quality digital health operations
Strategic Planning & Market Expansion	Market analysis, growth opportunities, competitive differentiation	Supports successful market entry and sustained business growth
Collaborative Innovation & Knowledge Exchange	Open innovation, shared expertise, continuous learning	Fosters creative problem-solving and healthcare innovation
Trustworthy Execution & Market Engagement	Regulatory compliance, transparency, credibility building	Strengthens market trust and promotes adoption of digital health solutions

4. AI-Powered Biologics Discovery (B2B) Platform

Table 8: Aggregate Dimensions of the AI-Powered Biologics Discovery (B2B) Platform

Dimension	Key Focus Areas	Impact
Strategic Market Engagement & Business Model Innovation	Market dynamics, stakeholder engagement, business model innovation	Enhances market understanding and develops innovative business models to address unmet needs

Dimension	Key Focus Areas	Impact
Customer Acquisition Efficiency & Revenue Optimization	Customer acquisition, revenue cycles, funding, performance evaluation	Optimizes acquisition processes and revenue cycles for sustainable business growth
Pilot Project Implementation & Assessment	Pilot testing, product validation, service evaluation	Ensures the feasibility and effectiveness of new solutions through pilot projects
Regulatory & Intellectual Property Management Complexity	Regulatory navigation, intellectual property rights, compliance challenges	Addresses legal and IP complexities to sustain competitive advantage
Strategic Market Expansion & Cost Management	Market growth, cost management, competitive landscape	Facilitates expansion while maintaining cost efficiency and market positioning
Cultivating a Diverse, Stakeholder-Centric Environment	Diversity, stakeholder collaboration, leadership dynamics	Fosters an inclusive and collaborative environment to drive innovation and success
Strategic Alignment with Unmet Needs for Optimal Product-Market Fit	Market alignment, value proposition, customer insights	Ensures that solutions align with market needs for a strong product-market fit
Strategic Entrepreneurship in Competitive Environments	Entrepreneurial strategy, competitive positioning, leadership	Strengthens start-up resilience and adaptability in competitive markets

1.1.1 Archetype-specific Convergence and Divergence Models

The convergence and divergence of dimensions depict the commonalities and differences of attributes between the subject matter experts' views and start-up representatives' understandings.

1. Personalized Chronic Disease Management (B2C) Platform

To create a convergence and divergence model between the two cohorts—subject matter experts and start-up representatives—let us first outline the aggregate dimensions of each cohort, identify overlaps and unique elements, and then delve into the specifics of how these dimensions have converged and diverged.

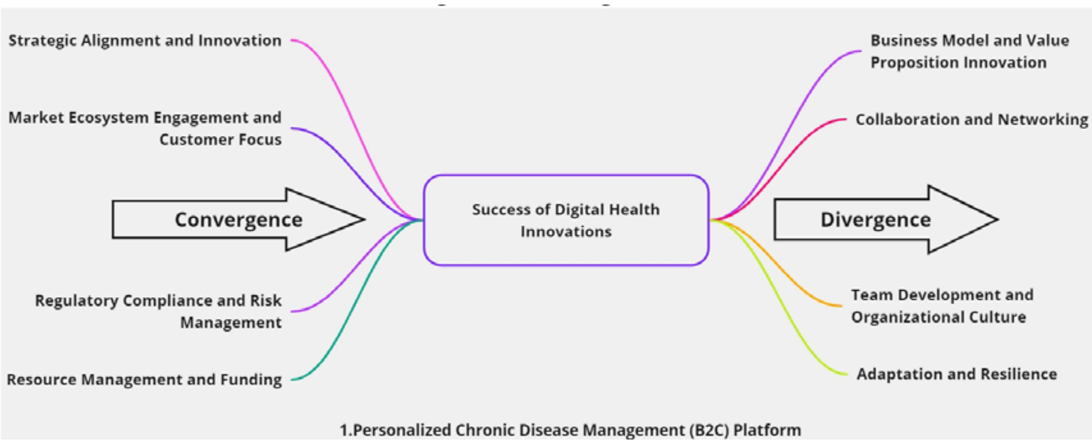

Figure 4: Convergence and Divergence model for Personalized Chronic Disease Management (B2C) Platform.

Convergence Model

1. Strategic Alignment and Innovation:
Both cohorts emphasized the critical role of strategic alignment between business development, market entry, and innovation efforts. Subject matter experts focused on strategic business development, planning, and innovation as foundational elements. This paralleled the start-up representative's emphasis on strategic resource management and innovation, as well as patient-centric innovation for solution validation. There was a clear convergence in the understanding that strategic planning and continuous innovation were paramount for navigating market dynamics and sustaining competitive advantage.

2. Market Ecosystem Engagement and Customer Focus:
The convergence was evident in the shared emphasis on market ecosystem engagement and maintaining a customer-centric approach. Subject matter experts' dimensions of market ecosystem engagement closely aligned with start-up representatives' focus on understanding market needs and developing tailored solutions. Both cohorts recognized the importance of engaging with market ecosystems, understanding customer needs, and refining value propositions to enhance user engagement and drive business success.

3. Regulatory Compliance and Risk Management:
Both groups underscored the significance of navigating regulatory challenges and managing operational risks. Subject matter experts and start-up representatives highlighted regulatory compliance as a critical dimension, integrating it with market expansion strategies and innovation processes. This alignment illustrated a common understanding that compliance and risk management were integral to operational efficiency and market viability.

4. Resource Management and Funding:
Efficient resource management and securing funding were focal points for both cohorts. Subject matter experts' emphasis on resource management and funding found a counterpart in start-up representative's strategic resource management and innovation. The collective insight was that managing resources efficiently and securing appropriate funding were essential for supporting business operations, growth, and innovation.

Divergence Model

1. Business Model and Value Proposition Innovation:
While both cohorts focused on value proposition and business model innovation, subject matter experts provided a more structured approach to integrating these innovations within broader business development strategies and frameworks like the BMC and VPC. In contrast, start-up representatives appeared to focus more on the practical implications of tailoring solutions to market needs and aligning value propositions with customer segments.

2. Collaboration and Networking:
Subject matter experts placed a strong emphasis on the importance of collaboration and networking within the ecosystem, viewing it as a strategic asset for business growth and innovation. Start-up representatives, while acknowledging the importance of strategic partnerships, especially in the context of intellectual property management, seemed to view collaboration more to an end rather than an integral part of the ecosystem engagement.

3. Team Development and Organizational Culture:
The dimension of team development and fostering a positive organizational culture was more explicitly addressed by subject matter experts, highlighting the strategic importance of human resources in driving business success. Start-up representatives touched on cultural and personal attributes in entrepreneurship, suggesting a divergence in the level of emphasis placed on organizational culture and team development as strategic assets.

4. Adaptation and Resilience:
Both cohorts recognized the importance of adaptation and resilience; however, subject matter experts provided a broader perspective on strategic engagement and navigating dynamic markets as part of fostering adaptability. In contrast, start-up representatives focused more on specific strategies such as market alignment and solution validation in response to market needs and regulatory challenges.

2. Integrated Multi-Omics Imaging (B2B) Platform
The convergence and divergence model based on the dimensions provided from both the subject matter expert and start-up representative interviews, with explanations for each convergence and divergence, is depicted in Figure 5:

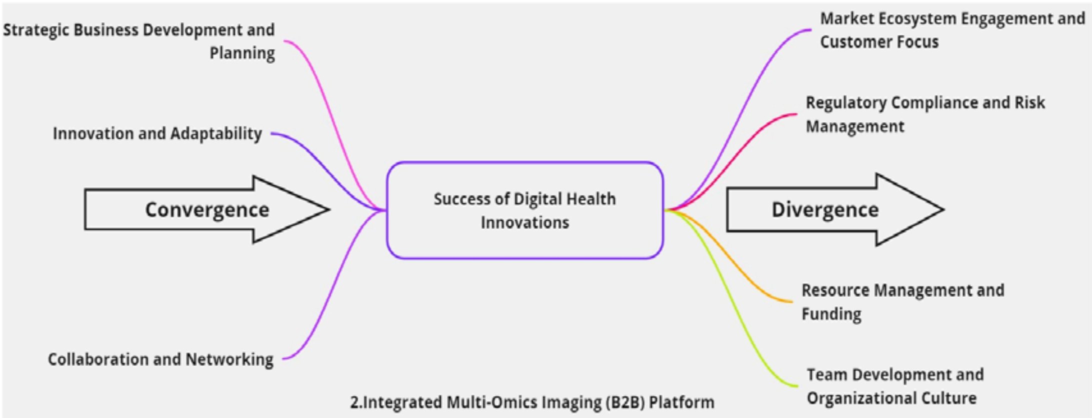

Figure 5: Convergence and Divergence model for Integrated Multi-Omics Imaging (B2B) Platform.

Convergence Model

1. Strategic Business Development and Planning (SBDP):
Both cohorts converged on the importance of strategic planning and development to drive business success. They emphasized aligning business strategies with operational activities and refining value propositions based on strategic planning insights. This alignment ensures efficient resource allocation and enhances customer segmentation and targeting strategies.

2. Innovation and Adaptability (IA):
Both cohorts recognized the significance of continuous innovation and adaptation to market dynamics. They integrated innovation into business processes and iterated value propositions based on market feedback and trends. This convergence fosters agility and competitiveness in responding to evolving customer demands and industry changes.

3. Collaboration and Networking (CN):
Collaboration and networking emerged as crucial elements endorsed by both cohorts. They highlighted the importance of building strategic partnerships and networks to enhance value propositions and support business growth. This convergence fosters a collaborative ecosystem that addresses customer needs and explores market opportunities effectively.

Divergence Model:

1. Market Ecosystem Engagement and Customer Focus (MECF):
While both cohorts emphasized understanding market needs and enhancing user engagement, the subject matter experts placed more emphasis on holistic market engagement and user-centric customization. In contrast, start-up representatives focused more on strategic market alignment and optimizing customer acquisition processes. This slight divergence highlights nuanced perspectives on market engagement strategies.

2. Regulatory Compliance and Risk Management (RCRM):
The subject matter experts and start-up representatives diverged slightly in their emphasis within this dimension. While both acknowledged the importance of regulatory compliance, subject matter experts focused more on navigating regulatory challenges and ensuring sustainability. In contrast, start-up representatives highlighted the complexity of managing intellectual property rights alongside regulatory requirements. This divergence underscores varied priorities in addressing regulatory and risk management complexities.

3. Resource Management and Funding (RMF):
There was a slight divergence between the two cohorts regarding resource management and funding strategies. While both emphasized optimizing resource allocation and securing funding, subject matter experts focused more on demonstrating value to investors through clear value propositions and revenue streams. In contrast, start-up representatives emphasized the importance of efficient resource management and strategic resource mobilization for sustainable growth. This discrepancy reflects nuanced perspectives on funding and resource allocation strategies.

4. Team Development and Organizational Culture (TDOC):
The cohorts exhibited a slight divergence in their emphasis on team development and organizational culture. While both recognized the importance of fostering a positive organizational culture, subject matter experts focused more on developing team expertise and driving innovation. In contrast, start-up representatives emphasized indirectly influencing team dynamics through strategic decisions impacting customer relationships and revenue streams. This divergence highlights varying perspectives on the role of organizational culture in driving innovation and success.

