



Unlocking the Potential of Consumer Wearables in Healthcare: Barriers to Adoption & Regulatory Impacts

Whitepaper



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Abstract

The integration of consumer wearables is transforming the landscape of patient care and health monitoring, particularly in the realm of cardiac health. This white paper examines the perspectives of multiple stakeholder groups, including cardiologists, insurance payers, and manufacturers of consumer wearables, on the evolving regulatory environment and the barriers that impact the adoption of wearables in healthcare settings. Focusing on cardiac applications, we provide a global perspective on regulatory comparisons between the European Union and the Asia-Pacific region and identify strategic insights to enhance the acceptance and integration of these technologies in clinical practise.

Drawing from qualitative interviews and quantitative surveys with global stakeholders, this research presents a comprehensive overview of current adoption trends and future directions for wearables. It highlights the complexities faced by manufacturers, cardiologists, and insurers operating within different regulatory frameworks. The paper aims to present practical recommendations for overcoming these challenges and support the development of actionable strategies for enhancing wearable adoption globally.

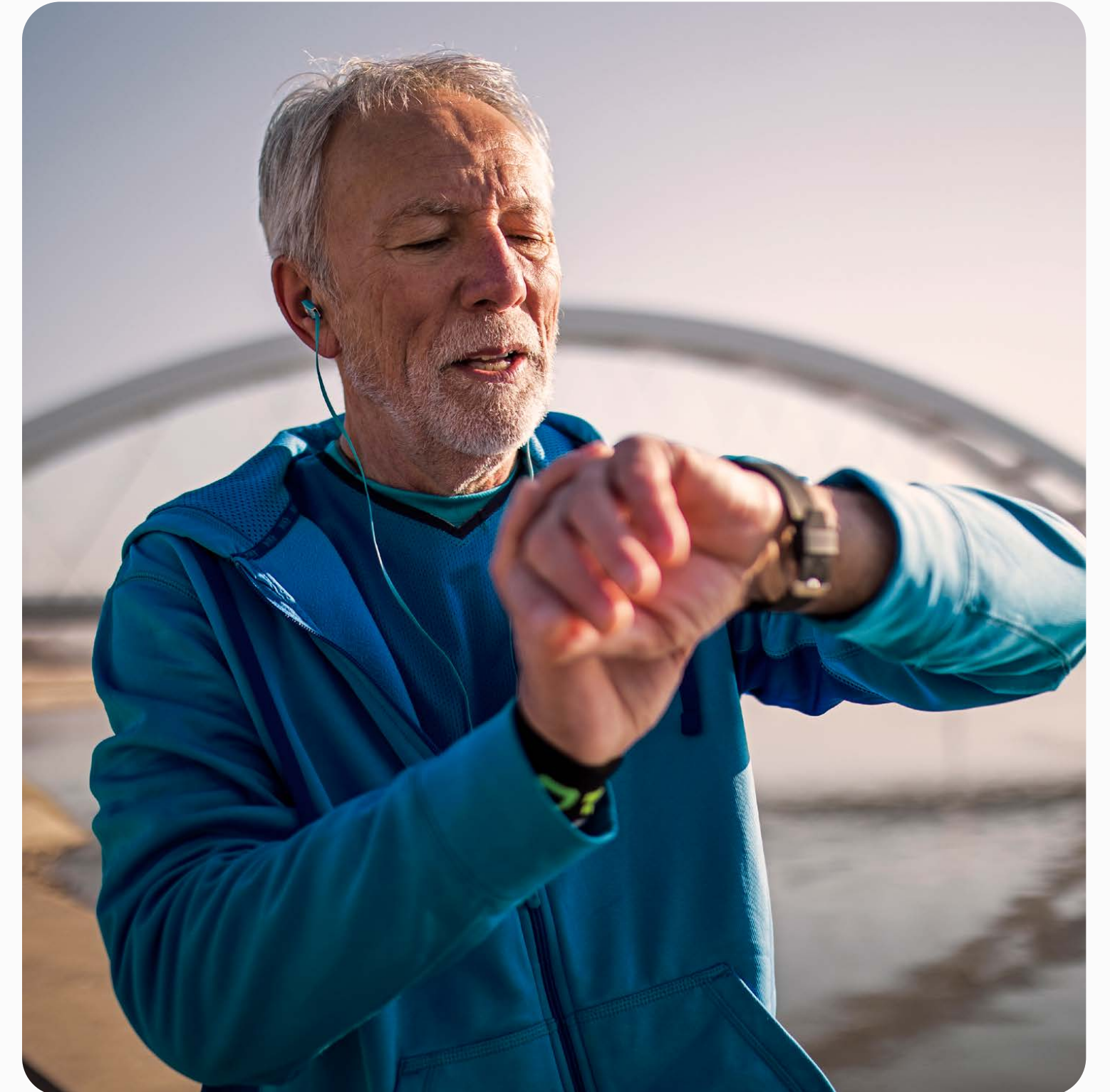
By reporting on these findings, we aspire to guide policymakers and industry stakeholders in fostering innovation, ensuring that wearable technologies effectively contribute to improved health outcomes.

1.0 Executive summary

The role of consumer wearables in healthcare, particularly for cardiac health monitoring, is gaining prominence amidst complex regulatory landscapes. These devices, which offer real-time data on health metrics like heart rate and sleep patterns, have evolved from niche gadgets to essential healthcare tools, with ownership rates between 41-53% in regions such as the EU, USA, and China. While promising, several challenges affect their integration into clinical settings, impacting both manufacturers and consumers. Key issues include complex regulations, usability concerns, data accuracy, and cost factors.

This white paper evaluates these adoption barriers and explores the impact of regulatory and standards frameworks on the integration of wearable technologies in healthcare, focusing primarily on cardiac applications. Through a comprehensive analysis of qualitative interviews and quantitative surveys with key stakeholders, including manufacturers, cardiologists, and insurers, this paper provides insights and recommendations to enhance the adoption of wearables in healthcare systems.

Key findings emphasise regional disparities in regulatory impacts on wearable adoption. The European Medical Device Regulation (MDR) 2017/745 imposes more stringent requirements compared to the relatively flexible frameworks of Singapore's Health Sciences Authority and the FDA's General Wellness exception in the USA. In the EU, over 1 in 2 stakeholders (57%) perceived the regulatory environment as a barrier to the clinical use of wearables, contrasting with 49% in the APAC region. Only 1 in 4 stakeholders in both regions did not perceive the regulatory environment as a barrier.



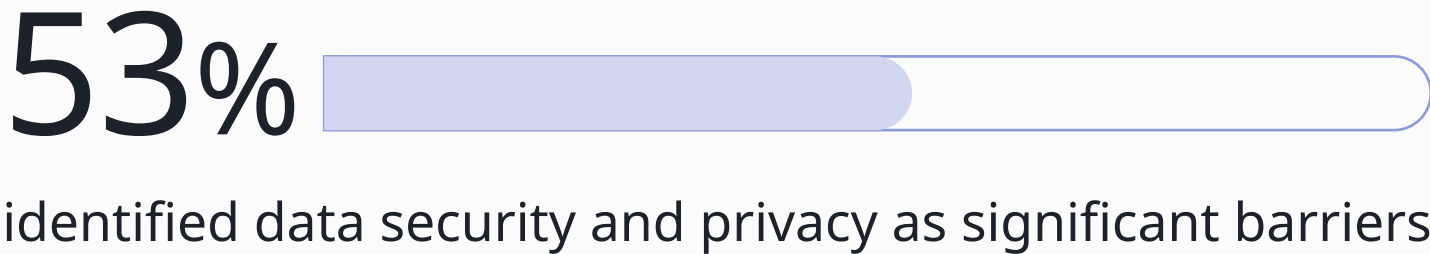
Stakeholders identified challenges such as usability, data accuracy, and data protection as significant barriers, with additional concerns about legal responsibilities in telemedicine and data interpretation. Among surveyed stakeholders, 53% identified data security and privacy as significant barriers. Regional differences were clear—60% of respondents in the Asia-Pacific (APAC) region flagged data accuracy as a significant concern, compared to only 33% in the European Union (EU).

The importance of standards set by organisations like the International Electrotechnical Commission (IEC) and International Organization for Standardization (ISO) is highlighted for ensuring product quality and safety. However, a lack of awareness about these standards among stakeholders indicates the need for enhanced collaboration and education initiatives.

The complexity and associated costs of MDR compliance particularly affect small to medium enterprises, restricting innovation by lengthening time-to-market. While regulatory frameworks provide a basis for trust and safety, they also introduce substantial obstacles. Positively, there is a growing inclination among insurance payers, especially in the EU, to support wearable use within medical devices, exemplified by initiatives like *Prise en charge anticipée numérique* (PECAN) and *Digitale Gesundheitsanwendungen* (DiGA) in France and Germany.

Moving forward, incorporating patient perspectives, and the inclusion of global perspectives especially in the USA, are essential to fully understand wearable adoption. Moreover, the implications of emerging EU legislation, such as the EU AI Act and the European Health Data Space, require further exploration. Addressing concerns related to access, affordability, and digital literacy is vital for enhancing wearables’ adoption in healthcare.

Overall, wearables hold significant promise for improving healthcare delivery through continuous and personalised monitoring. By addressing the identified barriers with targeted strategies, regulatory alignment, and inclusive policies, stakeholders can effectively support the integration of these technologies into healthcare systems. This white paper aims to catalyse ongoing discussion and research, reinforcing the essential role of wearables in global health management.



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2.0 Introduction

The integration of consumer wearables is redefining the landscape of patient care and health monitoring, especially within cardiac health applications. These devices, which are designed for individual use and equipped with multiple sensors, provide real-time data on various health metrics such as heart rate, sleep patterns, and physical activity. In addition to these basic functions, wearables now include features like ECG and blood pressure monitoring, with the capability for preliminary data analysis to detect abnormalities such as heart arrhythmias.

