

## Development Status and Trends of Digital Therapeutics in China: A Multi-dimensional Analysis Based on Approved Products (Postprint)

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### Abstract

**Background** Digital therapeutics (DTx), as an innovative digital intervention, is regarded internationally as prescribable “digital drugs” and demonstrates significant potential in chronic disease management, mental health, and other fields. China’s “Healthy China 2030” strategy supports the digital transformation of healthcare; however, there is currently a lack of systematic analysis of DTx products approved by China’s National Medical Products Administration (NMPA), and challenges such as an imperfect regulatory framework and insufficient clinical evidence exist. **Objective** To systematically analyze the characteristics of DTx products approved by the NMPA, summarize approval trends, indication distributions, and industry landscape, and provide a basis for regulatory policy optimization and industrial development. **Methods** The data for this study were primarily sourced from 8 NMPA medical device databases. Using independent keyword searches, a total of 20,107 candidate devices were generated, and after screening, 235 devices meeting the DTx definition were identified. Seventeen product characteristics were extracted, and statistical analysis was performed using SPSS 25.0 software. **Results** As of December 2024, the NMPA had approved 235 devices meeting the DTx definition, with the number of approvals increasing year by year since 2018 and a significant increase in 2022. The majority were domestically produced devices (n=227, 96.6%), primarily approved by local Medical Products Administrations (n=219, 93.2%). The products were mainly Class II medical devices (n=224, 95.32%), with the core function predominantly being disease treatment (n=207, 88.09%), and the most extensive application in the field of neurological diseases (n=108, 45.96%). The vast majority required prescription use (n=227, 96.6%), and most employed guided behavioral intervention techniques (n=135, 57.45%). Digital technology was dominated by online medical services (n=145, 61.70%), primarily targeting adults (n=163, 69.36%).

Manufacturers were concentrated in economically developed regions. Conclusion China's DTx industry exhibits policy-driven growth; however, bottlenecks exist such as an imperfect regulatory system, insufficient generation of clinical evidence, and a singular business model. It is recommended to improve regulatory policies, strengthen real-world evidence, and increase academic attention to support broader adoption of DTx.

## Full Text

### Development and Trends of Digital Therapeutics Industry in China: A Multidimensional Analysis Based on Approved Products

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## Abstract

**Background:** Digital Therapeutics (DTx), as an innovative digital interventional method, is internationally regarded as a prescription “digital drug” with significant potential in chronic disease management and mental health. China’s “Healthy China 2030” strategy supports healthcare digital transformation. However, there’s a lack of systematic analysis on DTx products approved by China’s National Medical Products Administration (NMPA). Also, there are challenges such as an imperfect regulatory framework and insufficient clinical evidence.

**Objective:** Conduct a systematic analysis of the characteristics of DTx products approved by the NMPA, systematically review approval trends, indication distribution, and industrial landscape, to provide evidence for regulatory policy optimization and industrial development.

**Methods:** Research data were primarily sourced from eight medical device databases of the NMPA. Using independent keyword searches, a total of 20,107 candidate devices were generated. After screening, 235 devices meeting the definition of DTx were identified. Seventeen product features were extracted, and statistical analysis was performed using SPSS 25.0 software.

**Results:** As of December 2024, the NMPA had approved 235 devices that meet the definition of DTx. The number of approvals has increased yearly since 2018, with a significant increase in 2022. Most are domestically produced (n=227, 96.6%) and approved (n=219, 93.2%) by local medical products administrations. The majority are Class II medical devices (n=224, 95.32%), with core functions mostly focused on disease treatment (n=207, 88.09%), widely used for nervous system diseases (n=108, 45.96%). Nearly all require prescriptions (n=227, 96.6%) and often use guided behavioral intervention techniques (n=135, 57.45%). Digital technologies mainly involve online medical services (n=145, 61.70%) and primarily target the adult population (n=163, 69.36%). Manufacturers are mostly in economically developed regions.

**Conclusion:** China’s DTx industry is growing due to policy support. But there are obstacles like an incomplete regulatory framework, insufficient evidence generation, and a lack of business models. It’s suggested to enhance regulatory policies, emphasize real world evidence, and raise academic attention to support wider DTx adoption.

