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PATENT ANALYSIS ON DIGITAL THERAPEUTICS IN THE UNITED STATES: A CROSS-SECTIONAL STUDY OF KEY DRIVERS

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Abstract

Background: Digital therapeutics (DTx) represent an innovative integration of technology and healthcare, employing software and digital tools to enhance, complement, or directly deliver medical interventions, including disease prevention, diagnosis, and treatment. With recent approvals of prominent digital therapeutic solutions, such as anti-smoking programs and treatments for diabetes, major depressive disorder, and ADHD, there is a clear trajectory toward increased acceptance and regulatory approvals in this field. Consequently, patent activity related to DTx technologies is also anticipated to grow significantly, making it crucial to understand the underlying intellectual property trends and key technological drivers.

Methodology: This study provides a comprehensive analysis of DTx-related patents filed in the United States, leveraging patent databases and the International Patent Classification (IPC) system. We focused specifically on patent applications incorporating applied technology and medical indications as primary drivers. To elucidate the most influential innovations, we conducted both patent application trend analyses and patent citation analyses. The latter included citation matrix analyses for prominent U.S. companies involved in digital therapeutics, offering insights into technological dominance and market growth potential based on the citation frequency and self-citation ratios of patents.

Results: Our analysis identified several key technological drivers in the DTx space, notably within the realms of healthcare informatics and diagnostics. The patents predominantly focused on areas such as "Sensor," "Blood Vessel," "Medical Image," "Heart," "Central Nervous System," "Psychiatry," and "Application," underscoring a wide range of medical and technological foundations supporting DTx advancements. Furthermore, companies such as Akili and Welldoc emerged prominently, demonstrating significant patent activity and technological influence through customized cognitive training regimens and adaptive health assistant systems, respectively.

Keywords: *Digital Therapeutics, DTx, Key Driver, Patent Analysis, Patent Citations.*

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1. INTRODUCTION

Digital Therapeutics (DTx) represent an innovative intersection of technology and healthcare, leveraging software and digital tools to augment traditional medical practices. These include disease prevention, diagnosis, and management through digital means.

A notable example of DTx in action is the collaboration between Cure-Up Inc. and Keio University School of Medicine, which, on June 19, 2020, yielded an anti-smoking system. This system combines a breath analyzer, measuring exhaled carbon monoxide levels, with a digital program designed to support smoking cessation by promoting behavioral changes. This initiative received approval for manufacturing and sale as a medical device. Other significant DTx applications span a variety of health issues, such as a platform by Mitsubishi Tanabe Pharma Corporation aimed at enhancing the lifestyles of

diabetes patients, an app developed by Otsuka Pharmaceutical and Click Therapeutics for managing major depressive disorder (MDD), and a solution by Shionogi Pharmaceutical Co. in collaboration with Akili Interactive Inc. for treating attention deficit hyperactivity disorder (ADHD), among other innovations under development.

Parallel to these advancements, global patent filings seek to safeguard the intellectual property born from the creation of these digital therapies.

This study aims to dissect the primary motivators behind the surge in digital therapy solutions by analyzing patents within healthcare informatics and diagnostics realms, specifically focusing on DTx. These driving forces will be identified by examining key technologies and applications within the medical information domain, spotlighting the keywords that propel DTx development.

2. MATERIALS AND METHODS

Key drivers are identified as the pivotal keywords that promote the development of Digital Therapeutics (DTx). To analyze these key drivers, this study leverages the International Patent Classification (IPC) of 2021. The IPC offers a systematic, language-independent framework for categorizing patents and utility models across diverse technical fields. Through the patent database provided by Panasonic, we have collated data on patents, distinguishing both existing DTx technologies and potential DTx technologies. It is noted that even patents with identical IPC codes can fall under similar technological domains. By conducting a detailed text analysis, we have successfully extracted the key drivers associated with DTx technologies and potential technologies, based on the keywords linked to each.

Illustrated in Figure 1, our methodology encompasses Patent Application Analysis (utilizing Time Series Analysis), Citation Analysis, and Patent Technology Analysis. This comprehensive approach, underpinned by keyword extraction, draws upon IPC data, IPC descriptions, applicant details, filing dates, citations, and descriptions within patent databases.

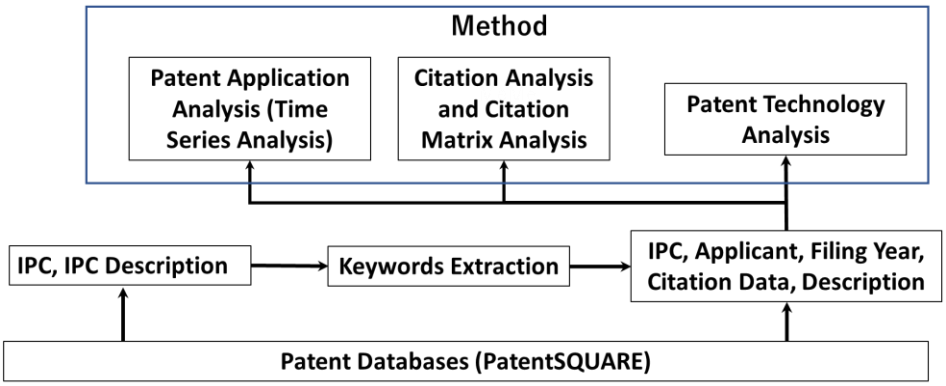

Figure 1. Methods and Process of the Analysis

2.1. Patent Application Analysis (Time Series Analysis)

This study aims to visualize the outcomes of patent analysis in digital therapy, exploring patent applications within the medical information field. By leveraging applied technology and indications as key drivers, we seek to thoroughly investigate the key drivers of digital therapy. The analysis will include:

Visualization through Quantitative Analysis: Employing patent data extracted from a comprehensive database to visually interpret the landscape of digital therapy innovation.