3. Global Medical Tourism (B2C) Platform

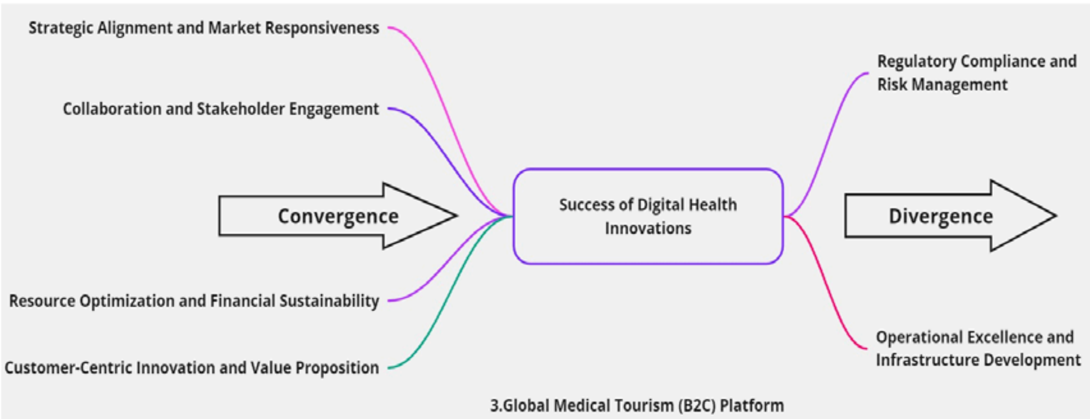

Figure 6: Convergence and Divergence model for Global Medical Tourism (B2C) Platform.

Convergence Model:

The convergence model identified common dimensions and areas where the insights from both cohorts aligned, suggesting a unified approach to navigating the digital health startup ecosystem.

1. Strategic Alignment and Market Responsiveness (SAMR):
Both cohorts emphasized the importance of strategic planning, market analysis, and adaptation to market dynamics. This converged on the need for continuous innovation and strategic flexibility to respond to market needs and competitive pressures.

2. Collaboration and Stakeholder Engagement (CSE):
The emphasis on collaboration, networking, and stakeholder engagement across both cohorts highlighted

the importance of building strategic partnerships and leveraging collective expertise for innovation and market expansion.

3. Resource Optimization and Financial Sustainability (ROFS):
Efficient management of resources and securing funding were critical themes, underscoring the importance of financial sustainability and strategic resource allocation for growth and innovation.

4. Customer-Centric Innovation and Value Proposition (C-CIVP):
Prioritizing customer needs and experiences to drive innovation and enhance value propositions was a common thread, emphasizing the importance of patient-centered approaches in developing digital health solutions.

Divergence Model

The divergence model explored each cohort's unique perspectives and focuses, highlighting the diverse approaches within the digital health start-up ecosystem.

1. **Regulatory Compliance and Risk Management (RCRM)** (subject matter expert cohort):
A focus on navigating regulatory challenges and managing operational risks was more pronounced in the subject matter expert cohort, reflecting a broader concern for ensuring compliance and sustainability.

2. **Operational Excellence and Infrastructure Development (OEID)** (start-up representative cohort):
The start-up representative cohort strongly emphasized optimizing processes and infrastructure development, indicating a hands-on approach to ensuring quality and efficiency in service delivery.

4. AI-Powered Biologics Discovery (B2B) Platform

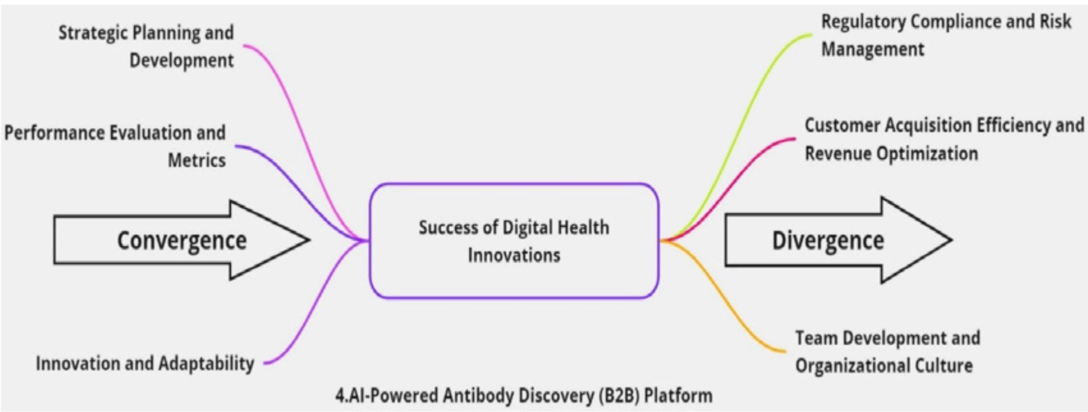

Figure 7: Convergence and Divergence model for AI-Powered Biologics Discovery (B2B) Platform.Platform.

Convergence Model:

1. Strategic Planning and Development (SPD):
- Both cohorts emphasized strategic planning and development, albeit with different focuses (start-up representatives on market dynamics and subject matter experts on business strategies).
- Integration Point: Aligning strategic planning with market dynamics for optimal business development.

2. Innovation and Adaptability (IA):

- Both cohorts acknowledged the importance of innovation and adaptation in response to market changes.
- Integration Point: Incorporating market insights from start-up representatives into strategic adaptation strategies suggested by subject matter experts.

3. Performance Evaluation and Metrics (PEM):

- Both cohorts highlighted the significance of performance evaluation and metrics in assessing business success.
- Integration Point: Establishing common KPIs and metrics that align with both strategic objectives and startup performance goals.

Divergence Model:

1. Regulatory Compliance and Risk Management (RCRM):

- While subject matter experts focused on regulatory compliance, start-up representatives emphasized intellectual property management and regulatory challenges.
- Divergence: Different priorities in regulatory aspects suggested a need for separate strategies in this dimension.

2. Customer Acquisition Efficiency and Revenue Optimization (CAERO):

- Start-up representatives prioritized customer acquisition efficiency and revenue optimization, while subject matter experts emphasized market engagement and differentiation.
- Divergence: Different emphases suggested separate strategies to be pursued in customer-centric approaches versus market-driven differentiation.

3. Team Development and Organizational Culture (TDOC):

- Subject matter experts emphasized team development and organizational culture, while start-up representatives focused on stakeholder-centric environments and soft skills development.
- Divergence: Different focuses suggested distinct strategies for fostering organizational culture versus stakeholder engagement.

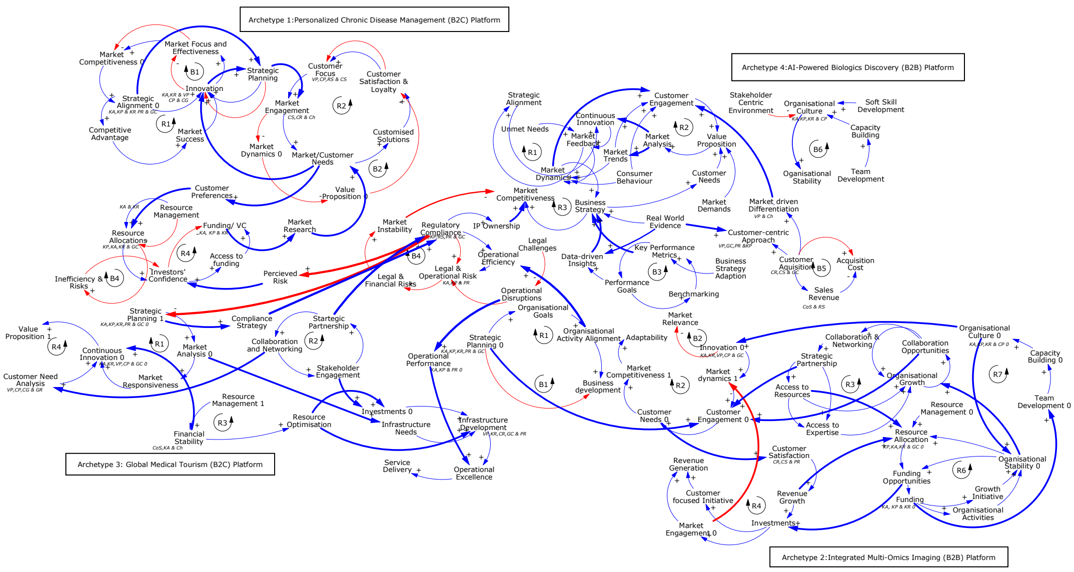

Figure 8: Canvas of the Archetype-Specific Research of Digital Health Landscape.

4. Conclusions

The research on "archetype-specific research of digital health landscape" across different platforms reveals a comprehensive exploration of the systemic interactions that drive success in various business contexts. The research smartly decomposes complex business ecosystems into interconnected feedback loops, identifying both reinforcing and balancing dynamics that underlie the operations of B2C and B2B platforms [1]. Here is an integrated analysis:

Common Themes Across Platforms

1. Strategic Alignment and Innovation: Across the platforms, there is a unanimous emphasis on the synergy between strategic planning and innovation. The iterative relationship between these elements serves as a backbone for sustainable competitive advantage, irrespective of the business model (B2C or B2B) or industry (healthcare, biotech, etc.).

2. Market Dynamics and Customer Focus: The diagrams underscore the necessity of understanding and engaging with market dynamics and customer needs. This engagement is not just a driver of product or service development but also a critical factor in regulatory compliance, resource allocation, and strategic direction.

3. Regulatory Compliance and Risk Management: Particularly prominent in sectors like healthcare and biotech, regulatory compliance is both a loop and a critical intersection point with other loops. It impacts and is impacted by strategic planning, market engagement, and resource management, emphasizing the need for agility and foresight in navigating legal landscapes.

4. Resource Management and Funding: Efficiency in using available resources and securing additional funding is depicted as crucial for both operational stability and strategic ventures. This loop interacts closely with market engagement, strategic alignment, and regulatory compliance, highlighting the interconnectedness of financial health and strategic objectives.

5. Feedback Mechanisms: The causal loop diagrams illustrate the existence of both positive and negative feedback mechanisms within and across the loops. These mechanisms ensure that the system can self-regulate and adapt, underlining the importance of feedback in strategic decision-making.

Unique Insights

Table 9: Key Insights of each Archetype

Archetype	Key Insights
Personalized Chronic Disease Management (B2C)	Emphasizes "Strategic Alignment and Innovation Loop" and "Market Engagement and Customer Focus Loop," ensuring continuous innovation and customer-centric strategies.
Integrated Multi-Omics Imaging (B2B)	Highlights "Strategic Business Development and Planning Loop" and "Innovation and Adaptability Loop," focusing on aligning strategic initiatives with market demands and leveraging partnerships for growth.
Global Medical Tourism (B2C)	Underscores "Strategic Alignment and Market Responsiveness" and "Collaboration and Stakeholder Engagement," showcasing agility and external collaborations to meet diverse global market needs.
AI-Powered Biologics Discovery (B2B)	Stresses "Strategic Planning and Development" and "Regulatory Compliance and Risk Management" as critical in navigating the evolving biotech landscape.

Conclusions of Strategic Implications

Table 10: Robust Strategic Implications

Strategic Insight	Implication
Holistic Management	Success demands an integrated approach, considering the dynamic interplay between feedback loops. Ignoring one loop may lead to unintended consequences.
Agility and Adaptation	Rapid adaptation to market dynamics and regulatory shifts is crucial for sustained growth.
Collaboration Across Ecosystems	Particularly vital for B2B platforms, fostering partnerships enables access to new markets, resources, and innovations.
Customer-Centric Innovation	Across all platforms, understanding and anticipating customer needs remain central to driving innovation and market success.

5. Acknowledgments

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7. Conflicts of Interest

The authors declare that there is no conflict of interest regarding the publication of this paper.