**Keywords:** Digital therapeutics; Medical devices; Regulatory approval; Policy; National Medical Products Administration

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Digital therapeutics (DTx) represent evidence-based, high-quality software-driven, patient-centered interventions designed to prevent, manage, or treat diseases. In recent years, DTx has garnered global attention for its innovation, convenience, and practical utility. China’s “Healthy China 2030” initiative explicitly promotes digital transformation in healthcare and supports the

innovative development of digital health industries. Since 2022, DTx has been piloted in Hainan Province with plans for inclusion in medical insurance coverage. Currently, DTx encompasses critical areas including chronic disease management, mental health, and rehabilitation training. Numerous studies and practices have demonstrated DTx's substantial potential to improve patient compliance, reduce healthcare costs, and optimize resource allocation, gradually transforming existing healthcare service models and patient experiences.

Existing DTx research primarily focuses on three aspects: pre-market clinical trials, approval status, and product promotion strategies. Recently, clinical trials and approved products have attracted scholarly attention. However, these studies have limitations, including insufficient exploration of DTx products approved by China's National Medical Products Administration (NMPA) and inadequate extraction of product characteristics. Moreover, current exploration of DTx remains insufficient, and its development faces significant challenges. Therefore, this study aims to systematically analyze NMPA-approved DTx products by identifying devices that meet the DTx definition from NMPA databases and extracting information across multiple dimensions (such as digital technology, intended use, behavioral intervention techniques, target diseases, and intervention methods) to comprehensively map China's DTx industry and provide support for policy development and industrial growth.

## Methods

### Data Sources

This study utilized eight medical device sub-databases from China's NMPA, specifically covering domestic medical devices (registration, registration history, filing, filing history) and imported medical devices (registration, registration history, filing, filing history). To ensure comprehensive data collection, the International Digital Therapeutics Alliance (DTA) and DXY.cn (a Chinese healthcare platform) were also searched for supplementary data.

### Data Collection and Screening

NMPA's database query capabilities are limited, allowing searches only by registration number, registrant name, and product name, without direct export functionality. Additionally, anti-scraping measures complicate data acquisition. Therefore, this study employed manual retrieval strategies at the end of 2024. Based on NMPA's naming conventions for medical devices and considering that DTx products as software medical devices typically include "software" or "system" in their names, "software" and "system" were identified as core search keywords. To more comprehensively cover potential DTx product functions and application scenarios and reduce omission risk, the keyword list was expanded to include "treatment," "training," "rehabilitation," and "assessment." A trained student team independently searched the databases using these keywords, compiling preliminary results in Excel to generate 20,107 candidate devices.

Two researchers (FANG Qichuan and LIANG Jun) then screened the data, removing duplicate devices and those without software components, yielding 11,021 eligible candidate devices. Based on the precise and comprehensive definition of DTx published by the International Organization for Standardization (ISO) with DTA support, strict inclusion and exclusion criteria were developed for secondary screening, which were reviewed by domain experts. Inclusion criteria were: (1) software-driven—software used alone or in combination with drugs, medical devices, or other therapies; (2) evidence-based support—supported by randomized controlled trials, cohort studies, case-control studies, or other evidence; (3) disease intervention—used for disease prevention, management, or treatment; (4) patient-centered—intended for use by patients or their families, with or without medical supervision. Exclusion criteria were: (1) hardware-based interventions; (2) software providing only data collection/analysis/alerting/diagnosis without disease prevention, management, or treatment; (3) devices for physician use only, not applicable to patients or families; (4) lacking official approval, registration, or certification; (5) missing basic product information (e.g., product name, company name, approval date).

To ensure screening consistency, two researchers independently screened 40 identical device samples, achieving a Kappa coefficient of 0.812 ( $P < 0.01$ ), indicating high agreement. When disagreements arose, a third researcher (XIANG Peng, editor of *Digital Health and Digital Therapeutics Technology Rules and Application Guidelines* authorized by DTA) provided final arbitration to reach consensus. After consistency evaluation, the two researchers independently screened remaining candidate devices according to established criteria, ultimately identifying 235 devices meeting the DTx definition. All devices were reviewed by the third researcher (XIANG Peng) to ensure accuracy and reliability. The screening flowchart is shown in [Figure 1: see original paper].

### Data Extraction and Standardization

To ensure comprehensive and useful data for subsequent comparison and querying, this study developed an information extraction framework. Based on analysis of DTx characteristic extraction in previous studies, the framework encompassed 17 product features across three dimensions: product approval information (e.g., approval date, regulatory class), product characteristics (e.g., function classification, digital technology, target disease, target audience, software type, behavioral intervention technologies), and manufacturer information (e.g., manufacturer size, province). Specific definitions for each feature are provided in . Data extraction was conducted collaboratively by two researchers (FANG Qichuan and LIANG Jun) ( $\text{Kappa} = 0.817$ ,  $P < 0.01$ ). When disagreements occurred during extraction, independent review was followed by arbitration from a third expert (XIANG Peng or LEI Jianbo) to ensure scientific and professional decision-making.