Utilization of the Panasonic Patent Database: This resource, which houses patent records published since 1971, serves as the foundation for our analysis, offering a broad spectrum of technological developments over time.

Analysis of Patent Applicants: By examining the data pertaining to patent applicants, we can clarify the dynamics of intellectual property rights management. This is particularly relevant for mapping out the collaborations in research and development undertaken jointly by medical institutions and corporations. This structured approach allows for a detailed examination of the evolution and key drivers in the field of digital therapy, providing insights into the technology trends and collaborative networks that shape this domain.

2.2. Citation Analysis and Citation Matrix Analysis

Here's a refined version of your text, aiming for clarity and conciseness while preserving the essence of the original information:

This study incorporates Patent Citation Analysis, a method premised on the notion that a patent's value correlates with its citation frequency. High citation counts not only suggest significant value but also indicate a crowded field of related research and development, highlighting areas of intense competition. We calculate the citation count per patent application to pinpoint sectors where patent applications hold high value amidst fierce competition.

Furthermore, we conduct a Patent Citation Matrix Analysis focusing on U.S. companies engaged in digital

therapy. This approach adapts the Boston Consulting Group's Product Portfolio Matrix, analyzing market growth and share-to assess patent value based on citation numbers (indicating growth potential) and the company's citation ratio (representing technological market share) [1]. This methodology enables the visualization of patent value within the digital therapy sector.

By extracting patent applications pertinent to digital therapy from the U.S. patent database, we reveal trends in patent technology via comprehensive citation analysis, thereby providing insights into the dynamics of innovation and competition in this emerging field.

2.3. Patent Technology Analysis

This study aims to identify the key drivers of digital therapy. It will do so by extracting distinctive patent applications using a combination of time series analysis, citation analysis, and citation matrix analysis. The focus will be on patent applications characterized by a high number of citations or a significant self-citation ratio, indicating their influence and relevance in the field. For a comprehensive patent technology analysis, details such as the applicant's name, the title of the invention, and the abstract of the patent application will be meticulously reviewed and presented.

3. Results

3.1. Keyword Extraction

To ensure global accessibility, patent documents are categorized using the International Patent Classification (IPC) system. This study involves an IPC analysis where patents are extracted from databases and statistically analyzed. Specifically, IPC codes "G16H" and "A61B" are pertinent to digital therapy, with "G16H" dedicated to "Healthcare Informatics," focusing on IT solutions for medical or healthcare data processing, and "A61B" covering "diagnosis, surgery, and personal identification." This classification was explored using a patent analysis website.

Table 1 illustrates the IPC codes "G16H", "A61B", among others, highlighting the diversity of technical fields inventions can span, often necessitating multiple IPC assignments. The codes are further detailed into subclasses for precision, such as:

"A61B 5/00" for diagnosis-related detection and measurement;

"G16H 10/60" for patient-specific data;

"G06Q 50/22" for social welfare services;

"G16H 50/20" for computer-aided diagnosis;

"G06Q 50/24" for educational management;

"G16H 50/30" for health indicators and risk assessment;

"G06F 19/00" for digital computing applications;

"G16H 40/63" for localized operations;

"A61B 5/11" for body movement measurements;

"A61B 6/00" for radiological equipment.

Furthermore, to deepen the patent analysis, keywords were extracted using the F-term, a technical classification by the Japan Patent Office (JPO) designed for computerized searches and focusing on technical features. Initial keywords were chosen based on digital therapy's technical aspects and indications or treatment sites. Then, F-term definitions containing these primary keywords were consulted to select secondary keywords (sub-terms). Table 2 displays the extracted primary keywords.

Patents featuring IPC codes "G16H" and "A61B", alongside the mentioned sub-term keywords, were searched within abstracts, with findings presented in separate analyses: one for patent application trends over time and another for citation patterns. The time series analysis shows the yearly distribution of patent applications per primary keyword, while the citation analysis focuses on the citation counts per keyword, organized by filing year. This search covered the period from September 1st to 10th, 2021.

Table 1. Description of IPC subclasses for precise therapeutics, detailing related to digital categorization of patents

IPC (Subclass)	Description.
A61B 5/00	Detection, measurement, recording, and identification for diagnosis
G16H 10/60	Patient-specific data
G06Q 50/22	Social welfare service
G16H 50/20	Computer aided diagnosis
G06Q 50/24	Educational Management or Guidance
G16H 50/30	Calculating health indicators, Individual health risk assessment
G06F 19/00	Digital computing, Data processing equipment or methods, Special applications
G16H 40/63	Local operation
A61B 5/11	Measuring movement of the whole body or parts thereof
A61B 6/00	Equipment for radiological diagnosis

Table 2. Extracted keywords extracted using the F-term classification, which is designed for computerized searches

Artificial Intelligence	Application	Biodata	Prediction	Big Data
Remote	Robot	Sensor	Medical Image	Image Processing
Diabetes	Obesity	Heart	Blood Vessel	CNS & Psychiatry
Digestive Organs	Respiratory Organs	Ophthalmology	Cancer/Tumors	Nose/Ears
Oral Cavity	Dentistry			

3.2. Time series analysis and citation analysis of patent applications

3.2.1. Time Series Analysis of the US Patent Applications

Tables 3 to 6 categorize patent applications over time, organized by the ascending total number of applications in each category. Table 3 details applications ranging from Sensor to Biodata. Table 4 covers applications from Remote to Nose and Ears.

