Digital Therapeutics Market Study

Independent Market Research Report

Confidential For

Date : December 30, 2024

For and on behalf of
Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.

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Frost & Sullivan
Dec, 2024

Table of Contents

1 Analysis of Digital Therapeutics (DTx) Market

- 1.1 Overview of Digital Therapeutics
- 1.2 Development Path and Timeline of Digital Therapeutics
- 1.3 Classification of Digital Therapeutics
- 1.4 Trends and Advantages of Combining Digital Therapeutics with AI and Digital Big Data
- 1.5 Key Value of Digital Therapeutics
- 1.6 FDA and NMPA Approved Digital Therapeutics Products
- 1.7 Analysis of Digital Therapeutics Pipeline Distribution
- 1.8 Analysis of Business Model of Digital Therapeutics
- 1.9 Competitive Landscape of Leading Digital Therapeutics Companies
- 1.10 Digital Therapeutics Product Registration Certification Process

Table of Contents

1 Analysis of Digital Therapeutics (DTx) Market

- 1.11 Main Agencies Regulating Digital Therapeutics Industry in China
- 1.12 Regulations of Digital Therapeutics Industry in China
- 1.13 Supportive Policies of Digital Therapeutics Industry in China
- 1.14 Market Size of Digital Therapeutics in China and Globally, 2018-2030E
- 1.15 Entry Barriers of Digital Therapeutics Industry in China
- 1.16 Growth Drivers of Digital Therapeutics Industry in China
- 1.17 Future Trends of Digital Therapeutics Industry in China
- 1.18 Major Industry Risk and Substitutes in China

2 Cognitive Impairment Digital Therapeutics Market

Overview of Digital Therapeutics (DTx)

- Digital therapeutics (DTx) refers to delivering medical therapies directly to patients using evidence-based, clinically evaluated software to treat, manage, and prevent a broad spectrum of diseases and disorders. It is a subset of digital medicine, which belongs to the broad term digital health.

Digital Health

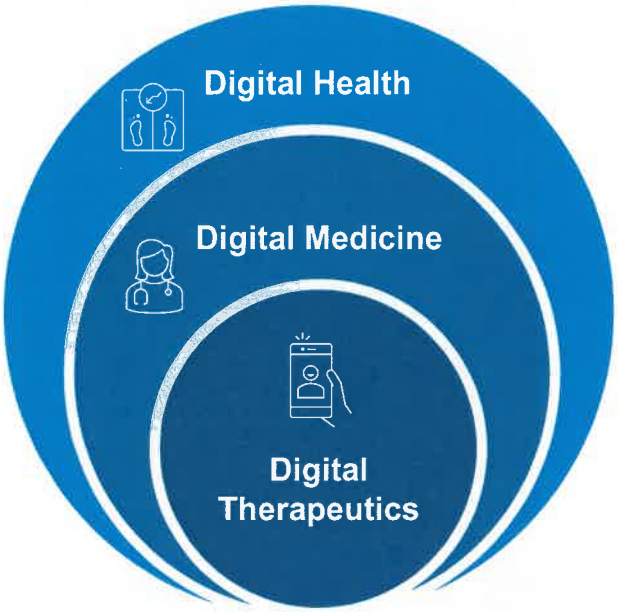
Digital health is an umbrella term that covers many types of technology used in the healthcare community. It includes health management for not only patients but also healthy people.

Digital Medicine

Digital medicine focus on patients with specific diseases. It is evidence-based technology that can measure or intervene in health condition.

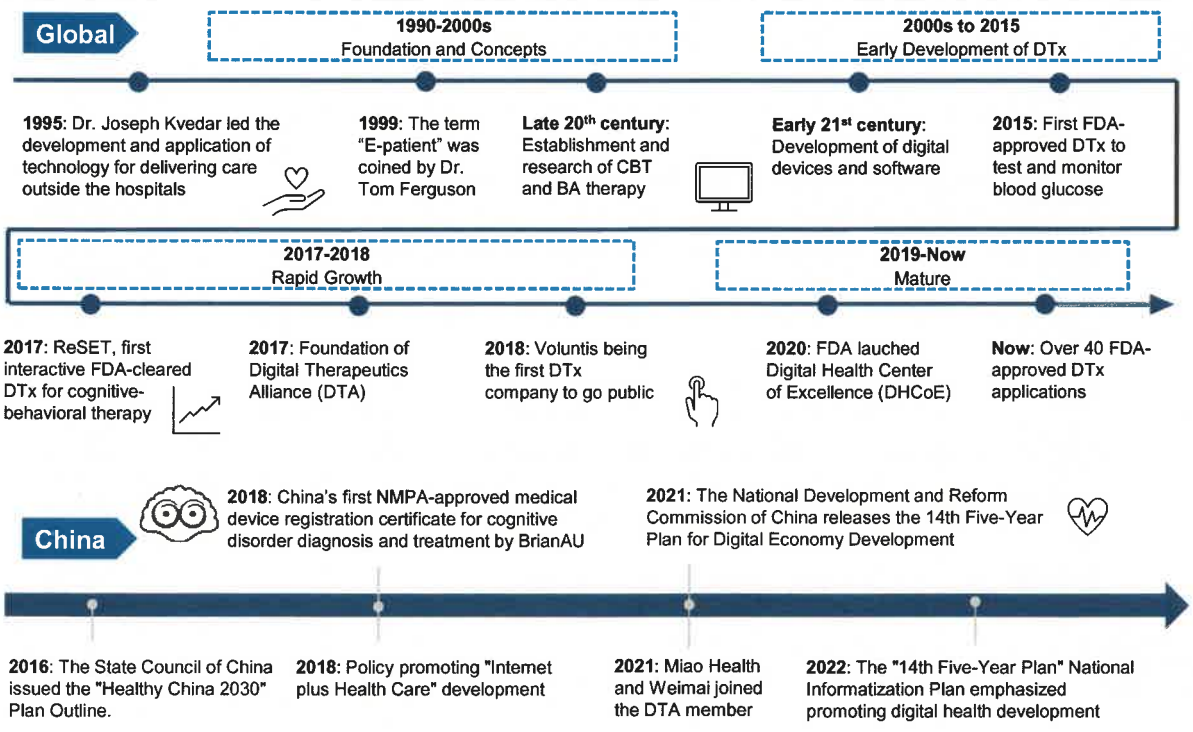
Digital Therapeutics

Digital therapeutics is a narrower concept with software-based and clinically validated technologies for treating, managing and preventing diseases. It is still a rather new area being explored.



Source: Frost & Sullivan Analysis

Development Path and Timeline of Digital Therapeutics



Source: Literature Review, Frost & Sullivan Analysis

Classification of Digital Therapeutics

- Digital therapeutics can be classified based on their usage, functions, and indications. Digital therapeutics can be used alone or with drugs and medical devices. Based on functions, they could be used for assessment, intervention, and management. There are a variety of indications for digital therapeutics.

Usage

Software

A digital intervention based on a medical principle, medical guidelines, or standard treatment that is independently operated by software to achieve disease intervention

Software + Medications or Medical devices

be used in combination with medications or medical devices

Functions

Application Classification

- **Lung:** Asthma, chronic obstructive pulmonary disease (COPD), etc.
- **Heart:** Cardiovascular disease
- **Brain:** Psychiatric and neurological diseases
- **Endocrine:** Diabetes, metabolic syndrome, obesity, etc.
- **Motor system diseases:** Musculoskeletal pain, osteoarthritis
- **Eye:** strabismus, etc.

Source: Frost & Sullivan analysis

Classification of Digital Therapeutics

Non-Medical

Definition:
- Non-medical grade DTx refers to applications designed to help individuals maintain wellness and prevent diseases by providing DTx-based preventive care with a focus on cognitive and mental health

Benefits:
- Prevention before treatment: DTx will be doing this across people's lives creating comprehensive preventive care
- Emphasis on cognitive and mental health

Application areas:
- Health promotion
- Disease prevention
- Self-diagnosis
- Management
- Rehabilitation and palliative care
- Epidemic or pandemic care

Classification Criteria:
- The safety and efficacy are typically not validated through rigorous evidence-based clinical processes

Medical

Prescription | **Internet hospitals**

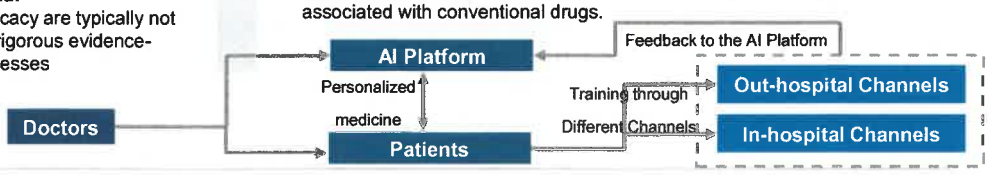
Definition:
- Medical-grade DTx are typically required to undergo rigorous clinical evaluation processes to demonstrate safety and efficacy in clinical trials and can be prescribed as effective first-line treatments.

Evidence-based:
- Digital therapeutics is the therapy that follows scientific evidence and emphasizes the physician's clinical, combined with the clinical experience, medical conditions and the patient's circumstances and choices, to develop a rational plan of diagnosis and treatment.

Similar to traditional biologics or drugs, DTx:
- Directly treat diseases
- Demonstrate safety and efficacy in clinical trials

Prescription DTx:
- offer patients effective first-line treatment without the side effects associated with conventional drugs.

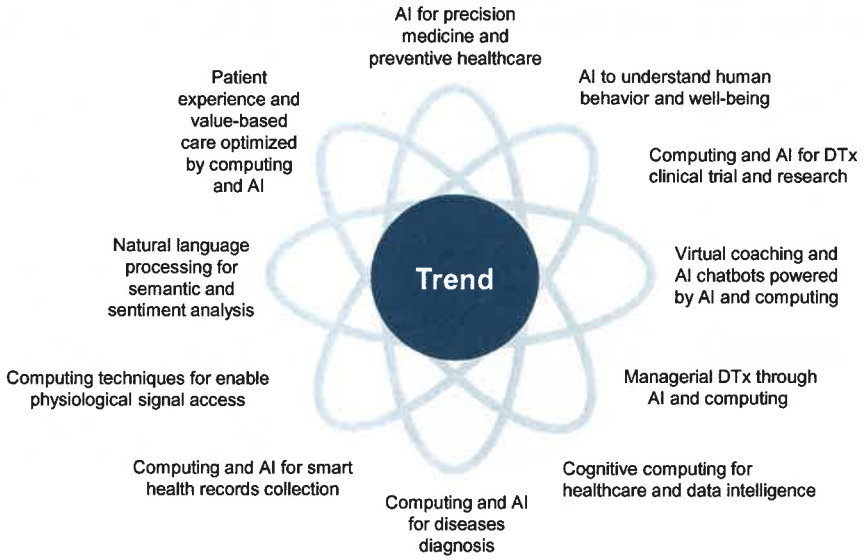
Internet hospitals can be combined with prescription DTx:
- Manage appointments or renew prescriptions
- Can prescribe treatment for related diseases online
- Internet hospitals purchase DTx and prescribe the corresponding prescription to patients



Source: Literature Review, Frost & Sullivan Analysis

Trends of Combining Digital Therapeutics with AI and Digital Big Data

- AI is a technology revolutionising the digital therapeutics industry. AI algorithms can analyse large amount of data to identify patterns and trends that can impact the design of DTx. This indicates a robust and rapidly expanding market with many opportunities for businesses and investors in the healthcare industry.



Source: Literature Review, Frost & Sullivan Analysis

Combining Digital Therapeutics with AI and Digital Big Data

- The Digital therapeutics industry has invested heavily in advanced AI technologies and big data that are more accurate and interpretable. The sophisticated AI models can leverage big data to improve the user experience and the therapeutic effects of DTx. As a result, DTx has become more intuitive to use and provides valuable feedback to patients and physicians. AI-driven solutions will only continue to become more prevalent and beneficial for healthcare providers and patients alike.

Studies have shown that AI can improve the accuracy of diagnoses by more than 40% compared to traditional methods. In some cases, AI outperforms experienced professionals in terms of iagnostic accuracy

AI-driven therapeutics can use patient data to identify potential risks and develop treatment plans that better meet their specific needs. DTx also help analyse patient challenges and needs based on their behaviour.

AI can automate many routine tasks, such as maintaining records, data entry and scan analysis. With less time being spent on administrative tasks, medical professionals can place more focus on patient care, which is especially important when the need for healthcare is driving by our aging population

Source: Literature Review, Frost & Sullivan Analysis

Key Value of Digital Therapeutics

- Digital therapeutics shows promise for improving patient outcomes and reducing healthcare costs. It complements and betters areas where traditional healthcare falls short, such as lack of long-term adherence to treatment and the time and financial costs of hospital visits. Therefore, DTx creates significant value for patients, healthcare providers, payers, and pharmacy companies.

Patients: Improve the accessibility of healthcare

- **Manage health from home:** there is no need to travel to appointments, so patients can simply use their DTx app and are more likely to stay on track with their treatment plan.
- **Receive personalized treatment:** the sophisticated AI models can tailor treatment plans to each patient's symptoms, progress, and demographic characteristics and deliver better results.
- **Save Money:** there is no need to pay for office visits, procedures, unnecessary medications or travel.

Payors: reduce expenditures

- Reduced medical costs can help insurers control costs and decrease employer business premium expenses

Healthcare providers: improve patient care

- **Increase efficiency:** DTx help track patient changes and help with diagnostics and medications.
- **Expand care:** DTx extend care despite a shortage of physicians and provide help when needs occur outside of normal office hours

Pharmacy companies: increase competitiveness

- **Target marketing:** DTx can provide timely data feedback, which help companyies capture potential consumers and send targeted information.
- **Real-world data: DTx record real-world data, helping** companyies to evaluate the effectiveness of their products, which carries significant value for R&D

Source: Literature Review, Frost & Sullivan analysis

Key Value of Digital Therapeutics(For patients)

- DTx serves as an effective therapy for a variety of indications which traditional drug therapies cannot address on its own, or at all. DTx also reduces barriers to care by enabling patients to use digital solutions from the comfort of their own homes, reducing the cost of care and the need for travel, while enabling the delivery of personalized treatment plans tailored to each patient's symptoms, progress and demographics through the use of sophisticated AI models. By automating and digitizing healthcare services, DTx offers significant potential for cost savings for patients.C

Personalized care

- **Improve Patient engagement:** DTx can deliver a personalized therapeutic intervention based on the patient's needs and tailored to their outcomes and abilities.
- **Encourage and drive behavioral change:** DTx products can provide patients with real-time results and insights to help reinforce healthy behaviors, provide timely interventions, and celebrate progress

Save money

- **Optimizing treatment pathways:** DTx can have a direct economic impact by lowering the cost compared to traditional treatment avenues and accelerating progress through continuous treatment.
- **Service scope not limited by geography:** There is no need to pay the offline medical expenses and related travel costs

No time and geographic barriers

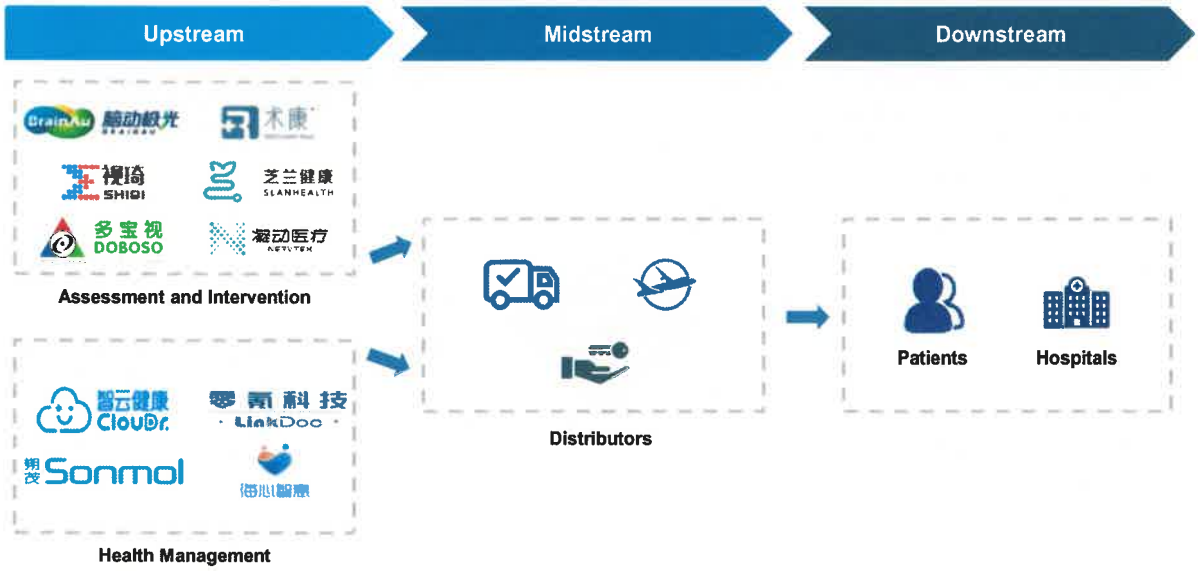
- **Deliver high quality therapies to underserved populations:** Providing medical services to residents in Settings with varying degrees of medical infrastructure has expanded access to medical services
- **Easily scale and add accessibility through patient-owned devices:** Patients can receive high-quality medical services anytime and anywhere, and the privacy of the medical service process is improved

Provide advanced treatment options

- **Improve diagnostic accuracy:** DTx can reduce the misdiagnosis rate and improve the diagnostic efficiency. There's currently no cure for Alzheimer's disease. But there is medicine available that can temporarily reduce the symptoms. DTx provides a new way of delivering treatment for **behavioral health** and other specialties

Value Chain of Digital Therapeutics

- The value chain of digital therapeutics industry involves upstream digital therapeutic enterprises, medical cloud platform service providers, and digital therapeutic service operators, midstream distributors and logistic providers, and downstream end-users which are usually hospitals and patients.



Source: Frost & Sullivan analysis

FDA Approved Digital Therapeutics Products (1/2)

- Digital therapeutics are considered and recognized as medical devices. These products are regulated under the software as a medical device (SaMD) framework, and they can be classified either through the 510(k) pathway or the de novo pathway. Below are the list of current FDA-approved digital therapeutics products.

Product Name	Company	Indication	Pathway	Approval Year
Dario	LabStyle Innovations	Type 1,2 diabetes	510(k)	2015
Insulia	Voluntis	Type 1,2 diabetes	510(k)	2016
Inpen	Companion Medical	Type 1,2 diabetes	510(k)	2016
reSET	Pear Therapeutics	Substance use disorder	De novo	2016
Natural Cycles	Natural Cycles	Birth control	De novo	2017
isageRX	Amalgam Rx	Type 2 diabetes	510(k)	2017
MindMotion Go	Mindmaze	Neurorehabilitation	510(k)	2017
My Dose Coach	Sanofi	Type 1, 2 diabetes	510(k)	2017
Kaia Health	Kaia Health	Musculosketetal pain	De novo	2017
reSET-O	Pear Therapeutics	Opioid use disorder	510(k)	2018
Freespira	Palo Alto Health Sciences	Post-traumatic stress disorder	510(k)	2018
Propeller	RESMED (Propeller Health)	Chronic obstructive pulmonary disease	510(k)	2018
TALi Train	TALI Digital	Attention impairment	510(k) exempt	2018
leva	Renovia, Inc	Urinary incontinence	510(k)	2018
myPKFiT	Baxalta	PK dosing for Advate	510(k)	2018

Source: FDA, Frost & Sullivan Analysis

FDA Approved Digital Therapeutics Products (2/2)

Product Name	Company	Indication	Pathway	Approval Year
d-Nav	HYGIEIA	Type 1,2 diabetes	510(k)	2019
Somryst	Pear Therapeutics	Chronic Insomnia	510(k)	2019
Oleena	Voluntis	Cancer	510(k)	2019
BlueStar®	Welldoc	Type 1,2 diabetes	510(k)	2020
EndeavorRx	Akili Interactive Labs	Pediatric attention deficit hyperactivity disorder	De novo	2020
Nerivio	Theranica	Migraine	510(k)	2020
Nightware	NightWare	Post-traumatic stress disorder	De novo	2020
Vorvida	Orexo	Alcohol use disorder	De novo	2020
Parallel	Mahana Therapeutics	Irritable bowel syndrome	De novo	2020
Deprexis	Orexo, GAIA AG	Depression	510(k)	2020
Sleepio	Big Health	Insomnia	FDA's enforcement discretion	2020
RelieVRx	AppliedVR	Pain relief	De novo	2021
Mahana	Mahana Therapeutics	Irritable bowel syndrome	510(k)	2021
BiovitalsHF	Biofourmis	Congestive heart failure	510(k)	2021
EaseVRx	AppliedVR	low back pain	De Novo	2021
SparkRx®	Limbix	Adolescent depression	EUA	2021
Cognoa ASD Diagnosis Aid	Cognoa, Inc.	ASD	De Novo	2021
Kaiku Health	Elekta	Cancer care	FDA's enforcement discretion	2021
Luminopia One	Luminopia, Inc.	Amblyopia	De Novo	2022
SleepCheckRx	ResApp Health	Obstructive sleep apnoea	510(k)	2022
Daylight	Big Health	Generalized anxiety disorder	FDA's enforcement discretion	2022
BT-001	Better Therapeutics	Type 2 diabetes	De Novo	2023
Stanza	Swing Therapeutics, Inc.	Fibromyalgia symptoms	De Novo	2023

Source: FDA, Frost & Sullivan Analysis

NMPA Approved Digital Therapeutics Products (1/2)

- Currently, there is no specific approval channel for digital therapeutics in China. They are now approved according to medical device regulations. Based on the level of risk posed to patients, they are categorized into three classes, most of which belong to Class II. Among the approved digital therapeutics, most are for cognitive disorders and visual training.

Registration Certificate No.	Product Name	Company	Type	Approval Date
湘械注准2018221014	Brain Function Information Management Platform Software System	Changsha BrainAu Technology	Class II	2018/9/3
粤械注准20142210073	Grading Examination and Treatment Software for Children's Amblyopia Applied with Visual Biological Information Stimulation Technology	Guangdong Gaierlun Medical Development	Class II	2019/7/17
粤械注准20202210139	Visual Perception Training Software	Zhuhai Guangmu Ruishi Medical Technology	Class II	2020/1/31
湘械注准20202210260	Cognitive Function Disorder Assessment and Correction Software	Hunan Suoai Technology	Class II	2020/2/26
辽械注准20202140199	Visual Function Training and Treatment Software	Shenyang Beiyou Technology	Class II	2020/4/26
皖械注准20202210321	Visual Perception Learning Treatment Software	Hefei Kefe Vision Technology	Class II	2020/6/9
浙械注准20202210779	Cognitive Function Rehabilitation Software	Hangzhou Yikang Medical Technology	Class II	2020/9/22
川械注准20202210188	Motion Testing and Prescription Video Software	Chengdu Shangyi Information Technology	Class II	2020/11/3
国械注进20203210480	Sparse sample PK profile and dosing software	Baxalta US Inc.	Class III	2020/11/17
浙械注准20202160867	Visual function examination and treatment instrument	Hangzhou V-sense Vision Technology	Class II	2020/12/1
苏械注准20182700112	Cognitive function disorder treatment software	Nanjing Vico Medical Technology	Class II	2021/1/18
粤械注准20162701452	Visual function training and treatment software	Guangzhou Shijing Medical Software	Class II	2021/2/23
浙械注准20192210633	Hepatitis B mother-to-child transmission prevention and management software	Hangzhou Zhilan Health	Class II	2021/3/29
浙械注准20192210506	Cognitive rehabilitation training and evaluation software	Hangzhou Jizhi Medical Technology	Class II	2021/6/7

Source: NMPA, Frost & Sullivan Analysis

NMPA Approved Digital Therapeutics Products (2/2)

Registration Certificate No.	Product Name	Company	Type	Approval Date
京械注准20162210965	Amblyopia and strabismus correction system	Beijing Jiaduoxin Digital Medical Technology	Class II	2021/6/8
浙械注准20212210379	Visual training system	Hangzhou V-sense Vision Technology	Class II	2021/8/27
沪械注准20212210502	Children's amblyopia training software	Shanghai Simingtang Biotechnology	Class II	2021/9/1
湘械注准2021221207	Binocular vision function training and treatment software	Changsha Huan Yuan Shi Jie Technology	Class II	2021/11/16
湘械注准20222210042	Cognitive function disorder treatment software	Hunan Wangli Medical Technology	Class II	2022/1/18
湘械注准20222210270	Visual function training and treatment software	Hunan Aoshi Medical Technology	Class II	2022/1/29
湘械注准20222210096	Cognitive function evaluation and training software	Changsha Bostent Cognitive Technology	Class II	2022/1/19
湘械注准20222190047	Cognitive ability testing and training system	Elite (Hunan) Medical Technology	Class II	2022/1/18
苏械注准20222210699	Amblyopia and visual function software	Jiangsu Juehua Medical Technology	Class II	2022/2/10
鄂械注准20222213650	Specific phobia psychological rehabilitation training software	Ningdong Wansheng Medical Technology (Wuhan)	Class II	2022/2/16
苏械注准20222210934	Cognitive function disorder evaluation and training software	Nanjing Vico Medical Technology	Class II	2022/3/25
湘械注准20222210661	Cognitive function disorder examination and correction software	Hunan Xinkang Medical Science and Technology	Class II	2022/4/15
粤械注准20222210474	Visual function training and treatment software	Guangzhou Liweitoo Technology	Class II	2022/4/12
湘械注准20222210613	Cognitive evaluation and training software	Hunan Kaisiman Technology	Class II	2022/4/13
冀械注准20222210143	Physiological parameter management software	Xingtai Miaojia Health Technology	Class II	2022/4/20
苏械注准20222211090	Pulmonary rehabilitation management and training software	Zhongxi Medical Technology (Wuxi)	Class II	2022/4/24
湘械注准20222211862	Basic cognitive ability test software	Changsha BrainAu Technology	Class II	2022/10/12
湘械注准20222212193	Cognitive function screening and evaluation software	Changsha BrainAu Technology	Class II	2022/12/26

Source: NMPA, Frost & Sullivan Analysis

Regulations for Digital Therapeutics Industry in China, 2018-2023 (1/3)

Date	Government	Policies	Comments
Dec. 2017	National Medical Products Administration	Guiding Principles for Technical Review of Mobile Medical Device Registration *移动医疗器械注册技术审查指导原则*	All mobile medical software, or software with hardware for patient management are medical devices. The regulatory scope and requirements need to be clear, whether software or hardware manufacturers, should be based on the product characteristics of mobile medical devices to submit the corresponding registration information, to determine whether the specific content of the guidelines are applicable, not applicable content should be detailed reasons.
April 2018	General Office of the State Council	Opinions on the Promotion of "Internet plus Medical Health" Development of Views *关于促进“互联网+医疗健康”发展的意见*	About the "Internet plus medical health" service system construction, industry supervision, safety and security proposed guidelines, requiring that in 2020, more than two hospitals generally provide online services, three hospitals to achieve interoperability and sharing of information within the hospital.
Sept. 2019	National Healthcare Security Administration, NMPA, NDRC, etc.	Action Plan for Promoting High Quality Development of Health Industry (2019-2022) *促进健康产业高质量发展行动纲要（2019-2022年）*	Accelerate the development of the health industry, proposed to form a health industry system with rich connotations and reasonable structure by 2022, decided to implement 10 major projects, of which the "Internet + medical health" project is directly related to medical IT, other projects also need information technology support content.
Dec. 2020	National Health Commission, National Health Security Administration, etc.	Notice on the Promotion of the "Internet plus Medical Health" Five Service Action *关于深入推进“互联网+医疗健康”“五个”服务行动的通知*	The scope and manner of the Internet+ medical payment is clearly defined. For example, the scope of the "Internet plus" medical insurance payment is to pay for outpatient chronic and special diseases, such as follow-up consultations and prescriptions in the "Internet+" designated medical institutions in the region, in accordance with the local medical insurance regulations.

Source: Government Website, Frost & Sullivan Analysis

Regulations for Digital Therapeutics Industry in China, 2018-2023 (2/3)

Date	Government	Policies	Comments
Jan. 2021	General Office of the State Council	Action plan on Building a High Standard Market System *建设高标准市场体系行动方案*	The implementation of education, medical, express logistics and other network infrastructure renovation and upgrading projects to promote the development of new service platforms such as Internet medical, online education, third-party logistics, instant delivery, online office, online business and effectively play the role of optimization and integration of platform enterprises in the allocation of factors.
Nov. 2021	Beijing Municipal People's Government	*Plan for the Construction of an International Science and Technology Innovation Centre in Beijing* *《北京市“十四五”时期国际科技创新中心建设规划》*	In the direction of digital therapeutics industry, Beijing will accelerate the integration and development of the pharmaceutical and healthcare industries with artificial intelligence, big data, 5G and other emerging technologies, and support the technological research and development of DTx.
Jan. 2022	National Health Commission	*Notice on the Issue of the "14th Five-Year Plan" Health Standardization Work Plan* *关于印发“十四五”卫生健康标准化工作规划的通知*	For new technologies in the field of health, new products, new services to follow up on the timely development of relevant standards to meet the Internet health services, fitness and leisure, health management, intelligent health products and services, health care tourism and other emerging industries on the demand for standards.
Feb. 2022	National Development and Reform Commission	*The 14th Five-Year Plan for the Development of the Bioeconomy* *《“十四五”生物经济发展规划》*	Promote the integration and innovation of biotechnology and information technology, and expand the clinical application of advanced therapeutic technologies such as intelligent surgical robots, digital therapeutics and particle radiotherapy.