## Statistical Analysis

SPSS 25.0 software was used for statistical analysis. First, descriptive statistics characterized NMPA-approved DTx devices and their manufacturers. Second, correlations were analyzed between risk level (regulatory class), healthcare dependency (behavioral intervention technology), and other features. Statistical methods were selected based on data type: Kruskal-Wallis test for unordered categorical variables, Wilcoxon test for binary variables, and Kendall's tau-b rank correlation coefficient for ordered categorical variables. All tests used  $P < 0.05$  as the significance threshold. Data were entered and organized using Excel 2021, with visualization performed using Origin 2021.

## Results

### Approval Trends and Characteristics

As of December 2024, the NMPA had approved 235 devices meeting the DTx definition. The earliest approval occurred in 2009. China's first internationally recognized DTx product was ZhiLan Health's hepatitis B mother-to-infant blocking DTx, first approved by NMPA in November 2019. Prior to this, NMPA had already approved 23 devices meeting the DTx definition. Since 2018, annual approval numbers have increased progressively, with a significant surge in 2022 (from 18 in 2021 to 52 in 2022). Most approved DTx devices are domestically produced ( $n=227$ , 96.6%). In terms of approval authorities, most devices were approved by local medical products administrations, with Hunan Province approving the most ( $n=88$ , 37.4%), followed by Guangdong ( $n=23$ , 9.8%) and Jiangsu ( $n=22$ , 9.4%), as shown in [Figure 2: see original paper].

### Product Characteristics

Main characteristics of approved DTx products are presented in and [Figure 3: see original paper]-[Figure 5: see original paper]. The majority are Class II medical devices ( $n=224$ , 95.32%), primarily for disease treatment ( $n=207$ , 88.09%), with the widest application in nervous system diseases ( $n=108$ , 45.96%). A small proportion are Class III devices ( $n=11$ , 4.68%), mostly for disease management in endocrine, nutritional, and metabolic diseases. Notable device numbers also exist for eye and adnexa diseases ( $n=50$ , 21.28%) and mental/behavioral disorders ( $n=48$ , 20.43%), as shown in [Figure 3: see original paper].

Nearly all DTx products require prescriptions ( $n=227$ , 96.60%), with most employing guided behavioral intervention techniques ( $n=135$ , 57.45%). These products primarily provide computer-based cognitive correction therapy ( $n=62$ , 26.38%), exercise therapy ( $n=39$ , 16.60%), and health status monitoring ( $n=35$ , 14.89%). Notably, most non-prescription DTx products use fully automated behavioral intervention technologies ( $n=6$ , 75.00%) and focus on health status monitoring, as shown in [Figure 4: see original paper].

Most DTx products utilize online medical services ( $n=145$ , 61.70%), followed

by mobile health (n=51, 21.70%) and immersive technologies (n=22, 9.36%), with relatively limited application of artificial intelligence and machine learning (n=15, 6.38%) and other digital technologies. The majority target adults (n=163, 69.36%). Mobile health products typically deliver services through approved devices or mobile applications, as shown in [Figure 5: see original paper].

### Manufacturer Characteristics

After compiling NMPA-approved DTx products and removing duplicate manufacturers, 171 distinct DTx manufacturers were identified. These manufacturers are concentrated in economically developed regions, with relatively high numbers in Guangdong (n=16, 9.36%), Jiangsu (n=16, 9.36%), Zhejiang (n=17, 9.94%), and Shanghai (n=9, 5.26%). Notably, Hunan (n=72, 42.11%) ranks first nationally by a significant margin. In terms of enterprise size, the vast majority are micro or small enterprises (micro: n=77, 45.03%; small: n=76, 44.44%), as shown in [Figure 6: see original paper].

### Correlation Analysis

Kruskal-Wallis tests revealed significant correlations between device risk level and function classification (H=75.021,  $P<0.01$ ), digital technology (H=30.331,  $P<0.01$ ), target disease (H=168.822,  $P<0.01$ ), target audience (H=36.588,  $P<0.01$ ), software type (H=17.236,  $P=0.001$ ), and intervention method (H=104.347,  $P<0.01$ ). Healthcare dependency also showed significant correlations with function classification (H=48.769,  $P<0.01$ ), digital technology (H=17.864,  $P=0.003$ ), target disease (H=65.306,  $P<0.01$ ), target audience (H=25.441,  $P<0.01$ ), software type (H=10.648,  $P=0.014$ ), and intervention method (H=74.380,  $P<0.01$ ). Wilcoxon tests indicated significant correlations between healthcare dependency and import status ( $Z=-9.184$ ,  $P<0.01$ ) and prescription requirement ( $Z=-9.385$ ,  $P<0.01$ ). Kendall's tau-b tests further showed significant correlations between risk level and healthcare dependency ( $\tau=0.341$ ,  $P<0.01$ ) and manufacturer size ( $\tau=0.225$ ,  $P<0.01$ ).