Table 5 lists applications from Cancer/Tumor to Pain. Table 6 outlines applications from Obesity to Radiation Therapy.

The category with the most patent applications is Sensors, boasting 1,279 applications, followed by notable counts in Blood Vessels (913), Medical Imaging (792), Heart (655), and Central Nervous System (CNS)/Psychiatry (591), among others. Categories such as Apps (568), Artificial Intelligence (507), and Biometric Data (374) also show significant activity, with lower counts observed in areas like Dental (110), Robotics (100), and down to Radiation Therapy (4), indicating varied interest across fields. A marked increase in patent applications has been noted since around 2014, with even the categories traditionally receiving fewer applications experiencing growth since 2016.

Table 3. Time Series Analysis (Sensor to Biodata) providing a year-by-year breakdown of patent applications from 2005 to 2021 in categories from Sensor to Biodata, showing trends and the evolution of patent filings over time

Filing Year	Sensor	Blood Vessel	Medical Image	Heart	CNS/ Psychiatry	App	Artificial intelligence	Biodata
2005	1	1	0	0	0	0	0	0
2006	0	0	0	0	2	0	0	0
2007	3	1	0	0	1	0	0	0
2008	0	4	0	1	0	1	0	0
2009	0	2	0	2	1	1	0	2
2010	2	2	5	1	1	2	1	2
2011	6	2	1	2	2	0	0	1
2012	9	6	6	5	1	4	0	4
2013	13	20	12	10	7	8	2	3
2014	37	30	22	27	20	21	4	9
2015	60	60	48	46	30	29	9	18
2016	170	126	66	86	81	85	19	53
2017	188	102	112	92	57	71	55	54
2018	255	170	168	140	116	108	116	71
2019	253	195	187	110	136	118	140	66
2020	219	145	127	101	110	101	126	74
2021	63	47	38	32	26	19	35	17
Total	**1279**	**913**	**792**	**655**	**591**	**568**	**507**	**374**

Table 4. Time Series Analysis (Remote to Nose and Ears) providing a year-by-year breakdown of patent applications from 2005 to 2021 in categories from Remote to Nose/Ears, showing trends and the evolution of patent filings over time

Filing Year	Remote	Prediction	Sleep	Diabetes	Image processing	Respiratory organs	Taking Medicine	Nose/ Ears
2007	0	0	1	1	0	0	0	0
2008	0	0	0	1	1	0	0	0
2009	1	0	1	0	1	0	0	0
2010	3	1	0	2	0	0	2	0
2011	1	1	1	0	0	1	0	1
2012	5	4	1	5	0	0	1	0
2013	2	8	5	5	3	3	1	3
2014	9	12	12	10	2	6	1	1
2015	22	11	18	10	10	5	6	6
2016	36	31	39	23	10	21	13	16
2017	39	37	31	36	18	15	10	22
2018	78	55	58	47	36	27	34	36
2019	70	73	66	54	46	28	27	19
2020	83	61	49	47	30	28	26	20

Table 5. Time Series Analysis (Cancer/Tumor to Pain) providing a year-by-year breakdown of patent applications from 2005 to 2021 in categories from Cancer/Tumors to Pain, showing trends and the evolution of patent filings over time

Filing Year	Cancer/ Tumors	Dentistry	Robot	Genitourinary	VRAR	Big Data	Digestive Organs	Ophthal mology	Pain
2007	0	0	0	0	0	1	0	0	0
2008	1	0	0	0	0	0	0	0	0
2010	0	0	1	0	0	0	0	0	0
2011	0	0	0	0	1	0	1	0	0
2012	0	0	1	1	0	0	1	0	0
2013	1	1	0	1	0	0	1	1	1
2014	4	2	3	5	0	1	2	2	3
2015	9	3	3	4	2	4	3	1	1
2016	16	12	10	12	5	10	11	8	11
2017	15	15	10	12	12	12	7	6	4
2018	21	21	25	21	30	28	8	14	12
2019	31	31	27	28	22	16	14	12	12
2020	12	21	17	12	18	18	10	15	7
2021	4	4	3	2	3	2	6	3	4
Total	**114**	**110**	**100**	**98**	**93**	**92**	**64**	**62**	**55**

Table 6. Time Series Analysis (Obesity to Radiation Therapy) providing a year-by-year breakdown of patent applications from 2005 to 2021 in categories from Obesity to Radiation Therapy, showing trends and the evolution of patent filings over time

Filing Year	Obesity	Breast	Electrical	Diet	Game	Genetic	Allergy	Oral Cavity	Addictive Behavior	Infectious Disease	Radiation Therapy
2009	0	0	0	0	0	1	0	0	0	0	0
2010	0	0	0	0	2	0	0	1	0	0	0
2013	0	0	3	0	0	0	0	0	0	0	0
2014	0	0	1	0	0	2	0	0	0	0	0