Source: Government Website, Frost & Sullivan Analysis

Regulations for Digital Therapeutics Industry in China, 2018-2023 (3/3)

Date	Government	Policies	Comments
April 2022	Central Cyberspace Affairs Commission	"14th Five-Year Plan" for National Informatization *“十四五”国家信息化规划*	To support the sustainable, healthy and standardized development of private health institutions. To support healthcare institutions affected by the epidemic. To formulate opinions on comprehensively establishing a high-quality and efficient healthcare service system with Chinese characteristics.
March 2023	General Office of the Chinese Communist Party, General Office of the State Council	Notice on Promoting the Sustainable and Healthy Development of Private Healthcare Institutions *关于进一步完善医疗卫生服务体系的意见*	Emphasis on the role of information technology support, the development of "Internet plus medical health" and so on. Continued the policy level has been to encourage the attitude of the digital healthcare industry, and made more grounded work arrangements. On this basis, it is clear that "socially run medical institutions can lead the medical association".
Oct. 2022	People's Government of Hainan Province	*Several Measures to Accelerate the Development of* Digital Therapeutics *Industry in Hainan Province* *《海南省加快推进数字疗法产业发展的若干措施》*	A total of 21 initiatives have been put forward in the following six areas of DTx: promoting the development of the DTx industry from building the nation's leading clinical research demonstration base for DTx, accelerating the registration and approval, promoting the application of DTx, encouraging the exploration of a variety of payment modes, strengthening the publicity of DTx and the construction of industrial clusters, regulating the development of DTx, and other safeguards.
Dec. 2023	National Development and Reform Commission, Ministry of Commerce	*Overall programme of construction of Guangdong-Macao In-Depth Cooperation Zone* *《横琴粤澳深度合作区建设总体方案》*	The programme stresses the creation of innovative ways of market access in the field of medicine and health, and support for the development of digital therapeutics and mobile healthcare in the cooperation zone.

Source: Government Website, Frost & Sullivan Analysis

Analysis of Digital Therapeutics Pipeline Distribution (1/2)

Class I indications	Class II indications
Mental, behavioral, and cognitive disorders	ADHD
	Autism spectrum disorder
	Depression
	Cognitive impairment
	Substance use disorder
	Opioid use disorder
	Chronic insomnia
	Schizophrenia
	Post-traumatic stress disorder
	Panic disorder
	Hypertension
	Generalized anxiety disorder
Hypertensive heart disease	Heart failure
Respiratory Diseases	Asthma, chronic obstructive pulmonary disease
Immune disorder	Multiple sclerosis

Source: Frost & Sullivan Analysis

Analysis of Digital Therapeutics Pipeline Distribution (2/2)

Class I indications	Class II indications
Hypertensive heart disease	Heart failure
Respiratory Diseases	Asthma, chronic obstructive pulmonary disease
Immune disorder	Multiple sclerosis
Digestive system	Gastrointestinal conditions
Endocrine, nutritional and metabolic disorders	Diabetes
Hematologic Disorders	Hypertension
	Myocardial ischemia
	Hemophilia
Respiratory diseases	Chronic obstructive pulmonary disease
Urinary tract diseases	Kidney disease
Skin and subcutaneous tissue diseases	cutaneous condition
Tumor	Tumor complications
Pain	Chronic pain
	Acute postoperative pain
	Genito-pelvic pain/penetration disorder

Source: Frost & Sullivan Analysis

Analysis of Business Model of Digital Therapeutics

2H

2H
To Hospital

2C
To Customer

2B
To Business

2G
To Government

2I
To Insurance

- The 2H business model of digital therapeutics involves the purchase of digital therapy products by medical institutions, which are then used under the guidance of medical professionals. It is expected to be the major business model for DTx, especially for cognitive behavior therapy.
- 2H will be the mainstream development direction and the leading trend in the future.

Characteristics

Higher entry barrier

Guaranteed product safety and effectiveness

Advantages Compared to General Healthcare Products

Credibility and endorsement from hospitals

Higher acceptance from patients when integrated with regular guidance and assessments from doctors

Better control of the associated risk and ensures that patients are using the products safely and effectively

Source: Frost & Sullivan Analysis

Analysis of Business Model of Digital Therapeutics

2C&2B

2H
To Hospital

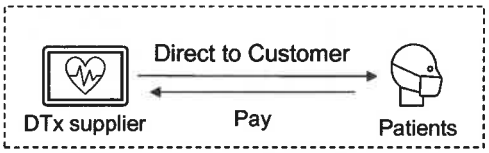
2C
To Customer

2B
To Business

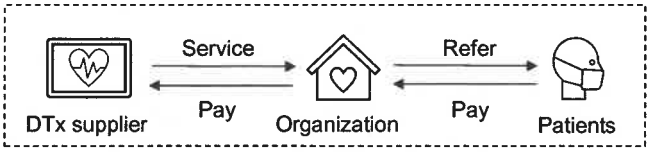
2G
To Government

2I
To Insurance

- The 2C business model means payment of digital therapeutics directly by customers. Since digital therapeutics have not been officially covered by medical insurance, the 2C business model was the leading digital therapy product business model.



- Under the 2B business model, digital therapeutics companies collaborate with traditional rehabilitation institutions or cognitive centers to achieve a holistic solution.
- In these organizations, traditional treatment methods are the core, while digital therapeutics serve as a management tool to address complications and promote overall patient benefit.



Source: Frost & Sullivan Analysis

Analysis of Business Model of Digital Therapeutics

2G&2I

2H

To Hospital

2C

To Customer

2B

To Business

2G

To Government

2I

To Insurance

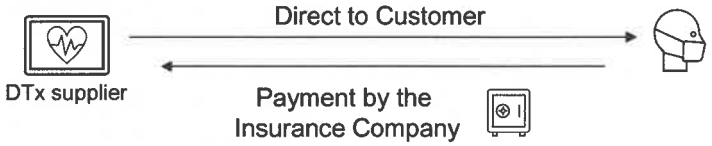
- The 2G business model means payment of digital therapeutics by the government and distribution to patients. With the proven effectiveness of digital therapeutics, governments are beginning to allocate special funds to support DTx.

Application Scenarios

Drug addiction withdrawal

Infantile autism

- Under the 2I business model, the cost of digital therapeutics from the insurance receivers is covered by the insurance company.
- Through the intervention of digital therapy, the progression of the disease is controlled, which reduces medical cost support, and achieves the effect of insurance cost control.



Source: Frost & Sullivan Analysis

2023[1]	2023[2]		Scenario			Year	
25.00%	91.60%	People with cognitive impairment, the elderly, children and adolescents	Hospital & Medical institution: Digital interventions for cognitive impairment	Cognitive Ability Supplemental Screening and Assessment Software	Self-developed	2022	It is a multi-modal interactive evaluation system based or digital human and artificial intelligence, which provides functions such as voice interaction, intention recognition and automatic interpretation.
				Basic Cognitive Ability Testing Software	Self-developed	2022	It is a computerized system that assesses the basic cognitive abilities in comprehensive aspects, with measuring different cognitive abilities in a task-based manners.
				Brain Function Information Management Platform Software System	Self-developed	2018	It is a brain health screening and cognitive rehabilitation intervention system based on the classical research paradi of neuropsychology, combined with the cutting-edge theorie cognitive neuroscience and artificial intelligence recommendation algorithms.
				Dyslexia Assisted Screening Management Software	Self-developed	2023	It is a comprehensive system that includes both systemat "behavior-reading-cognition" assessments, as well as ar customized, intelligent-based interventions for children wi dyslexia.
33.5%	6.1%	Elderly people with cognitive impairment	Individual & Community: Early screening and intervention treatment for Alzheimer's Disease	Intelligent Speech Cognitive Function Assessment System	Self-developed	2022	It is a new generation of cognitive function assessment method using voice as a digital biomarker.
				Multidimensional Cognitive Rehabilitation System	Self-developed		An innovative digital therapy with a multi-dimensional cognitive intervention system as its core. Through the collection and analysis of posture/video, picture/trajectory voice/voiceprint data, and based on cognitive assessmer results, it intelligently matches personalized training task for users.
3.2%	1.2%	People with anxiety and insomnia, children with ADHD, autism, drug and alcohol addicted people	Hospital & Medical institution: Mental illness interventions	VR Cognitive Assessment and Training Software	Self-developed	2023	The system uses the unique immersive, interactive, and imaginative features of virtual reality technology (VR) an combines it with the principles and methods of traditiona clinical psychology for the treatment of anxiety disorders
				Sleep Disorder Assisted Therapy Software	Self-developed	2023	The system uses virtual reality (VR) technology as an auxiliary treatment for sleep disorders
1.5%	1.1%	People with cognitive impairment, people with anxiety and depression	Individual & Community: Early screening for Alzheimer's Disease and digital interventions for others mental illness	Cognitive Self-Assessment Software	Self-developed	2024	The system uses AI algorithms and big data analysis to achieve intelligent screening and analysis of cognitive impairment. It can quickly complete cognitive risk assessment within 3 minutes and is suitable for screenin large populations.
0.4%	0%	People with mental illness, children and adolescents People in drug	Hospital & Medical institution:	Cognitive Dysfunction Treatment Software	No pubic information	2022	Patients are required to perform specific tasks through software and games. During the process, the system collects the user's physiological data and uses specific A algorithms to analyze and judge the data as quantitative

Competitive Landscape of Leading Digital Therapeutics Companies In China

Company	BrainAu		WonderLab		Thoven		BEST COVERED		MED-VISION
	Assessment	Intervention	Assessment	Intervention	Assessment	Intervention	Assessment	Intervention	Intervention
Product	Brain Function Information Management Platform Software System		AI Depression Assessment System/Visualized Data Analysis System/Group Rapid Assessment System	Wangli SmartHealth /Wangmian	TCSA	Jianjing/Heartland Resort/Attention Four Week Challenge	Intelligent Speech Cognitive Function Assessment System	Multidimensional Cognitive Rehabilitation System	VR Mental Health Training System/VR Children's Attention Training System/VR Alcohol Addiction Recovery Training System
Accumulated Users	100-200 Thousand	Over 10 Million	Over 100 Thousand		Over 200 Thousand		16 Million		NA
AI Technology	Virtual human + AI	Deep learning AI	AI algorithm & Big Data		AI Screening Digital Drug System & AI Digital Gaming Technology		AI Deep learning driven BCii risk assessment models		VR technology (CBT) & Internet cloud platform & Big data technology
Clinical Trials Results	Higher efficiency, 2-3 times, with an accuracy rate of 94%	NA	Cognitive behavioral therapy (CBT) significantly decreased craving over the course of a 12-week period was reported	68% of participants completed more than half of the course and had moderate to high compliance	The detection rate of early cognitive impairment (MCI) reaches over 85% with 85.4% specificity	NA	The AUC for dementia detection is 0.921, the AUC for MCI detection is 0.838	The cognitive function score of the intervention group increased by 5.32%, and the cognitive score of MCI patients increased by 12.85%	NA

Source: Frost & Sullivan Analysis

Competitive Landscape of Leading Digital Therapeutics Companies In China

Company	BrainAu		WonderLab		Thoven		BEST COVERED		MED-VISION
Candidate Number	330	1,600	NA	194	151	NA	251	2,133	
Paper	NA	A randomized controlled trial of cognitive digital therapy in patients with coronary heart disease complicated with cognitive impairment but without dementia.	Kakko, J., Alho, H., Baldacchino, A., Molina, R., Nava, F. A., & Shaya, G. (2019). Craving in Opioid Use Disorder: From Neurobiology to Clinical Practice. Frontiers in psychiatry, 10, 592. https://doi.org/10.3389/fpsyt.2019.00592	Liu, X., Li, Y., Yan, R., Timo, H., Li, D., Liu, S., Zhang, C., Xu, Y., Luo, X., & Zhang, B. (2022). The platform development, adherence and efficacy to a digital Brief therapy for insomnia (dBTI) during the COVID-19 pandemic. Methods (San Diego, Calif.), 205, 39–45. https://doi.org/10.1016/j.ymeth.2022.04.016	Nie, J., Yang, Y., Gao, Y., Jiang, W., Aidina, A., Sun, F., Prieto, L. R., Yu, J., Ju, K., Song, L., & Li, X. (2023). Newly self-administered two-step tool for screening cognitive function in an ageing Chinese population: an exploratory cross-sectional study. General psychiatry, 36(1), e100837. https://doi.org/10.1136/gpsych-2022-100837	NA	Huang, L., Li, Y., Wu, J., Chen, N., Xia, H., & Guo, Q. (2023). Shanghai Cognitive Screening: A Mobile Cognitive Assessment Tool Using Voice Recognition to Detect Mild Cognitive Impairment and Dementia in the Community. Journal of Alzheimer's disease : JAD, 95(1), 227–236. https://doi.org/10.3233/JAD-230277	Evaluate the cognitive intervention effect of Bosten's multi-dimensional composite cognitive intervention training digital therapy on middle-aged and elderly populations, especially MCI population* https://www.bestcovered.com/reserach#section7-pre	NA

* The clinical trial was not registered on the clinical website and is a real-world research result.

Source: Frost & Sullivan Analysis

Competitive Landscape of Leading Digital Therapeutics Companies In China

Company	Our Company	Company A	Company B	Company C	Company D
Background	Founded in 2012, a company that provides a broad range of cognitive impairment assessment and Intervention DTx products.	Founded in 2016, a company that provides assessment and intervention DTx products for early cognitive impairment.	Founded in 2016, a company that provides VR DTx solutions focusing on the field of psychology.	Founded in 2020, a company that provides digital screening and diagnosis systems, digital drugs, and digital vaccines for brain diseases.	Founded in 2018, a company that provides assessment and intervention DTx products in the field of psychology.
Market Share, 2023[1]	25.0%	33.5%	3.2%	1.5%	0.4%
Medical Grade Market Share, 2023	91.6%	6.1%	1.2%	1.1%	0.0%
Targeted Customers	People with cognitive impairment, the elderly, children and adolescents	Elderly people with cognitive impairment	People with anxiety and insomnia, children with ADHD, autism, drug and alcohol addicted people	People with cognitive impairment, people with anxiety and depression	People with mental illness, children and adolescents People in drug rehabilitation, specific occupational groups
Usage Scenario	Hospital & Medical institution: Digital interventions for cognitive impairment	Individual & Community: Early screening and intervention treatment for Alzheimer's Disease	Hospital & Medical institution: Mental illness interventions	Individual & Community: Early screening for Alzheimer's Disease and digital interventions for others mental illness	Hospital & Medical institution: Mental illness interventions

(1) Market Share measured by percentage of 2023 DTx revenue in China.

Source: Frost & Sullivan Analysis

Competitive Landscape of Leading Digital Therapeutics Companies Worldwide

Manufacturer	Akili Interactive Labs				Better Therapeutics				Aptar Digital Health
Product	EndeavorRx	NA	NA	AKL-T01	BT-001	BT-002	BT-003	BT-004	Oleena
Product Indication	Pediatric ADHD	Adult AHDH	Early childhood ADHD	Acute cognitive dysfunction	Type 2 Diabetes	Hyper-tension	Hyper-lipidemia	NASH/ NAFLD	Oncology
Product Access	Prescription	NA	NA	NA	Prescription*	NA	NA	NA	Prescription
Product Progress	FDA authorization / CE mark certification	Pivotal	Proof of concept	Proof of concept	Pivotal	Pilot	Pilot	Discovery	Authorized in the US and Europe
Focus Areas	Neurodevelopmental disorders and other cognitive impairment				Cardiometabolic diseases				Oncology Respiratory Immunology Neurology
Technologies	Selective Stimulus Management Engine, Body Brain Trainer, Spatial Navigation Engine				Better Therapeutics software platform				NA
Pipeline	DTx for ADHD and COVID Brain Fog				Prescription DTx for cardiometabolic diseases				NA
Collaborator	TALi, Shionogi, Weill Cornell Medicine				Mass General Brigham, Catalyst Health Network, Arizona Liver Health				Chiesi Gorup, Healint
Clinical Trials	19 clinical trials				5 clinical trials				NA
Research	22 peer-reviewed publications and conference presentations				8 peer-reviewed publications and conference presentations				Paper collaborate with AZ and NCI

* According to BT-001 fast facts sheet by Better Therapeutics, BT-001 is an FDA-regulated prescription digital therapeutic in development

Source: Frost & Sullivan Analysis

Competitive Landscape of Leading Digital Therapeutics Companies Worldwide

Manufacturer	GAIA*			Vine Heath		CureApp		
Product	Deprexis	Vorvida	MODIA	Vinehealth mobile app	VinehealthPRO web dashboard	HERB	CureApp SC	NASH App
Product Indication	Depression	Alcohol management	Opioid use disorder	Cancer		Hypertension	Smoking Cessation	Nonalcoholic steatohepatitis
Product Access	Prescription not required		Prescription*	NA		Prescription	Prescription	Prescription*
Product Progress	Authorized in the US, Germany, and Switzerland	Authorized in the US	Registration completed	Class 1 Medical Device CE Mark in the UK & EU		Japan: PMDA cleared class II medical device		Under-development
Focus Areas	Depression, anxiety, multiple sclerosis			Oncology		Hypertension, smoking cessation		
Technologies	Broca forms platform			Data science		NA		
Pipeline	NA			NA		NA		
Collaborator	HanseMerkur, Ferring, Ethypharm, E. Lilly, J & J, Merck, Merz, Orexo, Pfizer, etc			UK Oncology Nursing Society, Cancer Research UK		Jichi Medical University		
Clinical Trials	19 clinical trials and 2 meta-analyses			NA		1 clinical trial on hypertension		
Research	16 peer-reviewed publications 4 research projects			6 peer-reviewed publications and abstracts		10 peer-reviewed publications		

* The DTx are developed by GAIA AG or in collaboration with Orexo
* MODIA is anticipated to be a prescription digital therapeutic
* NASH app is anticipated to be prescribed by physicians

Source: Frost & Sullivan Analysis

Competitive Landscape of Leading Digital Therapeutics Companies in China

Manufacturer	BrainAU							
Product	Cognitive impairment -related e-diagnosis	Basic cognition assessment	Psycho-psych-related e-assessment	Neuro-degenerative diseases	Cognitive impairment due to cerebro-vascular disease	Cognitive impairment due to cardio-vascular disease	Psychiatric Diseases	Developmental diseases
Product Indication	Cognitive impairment	Cognition	Psycho-psych-conditions	Alzheimer's disease	Vascular cognitive impairment No dementia	• Atrial fibrillation combined with MCI • Coronary artery disease with CI • Hypertension with CI	• Depression • Schizophrenia • Sleep disorders • Anxiety	• AHDH • Autism
Product Progress	Commercialization							
Focus Areas	Cognitive impairment							
Technologies								
Pipeline	Assessment DTx for psychology and cognition, intervention DTx for Cognitive and psychiatric disorders associated with other diseases, Parkinson's disease, vascular dementia, depression, developmental disorders							
Collaborator	Tsinghua University, Chinese Academy of Sciences, Xuanwu Hospital of Capital Medical University, China-Japan Friendship Hospital							

Source: Frost & Sullivan Analysis

Competitive Landscape of Leading Digital Therapeutics Companies in China

Manufacturer	尚医	虚之实医疗	SLANHEALTH		
Product	Recover plus APP	Cognitive function rehabilitation system YKVR-1	Small shells	DTx platform for sleep specialists	SLANHEALTH internet hospital
Product Indication	Cardiovascular disease, metabolic syndrome, post-surgical rehabilitation	Cognitive impairment due to various brain function disorders	Hepatitis B mother-to-child interruption	Insomnia, obstructive sleep apnea, secondary sleep problems such as migraines	General Medicine, Psychiatry
Product Access	Prescription	In hospital/ for medical staffs	Prescription level	NA	NA
Product Progress	NMPA Class II medical device approval	NMPA Class II medical device approval	NMPA Class II medical device approval	NA	NA
Focus Areas	Chronic disease, chronic pain, cognitive impairment	Psychiatric disorders, cognitive disorders	NA		
Technologies	Layered ability structure engine	VR	Digital intelligence platform		
Pipeline	Brain training, nutritional treatment	Follow-up system, metaverse hospital	DTx CDMO and Full Process Services		
Collaborator	America Heart Association, Pharscin Pharma, etc	NA	HUAWEI, J&J, AstraZeneca, State Key Laboratory of Respiratory Disease, etc		
Clinical Trials	17 clinical trials	More than 10000 clinical trials	More than 40,000 real-world data governance		
Research	NA	157 publications	16 peer-reviewed publications		

Source: Frost & Sullivan Analysis

Competitive Landscape of Leading Digital Therapeutics Companies in China

Manufacturer	强联智创			BestCovered
Product	Uknow	Uguard	Usearch	Cognitive function assessment and training software
Product Indication	Intracranial aneurysm	Cerebralvascular imaging	Cerebralvascular health	Cognitive impairment
Product Access	For doctors		Prescription not required	For hospitals, government organizations, and financial institutions
Product Progress	NMPA Innovative Medical Device Class III Certificate	NMPA Class II medical device approval	Commercialization	NMPA Class II medical device approval, FDA registration certificate for Class II medical devices
Focus Areas	Acute and chronic cerebrovascular disease			Digital assessment and intervention for early risk of cognitive impairment
Technologies	Medical case database, image file processing			BBRT brain training, BCii risk assessment model
Pipeline	NA			Intelligent speech cognitive function assessment system, multidimensional cognitive rehabilitation system
Collaborator	Xuanwu Hospital, Tiantan Hospital, Changhai Hospital,Huashan Hospital, GE health			• With hospitals such as Tiantan Hospital and West China Hospital: cognitive training centers • With government organizations such as Shenzhen Civil Affairs Bureau and China Aged Care Development Foundation: cognition-friendly communities • With financial institutions such as CPIC and Bank of China: digital retirement benefits for VIP customers
Clinical Trials	A clinical trial for Uknow at Huashan Hospital			Multiple clinical trials and real-world studies published in top peer-reviewed journals
Research	More than 10 peer-reviewed publications			

Source: Frost & Sullivan Analysis

Entry Barriers of Digital Therapeutics in China

Technology	• Advanced artificial intelligence and machine learning technologies that are more accurate and interpretable are being integrated into Digital therapeutics, helping DTx to become more intuitive and helpful. The optimization of AI/ML models require the collection of first-hand medical experience, engineers, and algorithmic scientists. Creating models that can compete with existing one is a challenge for newcomers.
Big Data	• Digital therapeutics face entry barriers related to the acquisition and utilization of sufficient and high-quality clinical data. Digital therapeutics, especially intervention products, need large amounts of diverse and representative patient data necessary for training and refining models. Data acquisition requires collaboration with healthcare institutions and patients to obtain consent, ensuring data privacy and security. This could be a big challenge for emerging DTx companies.
Supply Chain	• Challenges exist to establish partnerships between digital therapeutics companies and healthcare institutions. There will be considerate labor cost and capital expenditure to integrate DTx products to a hospital's system. Upon successful collaboration, it can create a significant barrier for other competitors to enter and replace them. It is noteworthy that this barrier will provide sufficient clinical data for the DTx company and reinforce the barrier of big data.
Market Access	• The immature market imposes a barrier to entry for emerging DTx companies. Related policies and market environment are still developing, so there is no clear definition of the scope and application of DTx. Moreover, because the market access of China's digital health industry is in the development stage, companies need to keep up with relevant policies to ensure compliance and take full advantage of regulations or policies that favor the development of the DTx market in China.

Source: Literature Review, Frost & Sullivan Analysis

Growth Drivers of Digital Therapeutics in China

Large Demand and Potential Market	• Chronic diseases are on the rise globally, and digital therapeutics offer a more personalized and cost-effective approach to managing these conditions. Moreover, almost two-thirds of the global population now has internet access, so that digital solutions for disease management can reach a large audience. Digital therapeutics can be used across different disease areas, from mental health to diabetes to cardiovascular disease, which further drives the growth of the potential market.
Advancements in Innovative Technologies	• In the field of digital therapeutics, AI algorithms are being used to develop personalized treatment plans based on patient data, which has the potential to improve patient outcomes. Additionally, technologies such as extended reality and virtual reality are being used to create immersive and engaging patient experiences, which can increase treatment adherence and overall effectiveness. These innovative technologies are expected to promote the advancement digital therapeutics.
Growing Investment in DTx Products	• Investments in digital therapeutics have been steadily growing in recent years. The second quarter of 2022 saw 24 investment deals in digital therapeutics with a total investment of around 600 million US dollars. The market for digital therapeutics products and services is expected to continue to grow in the coming years, with more companies and investors entering the space. This will in turn boost the market of digital therapeutics.
Local Policies Promoting the Development of DTx	• Local government such as Hainan Province has released policies promoting the development of digital therapeutics. These policies provide support and guidance for various stakeholders, including enterprises, healthcare institutions, and medical physicians, to participate in the development and application of digital therapeutics. Through these initiatives, local policies help to build a supportive ecosystem for the digital therapeutics industry, paving the way for its sustainable and high-quality development.

Source: Frost & Sullivan Analysis

Future Trends of Digital Therapeutics in China

Emphasis on Evidence-based Medicine	• Evidence-based medicine is the basis of digital therapeutics. It is expected to gain increasing attention in the future given the need for robust scientific evidence. Using scientific methods to organize and apply current data to improve healthcare decisions, digital therapeutics can enhance their credibility and acceptance within the medical community. Emphasizing evidence-based medicine ensures that they meet rigorous scientific standards, paving the way for their integration into healthcare system.
Transition of Leading Business Model	• Initially, the leading business model for digital therapeutics was the 2C approach. With the growing recognition and acceptance of digital therapeutics by healthcare institutions, hospitals are expected to become the major adopters and providers of DTx, especially for cognitive behavior therapy. This transformation in the business model signifies a shift towards integrating digital therapeutics into mainstream healthcare systems.
Developing Regulatory Framework	• Currently, there is no specific approval channel for digital therapeutics in China. They are now approved according to medical device regulations. There is a gap in regulations for digital therapies from R&D, clinical to commercialization, and post-marketing supervision. In most cases, policies within a certain industry is developed after the initial exploration and verification. As for digital therapies, which are currently being explored by many companies, regulatory framework is expected in the future.
Higher Willingness to Pay	• In the future, there is expected to be a notable shift in patient attitudes towards digital therapeutics, with an increasing willingness to pay. Patients are gradually seeking out digital therapeutics as a complementary or alternative approach to traditional treatments, driven by the desire for greater control over their health and the convenience of accessing therapy remotely. This changing patient mindset for the adoption of digital therapeutics present a future trend in this field.