### Discussion

This study reveals China's DTx regulatory model and market development trends. Currently, China has not issued specialized regulatory documents for DTx products, instead managing them within the existing software-based medical device approval system. In recent years, DTx product approvals have increased annually, likely driven by government initiatives to accelerate DTx development. For example, in 2021, Hunan Province pioneered a reduction in Class II medical device approval time from 80 to 40 working days, attracting numerous DTx enterprises and making the region an industry hub (n=72). In the same year, Zhejiang Province established China's first DTx industrial park, while Hainan Province incorporated DTx industry development into its 2022 provincial plan. These policy factors likely collectively drove the substantial

increase in DTx approvals in 2022.

China's DTx regulatory model remains in development. In contrast, European countries like Germany and Belgium have established dedicated approval pathways, while the United States launched the Digital Health Pre-Certification Program to provide expedited review for DTx products. Regarding reimbursement, some European countries including Germany, France, and Belgium have integrated DTx into their healthcare systems, and the U.S. Centers for Medicare & Medicaid Services (CMS) included three reimbursement codes for Digital Mental Health Interventions (DMHT) in its 2025 Physician Fee Schedule proposed rule. In China, only Hainan Province plans to include DTx in medical insurance reimbursement starting June 2025.

In terms of indications, DTx for nervous system diseases and eye/adnexa diseases dominate China's market. The development of DTx for cognitive disorders likely stems from rapid population aging increasing the number of patients. By the end of 2024, China's population aged 60 and above reached 310.31 million, creating substantial market demand. In ophthalmology, DTx development focuses primarily on amblyopia in children and myopia prevention/control in adolescents. These conditions require long treatment cycles with early intervention and recovery characteristics that directly influence parental payment willingness. Overall, China's DTx indication distribution differs significantly from other countries, where markets in the U.S., Germany, and Belgium may focus more on chronic disease management and mental health interventions.

DTx market performance is influenced by multiple factors including clinical trial uncertainty, insufficient patient acceptance, weak academic research foundations, and limited clinician trust. These factors have constrained DTx promotion in the U.S., Germany, and Belgium. In contrast, China's government-led model has effectively increased domestic approval numbers, though its long-term impact remains uncertain. To overcome promotion barriers, China should establish an evidence-based medicine strengthening mechanism within its policy framework. Current policies plan breakthroughs in three areas: (1) incorporating DTx into medical service item catalogs to enable payment pathways; (2) establishing hospital-enterprise cooperation pilots to drive clinical translation; and (3) strengthening real-world research requirements for clinical validation. These measures may optimize business model feasibility and enhance adoption willingness by improving evidence quality, though their long-term ecosystem impact requires systematic evaluation. Meanwhile, DTx manufacturers should continuously drive underlying technological innovation and explore diversified business models to improve market penetration. Academia must deepen evidence-based research, promote technological breakthroughs, and complete the evidence generation-transformation chain to ultimately facilitate clinician and patient awareness-adoption loops.

## Limitations

This study has several limitations. First, during data collection, searching NMPA-approved DTx products using selected keywords may have omitted some products, though this study represents one of the most comprehensive DTx product inclusions to date. Second, the information extraction framework may not capture all product characteristics, though the selected features represent key attributes and constitute a relatively comprehensive framework. Future research should explore solutions to DTx bottlenecks, including how to facilitate behavior change, gain physician support, improve patient compliance, and maximize therapeutic effects. Additionally, analyzing real-world clinical application and validation of DTx products would provide deeper insights and explore mature, sustainable development models.

## Author Contributions

FANG Qichuan: conceptualization, design, implementation, statistical analysis, figure/table preparation, manuscript writing. LIANG Jun: primary research objective, conceptualization, design, implementation, manuscript revision, quality control, overall responsibility, supervision. JIAO Xiaoyi: data collection and organization, manuscript revision, quality control. LIU Yongcheng: manuscript revision, quality control. ZHANG Lifang: data collection and organization. ZHANG Huaqing, HE Yunfan, DONG Lei: research design assistance. XIANG Peng: implementation, quality control. LEI Jianbo: primary research objective, conceptualization, design, implementation, quality control, overall responsibility, supervision.

The authors declare no conflicts of interest.

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