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Bioelectronic Medicine and Non-Communicable Diseases: Rationale for Clinical Significance, Prospects and Problems

Ganna V. Nevoit,[a,b] Inga A. Bumblyte,[a] Maksim M. Potyazenko,[b] Olena Filyunova,[c] Alfonsas L. Vainoras,[a] Ozar P. Mintser[d]

[a]Lithuanian University of Health Sciences, Kaunas, Lithuania
[b]Poltava State Medical University, Poltava, Ukraine
[c]Preventive Medicine Center of Genesis Center LLC, Kyiv, Ukraine
[d]Shupyk National Healthcare University of Ukraine, Kyiv, Ukraine

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ABSTRACT

The results of a theoretical study of the possibilities and prospects for solving the problem of non-communicable diseases (NCDs) are reported in the article. The authors present the ideas of the educational and scientific project "Bioelectronic Medicine or Look at Medicine Differently", which is the result of the research. The aim of the study was to introduce the ideas of bioelectronic medicine as a promising direction for solving the problem of NCDs. This study is a fragment of the research work on "The development of algorithms and technologies for implementing a healthy lifestyle in patients with non-communicable diseases based on the study of functional status" (state registration number 0121U108237: UDC 613 616-056-06: 616.1/9-03). General scientific methods and theoretical methods were used in this theoretical study. Conclusions: Bioelectronic medicine is a promising direction for the further development of medicine and for solving the problem of NCDs because its ideas integrate modern biophysical knowledge about the structure and functioning of the nanolevel of living matter in vivo into knowledge about the functioning of the human body. This opens up new perspectives for studying the pathology of NCDs. Bioelectronic medicine, as a promising direction for solving the problem of NCDs, needs to be further developed and its ideas need to be popularized among the world's scientific community.

KEYWORDS

Non-communicable diseases, Magnetoelectrochemical Theory of Metabolism, bioelectronic medicine, quantum medicine

1. Introduction

Chronic non-communicable diseases (NCDs) are an important health and social problem worldwide. Significant advances have been made in the pharmacological and surgical treatment of NCDs, but morbidity and mortality from NCDs continue to be high. It is recognized that NCDs are a pandemic [1–3]. This was why that the World Health Organization formulated new goals and targets to combat

NCDs until 2030 [4, 5]. Therefore, searching for new medical approaches to solve the problem of NCDs is an urgent scientific task.

Nowadays, fundamental knowledge about the structure of the human body has significantly increased and deepened. Science has studied the nano-level structure of matter and the human body [6–10]. This has opened up further prospects for finding new approaches to solving the problem of NCDs. Deepening the scientific understanding of the pathogenesis of NCDs has been made possible by extrapolating modern biophysical knowledge to medical knowledge about the functioning of the human body [11]. A foundation of new knowledge about the functioning of the human body at the quantum level has emerged that should deepen the current paradigm of knowledge about NCDs. This requires further theoretical research and constitutes a promising direction for science in the further development of medicine and in solving the problem of NCDs.

Therefore, the aim of this theoretical study was to present the ideas of bioelectronic medicine as a promising direction for solving the problem of NCDs.

An Explanation of the Methodology

The analysis of the presented data is a fragment of the research work of the Department of Internal Medicine and Emergency Medicine of Poltava State Medical University (23, Shevchenko St., 36011, Poltava, Ukraine) on the "Development of algorithms and technologies for implementing a Healthy Lifestyle in patients with NCDs based on the study of functional status" (state registration number 0121U108237: UDC 613 616-056-06: 616.1 / 9-03).

Scientific work is carried out in conjunction with the following scientific institutions: 1) Poltava State Medical University (23, Shevchenko St., 36011, Poltava, Ukraine), the cooperation coordinator is the Head of the Department of Internal Medicine and Emergency Medicine, Prof. DM M. Potyazenko; 2) Shupyk National Healthcare University of Ukraine (9, Dorogozhytska St., 04112, Kyiv, Ukraine), the cooperation coordinator is the Head of the Department of Fundamental Disciplines and Informatics, Prof. DM O. Mintser; 3) Lithuanian University of Health Sciences (9, A. Mickevičius St., LT-44307, Kaunas, Lithuania), the cooperation coordinators are the Head of the Nephrology Department, Prof. DM I.A. Bumblyte and Senior Researcher of the Laboratory of Automation of Cardiology Research of the Institute of Cardiology of the Lithuanian University of Health Sciences, Prof. DM A. Vainoras.
General scientific methods (dismemberment and integration of elements of the studied system, imaginary experiment, logical, historical research, analysis, induction, deduction, and synthesis of knowledge) and theoretical methods (method of constructing theory, logical methods, and rules of normative nature) were used in this theoretical study.

To search for information at different stages of the long-term study, the following scientometric databases were used: Scopus, Web of Science, PubMed, ScienceDirect, Directory of Open Access Journals (DOAJ), and JSTOR.

Results and Discussion

Knowledge about the existence of a nano-level structure and the functioning of the human body is the main theoretical concept of bioelectronic medicine. To extrapolate this biophysical knowledge, work has been underway to conceptualize the Magnetoelectrochemical Theory of Metabolism in the human body from 2019 to the present [12]. Key conclusions were that the human body at the nanoscale (≤ 1nm) consists of conglomerates of electromagnetic fields [13, 14]. This made it possible to deepen the paradigm of medical scientific knowledge and highlight the quantum level of the structure and functioning of the human body (Figure 1 and Figure 2) [15].

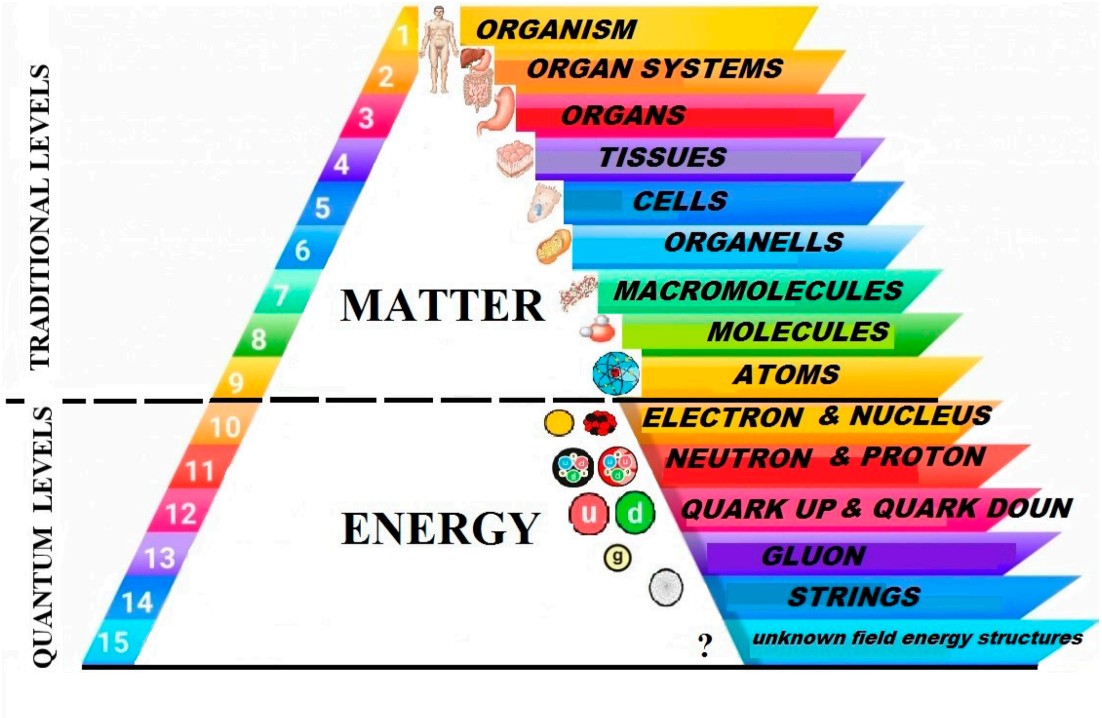

Figure 1. Graphic representation of the structural levels of organization of the human body, considering modern fundamental biophysical knowledge [15].

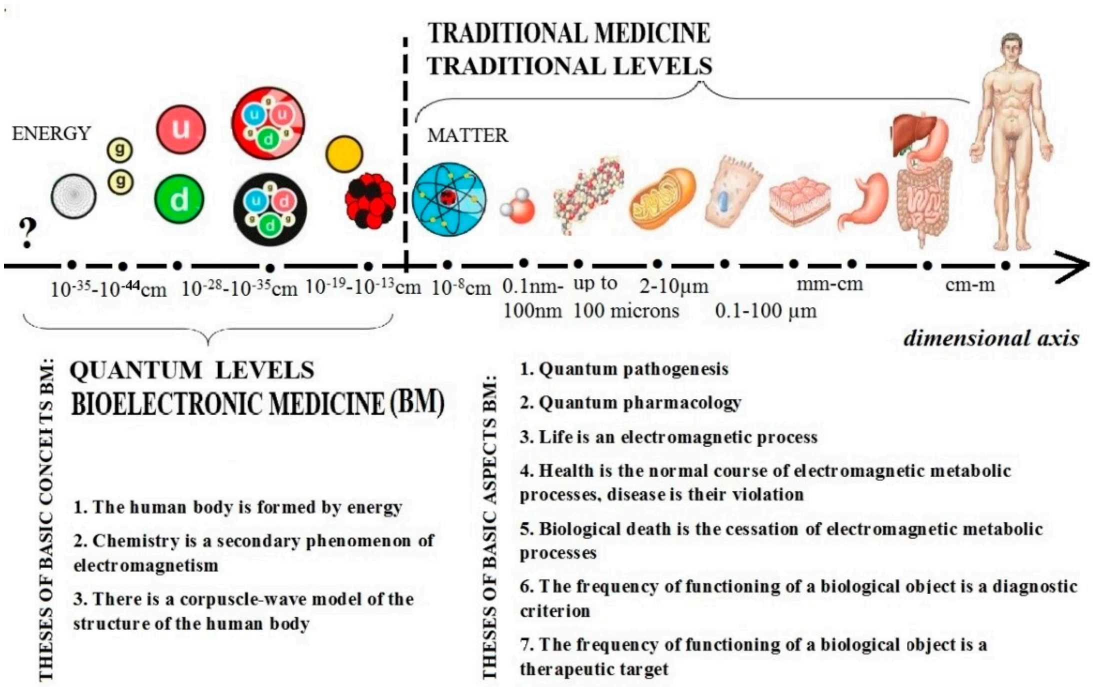

Figure 2. Diagram of the dimensional axis of the structural levels of the organization of the human body, indicating the levels of theoretical concepts of medicine and bioelectronic medicine, as well as theses of the main basic concepts and aspects of bioelectronic medicine, developed in the theoretical study [15].

Key conclusions were made that the basis of molecular metabolism at the quantum level is the quantum processes of magnetoelectrochemical interaction [12–15]. In this case, chemical reactions between molecules are the visible, recorded result of the interaction of the magnetoelectric fields of atoms and subatomic structures that form these molecules [12–15]. It is magnetoelectrochemical processes at the nano level that are the biophysical basis of metabolism in the human body and the basis for the phenomenon of its biological life [12–15]. Magnetoelectric processes, as the basis of metabolism and the phenomenon of biological life, are present at all hierarchical levels of the structure of the human body (Figure 3) [16].