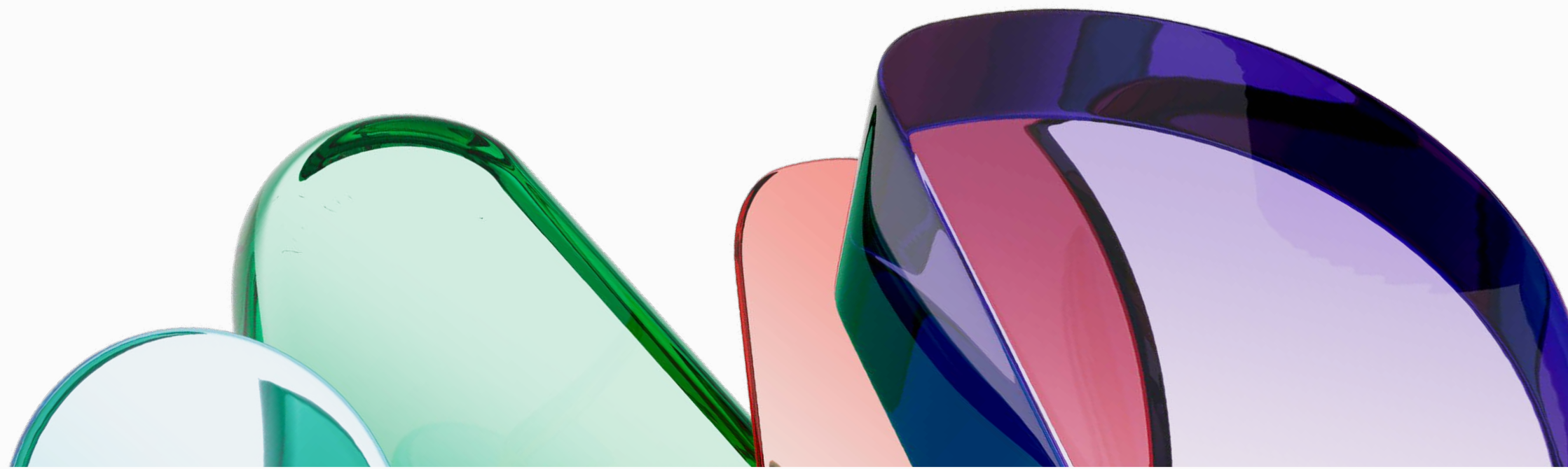
Over the past decade, wearables have transitioned from niche gadgets to essential tools in the healthcare arsenal, marked by a substantial increase in device ownership, reported between 41-53% in regions including the EU, USA, and China (Statistica, 2024).

Despite their potential to significantly enhance health monitoring and chronic condition management (Kim 2019), the adoption of wearables in clinical settings faces various barriers. These range from usability challenges and data management complexities to interoperability issues and concerns around security and privacy (Chakrabarti 2022). Moreover, the evolving regulatory landscapes further complicate their integration into healthcare systems.

In particular, the redefinition of medical devices under the European Union's Medical Device Regulation (MDR) presents unique challenges, as different countries require varying levels of registration for certain functionalities.

This technical paper seeks to explore these challenges in detail, focusing on cardiac applications and providing a global perspective on the differences in regulatory frameworks between the EU and the Asia-Pacific region. Through qualitative interviews and quantitative surveys with key stakeholders, including manufacturers, cardiologists, and insurers, we offer a comprehensive analysis of current adoption trends and future directions. Our aim is to identify strategic insights and practical recommendations that can help overcome regulatory barriers, thereby facilitating the integration of wearables in healthcare.

By disseminating our findings, we aim to guide policymakers and industry stakeholders in adopting strategies that support innovation while ensuring that wearable technologies contribute effectively to health outcomes. This paper will serve as a foundation for ongoing dialogue and research, contributing to the development of global common standards and enhancing the utility of wearables in clinical practise.



3.0 Background



3.1 Regulatory landscape

The regulatory landscape for consumer wearables in healthcare is characterised by diverse frameworks that differ across regions. In the European Union (EU), the Medical Device Regulation (MDR) 2017/745 provides a comprehensive system for determining whether wearables qualify as medical devices. The classification largely depends on the intended use defined by manufacturers, potentially categorising devices intended for diagnosis, monitoring, or treatment under the MDR. Accessories integral to the functionality of these medical devices also fall under this regulation. However, wearables often reside in a grey area between general consumer electronics and medical devices, which results in regulatory ambiguity.

This ambiguity is particularly evident as the functionality of wearables extends beyond basic activity tracking to include more advanced capabilities, such as ECG and blood pressure monitoring and the detection of cardiac arrhythmias. As metrics and technological capabilities advance, the distinction between simple fitness trackers and sophisticated health monitoring devices which fall under SaMD regulation becomes increasingly important.



In the United States, the Food and Drug Administration (FDA) adopts a different stance by allowing a 'General Wellness' exception. This exception offers a regulatory pathway for low-risk devices aimed at promoting general health without medical claims. This provision allows companies such as Apple and Fitbit to introduce wearables with health-monitoring features without extensive medical device clearances, although they frequently secure 510(k) clearances for specific functionalities like ECG (Food, Drug, and Cosmetic Act, Section 201(h)).

In Asia-Pacific, Singapore's healthcare sector combines public regulation and private innovation. The Health Sciences Authority (HSA) regulates Software as a Medical Device (SaMD), setting criteria for software that performs medical functions independently from hardware. These regulations ensure SaMD products meet safety and efficacy standards, aligning with international digital health best practises (HSA Medical Device Framework).

Collectively there are large variances in the regulatory requirements between different regions with the EU MDR viewed as having the highest regulatory burden.

3.2 Other regulatory areas

European Union (EU)

In addition to regulations primarily focused on medical devices, the EU enforces the General Data Protection Regulation (GDPR), ensuring the proper handling of users' personal and health data by consumer wearables. The EU Data Act aims to facilitate data access and sharing, while the Cybersecurity Act sets an EU-wide certification framework to bolster trust in digital products, including wearables. Furthermore, the EU AI Act seeks to establish secure and ethically aligned use of AI systems, which are increasingly integral to health monitoring in wearables.

United States (USA)

In the United States, the Health Insurance Portability and Accountability Act (HIPAA) remains a significant federal regulation for protecting patient information, which extends to data managed by consumer wearables interacting with healthcare providers. Beyond federal oversight, the Federal Trade Commission (FTC) ensures transparency in advertising claims and data security practises for wearables. In addition, twenty states (including California, Virginia and Colorado) have introduced data privacy regulations with several at committee stage.

Asia-Pacific (APAC)

The Asia-Pacific region exhibits a variety of regulatory approaches concerning data privacy and consumer wearables in the Act on the Protection of Personal Information (APPI) in Japan, Australia's Privacy Act and The Personal Data Protection Act (PDPA) of Singapore all seek to safeguard individual personal data against misuse. Additionally various national cybersecurity regulations are in play such as Singapore's Cybersecurity Act, enforced by the Cyber Security Agency (CSA), ensuring the protection of critical information infrastructure, addressing the security needs of data processed through wearables and other health-related digital devices.

Overall, while regions like the EU and APAC maintain multiple regulatory structures for data privacy and cybersecurity, the USA primarily relies on HIPAA as a central component in managing technology use in healthcare environments.

“As metrics and technological capabilities advance, the distinction between simple fitness trackers and sophisticated health monitoring devices which fall under SaMD regulation becomes increasingly important.”

3.3 Standards landscape

Standards play a fundamental role in the development and deployment of technologies across various sectors, including consumer wearables in healthcare. They provide a framework for ensuring product quality, safety, interoperability, and performance consistency. The creation of standards is a collaborative process, involving representatives from industry bodies, research institutions, government agencies, consumers, and users of standards. These stakeholders come together in technical committees to draught and review standards, facilitated by national organisations.

In the global arena, two key organisations responsible for developing and maintaining international standards are the International Electrotechnical Commission (IEC) and the International Organisation for Standardisation (ISO). The IEC, a global membership body of experts developing standards for electrical and electronic goods, ensuring safety and interoperability of devices and systems. ISO, brings together global experts to set standards for various fields and industries, promoting quality and efficiency and facilitating international trade and cooperation.

The standards, developed through a consensus-driven process, with joint working between ISO and IEC are used by manufacturers to enhance quality management and, where applicable, to support conformity assessment. By adopting these standards, manufacturers can ensure that their products meet the required safety and performance benchmarks, enabling consistent quality and fostering trust in the global market.

In regard to wearables, the standards landscape is predominately driven by IEC committee TC124 (Wearable electronic devices and technologies), which focuses on standardisation across a broad range application. This committee emphasises performance measurement standards for wearables, seeking consistency and reliability in metrics like heart rate and step counting. Current published standards include IEC 63203-402-3:2024, which addresses heart rate accuracy, and IEC 63203-402-2:2024, focusing on step counting precision.

Looking forward, future standards under development aim to cover stress measurements, sleep tracking, and mobile data security, aligning with emerging needs in wearable technology. These efforts aim to ensure interoperable, reliable, and secure wearable device integration within healthcare systems with significant buy-in from manufacturers.

Joint Working Group 7 (JWG7) is a collaborative initiative between ISO/TC 215 and IEC/SC 62A aimed at standardising health software and IT systems including medical devices. It focuses on developing joint standards to ensure these technologies are safe, effective, and secure throughout their lifecycle. The group covers significant areas like risk management for IT networks and health software, ensuring high safety and performance standards in clinical settings and coordinates the 82304, 81001 and 80001 series of standards.





3.4 Perceived barriers to adoption

Usability challenges

The adoption of consumer wearables in healthcare encounters several usability challenges primarily related to user characteristics, interaction and device utilisation. A key concern is ensuring that users achieve accurate and consistent measurements, as the effectiveness of these devices can be significantly influenced by individual differences. For example, variations in skin colour, body weight, and body composition can affect how users interact with wearable sensors and the quality of data captured.

These considerations necessitate design features that are adaptable to diverse user profiles. Factors like temperature, altitude, and humidity further complicate maintaining consistent data quality. Additionally, efficient internet connectivity is essential for these devices to function properly as it enables data transmission and processing; a lack of connectivity can hinder real-time health data analysis, particularly in rural or developing areas (Chakrabarti 2022).

Variability in accuracy across devices

The accuracy of the sensors themselves presents another adoption barrier. There are inconsistencies in the biometric data reported by various consumer wearables, such as heart rate, blood pressure, and oxygen saturation measurements (Hahnen 2020 and Nelson 2019). For these devices to gain trust and acceptance within healthcare settings, it is important that their sensors consistently meet the precision levels of traditional diagnostic tools. Moreover, while some devices have been approved by the FDA, others lack complete CE marking, which affects their perceived reliability and emphasises the necessity for thorough validation (Brönneke 2021).

Volume and analysis of wearable data

Cardiologists already have concerns of being overwhelmed by data from consumer wearables, even before anticipating future adoption (Cardiologist FR) with the current manual sharing of data with clinicians (via email and PDF) needing to be summarised rather than directly integrating raw data. (Cardiologist, SGP).

As wearable devices continue to integrate into medical practice, they introduce several legal considerations that stakeholders must address to ensure their safe use (DeClue 2023). A key issue is the legal responsibility of clinicians when receiving, interpreting, and acting upon data from wearables (Cardiologist FR).

Ensuring data protection and compliance

Data privacy and security are of critical importance for consumer wearables, given their close association with personal health information. Regulatory requirements such as the GDPR in the EU and HIPAA in the US mandate robust privacy information management systems to safeguard user data (Brönneke 2021).

However wearable devices are susceptible to cybersecurity risks, particularly those that are networked or internet-connected, which introduces vulnerabilities due to dependencies on third-party components (Brönneke 2021). Whilst the nature of complex calculation and data flows gives rise to major data security and privacy challenges exacerbated by poor data encryption and protection. (Chakrabarti 2022).