Source: Frost & Sullivan Analysis

Digital Therapeutics Product Registration Certification Process: FDA

Category Name: Medical Device—includes Software as a Medical Device (SaMD) and Software in a Medical Device (SiMD)

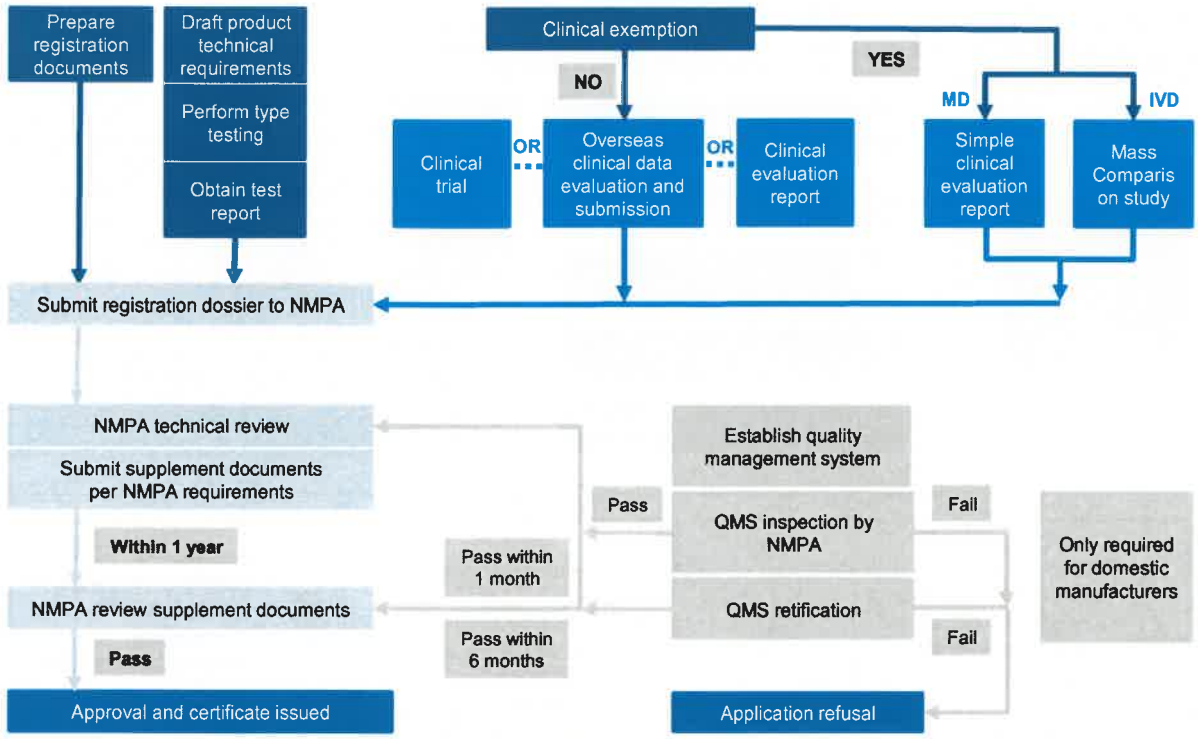
Class I	Class II	Class III
	If no predicate exists, submit 513(g) application to reclassify the device as Devo	Search for predicate on the FDA website
		NO / YES
	Innovative devices may require FDA pre-IDE and clinical data	• Submit pre-IDE and develop clinical trial protocal. • Obtain FDA IDE approval and conduct clinical trials.
	• Prepare and submit 510(k) application • Pay 510(k) application fee	• Submit PMA for completeness review • Pay PMA submission fee
	FDA reviews most 510(k) applications within 90 days	If accepted by FDA, application is reviewed within 180 days
		FDA conducts facility inspections
	FDA issues 510(k) clearance letter and posts it on its website	FDA issues PMA clearance letter and posts it on its website

- If located outside of the US, appoint "US Agent" then register company and device and pay annual fee on FDA website.
  - No certificate will be issued by FDA but company will be subject to random FDA inspections for QSR compliance

- The company can tell its device in the US.
- The FDA does not issue device approval certificates and the listing on the FDA website will serve as proof of compliance.
  - Registrations do not expire as long as no changes are made to the indications for use, labeling, or product design

Source: Frost & Sullivan Analysis

Digital Therapeutics Product Registration Certification Process: NMPA



Source: Frost & Sullivan Analysis

Table of Contents

1 Analysis of Digital Therapeutics (DTx) Market

2 Cognitive Impairment Digital Therapeutics Market

2.1 Overview of Cognitive Impairment Digital Therapeutics Market

2.1.1 Overview of Cognitive Impairment

2.1.2 Treatment Paradigm of Cognitive Impairment

2.1.3 Development Path of Cognitive Impairment Digital Therapeutics Market

2.1.4 Competitive Landscape of Cognitive Impairment Digital Therapeutics Market

2.1.5 Market Size Of Cognitive Impairment Digital Therapeutics In China and Globally, 2018-2030E

2.1.6 Future Trends of Cognitive Impairment Digital Therapeutics Market

2.2 Digital Therapeutics Assessment and Intervention Products Market

Overview of Cognitive Impairment

- Cognitive impairment refers to deficits in neurocognitive domains, such as complex attention, executive function, perceptual-motor, and learning and memory, that lead to a decline in cognition function

- Vascular cognitive impairment
- Neurodegenerative diseases
- Psychiatric diseases
- Developmental diseases
- Others

Causes

Short-term or reversible:
- head injury
- anxiety or depression
- recreational use of alcohol/ drugs
- infections
- vitamin deficiency
- dehydration
- reactions to medicines

Permanent:
- dementia
- stroke
- brain injury
- intellectual disability
- drug use

Stages

Mild:
changes in cognitive functionsm but still be able to do everyday activities.

Mid-term:
- more forgetful, especially of recent events
- communication becomes increasingly difficult
- unable to live alone
- wanders aimlessly

Severe:
- inability to recognize friends and family
- incontinence
- behavior become more abnormal

Source: Literature Review, Frost & Sullivan Analysis

Unmet Clinical Needs of Cognitive Impairment

Unmet Clinical Needs	Current Situations	DTx
Assessment • The number of people with cognitive impairment is increasing • However, people are usually diagnosed when their symptoms are severe, missing the best time to intervene • Thus, cognitive impairment has become an important public health issue, and large-scale early screening is needed	• The process of diagnosing cognitive impairment is complex, requiring a combination of test scales, patient personal and medical history, neurological exam, and examinations of other biomarkers • The process of diagnosing is inconvenient and time-consuming	• DTx can computerize part of the work and perform it without the involvement of professionals • People can closely monitor their cognition, without missing the best time to intervene • DTx makes the process more efficient and is suitable for large-scale usage
Intervention • Cognitive impairment imposes a heavy burden on patients and the society • There is a great need for new treatment options which can effectively delay disease progression or stop disease development • There is a great need for cheaper and more accessible intervention methods	• The mechanism of many cognitive impairments is not clear, so treatments can only delay the development of the disease to a certain degree • Non-pharmacological interventions, such as therapy, are restricted by the limited number of healthcare providers, making them expensive and inconvenient for patients	• By combining AI/ML or devices such as VR, DTx can offer a novel way of intervention, which can potentially be more effective • DTx enables one-to-many therapy and unsupervised cognitive training, alleviating the shortage of medical staff and making intervention more accessible

Source: Literature Review, Frost & Sullivan Analysis

Treatment Options of Cognitive Impairment

- There currently is no standard treatment or medication, but cognitive impairment is an active area of research. Clinical studies are being conducted to better understand the disorder and find treatments that may improve symptoms or prevent or delay dementia.

Medications	**Cholinesterase inhibitors:** A Alzheimer's medicine given to people whose main symptom is memory loss, but they aren't recommended for routine treatment because they haven't been found to affect progression to dementia and can cause side effects
	Aricept, Razadyne and Exelon: drugs that boost neurotransmitter levels
	Memantine: A drug that works via a different pathway to regulate the activity of the neurotransmitter glutamate to improve memory and learning
Occupational therapy	The therapy focuses on teaching the patient strategies to minimize the effect that cognitive impairment has on day-to-day living, but in the case of degenerative neurological disorders, such as Alzheimer's or Parkinson's disease, the efficacy of such treatment can be limited
Cognitive disorder treatment	Patients leave their home environments and enter a controlled environment that has been designed specifically to cater to the needs of people with cognition issues.
Clinical trials	People with cognitive impairment may also consider participating in clinical trials or studies. Some new drags such as lecanemab are showing promising result. People with and without memory problems can take part in clinical trials, which may help themselves or future generations.
Reversible causes	**Stopping certain medicines:** Certain medicines can cause side effects that affect thinking, such as Benzodiazepines, Anticholinergics, Antihistamines, Opioids, Proton pump inhibitors. These side effects are thought to go away once the medicine is stopped.
	Other conditions: High blood pressure, depression, and sleep apnea can cause mild cognitive impairment. Treating these conditions can help improve memory and overall mental function.

Source: Literature Review, Frost & Sullivan Analysis

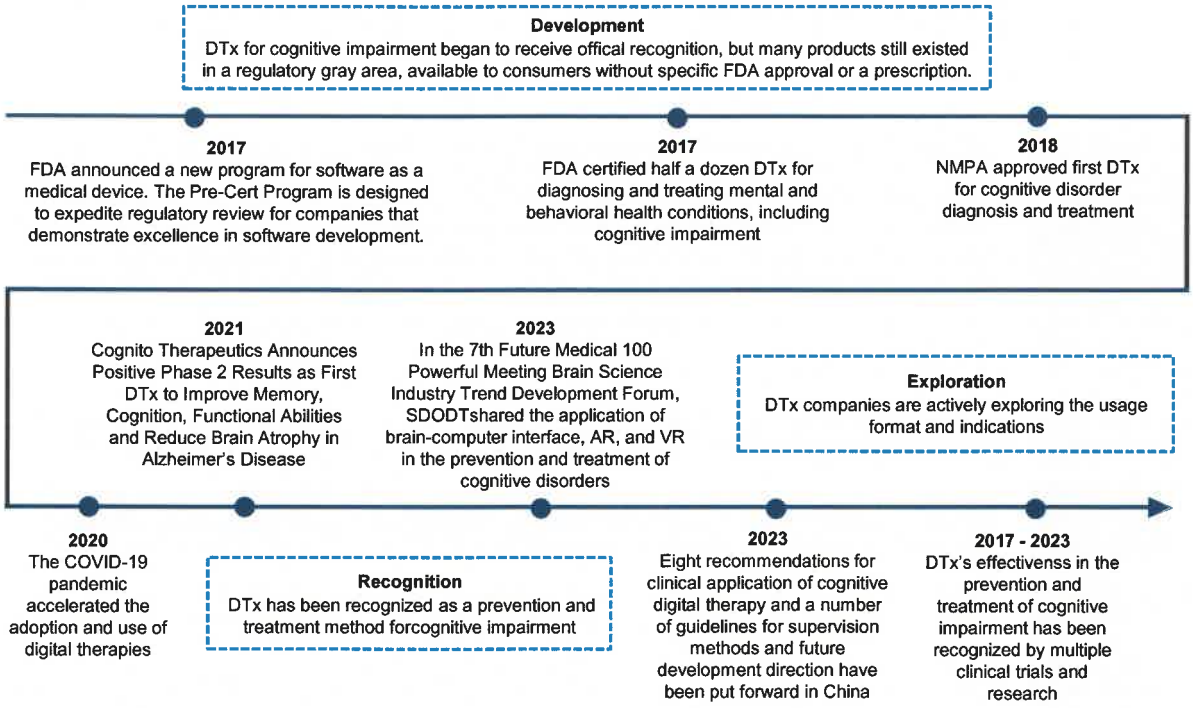
Diagnosis and Prevention of Cognitive Impairment

- Because the lacking of effective treatment, it is important to recognise cognitive impairment at an early stage and take remedies. A doctor can help track changes in memory and thinking skills over time. Keeping a record of any changes can also be helpful.

Diagnosis	**Neurological exam:** As part of a physical exam, a health care provider may perform some basic tests that can reveal how well the brain and nervous system are working.
	Lab tests: Blood tests can help rule out physical problems that may affect memory.
	Memantine: Blood tests can help rule out physical problems that may affect memory. This can include not enough vitamin B-12 or thyroid hormone.
	Brain imaging: An MRI or CT scan can check for a brain tumor, stroke or bleeding.
	Mental status testing: Tests can provide details about how someone's mental function compares with others of a similar age and education. These tests also may help identify patterns of change that offer clues about the cause of symptoms.
Prevention and delay progression methods	**Regular physical exercise** may help prevent or slow cognitive decline.
	A diet low in fat and rich in fruits and vegetables may help protect brain health.
	Omega-3 fatty acids shows a possible benefit for brain health by looking at how much fish people eat.
	Keeping the brain active such as playing games, playing an instrument, reading books and other activities may help preserve brain function.
	Being social helps preserve mental function and slow mental decline.
	Memory training and other cognitive training may help improve your function.

Source: Literature Review, Frost & Sullivan Analysis

Development Path of Cognitive Impairment Digital Therapeutics Market



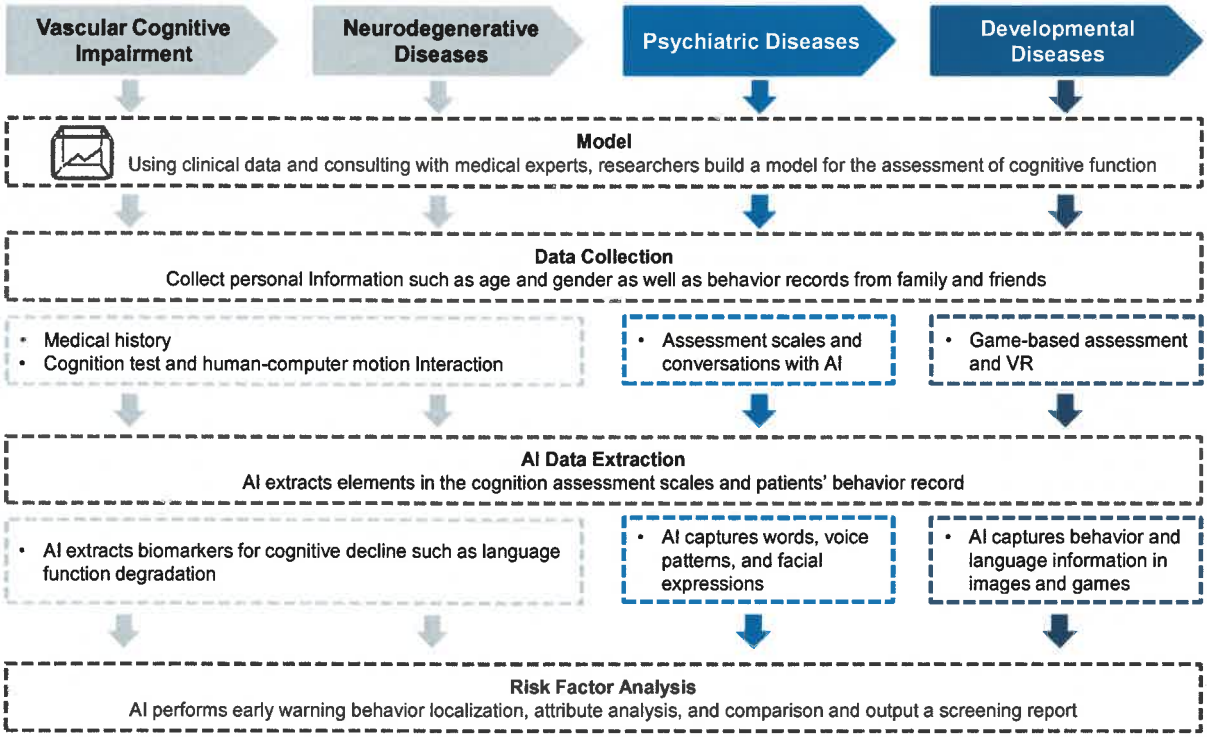
Source: Literature Review, Frost & Sullivan Analysis

Advantages of Cognitive Impairment Digital Therapeutics

	Traditional Methods	DTx
Effectiveness	• Use diagnostic methods, such as scales and inquiry of medical history, for assessment.	• Computerized traditional methods while remaining the same accuracy.
	• Intervention requires non-pharmaceutical therapy in addition to medications	• Better cognitive performance of therapy through multi-domain, adaptive computerized training.
Efficiency	• The assessment relies on the manual operation of professionals. Screening is time-consuming and difficult to carry out on a large scale.	• Use AI to carry out some assessments, shortening screening time and reducing the involvement of healthcare providers
	• It's difficult for one therapist to attend to multiple patients at the same time. The waiting time for patients to receive treatment is long.	• One therapist can work with multiple patients at the same time. With the help of DTx, patients can also complete part of the intervention alone.
Accessibility	• Patients need to go to hospitals for professional assessment and intervention.	• Patients can manage their health from home, making the process more convenient and increasing accessibility for places with limited medical resources.
Cost	• Costly therapy for patients.	• Reduce cost by improving efficiency and accessibility.
Feedback	• Patients need to be examined by doctors to know the effectiveness of treatment and disease progression. There is no timely feedback.	• Provide real-time monitoring, promoting effective hospital-patient linkage and forming a dynamic closed loop of data transmission with the intervention process.
Personalization	• Offer standard treatment to all patients.	• Offer personalized treatment based on the patient's own medical profile, optimizing treatment result.

Source: Frost & Sullivan Analysis

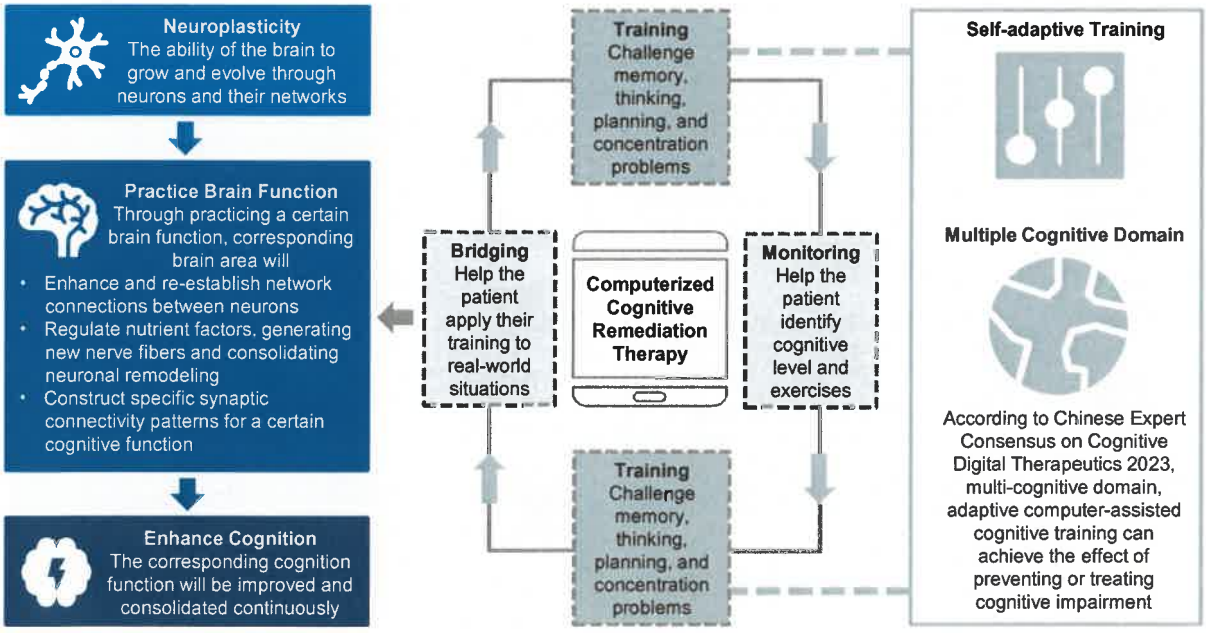
Assessment Mechanism of DTx for Cognitive Impairment



Source: Frost & Sullivan Analysis

Intervention Mechanism of DTx for Cognitive Impairment (1/2)

- Because the nervous system can change its activity in response to stimuli, practicing cognition domains in the brain can enhance the corresponding cognitive abilities. DTx computerizes cognitive remediation therapy, implementing computer-assisted, multi-domain, adaptive training, to practice the impaired functions and, thus, improve neurocognitive abilities.



Source: Frost & Sullivan Analysis

Intervention Mechanism of DTx for Cognitive Impairment (2/2)

Disease-Specific Intervention Mechanism

Vascular Cognitive Impairment

Management of the Underlying Diseases

- In addition to cognition training, DTx also helps patients manage the underlying diseases that contribute to vascular cognitive impairment such as diabetes and hypertension, which is important for overall cognitive improvement
- By providing healthy lifestyles advice and high-risk factor management, DTx helps patients improve disease awareness and treatment adherence

Neurodegenerative Diseases

Combination of Diagnostic And Interventional functions

- Cognitive decline is progressive, and early intervention is important for delaying disease progression
- However, many patients are not diagnosed in the early stages, missing the optimal opportunity for intervention
- By combining with the screening function, DTx can maximize the intervention's effectiveness

Psychiatric Diseases

Computerized Cognitive Behavioral Therapy

- A common type of psychotherapy, where the patient works with a therapist in a structured way to respond to negative thinking and behavior patterns in a positive way
- DTx achieves treatment of cognitive impairment by computerizing cognitive behavioral therapy through remote therapy with licensed therapist and AI therapist

Developmental Diseases

Computerized Applied Behavior Analysis

- Impart skills such as academic and social skills for children with autism and other developmental disorders
- Computerized through online training, remote session, and AI therapist

Attention Reinforcement Training

Improve the attention function of ADHD children through computer-based games

Source: Frost & Sullivan Analysis

Introduction of Cognitive Impairment Digital Therapeutics

Assessment

DTx enables assessment of overall cognition and specific cognitive domains, social and daily living abilities, and psychiatric behavioral symptoms. It can be used in clinical diagnosis, large-scale screening, and health promotion

Neurological Exams

DTx can achieve the integration of multiple modalities for a comprehensive assessment

- Combined with VR for the assessment of spatial cognitive functions
- Combined with speech recognition devices to analyze key language features of cognitive impairment patients
- Combined with eye tracking-devices for cognitive assessment

Neuro-psychological Assessments

The standard assessment can be digitally applied in a computerized framework, with good consistency between the original test methods

- Standard computerized scale-based cognitive assessments: the montreal cognitive assessment, mini-mental state examination, and Alzheimer's disease assessment scale-cognitive subscale

The computerized can also take into account medical history, age, and other factors to generate a more accurate assessment report

Intervention

DTx uses computerized cognitive training in combination with devices such as VR to improve the cognitive function in patients with SCD, MCI, and dementia, preventing or delaying cognitive decline

Synergistic intervention in Multiple Domains

- In line with the actual pattern of brain activity, helping produce compensatory, transferable and maintenance treatment effects
- Clinical trials show that DTx can improve overall cognition and language and memory function

Multi-instrument Intervention

- Can be combined with medications and non-pharmaceutical methods for the maximization of effects
- Current focuses: game, VR, and physical stimulation

Risk Factor Management

- Effective control of risk factors, such as diabetes, alcohol abuse, and substance use is important
- Some DTx for associated risk factors have received FDA approval

Source: Frost & Sullivan Analysis

Introduction of Cognitive Impairment Digital Therapeutics: Assessment

- Digital cognitive assessment enables assessment of overall cognitive functioning and specific cognitive domains, social and daily living abilities, and psychiatric behavioral symptoms. It can be used in scenarios such as clinical diagnosis, large-scale cognitive function screening, and community health promotion

Neurological exams

- Neurological exams can be completed through the platform interface built in DTx , achieving effective integration of multiple modalities for a comprehensive assessment
- DTx can be combined with VR for assessment of spatial cognitive functions
- DTx can be combined with speech recognition devices to analyze key language features of cognitive impairment patients
- DTx can be combined with eye tracking-devices for cognitive assessment

Neuropsychological assessments

- The standard neuropsychological assessment can be digitally applied in a computerized framework, with good consistency between the original test methods
- Standard computerized scale-based cognitive assessments: the montreal cognitive assessment, mini-mental state examination, and Alzheimer's disease assessment scale-cognitive subscale

MRI and CT scans

- The analysis and interpretation of MRI and CT scans usually require experienced physicians, but deep learning artificial intelligence can share some of the work, improving the efficiency and accuracy of diagnosis
- DTx can use machine learning to analyze structural neuroimaging data and predict brain age

Compared to traditional diagnosis methods, DTx can provide comparable results in some areas

Compared to traditional diagnosis methods, DTx can reduce medical costs and save money

Compared to traditional diagnosis methods, DTx can improve efficiency of disease diagnosis and patient accessibility

Source: Frost & Sullivan Analysis

Introduction of Cognitive Impairment Digital Therapeutics: Intervention

- Cognitive interventions in DTx use computerized cognitive training and a combination of wearable devices, VR, and physical stimulation to improve the overall cognitive function and specific cognitive domains in patients with SCD, MCI, and dementia and prevent cognitive decline.

Application and Usage

Synergistic intervention in multiple domains

- In line with the actual pattern of brain activity, helping produce compensatory, transferable and maintenance treatment effects
- Improve overall cognition and language and memory function

Combined multi-instrument intervention

- Can be combined with other non-pharmaceutical methods for the maximization of effects
- Current focuses: game, VR, and physical stimulation

Risk factor intervention

- Effective control of risk factors, such as diabetes, alcohol abuse, and substance use is important
- Some DTx for associated risk factors have received FDA approval

Advantage

Enhance treatment effectiveness

- Cognitive impairment often requires non-pharmaceutical therapy or lacks the traditional medication solution
- Computerized cognitive therapy offers an innovative way of treatment with high safety and proven clinical results

Optimize treatment protocols

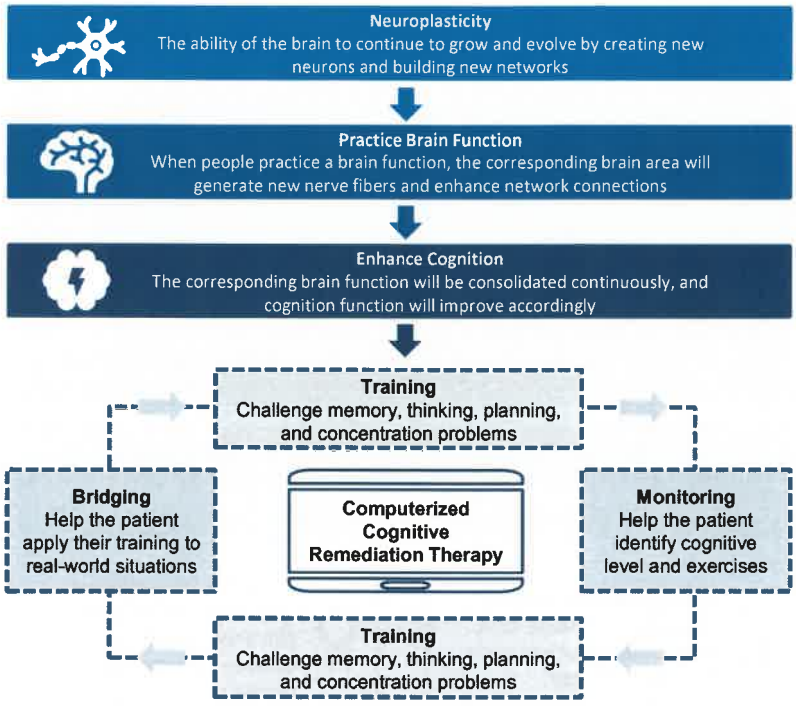
- Personalized treatment based on patients' own profile and disease progression
- Enable one-to-many therapy: increase efficiency and reduce cost

Interactive intervention process

- Real-time monitoring of treatment results, promoting effective hospital-patient linkage
- Form a dynamic closed loop of data transmission with the intervention process when combined with assessment DTx

Source: Frost & Sullivan Analysis

Intervention Mechanism of DTx for Cognitive Impairment



Self-adaptive Intervention

Multiple Cognitive Domains

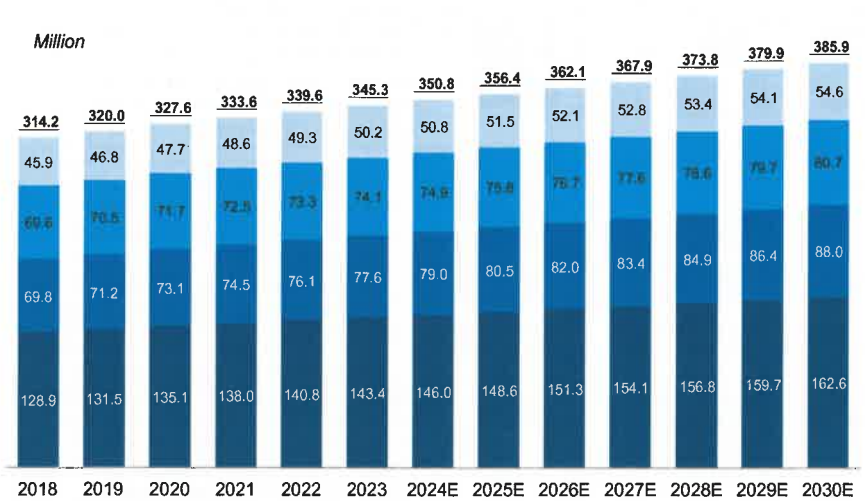
- DTx improves overall cognitive function by using self-adaptive interventions on multiple cognitive domains
- Chinese Guidelines on Cognitive Training has approved the effectiveness of multi-cognitive domain, adaptive computer-assisted cognitive training

Source: Frost & Sullivan Analysis

Prevalence of Cognitive Impairment in China, 2018-2030E

- Cognitive impairment is rising in China. During 2018 to 2023, the number of cognitive impairment increased to 345.3 million from 314.2 million with the CAGR of 1.9% and is forecasted to be 356.4 million in 2025 and 385.9 million in 2030.

Prevalence of Cognitive Impairment in China, 2018-2030E



	CAGR 18-23	CAGR 23-25E	CAGR 25E-30E
Total	1.9%	1.6%	1.6%
PCI	1.8%	1.3%	1.2%
NCI	1.3%	1.1%	1.3%
VDCI	2.1%	1.9%	1.8%
CDDCI	2.2%	1.8%	1.8%

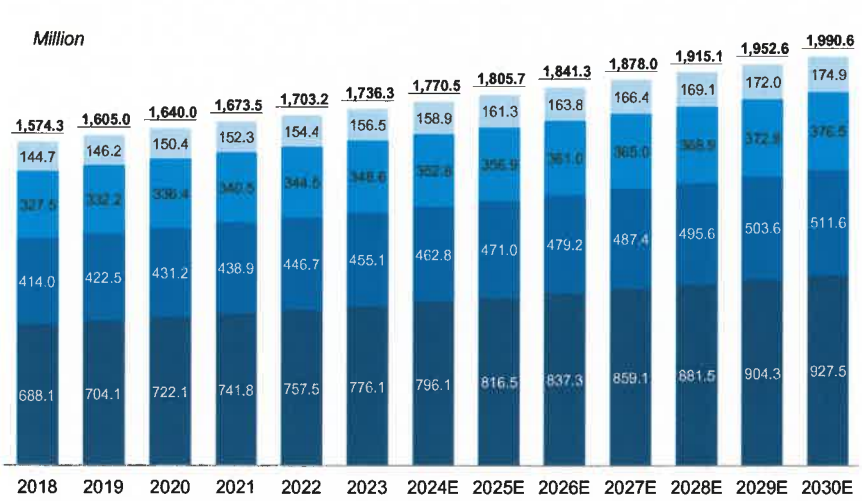
Note: The overall prevalence and prevalence in each field of cognitive impairment include patients with comorbidities.