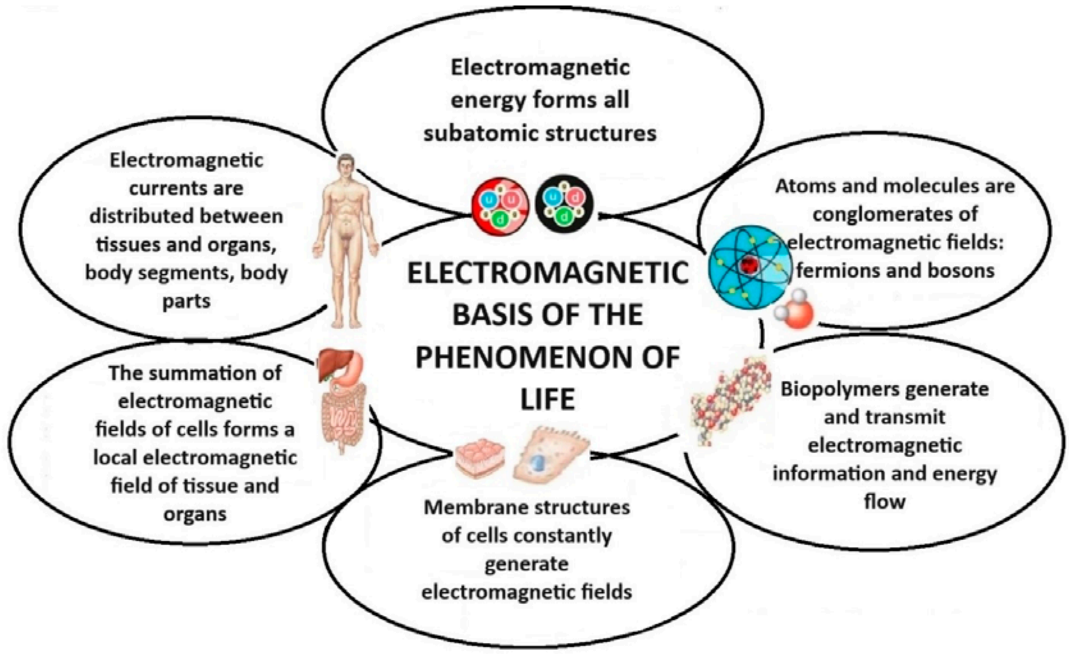

Figure 3. Participation of electromagnetic processes in the implementation of the phenomenon of life at all structural levels of the human body [16].

During the study, the role of electromagnetic processes in the functioning of cell membranes [17] and the biological role of water [18] were conceptualized. The role of biophotons in the functioning of the human body was also conceptualized [19]. The presentation of a newly developed concept of biophoton signaling makes it possible to explain the mechanisms of intercellular signaling at the level of tissues, organs, and the entire organism as a whole [20]. All this became the scientific foundation for further consideration and study of the human body from the standpoint of the frequency-wave model of the body structure and the further development of the ideas of bioelectronic medicine [15, 21].

The use of the term “bioelectronic medicine” is justified by the fact that the electron is, in the understanding of a significant number of modern scientists, a material carrier of an energy charge through which energy exchange and magnetoelectrochemical interaction between atoms of molecules in the cells and tissues of the human body are carried out in vivo. Therefore, this term is understandable to modern scientists and exists in modern science [15, 21–23]. In our opinion, the use of this term in science is sufficient today to explain/describe the processes of biophysical interaction in the molecules of the human body's tissues. To a certain extent, it is synonymous with the term “quantum medicine”, but it seems to more specifically specify electrons as the final material target in treating NCDs. Indeed, from the standpoint of bioelectronic medicine, the treatment task should be precisely the improvement/optimization of magnetoelectrochemical processes at the nano level of the structure of human tissues, and the electron is the material component to which treatment should be directed.

To further popularize and develop these ideas, the educational and scientific project “Bioelectronic Medicine or Look at Medicine Differently” was launched in 2024. This project is being implemented based on the Department of Internal Medicine and Emergency Medicine of the Educational and Scientific Institute of Postgraduate Education of Poltava State Medical University and the Department of Fundamental Disciplines and Informatics of the Shupyk National Healthcare University with the assistance of partner scientists from the Lithuanian University of Health Sciences. The project was supported by scientists from the Faculty of Medicine of Kherson State University, whose website lectures are posted [24]. The implementation of the project involves the creation of new educational and methodological material for introducing quantum medicine issues into education and conducting further scientific research to study the mechanisms of the possible effectiveness of existing bioelectronic medicine techniques in the management of patients with NCDs.

Bioelectronic medicine is a promising direction for the further development of medicine and the understanding of the pathogenesis of NCDs. The further development of the ideas of bioelectronic medicine may have such scientific prospects as:

- To study and conceptualize the values of quantum magnetoelectric indicators of tissue functioning and magnetoelectrochemical metabolic processes of the human body in normal and pathological conditions;
- To study and conceptualize aspects of magnetoelectric interaction/mutual influence between organs of the human body in health and disease, which may help to reveal the mechanisms of the occurrence of polymorbidity and comorbidity in NCDs in the future;
- To study and conceptualize the quantum pathogenesis of the occurrence of pathology of internal organs in NCDs;
- To study and conceptualize aspects of quantum pharmacology as a result of quantum magnetoelectrochemical interaction of molecules of pharmacological substances with molecules of the human body;
- To carry out a new theoretical clinical and pathogenetic substantiation of the feasibility of using existing bioelectronic medicine methods in medicine for the treatment of NCDs and to develop new therapeutic and diagnostic approaches.

A significant achievement of fundamental science of our time is a large number of results of scientific research into electrical and magnetic processes in nature and the human body, as well as scientific breakthroughs in quantum physics. This is a challenge for medicine and this necessitates its further development in this direction as well. However, there may be difficulties in overcoming the inertia of some medical scientists’ thinking. This can be a big problem in the development of bioelectronic medicine. Also, a significant obstacle to the extrapolation of modern biophysical knowledge to the physiology of the functioning of the human body is the lack of a biological theory that could fully and logically describe the course of magnetoelectrochemical processes at all hierarchical levels of the structures of the human body, fitting them into one single whole. Therefore, the educational and scientific project “Bioelectronic Medicine or Look at Medicine Differently” is one of the possible options for overcoming these problems. This project continues to conduct theoretical research into the conceptualization of many aspects of quantum/bioelectronic medicine and to popularize these ideas.
Discussing the issues of correspondence between the ideas of the Magnetoelectochemical Theory of Metabolism and the educational and scientific project “Bioelectronic Medicine or look at Medicine differently,” we, as the authors, want to note the absence of contradictions to the existing paradigm of scientific knowledge. The ideas, concepts, and theory we present deepen and continue learning within the boundaries of existing knowledge. The data we presented results from systematization and systematic analysis of existing scientific data from various biophysical and biological areas of scientific research.

Therefore, the study of electromagnetic mechanisms of cellular communication/biophotonic signaling [19, 25, 26], biophotonics of the human body [11, 16, 19, 27], and interactions of the human body with the electromagnetic field of the Earth [28] are avant-garde directions in science that are already being successfully developed and require further attention from scientists.

2. Conclusions

Bioelectronic medicine is a promising direction for the further development of medicine and solving the problem of NCDs because its ideas integrate modern biophysical knowledge about the structure and functioning of the nano level of living matter in vivo into knowledge about the functioning of the human body. This opens up new perspectives for studying pathology in NCDs. Bioelectronic medicine, as a promising direction for solving the problem of NCDs, needs to be further developed and its ideas need to be popularized among the world's scientific community.

3. Conflict of interest

The authors declare that there is no conflict of interest.

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Alumni Voice Session at the DigiHealthDayS-2024*

Camila Tomikawa,[a] Oscar Blanco[b]

[a]LIMAA Technologies, Cologne, Germany/HIMSS DACH Committee
[b]Deggendorf Institute of Technology (DIT)/European Campus Rottal-Inn (ECRI), Pfarrkirchen, Germany; University of Agder, Kristiansand, Norway; International Health Literacy Association (IHLA), St. Louis, MO, USA

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ABSTRACT

The Alumni Voice session during the DigiHealthDayS-2024 highlighted the importance of digital health literacy as well as the academic and professional trajectories of the Master of Digital Health graduates. Three brilliant alumni shared their personal and diverse experiences, offering insights that may shape students' perspectives on career development and industry challenges. The session concluded with a forward-looking dialogue about the future of healthcare.

KEYWORDS

Education, alumni, digital health

1. Introduction

Digital health advances are happening at an unprecedented scale and are poised to change the way healthcare is delivered. Training and education programs are fundamental for the future workforce to keep up with the speed of innovation, as well as to develop and use technologies while pondering their risks and limitations.

At the Deggendorf Institute of Technology (DIT), the Master's in Digital Health (MDH) has provided many students from different backgrounds with the opportunity to deepen their knowledge of emerging digital health technologies. Since the first graduating cohort in 2018, alumni have successfully transitioned into professional roles, contributing to the ongoing development of the digital health sector. The Alumni Voice session during the DigiHealthDayS-2024 aimed to bridge the gap between MDH students, graduates, and established professionals by:

1. Creating and fostering a space for dialogue that engages alumni and students as well as a space to share experiences, concerns, and achievements;
2. Encouraging students and alumni to engage in extension activities, such as working groups, mentoring activities, and communities of practice.

*DIALOGUE @ DigiHealth Alumni – Research, Education, Workforce. Hosts: Camila Tomikawa (HIMSS, Germany) & Oscar Blanco (DIT, Germany). Speakers – MDH Alumni: Mahsa Rouzkhatouni (Iran), Eugene Amponsah, (Ghana), Helana Lutfi (Germany).

2. Key Considerations

The Alumni Voice session at the DigiHealthDayS-2024 kicked off with an overview of its goals and a brief review of the Master's history. Since its beginning, the Master in Digital Health (MDH, formerly Master in Medical Informatics or MMI) has offered many students from different backgrounds to expand their knowledge and prepare for the future of healthcare. The original course syllabus was built to accommodate students with a computer sciences background as well as life sciences studies background. In 2021, the study program changed its syllabus and name to reflect the developments in the field, such as the growth of generative AI, privacy regulations, and cloud-based solutions.

As preparation for the session, alumni of the study program were polled and the results showed that after graduation, most of them stayed in Germany (80 %), taking on different roles such as clinical research associates (CRAs), medical quality specialists, PhD students, software developers, project managers, founders, and more. The top three industries are software development, consulting, and pharmaceuticals.

Beyond the academic and career trajectories of graduates, the session addressed the critical role of digital health literacy in contemporary society. Patients with low health literacy in general are more likely to visit an emergency room, have more hospital stays, have higher mortality rates, and are less likely to follow treatment plans [1]. With the rapid development and increasing adoption of new technologies in healthcare, it is pressing to transition from "traditional" health literacy into a version that encompasses digital health literacy.

After this initial section, three graduates were invited to share their individual experiences as MDH students during and after graduation. Their perspectives were varied, offering insights that may influence how students perceive themselves and their potential future career paths. The graduates contributed to a diverse representation and fostered a connection between the conference attendance.

The session concluded with a forward-looking discussion on the evolution of digital health, guided by the Global Strategy on Digital Health [2]. After considering the course developments and the students' testimonials, we proposed a step back to look at the bigger picture: how is the field evolving and describing how the future will look. The panelists explored key strategic priorities and shared insights on the expected future of the field, fostering an engaging dialogue among participants.

3. Conclusion

The Alumni Voice session during the DigiHealthDayS-2024 aimed to aid in bridging the gap between students, graduates, and established professionals through networking, project collaboration, mentorship, and community and belonging. The session highlighted the importance of digital health literacy as well as the academic and professional trajectories of the MDH graduates. Three brilliant alumni shared their diverse experiences, offering insights that may shape students' perspectives on career development and industry challenges. The session concluded with a forward-looking dialogue, encouraging participants to critically examine the field's evolution and the future directions of digital health.

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Scientific Session on Thursday, November 14th*

Martin Gerdes,[a] Fara Aninha Fernandes[b]

[a]University of Agder, Kristiansand, Norway
[b]Deggendorf Institute of Technology (DIT)/European Campus Rottal-Inn (ECRI), Pfarrkirchen, Germany

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ABSTRACT

The scientific session encompassed a range of topics centred around the application of technology to advance healthcare and medical education.

David Naguib's presentation explored the potential and challenges of using artificial intelligence (AI) in electronic health record-(EHR-)based pharmacovigilance in Germany and Egypt to improve adverse drug reactions (ADR) detection.