Compliance with these privacy and data security regulations is essential for gaining market access and ensuring the adoption of wearables in applications like cardiac monitoring (Brönneke 2021). As these regulations are fundamental to building consumer trust, attention must be paid to integrating strong compliance measures into product development processes.

3.5 Impacts of wearables on healthcare

The integration of consumer wearables into national healthcare programmes across different regions highlights its growing role in enhancing health management and patient outcomes. In Europe, France and Germany are leading with reimbursement processes such as PECAN and DiGA, requiring evidence of cost and clinical effectiveness, alongside technical standards.



Germany has incorporated wearables into digital therapeutics, focusing on obesity and insomnia, while France's collaboration with Withings facilitated a significant integration of consumer health data into the national health record through Mon Espace Santé.

Conversely, in the APAC region, South Korea's My HealthWay platform aims to integrate wearable data into chronic disease management, enhancing diabetes care through consolidated health records.

Similarly, Japan's partnership between Fujitsu and Sapporo Medical University Hospital underscores efforts to improve healthcare data accessibility and management, setting a precedent for future digital health initiatives.

These initiatives, while still evolving, reflect a global trend towards leveraging wearable technology to enhance healthcare delivery and patient empowerment, potentially leading to improved healthcare outcomes and economic benefits.

4.0 Methods



4.1 Research design

This study employs a mixed-methods approach to explore the impact of regulatory environments on the adoption and utilisation of consumer wearables in healthcare settings, particularly focusing on cardiac health applications. Our research design integrates both qualitative and quantitative methodologies to obtain a comprehensive view of current practises and challenges.

Literature review

The literature review employed a structured approach to assess resources aligned with the research interests. Initially, objectives and hypotheses were articulated to develop detailed search strings using PubMed Boolean operators. This involved identifying key search terms and their synonyms to ensure a comprehensive yet precise search.

A PubMed search API was utilised to retrieve relevant articles efficiently with content analysis conducted to evaluate the relevance of each study to the research aims. Summaries were generated employing the PICOS framework to systematically consider the Participants, Interventions, Comparisons, Outcomes, and Study Design within each study.

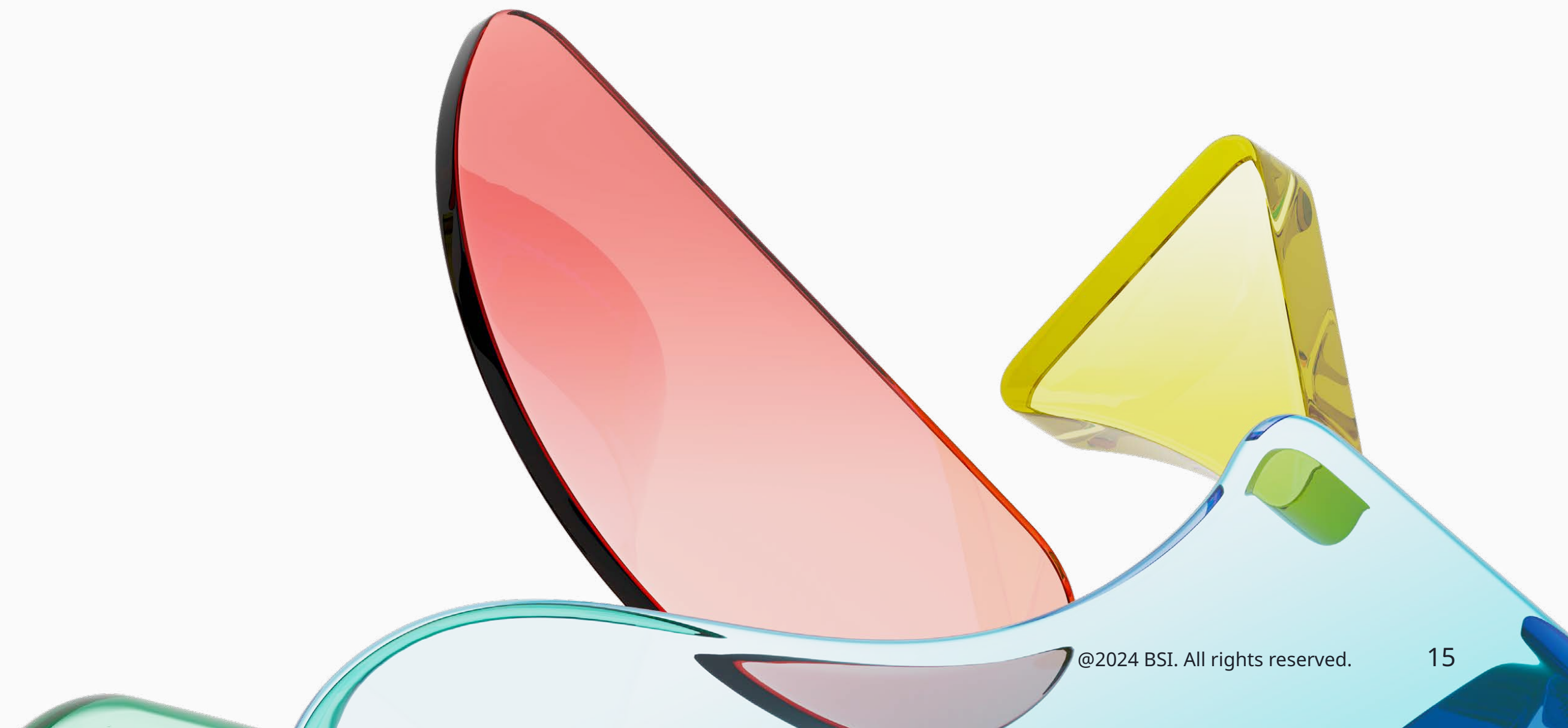
This methodology assisted in integrating insights from the literature into the broader research context focusing on regulatory environments and the adoption of consumer wearables in healthcare settings.

Qualitative interviews

For the qualitative component, we conducted semi-structured one-to-one 30-minute interviews with stakeholders, including cardiologists, manufacturers, insurance payers, and regulators. A total of 20 interviews were held with participants from France, Germany, Finland, Singapore, China, and Japan. These interviews were conducted in English via Zoom, allowing for flexible scheduling to accommodate participants' time zones and ensuring a diverse range of perspectives. Transcripts were made with participant consent, and all data was anonymised to maintain confidentiality.

Quantitative survey

The quantitative aspect consisted of an online survey administered to 139 participants across France, Germany and Singapore designed following the CHERRIES framework to ensure methodological rigour and consistency. The survey population included cardiologists, manufacturers of wearables and insurance payers. The survey was developed in light of themes identified in the preliminary literature review and input from qualitative interviews, ensuring relevance and comprehensiveness.



4.2 Data analysis

Thematic analysis

The qualitative data collected from interviews were analysed through thematic analysis. Our approach began with a review of existing literature to develop an initial coding framework, which guided the identification of key themes. We employed a Large Language Model (GPT-3.5-16k-turbo) for AI-assisted coding. The model was deployed via a commercial API specifically prompted and guard-railed to perform analysis, allowing it to accurately identify and categorise themes within the data.

This AI integration facilitated efficient data processing while allowing for flexibility, enabling new themes to emerge naturally from the data without being constrained by pre-established categories. This dual strategy ensured that our analysis was grounded in established knowledge yet responsive to fresh insights, capturing diverse stakeholder perspectives across different international contexts.

Statistical analysis

For the quantitative survey data, we employed both descriptive and exploratory methods. In the descriptive phase, we calculated means and frequency distributions to summarise participant responses, providing an initial understanding of the data. Cross-tabulations were performed based on region (EU vs. APAC) and stakeholder roles (cardiologists, manufacturers, insurers) to identify potential trends or differences within the data.

These preliminary analyses were initially conducted in the Forsta Surveys platform and subsequently detailed in Excel, ensuring consistent and organised data management. While we did not perform formal significance testing our analysis included cross-tabulation techniques that offers preliminary exploratory insights. This dual approach facilitated a comprehensive understanding of patterns within the sample and provided a quantitative counterpart to the qualitative themes, allowing a triangulation of findings that supports robust conclusions and recommendations.

5.0 Findings



5.1 Demographics of respondents

The interviews were conducted with a mix of stakeholders, consisting of 9 manufacturers of consumer wearables, 5 cardiologists, 4 insurance payers, and 2 regulators. Participants were distributed across regions with 11 from the EU and 9 from APAC countries.

The survey reached a wider audience of 137 respondents, including diverse stakeholders such as cardiologists (34), insurance payers (53), and manufacturers (50), with almost equal representation from the EU and APAC regions from France, Germany and Singapore. This demographic data offers an expanded understanding, reflecting balanced insights from both regional and professional standpoints.



The majority, 57%, rated wearables as “very important” for improving health outcomes, especially in post-treatment recovery and chronic disease management.

5.2 Awareness and importance of wearables

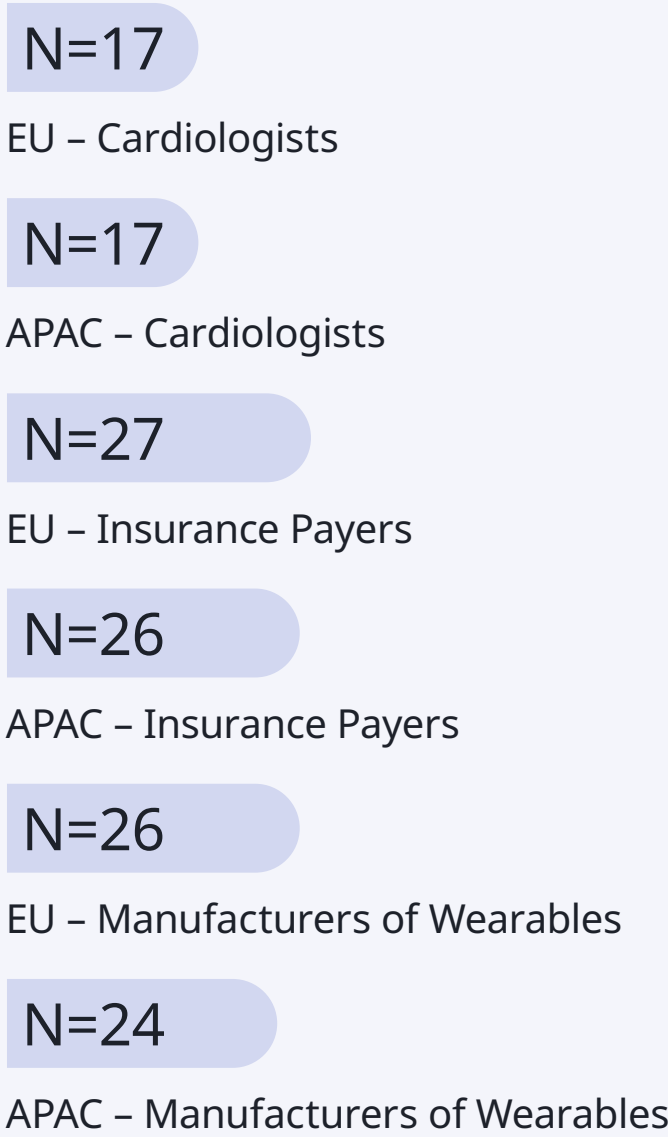
Familiarity with consumer wearables was high, with 60% reporting they were “very familiar” with their use. Manufacturers showed the highest familiarity (70%), underscoring the industry’s focus on these technologies. The majority, 57%, rated wearables as “very important” for improving health outcomes, especially in post-treatment recovery and chronic disease management. This finding is echoed by an APAC cardiologist: “Wearable devices provide continuous health data, allowing doctors to monitor long-term health conditions.”