Source: Frost & Sullivan Analysis

Global Prevalence of Cognitive Impairment, 2018-2030E

- During 2018 to 2023, the number of cognitive impairment increased to 1,736.3 million from 1,574.3 million with the CAGR of 2.0% and is forecasted to be 1,805.7 million in 2025 and 1,990.6 million in 2030.

Global Prevalence of Cognitive Impairment, 2018-2030E



	CAGR 18-23	CAGR 23-25E	CAGR 25E-30E
Total	2.0%	2.0%	2.0%
NCI	1.6%	1.5%	1.6%
PCI	1.3%	1.2%	1.1%
VDCI	1.9%	1.7%	1.7%
CDDCI	2.4%	2.6%	2.6%

Note: The overall prevalence and prevalence in each field of cognitive impairment include patients with comorbidities.

Source: Frost & Sullivan Analysis

FDA Approved DTx for Vascular Disease Cognitive Impairment (1/1)

	Product Name	Company	Indication	Pathway	Approval Year
1	MindMotion® GO	MindMaze	Neurorehabilitation Neurological conditions such as stroke, brain injury, and neurodegenerative diseases	510(k)	2018
2	MindMotion® PRO				2017

Source: FDA, Frost & Sullivan Analysis

FDA Approved DTx for Psychiatric Disorder Induced Cognitive Impairment (1/1)

	Product Name	Company	Indication	Pathway	Approval Year
1	DaylightRx	Big Health	GAD (Generalized Anxiety Disorder)	FDA approval	2024
2	SleepioRx		Insomnia	FDA approval	2024
3	Mamalift PlusTM	Curio	Mild to Moderate Postpartum Depression (PPD)	510(k)	2024
4	biofeedback (ABS) software development kit (SDK)	Better Therapeutics	Future Pain, Post-traumatic Stress Disorder, Epilepsy, Sleep Disorders, Immune Diseases, Parkinson's, Alzheimer's Disease	510(k)	2024
5	Rejoyn®	Otsuka Pharmaceutical, Co. Ltd. (Otsuka) and Click Therapeutics, Inc., (Click)	MDD (Major Depressive Disorder); Emotional Cognitive Impairment	510(k)	2024
6	Prism for PTSD	GrayMatters Health	PTSD(Post-traumatic stress disorder)	510(k)	2023
7	Stanza	Swing Therapeutics	Fibromyalgia Symptoms; Chronic Pain, Fatigue, Sleep Disorders, Depression, and Cognitive symptoms	De Novo	2023
8	Sleepio	Big Health	Insomnia	EUA	2023
9	Daylight		Anxiety	EUA	2023
10	01 Depression	Feel Therapeutics	MDD (Major Depressive Disorder)	EUA	2023
11	02 Anxiety		GAD (Generalized Anxiety Disorder)	EUA	2023
12	SparkRx	Limbix	Adolescent depression	EUA	2021
13	Ensemble	Happify Health	Depression&Anxiety	EUA	2021
14	LIMBIX SparkRx	Limbix	Depression&Anxiety	EUA	2021
15	Somryst (SHUTi)	Pear Therapeutics	Chronic insomnia	510(k)	2020
16	Deprexis	Orexo, GAIA AG	Depression	510(k)	2020
17	reSET-O	Pear Therapeutics, Inc.	Opioid use disorder	510(k)	2018
18	ReSet		Substance use disorders	De novo	2017

Source: FDA, Frost & Sullivan Analysis

FDA Approved DTx for Neurodegenerative Disease Induced Cognitive Impairment (1/1)

	Product Name	Company	Indication	Pathway	Approval Year
1	biofeedback (ABS) software development kit (SDK)	Better Therapeutics	Future Pain, Post-traumatic Stress Disorder, Epilepsy, Sleep Disorders, Immune Diseases, Parkinson's, Alzheimer's Disease	510(k)	2024
2	Stanza	Swing Therapeutics	Fibromyalgia Symptoms; Chronic Pain, Fatigue, Sleep Disorders, Depression, and Cognitive symptoms	De Novo	2023
3	MindMotion® GO	MindMaze	Neurorehabilitation Neurological conditions such as stroke, brain injury, and neurodegenerative diseases	510(k)	2018
4	MindMotion® PRO				2017

Source: FDA, Frost & Sullivan Analysis

FDA Approved DTx for Child Development Deficiency Induced Cognitive Impairment (1/1)

	Product Name	Company	Indication	Pathway	Approval Year
1	EndeavorOTC®	Akili Interactive Labs	ADHD	510(k)	2024
2	EndeavorRx		ADHD	De novo	2020
3	TALi Train	TALI Digital	Attention impairment	510(k) exempt	2018

Source: FDA, Frost & Sullivan Analysis

NMPA Approved DTx for Vascular Disease Cognitive Impairment (1/2)

	产品名称	注册人名称	适用范围/预期用途	年份
1	认知功能辅助筛查评估软件	长沙智精灵教育科技有限公司	认知功能	2022
2	基本认知能力测验软件		认知功能	2022
3	脑功能信息管理平台软件系统		轻度认知障碍	2018
4	认知功能筛查测评与训练软件	南京健脑健康科技有限公司	轻度认知障碍。不涉及精神分裂症、焦虑症、抑郁症、精神、心理疾病患者	2024
5	认知康复训练与评估系统	卓道医疗科技（浙江）有限公司	脑功能损伤、脑卒中所致认知障碍	2024
6	认知功能康复软件	长沙元颐科技有限公司	脑功能损伤、脑卒中	2024
7	认知障碍康复评估训练系统	河南翔宇医疗设备股份有限公司	脑卒中引起轻度认知障碍	2024
8	认知功能训练系统	长沙华鹊景医疗科技有限公司	脑外伤、脑卒中所致轻度认知障碍	2024
9	认知康复训练与评估软件	长沙龙之杰科技有限公司	认知康复训练与评估软件	2023
10	VR认知能力评估与训练软件	湖南心景医疗器械有限公司	脑损伤疾病导致的认知、言语、精神心理功能方面的脑功能障碍	2023
11	认知功能障碍评估与训练软件	湖南万物成理医疗科技有限公司	认知障碍	2023
12	VR认知功能康复软件	湖南赛翁思医疗器械有限公司	脑功能损伤、脑卒中所致认知障碍	2023
13	认知功能评估训练软件	长沙脑吾脑网络科技有限公司	轻度认知障碍	2023
14	言语认知康复训练系统	上海中医大资产经营有限公司	脑卒中后言语认知功能障碍	2023
15	认知康复训练系统		脑卒中后认知功能障碍	2023
16	认知障碍康复评估训练系统	河南翔宇医疗设备股份有限公司	脑卒中引起轻度认知障碍	2023
17	VR认知功能康复软件	湖南露电医疗科技有限公司	脑功能损伤、脑卒中所致认知障碍	2023
18	成人认知能力测试与训练仪	常州市钱璟康复股份有限公司	脑损伤疾病所致的智力低下、记忆障碍以及认知障碍	2022
19	认知能力测试与训练系统	艾利特（湖南）医疗科技有限公司	语言认知能力	2022

批注：所列适应症为NMPA官网登记描述，临床使用时的应用范围与VDCI有关。

Source: FDA, Frost & Sullivan Analysis

NMPA Approved DTx for Vascular Disease Cognitive Impairment (2/2)

	产品名称	注册人名称	适用范围/预期用途	年份
20	认知功能障碍评估与训练软件	南京伟思医疗科技股份有限公司	轻度认知障碍	2022
21	认知功能障碍检查与矫正软件	湖南心康医学科技有限公司	轻度认知障碍	2022
22	认知障碍评估康复软件	桂林宜康电子科技有限公司	轻度认知障碍	2022
23	认知功能评估与训练软件	长沙知松科技有限公司	轻度认知障碍	2022
24	认知功能评估与训练软件	南京健脑健康科技有限公司	脑功能损伤、脑卒中所致认知障碍	2022
25	认知障碍康复训练与脑电刺激治疗系统	江西华恒京兴医疗科技有限公司	成人及儿童的认知障碍、运动功能障碍、语言障碍（失语症）、吞咽障碍，以及失眠、心境低落、情绪障碍症状	2022
26	认知康复训练与评估软件	杭州极智医疗科技有限公司	脑功能损伤、脑卒中所致认知障碍	2019
27	认知能力测试与训练仪	广州康泽医疗科技有限公司	脑损伤疾病所致的成年认知障碍	2019
28	认知功能障碍治疗软件	南京伟思医疗科技股份有限公司	轻度认知障碍	2018

NMPA Approved DTx for Vascular Disease Cognitive Impairment (1/2)

	Product Name	Company	Indication*	Approval Year
1	Cognitive Ability Supplemental Screening and Assessment Software	Changsha Zhijingling Education Technology	Cognitive Function	2022
2	Basic Cognitive Ability Testing Software		Cognitive Function	2022
3	Brain Function Information Management Platform Software System		Mild Cognitive Impairment	2018
4	Cognitive function screening assessment and training software	Nanjing Brain Health Technology Co., Ltd	Mild Cognitive Impairment(Not Involve Patients with Schizophrenia, Anxiety, Depression, Mental and Psychological Diseases)	2024
5	Cognitive rehabilitation training and evaluation system	ZD Medical Technology (Zhejiang) Co., Ltd	Cognitive Impairment Due to Brain Function Injury and Stroke	2024
6	Cognitive function rehabilitation software	Changsha Yuanyi Technology Co., Ltd	Cognitive Impairment Due to Brain Function Injury and Stroke	2024
7	Cognitive Impairment rehabilitation assessment training system	Xiangyu Medical Co., Ltd	Mild Cognitive Impairment Due to Stroke	2024
8	Cognitive function training system	Changsha Huaquejing Medical Technology Co., Ltd	Mild Cognitive Impairment Due to Brain Trauma and Stroke	2024
9	Cognitive Rehabilitation Training and Assessment Software	Changsha Longzhijie Technology Co., Ltd	Cognitive Impairment Due to Brain Function Injury or Stroke	2023
10	VR Cognitive Assessment and Training Software	Hunan Xinjing Medical Equipment Co., Ltd	Brain Dysfunction in Cognition, Speech, and Psychosomatic Functions Due to Brain Injury Disorders	2023
11	Cognitive Dysfunction Assessment and Training Software	Hunan Wanwu Chengli Medical Technology Co., Ltd	Cognitive Impairment	2023
12	VR Rehabilitation Software for Cognitive Function	Hunan Saionsi Medical Device Co., Ltd	Cognitive Impairment Due to Brain Function Injury or Stroke	2023
13	Cognitive Function Assessment Training Software	Changsha Braingine Network Technology Co., Ltd	Mild Cognitive Impairment	2023
14	Speech Cognition Rehabilitation Training System	Shanghai University of Traditional Chinese Medicine Asset Management Co., Ltd	Verbal Cognitive Dysfunction Due to Brain Stroke	2023
15	Cognitive Rehabilitation Training System		Cognitive Impairment Due to Brain Stroke	2023

Note: All indication descriptions are extracted from the NMPA website and their scope relates to VDCI.

Source: FDA, Frost & Sullivan Analysis

NMPA Approved DTx for Vascular Disease Cognitive Impairment (2/2)

	Product Name	Company	Indication*	Approval Year
16	Cognitive Impairment Rehabilitation Assessment and Training System	Henan Xiangyu Medical Equipment Co., Ltd	Cognitive Impairment Due to Brain Stroke	2023
17	VR Cognitive Rehabilitation Software	Hunan Ludian Medical Technology Equipment Co., Ltd	Cognitive Impairment Due to Brain Function Injury or Stroke	2023
18	Adult Cognitive Testing and Training Instrument	Changzhou Qianjing Rehabilitation Co., Ltd	Mental retardation, Memory impairment, Cognitive Disorders Due to Brain-injury Disorders	2022
19	Cognitive Ability Testing and Training System	Alite (Hunan) Medical Technology Co., Ltd	Linguistic Cognitive Ability	2022
20	Cognitive Dysfunction Assessment and Training Software	Nanjing Weisi Medical Technology Co., Ltd	Mild Cognitive Impairment	2022
21	Cognitive Dysfunction Examination and Correction Software	Hunan Xinkang Medical Technology Co., Ltd	Mild Cognitive Impairment	2022
22	Cognitive Impairment Assessment of Rehabilitation Software	Guilin Yikang Electronic Technology Co., Ltd	Mild Cognitive Impairment	2022
23	Cognitive Function Assessment and Training Software	Changsha Zhisong Technology Co., Ltd	Mild Cognitive Impairment	2022
24	Cognitive Function Assessment and Training Software	Nanjing Jianbrain Health Technology Co., Ltd	Cognitive Impairment Due to Brain Function Injury or Stroke	2022
25	Rehabilitation Training for Cognitive Impairment and the EEG Stimulation Treatment System	Jiangxi Huaheng Jingxing Medical Technology Co., Ltd	Cognitive Impairment, Motor Dysfunction, Language Disorders (Aphasia), Swallowing Disorders, and Symptoms of Insomnia, Depression, and Mood Disorders In Adults and Children	2022
26	Cognitive Rehabilitation Training and Assessment Software	Hangzhou Jizhi Medical Technology Co., Ltd	Cognitive Impairment Due to Brain Function Injury or Stroke	2019
27	Cognitive Ability Test and Training Apparatus	Guangzhou Kangze Medical Technology Co., Ltd	Adult Cognitive Impairment Due to Brain-injurious Diseases	2019
28	Cognitive Dysfunction Treatment Software	Nanjing Weisi Medical Technology Co., Ltd	Mild Cognitive Impairment	2018

Note: All indication descriptions are extracted from the NMPA website and their scope relates to VDCI.

Source: FDA, Frost & Sullivan Analysis

NMPA Approved DTx for Psychiatric Disorder Induced Cognitive Impairment (1/2)

	产品名称	注册人名称	适用范围/预期用途	年份
1	认知功能辅助筛查评估软件	长沙智精灵教育科技有限公司	认知功能	2022
2	基本认知能力测验软件		认知功能	2022
3	脑功能信息管理平台软件系统		轻度认知障碍	2018
4	认知功能障碍评估与训练软件	海南元医康健医疗科技有限公司	轻度认知功能障碍	2024
5	认知功能评估与训练软件	四川玉安智康医疗科技有限公司	轻度认知障碍	2024
6	认知康复训练与评估系统	卓道医疗科技（浙江）有限公司	脑功能损伤、脑卒中所致认知障碍	2024
7	认知功能康复软件	长沙元颐科技有限公司	脑功能损伤、脑卒中所致认知障碍	2024
8	认知功能障碍矫正软件	湖南欧宁慧心科技有限公司	轻度认知障碍	2024
9	认知功能康复软件	长沙元域绿洲科技有限公司	轻度认知障碍	2024
10	认知功能训练软件	湖南飞思迈科医疗科技有限公司	轻度认知障碍	2024
11	数字化认知功能障碍康复训练软件	湖南颐启科技有限公司	轻度认知障碍	2024
12	认知功能评估与训练软件	湖南特霍芬智能科技有限公司	轻度认知障碍	2024
13	认知功能训练软件	精准视光（长沙）医疗科技有限公司	轻度认知障碍	2024
14	认知功能障碍评估与训练软件	成都基底互动科技有限公司	轻度认知障碍	2024
15	认知功能训练系统	长沙华鹊景医疗科技有限公司	脑功能损伤、脑卒中所致认知障碍	2024
16	认知功能障碍评估与训练软件	湖南万物成理医疗科技有限公司	认知障碍	2023
17	认知障碍评估软件	湖南鸿钧智能科技有限公司	轻度认知功能障碍	2023
18	认知障碍康复训练软件	湖南谱云数字医疗科技有限公司	轻度认知障碍	2023
19	认知功能评估与训练软件	长沙集思鸣智科技有限公司	知障碍、精神分裂症、双相情感障碍、抑郁症、焦虑症、阿尔兹海默症、睡眠障碍、孤独症、多动症	2023
20	认知功能评估与训练软件	深圳市鹤灵医疗设备技术开发有限责任公司	轻度认知障碍	2023
21	心理测量与认知评估软件	湖南凯司曼科技有限公司	精神、心理状况	2023
22	VR认知能力评估与训练软件	湖南心景医疗器械有限公司	脑损伤疾病导致的认知、言语、精神心理功能方面的脑功能障碍	2023

批注：所列适应症为NMPA官网登记描述，临床使用时的应用范围与PCI有关。

Source: NMPA, Frost & Sullivan Analysis

NMPA Approved DTx for Psychiatric Disorder Induced Cognitive Impairment (2/2)

	产品名称	注册人名称	适用范围/预期用途	年份
23	失眠认知行为疗法临床管理软件	湖南弗界数字医疗科技有限公司	睡眠障碍	2023
24	认知功能障碍康复训练软件	希迪克（郑州）智能康复设备有限公司	脑损伤疾病所致认知障碍	2023
25	认知功能障碍评估与训练软件	南京伟思医疗科技股份有限公司	轻度认知障碍	2022
26	成人认知能力测试与训练仪	常州市钱璟康复股份有限公司	轻度认知障碍	2022
27	认知功能障碍检查与矫正软件	湖南心康医学科技有限公司	轻度认知障碍	2022
28	认知功能障碍康复训练软件	湖南艾泽医疗科技有限公司	认知障碍、精神分裂症、双相情感障碍、抑郁症、焦虑症、阿尔兹海默症、睡眠障碍、孤独症、多动症	2022
29	认知功能障碍治疗软件	湖南望里医疗科技有限公司	轻度认知障碍	2022
30	认知障碍评估康复软件	桂林宜康电子科技有限公司	轻度认知障碍	2022
31	认知障碍康复训练与脑电刺激治疗系统	江西华恒京兴医疗科技有限公司	成人及儿童的认知障碍、运动功能障碍、语言障碍（失语症）、吞咽障碍，以及失眠、心境低落、情绪障碍症状	2022
32	认知功能评估与训练软件	长沙知松科技有限公司	轻度认知障碍	2022
33	认知功能康复软件	杭州颐康医疗科技有限公司	精神分裂症、分裂型障碍、心境（情感）障碍	2020

批注：所列适应症为NMPA官网登记描述，临床使用时的应用范围与PCI有关。

Source: NMPA, Frost & Sullivan Analysis

NMPA Approved DTx for Psychiatric Disorder Induced Cognitive Impairment (1/2)

	Product Name	Company	Indication	Approval Year
1	Cognitive Ability Supplemental Screening and Assessment Software	Changsha Zhijingling Education Technology	Cognitive Function	2022
3	Basic Cognitive Ability Testing Software		Cognitive Function	2022
4	Brain Function Information Management Platform Software System		Mild Cognitive Impairment	2018
5	Cognitive Impairment assessment and training software	Hainan Yuanyi Kangjian Medical Technology Co., Ltd	Mild Cognitive Impairment	2024
6	Cognitive function assessment and training software	Sichuan Yuan Zhikang Medical Technology Co., Ltd	Mild Cognitive Impairment	2024
7	Cognitive rehabilitation training and evaluation system	ZD Medical Technology Co., Ltd	Cognitive Impairment Due to Brain Function Injury and Stroke	2024
8	Cognitive function rehabilitation software	Changsha Yuanyi Technology Co., Ltd	Cognitive Impairment Due to Brain Function Injury and Stroke	2024
9	Cognitive dysfunction correction software	Hunan Ouning Huixin Technology Co., Ltd	Mild Cognitive Impairment	2024
10	Cognitive function rehabilitation software	Changsha Yuanyu Oasis Technology Co., Ltd	Mild Cognitive Impairment	2024
11	Cognitive function training software	Hunan Feisimaike Medical Technology Co., Ltd	Mild Cognitive Impairment	2024
12	Digital cognitive dysfunction rehabilitation training software	Hunan BQBrain Technology Co., Ltd	Mild Cognitive Impairment	2024
13	Cognitive function assessment and training software	Hunan Thoven intelligent Technology Co., Ltd	Mild Cognitive Impairment	2024
14	Cognitive function training software	Precision Technology of Sight Care (Changsha) Medical Technology Co., Ltd	Mild Cognitive Impairment	2024
15	Cognitive Impairment assessment and training software	Chengdu Base Interactive Technology Co., Ltd	Mild Cognitive Impairment	2024
16	Cognitive function training system	Changsha Huaquejing Medical Technology Co., Ltd	Cognitive Impairment Due to Brain Function Injury and Stroke	2024
17	Cognitive Dysfunction Assessment and Training Software	Hunan Wanwu Chengli Medical Technology Co., Ltd	Cognitive Impairment	2023

Note: All indication descriptions are extracted from the NMPA website and their scope relates to PCI.

Source: NMPA, Frost & Sullivan Analysis

NMPA Approved DTx for Psychiatric Disorder Induced Cognitive Impairment (2/2)

	Product Name	Company	Indication	Approval Year
18	Cognitive Dysfunction Assessment and Training Software	Hunan Wanwu Chengli Medical Technology Co., Ltd	Cognitive Impairment	2023
19	Cognitive Impairment Assessment Software	Hunan Hongjun Intelligent Technology Co., Ltd	Mild Cognitive Impairment	2023
19	Psychometric and Cognitive Assessment Software	Hunan Kaesman Technology Co., Ltd	Mental and Psychological Condition	2023
20	Cognitive Impairment rehabilitation training software	Hunan Aiyun Digital Medical Technology Co., Ltd	Cognitive Function	2023
21	Cognitive function assessment and training software	Changsha Jisi Mingzhi Technology Co., Ltd	Cognitive Disorders, Schizophrenia, Bipolar Disorder, Depression, Anxiety, Alzheimer's Disease, Sleep Disorders, Autism, ADHD	2023
22	Cognitive function assessment and training software	Shenzhen Heling Medical Technology Co., Ltd	Cognitive Function	2023
23	VR Cognitive Assessment and Training Software	Hunan Xinjing Medical Equipment Co., Ltd	Brain Dysfunction in Cognition, Speech, and Psychosomatic Functions Due to Brain Injury Disorders	2023
24	Clinical Management Software for Cognitive Behavioral Therapy for Insomnia	Hunan Fujie Digital Medical Technology Co., Ltd	Sleeping disorders	2023
25	Cognitive dysfunction rehabilitation training software	Xidike (Zhengzhou) Intelligent Rehabilitation Equipment Co., Ltd	Cognitive Impairment Due to Brain-Injuring diseases	2023
26	Cognitive Dysfunction Assessment and Training Software	Nanjing Weisi Medical Technology Co., Ltd	Mild Cognitive Impairment	2022
27	Cognitive Dysfunction Examination and Correction Software	Hunan Xinkang Medical Technology Co., Ltd	Mild Cognitive Impairment	2022
28	Rehabilitation Training Software for Cognitive Dysfunction	Hunan Aze Medical Technology Co., Ltd	Cognitive Impairment, Schizophrenia, Bipolar Disorder, Depression, Anxiety, Alzheimer's Disease, Sleep Disorders, Autism, ADHD	2022
29	Cognitive Dysfunction Treatment Software	Hunan Wangli Medical Technology Co., Ltd	Mild Cognitive Impairment	2022
30	Cognitive Impairment Assessment of Rehabilitation Software	Guilin Yikang Electronic Technology Co., Ltd	Mild Cognitive Impairment	2022
31	Rehabilitation Training for Cognitive Impairment and the EEG Stimulation Treatment System	Jiangxi Huaheng Jingxing Medical Technology Co., Ltd	Cognitive Impairment, Motor Dysfunction, Language Disorders (Aphasia), Swallowing Disorders, and Symptoms of Insomnia, Depression, and Mood Disorders In Adults and Children	2022

NMPA Approved DTx for Neurodegenerative Disease Induced Cognitive Impairment (1/2)

	产品名称	注册人名称	适用范围/预期用途	年份
1	认知功能辅助筛查评估软件	长沙智精灵教育科技有限公司	认知功能	2022
2	基本认知能力测验软件		认知功能	2022
3	脑功能信息管理平台软件系统		轻度认知障碍	2018
4	认知功能障碍评估与训练软件	湖南万物成理医疗科技有限公司	认知障碍	2023
5	认知评估与训练软件	长沙数丹医疗科技有限公司	认知障碍	2023
6	认知功能评估与训练软件	长沙集思鸣智科技有限公司	知障碍、精神分裂症、双相情感障碍、抑郁症、焦虑症、阿尔兹海默症、睡眠障碍、孤独症、多动症	2023
7	认知功能康复软件	长沙艾蒂生物科技有限公司	轻度认知障碍	2023
8	认知功能评估与训练软件	深圳市鹤灵医疗设备技术开发有限责任公司	轻度认知障碍	2023
9	VR认知能力评估与训练软件	湖南心景医疗器械有限公司	脑损伤疾病导致的认知、言语、精神心理功能方面的脑功能障碍	2023
10	认知能力数字康复软件	长沙鲤心医疗科技有限公司	轻度认知障碍	2023
11	认知功能障碍康复训练软件	湖南波克医疗科技有限公司	轻度认知障碍	2023
12	认知功能评估训练软件	长沙脑吾脑网络科技有限公司	轻度认知障碍	2023
13	大脑生理与认知功能辅助评估系统	成都集思鸣智科技有限公司	轻度认知功能障碍	2023
14	数字认知功能训练软件	长沙市和家健脑智能科技有限公司	轻度认知障碍	2023
15	认知功能评估与训练软件	长沙知松科技有限公司	轻度认知障碍	2022
16	认知功能障碍康复训练软件	湖南艾泽医疗科技有限公司	认知障碍、精神分裂症、双相情感障碍、抑郁症、焦虑症、阿尔兹海默症、睡眠障碍、孤独症、多动症	2022
17	认知功能障碍检查与矫正软件	湖南心康医学科技有限公司	轻度认知障碍	2022
18	认知功能评估与训练软件	长沙博斯腾认知科技有限公司	认知障碍	2022
19	认知评估与训练软件	长沙数丹医疗科技有限公司	认知障碍	2023
20	认知功能评估与训练软件	长沙集思鸣智科技有限公司	知障碍、精神分裂症、双相情感障碍、抑郁症、焦虑症、阿尔兹海默症、睡眠障碍、孤独症、多动症	2023
21	认知功能康复软件	长沙艾蒂生物科技有限公司	轻度认知障碍	2023
22	认知功能评估与训练软件	深圳市鹤灵医疗设备技术开发有限责任公司	轻度认知障碍	2023

批注：所列适应症为NMPA官网登记描述，临床使用时的应用范围与NCI有关。

Source: NMPA, Frost & Sullivan Analysis

NMPA Approved DTx for Neurodegenerative Disease Induced Cognitive Impairment (2/2)

	产品名称	注册人名称	适用范围/预期用途	年份
23	VR认知能力评估与训练软件	湖南心景医疗器械有限公司	脑损伤疾病导致的认知、言语、精神心理功能方面的脑功能障碍	2023
24	认知能力数字康复软件	长沙鲤心医疗科技有限公司	轻度认知障碍	2023
25	认知功能障碍康复训练软件	湖南波克医疗科技有限公司	轻度认知障碍	2023
26	认知功能评估训练软件	长沙脑吾脑网络科技有限公司	轻度认知障碍	2023
27	大脑生理与认知功能辅助评估系统	成都集思鸣智科技有限公司	轻度认知功能障碍	2023
28	数字认知功能训练软件	长沙市和家健脑智能科技有限公司	轻度认知障碍	2023
29	认知功能评估与训练软件	长沙知松科技有限公司	轻度认知障碍	2022
30	认知功能障碍康复训练软件	湖南艾泽医疗科技有限公司	认知障碍、精神分裂症、双相情感障碍、抑郁症、焦虑症、阿尔兹海默症、睡眠障碍、孤独症、多动症	2022
31	认知功能障碍检查与矫正软件	湖南心康医学科技有限公司	轻度认知障碍	2022
32	认知功能评估与训练软件	长沙博斯腾认知科技有限公司	认知障碍	2022
33	认知功能障碍治疗软件	湖南望里医疗科技有限公司	轻度认知障碍	2022
34	认知功能障碍评估与训练软件	南京伟思医疗科技股份有限公司	轻度认知障碍	2022
35	认知障碍评估康复软件	桂林宜康电子科技有限公司	轻度认知障碍	2022
36	认知障碍康复训练与脑电刺激治疗系统	江西华恒京兴医疗科技有限公司	成人及儿童的认知障碍、运动功能障碍、语言障碍（失语症）、吞咽障碍，以及失眠、心境低落、情绪障碍症状	2022

批注：所列适应症为NMPA官网登记描述，临床使用时的应用范围与NCI有关。

Source: NMPA, Frost & Sullivan Analysis

NMPA Approved DTx for Neurodegenerative Disease Induced Cognitive Impairment (1/2)