2015	0	4	0	0	0	2	1	1	0	0	1
2016	5	1	5	2	2	1	6	1	1	0	0
2017	5	8	4	1	6	3	5	1	1	0	0
2018	8	12	2	5	5	5	2	1	0	1	0
2019	15	8	6	8	7	3	2	2	2	3	2
2020	12	4	7	10	3	4	4	2	2	2	1
2021	0	0	2	0	1	0	0	0	1	0	0
Total	**45**	**37**	**30**	**26**	**26**	**21**	**20**	**9**	**7**	**6**	**4**

3.2.2. Citation Analysis of the US Patent Applications

Tables 7 to 10 present a citation analysis over time, categorizing the data by the number of citations each major category keyword received. Table 7 details citations from Sensor to Remote. Table 8 enumerates citations from Sleep to VR/AR. Table 9 lists citations from Big Data to Nose and Ears. Table 10 outlines citations from Ophthalmology to Radiation Therapy. The category receiving the highest number of citations is Sensors, with 7,433 citations, closely followed by Blood Vessels (3,939 citations), Apps (3,140 citations), Heart (2,442 citations), and Medical Imaging (2,128 citations). Other notable fields include Central Nervous System/Psychiatry (1,759 citations), Remote (1,393 citations), and Sleep (1,283 citations), down to areas with fewer citations such as Radiation Therapy (8 citations), indicating the diverse impact of innovations across various fields. A significant uptick in citations is observed for patents filed from 2012 onwards, reflecting the growing influence and recognition of technological advancements in these areas.

Table 7. Citation Analysis (Sensor to Remote) showing the number of citations received per year for categories from Sensor to Remote

Filing Year	Sensor	Blood Vessel	App	Heart	Medical Image	CNS/ Psychiatry	Remote
2005	20	109	0	0	0	0	0
2006	0	0	0	0	0	7	0
2007	348	18	0	0	0	145	0
2008	0	122	3	49	0	0	0
2009	0	248	11	313	0	15	15
2010	12	28	29	22	83	7	458
2011	265	166	0	179	299	166	10
2012	742	225	111	68	212	0	39
2013	301	492	213	170	147	102	31
2014	1069	232	187	238	400	246	150
2015	474	413	193	394	145	153	127
2016	904	756	1717	304	153	252	181
2017	1699	347	246	441	246	155	105
2018	1289	438	212	202	208	393	192
2019	272	320	198	45	216	59	59
2020	38	25	20	17	19	59	26
Total	**7433**	**3939**	**3140**	**2442**	**2128**	**1759**	**1393**

Table 8. Citation Analysis (Sleep to VR/AR) showing the number of citations received per year for categories from Sleep to VR/AR

Filing Year	Sleep	Biodata	AI	Robot	Diabetes	Respiratory Organs	Prediction	VRAR
2007	145	0	0	0	18	0	0	0
2008	0	0	0	0	31	0	0	0
2009	15	261	0	0	0	0	0	0
2010	0	30	22	7	26	0	22	0
2011	165	1	0	0	0	165	6	6
2012	4	192	0	0	162	0	58	0
2013	69	54	132	0	91	46	69	0
2014	185	152	28	341	53	41	60	0
2015	161	99	81	1	95	51	45	142

2016	138	133	102	53	68	81	82	61
2017	48	127	186	45	67	8	81	121
2018	317	180	321	366	162	143	48	221
2019	28	22	114	154	29	154	158	18
2020	8	17	70	0	0	4	50	10
Total	**1283**	**1268**	**1056**	**967**	**802**	**693**	**679**	**579**

Table 9. Citation Analysis (Big Data to Nose and Ears) shows the number of citations received per year for categories from Big Data to Nose/Ears

Filing Year	Big Data	Taking Medicine	Image processing	Digestive Organs	Pain	Dentistry	Genitourinary	Cancer/ Tumors	Nose/ Ears
2007	59	0	0	0	0	0	0	0	0
2008	0	0	49	0	0	0	0	12	0
2009	0	0	9	0	0	0	0	0	0
2010	0	11	0	0	0	0	0	0	0
2011	0	0	0	165	0	0	0	0	0
2012	0	57	0	49	0	0	0	0	1
2013	0	3	132	0	7	2	2	1	4
2014	32	22	2	3	42	7	87	8	10
2015	51	148	36	22	16	24	8	49	18
2016	236	17	76	60	79	69	42	51	35
2017	53	28	18	9	17	69	5	10	43
2018	125	120	53	2	24	12	12	17	39
2019	15	79	32	6	9	28	24	10	5
2020	2	0	9	4	46	6	3	1	4
Total	**573**	**485**	**416**	**320**	**240**	**217**	**183**	**159**	**159**

Table 10. Citation Analysis (Ophthalmology to Radiation Therapy) showing the number of citations received per year for categories from Game to Radiation Therapy

Filing Year	Ophthalmology	Game	Obesity	Breast	Genetic	Diet	Allergy	Electrical	Addictive Behavior	Oral Cavity	Radiation Therapy
2009	0	0	0	0	11	0	0	0	0	0	0
2010	0	55	0	0	0	0	0	0	0	2	0
2011	0	0	0	0	0	0	0	0	0	0	0
2013	20	0	0	0	0	0	0	2	0	0	0
2014	10	0	0	0	4	0	0	0	0	0	0
2015	3	0	0	35	1	0	7	0	0	0	6
2016	37	7	19	0	3	8	13	12	14	4	0
2017	40	34	33	21	2	0	0	3	0	0	0
2018	9	9	2	12	6	1	0	2	0	0	0
2019	1	2	16	1	0	10	0	1	1	1	1
2020	0	0	4	0	0	4	0	0	1	3	1
Total	**120**	**107**	**74**	**69**	**27**	**23**	**20**	**20**	**16**	**10**	**8**