Mariam Barseghyan and colleagues discussed a digital intervention using the ICOnnecta't App to address the psychological impact of breast cancer and premature menopause.

Tatul Saghatelyan and colleagues presented the successful pilot implementation of a mobile mammographic screening program in Armenia, highlighting its IT infrastructure and impact on early detection.

Arman Darbinyan and colleagues detailed the use of deep learning for automatic electrocardiography (ECG) and mammography analysis to detect cardiovascular diseases and cancer.

Arsen Arakelyan introduced the Armenian Genome Project as a pathway to personalized medicine, focusing on characterizing the Armenian genome and its implications for health.

Finally, Ozar Mintser's presentation addressed AI-powered learning technologies and the knowledge tracing problem in medical education, advocating for proactive educational strategies.

Overall, the session showcased diverse applications of AI and digital platforms in screening, diagnosis, monitoring, and education across different medical fields and geographical contexts.

KEYWORDS

Artificial intelligence (AI), digital healthcare platforms, diagnosis, education

**Scientific Session. Hosts: Fara Fernandes (DIT, Germany) & Prof. Martin Gerdes (UiA, Norway). Speakers: David Naguib (DIT, Egypt), Mariam Barseghyan (UB, Spain), Dr. Tatul Saghatelyan (RAU/AADH, Armenia), Prof. Arman Darbinyan (RAU, Armenia), Prof. Arsen Arakelyan (RAU, Armenia), Prof. Ozar P. Mintser (NHI, Ukraine).*

1. Introduction

The Scientific Session of the DigiHealthDayS-2024 Scientific Congress took place on Thursday, November 14th in Pfarrkirchen, Germany. The overall theme was "Global Digital Health – today, tomorrow, and beyond".

The Scientific Session included the following presentations:

(1) "The Adoption and Use of AI in EHR-Based Pharmacovigilance; Reality, Challenges, and Potential Impact on Early Detection of ADRs in Germany and Egypt" (D. Naguib)
(2) "Psychological Impact of Breast Cancer and Premature Menopause; Digital Intervention Approach" (M. Barseghyan, N. Belousova, V. Ziablov, M. Ruiz Romeo, A. Rodríguez- Ortega, A. Flix-Valle, C. Ochoa-Arnedo)
(3) "Mobile Mammographic Screening Program in Armenia: IT Infrastructure and Pilot Implementation", T. Saghatelyan, N. Manukyan, A. Avetisyan, S. Jilavyan, H. Nersoyan)
(4) "Automatic ECG Analysis Using Deep Learning" (A. Darbinyan, S. Tigranyan, A. Asatryan)
(5) "Armenian Genome Project: A path to personalized medicine in Armenia" (A. Arakelyan)
(6) "Proactive and Reactive Deployment of AI-Driven Knowledge Tracing Techniques" (O. Mintser)

2. Key Considerations

The adoption and use of AI in EHR-based pharmacovigilance (PV) presents several key considerations. The reality is that both Germany and Egypt are in the early stages of adoption, facing challenges such as technical barriers, lack of resources, and data privacy concerns. The implication is that the potential for early detection of ADRs is not yet fully realized, despite a generally positive attitude among PV specialists. Addressing these barriers through education, training, secure data sharing methods, and regulatory adaptation is crucial to unlock the potential impact of AI in improving drug safety and public health.

Digital interventions for mental health, exemplified by the ICOnnecta't App, highlight the importance of personalized support and active patient engagement. A key consideration is the high prevalence of psychological distress, including anxiety, depression, and post-traumatic stress disorder (PTSD), among breast cancer patients experiencing premature menopause. The implication is that digital platforms offer a promising avenue for alleviating this burden by tracking symptoms, providing reliable information, and facilitating communication with healthcare professionals. Further research into the relationship between physical activity, sleep, and mental well-being, potentially through the integration of wearable devices, could significantly enhance patient care.

Mobile mammography screening programs, as implemented in Armenia, demonstrate the critical consideration of increasing accessibility to early cancer detection in remote and underserved areas. The implication is a reduction in late-stage diagnoses and improved breast cancer mortality rates, as evidenced by the Armenian program's high participation rate and detection of early-stage cancers. The success of such initiatives hinges on a robust IT infrastructure for data transmission, secure storage, and remote analysis, providing a scalable model for addressing healthcare disparities.

AI-powered medical image analysis for ECG and mammography presents a significant consideration in automating the detection of cardiovascular diseases and breast cancer. The implication is the potential for faster and more accurate diagnoses, which is particularly important given the global burden of these conditions. Key considerations include ensuring the robustness and stability of deep learning models across diverse datasets and integrating these tools effectively into clinical workflows.

The Armenian Genome Project underscores the key consideration of leveraging genomic information to advance personalized medicine. By characterizing the Armenian genome and identifying population-specific genetic variants, the project aims to understand disease risks, develop targeted diagnostics and treatments, and ultimately improve healthcare outcomes. The implication is a shift towards more precise and individualized medical interventions, with potential economic, regulatory, and educational benefits for Armenia.

AI in education and knowledge tracing highlights the crucial consideration of enhancing learning processes and ensuring the competence of healthcare professionals. Proactive education strategies, enabled by AI, aim to predict learning needs, personalize pathways, and provide timely interventions. The implication is improved knowledge retention, reduced costs in education, and better long-term results. A key challenge is the effective tracing of procedural knowledge, where virtual reality simulations offer a promising solution for assessment and feedback.

3. Future Directions

Several potential future developments and research areas emerge from the presentations. In the field of pharmacovigilance, future efforts could focus on developing and implementing specific regulations that accommodate the use of AI in ADR detection, alongside establishing robust data protection frameworks to enable the secure secondary use of EHR data for PV purposes. Further research could evaluate the effectiveness of different training programs in increasing PV specialists' knowledge and adoption of AI and EHR technologies.

Regarding digital mental health interventions, future research could explore in greater depth the relationships between physical activity levels, sleep patterns, and mental well-being in patients with breast cancer and premature menopause, potentially leveraging data from wearable devices for continuous monitoring and personalized support. The long-term efficacy and scalability of digital platforms like ICOnnecta't in diverse patient populations also warrant further investigation.

The success of the mobile mammography program in Armenia suggests potential for broader national implementation and adaptation of this model for other cancer screenings and healthcare services in underserved regions. Future research could focus on optimizing the IT infrastructure and workflow for such mobile screening initiatives and evaluating their cost-effectiveness and long-term impact on healthcare disparities.

In AI-powered diagnostics, future developments will likely concentrate on enhancing the robustness and generalizability of deep learning models for ECG and mammography analysis across diverse datasets and clinical settings. Research will also be needed to develop seamless integration strategies for these AI tools into existing hospital medical information systems to facilitate their adoption in clinical practice. The Armenian Genome Project lays the groundwork for extensive future research into characterizing the Armenian genome in more detail, identifying specific genetic variants associated with disease risks, and developing population-specific diagnostic tests and treatment strategies. Future efforts will likely involve integrating this genomic data with EHR systems to enable personalized medicine approaches and further understanding the genetic history and origins of the Armenian population.

Finally, in the domain of AI in education, future research will likely focus on refining proactive, AI-driven knowledge tracing methodologies to better predict student learning needs and personalize educational pathways. The development and validation of virtual reality simulations for assessing procedural knowledge represent a significant area for future work. Addressing the ethical considerations and potential biases in AI algorithms used in education will also be a crucial focus.

4. Conclusion

Overall, the presentations in this scientific session highlight the growing importance and potential of digital technologies, particularly Artificial Intelligence (AI), in various aspects of healthcare, ranging from pharmacovigilance and mental health support to disease screening, diagnostics, and medical education. A key conclusion across several presentations is that while the potential benefits are significant, the widespread adoption and effective implementation of these technologies face challenges that need to be addressed.

In the realm of pharmacovigilance in Germany and Egypt, the overarching conclusion is that AI and EHRs are underutilized, and that there is a lack of knowledge and awareness among PV specialists regarding their application. The presentations suggest a need for regulatory support, training initiatives, and the development of data protection frameworks to leverage these technologies for better ADR detection.

Regarding digital interventions, the ongoing research suggests the potential of platforms like the ICOnnecta't App to alleviate the psychological burden of conditions like breast cancer and premature menopause, and the value of integrating wearable technology for continuous monitoring. The mobile mammography program in Armenia provides a successful example of how accessible screening programs, enabled by mobile technology and IT infrastructure, can improve early cancer detection rates in underserved populations.

In diagnostics, the presentations on automated ECG and mammography analysis conclude that deep learning models show promising accuracy in detecting cardiovascular diseases and breast cancer, paving the way for AI-powered tools in clinical practice. The Armenian Genome Project concludes with the ambition of leveraging genomics to understand population-specific health risks and advance personalized medicine, with expected benefits across economic, regulatory, and educational sectors.
Finally, the discussion on AI in education concludes that proactive, AI-driven approaches to knowledge tracing and personalized learning hold significant potential for enhancing medical education, although challenges related to bias, ethical considerations, and the definition of learning curves need to be overcome. Effective knowledge tracing is identified as crucial for the success of proactive educational strategies.

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Engaging Patients and Citizens in Digital Health – Opportunity or Challenge?*

Birgit Bauer,[a] Benjamin Friedrich[b]

[a]CEO of european digital health academy gGmbH, Project Data Saves Lives Germany
[b]CMO of Temedica, Member of the Ad-Board Data Saves Lives Germany

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ABSTRACT

Digital health innovations thrive when patient involvement is integrated from the outset. This commentary highlights insights from the DigiHealthDayS-2024 Scientific Congress, emphasizing the pivotal role of patient engagement in shaping digital health solutions. Drawing on recent presentations, it is evident that early collaboration with patients—not merely as end users, but as co-creators and experts—yields solutions that are more user-centered, effective, and sustainable. The WHO has been strongly recommending patient engagement in primary care ever since 2016, underscoring its importance in improving care quality and fostering trust. Key innovations include the structured use of advisory boards, focus groups, real-world evidence platforms, agile development processes, and the acknowledgment of patient diversity. Furthermore, the session calls for embedding patient collaboration modules into digital health curricula, ensuring that future practitioners are well-versed in participatory design and ethical compensation. This commentary discusses these findings, identifies critical considerations for effective patient involvement, and outlines future directions for research and policy in digital health innovation.

KEYWORDS

Digital Health, patient involvement, patient engagement, co-creation, healthcare innovation

1. Introduction

Digital Health is rapidly transforming healthcare delivery, and patient involvement has emerged as a critical success factor. This commentary explores the importance of integrating patient perspectives into digital health development and highlights key insights from the DigiHealthDayS-2024 Scientific Congress. With increasing demands for personalized and effective care, engaging patients from the early stages of design is essential. The session underscored how patient co-creation and adherence to WHO recommendations can bridge the gap between technology and patient needs.

