JOE International Journal of Online and Biomedical Engineering

iJOE | elSSN: 2626-8493 | Vol. 21 No. 2 (2025) | OPEN ACCESS

https://doi.org/10.3991/ijoe.v21i02.52327

PAPER

Patent Landscapes in Digital Health: Insights from Smartphone Technologies

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ABSTRACT

Digital health, such as mobile health apps, has garnered significant attention, leading to an increase in patent applications. This study investigates patent applications related to digital health using smartphones to elucidate the overall state of patenting in this domain and the characteristics of applicants based on nationality and industry type. We analyzed 11,139 patent families filed between 2015 and 2019, featuring the international patent classification (IPC) code G16H (healthcare informatics) and keywords related to smartphones. Our findings indicate that the United States (US) is the most significant market and leader in digital health technology. Correspondence analysis revealed that applications from the US and Europe share similar content, while those from Japan and China exhibit distinct characteristics. Additionally, industry-based correspondence analysis showed that patents from the machinery industry are often related to imaging technology, whereas those from the information technology (IT) sector are primarily associated with medical information-based applications.

KEYWORDS

digital health, smartphone, patent landscape, text mining

1 INTRODUCTION

Recently, the technology and businesses within the digital health field have expanded exponentially. The size of the digital health market exceeded USD 233.5 billion in 2022 and is projected to grow at a compound annual growth rate (CAGR) of 15% from 2023 to 2032 [1]. In 2020, the United States (US) Food and Drug Administration (FDA) launched the Digital Health Center of Excellence (DHCoE) within the Center for Devices and Radiological Health (CDRH) to promote digital health innovation [2]. The German government enacted the digital healthcare act in 2019, which allows digital therapeutic (DTx) products to be approved by regulatory authorities if they meet standards for safety, data security, and quality [3]. Moreover, the COVID-19 pandemic has further increased interest in digital health [4, 5].

Morishita, W., Takayama, K., Saotome, C. (2025). Patent Landscapes in Digital Health: Insights from Smartphone Technologies. *International Journal of Online and Biomedical Engineering (iJOE)*, 21(2), pp. 84–97. https://doi.org/10.3991/ijoe.v21i02.52327

Article submitted 2024-09-20. Revision uploaded 2024-12-04. Final acceptance 2024-12-05.

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Although no universally accepted definition of digital health exists, the FDA describes its broad scope as including categories such as mobile health (mHealth), health information technology (IT), wearable devices, telehealth, telemedicine, and personalized medicine [6]. The World Health Organization (WHO) uses "digital health" as an umbrella term that includes eHealth (which covers mHealth) and emerging areas such as big data, genomics, and artificial intelligence (AI) [7]. According to the Digital Medicine Society (DiMe) [8], digital health is a broad category encompassing digital medicine, which includes DTx. DiMe explains that digital health addresses lifestyle, wellness, and health-related purposes while digital medicine focuses on evidence-based products for measuring and/or intervening in human health. DTx products deliver evidence-based therapeutic interventions. In addition to diagnosis and treatment, digital health is expected to benefit aging populations and support clinical trials [9–11]. Smartphones are one of the key tools for digital health, and many people are thought to use health-related apps; however, the market and business outlook remains unclear [12].

Patent landscapes are valuable for understanding trends in technological and business innovation. Specifically, analyzing invention contents and timelines, such as filing dates, can reveal technological trends. Examining patent applicants can highlight key innovators and the extent of collaboration. Additionally, reviewing the countries in which patents are filed helps identify potential markets for innovation. Recently, there has been an increase in patent landscape publications [13], including COVID-19 vaccines and therapeutics [14, 15].