This was consistent with interview insights, where most stakeholders, except for some cardiologists, recognised their importance in enhancing patient care (Cardiologist FR).

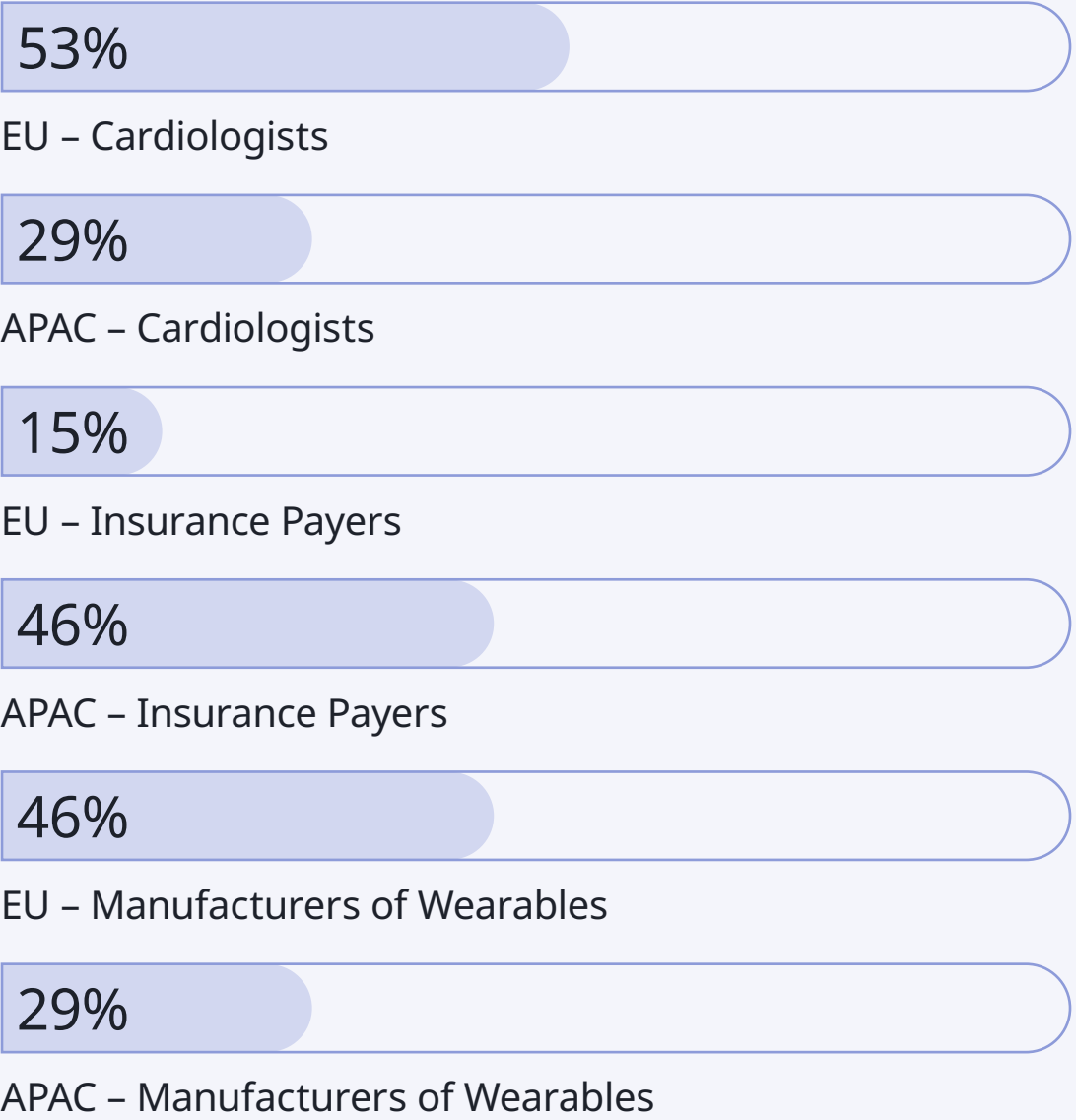


5.3 Perceived barriers to adoption

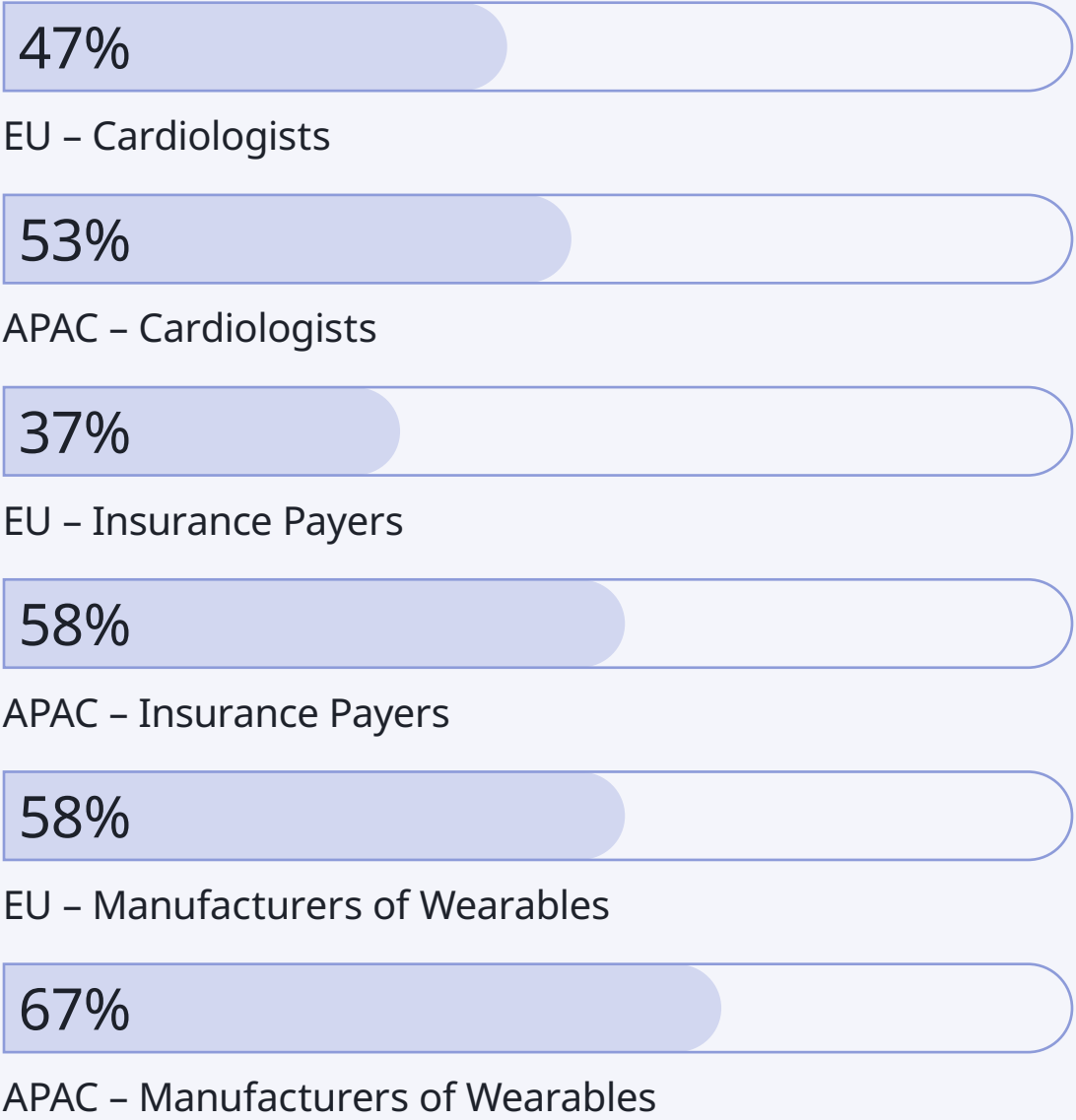
Total



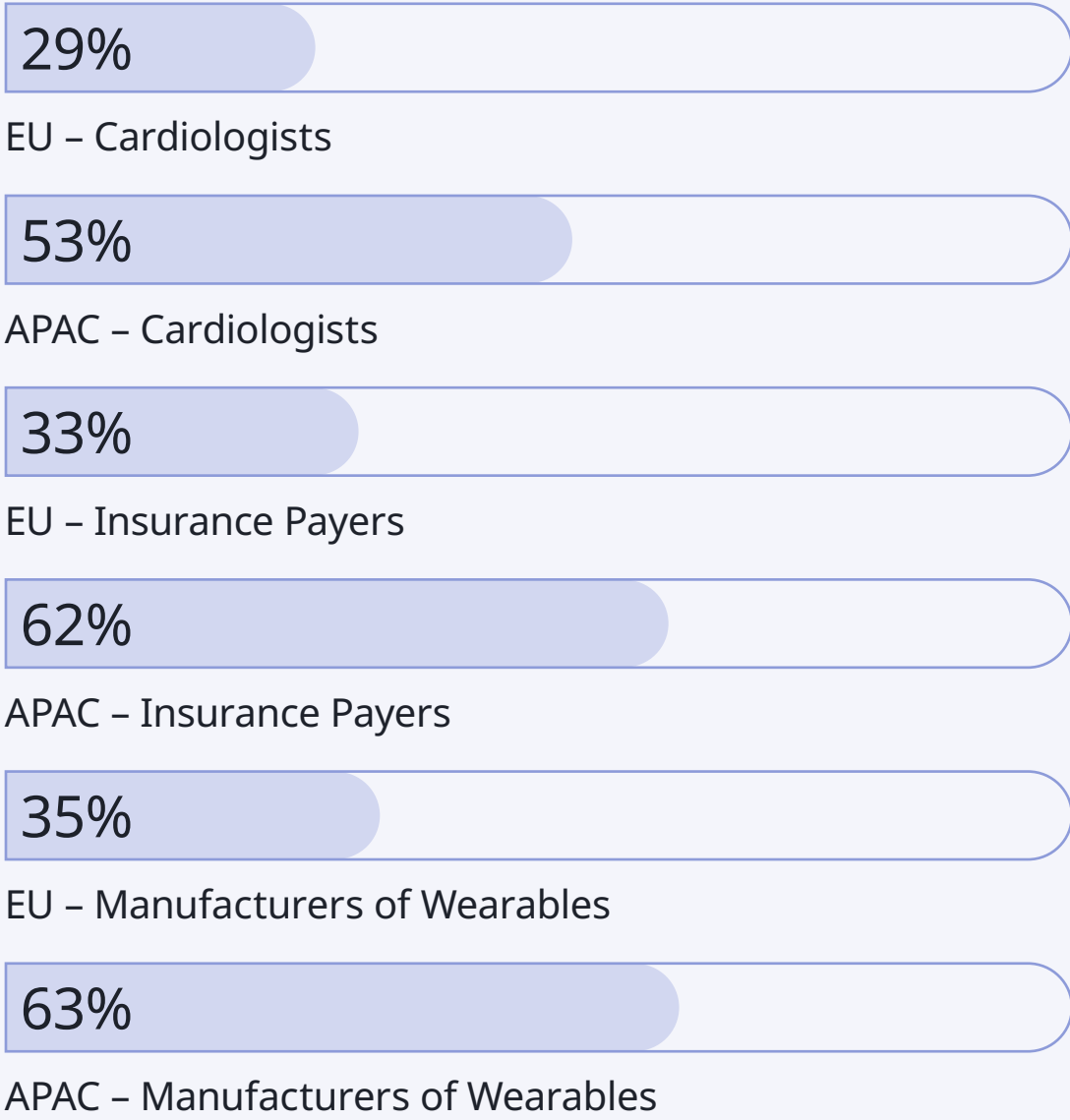
Regulatory compliance



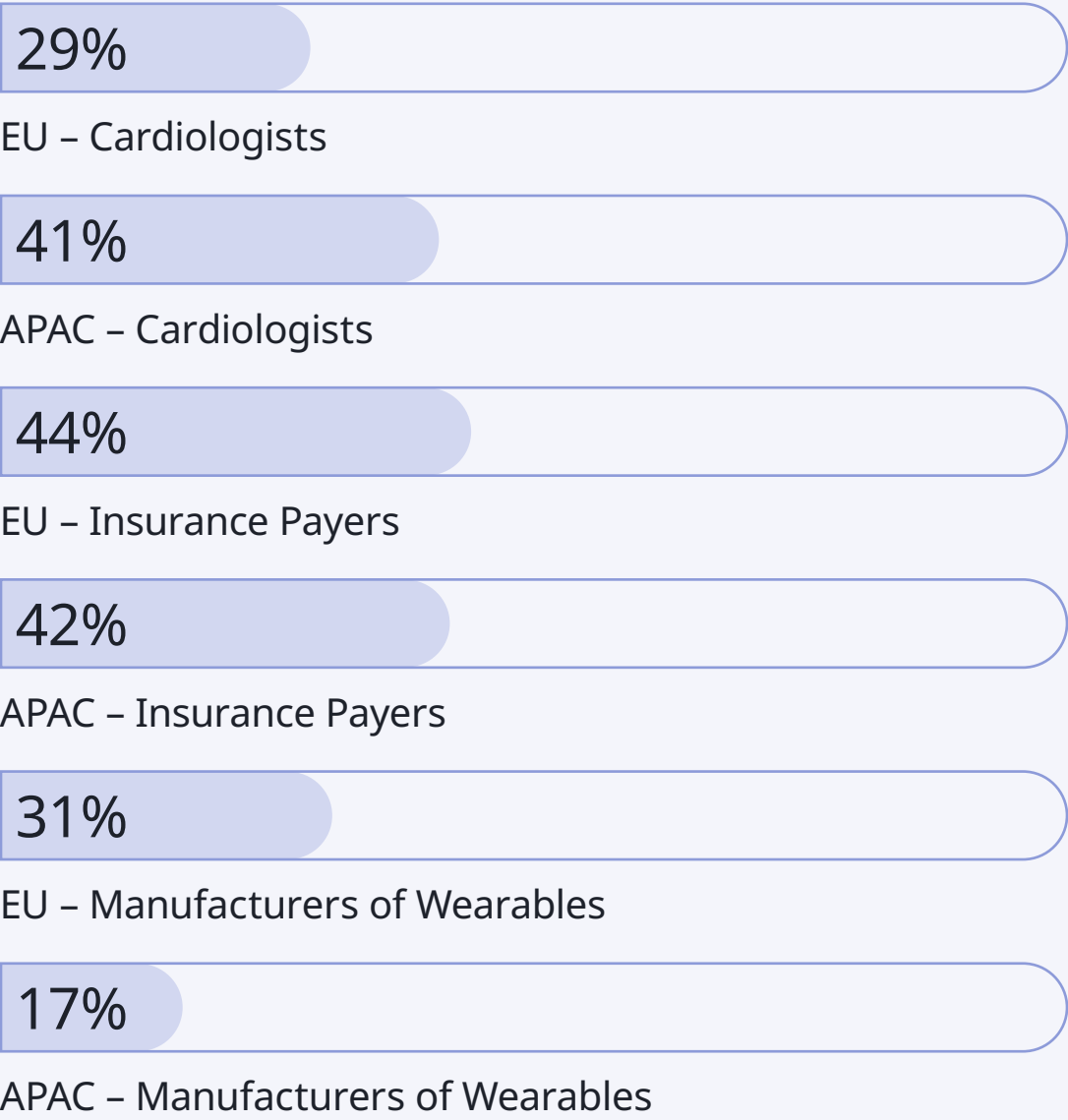
Data security/privacy



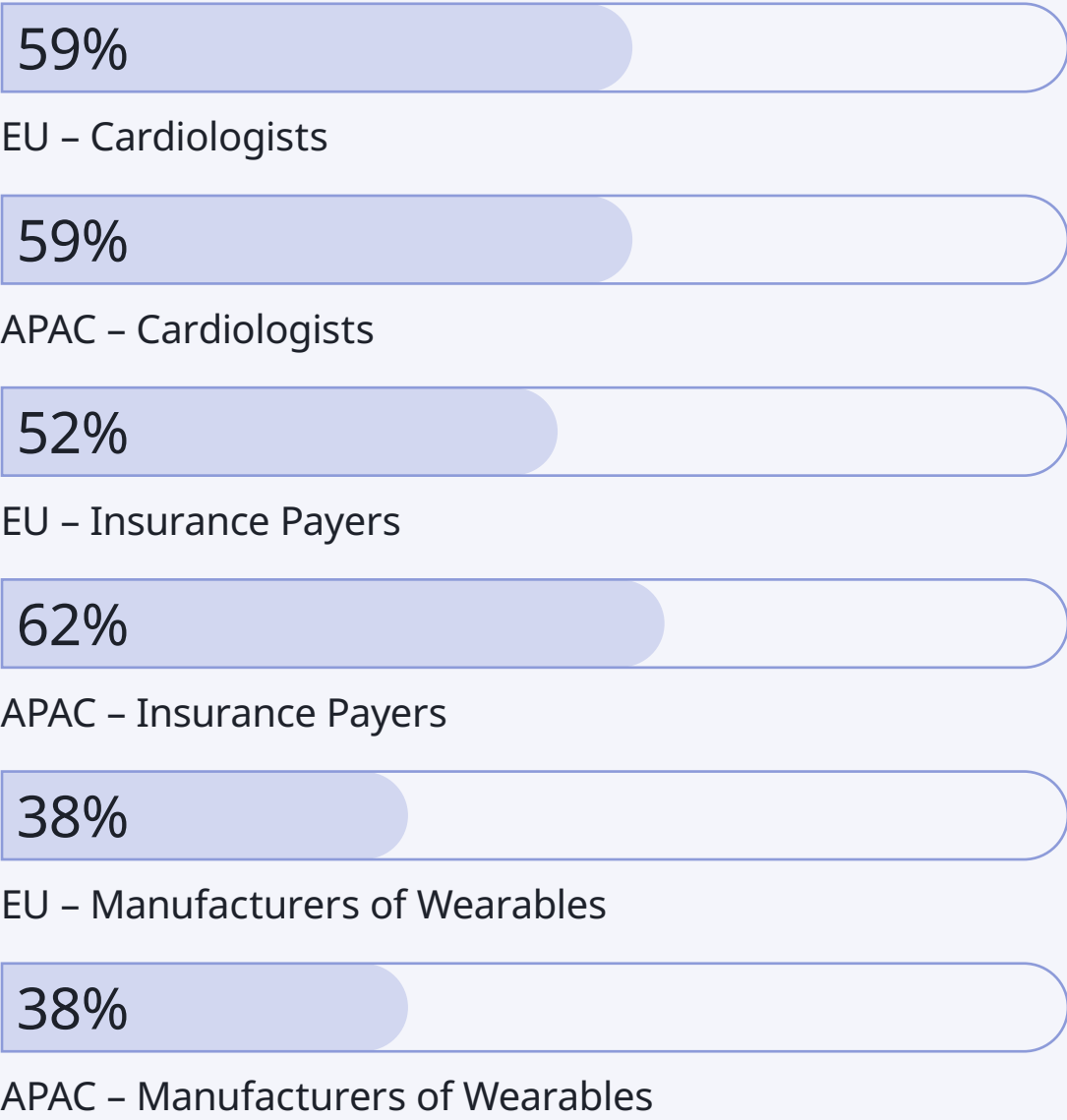
Data accuracy