**WORKSHOP @ Data Saves Lives (DSL) Germany: Patient Involvement – Burden or Unknown Resource? Hosts: Birgit Bauer & Dr. Benjamin Friedrich (DSL, Germany).*

2. Key Considerations

1. **Early Patient Engagement**
   Involving patients early in the development process enhances the relevance and usability of digital solutions. Patients lived experiences provide unique insights that drive patient-centered innovation and improve treatment outcomes.
2. **Integration into Curricula**
   There is a pressing call to incorporate patient collaboration modules into every digital health curriculum. This ensures that future healthcare professionals are equipped to engage patients meaningfully and ethically in technology design.
3. **Ethical and Structured Involvement**
   Structured frameworks such as advisory boards and focus groups are essential for effective patient engagement. Recognizing patient expertise through fair compensation reinforces their role as critical contributors to co-creation.
4. **Leveraging Real-World Evidence and Agile Development**
   Integrating robust patient-reported data and agile methodologies—like the Build-Measure-Learn cycle—enables continuous refinement of digital health solutions based on real-world evidence, ultimately enhancing patient–provider interactions.
5. **Embracing Patient Diversity and Inclusiveness**
   Patients represent a diverse group—from general end users to expert advocates and caregivers. Tailoring engagement strategies to accommodate varied experiences ensures all voices are heard, leading to more inclusive and effective digital solutions.
6. **Digital-First Approach and Agile Methodology**
   A digital-first strategy, supported by agile development and early involvement of key opinion leaders, ensures that tools are state-of-the-art, continuously refined, and seamlessly integrated into daily life for both patients and healthy individuals.
7. **Addressing Data Privacy and Investment Concerns**
   Community discussions at the DigiHealthDayS-2024 raised concerns about data privacy and the resources required for tool development. Bauer and Friedrich emphasized that strategic investments in secure, patient-centered development yield strong returns on investment (ROI), foster early community engagement, and enhance trust and communication, ultimately supporting a robust market reputation.

3. Future Directions

Future research should explore scalable models for patient engagement and investigate long-term impacts on treatment adherence and system efficiency. Patient participation, along with the involvement of caring persons, is a must for the future. Such collaboration not only empowers developers to create valuable tools that support patients in daily life and disease management but also enhances the quality and quantity of health data, offering deeper insights into diseases. These approaches must be implemented transparently throughout the development process, ensuring that stakeholders are informed and involved in shaping ethical and effective digital health innovations.

4. Conclusion

Integrating patient involvement from the outset is essential for advancing digital health. The insights presented at the DigiHealthDayS-2024 reinforce that early, structured, and ethically managed patient engagement leads to superior healthcare solutions that extend beyond clinical benefits, transforming digital health into a true lifestyle component for both patients and healthy individuals. It is crucial to ensure fair conditions for all participants, recognizing patients as valuable partners who deserve compensation through improved data access, information, and knowledge sharing, rather than being exploited as free resources. Embracing a digital-first, agile approach empowers developers to create responsive, state-of-the-art tools that adapt continuously to real-world needs. Furthermore, addressing community concerns about data privacy and the necessary investment through secure, patient-centered development builds trust and fosters early community engagement, ultimately enhancing market reputation. Embedding these practices into academic and professional curricula will have a transformative impact on digital health innovation, ensuring a sustainable ecosystem that is both effective and widely trusted.

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Navigating the Divide: Informatics as Science and Digitalization as Practice*

Lars Lindsköld,[a] Camila Tomikawa[b]

[a]EFMI & SciLifeLab Data Centre, Sweden
[b]LIMAA Technologies, Cologne, Germany/HIMSS DACH Committee

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ABSTRACT

The dialogue session "Navigating the Divide: Informatics as Science and Digitalisation as Practice" on the first day of the DigiHealthDayS-2024 proposed a discussion around the intersection of informatics—the science—and digitalization—the practice—and how to navigate these (uncharted) waters safely.

To explore future directions for informatics professionals in bridging the gap between science and practice, the keynote speakers and panelists explored strategies for integrating data-driven insights with digital technologies to enhance patient care and create new knowledge.

KEYWORDS

Health informatics, digital transformation, data-driven healthcare

1. Introduction

The dialogue session "Navigating the Divide: Informatics as Science and Digitalisation as Practice" proposed a discussion around the intersection of informatics and digitalization. One way to apprehend this apparent dichotomy is to search for inspiration in the past. For instance, by drawing parallels between the present and ancient Greek philosophy, one can find harmony in the balance between similarities and opposites and can look forward and envision what Informaticians can contribute together with other specialists.

The session had the following objectives:

- To examine the philosophical foundations of informatics as a scientific discipline and its role in shaping digital health practices;
- To discuss strategies for integrating data-driven insights with digital technologies to enhance patient care and knowledge;
- To explore future directions for informatics professionals in bridging the gap between science and practice.

**DIALOGUE @ EFMI – Navigating the Divide: Informatics as Science & Digitalization as Practice. Hosts: Camila Tomikawa (HIMSS, Germany) & Lars Lindsköld (EFMI, Sweden). Featured Keynote by Prof. Dr. habil. Bernd Blobel (EFMI, Germany): „Why we need to advance from data to knowledge level for successfully transforming health ecosystems". Featured Keynote by Prof. Dr. Evan Brittain (All of Us, USA): „Integrating Wearables and the Electronic Health Record: Insights from the All of Us Research Program"*
Panelists: Helana Lutfi (DIT, Germany), Dr. Dennis Rausch (Dedalus, Germany), Dr. Robin Ohannessian (RAU/AADH, Armenia).

- By leveraging health informatics methodologies and data-driven healthcare approaches, practitioners can ensure that patient-centerd care remains at the forefront of digital transformation initiatives.

2. Key Considerations

The session started with a digital reflection from Prof. Bernd Blobel, which was followed by an extensive webinar on healthcare transformation based on his wisdom and experience for the participants of this year's [2024] DigiHealthDayS. Prof. Blobel discussed "Why we need to advance from data to knowledge level for successfully transforming health ecosystems".

After that, Prof. Evan Brittain presented his keynote "Integrating Wearables and the Electronic Health Record: Insights from the All of Us Research Program". His insights showcased how integrating daily life data and clinical data can be leveraged to advance our understanding of diseases and their effects [1].

The session continued with a detailed discussion of the philosophical divide between informatics, viewed as a science, and digitalization, considered as a practice. Drawing inspiration from Heraclitus' concept of panta rhei ("everything flows") and the Logos as a unifying principle, we aimed for the panel to explore how informatics and digitalization, despite their apparent differences, can be harmonized to advance healthcare.

Heraclitus suggested that opposites are interconnected and interdependent, and our discussion explored how scientific rigor in informatics can work alongside practical digital solutions to create a cohesive healthcare ecosystem.

Another important point was that digitalization is not uniform across all levels. Different departments may experience varying levels of digital transformation within the same hospital.
For example, radiology and pathology are two specialties that share similarities; both involve working with images, providing diagnoses or supporting clinical decisions, handling large volumes of data, and promising future advancements such as GenAI and personalized medicine. However, they also differ in terms of their levels of digitalization, associated costs, available budgets, and the adoption of interoperable standards [2].

Despite these variations in digital maturity, pathology and radiology professionals can exchange knowledge and experiences, enhancing the overall quality of care. Digital transformation journeys are unique to each department, and this notion applies to broader discussions about digitalization in healthcare, both in theory and practice. Therefore, healthcare professionals must embrace solutions that align with the needs and realities of users and patients.

The panelists then shared insights into how data and formal knowledge can be stepping stones to practice and how the wisdom that arrives from practical knowledge can further consolidate into formal knowledge used to benefit the patients.

3. Future Directions

The gap, no matter how lengthy or deep, between science and practice in the digital transformation of healthcare reflects, to some extent, the distance between acquiring raw data and generating actionable knowledge. As a community, professionals engaged in the digital transformation of healthcare can consider disparities in their daily activities and act as facilitators to try and approximate the parties.

4. Conclusion

The "Navigating the Divide: Informatics as Science and Digitalisation as Practice" session explored the interplay between science and practice. Drawing from philosophical foundations and real-world applications, the discussion highlighted the critical role of integrating data-driven methodologies with digital health technologies, the necessity of tailoring digital solutions to diverse healthcare environments, and the potential of interdisciplinary collaboration in bridging the gap between informatics and digital practice.

Ultimately, digitalization in healthcare can be approached as a dynamic and evolving process. By embracing both the theoretical and practical dimensions of informatics, the digital health community can drive meaningful digital transformation, ensuring that technological advancements translate into tangible improvements in patient care and health outcomes.

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True Innovation is an Idea Turned into Value*

Armin Scheuer,[a] Pilar Fernández Hermida[b]

[a]Lemonmint HealthTech Communications, Berlin, Germany
[b]i-expand, London, UK

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ABSTRACT

The session "El Futuro Es Nuestro", held at the DigiHealthDays-2024 in Pfarrkirchen, Germany, explored the transformative power of true innovation in healthcare. Hosted by Lemonmint in collaboration with i-xpand, the session featured a keynote by Hal Wolf, CEO and President of HIMSS, and highlighted the importance of turning ideas into tangible value. Student-led presentations showcased innovative approaches to addressing local healthcare challenges, emphasizing the balance between purpose and practical application. Participants discussed how meaningful innovation can impact healthcare systems, patient outcomes, and future industry leaders.

KEYWORDS

Healthcare innovation, digital health, patient outcomes, start-ups, global transformation

1. Introduction

The DigiHealthDayS-2024 at the European Campus Rottal-Inn (Deggendorf Institute of Techology) in Pfarrkirchen, Germany, featured a transformative session titled "El Futuro Es Nuestro", hosted by Lemonmint and i-xpand. This session brought together experienced leaders and emerging voices in healthcare innovation to explore how ideas can be transformed into meaningful value. Hal Wolf, CEO and President of HIMSS, delivered a keynote on the critical interplay between people, processes, and technology in driving impactful innovation. The session offered students an opportunity to gain real-time insights and engage with Wolf and other leaders about their projects. The event emphasized that true innovation requires not only fresh ideas but also a purpose-driven approach and practical implementation.

2. Key Considerations

Hal Wolf emphasized the distinction between data and information, reminding participants that the true value lies in the insights derived from data. He stated: "Data itself is merely '0s and 1s on a server', but the information it contains holds the keys to improving health and care." This perspective framed the discussion around innovation as a process of delivering tangible outcomes that address pressing healthcare challenges.

Armin Scheuer, CEO and Founder of Lemonmint, highlighted the importance of translating innovation

**INTERACTIVE DISCUSSION – "El Futuro Es Nuestro": Uniting Innovation and Experience Hosts: Pilar Fernández Hermida (i-Expand, UK/UAE) & Armin Scheuer (Lemonmint, Germany) Featured Speaker: Hal Wolf (CEO of HIMSS, USA) Presenters – MDH Students: Hazel D'Couto (India), Peachapong Poolpol (Thailand), Rupa Ramachandran (India), Hong Ear (USA).*

into actionable solutions. He stressed that innovation must go beyond theoretical concepts and focus on creating real-world impact, particularly in healthcare systems where patient outcomes depend on practical implementation. “Innovation is not just about having great ideas”, Scheuer said: “It’s about transforming those ideas into measurable value that resonates with the needs of healthcare providers and patients”.

Student-Led Innovations:
Several presentations by students highlighted how local innovations can solve critical healthcare issues:

- **Hazel D’Coutu:** Proposed strategies to enhance diabetes management in rural Kerala, India, where low digital literacy and limited outreach hinder care access for the elderly.
- **Huohong Ear:** Advocated for global expansion of data-sharing frameworks like the US TEFCA™ (Trusted Exchange Framework and Common Agreement™) initiative to overcome regulatory and cultural barriers.
- **Rupa Ramachandran:** Presented a creative proposal to involve men in menopause awareness campaigns in rural India using solar-powered digital posters at ATMs (automatic teller machines).
- **Peachapong Poolpol:** Addressed inefficiencies in Thailand’s patient referral system caused by inconsistent hospital information systems, proposing streamlined data exchange strategies.

Pilar Fernández Hermida, CEO and Founder of i-expand, highlighted the dual challenge for start-ups: creating impactful solutions while navigating complex regulatory and market environments. She stressed the need for practical approaches to scaling innovation sustainably.