Several patent analyses have focused on specific digital health products. A patent landscape of pills with digital sensors found that the number of patents related to digital pills has been rising, with most being issued mainly in the US, Europe, Canada, Australia, and China, which together account for 72% of the total [16]. A patent analysis of digital sensors for continuous glucose monitoring from 2000 to 2022 showed that smartphone-based monitoring and telemedicine have emerged since 2006, with Dexcom, a US company, leading in patent applications for visualizing blood glucose levels via smartphone apps [17]. An analysis of AI precision tools for mental health found that most patents were filed by applicants from the US, followed by China, South Korea, and India [18].

Some patent analyses in broader areas of digital health have also been reported, though they often focus on a single country. For example, a study analyzing US patents granted between 2002 and 2016 for telemedicine found that inventions related to user interfaces (automated or user-controlled interfaces for local medical devices) were the most common, followed by inventions related to health information systems (e.g., management of patient data). The top ten fields of invention remained relatively consistent during this period [19]. A patent application and citation analysis of DTx patents in Japan revealed that many patents were related to "applications," "sensors," "medical imaging," "central nervous system/psychiatry," and "cardiac" technologies [20].

In a more comprehensive patent analysis, Kunimitsu et al. [21] reported a dramatic increase in digital health-related patent applications classified under G16H (healthcare informatics) as the international patent classification (IPC) in the US and China, with moderate growth in Japan and Europe. Gu et al. [22] showed that the number of granted digital health patents published between 2017 and 2021 has been steadily growing, particularly in China and the US. Their analysis also indicated that highly cited patents primarily focused on algorithms for improving surgical devices. Overall, these patent landscape analyses reveal trends in digital health innovation by country and major technological fields.

Our study aims to provide a comprehensive overview of digital health technology development using smartphones—the most widely used technology in this sector—through a patent landscape analysis. The specific research questions are as follows:

- **1.** Which country presents the most promising market for digital health using smartphones based on the number of patent applications?
- **2.** Which countries are the most active in developing digital health services using smartphones?
- 3. Do foreign patent filing strategies differ depending on the applicant's nationality?
- **4.** Which industries are leading the development of smartphone-based digital health technologies?
- 5. Does the content of inventions vary by the applicant's industry and nationality?

2 DATA AND METHODS

To clarify the overall state of digital health technology development using smartphones, we searched the JP-NET dedicated browser (Japan Patent Data Service) for patent applications filed between 2015 and 2019. The search criteria included patents with G16H (healthcare informatics) as the IPC code (IPC: G16H) and "smart phone" or "cell phone" in the full text. The search, conducted between July 27 and August 20, 2021, yielded 11,139 patent families (see <u>Appendix 1</u>). A patent family consists of patent applications filed in different countries for the same invention.

First, we analyzed the countries in which the patents were filed and whether each patent family included a Patent Cooperation Treaty (PCT) application, an international patent application with the same effect as filing in all treaty member countries simultaneously. In this study, we analyzed countries under the jurisdiction of the European Patent Office as Europe.

Next, we investigated the nationality and industry type of the applicants. Applicant nationality was identified using the bibliographic information of the patent applications. For non-individual applicants (n = 1,123) who filed two or more patents, we categorized their industries into one of eight groups: machinery, IT, pharmaceuticals, university, hospital, public research institution, other, or unknown. Industry classification was based on (1) the industry with the highest sales in the most recent financial data or (2) the main product or service when financial data was unavailable. If neither source provided information, the applicant was classified as "unknown." Machinery and IT were distinguished by the main product: medical equipment for machinery and computers or cloud services for IT. Public institutions were defined as government agencies or nonprofit research institutions. All classifications were done independently and in duplicate by the authors, with disagreements resolved by consensus.

Finally, to characterize the content of the patent applications, we conducted quantitative text analysis using KH Coder 3, a free text-mining software [23]. KH Coder is widely used and includes features such as word-frequency statistics, correlation analysis, and visualization [24]. We used patent abstracts for the analysis, which provide concise descriptions of the inventions. For non-English patents, the abstracts were translated into English using the translation function in Espacenet (European Patent Office, <u>http://worldwide.espacenet.com/</u>). Frequently occurring words were extracted from each abstract using KH Coder. As a pretreatment step, 14 common words (e.g., be, more, least, first, second, that, use, comprise, which) were excluded from the analysis. We then conducted correspondence analysis and co-occurrence network analysis. Correspondence analysis identified significant variations in word usage among different applicant types, while co-occurrence network analysis identified relationships between words, highlighting characteristic features of the inventions.