3.2.3. Number of citations per patent application

Table 11 illustrates the average number of citations received per patent application across various fields, highlighting the impact and recognition of technological advancements within the U.S. The keywords and their corresponding average citations are as follows:

Robotics leads with 9.67 citations per application, showcasing its significant influence. Big Data and VR/AR both follow closely, each with an average of 6.23

citations, indicating strong interest and research activity. Sensors (5.81) and Applications (5.53) also demonstrate notable impacts in their respective areas. Other key areas include Digestive Organs (5.00), Respiratory Organs (4.91), and Sleep (4.44), down to Diet (0.88) and Electrical Stimulation (0.67), reflecting a diverse range of research focuses and their varying levels of citation engagement. This distribution underscores the varying degrees of research attention and technological innovation across different domains, with robotics standing out as a particularly influential field.

Ranking	Major Item of Keywords	Citation/ Application	Ranking	Major Item of Keywords	Citation/ Application
1	Robot	9.67	18	Image Processing	2.6
2	Big Data	6.23	19	Addictive Behavior	2.29
3	VR/AR	6.23	20	Prediction	2.21
4	Sensor	5.81	21	Artificial Intelligence	2.08
5	Application	5.53	22	Radiation Therapy	2
6	Digestive Organs	5	23	Dentistry	1.97
7	Respiratory Organs	4.91	24	Ophthalmology	1.94
8	Sleep	4.44	25	Genitourinary	1.87
9	Pain	4.36	26	Breast	1.86
10	Game	4.12	27	Obesity	1.64
11	Taking Medicine	3.79	28	Cancer/Tumors	1.39
12	Remote	3.75	29	Genetic	1.29
13	Heart	3.73	30	Nose and Ears	1.25
14	Biometric Data	3.39	31	Oral Cavity	1.11
15	Diabetes	3.13	32	Allergy	1
16	CNS & Psychiatry	2.98	33	Diet	0.88
17	Medical Imaging	2.69	34	Electrical Stimulation	0.67

Table 11. Number of citations per patent application in the US, indicating the relative importance and research focus on these technologies in the US

3.3. Patent Technology Analysis

We conducted an analysis of the most-cited US patent applications by category (major term keywords). The patent technology analysis is conducted by referring to the applicant, the name of the invention, and the technology.

3.3.1. Patent Technology Analysis

(1) U.S. Patent Application Number: 14/203,243 (Citations: 345, Keyword: Sensor)

Applicant: CERCACOR LABORATORIES, INC.

Invention: Cloud-based physiological monitoring system

Technology Summary: The cloud-based physiological monitoring system includes sensors that communicate with the body to generate a data stream that responds to the physiological state of the body. The cloud server derives medical indicators based on combinations of physiological parameters.

(2) U.S. Patent Application Number: 13/36,783 (Citations: 299, Keyword: Medical Image)

Applicant: MYSKIN, INC.

Invention: Analysis method for tissue evaluation

Technology Summary: This invention involves the evaluation of skin using bioimpedance and fractional calculus, implementing methods and systems for assessing skin's moisture content based on bioimpedance and fractional calculus, and enhanced qualitative and quantitative parameters for analyzing water based on the "cone rod" principle of RGB and gray image data using photomagnetic properties.

(3) U.S. Patent Application Number: 12/469,236 (Citations: 246, Keywords: Blood Vessel, Heart, Biometric Data)

Applicant: SOTERA WIRELESS, INC.

Invention: Method to generate alarms/alerts based on patient's posture and vital signs

Technology Summary: The invention provides a body-worn monitor that measures vital signs (blood pressure, SpO2, heart rate, respiration rate, body temperature, etc.) while characterizing the patient's activity state (resting, walking, convulsing, falling, etc.).

3.3.2. Citation Matrix Analysis and Patent Technology Analysis of the Featured Company

Prominent U.S. companies identified in this study include Big Health (specializing in Insomnia), Pear Therapeutics (Substance Use Disorders), Click Therapeutics (Major Depressive Disorder), Noom (Health Care), Akili (Pediatric ADHD), Omada Health (Diabetes), Ellipsis Health (depression and anxiety), and Welldoc (Diabetes). For these selected companies, we performed a citation matrix analysis to assess the growth potential of their patents (measured by the number of citations) and their technological dominance (indicated by the company's citation ratio).

Figure 2 illustrates the outcomes of this citation matrix analysis for the noted U.S. firms. The self-citation ratio is plotted on the horizontal axis, while the vertical axis measures the total number of citations. A bold line intersects both axes at their averages, serving as reference lines for the analysis. The size of each bubble in the chart correlates with the number of patent application families owned by each company.

Table 12 ranks the companies based on the number of citations received, indicating the impact and recognition of their patents. Table 13 lists the companies by the percentage of self-citations, highlighting those with significant internal references.

Companies whose patents surpass the reference lines in both self-citation ratio and total citations demonstrate high patent value and strong technology control. In this study, Welldoc and Akili's patents met these criteria. Conversely, patents exceeding only in the number of citations, like those of Welldoc, Akili, Omada Health, and Click Therapeutics, are recognized for their high value, though they indicate lower technology occupancy.