3. Future Directions

The session underscored the importance of fostering a culture of high-quality data capture within healthcare systems. Key recommendations included:

- Encouraging healthcare providers to prioritize actionable insights over raw data
- Involving patients and citizens in developing ethical frameworks for health data use
- Supporting start-ups in balancing innovative solutions with regulatory compliance and sustainability

Armin Scheuer also emphasized the need for greater collaboration between industry leaders and emerging innovators. He proposed creating mentorship programs and innovation hubs that allow experienced professionals to guide the next generation of healthcare leaders in transforming ideas into scalable solutions.

4. Conclusion

“El Futuro Es Nuestro” provided a platform for meaningful exchange between experienced leaders and emerging innovators. The session reinforced that true innovation emerges when ideas are transformed into practical, impactful solutions that address real healthcare challenges. By bridging purpose and action, events like this pave the way for the next generation of healthcare professionals to lead transformative change.

Transforming Healthcare: Bridging Digital Maturity, Health Data, and Global Policy*

Armin Scheuer,[a] Angela Ahrendt[b]

[a]Lemonmint HealthTech Communications, Berlin, Germany
[b]FTI Consulting, Berlin, Germany

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ABSTRACT

The session "Transforming Healthcare: Bridging Digital Maturity, Health Data, and Global Policy," held at the DigiHealthDayS-2024 in Pfarrkirchen, Bavaria, Germany, examined how digital transformation can create measurable value in healthcare. Hosted by Angela Ahrendt (FTI Consulting) and Armin Scheuer (Lemonmint), the session featured a keynote by Hal Wolf (HIMSS) and contributions on digital maturity in healthcare, digital health literacy and the European Health Data Space (EHDS). Discussions emphasized the role of data-driven decision-making, interoperability, and policy frameworks in shaping a sustainable digital health ecosystem. The session underscored that true innovation emerges when technology, policy, and strategy align to enhance patient outcomes and system efficiency.

KEYWORDS

Digital health, healthcare innovation, digital maturity, European Health Data Space, interoperability, global health policy

1. Introduction

The DigiHealthDayS-2024 in Pfarrkirchen, Bavaria, Germany, brought together global health leaders, policymakers, and digital transformation experts for a session exploring the intersection of digital maturity, health data, and policy. Moderated by Angela Ahrendt (FTI Consulting) and Armin Scheuer (Lemonmint), the discussion featured a keynote by Hal Wolf (HIMSS) and presentations by experts on critical elements of digital health transformation. The session highlighted the challenges and opportunities in achieving meaningful innovation through strategic investment, governance, and digital literacy.

**DIALOGUE @ StMGP – Global Digital Health: From Bavaria to the World. And Back. Hosts: Angela Arendt (FTI Consulting, Germany) & Armin Scheuer (Lemonmint, Germany). Featured Keynote by Hal Wolf (CEO of HIMSS, USA): "Transforming our Health Ecosystem". Featured Keynote by Dr. Georg Münzenrieder (StMGP): "Digital Health Close to the Patients: The Bavarian Approach". Panelists: Hal Wolf (HIMSS), Dr. Georg Münzenrieder (Bavarian State Ministry of Health, Care and Prevention [StMGP]), Ryan Dos Santos (WHO), Benedikt Aichinger (x-tention – principal sponsor).*

2. Key Considerations

Hal Wolf: Data, Innovation, and System Transformation

Hal Wolf opened the session with a keynote emphasizing the shift from data collection to actionable insights in healthcare. He noted that data itself holds no intrinsic value unless it informs clinical decision-making, operational efficiencies, and patient-centered outcomes. Wolf highlighted artificial intelligence (AI) and predictive analytics as key enablers of a proactive healthcare system, stressing the importance of interoperability and governance in building a mature digital ecosystem. While his focus was global, he emphasized the necessity of scalable solutions that transcend regional boundaries: digital transformation must be driven by universal principles of efficiency, accessibility, and sustainability across diverse healthcare environments.

Angela Ahrendt: The European Health Data Space and Policy Implications

Angela Ahrendt provided an overview of the European Health Data Space (EHDS), outlining its role in unifying health data across EU member states. She highlighted existing challenges, including fragmented national infrastructures, data privacy concerns, and regulatory complexities. Ahrendt underscored that the EHDS aims to facilitate both primary and secondary use of health data, ensuring that patients can access and share their information while enabling research and innovation. She stressed that implementation will require strong governance, standardized frameworks, and sustained investment, aligning with Bavaria's digital health transformation strategy.

Armin Scheuer: Measuring Digital Maturity for Sustainable Innovation

Armin Scheuer discussed the importance of structured digital maturity assessments to guide hospitals through their transformation journey. He presented digital maturity models as tools for benchmarking progress and linking investment to measurable improvements. Drawing on findings from the DigitalRadar project, Scheuer emphasized the role of scientific methodologies, stakeholder engagement, and continuous evaluation in driving sustainable digital health advancements. His discussion also referenced Germany's large-scale hospital digital maturity assessment as a model for other countries looking to develop targeted investment strategies.

Ryan Dos Santos: WHO's Perspective on Digital Transformation

Ryan Dos Santos focused on the global implications of digital health policies, particularly in the WHO European Region. He addressed disparities in digital literacy, healthcare workforce readiness, and interoperability across different health systems. He emphasized that sustainable digital transformation requires responsible data governance, investment in digital competencies, and regulatory alignment to ensure equitable access to health technologies. Dos Santos also stressed the need for ethical AI applications and transparent digital health strategies to build public trust. He highlighted how digital health literacy is crucial to the adoption of new technologies and their integration into daily clinical workflows.

3. Future Directions

The session provided several key recommendations for advancing digital health transformation:

- **Bridging Data and Decision-Making:** Healthcare organizations should prioritize actionable insights over raw data collection to drive meaningful system improvements.
- **Strengthening Digital Governance:** Policies must balance data accessibility with privacy and security considerations, ensuring compliance with frameworks like the EHDS and the General Data Protection Regulation (GDPR).

- **Investing in Workforce Development:** Digital literacy and upskilling initiatives should be a priority to equip healthcare professionals with the tools needed for effective digital adoption.
- **Advancing Digital Maturity:** Establishing structured digital maturity models will enable healthcare systems to track progress, optimize investments, and refine digital strategies for long-term success.
- **Enhancing Global Collaboration:** Cross-border initiatives and knowledge exchange programs can accelerate progress in digital health transformation, ensuring best practices are shared across regions.

4. Conclusion

This session at the DigiHealthDayS-2024 demonstrated the tangible progress and strategic alignment needed to transform digital healthcare on multiple levels. By leveraging insights from Bavaria's digital health initiatives, the European Health Data Space, and WHO's global strategies, the discussions provided a comprehensive roadmap for implementing data-driven healthcare transformation. The speakers reinforced that sustainable digital health ecosystems require a combination of innovation, strong governance, and collaborative policymaking. The session highlighted that the path to true digital maturity is not merely about adopting technology but about ensuring its integration creates measurable value for both healthcare systems and patients.

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Digital Health: Implementing at Scale (How Can International and Bavarian Experiences Cross-Fertilize Each Other?)*

Laura Stahl,[a] Rajendra Pratap Gupta[b]

[a]Project Manager Digital Health @Bayern Innovativ GmbH, Nuremberg, Germany
[b]Chairman @Health Parliament, India; Digital Health Academy, India

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ABSTRACT

Digital health has existed for decades, but it gained traction only after the COVID-19 pandemic. In this session we discussed the scope and scale of digital health and what we have learned from the implementations at scale. The goal was to identify how other nations and healthcare systems can benefit from the lessons learned for the mass adoption of digital health. The session started with a quick overview about digital health at scale and why experience and best practice-sharing is integral to enhance the scope and increase the scale of digital health adoption. The session was chaired by Dr. Rajendra Pratap Gupta, a global expert on digital health and former advisor to the Health Minister of India, who then discussed the present digital health projects with the other digital health experts from this session. He shared the details of the PRICE Model on scaling up digital health interventions by the government and how it can be leveraged by organizations and governments across the globe.

KEYWORDS

Digital health, intersectoral healthcare, PRICE Model, healthcare innovation, cross-border collaboration

1. Introduction

The session "Digital Health: Implementing at Scale" held at the 2024 DigiHealthDayS at the Deggendorf Institute of Technology (DIT-ECRI) provided a platform for exploring how international and Bavarian experiences in digital health can mutually inspire and enhance each other. This discussion was part of the broader DigiHealthDayS initiative, a global forum for education, research, and networking in digital health. The session highlighted strategies, challenges, and opportunities for scaling digital health solutions effectively by leveraging cross-border collaboration.

**DIALOGUE @ StMGP – Digital Health: Implementing at Scale (How Can International and Bavarian Experiences Cross-Fertilize Each Other?). Hosts: Laura Stahl (Bayern Innovativ, Germany) & Prof. Rajendra Gupta (Digital Health Academy, India). Speakers: Prof. Dr. Michael Nerlich (UK, Germany), Prof. Thomas Spittler (DIT, Germany), Bence Török (BrightHills – premier sponsor).*

2. Key Considerations

The session focused on several critical aspects of implementing digital health solutions at scale. Below are the key takeaways:

Cross-Border Learning and Collaboration:

Cross-border collaboration is a crucial factor in the success of digital health initiatives. Different experiences provide valuable insights into overcoming barriers to digital health implementation. For example, lessons from countries with advanced telehealth systems can guide Bavaria in optimizing its healthcare infrastructure. Networks were identified as essential for the success of digital health initiatives. The exchange of best practices between international and Bavarian stakeholders enables learning from each other's experiences, facilitating more effective solution implementation. This collaboration not only enhances the implementation of digital health solutions but also strengthens the ability to tackle challenges collectively. By sharing experiences and knowledge, regional healthcare systems can be improved, ultimately leading to better health outcomes for the population.

Need for Practical Tools that are Easy to Use and the Role of Technology:

Scaling digital health solutions effectively requires addressing several critical challenges. These include resolving interoperability issues between systems, ensuring robust data security, and managing resource constraints. A key aspect of successful digital health implementation is the availability of practical, user-friendly digital tools. Usability was identified as a crucial factor for the successful implementation and acceptance of these tools, as they must be intuitive and accessible to a wide range of users. Emerging technologies, such as artificial intelligence (AI), telemedicine, and mobile health applications, are pivotal in transforming healthcare delivery. These technologies have the potential to revolutionize patient care by providing more accessible, efficient, and personalized services. However, it is essential to tailor these technologies to local needs while leveraging regional best practices. This approach ensures that solutions are not only effective but also culturally and contextually relevant, thereby maximizing their impact and adoption in diverse healthcare settings. By aligning technology with local needs and best practices, healthcare systems can harness the full potential of digital innovations to improve patient outcomes and enhance overall healthcare delivery.

Education and Workforce Development:

Building a skilled workforce in digital health is crucial for the sustainable implementation of digital solutions. This involves training professionals to effectively manage and utilize digital tools, as well as fostering interdisciplinary collaboration to ensure that all stakeholders are aligned and equipped to maximize the benefits of digital health technologies. By developing a workforce that is adept in navigating and leveraging digital tools, healthcare systems can ensure that these technologies are integrated seamlessly into existing practices. Participants were encouraged to focus on the diverse opportunities that digitization offers, recognizing the transformative potential it holds for healthcare delivery. Discussions highlighted the importance of adjusting existing processes to fully leverage the potential of digital solutions. By adapting workflows and operational frameworks to accommodate digital innovations, healthcare organizations can optimize their use of technology, streamline services, and ultimately enhance patient care. This strategic approach to workforce development and process optimization is essential for unlocking the full potential of digital health and driving meaningful improvements in healthcare outcomes.