3 **RESULTS**

3.1 Filed county

Of the 11,139 patent families, 7,099 (64%) were filed in the US, 4,731 (43%) in China, 3,715 (33%) in Japan, and 3,443 (31%) in Europe. PCT applications were filed by 4,996 families (46%). A total of 1,246 patent families (11%) were filed in all four regions (hereinafter referred to as "quadruple application"). As of the search date, there were 313 families (3%) for which 30 months had not yet elapsed from the priority date and for which a domestic transition procedure might be conducted in the future.

3.2 Nationality of the applicant

Among the 11,139 patent families, 108 were filed by applicants from two countries, and one was filed by applicants from three countries, resulting in a total of 11,249 applicants from various nationalities. The US had the largest number of applicants (4,367; 39%), followed by Japan (2,319; 21%), China (2,075; 18%), Europe (1,419; 13%), and other nations (1,069; 9%).

Figure 1 illustrates the percentage of patent applications filed in the US, Japan, China, and Europe, as well as quadruple application and PCT applications by applicant nationality. For applicants from the US, Japan, and China, the percentage of applications filed in their home countries was greater than 99%, indicating that nearly all patent families were filed domestically. The second most common destination for US applicants was Europe, with 1,613 patent applications (37%). For Japanese applicants, the US was the second most common destination (617; 27%). Chinese applicants predominantly filed in their home country, with the US being the next most common destination (142; 7%). European applicants filed slightly more applications in the US (1,163; 82%) than in Europe (1,122; 79%).

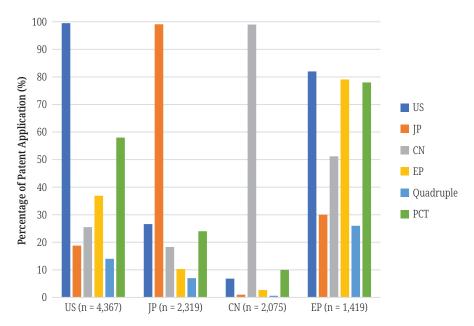


Fig. 1. Percentage of patent applications in each country by applicant nationality *Notes:* US: United States; JP: Japan; CN: China; EP: Europe. Quadruple: United States, Japan, China, and Europe. PCT: Patent Cooperation Treaty application.

The number and percentage of PCT applications were as follows: 2,551 (58%) for US applicants, 561 (24%) for Japanese applicants, 209 (10%) for Chinese applicants, and 1,102 (78%) respectively.

Regarding quadruple applications, there were 598 (14%) from the US, 155 (7%) from Japan, 12 (0.6%) from China, and 376 (26%) from Europe.

To assess collaboration, we examined joint applications and found that only 327 (3%) were joint applications with external organizations, excluding those with subsidiaries.

3.3 Industry types of the applicants

An analysis of the 6,462 patent applications surveyed revealed that the machinery industry was the most common source of applications (2,610; 40%), followed by the IT industry (2,036; 32%) and the pharmaceutical industry (209; 3%) (see Figure 2a). Among nonprofit organizations, universities were the most frequent applicants (444; 7%), followed by hospitals (155; 2%). By nationality, IT companies from the US submitted more applications (785; 35%) than machinery companies (738; 32%), differing from the overall trend (see Figure 2b). Chinese applicants showed a significant increase in applications from IT companies (408; 44%; see Figure 2d). Japanese and European applicants were predominantly machinery manufacturers (Japan: 913; 52%; Europe: 599; 60%; see Figures 2c and 2e). European pharmaceutical companies filed a higher percentage of applications (144; 14%) compared to other regions (US: 59; 3%; Japan: 4; 0%; China: 2; 0%).