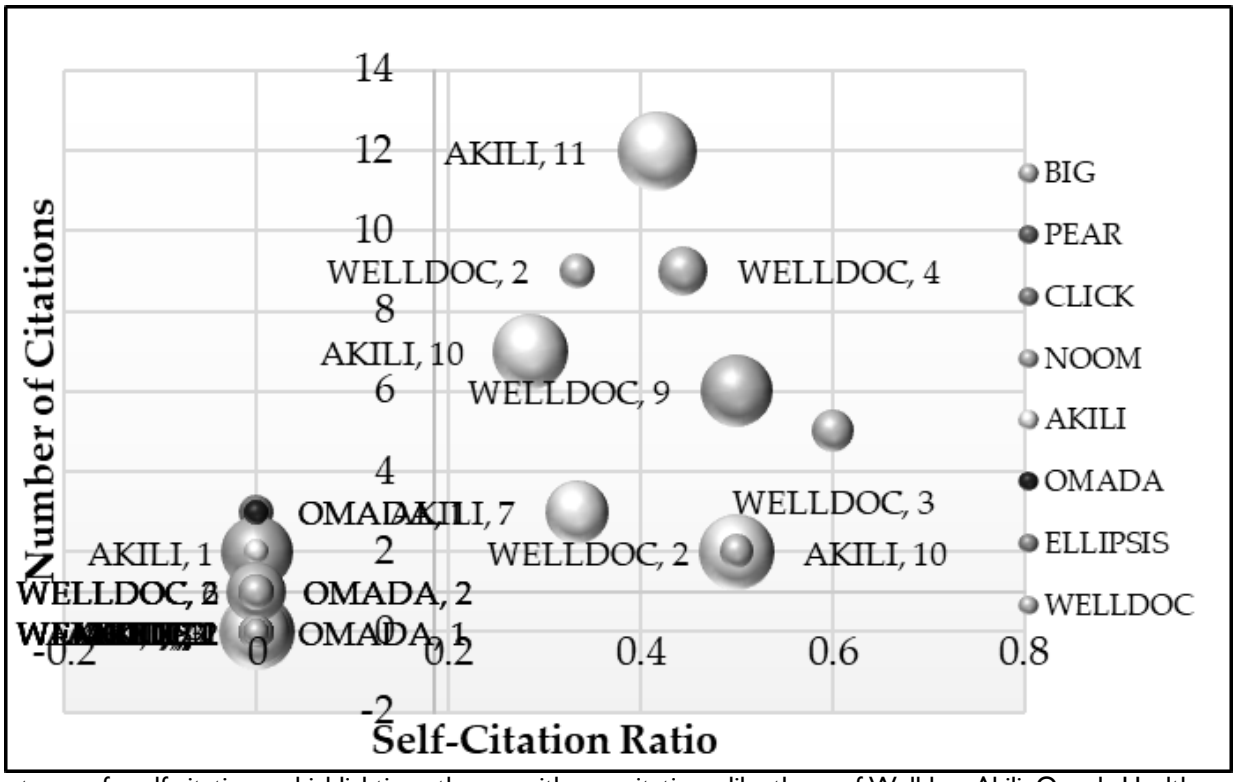

Figure 2. Citation Matrix Analysis of Featured Companie

Table 12. Top Featured Companies in Number of Citations, highlighting those with significant impact and recognition in the field of digital therapeutics

Citations	Family Patents	AE(Applicant)	PN(Publication Number of Family Patents)
12	11	AKILI	WO2015179522-A1; CA2949431-A1; AU2015264260-A1; KR2017007431-A; EP3146701-A1; US2017098385-A1; JP2017518856-W; EP3146701-A4; HK1236293-A0; AU2019271911-A1; US10559221-B2
9	4	WELLDOC	US2012246102-A1; WO2012129507-A1; US8838513-B2; WO2012129507-A8
9	2	SUDHARSAN B WELLDOC	US2014358581-A1; US9064040-B2
7	10	AKILI	WO2018039610-A1; CA3035122-A1; AU2017314831-A1; KR2019067774-A; EP3503809-A1; US2019216392-A1; CN110022768-A; JP2019534061-W; EP3503809-A4; HK40011871-A0
6	9	WELLDOC COMMUNICATIONS INC SYSKO S K	WO2008103827-A1; US2008306770-A1; US2017076053-A1; US9754077-B2; US2017364641-A1; US2019180855-A1; US2020242499-A1; US2020251199-A1; US10818389-B2
5	3	SYSKO S WELLDOC COMMUNICATIONS INC	US2007288266-A1; WO2007143083-A2; WO2007143083-A3

3	1	OMADA LLP (OMAD-Non-standard)	WO2011112655-A1
3	7	AKILI	WO2018081134-A1; AU2017347975-A1; CA3041648-A1; EP3531915-A1; JP2020500360-W; US2020060603-A1; EP3531915-A4
3	2	CLICK THERAPEUTICS	WO2016161416-A1; US2018075219-A1

Table 13. Top Featured Companies in Self-Citation Ratio, providing a perspective on how much of their patent citations come from their own later patents, which is an indicator of self-referencing in innovation