	Product Name	Company	Indication	Approval Year
1	Cognitive Ability Supplemental Screening and Assessment Software	Changsha Zhijingling Education Technology	Cognitive Function	2022
2	Basic Cognitive Ability Testing Software		Cognitive Function	2022
3	Brain Function Information Management Platform Software System		Mild Cognitive Impairment	2018
4	Cognitive Impairment assessment and training softwareCognitive Impairment assessment and training software	Hainan Yuanyi Kangjian Medical Technology Co., Ltd	Mild Cognitive Impairment	2024
5	Cognitive function assessment and training software	Sichuan Yuan Zhikang Medical Technology Co., Ltd	Mild Cognitive Impairment	2024
6	Adult cognitive ability test and training instrument	Changzhou Qian Jing Rehabilitation Co., Ltd	Mental Retardation, Memory Impairment, and Cognitive Impairment Due to Brain Injury and Disease	2024
7	Cognitive rehabilitation training and evaluation system	ZD Medical Technology (Zhejiang) Co., Ltd	Cognitive Impairment Due to Brain Function Injury and Stroke	2024
8	Cognitive function rehabilitation software	Changsha Yuanyi Technology Co., Ltd	Cognitive Impairment Due to Brain Function Injury and Stroke	2024
9	Cognitive ability training system	Hunan Youerkang Medical Technology Co., Ltd	Mental Retardation, Memory Impairment, and Cognitive Impairment Due to Traumatic Brain Disease	2024
10	Cognitive dysfunction correction software	Hunan Ouning Huixin Technology Co., Ltd	Mild Cognitive Impairment	2024
11	Cognitive function rehabilitation software	Changsha Yuanyu Oasis Technology Co., Ltd	Mild Cognitive Impairment	2024
12	Cognitive function training software	Hunan Feisimaike Medical Technology Co., Ltd	Mild Cognitive Impairment	2024
13	Digital cognitive dysfunction rehabilitation training software	Hunan BQBrain Technology Co., Ltd	Mild Cognitive Impairment	2024
14	Cognitive function assessment and training software	Hunan Thoven intelligent Technology Co., Ltd	Mild Cognitive Impairment	2024
15	Cognitive function training software	Precision Technology of Sight Care (Changsha) Medical Technology Co., Ltd	Mild Cognitive Impairment	2024
16	Cognitive Impairment assessment and training software	Chengdu Base Interactive Technology Co., Ltd	Mild Cognitive Impairment	2024
17	Cognitive function training system	Changsha Huaquejing Medical Technology Co., Ltd	Cognitive Impairment Due to Brain Function Injury and Stroke	2024
18	Cognitive Dysfunction Assessment and Traini ng Software	Hunan Wanwu Chengli Medical Technology Co., Ltd	Cognitive Impairment	2023

NMPA Approved DTx for Neurodegenerative Disease Induced Cognitive Impairment (2/2)

	Product Name	Company	Indication	Approval Year
19	Cognitive Assessment and Training Software	Changsha Shudan Medical Technology Co., Ltd	Cognitive Impairment	2023
20	Cognitive function assessment and training software	Changsha Jisi Mingzhi Technology Co., Ltd	Cognitive Disorders, Schizophrenia, Bipolar Disorder, Depression, Anxiety, Alzheimer's Disease, Sleep Disorders, Autism, ADHD	2023
21	Cognitive Rehabilitation Software	Changsha Aidi Biotechnology Co., Ltd	Mild Cognitive Impairment	2023
22	Cognitive function assessment and training software	Shenzhen Heling Medical Technology Co., Ltd	Cognitive Function	2023
23	VR Cognitive Assessment and Training Software	Hunan Xinjing Medical Equipment Co., Ltd	Brain Dysfunction in Cognition, Speech, and Psychosomatic Functions Due to Brain Injury Disorders	2023
24	Cognitive Digital Rehabilitation Software	Changsha Lixin Medical Technology Co., Ltd	Mild Cognitive Impairment	2023
25	Cognitive Dysfunction Rehabilitation Software	Hunan Boke Medical Technology Co., Ltd	Mild Cognitive Impairment	2023
26	Cognitive Function Assessment Training Software	Changsha Braingine Network Technology Co., Ltd	Mild Cognitive Impairment	2023
27	Brain Physiology and Cognitive Function Assessment System	Chengdu Jisi Mingzhi Technology Co	Mild Cognitive Impairment	2023
28	Digital Cognitive Function Training Software	Changsha Hejia Jiannao Intelligent Technology Co., Ltd	Mild Cognitive Impairment	2023
29	Cognitive Function Assessment and Training Software	Changsha Zhisong Technology Co., Ltd	Mild Cognitive Impairment	2022
30	Rehabilitation Training Software for Cognitive Dysfunction	Hunan Aze Medical Technology Co., Ltd	Cognitive Impairment, Schizophrenia, Bipolar Disorder, Depression, Anxiety, Alzheimer's Disease, Sleep Disorders, Autism, ADHD	2022
31	Cognitive Dysfunction Examination and Correction Software	Hunan Xinkang Medical Technology Co., Ltd	Mild Cognitive Impairment	2022
32	Cognitive Function Assessment and Training Software	Changsha Best Covered Cognitive Technology Co., Ltd	Cognitive Impairment	2022
33	Cognitive Dysfunction Treatment Software	Hunan Wangli Medical Technology Co., Ltd	Mild Cognitive Impairment	2022
34	Cognitive Dysfunction Assessment and Training Software	Nanjing Weisi Medical Technology Co., Ltd	Mild Cognitive Impairment	2022
35	Cognitive Impairment Assessment of Rehabilitation Software	Guilin Yikang Electronic Technology Co., Ltd	Mild Cognitive Impairment	2022
			Cognitive Impairment, Motor	

NMPA Approved DTx for Child Development Deficiency Induced Cognitive Impairment (1/2)

	产品名称	注册人名称	适用范围/预期用途	年份
1	阅读障碍补充筛查与评估软件	长沙智精灵教育科技有限公司	阅读障碍补充筛查与评估软件	2024
2	基本认知能力测验软件		认知功能	2022
3	脑功能信息管理平台软件系统		轻度认知障碍	2018
4	认知功能障碍评估与训练软件	海南元医康健医疗科技有限公司	轻度认知障碍	2024
5	认知功能评估与训练软件	四川玉安智康医疗科技有限公司	轻度认知障碍	2024
6	儿童认知能力测试与训练仪	常州市钱璟康复股份有限公司	疾病引起的智力低下、记忆障碍以及认知障碍的特殊儿童	2024
7	成人认知能力测试与训练仪	常州市钱璟康复股份有限公司	脑损伤疾病所致的智力低下、记忆障碍以及认知障碍	2024
8	认知功能障碍矫正软件	湖南欧宁慧心科技有限公司	轻度认知障碍	2024
9	认知功能康复软件	长沙元域绿洲科技有限公司	轻度认知障碍	2024
10	认知功能训练软件	湖南飞思迈科医疗科技有限公司	轻度认知障碍	2024
11	数字化认知功能障碍康复训练软件	湖南茵启科技有限公司	轻度认知障碍	2024
12	认知功能评估与训练软件	湖南特霍芬智能科技有限公司	轻度认知障碍	2024
13	认知功能训练软件	精准视光（长沙）医疗科技有限公司	轻度认知障碍	2024
14	认知功能障碍评估与训练软件	成都基底互动科技有限公司	轻度认知障碍	2024
15	认知功能障碍评估与训练软件	湖南万物成理医疗科技有限公司	认知障碍	2023
16	认知功能评估训练软件	长沙脑吾脑网络科技有限公司	轻度认知障碍	2023
17	认知功能评估与训练软件	长沙知松科技有限公司	轻度认知障碍	2022
18	儿童认知行为能力早期筛查与评估软件	长沙康安启元医疗科技有限公司	儿童认知障碍、发育迟缓、孤独症谱系障碍、注意力缺陷与多动障碍、言语障碍、学习障碍	2022

批注：所列适应症为NMPA官网登记描述，临床使用时的应用范围与CDDCI有关。

Source: NMPA, Frost & Sullivan Analysis

NMPA Approved DTx for Child Development Deficiency Induced Cognitive Impairment (2/2)

	产品名称	注册人名称	适用范围/预期用途	年份
19	认知功能障碍康复训练软件	湖南艾泽医疗科技有限公司	认知障碍、精神分裂症、双相情感障碍、抑郁症、焦虑症、阿尔兹海默症、睡眠障碍、孤独症、多动症	2022
20	认知功能障碍检查与矫正软件	湖南心康医学科技有限公司	轻度认知障碍	2022
21	认知能力测试与训练系统	艾利特（湖南）医疗科技有限公司	语言认知能力	2022
22	认知功能障碍评估与训练软件	南京伟思医疗科技股份有限公司	轻度认知障碍	2022
23	认知障碍评估康复软件	桂林宜康电子科技有限公司	轻度认知障碍	2022
24	认知障碍康复训练与脑电刺激治疗系统	江西华恒京兴医疗科技有限公司	成人及儿童的认知障碍、运动功能障碍、语言障碍（失语症）、吞咽障碍，以及失眠、心境低落、情绪障碍症状	2022
25	儿童认知行为能力测评软件	北京北大医疗脑健康科技有限公司浏阳融博分公司	轻度认知障碍	2022

批注：所列适应症为NMPA官网登记描述，临床使用时的应用范围与CDDCI有关。

Source: NMPA, Frost & Sullivan Analysis

NMPA Approved DTx for Child Development Deficiency Induced Cognitive Impairment (1/2)

	Product Name	Company	Indication	Approval Year
1	Dyslexia Supplemental Screening and Assessment Software	Changsha Zhijingling Education Technology	Dyslexia Supplemental Screening and Assessment Software	2024
2	Basic Cognitive Ability Testing Software		Cognitive Function	2022
3	Brain Function Information Management Platform Software System		Mild Cognitive Impairment	2018
4	Cognitive Impairment assessment and training software	Hainan Yuanyi Kangjian Medical Technology Co., Ltd	Mild Cognitive Impairment	2024
5	Cognitive function assessment and training software	Sichuan Yuan Zhikang Medical Technology Co., Ltd	Mild Cognitive Impairment	2024
6	Cognitive ability test and training instrument for children	Changzhou Qian Jing Rehabilitation Co., Ltd	Special children with mental retardation, memory impairment and Cognitive Impairment Due to disease	2024
7	Adult cognitive ability test and training instrument	Changzhou Qian Jing Rehabilitation Co., Ltd	Mental retardation, memory impairment, and Cognitive Impairment Due to Brain Injury and Disease	2024
8	Cognitive dysfunction correction software	Hunan Ouning Huixin Technology Co., Ltd	Mild Cognitive Impairment	2024
9	Cognitive function rehabilitation software	Changsha Yuanyu Oasis Technology Co., Ltd	Mild Cognitive Impairment	2024
10	Cognitive function training software	Hunan Feisimaike Medical Technology Co., Ltd	Mild Cognitive Impairment	2024
11	Digital cognitive dysfunction rehabilitation training software	Hunan BQBrain Technology Co., Ltd	Mild Cognitive Impairment	2024
12	Cognitive function assessment and training software	Hunan Thoven intelligent Technology Co., Ltd	Mild Cognitive Impairment	2024
13	Cognitive function training software	Precision Technology of Sight Care (Changsha) Medical Technology Co., Ltd	Mild Cognitive Impairment	2024
14	Cognitive Impairment assessment and training software	Chengdu Base Interactive Technology Co., Ltd	Mild Cognitive Impairment	2024
15	Cognitive Dysfunction Assessment and Training Software	Hunan Wanwu Chengli Medical Technology Co., Ltd.	Cognitive Impairment	2023

Note: All indication descriptions are extracted from the NMPA website and their scope relates to CDDCI.

Source: NMPA, Frost & Sullivan Analysis

NMPA Approved DTx for Child Development Deficiency Induced Cognitive Impairment (2/2)

	Product Name	Company	Indication	Approval Year
16	Cognitive Function Assessment Training Software	Changsha Braingine Network Technology Co., Ltd.	Mild Cognitive Impairment	2023
17	Cognitive Function Assessment and Training Software	Changsha Zhisong Technology Co., Ltd.	Mild Cognitive Impairment	2022
18	Early Screening and Assessment of Children's Cognitive Behavior Ability Software	Changsha Kang'an Qiyuan Medical Technology Co., Ltd.	Childhood Cognitive Disorders, Developmental Delays, ASD, ADHD, Speech and Language Disorders, Learning Disabilities	2022
19	Rehabilitation Training Software for Cognitive Dysfunction	Hunan Aize Medical Technology Co., Ltd.	Cognitive Impairment, Schizophrenia, Bipolar Disorder, Depression, Anxiety, Alzheimer's Disease, Sleep Disorders, Autism, ADHD	2022
20	Cognitive Dysfunction Examination and Correction Software	Hunan Xinkang Medical Technology Co., Ltd.	Mild Cognitive Impairment	2022
21	Cognitive Ability Testing and Training System	Alite (Hunan) Medical Technology Co., Ltd.	Linguistic Cognitive Ability	2022
22	Cognitive Dysfunction Assessment and Training Software	Nanjing Vishee Medical Technology Co., Ltd.	Mild Cognitive Impairment	2022
23	Cognitive Impairment Assessment of Rehabilitation Software	Guilin Yikang Electronic Technology Co., Ltd.	Mild Cognitive Impairment	2022
24	Rehabilitation Training for Cognitive Impairment and the EEG Stimulation Treatment System	Jiangxi Huaheng Jingxing Medical Technology Co., Ltd.	Cognitive Impairment, Motor Dysfunction, Language Disorders (Aphasia), Swallowing Disorders, and Symptoms of Insomnia, Depression, and Mood Disorders In Adults and Children	2022
25	Children's Cognitive Behavioral Ability Assessment Software	Beijing Pkucare Brain Health Technology Co., Ltd. Liuyang Rongbo Branch	Mild Cognitive Impairment	2022

Note: All indication descriptions are extracted from the NMPA website and their scope relates to CDDCI.

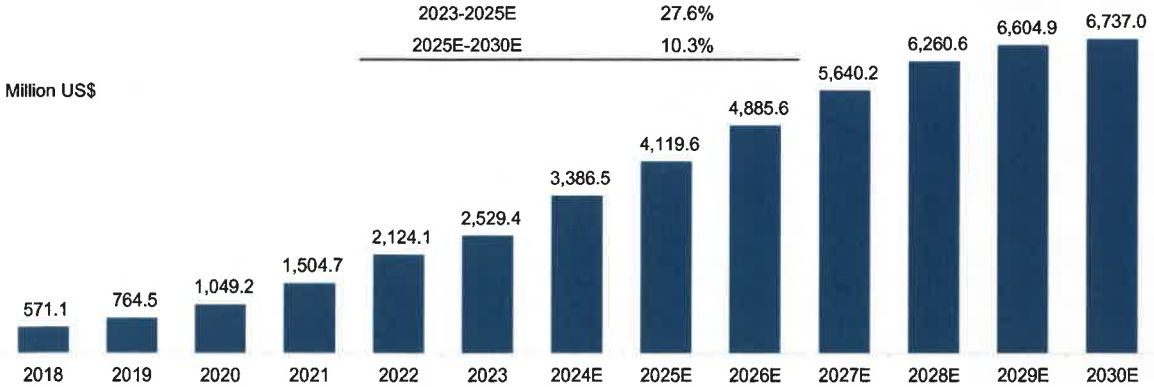
Source: NMPA, Frost & Sullivan Analysis

Global Cognitive Impairment Digital Therapeutics Market Size, 2018-2030E

- The market size of global cognitive impairment digital therapeutics is US$ 2,529.4 million in 2023 and is expected to increase to US$ 4,119.6 million and US$ 6,737.0 million in 2025 and 2030, with a CAGR of 27.6% and 10.3% during this period, respectively.
- The global cognitive impairment digital therapeutics market is growing at a high rate mainly due to the increasing number of patients suffering from cognitive disorders as a result of the deepening aging of the population globally and digital therapeutics serves as an effective therapy for a variety of indications which traditional drug therapies cannot address, and also driven by the fact that digital therapeutics products would start enjoying a green channel for approvals and a fast-track mechanism for launching them after 2020.

Global Cognitive Impairment Digital Therapeutics Market Size, 2018-2030E

Period	CAGR
2018-2023	34.7%
2023-2025E	27.6%
2025E-2030E	10.3%



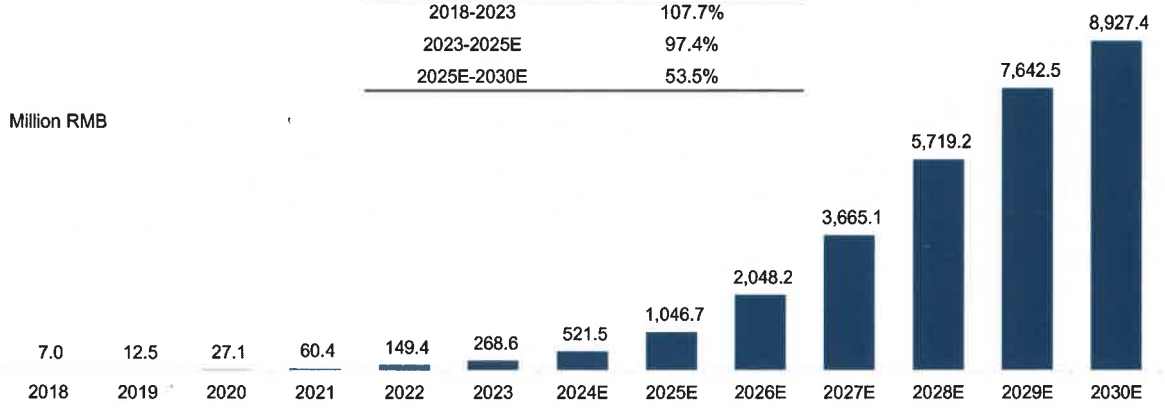
Source: Frost & Sullivan analysis

Cognitive Impairment Digital Therapeutics Market Size in China, 2018-2030E

- The market size of cognitive impairment digital therapeutics in China is 268.6 million RMB in 2023 and is expected to increase to 1,046.7 million RMB and 8,927.4 million RMB in 2025 and 2030, with a CAGR of 97.4% and 53.5% during this period, respectively.
- The cognitive impairment digital therapeutics market in China is growing at a high rate. The major drivers for the market growth are growing patient base due to aging population, rising awareness among patients about diagnosis and treatment of cognitive disorders, and government's focus on disease screening, early prevention and intervention of chronic diseases.

Cognitive Impairment Digital Therapeutics Market Size in China, 2018-2030E

Period	CAGR
2018-2023	107.7%
2023-2025E	97.4%
2025E-2030E	53.5%



Source: Frost & Sullivan analysis

Future Trends of Cognitive Impairment Digital Therapeutics Market

Emerging Business Model	• The prevalence of cognitive impairment such as Alzheimer's disease and Parkinson's disease are increasing with the aging of the population. In addition, the age of onset is becoming younger. Therefore, the early diagnosis and invention of diseases are important. DTx is more and more commonly used by government and medical institutions to diagnose cognitive impairment in senior citizens and delay the rate of cognitive decline
Combination With Technological Frontier	• DTx can be combined with VR and Brain-Computer Interface to improve the efficiency and convenience of human-computer interaction by helping users interact with computers more naturally and improving computers' ability to understand human intentions and needs. In the medical field, these technologies can be used to diagnose and treat brain diseases such as stroke, ADHD, Alzheimer's disease, and Parkinson's disease
Medical Usage	• Many DTx are used for the diagnosis of cognitive impairment and the enhancement of cognitive ability. However, many studies are also focusing on the medical role of DTx in the treatment of cognitive impairment. Clinical trials have proven the effectiveness of some DTx products for the treatment of cognitive impairment such as ADHD
Real World Study (RWS)	• Real World Study refers to the systematic collection of data from drugs and medical devices in real-world settings and the conduct of studies involving evidence-based medicine and clinical epidemiological methods. Using real world data and evidence helps bridge the evidence gap from the randomized, clinical trial to understand the true efficacy and safety profile of DTx in the real world, accelerating commercialization and assisting efficient marketing

Source: Literature Review, Frost & Sullivan Analysis

Growth Drivers of Cognitive Digital Therapeutics in China

Large Demand and Potential Market	• Driven by the aging population and the increased focus on cognitive health, cases of cognitive impairment are on the rise in China. DTx offers a more personalized and cost-effective approach to managing these conditions. With more than 70% of the population having access to the internet and cell phone, DTx can reach a population comparable to traditional hospitals and potentially, more. With the power of modern technology, such as AI/ML and VR, DTx can be used across different treatment aspects of cognitive impairment, from disease assessment to management to intervention.
Advancements in Innovative Technologies	• Innovative technologies are pushing the development of DTx. The advancements in AI/ML are being adopted to improve patient outcomes by providing clinically valid assessment and intervention services, which are personalized based on patient data. Additionally, technologies such as VR can create an immersive and engaging environment for patients to train their cognitive function and apply their newly acquired skills to real-life situations, increasing treatment adherence and overall effectiveness. These innovative technologies are expected to promote the advancement of DTx.
Policies Promoting the Development of Cognitive DTx	• The development of cognitive DTx is fueled by policies promoting digital health and cognitive health. In recent years, the State Council as well as local governments such as Hainan Province have released policies promoting the development of DTx. Moreover, China has put increasing efforts into the large-scale early screening and intervention of various cognitive impairments, which is the strength of DTx. Thus, these initiatives help to build a supportive ecosystem for cognitive DTx, paving the way for its sustainable and high-quality development.
Growing Recognition in Cognitive DTx	• Recognitions in DTx have been steadily growing in recent years. In 2023, the Chinese Expert Consensus on Cognitive Digital Therapeutics was published, representing growing recognition of DTx from the medical community. More and more medical facilities, including hospitals and rehabilitation centers, begin to adopt DTx in their treatment for cognitive impairment. Leading cognitive DTx companies also begin to participate in the establishment of cognitive centers in hospitals initiated by NHS.

Source: Frost & Sullivan Analysis

Entry Barriers of Cognitive Impairment Digital Therapeutics Market

Preemption in Opportunities	• DTx for cognitive impairment in China is an emerging field with increasing attention. The early entrants can participate in industry guidelines and expert consensus to help set industry standards, and they can also establish collaborations with researchers and hospitals for publications and research opportunities. However, the newcomers will face a situation where many opportunities have been occupied by the early entrants.
Emphasis on Evidence-Based Medicine	• The effectiveness of cognitive impairment DTx needs to be validated by evidence-based medicine. Prospective products need to undergo various clinical trials and real-world studies to verify their effectiveness in order to obtain trust from consumers. For newcomers, conducting enough clinical trials and obtaining sufficient real-world data comparable to existing ones are challenges to overcome.
Data Accumulation	• Unlike pharmaceutical drugs, DTx can evolve with capabilities and become more effective after being launched by updating the algorithm and the model. With increasing use, DTx can collect more data and update the model continuously to improve effectiveness in assessment and intervention. For newcomers with a smaller consumer group, they may not have enough data to train and better their model.
User Dependence	• DTx for cognitive impairment typically requires patients to undergo diagnosis, intervention, and feedback in arranged stages over a period of time. Therefore, it is difficult to change therapeutic midway. • DTx for cognitive impairment may use different treatment modalities and intervention exercises. Thus, when healthcare providers and patients are used to certain products, it may be difficult to convince them to change and adopt new products.

Source: Literature Review, Frost & Sullivan Analysis

Table of Contents

1 Analysis of Digital Therapeutics (DTx) Market

2 Cognitive Impairment Digital Therapeutics Market

2.1 Overview of Cognitive Impairment Digital Therapeutics Market

2.2 Digital Therapeutics Assessment and Intervention Products Market

2.2.1 Vascular Disease Cognitive Impairment Digital Therapeutics Market

2.2.2 Neurodegenerative Diseases Digital Therapeutics Market

2.2.3 Psychiatric Diseases Digital Therapeutics Market

2.2.4 Developmental Diseases Digital Therapeutics Markets

2.2.5 Other Diseases Concomitant Cognitive and Psychiatric Disorders Digital Therapeutics Markets

Overview of Vascular Disease Cognitive Impairment

- The concept of vascular disease cognitive impairment is a broad spectrum of syndromes ranging from mild cognitive impairment to dementia caused by cerebrovascular disease risk factors (e.g., hypertension, diabetes mellitus, and hyperlipidemia), significant (e.g., cerebral infarction and cerebral hemorrhage), or less significant cerebrovascular disease (e.g., leukopenia and chronic cerebral ischemia).

Causes

- Stroke (infarction) blocking a brain artery
- Brain hemorrhage
- Narrowed or chronically damaged brain blood vessels

Risk Factors

- Increasing age
- Abnormal aging of blood vessels (atherosclerosis)
- Smoking
- Obesity
- High cholesterol
- High blood pressure
- Diabetes
- Atrial fibrillation
- History of heart attacks, strokes or ministrokes

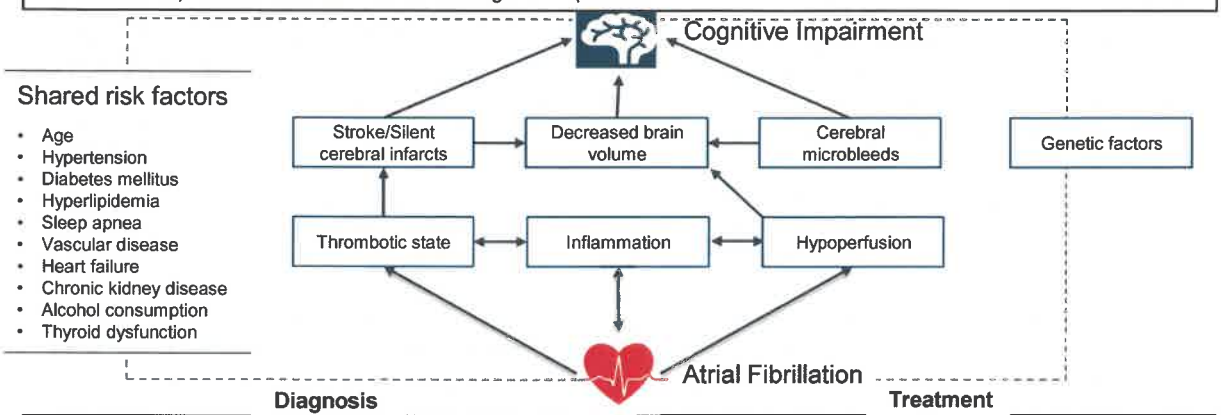
Symptoms

- Confusion
- Trouble paying attention and concentrating
- Decline in ability to analyze situation, develop and communicate plan
- Difficulty with organization
- Difficulty deciding what to do next
- Depression or apathy
- Unsteady gait
- Slowed thinking
- Reduced ability to organize thoughts or actions
- Sudden or frequent urge to urinate or inability to control passing urine
- Problems with memory
- Restlessness and agitation

Source: Literature Review, Frost & Sullivan Analysis

Overview of Atrial Fibrillation Induced Cognitive Impairment

- Atrial fibrillation (AF) is a common type of arrhythmia that occurs when the normal sinus rhythm of the atria is replaced with irregular and often rapid electrical depolarizations. Numerous observational studies over the past 10 years, including several meta-analyses, provide growing evidence that AF is associated with cognitive impairment. AF could lead to cognitive impairment through different mechanisms: cerebral infarcts, decreased brain volume, and cerebral microbleeds. Genetic factors and shared risk factors (showed in below chart) could contribute to both AF and cognitive impairment.



Diagnosis

1. **Examination of atrial fibrillation**: electrocardiogram
2. **Cognitive impairment evaluation**: MoCA and MMSE scale, combined with trail making test and Rey complex figure test can be used to evaluate single cognitive domain and identify the impaired cognitive domain of patients
3. **Neuroimaging examination** showed that the cerebral gray matter volume was reduced more significantly in patients with AF and cognitive impairment

Treatment

1. **Non-pharmacological therapy**: weight control
2. **Medical treatment**: (1) Anticoagulant drugs; (2) Statins; (3) control of rhythm and ventricular rate; (4) Other drugs: At present, there is a lack of studies on cholinesterase inhibitors or excitatory amino acid receptor antagonists for the treatment of AF related cognitive impairment.
3. **Cardiac Catheter Radiofrequency Ablation Interventional Therapy**

Source: Literature Review, Frost & Sullivan Analysis

Overview of Hypertension Induced Cognitive Impairment

- Prospective cohort studies have mostly reported a positive association between hypertension and the risk of cognitive impairment. Most of the vascular alterations induced by hypertension contribute to cognitive impairment by leading to hypoperfusion, ischemic and hemorrhagic stroke, and white matter injury. No definitive studies have demonstrated which antihypertensive agents and treatment regimens are optimal for maintaining cognitive health. In the future, there is a need to improve the detection of hypertension in the general public to reduce the global burden of cognitive impairment.

Characteristic cognitive dysfunction domains in hypertension

Cognitive impairments in hypertension can occur across multiple neuropsychological domains, including:

- **learning and memory**
- **Attention**
- **abstract reasoning**
- **mental flexibility**
- **psychomotor skills and visuospatial functioning.**

Diagnose

- Computed tomography (CT)
- Magnetic resonance imaging (MRI)
- Positron emission tomography (PET)

Treatment

- Reasonable and effective control of blood pressure can prevent and delay cognitive impairment. The optimal blood-pressure target for lowering risk for dementia or cognitive impairment in patients with hypertension is controversial. Excessive blood pressure or excessive blood pressure reduction can cause insufficient cerebral blood perfusion and lead to cognitive impairment.
- The five first-line classes of antihypertensive drugs - calcium channel blockers, angiotensin-converting-enzyme inhibitors (ACEI), angiotensin II receptor blockers (ARBs), diuretics, and β-blockers - all reduce the risk of dementia or cognitive impairment through blood pressure reduction or specific neuroprotective effects. Benefits for lowering risk for dementia or cognitive impairment have been equivocal across classes of antihypertensive drugs.