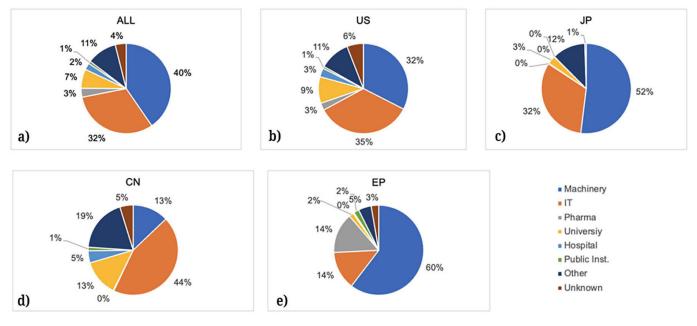


Fig. 2. Percentage of applicants by industry

Notes: a. All applicants (n = 6,462). b. United States applicants (n = 2,269). c. Japanese applicants (n = 1,757). d. Chinese applicants (n = 923). e. European applicants (n = 992).

In the machinery industry, top applicants included major manufacturers such as Philips, Samsung, and Panasonic (refer to Table 1). Leading IT companies such as IBM, Microsoft, and Apple from the US, and Fujitsu from Japan, were prominent applicants. In the pharmaceutical industry, European giants such as Roche and Novo Nordisk were among the top five applicants. In academia, the top five positions were all held by US universities.

| | 1 11 |) | |
|---------------------------------|----------------|------------------------|--|
| Applicant | Nationality* | Patent Application No. | |
| | (A) Machinery | | |
| Koninklijke Philips | EP | 386 | |
| Samsung Electronics | KR | 166 | |
| Panasonic | ЈР | 96 | |
| Siemens | EP | 84 | |
| General Electronics | US | 74 | |
| | (B) IT | | |
| IBM | US | 224 | |
| Fujitsu | ЈР | 102 | |
| Pin An Medical and Healthcare | CN | 46 | |
| Microsoft | US | 24 | |
| Apple | US | 23 | |
| | (C) Pharma | | |
| Roche | EP | 51 | |
| Novo Nordisk | EP | 32 | |
| Sanofi | EP | 22 | |
| Bayer | US | 10 | |
| Novartis | EP | 9 | |
| | (D) University | | |
| University of California | US | 30 | |
| Case Western Reserve University | US | 23 | |
| University of Virginia | US | 12 | |
| Duke University | US | 11 | |
| Johns Hopkins University | US | 11 | |
| | | | |

| Table 1 | . Top five | e applicants | in each | industry |
|---------|------------|--------------|---------|----------|
|---------|------------|--------------|---------|----------|

Notes: *US: United States, JP: Japan; CN: China, EP: Europe, KR: Korea.

3.4 Contents of patent applications

The correspondence analysis of frequent words in abstracts and applicants' nationalities showed that the US and Europe were similar, while Japan was positioned in the opposite direction along Component 1, which had the highest contribution rate (see Figure 3). For Component 2, China was the only country positioned far from the others. Co-occurrence network analysis of US and European applicants revealed that the largest cluster centered on the term "datum" (<u>Appendices 2</u> and <u>3</u>). In these networks, "glucose," a term prominent among US and European applicants,

was linked to "insulin," and "interface" was connected to "user." For Japanese applicants, the largest cluster centered on "information" (<u>Appendix 4</u>). Words associated with Japanese applicants, such as "acquisition" and "acquire," were linked to "unit" and "user" within the "information" cluster. Chinese applicants' characteristic word "accord" was connected to "information," "datum," and "method" in the co-occurrence network (<u>Appendix 5</u>). The word "improve," also notable in the correspondence analysis, was linked to "efficiency" in the network.