Self-Citations	Self-Citation Ratio	Citations	Family Patents	AE (Applicant)	PN (Publication Number of Family Patents)
3	0.6	5	3	SYSKO S WELLDOC COMMUNICATIONS	US2007288266-A1; WO2007143083-A2; WO2007143083-A3
3	0.5	6	9	WELLDOC COMMUNICATIONS INC SYSKO R A	WO2008103827-A1; US2008306770-A1; US2017076053-A1; US9754077-B2; US2017364641-A1; US2019180855-A1; US2020242499-A1; US2020251199-A1; US10818389-B2
1	0.5	2	2	WELLDOC	US2015112703-A1; US9881136-B2
1	0.5	2	10	AKILI	WO2018027080-A1; AU2017306678-A1; CA3032702-A1; US2019159716-A1; EP3494565-A1; KR2019075899-A; CN110024014-A; JP2019533215-W; EP3494565-A4; HK40011872-A0
4	0.444444	9	4	WELLDOC INC	US2012246102-A1; WO2012129507-A1; US8838513-B2; WO2012129507-A8
5	0.416667	12	11	AKILI	WO2015179522-A1; CA2949431-A1; AU2015264260-A1; KR2017007431-A; EP3146701-A1; US2017098385-A1; JP2017518856-W; EP3146701-A4; HK1236293-A0; AU2019271911-A1; US10559221-B2
3	0.333333	9	2	SUDHARSAN B WELLDOC INC	US2014358581-A1; US9064040-B2
1	0.333333	3	7	AKIL	WO2018081134-A1; AU2017347975-A1; CA3041648-A1; EP3531915-A1; JP2020500360-W; US2020060603-A1; EP3531915-A4
2	0.285714	7	10	AKIL	WO2018039610-A1; CA3035122-A1; AU2017314831-A1; KR2019067774-A; EP3503809-A1; US2019216392-A1; CN110022768-A; JP2019534061-W; EP3503809-A4; HK40011871-A0

3.3.3. Patent technology analysis of Featured Companies

Conducting a patent technology analysis on top patent applications from notable companies in the United States, focusing on the Number of Citations and Self-Citation Ratio. Patents whose technological content significantly differs from this study have been excluded.

(1) International Publication Number: WO2015179522-A1 Number of Citations: 12
Self-Citation Ratio: 0.42
Applicant: AKILI
Invention: Processor-implemented system and method for enhancing cognitive abilities by customizing cognitive training regimens for individuals.
Technology Summary: Presents a system and method for the implementation of customized cognitive training for individuals. It offers a processor-implemented method that enhances a user's cognitive abilities by tailoring cognitive training regimens through difficulty progression.

(2) U.S. Patent Application Number: US2012246102-A1

Number of Citations: 9
Self-Citation Ratio: 0.44
Applicant: WELLD0C
Invention: Adaptive analytical behavior and health assistant system and its usage method.
Technology Summary: Describes collecting at least one of a patient's behavioral, clinical, or personal information, learning patterns that trigger events, identifying interventions based on learned patterns, preparing and/or presenting/executing plans for the user.
(3) International Publication Number: WO2018039610-A1
Number of Citations: 7
Self-Citation Ratio: 0.29
Applicant: AKILI
Invention: Cognitive platform linked to physiological components.
Technology Summary: Introduces systems, methods, and devices including a cognitive platform that calculates individual performance metrics based on physiological measures, indicating cognitive abilities. Devices are configured to adapt challenges and/or interference to enhance cognitive functions.

3.4. Summary of Result

This study examined key drivers of digital therapy by analyzing patents in healthcare informatics and diagnostics (medical information field), using the applicable technologies and indications as key drivers. Table 14 shows the results of the analysis of the number of patent applications, number of citations, number of citations per patent application, and patented technologies. In the United States, there was a focus on specific sensors and devices and the algorithms that operate them. It would be important to advance research and development that aligns with the medical environment and needs.
Previous study analyzed patents filed with the United States Patent and Trademark Office and calculated the score of potential technologies on the basis of their thematic characteristics with respect to their digital capabilities and similarity to DTx technologies, and suggested the technologies use sensors to monitor patients' sleep and breathing patterns or especially symptoms related to environmental factors, for the target disorders [1].
Another previous report researched potential to pursue digital use-cases and analyzed DTx ecosystem in terms of therapeutics area (Endocrine, Central Nervous, System (CNS), Cardiovascular, Respiratory, Oncology, Immunology) and digital capabilities (Data tracking, Predictive analytics & algorithms, Communications & social media, Sensor & location services, Gaming & virtual reality, Artificial intelligence & machine learning) as highly potential markets of DTx.

Table 14. Key drivers based on the patent analysis showing the focus on technologies like sensors, medical imaging, and applications that are driving advances in this sector

Method of Analysis	US Patents
Number of Patent Application	Sensor/ Blood Vessel/ Medical Image/ Heart/ Central Nervous System/ Psychiatry/ Application
CI	Sensor/ Blood Vessel/ Application/ Heart/ Medical Image/ Central Nervous System & Psychiatry
Number of Citations per Patent Application	Robot/ Big Data / VRAR/ Sensor/ Application
Patented Technology	Technologies and algorithms related to the analysis, evaluation, and monitoring of patient information using sensors and devices