Source: Literature review, WHO, Frost & Sullivan Analysis

Overview of Aphasia

- Aphasia is a common impairment that is often experienced amongst stroke survivors. Aphasia is defined as an impairment of language, affecting the production or comprehension of speech and the ability to read or write.
- Communication skills are diminished in patients with post-stroke aphasia. Research has shown that language plays a centralized role in human cognition and therefore, cognitive impairments usually co-occur with language disturbances due to the interrelatory and complementary function of higher cognitive skills.

Symptoms

- **Global aphasia**: have difficulties with speaking or comprehending language
- **Broca aphasia**: They may eliminate the words "and" and "the" from their language, and speak in short, but meaningful, sentences. They usually can understand some speech of others. Because the damage is in the front part of the brain, is also important for motor movements, people with Broca's aphasia often have right-sided weakness or paralysis of the arm and leg.
- **Wernicke aphasia**: They may speak in long confusing sentences, add unnecessary words, or create new words. They usually have difficulty understanding the speech of others.

Classification

(1) **Broca aphasia**: have damage to the front portion of the language-dominant side of the brain
(2) **Wernicke aphasia**: have damage to the side portion of the language-dominant part of the brain
(3) **Global aphasia**: is the result of damage to a large portion of the language-dominant side of the brain

Diagnose

- Computed tomography (CT)
- Magnetic resonance imaging (MRI)
- Positron emission tomography (PET)

Treatment

Specific treatment for aphasia will be discussed with you by your healthcare provider based on:
•Your age, overall health, and medical history
•The cause and extent of the disorder
•Your handedness (left handed or right handed)
•Your tolerance for specific medicines, procedures, or therapies
•Expectations for the course of the disorder
•Your opinion or preference and motivation
The goal of treatment is to improve your ability to communicate through methods that may include:
•Speech-language therapy
•Nonverbal communication therapies, such as computers or pictures
•Group therapy for patients and their families

Source: Literature review, WHO, Frost & Sullivan Analysis

Unmet Clinical Needs of Vascular Disease Cognitive Impairment

Assessment

Neuropsychological Assessment

An important method for identifying vascular cognitive impairment and an important tool for observing treatment outcomes. but there is no standard uniform diagnostic scale

- Because of the heterogeneity in the etiology and pathology, VCI has different neuropsychological characteristics
- Due to ethnic, cultural, and linguistic differences, it is difficult for China to promote proven foreign measurement scales
- Due to China's complex cultural factors and diverse education levels, it is difficult to create a uniform standard

DTx

- Through big data and AI/ML, DTx can tailor the assessment to patients' unique characteristics, such as age, medical history, and education level
- Thus, DTx can help make a more accurate neuropsychological diagnosis to give a better assessment of the disease condition

Intervention

Medications

Medications are a major treatment method, but there are limitations in their effectiveness and scope of use. More intervention options are in great need

- Current research on vascular cognitive impairment has focused on vascular dementia. Other subtypes of vascular cognitive impairment lack attention on intervention medications
- The effectiveness of the current medications, such as cholinesterase inhibitors and NMDA receptor antagonists, needs further clinical evaluation

DTx

- DTx can be a great intervention tool for many aspects of vascular cognitive impairment, such as vascular cognitive impairment, no dementia (VCIND) and the psycho-behavioral symptoms present in patients
- Thus, DTx can effectively complement medications in the treatment of VCI

Source: Literature Review, Frost & Sullivan Analysis

Prevention and Treatment of Vascular Disease Cognitive Impairment

Prevention	Diagnosis	Treatment
The health of brain's blood vessels is closely linked to overall heart health. Some measure can help reduce the rish of vascular cognitive impairment	Diagnosis will be based on the information patitent provides, medical history for stroke or disorders of the heart and blood vessels, and results of tests	Treatment often focuses on managing risk factors that contribute to vascular dementia, which can sometimes slow the rate of cognotive decline and prevent further decline.
Keep blood pressure in the normal range	Lab tests: • Blood pressure • Cholesterol • Blood sugar	Lower blood pressure
A healthy, low-fat diet and cholesterol-lowering medications to reduce the amount of plaque deposits building up inside brain's arteries	Neurological exam	Reduce cholesterol level
• Quite smoking • Get physical exercise	Brain imaging: • Magnetic resonance imaging (MRI) • Computerized tomography (CT) scan	Prevent blood from clotting and keep your arteries clear
Avoid the onset of type 2 diabetes or control blood sugar	Neuropsychological tests	Control blood sugar if the patient has diabetes

Source: Literature Review, Frost & Sullivan Analysis

The Advantages and the Growth Drivers of Vascular Disease Cognitive Impairment Assessment and Intervention Digital Therapeutics

Accessment

Patitents will complete a serie of tests, DTx can help people complete the tests at home and on themselves. DTx can also track physical condition

Neurological exam:
Combining DTx with externel device such as VR, patients can self-test their eurological health such as reflexes, balance, coordination, and sense of touch and sight

Neuropsychological tests:
Combining DTx with externel device such as VR, patients can self-test their eurological health such as reflexes, balance, coordination, and sense of touch and sight

Blood pressure and Blood sugar:
DTx can help monitor, track, and control blood pressure and blood sugar, which helps doctors determine the causes of vascular cognitive impairment and the corresponding treatment

Intervention

Interventions usually focus on risk factors that contribute to vascular dementia

Offer personalized treatment:
AI-based DTx can provide personalized treatment tailed to patients' need, condition, and habits

Improve treatment adherence:
Treatent usually involves the control of blood suger, blood sugar, and cholesterol level. DTx can track treatment progress, saving patients' time to travel for appointment, and monitor treatment adherence

Provide timely feedback:
DTx can monitor treatment effect and disease progression at any time, alerting doctors if the treatment is not working or patients' condition declines

Source: Frost & Sullivan Analysis

Overview of Cognitive Impairment Due to Cerebrovascular Disease

Vascular Dementia (VaD)

The second most common cause of dementia after Alzheimer's disease

Symptoms

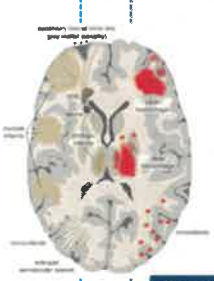
- Difficulty performing tasks and remembering events
- Changes in personality, behavior, and mood
- Loss of interest in things or people
- Hallucinations or delusions

Treatments

Treatment primarily deal with the underlying disease

FDA has not approved any drugs specifically to treat symptoms of vascular dementia

Drugs approved to treat Alzheimer's symptoms may also offer a modest benefit



Vascular Cognitive Impairment No Dementia (VCIND)

The mildest stage of vascular cognitive impairment

Symptoms

- A mild impairment of concentration
- A mild impairment ofexecutive function
- No dementia

Features

- Some patients further develop VaD
- Some patients return to a healthy state of cognitive function

Treatments

There is no specific treatment for VCIND

Clinical trainings show that cognitive training can help

DTx for Cognitive Impairment Due to Cerebrovascular Disease

Assessment: DTx may help doctors diagnose cognitive impairment through performing neurological exams and neuropsychological tests as well as analysing MRI and CT scans

Intervention: DTx may be used as an early invervention tool for both patients with vascular dementia and patients with vascular cognitive impairment no dementia

Source: Literature Review, Frost & Sullivan Analysis

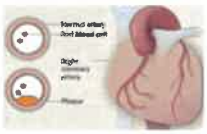
Overview of Cognitive Impairment Due to Cardiovascular Disease

Coronary Heart Disease

Coronary heart disease (CHD) is closely associated with cognitive impairment, especially in severe cases of heart failure. Patients with cognitive impairment in combination with coronary artery disease have a more rapid decline in cognitive function and a significantly increased risk of death. An impaired cardiac systolic function may play a key role in the relationship between CHD and cognitive impairment among patients with pre-heart failure conditions.

Pathogenesis

- Severe coronary artery stenosis
- High degree of angina pectoris
- Risk Gene: ApoE4



Symptoms

- Learning, memory, and word fluency, such as speech and semantic fluency, are impaired
- The ability to execute events is impaired
- Motor flexibility decreases

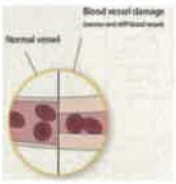
Treatments

- PCI and surgical treatment
- Medication: aspirin, beta-blockers, statins, drugs to control cardiovascular disease, and cholinesterase inhibitors

Hypertension

Compared to normotensive individuals, patients with hypertension have a 1.4-fold increased risk of dementia

Hypertension is the leading cause of stroke in China



Pathogenesis

- Promote changes in cerebral vascular structure
- Promote atrophy of hippocampal structures and accelerates cerebral white matter degeneration

Symptoms

- Decline in memory and information processing speed
- The ability to execute events is impaired
- Vocabulary fluency, immediate and delayed recall of vocabulary are impaired

Treatments

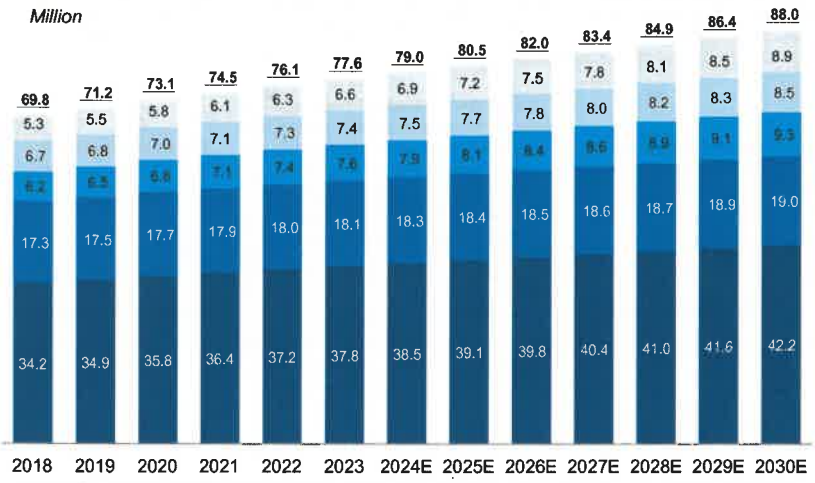
- Medication: drugs to control blood pressure, especially calcium channel blockers and renin angiotensin system blockers, and beta-blockers

Source: Literature Review, Frost & Sullivan Analysis

Prevalence of Vascular Disease Induced Cognitive Impairment in China, 2018-2030E

- Vascular diseases are an important risk factor for cognitive impairment. A significant portion of atrial fibrillation, coronary heart disease, and hypertension patients develops cognitive impairment and dementia. In addition, Aphasia, a cognitive-linguistic disorder that impairments cognitive functions such as the ability to understand language, is a frequent consequence of stroke.

Prevalence of Vascular Cognitive Impairment in China, 2018-2030E



	CAGR 18-23	CAGR 23-25E	CAGR 25E-30E
Total	2.1%	1.9%	1.8%
Aphasia	4.5%	4.3%	4.3%
Atrial Fibrillation Induced CI	2.0%	1.9%	2.1%
Coronary Heart Disease Induced CI	4.0%	3.4%	2.8%
Vascular Cognitive Impairment	0.9%	0.7%	0.7%
Hypertension Induced CI	2.0%	1.7%	1.5%

Note: The overall prevalence and prevalence in each field of cognitive impairment include patients with comorbidities.

Source: Frost & Sullivan Analysis

Global Prevalence of Vascular Disease Induced Cognitive Impairment, 2018-2030E

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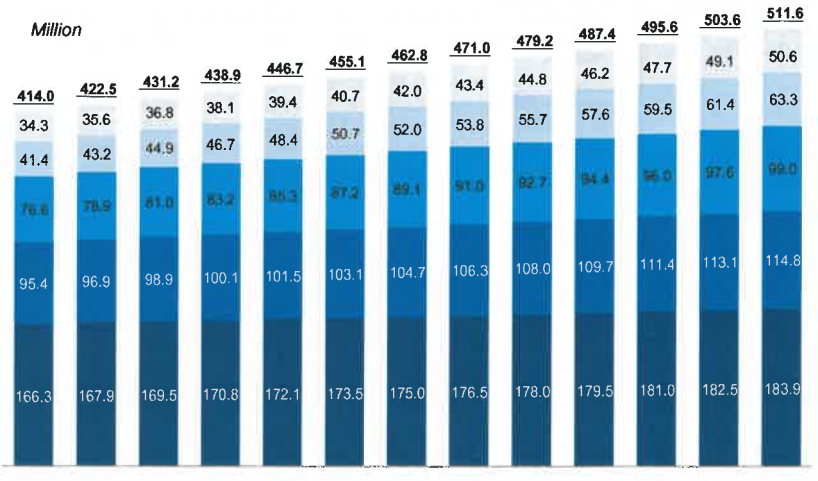
Global Prevalence of Vascular Cognitive Impairment, 2018-2030E



	CAGR 18-23	CAGR 23-25E	CAGR 25E-30E
Total	1.9%	1.7%	1.7%
Aphasia	3.5%	3.3%	3.1%
Atrial Fibrillation Induced CI	4.1%	3.1%	3.3%
Coronary Heart Disease Induced CI	2.6%	2.1%	1.7%
Vascular Cognitive Impairment	1.6%	1.6%	1.5%
Hypertension Induced CI	0.9%	0.9%	0.8%

Note: The overall prevalence and prevalence in each field of cognitive impairment include patients with comorbidities.

Source: Frost & Sullivan Analysis

Competitive Landscape of Vascular Cognitive Impairment Digital Therapeutics

Company	BrainAu	ECAN	Xinkang Yixue	Ultimate Medical
Class	Medical Level	Medical Level	Medical Level	Medical Level
Category	• Assessment • Intervention	• Intervention	• Assessment • Intervention	• Assessment • Intervention
Product Name	Brain function information management platform software system	Cognitive impairment assessment rehabilitation software	Cognitive dysfunction screening and correction software CCRT	Cognitive rehabilitation training and assessment software
Indication	Brain dysfunction due to various brain injuries, vascular cognitive impairment and other cognitive impairments	Cognitive impairment due to brain damage and stroke	Alzheimer's disease, Parkinson's, stroke, traumatic brain injury, memory disorders neurodevelopmental disorders, ADHD, schizophrenia, depression and anxiety disorders, obsessive-compulsive disorder post-traumatic stress disorder, etc.	Cognitive impairment due to brain function damage and cerebral stroke
Approval number	湘械注准20222211862 湘械注准20222212193 湘械注准20182210142	桂械注准20222210140	湘械注准20222210661	浙械注准20192210506

Source: Company Websites, Frost & Sullivan Analysis

Overview of Mild Cognitive Impairment

- Mild cognitive impairment (MCI) is defined as impairment in memory or other cognitive domains confirmed by objective testing with preserved activities of daily living.
- There are two major types of MCI:

Amnestic MCI

- Amnestic MCI is the most common form and primarily includes subtle changes in memory and thinking. Amnestic MCI is a condition in which people have memory problems more severe than normal for their age and education, but not serious enough to affect daily life.

Non-amnestic MCI

- Non-amnestic MCI affects other cognitive abilities. The person may experience changes to thinking skills, such as difficulties with language, attention, decision-making and/or changes to their visual perception.

Causes and risks

- The causes of AMCI are not yet completely understood. Experts believe that many cases — but not all — result from brain changes occurring in the very early stages of Alzheimer's or other neurodegenerative diseases that cause dementia.
- The risk factors most strongly linked to AMCI when the underlying cause is neurodegenerative disease and not another cause are advancing age, family history of Alzheimer's or another dementia, and conditions that raise risk for cardiovascular disease.

Diagnosis

The diagnosis of AMCI requires considerable clinical judgement, and as such a comprehensive clinical assessment including clinical observation, neuroimaging, blood tests and neuropsychological testing are best in order to rule out an alternate diagnosis. MCI is diagnosed when there is:

- Evidence of memory impairment
- Preservation of general cognitive and functional abilities
- Absence of diagnosed dementia

Neuropathology

Although amnestic MCI patients may not meet criteria for Alzheimer's disease, patients may be in a transitional stage of evolving Alzheimer's disease.

Magnetic resonance imaging can observe deterioration, including progressive loss of gray matter in the brain, from mild cognitive impairment to full-blown Alzheimer disease. A technique known as PiB PET imaging is used to show the sites and shapes of beta amyloid deposits in living subjects using a 11C tracer that binds selectively to such deposits.

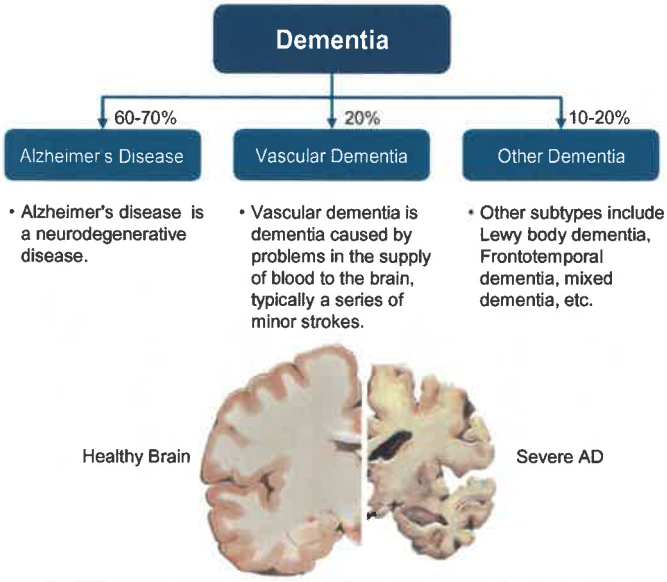
Treatment

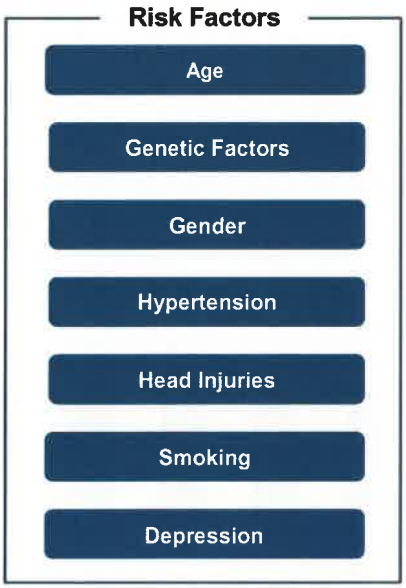
- Chinese herbal medicine
- Physical exercise to improve cognitive symptoms
- As AMCI may represent a prodromal state to clinical Alzheimer's disease, treatments proposed for Alzheimer's disease, such as antioxidants and cholinesterase inhibitors, could potentially be useful. Two drugs used to treat Alzheimer's disease have been assessed for their ability to treat AMCI or prevent progression to full Alzheimer's disease. Rivastigmine failed to stop or slow progression to Alzheimer's disease or to improve cognitive function for individuals with mild cognitive impairment;[24] donepezil showed only minor, short-term benefits and was associated with significant side effects.

Source: Literature Review, Frost & Sullivan Analysis

Overview of Alzheimer's Disease

- Alzheimer's disease (AD), is a neurodegenerative disease that usually starts slowly and progressively worsens. It is the cause of 60-70% of cases of dementia.
- Like other chronic diseases, Alzheimer's disease is not caused by a single factor, but is a common result of the interaction of multiple risk factors. Advanced age is the biggest risk factor for AD.



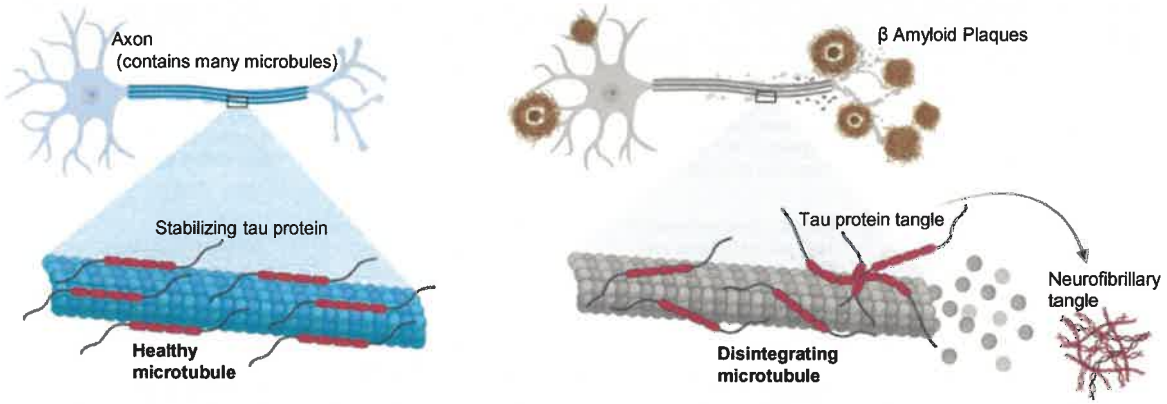


Source: Frost & Sullivan Analysis

Main Pathogenesis of Alzheimer's Disease

- The cause for most Alzheimer's disease is still mostly unknown, several hypotheses exist trying to explain the cause of the disease.
- Alzheimer's disease is believed to occur when abnormal amounts of amyloid beta, accumulating extracellularly as amyloid plaques, and tau proteins, accumulating intracellularly as neurofibrillary tangles.

Formation of neurofibrillary tangles and tau protein clumps in Alzheimer's disease



- Aβ plaques are formed by the polymerization of β-amyloid protein (Aβ), which is formed by the cleavage of amyloid precursor protein (APP).
- Neurofibrillary tangles are formed by the polymerization of hyperphosphorylated tau protein.

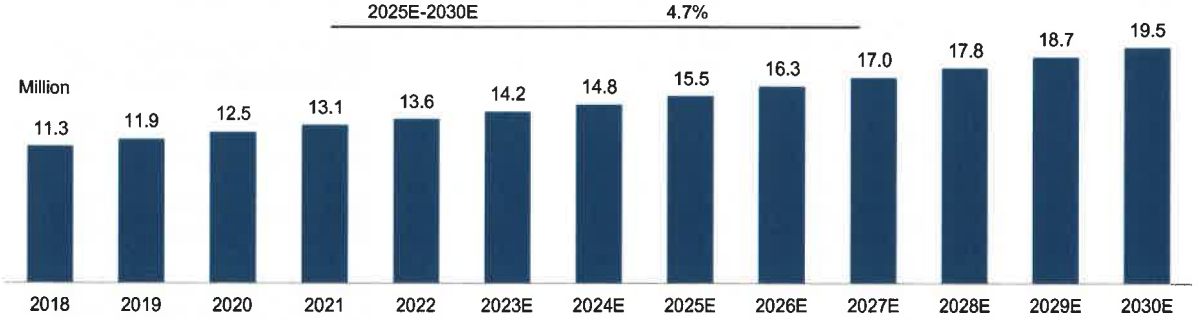
Source: Literature Review, Frost & Sullivan Analysis

Prevalence of Alzheimer's Disease (AD) in China, 2018-2030E

- The number of Alzheimer's disease (AD) patients in China is gradually increasing. During 2018 to 2022, the number of AD patients in China increased to 13.6 million from 11.3 million with the CAGR of 4.7%, and it is forecasted to be 15.5 million in 2025 and further to increase to 19.5 million in 2030.

Prevalence of AD in China, 2018-2030E

Period	CAGR
2018-2022	4.7%
2022-2025E	4.5%
2025E-2030E	4.7%



Source: National Bureau of Statistics, literature research and Frost & Sullivan analysis

Course Analysis of Alzheimer's Disease

- The course of Alzheimer's Disease is generally described in three stages, with a progressive pattern of cognitive and functional impairment. The segment is according to the deterioration of cognitive ability and physical function.

Stage	Duration	Signs and Symptoms		Care in Need
		Cognitive Ability	Physical Function	
Early or mild	1-3 years	• Memory loss, decreased judgment ability, decreased language skills, new facts or memories affected	• Perform many tasks independently • Difficulty with some fine motor tasks	• Need assistance or supervision with the most cognitively demanding activities
Middle or moderate	2-10 years	• Memory severely impaired, can't remember time and place, fail to recognize close relatives, long-term memory impaired	• Unable to engage in outdoor activities independently • unable to perform most common activities of daily living	• Need help in dressing, personal hygiene and maintaining personal appearance
Late or severe	8-12 years	• Language reduced to simple phrases or single words, eventually complete loss of speech	• Bedridden, unable to feed themselves • Some patients die for external factors, such as infection of pressure ulcers or pneumonia	• Not be able to perform even the simplest tasks independently • Completely dependent upon caregivers

Source: Literature Review, Frost & Sullivan Analysis

Analysis of Alzheimer's Disease Burdens

Economic Burden

- **Average cost in China:** 130,000 yuan per capita per year

- **Estimated Expenditure of Alzheimer's disease in China:** $1.89 trillion in 2050

Caregiving Burden

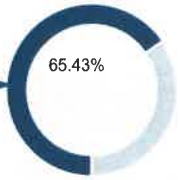
80.12%
The caregivers have to **look after the patient all the time**

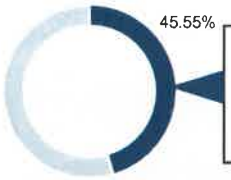
78.39%
The caregiver's **social life is affected**

68.6%
The caregivers **lack of sleep time**

74.39%
The caregivers hope to **get rid of the current state of life**

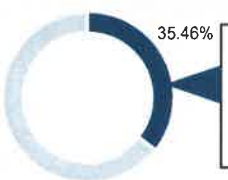
- The caregivers are under great psychological pressure, because **hope for getting the patient cured is limited**





- **Safety issues such as getting lost** have increased the anxiety of caregivers

- The caregivers claim that the patients have **abnormal mental behavior, which increases the difficulty of care**



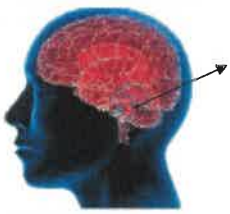
- The patient's family **does not know how to better care for the patient**

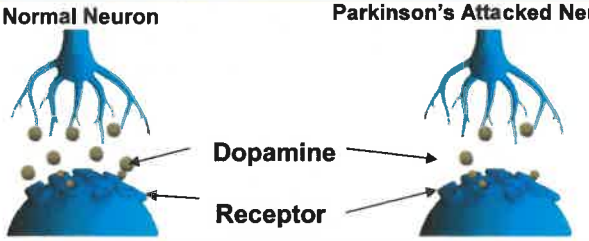
Source: Investigation report on the family survival status of Alzheimer's disease patients in 2019, Reassessment of the burden of Alzheimer's disease in China and around the world (April 2018), Frost & Sullivan Analysis

Overview of Parkinson's Disease (PD)

- Parkinson's disease is a brain disorder that leads to shaking, stiffness, and difficulty with walking, balance, and coordination. The Hoehn and Yahr scale was published in 1967 and was the first rating scale to describe the progression of PD. There is no cure for Parkinson's disease, but some treatment and support can help to manage the symptoms.

Pathophysiology of PD





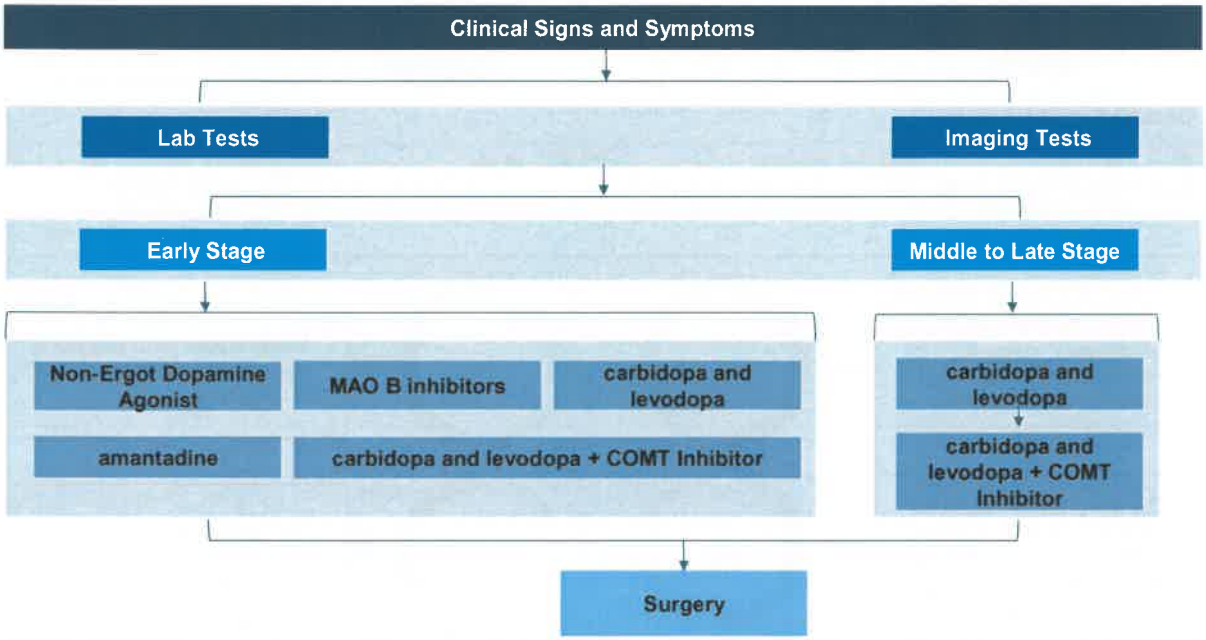
- Deep in the brain, there is an area called substantia nigra. Some of its cells make dopamine, a chemical that carries messages around your brain. Dopamine quickly carries a message to the nerve cell that controls that movement.
- When someone has Parkinson's, the cells of substantia nigra start to die. There's no replacing them, so the dopamine levels drop and people can't fire off as many messages to control the body.