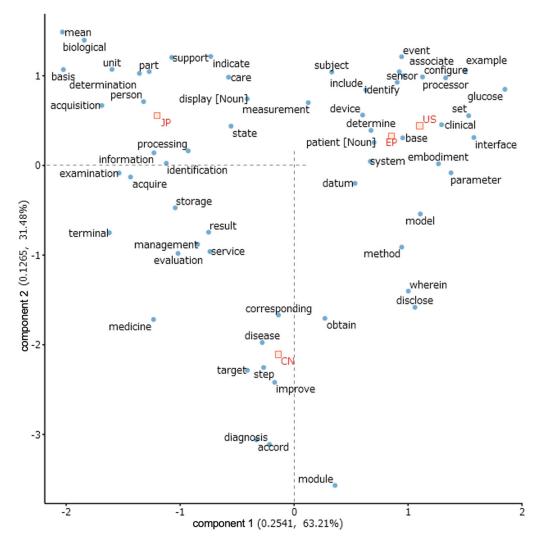


Fig. 3. Correspondence analysis on abstracts of inventions by applicant nationality *Note:* US: United States, JP: Japan, CN: China, EP: Europe.

Another correspondence analysis of frequently occurring words by industry is shown in Figure 4. For Component 1, machinery and pharmaceuticals were aligned positively, while IT, academia (universities and public research institutions), and hospitals were aligned negatively. In Component 2, pharmaceuticals were the only category positioned distantly. Machinery-related words included "imaging," "display," "apparatus," "unit," and "processor," all related to medical device components. In the co-occurrence network, "unit" was linked to "information" and "acquire" (Appendix 6). IT-related words included terms such as "health," "medical," and "medicine," with "medical" connected to "patient" in the co-occurrence

network (<u>Appendix 7</u>). The words "computer" and "program," characteristic of IT, were also linked. In pharmaceuticals, the key term was "drug," which was connected to "delivery" in the network (<u>Appendix 8</u>). The network also showed connections between "insulin" and other terms related to blood glucose measurement and drug administration. Academia-related words such as "step" and "disclose" were linked to "method" in the network (<u>Appendix 9</u>), and "feature" was connected to "extract," while "mobile" was linked to "phone." For hospitals, characteristic words included "disease" and "module," with "module" connected to "management" and "server" (<u>Appendix 10</u>).

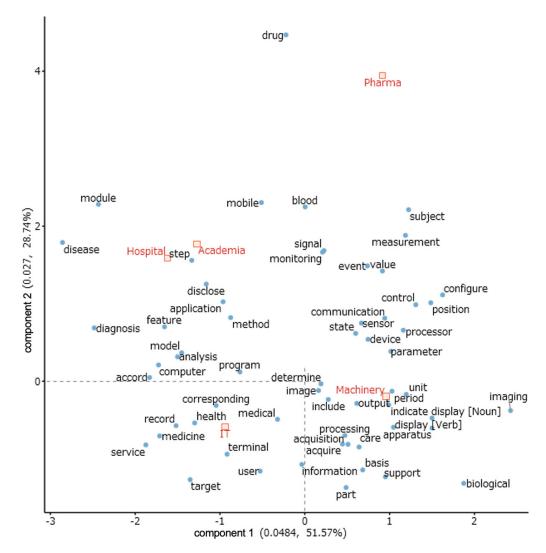


Fig. 4. Correspondence analysis on abstracts of inventions by applicant industry

4 **DISCUSSION**

We identified several features of patent applications related to digital health using smartphones, including the nationality and industry type of applicants and the content of the inventions.

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4.1 Overall trend

Our results indicate that the US was the most common destination for patent applications, accounting for 7,099 (64%) of the total, consistent with previous studies on digital health patents [15–16] [19–20]. This trend is likely due to the high volume of applications from US applicants, who represent nearly 40% of the total. Additionally, many overseas applications from Japanese and European applicants were filed in the US, highlighting its recognition as a key global market for digital health.

In terms of international applications, 45% of the surveyed patent families were filed as PCT applications, and 11% were filed in all four regions (US, Japan, China, and Europe). This suggests an active international filing strategy among applicants.