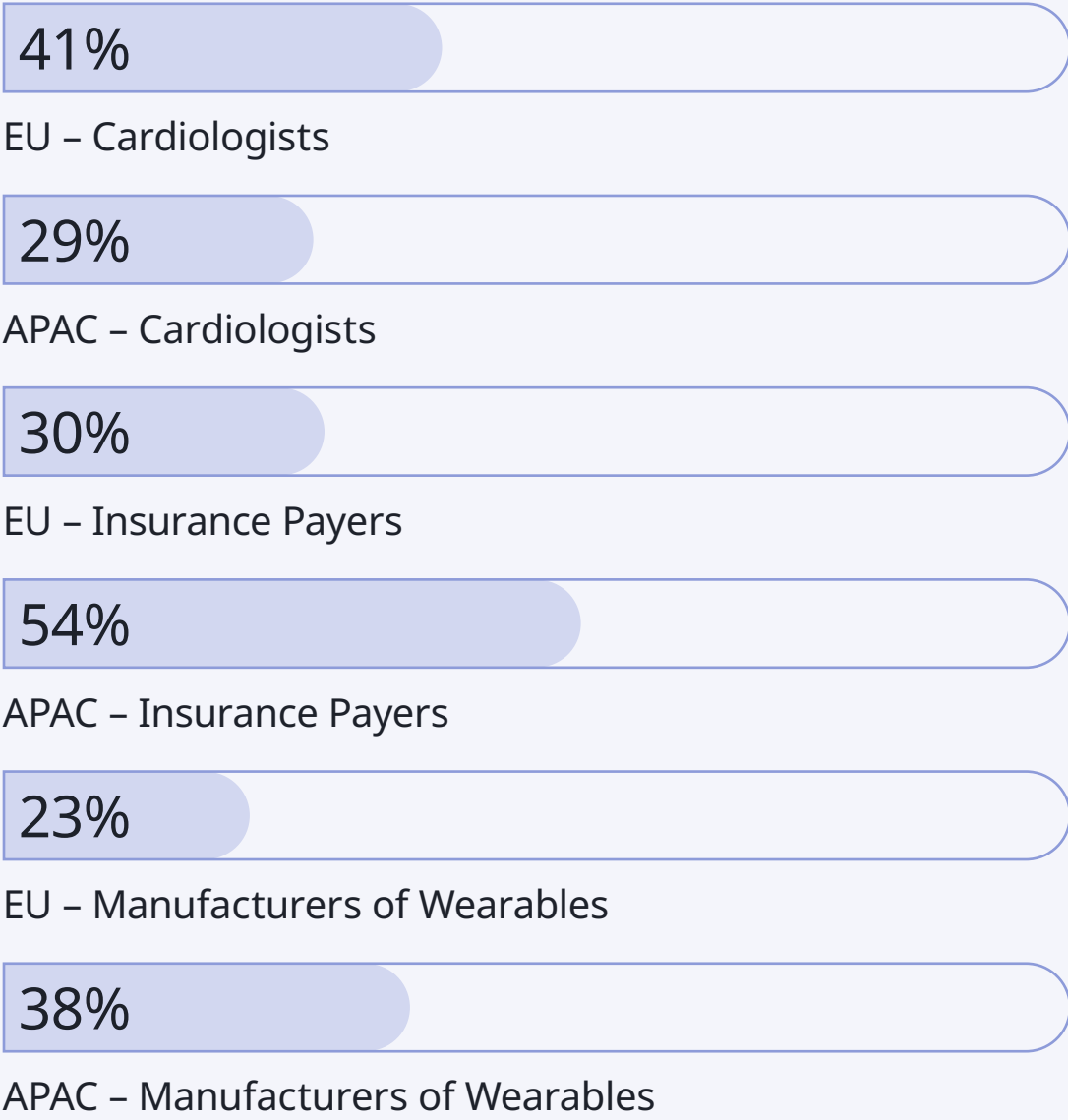
Usability concerns



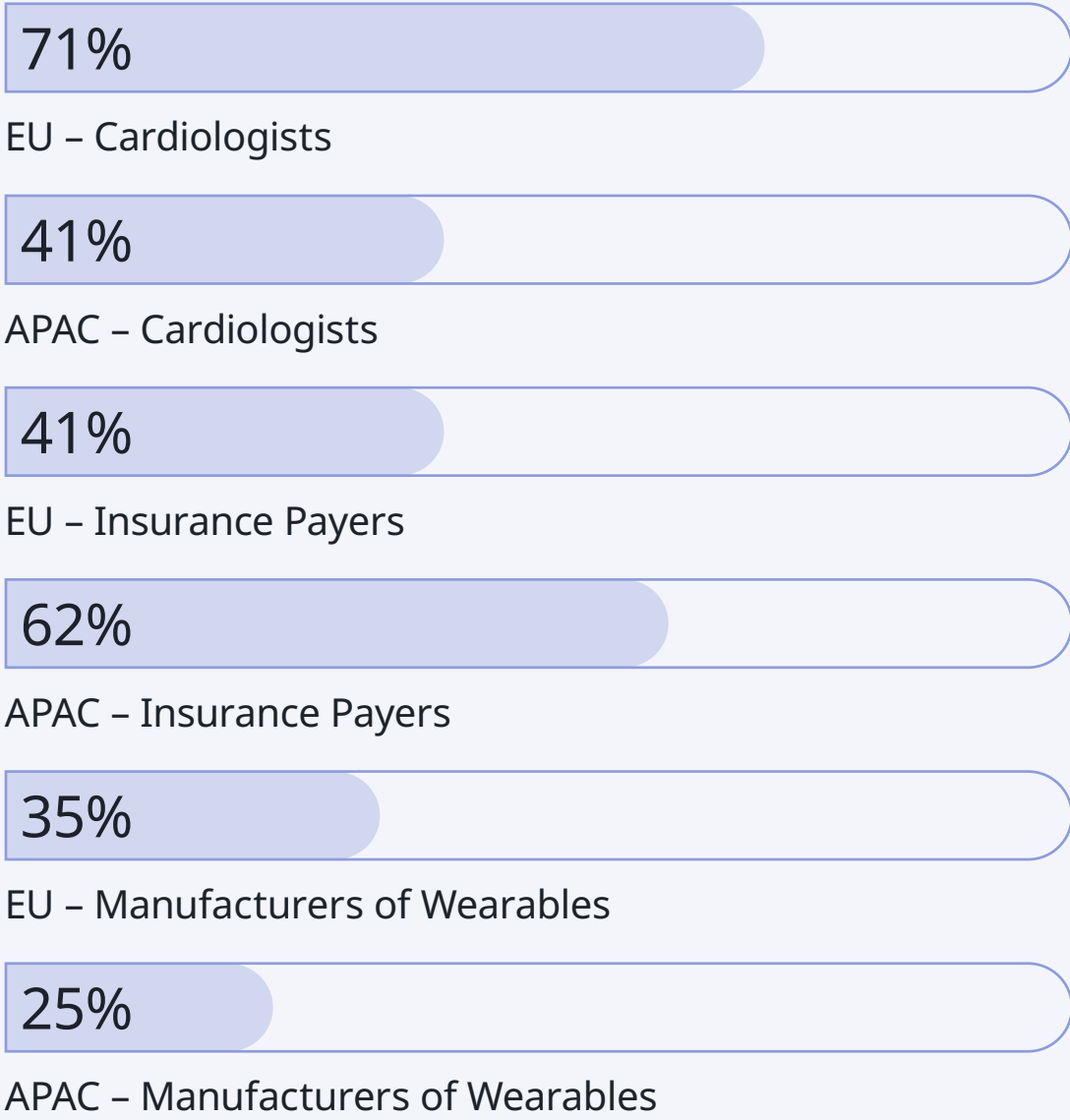
Cost of devices



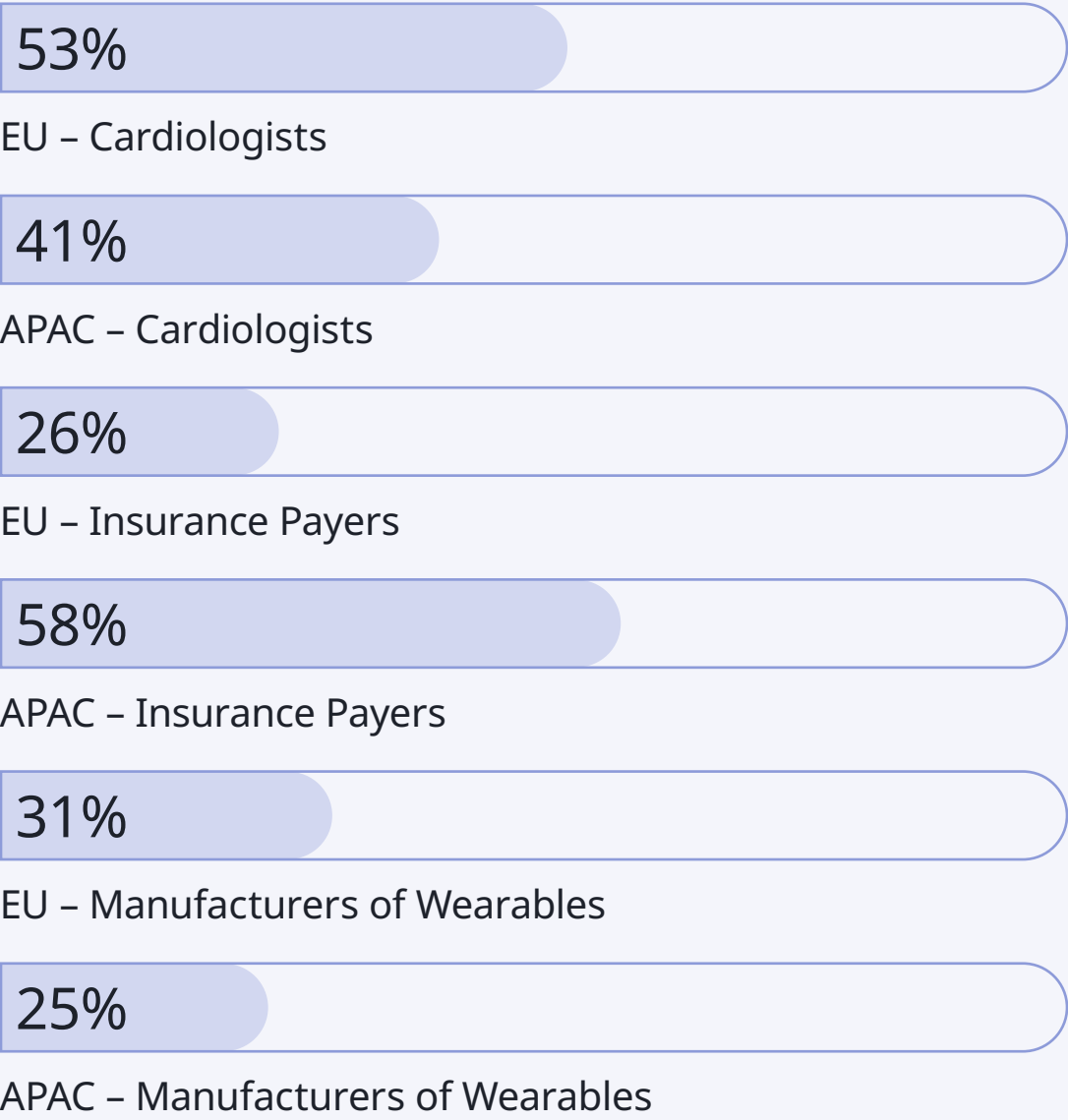
Lack of clinician trust



Patient usage/compliance



Reimbursement from insurance



Regulatory impact

The regulatory environment emerged as a significant factor influencing consumer wearable adoption. While some interviewees saw regulation as a barrier, particularly EU regulations under the MDR, there was also recognition that classifying wearables as medical devices might improve safety and encourage adoption among clinicians (Payor, FR; Cardiologist, FR). Global perspectives showed less stringent regulatory frameworks in Singapore encouraging innovation, though there was an acknowledgment that regulations might tighten over time (Cardiologist, SGP). Regulatory environments significantly influence wearable adoption in our wider survey, with 36% perceiving regulatory compliance as a barrier, notably higher among EU cardiologists (53%) compared to APAC (29%).