	Hoehn and Yahr Staging Scale	Most Common Symptoms
Early Stage	From Stage 1 to Stage 2.5	Tremor, rigidity, slowness of movement, loss of facial expression, speech abnormalities
Middle and Late Stage	From Stage 3 to Stage 5	Loss of balance, slowness of movement, a tendency to fall, hallucinations or delusions

Source: Frost & Sullivan Analysis

Diagnosis and Treatment of PD

- No specific test exists to diagnose Parkinson's disease. The doctor trained in nervous system conditions (neurologist) will diagnose Parkinson's disease based on the medical history of patient, a review of the signs and symptoms, and a neurological and physical examination.



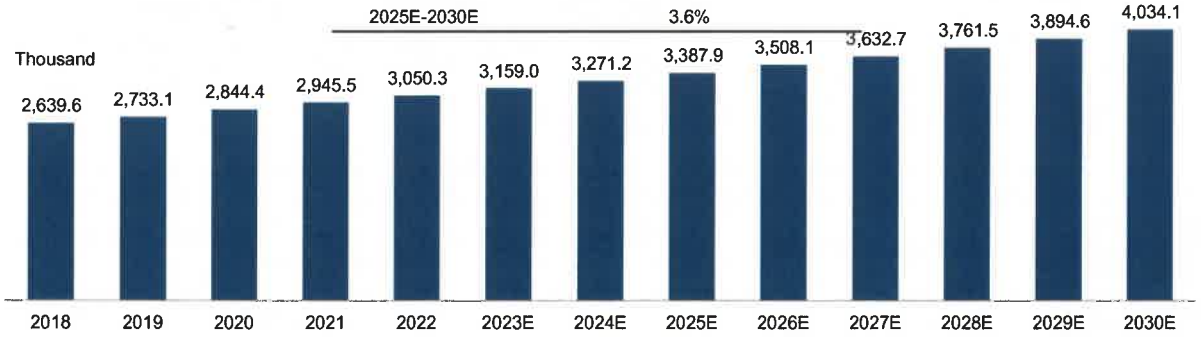
Source: Frost & Sullivan Analysis

Prevalence of Parkinson's Disease (PD) in China, 2018-2030E

- The number of Parkinson's (PD) patients in China is gradually increasing. During 2018 to 2022, the number of PD patients in China increased to 3,050.3 thousand from 2,639.6 thousand with the CAGR of 3.7%, and it is forecasted to be 3,387.9 thousand in 2025 and further to increase to 4,034.1 thousand in 2030.

Prevalence of PD in China, 2018-2030E

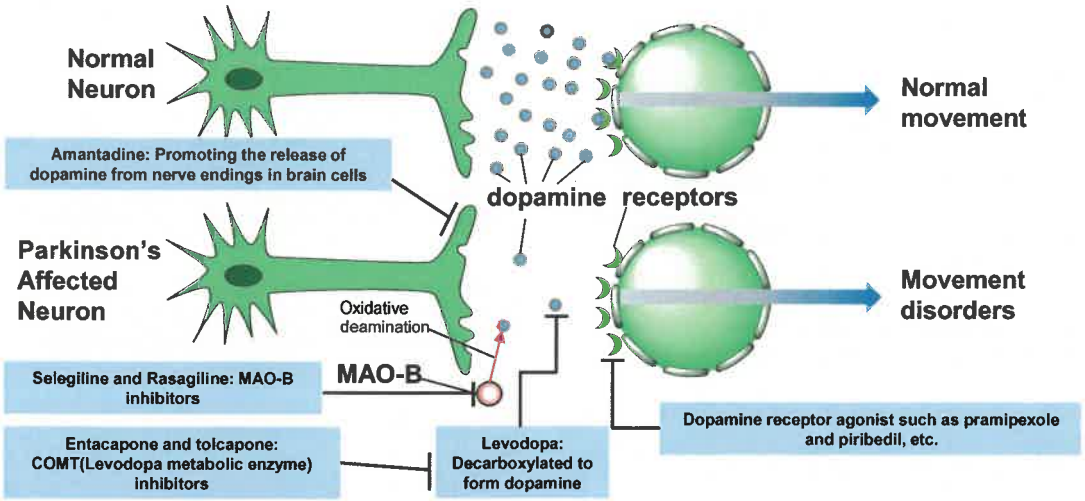
Period	CAGR
2018-2022	3.7%
2022-2025E	3.6%
2025E-2030E	3.6%



Source: Frost & Sullivan Analysis

Mechanism Action for Parkinson's Disease Treatment

- Parkinson's disease (PD) is a debilitating, age-associated movement disorder.
- Physiologically, the symptoms associated with Parkinson's disease are the result of the loss of a number of neurotransmitters, most notably dopamine.



Note:

- A central aspect of the pathophysiology of Parkinson's disease is the progressive demise of midbrain dopamine neurons and their axonal projections, but the underlying causes of this loss are unclear.
- In a normal, healthy individual, the neurotransmitter dopamine is released in the presynaptic neuron, and through activation of dopamine receptors in the postsynaptic neuron.
- Decreased dopaminergic input to the corpus striatum appears to be associated with motor manifestations of PD

Source: Frost & Sullivan Analysis

Unmet Clinical Needs of Neurodegenerative Diseases

Assessment

Early Assessment

Neurodegenerative diseases can begin to damage the brain more than a decade before symptoms appear, but many patients are not examined until severe symptoms of cognitive decline, resulting in missing the best time to intervene

Large-Scale Assessment

Therefore, large-scale early assessment is needed to reduce the burden of neurodegenerative diseases, but the screening process is time-consuming and expensive because trained physicians and multiple tests are required for a diagnosis to be made

DTx

Through using certain biomarkers, DTx can help physicians accurately diagnose neurodegenerative diseases or alert patients to seek help. AI/ML can also help physicians accelerate the screening process, making efficient large-scale early assessment possible.

Intervention

Early Intervention

If diagnosed in time, early intervention can help patients improve cognitive function and delay the clinical progression. Thus, there is a great need for early intervention methods.

DTx

DTx can provide cognitive training exercises and help manage risk factors to delay the progression of the disease. Thus, DTx can become an effective intervention method, in addition to medications.

Prevention of Disease Progression

While some therapies are currently available to treat the symptoms of neurodegenerative diseases, there is no treatment to stop the progression of the disease for now.

DTx

DTx is based on the principle of neuroplasticity, targeting specific brain functions to improve cognition. It has the potential to be a treatment option to prevent disease progression.

Source: Literature Review, Frost & Sullivan Analysis

Diagnosis and Treatment of Alzheimer's disease (AD)

Diagnosis

Doctors use several methods and tools to diagnosis

Ask the person experiencing symptoms, as well as a family member or friend, questions about overall health, use of prescription and over-the-counter medicines, diet, past medical problems, ability to carry out daily activities, and changes in behavior and personality

Conduct tests of memory, problem solving, attention, counting, and language

Order blood, urine, and other standard medical tests that can help identify other possible causes of the problem

Administer a psychiatric evaluation to determine if depression or another mental health condition is causing or contributing to a person's symptoms

Perform brain scans, such as CT ,MRI or PET

Collect cerebrospinal fluid (CSF) via a spinal tap and measure the levels of proteins associated with Alzheimer's and related dementias

Treatment

The treatment of Alzheimer's disease is divided into the treatment of mild to moderate Alzheimer's disease and the treatment of moderate to severe Alzheimer's disease

Mild to Moderate Alzheimer's Disease:
- Medical treatment: Galantamine, rivastigmine, and donepezil are cholinesterase inhibitors
- Immunotherapy: Lecanemab and aducanumab

Moderate to Severe Alzheimer's Disease:
- Medical treatment: 1. Memantine 2. Donepezil, the rivastigmine patch, and a combination medication of memantine and donepezil

The future of Alzheimer's disease treatments:
- Alzheimer's researchers continue to explore a variety of innovative approaches to treat symptoms as well as underlying disease processes. In ongoing clinical trials, they are developing and testing several new possible interventions. These include additional immunotherapy and other drug therapies, cognitive training, diet, and physical activity.

Source: Literature Review, Frost & Sullivan Analysis

Diagnosis and Treatment of Parkinson's disease (PD)

Diagnosis

There is no specific diagnostic test for Parkinson's disease. A doctor trained in neurological disorders (a neurologist) diagnoses Parkinson's disease based on your medical history, signs and symptoms, and neurologic and physical examination.

Dopamine Transporter (DAT) Scan

laboratory tests (such as blood tests)

Imaging tests (such as MRI, ultrasound of the brain, and PET scans)

Your healthcare provider may also prescribe the Parkinson's drug combination carbidopa-levodopa (Rytary, Sinemet, and others). Parkinson's disease is usually diagnosed when symptoms improve significantly with drug treatment.

Treatment

There is no cure for Parkinson's disease, but medication, surgery, and other treatments can often relieve some symptoms.

Medical treatment:
- Levodopa
- Dopamine agonist
- Enzyme inhibitors (eg MAO-B inhibitors, COMT inhibitors)
- Amantadine
- Anticholinergic drugs

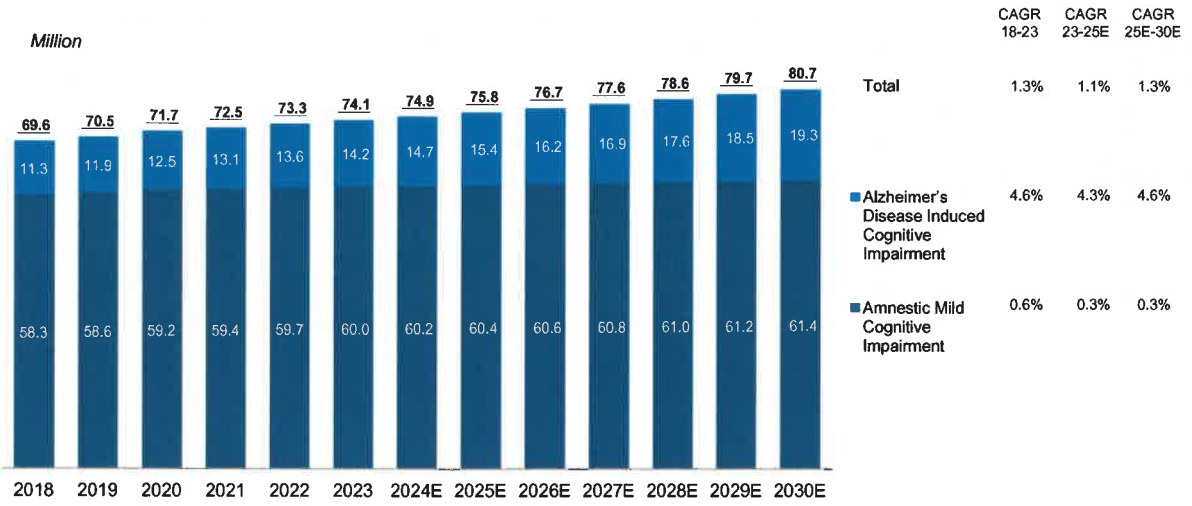
Other therapies:
- deep brain stimulation
- Physical, Occupational and Speech Therapy
- healthy diet
- Exercises to strengthen muscles, improve balance, flexibility and coordination
- massage therapy
- Yoga and Tai Chi

Source: Literature Review, Frost & Sullivan Analysis

Prevalence of Neurodegenerative Cognitive Impairment in China, 2018-2030E

- Amnestic mild cognitive impairment is characterized by cognition impairment, especially in free recall ability. It the subtype of mild cognitive impairment most correlated with Alzheimer's disease, the most common type of dementia. Dementia causes the decline in cognitive abilities, such as memory, reasoning, or other thinking skills, severe enough to interfere with daily life.

Prevalence of Neurodegenerative Cognitive Impairment in China, 2018-2030E



	CAGR 18-23	CAGR 23-25E	CAGR 25E-30E
Total	1.3%	1.1%	1.3%
Alzheimer's Disease Induced Cognitive Impairment	4.6%	4.3%	4.6%
Amnestic Mild Cognitive Impairment	0.6%	0.3%	0.3%

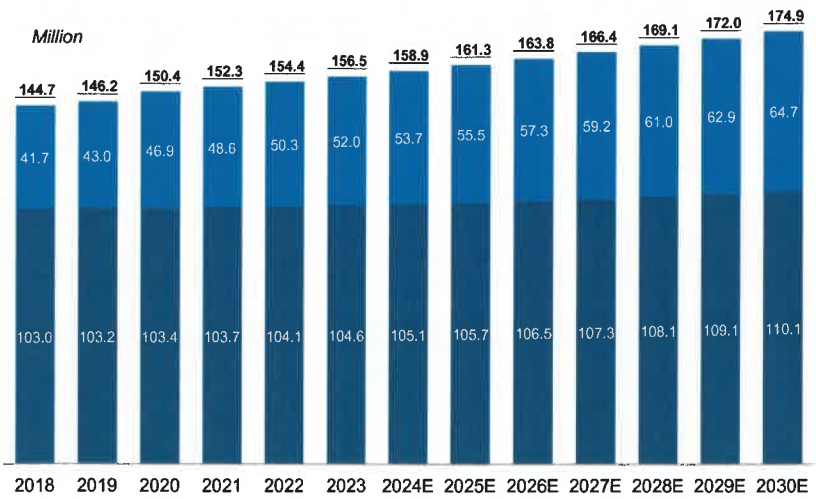
Note: The overall prevalence and prevalence in each field of cognitive impairment include patients with comorbidities.

Source: Frost & Sullivan Analysis

Global Prevalence of Neurodegenerative Cognitive Impairment, 2018-2030E

- Amnestic mild cognitive impairment is characterized by cognition impairment, especially in free recall ability. It the subtype of mild cognitive impairment most correlated with Alzheimer's disease, a type of dementia which causes the decline in cognitive abilities, such as memory, reasoning, or other thinking skills, severe enough to interfere with daily life.

Global Prevalence of Neurodegenerative Cognitive Impairment, 2018-2030E



	CAGR 18-23	CAGR 23-25E	CAGR 25E-30E
Total	1.6%	1.5%	1.6%
Alzheimer's Disease Induced Cognitive Impairment	4.5%	3.4%	3.1%
Amnestic Mild Cognitive Impairment	0.3%	0.6%	0.8%

Note: The overall prevalence and prevalence in each field of cognitive impairment include patients with comorbidities.

Source: Frost & Sullivan Analysis

Competitive Landscape of Neurodegenerative Diseases Cognitive Impairment Digital Therapeutics

Company	BrainAu	ECAN	Xinkang Yixue	WonderLan	BestCovered
Class	Medical Level	Medical Level	Medical Level	Medical Level	Medical Level
Category	• Assessment • Intervention	• Intervention	• Assessment • Intervention	• Intervention	• Assessment • Intervention
Product Name	Brain function information management platform software system	Cognitive impairment assessment rehabilitation software	Cognitive dysfunction screening and correction software	Cognitive dysfunction treatment software	Cognitive function assessment and training software
Indication	Brain dysfunction due to various brain injuries • Alzheimer's disease • other cognitive impairments	Cognitive impairment due to brain damage: • Alzheimer's disease • Parkinson's disease • other cognitive impairments	• Alzheimer's disease • Parkinson's disease • Other cognitive impairments	• Alzheimer's disease • Other cognitive impairments	• Alzheimer's disease • Mild cognitive impairment
Approval number	湘械注准20222211862 湘械注准20222212193 湘械注准20182210142	桂械注准 20222210140	湘械注准 20222210661	湘械注准 20222210042	湘械注准 20222210096

Source: Company Websites, Frost & Sullivan Analysis

Overview of Psychiatric Disorders

Definition

- Psychiatric disorder is characterized by a clinically significant disturbance in an individual's cognition, emotional regulation, or behaviour.

Causes

- There is no single cause for mental illness. A number of factors can contribute to risk for mental illness, such as: genes and family history, life experiences, use of alcohol or recreational drugs and other biological factors

Treatment

- Treatment depends on which mental disorder you have and how serious it is.
- It is usually a combination of medication and psychotherapy. In addition, the alternative therapies and brain stimulation therapies are also useful.

Psychiatric Disorders

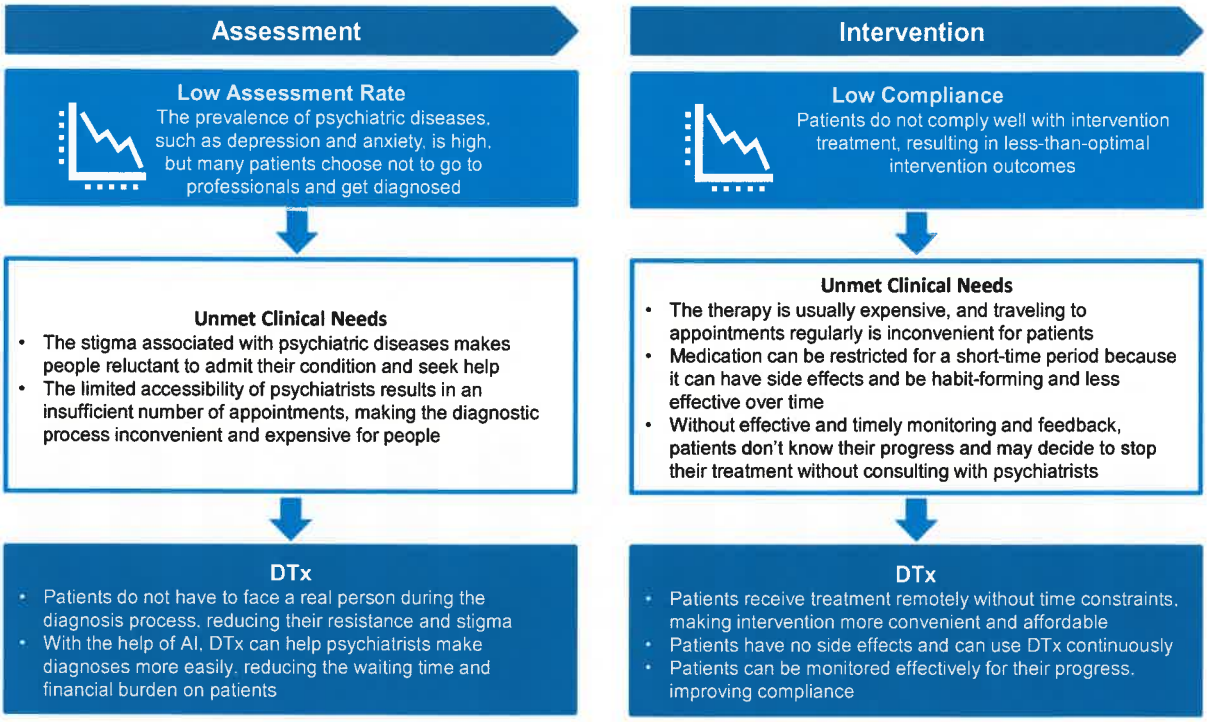
Depression	Schizophrenia	Sleep Disorders	Anxiety
• In 2019, 280 million people were living with depression, including 23 million children and adolescents. • During a depressive episode, the person experiences depressed mood.	• Schizophrenia affects about 24 million people or 1 in 300 people worldwide. • Schizophrenia is characterised by significant impairments in perception and changes in behaviour.	• Sleep disorders are conditions that disturb your normal sleep patterns. • Symptoms include excessive daytime sleepiness, irregular breathing or increased movement during sleep.	• In 2019, 301 million people were living with an anxiety disorder including 58 million children and adolescents. • Anxiety disorders are characterised by excessive fear and worry and related behavioural disturbances.

Stages of Psychiatric Disorders

Stage 1: mild symptoms and warning signs	Stage 2: symptoms increase in frequency and severity
Stage 3: symptoms worsen with relapsing and recurring	Stage 4: symptoms are persistent and severe and have jeopardized life

Source: Literature Review, Frost & Sullivan Analysis

Unmet Clinical Needs of Psychiatric Diseases



Source: Literature Review, Frost & Sullivan Analysis

Overview of Schizophrenia

- Schizophrenia is a chronic, severe mental disorder that affects the way a person thinks, acts, expresses emotions, perceives reality, and relates to others.
- Cognitive impairment is a central feature of schizophrenia and manifests itself as moderate to severe deficits in a number of domains, including attention, working memory, verbal learning and memory, and executive functioning.
- Cognitive impairment in schizophrenia represents one of the main obstacles to clinical and functional recovery.
- Antipsychotic medications have little impact on cognitive impairments in schizophrenia. Currently available antipsychotics not only do not restore cognitive dysfunction, but they may also aggravate it directly and indirectly

Causes

- Research has not identified one single cause of schizophrenia. It is thought that an interaction between genes and a range of environmental factors may cause schizophrenia. Psychosocial factors may also affect the onset and course of schizophrenia.

Treatment

Psychotherapy

- Psychotherapeutic approaches may be divided into three categories: individual, group, and cognitive behavioral.
- Emerging psychotherapies include meta-cognitive training, narrative therapies, and mindfulness therapy.
- Nonpharmacological treatments should be used as an addition to medications, not as a substitute for them.

Pharmacological Therapy

- Antipsychotics are usually recommended as the initial treatment for the symptoms of an acute schizophrenic episode.
- There are 2 main types of antipsychotics: (i) typical antipsychotics – the first generation of antipsychotics developed in the 1950s. (ii) atypical antipsychotics – newer-generation antipsychotics developed in the 1990s

Diagnosis

- Physical exam: This may be done to help rule out other problems that could be causing symptoms and to check for any related complications.
- Tests and screenings:These may include tests that help rule out conditions with similar symptoms, and screening for alcohol and drugs. The doctor may also request imaging studies, such as an MRI or CT scan.
- Psychiatric evaluationA doctor or mental health professional checks mental status by observing appearance and demeanor and asking about thoughts, moods, delusions, hallucinations, substance use, and potential for violence or suicide. This also includes a discussion of family and personal history.

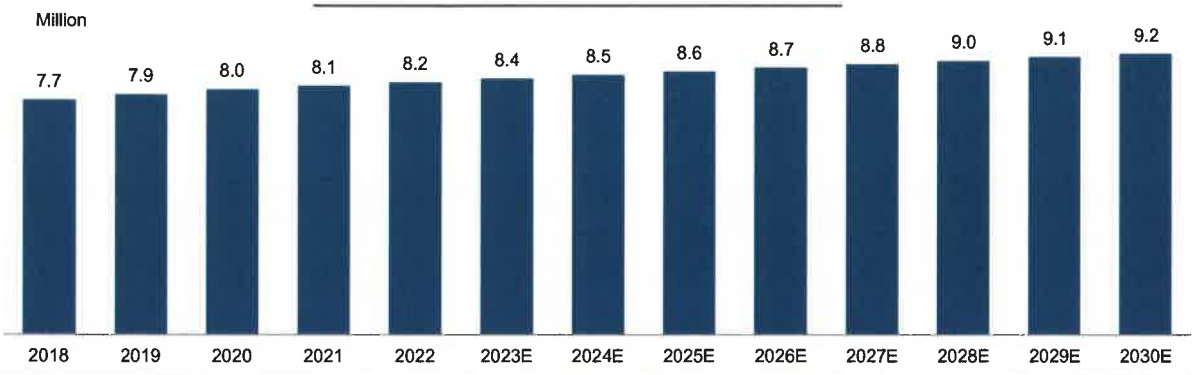
Source: Literature review, WHO, Frost & Sullivan Analysis

Prevalence of Schizophrenia in China, 2018-2030E

- In 2022, the number of patients with schizophrenia in China will reach 8.2 million, with a compound annual growth rate of 1.8% from 2018 to 2022. It is estimated that the number of patients will reach 8.6 million in 2025 and 9.2 million in 2030, with a compound annual growth rate of 1.3%.

Prevalence of Schizophrenia in China, 2018-2030E

Period	CAGR
2018-2022	1.8%
2022-2025E	1.4%
2025E-2030E	1.3%



Source: Frost & Sullivan Analysis

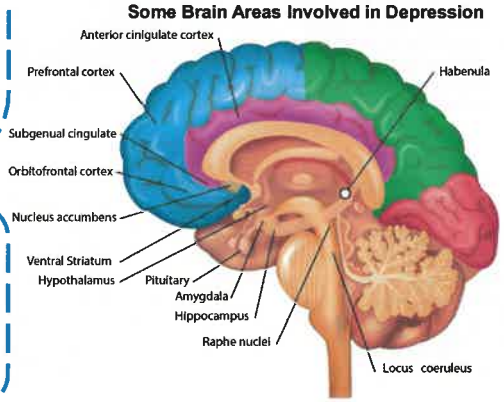
Overview of Depression

- Depression is a common mental disorder. It involves a depressed mood or loss of pleasure or interest in activities for long periods of time.
- In addition to affecting mood and emotions, depression can change the way the brain works. Depression may lead to some degree of cognitive impairment, as evidenced by executive dysfunction, impaired learning and memory, decreased attention and concentration, and reduced processing speed.
- Addressing cognitive impairment is consistent with traditional approaches to treating acute depression and managing patients with long-term, recurrent depression. Cognitive impairment often persists after other symptoms of depression have resolved and profoundly affects the patient's ability to function.
- Clinicians should develop an individualized, comprehensive management plan for cognitive impairment that includes pharmacologic and nonpharmacologic treatments.
- The FDA has not yet approved a drug to treat cognitive impairment in depression. Non-pharmacological approaches include psychological and behavioral therapies, neurostimulation procedures, and lifestyle interventions.

Symptoms

- A depressive episode is different from regular mood fluctuations. They last most of the day, nearly every day, for at least two weeks.
- Persistent sad, anxious, or "empty" mood
- Feelings of hopelessness or pessimism
- Feelings of guilt, worthlessness, or helplessness
- Difficulty sleeping and physical aches or pains
- Thoughts of death or suicide or suicide attempts

Some Brain Areas Involved in Depression



Treatment

- Psychological treatment: behavioural activation ,cognitive behavioural therapy, interpersonal psychotherapy, problem-solving therapy.
- Medications: Antidepressants including selective serotonin reuptake inhibitors (SSRIs) work by changing how the brain produces or uses certain chemicals involved in mood or stress.

Source: Literature review, WHO, Frost & Sullivan Analysis

Prevalence of Depression in China, 2018-2030E

- In 2022, the number of patients with depression in China will reach 30.8 million, with a compound annual growth rate of 1.5% from 2018 to 2022. It is estimated that the number of patients will reach 32.1 million in 2025 and 33.9 million in 2030, with a compound annual growth rate of 1.1%.

Prevalence of Depression in China, 2018-2030E

Period	CAGR
2018-2022	1.5%
2022-2025E	1.4%
2025E-2030E	1.1%

Source: Frost & Sullivan Analysis

Overview of Sleep Disorders and Anxiety

Sleep Disorders

Sleep disorders include problems with sleep quality, duration, and quantity that can lead to daytime distress and impaired functioning. Sleep disorders are risk factors for cognitive impairment. Reduced sleep duration may also lead to cognitive decline by causing hippocampal degeneration through a variety of pathways including changes in neuronal excitability, reduced synaptic plasticity, and decreased neurogenesis. In addition, some patients who already have dementia also experience varying degrees of sleep disorders. Sleep disorders portend a poorer prognosis, including more severe cognitive and neuropsychiatric symptoms and a poorer quality of life.

Treatments

Medication

- May become habit-forming and should only be used for short periods and under the care of a doctor
- May become less effective over time

Cognitive behavior therapy

Complementary health approaches
- Relaxation techniques
- Melatonin
- Mind and body approaches
- etc

Anxiety

People with anxiety disorders frequently have intense, excessive and persistent worry and fear about everyday situations, which are difficult to control

Symptoms

- Having a sense of impending danger, panic or doom
- Having an increased heart rate
- Having trouble sleeping
- Experiencing gastrointestinal problems
- Having the urge to avoid things that trigger anxiety

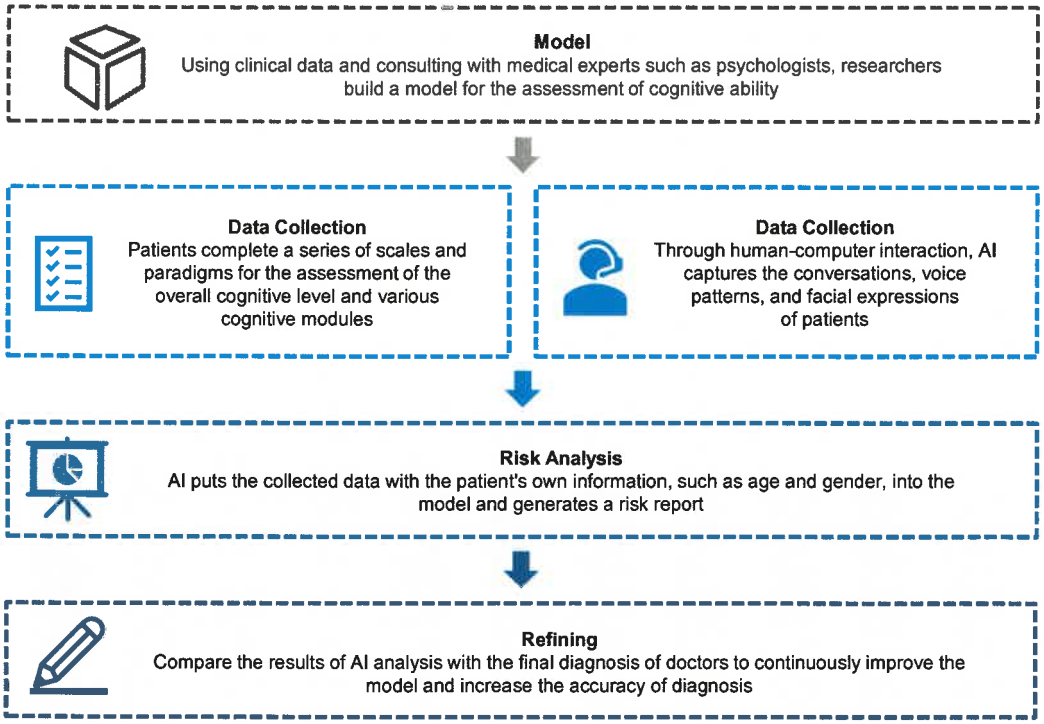
Treatments

Medications:
- Certain antidepressants
- An anti-anxiety medication called buspirone
- In limited circumstances, beta blockers can be used for short-term relief of anxiety symptoms and are not intended to be used long term.