The analysis of industry types reveals that machinery and IT industries together accounted for over 70% of the total applications. Major applicants in the machinery sector, such as Philips and Samsung, are known for manufacturing medical devices such as computed tomography and magnetic resonance imaging equipment. This suggests that their involvement in digital health is an extension of their medical device development. In the IT sector, leading companies such as IBM, Fujitsu, and Microsoft are applying technologies such as cloud services and AI to healthcare. This has led to many inventions related to digital health using smartphones being filed by the IT industry. Among pharmaceutical companies, the top five applicants represented about 60% of the total, indicating that fewer companies are actively engaged in digital health.

Joint patent applications constituted only 3% of the total, indicating relatively low collaboration within digital health research.

4.2 Foreign filing strategies and invention content by nationality

United States applicants exhibited a high percentage of PCT (58%) and quadruple applications (14%), suggesting a strong intention to pursue international business. US IT companies filed more applications than machinery manufacturers, diverging from the overall trend. Leading US IT firms are at the forefront of developing digital health technologies using smartphones. Additionally, US universities submitted a higher number of applications compared to other countries, indicating significant academic involvement in digital health. Correspondence analysis of abstracts showed that US and European applications had similar content. A notable characteristic of US patents is the emphasis on "interface," which was linked to "user" in the co-occurrence network, suggesting a focus on user interface innovations.

Japanese applicants showed lower percentages of PCT applications (24%) and quadruple applications (7%), indicating a preference for domestic markets. Japanese machinery manufacturers had a higher percentage of applications (52%) compared to other countries. Correspondence analysis placed Japan's patent content on the opposite side of the spectrum from US and European content. The characteristic words "acquisition" and "acquire," connected to "unit" and "user" in the "information" cluster, suggest that Japanese patents often focus on technologies for acquiring user information.

Among Chinese applicants, the percentage of foreign patent applications, such as PCT applications (10%) and quadruple applications (0.6%), was very low. This indicates that most Chinese applications are filed domestically, reflecting a strategy focused on the substantial domestic market. According to a World Intellectual Property Organization report, only 6.7% of all patent applications from China were filed abroad, compared to 45.6% from the US and 46.3% from Japan [25]. This finding aligns with the trend observed in our study, highlighting the domestic orientation of Chinese patent filings. In terms of industry, IT companies in China accounted for a larger share of applications (44%) compared to other countries. For example, Ping An Medical and Healthcare, a significant IT filer, is a subsidiary of Ping An Insurance, a major Chinese financial institution with a focus on healthcare services. This suggests that China has a higher concentration of relatively small IT companies engaged in digital health research and development compared to global IT giants. Correspondence analysis of the abstracts showed that Chinese patents were distinct from those of other countries, particularly along Component 2. The characteristic word "accord" was linked to "information," "datum," "user," and "medical," indicating a focus on medical and user information in Chinese inventions.

For European applicants, the number of patents filed in the US slightly exceeded those filed in Europe. The percentages of PCT (78%) and quadruple applications (26%) were also higher than those from other countries. This trend reflects the international filing strategies of European applicants, as only those patents filed with the European Patent Office were included in this study. Future research should consider European applicants' international filing strategies, including those filing only within their home countries. In terms of industry, machinery manufacturers constituted 60% of European applications, with Philips leading as the top applicant (386 applications). Pharmaceutical companies accounted for 14% of European applications, compared to just 3% overall, indicating a strong presence in digital health. Correspondence analysis showed that European patents had similar content to those from the US. One of the characteristic word, "glucose," in correspondence analysis was notably linked to "insulin" in the co-occurrence analysis, suggesting that their inventions were characterized by an invention related to insulin administration for diabetic patients. The significant number of pharmaceutical company applicants in Europe likely influenced this characteristic.