PRICE Model for Scaling up Digital Health Interventions

Based on the learnings from India, which has implemented digital health at an unprecedented scale, the model of implementation includes a few key elements and they are:

1. P – Political Understanding and Will – this is the starting point.
2. P – Political Priority: Once the political leaders have a political understanding they must translate it into a political priority.
3. P – After the political priority is in process, the next important thing is having a defined policy for digital health.
4. R – Rules and Regulations must follow the policy to plan the deployment and adoption of digital health.
5. R – Reimbursement – With all the infrastructural issues addressed, we need to take care of the reimbursement policies are crucial.
6. I – Institutions – We need dedicated institutions specialized in digital health rollout.
7. I – Incentives – Institutions are effective when there is an incentive for the rollout of digital health programs.
8. C – Clarity – Capacity – Collaborations. Clarity of goals and roles, capacity for institutional implementation and collaborations hold the key for scale-up.
9. E – Ecosystems – Evaluation: Digital health at scale requires an ecosystem approach and continuous monitoring and evaluation.

3. Future Directions and Conclusions

The successful implementation of digital health solutions at scale hinges on several key factors that enable international and Bavarian stakeholders to mutually benefit from each other's experiences. Cross-border collaboration plays a pivotal role in this process, as it facilitates the exchange of best practices and lessons learned from diverse healthcare systems. This collaborative approach allows Bavaria to draw insights from countries with advanced telehealth systems, thereby optimizing its own healthcare projects and infrastructure. The development and use of practical, user-friendly digital tools are also crucial, as they enhance the usability and acceptance of digital health solutions across different regions. Emerging technologies like artificial intelligence, telemedicine, and mobile health applications can revolutionize healthcare delivery, but their effectiveness is maximized when tailored to local needs and integrated with regional best practices. Furthermore, building a skilled workforce in digital health is essential for sustainable implementation. This strategic approach enables both international and Bavarian stakeholders to adapt existing processes to leverage digital innovations fully, ultimately enhancing patient care and outcomes. Through this collaborative framework, international and Bavarian experiences can be shared and built upon, driving meaningful improvements in healthcare delivery.

The key to digital health at scale lies in capacity building, knowledge sharing, best practices and collaboration.

AI Needs High-Quality Health Data at Scale - Will the EHDS Deliver?*

Dipak Kalra,[a] Eva Sabajova,[b] Birgit Bauer,[c] Dmitry Etin,[d] Henrique Martins[e]

[a]The European Institute for Innovation through Health Data, Ghent, Belgium
[b]Digital Health Slovakia
[c]european digital health academy edha gGmbH, Abensberg, Germany
[d]Deggendorf Institute of Technology (DIT)/European Campus Rottal-Inn (ECRI), Pfarrkirchen, Germany
[e]ISCTE-IUL, Lisbon, Portugal

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ABSTRACT

A panel discussion was held during the DigiHealthDayS-2024 Scientific Congress on 15th November 2025. It explored the potential for the European Health Data Space (EHDS) to become a high-value resource of good quality data for the development of AI innovations to support better and safer healthcare. Panel members discussed whether the measures presently intended for the provision of secondary used data sets within the EHDS and AI Act will be suitable for AI development. At present, a standardized data quality label will be defined, but its use will be optional, interoperability standards for data sets sharing for research are not mandated. However, AI innovators need access to large-scale, high-fidelity data sets that have well-documented provenance and quality, and which are accurately representative of the populations on whom the innovators wish to target their solutions. The EHDS has the potential to accelerate the availability of high-quality data sets, but the adoption of the data quality and utility label to assess the data sets must be strongly promoted and accompanied by measures and incentives for health systems to actively improve the quality of the data they routinely collect within EHR systems.

KEYWORDS

Artificial intelligence, data bias, health data quality, European Health Data Space

1. Introduction

A panel discussion was held during DigiHealthDayS-2024 Scientific Congress on 15th November 2024, comprising the authors of this paper. It explored the potential for the European Health Data Space (EHDS) to become a high-value resource of good quality data for the development of responsible AI innovations to support better and safer healthcare. However, its provisions for the secondary use of data, in particular the limited obligations that it places on the data holders of data sets regarding the structural and semantic representation of the data (the use of interoperability standards) and the optional nature of the data quality and utility label may lead to the proliferation of data sets that are difficult to use and that

**INTERACTIVE DISCUSSION – AI Needs High-Quality Health Data at Scale: Will the EHDS deliver? Hosts: Eva Sabajova (Digital Health Slovakia) & Prof. Dipak Kalra (i-HD, UK). Speakers: Birgit Bauer (DSL Germany), Dmitry Etin (Austria), Prof. Henrique Martins (ISCTE, Portugal).*

are of low quality. There is a risk that the EHDS will not contribute successfully to the development of safe and trustworthy AI, also in conjunction with the newly established AI Act.

2. Key Considerations

AI innovators need access to large-scale, high-fidelity data sets that have well-documented provenance and quality and which are accurately representative of the populations on whom the innovators wish to target their solutions.

AI developers also need to assure their end users, potential purchasers and national assessment bodies that they have utilized high-quality data that is traceable, as free from bias as possible, and that they have followed robust European ethical principles.

The EHDS is the European Union's flagship program for scaling up the availability of health data, for supporting continuity of patient care across borders and for providing the wide public and private stakeholder access to the vast array of data sets held across Europe. These data sets exist in healthcare provider organisations, research organizations, registries, public health agencies and other sources, which will be catalogued and made accessible for permitted purposes which include the development of AI algorithms for healthcare.

The regulation endorses the FAIR principles (Findable, Accessible, Interoperable, and Reusable). This should mean that data sets are discoverable through Member State and European catalogues, and that the use of interoperability standards (if any) is declared. However, none are mandated and whilst providing transparency about standards used this does not foster consistency and might not have any impact on the data harmonization workload and risk of error when data sets need to be combined to achieve a sufficient scale for AI learning. Similarly, the EU AI Act is regulating relevant quality management, data governance requirements, which could be fulfilled using EHDS mechanisms, if implemented well.

The panel members felt that a data provenance, data quality label is important for data sets that are published via catalogues maintained by Health Data Access Bodies (HDABs) – the designated agencies to regulate EHDS implementation in EU Member States – to provide transparency on the composition, origin and quality for potential data users such as AI developers. However, this transparency should lead to minimum standards and the promotion of better-quality data at its origin, which is usually healthcare provider EHR systems, but increasingly patient-generated data from wearables and wellness apps increasing the need to use EHDS provisions to also promote interoperability from these sources. Common EU efforts in semantics and data catalogues need to be reinforced and may benefit from new governance structures under the EHDS regulation and should be seen in light of primary use, secondary use of healthcare data including for AI applications.

The EHDS has the potential to drive progress also in Member States with less developed health data systems by mandating minimum standards for data quality, interoperability, and governance. It motivates these countries to adopt international standards and invest in modern digital health infrastructure.

Additionally, the panel agreed that especially patients and also citizens must be informed and educated in the use of their health data and also about the EHDS. It is essential that participation is a key element to create meaningful and ethical guidelines and frameworks for the use of health data in general and also especially for the secondary use of health data.

3. Future Directions

Panel members felt that a more proactive approach including mandating a limited subset of interoperability, common data model standards, provenance (with only limited grounds for exceptions) and the mandatory adoption of the data quality label should be enforced through forthcoming implementing acts.

Healthcare providers need support to better encourage and incentivize a culture of high-quality data capture by (admittedly busy) clinicians, and that the quality of the EHR systems (especially user interface design) needs to facilitate high-quality data entry and prompt users to correct clear-cut data entry errors in real time.

Citizens must be informed transparently and be involved in the development of tools, standards and frameworks.

3. Conclusion

Panel members were all enthusiastic about the EHDS and its importance for European research including AI development and adoption of the EU AI Act. However, more needs to be done to ensure that AI innovation in Europe can benefit from it.

Moonshot Dialogue: The Future of AI in Healthcare and Cutting Edge Digital Health Technologies*

Angela Ahrendt,[a] Rajendra Pratap Gupta[b]

[a]FTI Consulting
[b]Chairman @Health Parliament, India; Digital Health Academy, India

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1. Introduction

As societies around the world are grappling with the effects of aging populations, rising rates of chronic diseases, and overstretched health systems, the deployment of artificial intelligence (AI) in healthcare has emerged as both the beacon of hope but also as subject of close scrutiny. The promise of AI-powered digital health technologies to transform care delivery, enhance diagnostic precision, and improve outcomes is compelling, particularly in a context where progressive neurological disorders, cardiovascular diseases and cancer are expected to rise in prevalence. Yet, this transformation is unfolding against a backdrop of the need for a rigorous regulatory oversight, ethical deliberation, and a determined push to set global standards for responsible innovation.

Global healthcare systems are under acute pressure. As life expectancy increases and birth rates decline, a growing elderly population is placing unprecedented demands on healthcare and social support structures. The economic impact is twofold: direct strain on public health infrastructure and indirect stress on working-age populations who must simultaneously contribute to the economy and care for aging family members. In this landscape, AI offers a path toward systemic resilience.

During the DigiHealthDay's Moonshot session, the participants were unanimous that AI can dramatically improve efficiency and scalability in clinical care. From early diagnosis of cancer through breakthrough drug discoveries, AI enables faster, more personalized interventions. Digital tools that integrate data from wearables, genomics, and medical histories allow for real-time health monitoring and personalized treatment plans, potentially reducing hospital admissions and healthcare costs over the long term. Moreover, AI has the capacity to shift healthcare from reactive to preventive, an essential evolution that the Nordic countries are embracing for managing population-wide health challenges as explained by Bogi Eliasen, Director at the Copenhagen Institute of Future Studies and one of the frontrunners of the Nordic Health 2030 Movement initiative. In theory, this should relieve some of the economic burden by extending the independence and productivity of aging citizens while alleviating the pressure on healthcare professionals.

Despite its potential, the integration of AI into healthcare is not without risks, and the European Union (EU) is taking a notably cautious and ethical-first approach. Concerns around algorithmic bias, transparency, accountability, and data privacy are especially pronounced in health contexts where lives are at stake. Much like the impact of the EU's General Data Protection Regulation (GDPR) on global data privacy standards, the EU aims to establish global standards for AI in healthcare through its recently entered into force Artificial Intelligence Act (AI Act). The goal is to create trust in AI-powered health solutions, and therefore, balance innovation with responsible deployment.

As a reminder, the EU's AI Act designates healthcare-related AI systems as high-risk, subjecting them to rigorous regulatory requirements. These include comprehensive algorithm documentation, robust bias mitigation strategies, and mandatory human oversight in clinical decisions. Therefore, when participants were asked whether AI can replace doctors in the future, from a regulatory point of view,

**DIALOGUE – MOONSHOT: The Future of AI and Cutting-Edge Digital Health Technologies. Hosts: Angela Arendt (FTI Consulting, Germany) & Prof. Rajendra Gupta (Digital Health Academy, India). Speakers: Pilar Fernández Hermida (i-Expand, UK/UAE), Philippe Gerwill (Switzerland), Bogi Eliasen (Denmark), Lars Lindsköld (EFMI, Sweden).*

this possibility was dismissed. While these measures are designed to ensure patient safety and foster public trust, informal discussions have surfaced concerns that such strict oversight could impede the pace of AI adoption in healthcare, especially in comparison to more flexible regulatory environments in the United States and China. Albeit AI replacing doctors is a remote reality, doctors who work with AI will replace those who do not work with AI, as expressed by Philippe Gerwill, a digital health humanist and futurist based in Switzerland. Therefore, AI should be deployed in a manner that both meaningfully eases the burden on an already overstretched healthcare workforce and simultaneously promotes greater AI literacy and explainability across the healthcare system.

In conclusion, the future of AI in healthcare centers on the ability to navigate a delicate balance: harnessing transformative potential while safeguarding ethical standards, equity, and trust. The healthcare systems that succeed in ensuring regulation does not become a barrier to innovation, while still upholding patient safety and supporting workforce efficiency, will be the ones best positioned to truly unlock AI's transformative potential.

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