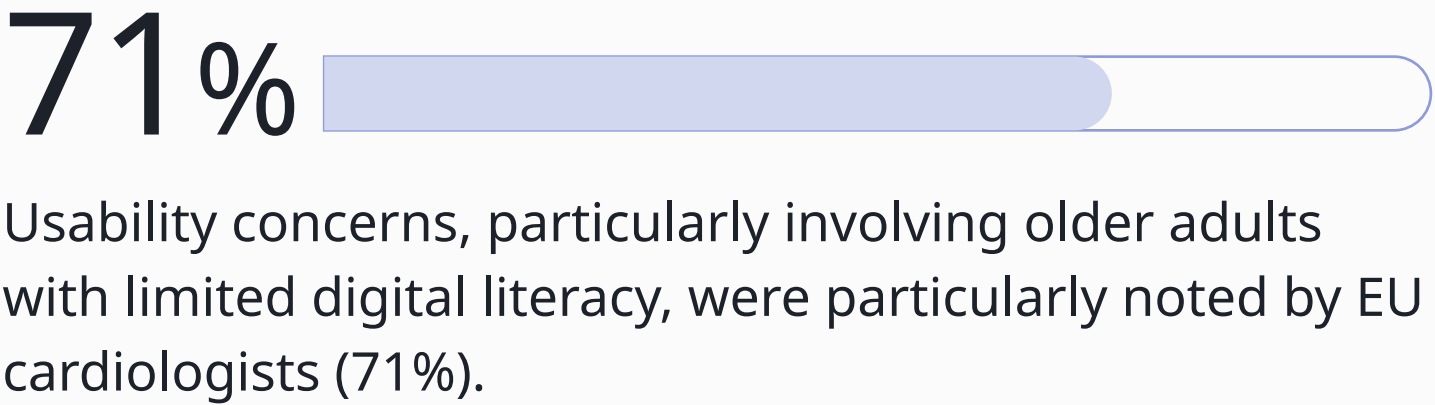
The classification of smart wearables as medical devices has elicited varied responses regarding its impact on adoption and innovation in healthcare. Among manufacturers of wearables, a notable 86% view this classification positively. Meanwhile, cardiologists express more caution; 38% expect somewhat negative impacts on device adoption and patient usage if costs rise due to reclassification.

This cautious stance is particularly pronounced among EU cardiologists, where 53% hold similar concerns. On the investment front, stakeholders generally foresee growth, with 79% predicting either an increase or slight increase in technology investment in wearables. Specifically, 54% of EU manufacturers believe this classification will slightly increase innovation, while 62% of APAC manufacturers anticipate a significant increase. Insurance payers, however, remain concerned about cost implications, with 11% of APAC insurance payers anticipating negative effects on adoption.

Acknowledgment of less restrictive environments in the USA and Singapore also emerged, with 39% citing these as more favourable, indicative of their influence on innovation and market strategies.

Usability

Interview results consistently identified data accuracy as a critical barrier. Concerns over the reliability of consumer wearables to support clinical decisions were prevalent, echoing interview findings centred on sensor accuracy and usability challenges (Cardiologist, FR; Manufacturer, FR). Usability issues, particularly among older patients with low digital literacy, were also noted, affecting both user and clinician adoption (Cardiologist, FR).



Data accuracy

Data accuracy remains a concern, identified by 46% of respondents, particularly within APAC groups (60%) over the EU (33%). Concerns were highlighted regarding the reliability of wearable data for clinical decisions, especially among the elderly, with quotes reflecting expectations for “accuracy improvements.” Usability concerns, particularly involving older adults with limited digital literacy, were particularly noted by EU cardiologists (71%).

Security and privacy concerns

Data security and privacy were viewed as significant barriers, with strong support for robust data protection measures. Although these issues were highlighted, they were often considered secondary to accuracy and usability in both survey responses and interviews.

With 53% identifying data security and privacy as barriers, these issues hold substantial weight, especially within APAC (60%) compared to the EU (47%). Concerns regarding data compliance with privacy regulations were common, with respondents expressing apprehensions about security breaches: “Although wearable devices can collect large amounts of health data, whether they comply with privacy and security regulations is still a question.”

“Although wearable devices can collect large amounts of health data, whether they comply with privacy and security regulations is still a question.”

Cost and reimbursement

The cost of devices emerged as another barrier in both the EU and APAC, with reimbursement policies under debate. While some currently offer reimbursement, types of coverage vary, and new regulations could induce changes (Manufacturer, DE).

This concern was indicated in 50% of participants, highlighted prominently by non-manufacturers. Reimbursement from insurance was noted as a potential barrier at 38%, reflecting diverse regional policies. Cost remains a key factor – “As the item is not cheap, perhaps we need to increase the reimbursement budget.” — suggests a need for systemic involvement to mitigate financial barriers.

5.4. Perceptions of regulatory changes

Awareness of the introduction of the European MDR in 2017 was high among respondents. Opinions varied on whether these regulatory changes would positively or negatively impact adoption, although some believed it could enhance safety and trust (Cardiologist SGP).

While high awareness of recent EU MDR changes was observed, perspectives on their impact were mixed. In the EU, 57% agreed the regulatory environment poses a barrier, whereas 49% of APAC stakeholders shared this view. Positively, regulatory adjustments are anticipated to enhance safety and trust, though concerns about delaying adoption exist across both regions with 77% saying they believe that will positively impact the adoption of consumer wearables in a clinical setting.

5.5 Future adoption trends

Forward-looking insights reveal increasing clinician advocacy for consumer wearables over the coming decade, with 65% very likely to recommend these devices in the next 5-10 years. Optimism was slightly higher in APAC, reflecting regional regulatory perceptions. Manufacturers are particularly optimistic, expecting these technologies to significantly impact healthcare delivery. Despite current regulatory and operational challenges, the anticipation for future integration of wearables remains strong, underscoring a shared belief in their potential to influence healthcare positively.

This optimism was echoed in interviews, particularly from manufacturers who are exploring strategies to navigate complex regulations through partnerships and understanding regional guidelines (Manufacturer, DE).



Forward-looking insights reveal increasing clinician advocacy for wearables over the coming decade, with 65% very likely to recommend these devices in the next 5-10 years.

5.6 Standards development

The development of global standards for consumer wearables was strongly supported by respondents, with 85% expressing a positive stance. This support was notably higher among manufacturers, with 96% in favour, indicating a broad recognition of the importance of standardisation in ensuring quality, safety, and performance. The emphasis on developing standards was reflected across various stakeholder groups, with cardiologists and insurers also showing significant backing. Key areas for standard development included data security and interoperability, underscoring the need for clear guidelines in data handling practises. Additionally, environmental standards in production and packaging were noted, reflecting broader sustainability concerns within the industry.

5.7 Stakeholder-specific insights

Cardiologists

Cardiologists demonstrated varied implementation levels, with some already using consumer wearables for cardiac monitoring. Notably, areas where wearables could potentially aid such as cardiac disease (Cardiologist FR) and lifestyle interventions were identified as impactful.

Within the survey data cardiologists show acknowledged wearables' potential in managing cardiac diseases and lifestyle interventions. EU practitioners were more likely to embrace wearables for cardiac care (88%) compared to APAC (71%). Data reliability issues persist, with 41% expressing concern over clinical application. Regulatory compliance remains a challenge, contrasting with more flexible environments seen in APAC.



EU practitioners were more likely to embrace wearables for cardiac care (88%).

Manufacturers of consumer wearables

Manufacturers highlighted regulatory compliance as a challenge during our interviews, with costs and data standards posing hurdles (Manufacturer, SGP). They are seeking more collaboration to streamline processes and facilitate market entry.

Consumer wearable manufacturers emphasise regulatory compliance as a barrier to adoption, with 62% highlighting country-specific laws’ strategic relevance, particularly in the EU (73%). Despite challenges, regulations are also seen as opportunities to enhance market trust. Manufacturers value partnerships with healthcare providers, with 64% underscoring this importance, expected to facilitate future integration and wearable adoption.

Insurance payers

Insurance payers emphasised the need for data-driven evidence from manufacturers to support reimbursement. They also expressed concerns about ensuring cost-effectiveness, reflecting the complexities in justifying consumer wearables from an insurance perspective (Payor, FR).

The survey confirmed Insurance payers’ willingness to support wearable use, with 81% in the EU and 92% in APAC engaged in reimbursement plans. However, concerns over privacy, security, and elevated reimbursement costs persist. APAC payers are less constrained by regulatory barriers compared to their EU counterparts, promoting a more proactive stance towards wearable adoption. Optimism for technological integration aligns with expectations for improved healthcare outcomes, albeit with careful cost management.



Wearable manufacturers emphasise regulatory compliance as a barrier to adoption, with 62% highlighting country-specific laws’ a strategic relevance.

6.0 Discussion



The integration of consumer wearables into the healthcare system, particularly in the realm of cardiac care, represents a significant shift in how patient data is collected and utilised. Our study has shown that despite numerous challenges, there is a strong interest among stakeholders ranging from clinicians and manufacturers to payers to adopt and integrate these technologies.

6.1 Summary of key findings

Differences in concerns over privacy and accuracy

Our study highlights a notable disparity in concerns regarding data privacy and accuracy between stakeholders in the APAC and EU regions. In the EU, stringent regulations, such as GDPR and MDR, seem to mitigate concerns related to these areas. This is likely due to the strong regulatory framework that addresses data protection comprehensively. On the other hand, stakeholders in APAC report higher concerns regarding data accuracy—particularly among clinicians—but express less apprehension about barriers like clinician trust and patient compliance, despite operating within a more flexible regulatory environment. This variance suggests that while regulatory contexts shape stakeholder concerns and expectations, they do not automatically ensure a consistent reduction in adoption barriers across regions.



Regulatory environment's positive impact

Interestingly, despite initial perceptions of regulation as a hurdle, many respondents note the positive impact of regulatory frameworks on the effective use of consumer wearables within clinical settings. This is particularly relevant in ensuring safety, effectiveness, and usability among stakeholders. The findings around current adoption by clinicians in the EU is higher than APAC may be due to regulation and impact on trusts and reimbursement. The challenge, however, lies in balancing these benefits with the increased costs and complexities associated with compliance to create an increased level of trust in wearables across groups.

Adoption supported by insurance payers

Our findings also highlight a growing willingness among insurance payers to support the use of consumer wearables in clinical environments, particularly in the EU. This support is crucial, particularly for cardiac applications, where continuous monitoring across the pathway can significantly enhance patient care and outcomes. Payers are beginning to appreciate the long-term benefits of wearables, paving the way for broader adoption as part of standard healthcare practises. The difference in Insurance Payers attitudes to reimbursement may be due to the advanced pathways for wearables in France and German under the PECAN and DiGA frameworks.