4. DISCUSSION

IPC "G16H" and "A61B" are assigned in the medical information field. Patent applications have been increasing since 2015 worldwide and since around 2012 in the US. In the field of medical information, the US has been one of the first countries in the world to file patent applications. Additionally, the US is considered to have been actively engaged in R&D in the medical information field. However, in terms of recent numbers of patent applications, many applications are filed in the U.S., China, and Korea, indicating that R&D is being conducted in these regions or that these regions are considered valuable as markets [1]. Major electronics manufacturers were the top applicants/right holders in the medical information field**Error! Bookmark not defined.**.
From the details of the IPC, the keywords "computing," "patient data," and "diagnostic radiology equipment" were found as applicable technologies, and "diagnosis" and "evaluation" as objectives.
Furthermore, in the medical information field, narrowing down the keywords in terms of applicable technologies and indications, in the US, there were many patent applications corresponding to applicable technologies and indications related to "medical images," "prediction," "sensors," "central nervous system/mental," and "biological data." It can be assumed that research and development in the medical information field are actively conducted in these applicable technologies and indications.
In terms of the number of citations in the medical information field, it is considered that in the US, a large number of highly valuable patent applications are filed in the fields of "medical imaging," "central nervous system/mental," "prediction," "biological data," "vascular," and "cardiac."

Based on the number of citations per patent application in the medical information field, it can be assumed that in the US, "apps," "cardiac," and "vascular" are most common, and the value per patent application is high in these applicable technologies and indications, and competition is intense.

As a result of the analysis of patent technologies with a large number of citations in the medical information field, in the US, "technologies and applications related to technologies and user interfaces that analyze medical images and patient data and lead to diagnostic evaluation and target conditions" have a large number of citations and are considered to have high value. The technologies developed in the US focus on data and user interfaces.

However, in the medical information field, there have been few patent applications for digital therapeutics for the direct purpose of disease prevention, diagnosis, and treatment, and they have been buried in many patent applications, making it difficult to distinguish between digital therapeutics and other medical information technologies.

From the details of the IPC, keywords such as "computing," "patient data," and "radiological diagnostic equipment" were identified as applied technologies, with "diagnosis" and "evaluation" seen as objectives. Furthermore, in the medical information field, narrowing down keywords from the perspectives of applied technologies and indications showed that in the United States, there were many patent applications corresponding to applied technologies and indications related to "Sensor," "Blood Vessel," "Medical Image," "Heart," "Central Nervous System/Psychiatry," and "Application." This suggests that research and development in these applied technologies and indications are actively being conducted in the medical information field.

Looking at the Number of Citations in the medical information field, the United States showed a high number of citations for "Sensor," "Blood Vessel," "Application," "Heart," "Medical Image," and "Central Nervous System/Psychiatry," indicating that many valuable patent applications have been filed.

From the Number of Citations per patent application in the medical information field, the United States had many citations for "Robot," "Big Data," "VRAR," "Sensor," "Application," suggesting that the value per patent application is high in these applied technologies and indications, and competition is becoming fierce.

The analysis of patent technologies with a high Number of Citations in the medical information field revealed that in the United States, technologies related to "the analysis, evaluation, and monitoring of patient information using sensors and devices, and the algorithms that enable these technologies" have many citations and are considered valuable. The United States is characterized by a focus on specific sensors, devices, and the algorithms that operate them.

However, in the medical information field, patent applications for digital therapeutics with direct objectives of disease prevention, diagnosis, and treatment were few and often buried among many other patent applications, making it difficult to distinguish digital therapeutics from other medical information technologies.

Next, by selecting notable companies in digital therapeutics in the United States and conducting a cited matrix analysis, it was found that patents believed to have high patent value and technology ownership include Welldoc's "system for providing an adaptive analytical behavior and health assistant based on learned patterns," "system for providing recommended treatments based on a model," "system for chronic disease management and health assessment," "system for managing patient treatment compliance," and Akili's "system for enhancing cognitive abilities by customizing cognitive training regimens for individuals," "cognitive platform that provides indicators of an individual's cognitive abilities based on computed personal performance metrics," "system that derives performance metrics as indicators of cognitive abilities and applies prediction models to generate indications of neurodegenerative states," "cognitive platform including computerized cue elements." Although Click Therapeutics' "smoking cessation system and remote patient monitoring device that provides digital therapeutic medication to patients and promotes smoking cessation" had lower technology ownership, it was considered to have high patent value.

The cited matrix analysis revealed that notable companies in digital therapeutics are developing high-value patent technologies in their respective categories. However, even among notable companies in digital therapeutics, there were patent technologies not directly aimed at digital therapeutic objectives such as disease prevention, diagnosis, and treatment, and it was sometimes not possible to extract digital therapeutics through cited matrix analysis alone. Moreover, extracting the key drivers of digital therapeutics as a whole from individual notable companies was challenging.

5. CONCLUSION

Key drivers of digital therapy were examined by analyzing patents in the fields of healthcare informatics and diagnosis (medical information field), using the applicable technologies and indications as key drivers.

In terms of the number of patent applications and citations in the US, there were many patents related to "Sensor", "Blood Vessel", "Medical Image", "Heart", "Central Nervous System", "Psychiatry", and "Application" indicating a common need in the US. Therefore, the US companies are expected to conduct R&D with an eye to overseas expansion. We suggest that the US companies have significant advantages and should utilize these technologies for DTx of the target disorders and pursue digital use-cases in the area as highly potential markets of DTx. The data that support the findings of this study are available from the corresponding author upon reasonable request.

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7. AUTHOR DISCLOSURE STATEMENT

The authors declare that (s)he has no relevant or material financial interests that relate to the research described in the manuscript.

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