4.3 Characteristics by applicant industry

Here, we analyze the characteristics of patent content based on the applicant's industry. Correspondence analysis indicates that the content of applications filed by machinery manufacturers and pharmaceutical companies is relatively similar along Component 1 (the horizontal axis), which has a high contribution rate (see Figure 4). Therefore, we will first discuss the characteristics of inventions of the machinery and pharmaceutical industries. Characteristic terms of the machinery industry, such as "imaging," "image," and "display," suggest a focus on imaging and image analysis technologies. Words such as "unit," "apparatus," and "processor," which are associated with medical device components, also characterize machinery patents. The connection of "unit" with "information" and "acquire" in the co-occurrence network (Appendix 6) further suggests that information-gathering units are a key feature of machinery inventions.

Pharmaceutical patents, characterized by the term "drug" (see Figure 4), are connected to "delivery" in the co-occurrence network, with a notable cluster around "insulin" (<u>Appendix 8</u>). This indicates that inventions related to insulin administration for blood glucose management in diabetes are prominent in the pharmaceutical sector.

IT patents, found to align with academia (universities and public research institutions) and hospitals along Component 1, share similar content characteristics (see Figure 4). IT patents are distinguished by terms related to medicine and computer programs, highlighting a focus on medical information-based applications.

In academia and hospitals, the content of patents is similar across both Component 1 and Component 2, featuring terms such as "disease," "feature," and "diagnosis." This suggests a focus on disease feature extraction and diagnostic applications. The alignment of academia and hospitals with IT along Component 1 implies that entering the IT field, predominantly software-based, is more accessible for these sectors compared to the hardware-dominated equipment field.

4.4 Limitations

The patent search conditions used in this study did not include distortions in the notation of smartphones (mobile phones, cellular phones, and so on), which may have led to an underestimation of the number of patent families covered. In addition, PCT applications were filed for 4,996 patent families, 313 of which had not yet reached the deadline for national entry procedures at the time of the survey. Although unentered applications are not expected to affect the majority of cases, there is a possibility that more applications will be filed for these families in the future.

5 CONCLUSIONS

In the field of digital health using smartphones, the US was the most common destination and nationality of applicants, indicating that it is the most important market and country with the most advanced development. Regarding international applications, PCT applications (45%) and quadruple applications (11%) were actively filed. In contrast, there were only a few joint applications (3%). Its main industries are machinery and information technology.

Regarding characteristics by nationality, among the US applicants, the IT industry (mainly world-class IT companies) filed many patent applications. Among the Japanese applicants, machinery manufacturers have filed many patent applications. Among the Chinese applicants, IT companies filed many applications, most of which were filed in China. Among European applicants, machinery manufacturers filed many applications, and pharmaceutical companies filed more applications than pharmaceutical companies in other countries. Our analysis clarified that the contents of applications filed by the US and European applicants were similar, whereas the contents of Japanese and Chinese applications differed from each other.

Regarding the content of inventions by industry, we inferred that applicants in the machinery industry filed mainly for image analysis technology, pharmaceutical companies filed mainly for digital health patents related to diabetes, and the IT industry and academia filed mainly for applications in diagnosis based on disease features. The strength of this study is that it identified differences in the technical fields being developed by nationalities and industry types of applicants by classifying applicants and text-mining the abstracts of patent applications.

6 ACKNOWLEDGMENTS

The authors thank all members of the Department of Management of Technology and Intellectual Property, Kyoto University Graduate School of Medicine, for their valuable comments and suggestions, and Mizuki Moriguchi for data entry. The authors would also like to thank Editage (<u>https://www.editage.jp/</u>) for English language review. This study was supported by a research grant from the Grant-in-Aid for scientific research KAKENHI (Nos. 18K01792 and 23K01508) from the Ministry of Education, Culture, Sports, Science, and Technology of Japan. This work was also supported in part by the project promoting clinical trials for the development of new drugs (JP21lk0201702) from the Japan Agency for Medical Research and Development (AMED).

7 COMPETING INTERESTS

The authors declare that they have no competing interests.

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