Broad applications across care pathways

Consumer wearables are gaining traction across cardiac pathways with only a small minority of physicians (6-9%) reporting they would not consider using wearables. This demonstrates a versatile application across various stages of patient care from prevention, diagnoses, pre-treatment and recovery reinforcing their utility beyond traditional clinical settings. The ability of wearables to provide continuous monitoring and real-time feedback is seen as a key advantage, offering insights into patients' health that were previously unavailable.

Concerns about increasing costs

Despite these positive trends, the costs of consumer wearables present an area of concern for adoption. This is seen as more acute given the expenses stemming from increased regulation. The potential impact of these costs touches not only on individual adoption rates but also on systemic issues such as widening health inequalities. The perceptions of cost and value are critical in addressing these; while some stakeholders may not view wearables as expensive, there is a need for clear communication on the benefits these devices offer. This could help offset concerns about their cost, particularly when compared to other consumer technologies like mobile devices.

Demonstrating the tangible benefits and value of wearables can play an essential role in enhancing their perceived worth and justifying the investment to both consumers and healthcare systems. If left unaddressed, these financial barriers could disproportionately affect underserved populations, limiting their access and further entrenching existing disparities in healthcare.

Optimism for future integration

The findings are encouraging as there remains a strong sense of optimism about the future role of consumer wearables in healthcare. This sentiment is shared across regions, though it seems particularly robust in APAC, however this may be due to the higher rate of adoption in the EU where benefits are already being realised. Stakeholders envisage an era where wearables become seamlessly integrated into clinical practise, a vision supported by ongoing improvements in technology and data management. The focus now shifts to how swiftly these technologies can be incorporated into everyday healthcare while addressing existing challenges.

“The ability of wearables to provide continuous monitoring and real-time feedback is seen as a key advantage, offering insights into patients' health that were previously unavailable.”



The role of standards and pragmatic balancing

The strong support for the development of global standards for consumer wearables reflects a consensus among stakeholders on the necessity of creating a reliable framework for the integration of these devices into healthcare. However, it is not entirely clear from the research whether respondents are fully informed of the existing standards relevant to wearable technology and its use in healthcare environments (For example the work of IEC committee TC214 or ISO TC215 / IEC SC62A Joint Working Group 7).

There appears to be a gap in awareness about the broader scope of non-medical device regulations and general standards that might support the adoption of wearables. Addressing barriers such as usability, accuracy, data privacy, and security could be facilitated through these broader standards, enhancing clinician trust and integration into clinical practise. As stakeholders consider the development of new standards, it is essential to also leverage existing frameworks that could indirectly support wearable technology's inclusion in healthcare and fostering adoption.

Overall perspective

The integration of consumer wearables into healthcare systems brings with it both challenges and opportunities. This discussion underscores the need for balanced approaches that consider regional regulatory impacts, cost implications, and the diverse needs of stakeholders. It is of note that more stringent regulation does not act as a panacea for all barriers to adoption.

As wearables continue to evolve, ensuring equitable access and robust data systems will be central to realising their full potential. The future of wearables in healthcare looks promising, provided stakeholders work collaboratively to address existing barriers and leverage the technology's benefits comprehensively.

6.2 Strengths and limitations

Strengths of the research undertaken centres on the comprehensive stakeholder involvement across payer, manufacturer and clinicians. The participants direct experience of the use of consumer wearables in healthcare environments gives us solid evidence from which to develop the next stage of the research. The participants give a solid contrast between the EU and Asia-Pacific.

Limitations exposed in the interview stage were lack of engagement from Japanese stakeholders. Responses from regulators were also hard to obtain, however their position was not considered necessary as this paper relates to stakeholders' response to the regulatory environments they work within.

The initial interviews (n=22) completed were felt to be an appropriate sample to identify key themes to develop and administer the survey. Participants (n=137) from Germany, France and Singapore are felt to be suitably representative to indicate robust contrast between clinical and regulatory environments in the EU and APAC at survey stage.

Whilst a cross section of stakeholders is included, they have all been self-selecting or identified by the research team and the risk of bias is acknowledged. In addition, all interviews and surveys were conducted in English, which is not the vast majority of participants first language which may have impacts on interpretation, however where practical the interviewer was a native speaker able to assist where needed and survey respondents were self-selecting on the basis of English proficiency.

Finally due to the focus on regulatory impacts and clinical use the research does not include patient or user input who are integral to adoption of wearables in healthcare. The findings of this paper could act as a basis for future work to determine patient and citizen insights.

7.0 Future direction and strategy recommendations

Standards awareness and development

Enhancing awareness around existing standards is key to advancing the integration of consumer wearables in healthcare. Encouraging collaboration among standards groups can facilitate greater clarity on how these standards apply to various aspects of wearable technology and their use in healthcare settings. It is crucial for both the industry and healthcare organisations to ensure these standards address specific market needs, particularly regarding data privacy and security. By leveraging standards beyond medical device regulations, such as ISO 82304-2 for healthcare software products, stakeholders can effectively address and overcome adoption barriers through product labelling.

Policy implications and reimbursement processes

Policymakers should focus on the intricacies of reimbursement processes, acknowledging their country-specific elements while ensuring cross-border applicability balanced against costs and resources required of evaluation. Engaging with digital health technology assessment initiatives, currently underway in the EU, can keep stakeholders informed on emerging trends that might impact standards and reimbursement. Aligning these processes with international healthcare systems and considering similar developments in the US through organisations such as the Peterson Health Technology Institute, will support a unified approach to technology adoption in healthcare.

Innovation facilitation

Stakeholders should proactively engage with evolving policies, like the European Health Data Space and the EU AI Act, to better align consumer wearables with regulatory requirements and opportunities. While advanced sensing capabilities continue to evolve, the focus should be on enabling data integration and interoperability across diverse healthcare environments. Wearables should aim to integrate seamlessly into these frameworks, potentially offering solutions to broader healthcare data challenges and be able to enable software developers to meet their obligations around data collection and sharing.

Industry guidelines

Manufacturers are encouraged to develop their product roadmaps with a comprehensive view of both regulatory requirements and clinical needs. Maintaining flexibility by staying informed on upcoming regulatory changes can enhance product readiness and market adaptability. Notwithstanding medical device regulation, manufactures should look to have processes and policies in place for Quality, Data Privacy and Information Security Management combined with a robust understanding of clinical risk in place to build trust amongst stakeholders. This approach ensures that wearables not only adhere to current regulations but are also well placed to meet future demands for safety, effectiveness, and security.

Future research directions

Future research should incorporate patient perspectives, providing insights into how consumer wearables can support general health and chronic condition management. Exploring the US market alongside EU and APAC comparisons can reveal strategies for broader adoption. Focusing on how wearables can empower individuals in managing their health outside traditional clinical settings can help reduce the burden on healthcare systems and enhance overall patient care.

8.0 Conclusion

As consumer wearables continue to advance, they hold significant promise for enhancing patient care and health monitoring, particularly within cardiac applications. This white paper has outlined the diverse benefits and challenges associated with integrating these devices into healthcare settings. Our findings indicate a strong interest among stakeholders across regions and sectors in adopting wearable technology, despite the various hurdles.

Key findings from this study include notable regional differences in data privacy and accuracy concerns and a recognition of the positive role robust regulatory environments can play in facilitating adoption. The support from insurance payers, especially in regions where reimbursement pathways are developed, underscores the growing acceptance of wearables in clinical settings. Nonetheless, issues such as cost, data accuracy, usability, and privacy remain significant barriers that need addressing to further enhance adoption rates.

The potential of consumer wearables to reshape healthcare extends far beyond cardiac monitoring. With advancements in technology and regulatory pathways providing better clarity, the integration of wearables in patient care is increasingly becoming a reality. By leveraging these technologies and addressing current limitations, stakeholders can improve health outcomes and foster innovative healthcare solutions.

Future opportunities lie in fostering greater awareness of standards, facilitating better collaboration among various stakeholders, and integrating patient perspectives into the development and deployment of wearable technologies. By refining regulatory frameworks and ensuring inclusivity in access, the adoption of wearables in healthcare settings can be expedited, allowing patients and providers alike to reap the benefits of these technologies. The journey ahead involves overcoming existing challenges, but the outlook for the integration of consumer wearables in healthcare is optimistic.

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International standards

Current

- **IEC 63203-402-3:2024** Wearable electronic devices and technologies – Part 402-3: Performance measurement of fitness wearables – Test methods for the determination of the accuracy of heart rate.
- **IEC 63203-402-2:2024** Wearable electronic devices and technologies – Part 402-2: Performance measurement of fitness wearables – Step counting.
- **IEC 63203-406-1:2021** Wearable electronic devices and technologies – Part 406-1: Test method for measuring surface temperature of wrist-worn wearable electronic devices while in contact with human skin.

In development

- **124-9 Future IEC 63203-402-X:** Wearable electronic devices and technologies – Part 402-X: Performance of Stress Measurements in wearables.
- **124-11 Future IEC 63203-402-X:** Wearable electronic devices and technologies – Part 402-X: Performance Measurement of Fitness Wearables – Sleep Measurements.
- **124-12 Future IEC 63203-40X-X:** Wearable electronic devices and technologies – Part 40X-X: Mobile wearable device data security.

Key comments

“Because most of the people have a consumer wearable for example from Apple or Samsung watch, it brings additional benefits. But of course, we would need to also consider the people who don’t have a watch and may find it expensive, they might have difficulty getting one.”

Insurer, APAC

“To facilitate the broader use of wearables in clinical settings, I’d like to see clearer guidelines on data privacy and security, ensuring that wearable data can be safely integrated into electronic health records.”

Manufacturer, EU

“Although wearables provide encouraging results, further study is required to guarantee consistency.”

Cardiologist, EU

“Such regulations are important for our customers too, it’s good for both the company and consumer.”

Manufacturer, EU

“I believe the regulatory changes will positively impact the adoption of wearables in healthcare. By classifying them as medical devices, wearables must meet higher standards for accuracy and safety, which can increase trust among healthcare providers and patients. This ensures better data quality and integration with healthcare systems, ultimately leading to improved patient outcomes and wider acceptance.”

Manufacturer, APAC

“As the item is not cheap, perhaps we need to increase the reimbursement budget. There might be influx of reimbursements. After consumer purchases the watch, I fear that they might not be compliant in using it.”

Insurer, APAC

“Fostering collaboration between regulatory bodies, healthcare providers, and technology developers can help create a more cohesive framework for integrating wearables into clinical practice. Regular dialogue and feedback loops can ensure that regulations keep pace with technological advancements and address the practical needs of healthcare settings. These changes would help in making wearables more accessible and widely adopted in clinical environments.”

Manufacturer, APAC

“Wearables should be a mandatory requirement especially for seniors with chronic illness that need immediate medical attention.”

Cardiologist, EU



BSI Group
389 Chiswick High Road
London, W4 4AL
United Kingdom
+44 345 080 9000
bsigroup.com