Psychotherapy: cognitive behavioral therapy (CBT) is the most effective form of psychotherapy for anxiety disorders

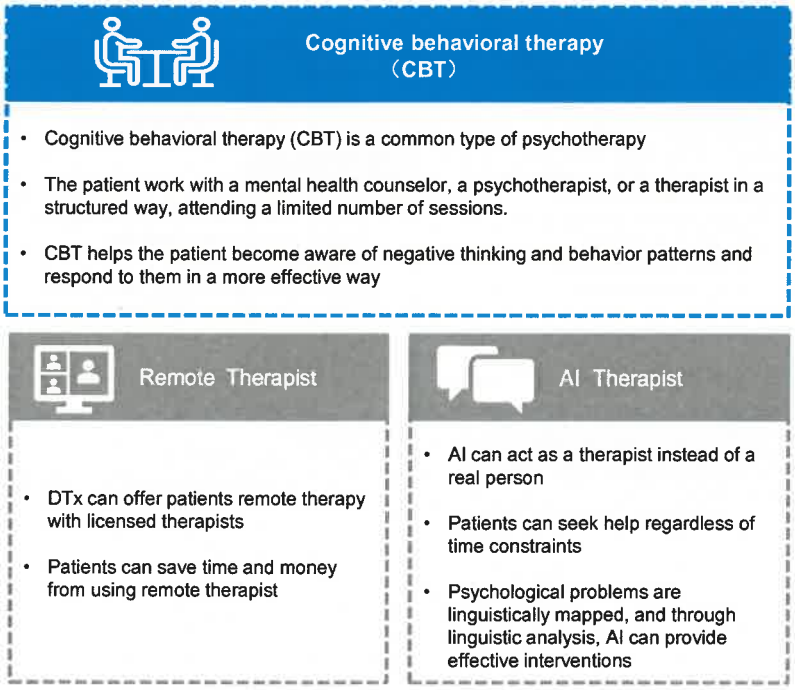
Source: Literature Review, Frost & Sullivan Analysis

Assessment Mechanism of DTx for Psychiatric Diseases



Source: Frost & Sullivan Analysis

Intervention Mechanism of DTx for Psychiatric Diseases



Source: Frost & Sullivan Analysis

Treatment Options for Psychiatric Induced Cognitive Impairment

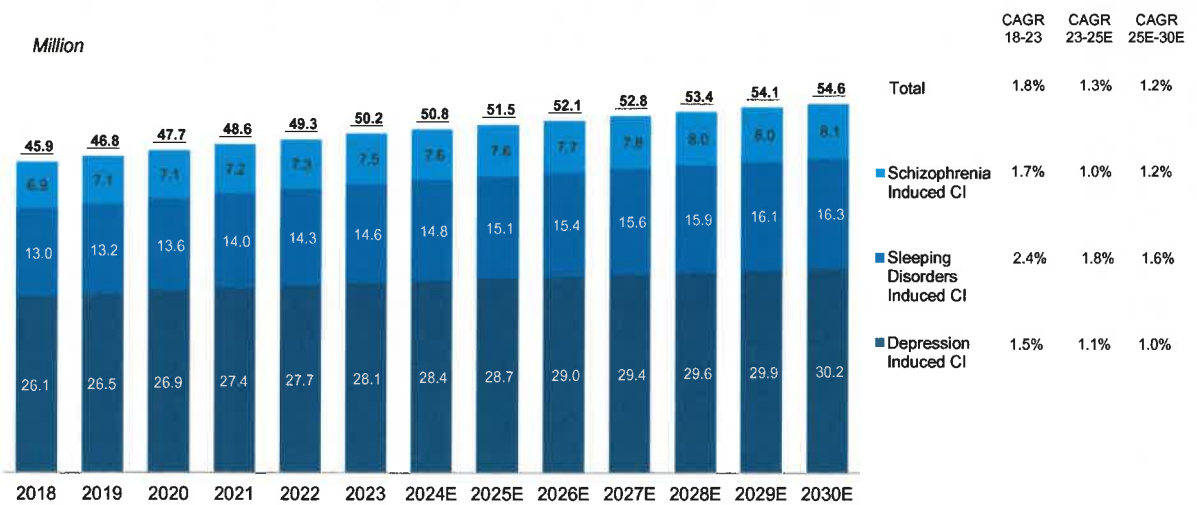
Neurotransmitter System	• The combination of peripheral blood-derived biomarkers with simple, minimally invasive accessibility provides a more accessible and inexpensive option for the diagnosis, monitoring, and prognosis of cognitive impairment in psychiatric disorders. Interleukin 6 (IL-6), IL-1β, tumor necrosis factor α (TNF-α), and C-reactive protein (CRP) in the peripheral blood of patients with SCZ, BD, ASD, and MDD have received considerable attention as representative molecules of inflammation.
Metabolic	• Cognitive dysfunction in SCZ may also be related to central insulin deficiency, which involves regulation of dopamine, glucose metabolism, and feeding, and exercise or drug interventions that increase insulin sensitivity may be a way to address cognitive deficits in SCZ
Microbial Gut-brain Axis	• Strategy 1: Wild-type and Genetically Modified Probiotics: One potential gut-targeted therapy to ameliorate symptoms of cognitive impairment is the administration of probiotics. • Strategy 2: Fecal Microbiota Transplantation: FMT may be a modulation strategy to target cognitive impairment. • Strategy 3: Physical Exercise: Physical exercise has been well established as a preventive health strategy and clinical intervention to improve physical function, reduce cardiovascular risks, all-cause mortality, cognitive decline, and dementia. • Strategy 4: High-Fiber Diet: cognitive impairment may at least partially, share the same pathophysiological background (ie, gut dysbiosis) as many as these gastrointestinal disorders and neurodegenerative diseases
Stem Cells	• Peripheral blood derived biomarkers, which are combined with easy and minimally invasive accessibility, provide a more acceptable and inexpensive option for the diagnosis, monitoring and prognosis of cognitive impairment in mental diseases • TNF-α plays a vital role in brain development as it regulates synaptic pruning and plasticity in preadolescence, adolescence, and early adulthood, mediating neuronal homeostasis and dysfunctional signaling

Source: Literature Review, Frost & Sullivan Analysis

Prevalence of Psychiatric Cognitive Impairment in China, 2018-2030E

- Cognitive deficits are a core feature of schizophrenia, account for much of the impaired functioning associated with the disorder. Major depression disorder significantly impairs individuals' cognitive subdomains such as memory, execution, and attention. And sleeping disorders can result in cognitive impairment. About 5% of sleeping disorders patients will develop cognitive impairment.

Prevalence of Psychiatric Cognitive Impairment in China, 2018-2030E



	CAGR 18-23	CAGR 23-25E	CAGR 25E-30E
Total	1.8%	1.3%	1.2%
Schizophrenia Induced CI	1.7%	1.0%	1.2%
Sleeping Disorders Induced CI	2.4%	1.8%	1.6%
Depression Induced CI	1.5%	1.1%	1.0%

Note: The overall prevalence and prevalence in each field of cognitive impairment include patients with comorbidities.

Source: Frost & Sullivan Analysis

Global Prevalence of Psychiatric Cognitive Impairment, 2018-2030E

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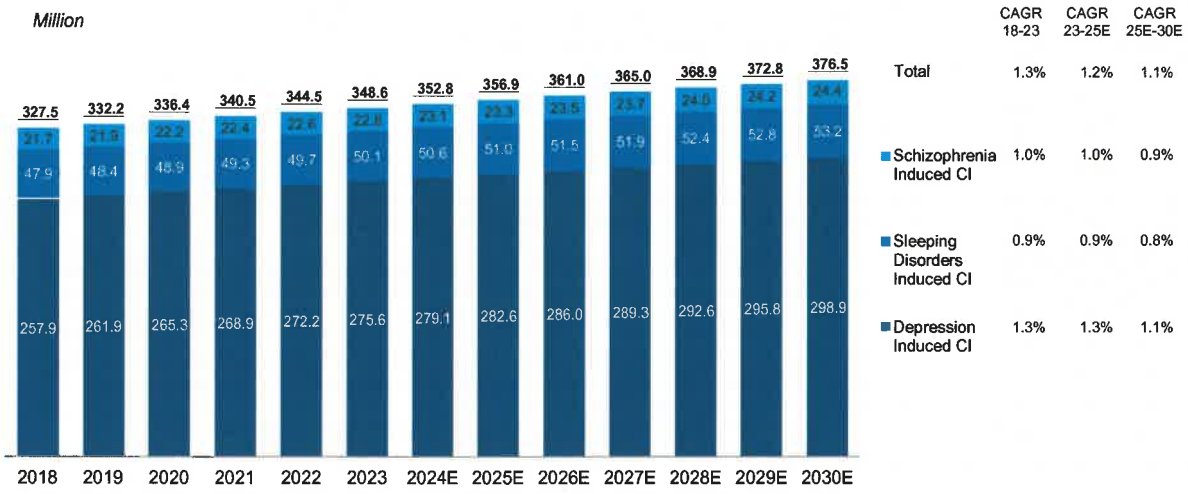
Global Prevalence of Psychiatric Cognitive Impairment, 2018-2030E



	CAGR 18-23	CAGR 23-25E	CAGR 25E-30E
Total	1.3%	1.2%	1.1%
Schizophrenia Induced CI	1.0%	1.0%	0.9%
Sleeping Disorders Induced CI	0.9%	0.9%	0.8%
Depression Induced CI	1.3%	1.3%	1.1%

Note: The overall prevalence and prevalence in each field of cognitive impairment include patients with comorbidities.

Source: Frost & Sullivan Analysis

Competitive Landscape of Psychiatric Diseases Cognitive Impairment Digital Therapeutics

Company	BrainAu	ECAN	Xinkang Yixue	WonderLan	VISHEE
Class	Medical Level	Medical Level	Medical Level	Medical Level	Medical Level
Category	• Assessment • Intervention	• Intervention	• Assessment • Intervention	• Intervention	• Assessment • Intervention
Product Name	Brain function information management platform software system	Cognitive impairment assessment rehabilitation software	Cognitive dysfunction screening and correction software	Cognitive dysfunction treatment software	Cognitive dysfunction assessment and training software
Indication	Brain dysfunction due to various brain injuries • depression • sleep disorders • schizophrenia • other cognitive impairments	Cognitive impairment due to brain damage: • schizophrenia • psychosomatic disorders • other cognitive impairments	• Schizophrenia • Depression and anxiety disorders • Obsessive compulsive disorder • Other cognitive impairments	• Anxiety • Depression • Sleep disorders • Other cognitive impairments	• Psychosomatic disorders
Approval number	湘械注准20222211862 湘械注准20222212193 湘械注准20182210142	桂械注准20222210140	湘械注准20222210661	湘械注准20222210042	苏械注准20222210934

Source: Company Websites, Frost & Sullivan Analysis

Overview of Child Development Induced Cognitive Impairment

- Child developmental deficiency refer to the abnormalities in the body structure or function of children due to certain reasons at birth or during growth and development, which affect their normal physiological and psychological development. These defects can occur in any organ system, including intelligence, language, hearing, vision, limbs, heart, lungs, etc., and may also be caused by a variety of factors such as genetics, environment, and drugs. Children's developmental defects can cause adverse effects on children's health, learning, social interaction, self-care ability and other aspects, which need timely monitoring and treatment.

Common cognitive disorders in children

1. Attention Deficit Disorder (ADD): Children with ADD may struggle with paying attention, focusing on specific tasks, staying organized, and completing assignments.
2. Autism Spectrum Disorder (ASD): ASD is a developmental disorder that affects social interaction, communication skills, and behavior.
3. Intellectual Disability: This is a general term used to describe individuals with significantly below-average intelligence and difficulties in adaptive behavior.
4. Language and Communication Disorders: Children with language and communication disorders may have difficulty understanding language, expressing themselves verbally or in writing, or comprehending speech.
5. Motor Skills Disorder: Children with motor skills disorder may have difficulty with coordination, balance, or fine motor skills.

The causes of cognitive impairment due to developmental defects in children (Autism spectrum disorder as an example)

Child development deficiency

- Genetic :1. Siblings with autism spectrum disorder; 2. Family history of schizophrenia, mood disorder, or other mental or behavioral problems; 3. People with certain genetic predisposes, such as Down syndrome
- Brain injury: maternal distress induced abortion during pregnancy and other factors resulting in cerebral hypoplasia or premature delivery, dystocia, neonatal brain injury and other factors
- Immune problems: Children with immunodeficiency can cause neurological damage or developmental abnormalities after viral infection, resulting in autism.
- Environmental problems: including environmental pollution, large-scale population migration, etc.

Cognitive impairment

Source: Literature Review, Frost & Sullivan Analysis

Overview of Developmental Diseases

Autism spectrum disorder

Autism spectrum disorder (ASD) is a developmental disability caused by differences in the brain

Symptoms

- Have problems with social communication and interaction
- Have restricted or repetitive behaviors
- Have different ways of learning and moving

Diagnosis

Doctors look at the child's developmental history and behavior to make a diagnosis

Can be detected as early as 18 months of age

However, many children do not receive a final diagnosis until much older

Treatments

There are many types of treatments: behavioral, developmental, educational, social-relational , pharmacological, psychological, and complementary and alternative

DTx for Developmental Diseases

Assessment

The diagnosis of ASD and ADHD involves muiti-dimentional analysis. DTx can help doctors make a decision more efficiently and accurately using AI/ML and big data

Intervention

DTx can be an effective treatment. It may be combined with VR and games to deliver better results. DTx can provide timely feedbacks to patients and doctors

ADHD

ADHD is one of the most common neurodevelopmental disorders of childhood

Symptoms

- Have trouble paying attention
- Have trouble controlling impulsive behaviors (may act without thinking about the result)
- Overly active

Diagnosis

There is no single test to diagnose ADHD

Ddiagnosis usually based on:

- The results of hearing and vision tests
- Information about the patients and their family
- ADHD rating scales or psychometric tests

Treatments

Behavior therapy and medication

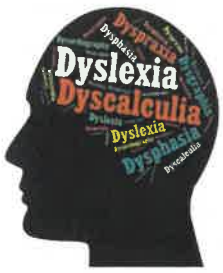
Early intervention is important
Good treatment includes close monitoring, follow-ups, and making changes along the way

Source: Literature Review, Frost & Sullivan Analysis

Overview of Dyslexia

- Dyslexia is also called reading disability. It is a learning disorder that involves difficulty reading due to problems identifying speech sounds and learning how they relate to letters and words. Dyslexia is not due to problems with intelligence, hearing or vision but a result of individual differences in areas of the brain that process language.

Symptoms	Children	Teens and adults
	Read well below the expected level for age	Mispronounce names or words, or problems retrieving words
	Difficulty seeing similarities and differences in letters and words	Difficulty reading, including reading aloud
	Problems remembering the sequence of things	Slow and labor-intensive reading and writing



Causes

- **Dyslexia results from individual differences** in the parts of the brain that enable reading.
- **Dyslexia appears to be linked to certain genes** that affect how the brain processes reading and language.
- **Dyslexia tends to run in families.** A family history of dyslexia or other reading or learning disabilities increases the risk of having dyslexia.

Complications

- **Trouble learning**: a child with dyslexia is at a disadvantage in most classes and may have trouble keeping up with peers.
- **Social problems**: dyslexia may lead to behavior problems and withdrawal from friends, parents, and teachers.
- **Problems as adults**: dyslexia can have negative long-term educational, social and economic impacts

Source: Frost & Sullivan Analysis

Treatment Options for Child Development Deficiency Induced Cognitive Impairment

- There is no one-size-fits-all treatment, and what works best can depend on the individual patient and family. The goal of treatment is to maximize the patient's ability to function by reducing the symptoms and supporting development and learning.

ADHD

Behavior Therapy
- Behavior therapy is a treatment option that can help reduce the disruptive behaviors of patients affected by ADHD. The goals of behavior therapy are to learn or strengthen positive behaviors and eliminate unwanted or problem behaviors.
- For ADHD children, parent training in behavior management is highly recommended.

Medications
- Medications for ADHD includes Stimulants and Nonstimulants, which help patients manage their symptoms in their everyday life and help them control the behaviors
- The dose of medication need to carefully planned to balance between benefits and side effects

Autism

Applied Behavior Analysis (ABA)
- ABA can help patients learn new skills and generalize them to multiple situations through a reward-based motivation system.

Therapy
- Educational, family, communication, and other therapies can help patients improve social skills, communication and behavior.

Medications
- Medications can help control symptoms of autism. For example, antipsychotic drugs may treat severe behavioral problems; and antidepressants may be prescribed for anxiety.

Dyslexia

Early Intervention
- There's no known way to correct the underlying brain differences that cause dyslexia. However, educational approaches and techniques can help children become competent readers.
- The sooner the intervention begins, the better. Children who get help before first grade often improve their reading skills enough to succeed in grade school and high school.

Educational Approaches
- Patients are evaluated on their reading skills, other academic skills, and mental health to develop an individual teaching program, which may use techniques involving hearing, vision and touch to improve reading skills.

Source: Frost & Sullivan Analysis

Unmet Clinical Needs of Developmental Diseases

Assessment

Without an Established Early Screening System

The number of child psychiatrists is still less than 500 in China, a ratio that falls far short of meeting the need for one of the fastest-growing diseases of the 21st century

- Lack of education and training for healthcare providers to inform parents about developmental diseases
- Insufficient resources and difficulty finding professionals
- Long waiting periods for diagnosis due to drawn-out diagnostic processes and visiting multiple doctors
- Problems with misdiagnosis

DTx

Developmental diseases are the most promising area where the shortage and uneven distribution of medical resources can be made up by internet, big data, AI, and other technologies

- Generate screening reports to help medical professionals conduct accurate diagnosis
- Reduce the financial burden and time cost
- Facilitate the integrated process of early detection and early intervention to improve the effectiveness of rehabilitation and intervention

Intervention

Insufficient Resources and Overlooked Needs

There is a serious imbalance between the supply and demand for intervention methods, and co-occurring health conditions are usually overlooked

- High-quality medical resources are concentrated in big cities, making access difficult, which results in poor patient compliance and a significant financial burden on families
- Intervention therapy requires a high level of the treatment environment, faculty, and standardization, resulting in poor feasibility and low prevalence of institutional interventions
- The need for mental health help is usually overlooked

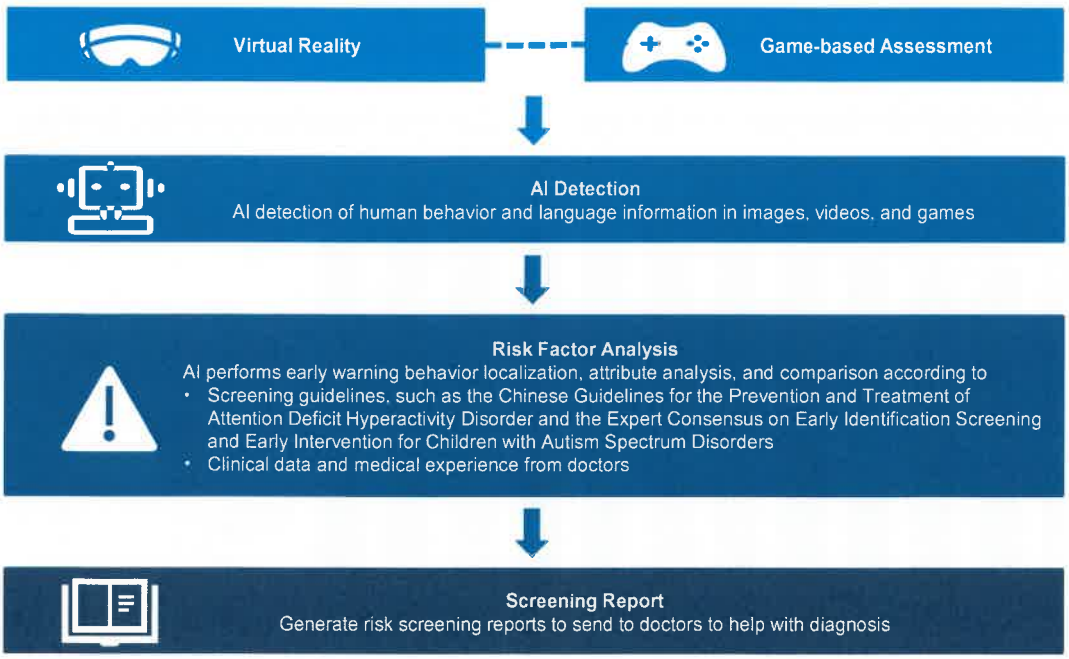
DTx

Based on evidence-based medicine, DTx makes the treatment with the advantages of easy operation, standardization, and specialization, effectively complementing medication and on-site therapy

- Make treatment accessible: treatment can be received regardless of time and space, improving patient compliance and lowering medical cost
- Expanding healthcare: the marginal cost of DTx is low, so it's easy to expand the scope of treatment
- Provide comprehensive care: help meet mental health needs and other co-occurring conditions

Source: Literature Review, Frost & Sullivan Analysis

Assessment Mechanism of DTx for Developmental Diseases



Intervention Mechanism of DTx for Developmental Diseases

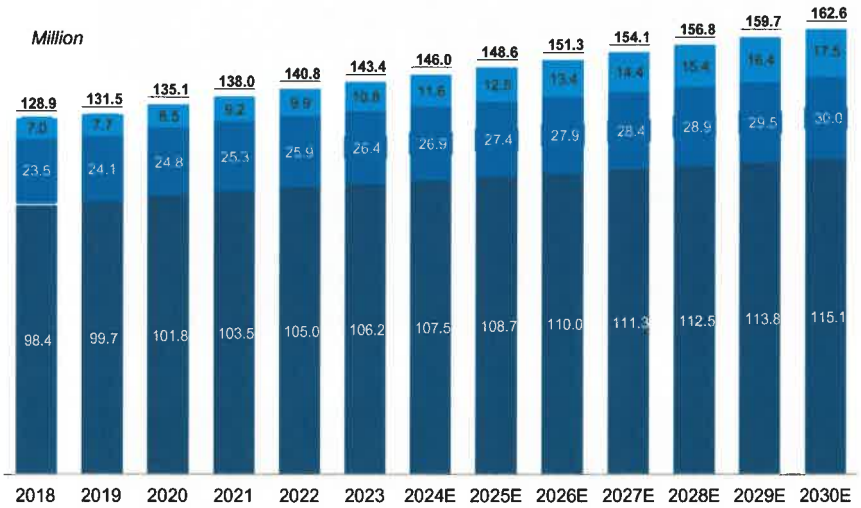
Applied Behavior Analysis	• Applied Behavior Analysis is a type of therapy frequently applied to children with autism and other developmental disorders that focuses on imparting skills in specific domains of functioning, such as social and academic skills, communication, motor dexterity, hygiene, and more • Applied Behavior Analysis is delivered in a variety of settings, including school, home, and other community settings, helping children function independently and successfully
AI and VR/AR Therapy	• AI can guide patients relentlessly, regardless of time and location, bringing a sense of security necessary for the treatment of autistic patients. AL can also collect treatment data, provide feedback to therapists, and support customized treatment plans • VR can create a virtual sensory space, one of the most effective calming techniques, for autistic patients. VR can make treatment more vividly and interesting to improve patient compliance
Patient Community	• Provide a space for patients and their families to communicate through an online internet platform, supporting intervention programs and result analysis
App Management	• Raise awareness of developmental diseases among the guardians of patients through pictures, articles, audio, animated videos, etc • Offer early assessment and intervention contents, providing medical benefit to patients, proven by clinical research

Source: Frost & Sullivan Analysis

Prevalence of Child Development Deficiency Induced Cognitive Impairment in China, 2018-2030E

- Child development deficiency can induce cognitive impairment. Autism spectrum disorder is associated with neurocognitive impairment, including executive dysfunctioning and social cognition deficits. In addition, ADHD has been conceptualized in relation to varying cognitive impairments including attention, reward response, executive functioning, and other cognitive processes.

Prevalence of Child Development Deficiency Induced Cognitive Impairment in China, 2018-2030E



	CAGR 18-23	CAGR 23-25E	CAGR 25E-30E
Total	2.2%	1.8%	1.8%
Autism Induced CI	9.0%	7.8%	7.0%
ADHD Induced CI	2.3%	1.9%	1.8%
Dyslexia Induced CI	1.5%	1.2%	1.2%

Note: The overall prevalence and prevalence in each field of cognitive impairment include patients with comorbidities.

Source: Frost & Sullivan Analysis

Global Prevalence of Child Development Deficiency Induced Cognitive Impairment, 2018-2030E

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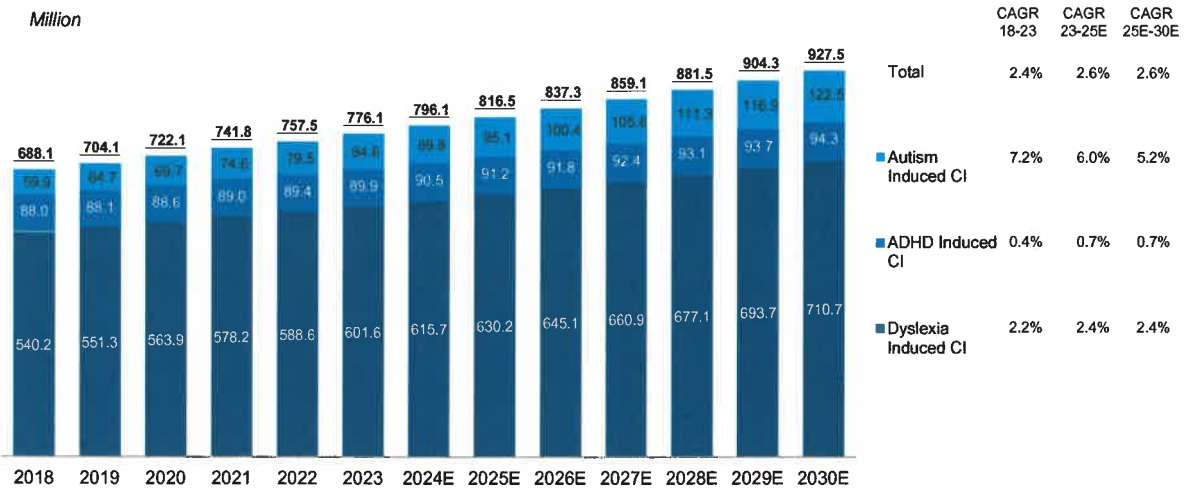


	CAGR 18-23	CAGR 23-25E	CAGR 25E-30E
Total	2.4%	2.6%	2.6%
Autism Induced CI	7.2%	6.0%	5.2%
ADHD Induced CI	0.4%	0.7%	0.7%
Dyslexia Induced CI	2.2%	2.4%	2.4%

Note: The overall prevalence and prevalence in each field of cognitive impairment include patients with comorbidities.

Source: Frost & Sullivan Analysis

Competitive Landscape of Developmental Diseases Cognitive Impairment Digital Therapeutics

Company	BrainAu	ECAN	Xinkang Yixue	WonderLan
Class	Medical Level	Medical Level	Medical Level	Medical Level
Category	• Assessment • Intervention	• Intervention	• Assessment • Intervention	• Intervention
Product Name	Brain function information management platform software system	Cognitive impairment assessment rehabilitation software	Cognitive dysfunction screening and correction software	Cognitive dysfunction treatment software
Indication	Brain dysfunction dur to various brain injuries • ADHD • Autism • other cognitive impairments	Cognitive impairment due to brain damage: • Autism • ADD/ADHD • developmental disability • other cognitive impairments	• ADHD • Neurodevelopmental disorders • Other cognitive impairments	• Autism • Other cognitive impairments
Approval number	湘械注准20222211862 湘械注准20222212193 湘械注准20182210142	桂械注准20222210140	湘械注准20222210661	湘械注准20222210042

Source: Company Websites, Frost & Sullivan Analysis

Overview of Orthopedic trauma

Definition

- Orthopedic trauma typically refers to an injury caused by some external force. These injuries occur in the musculoskeletal system, including bones, cartilage, joints, ligaments, muscles, and tendons of the body.

Common injuries

- Closed fractures (Broken bone that doesn't break the skin)
- Open fractures (Broken bone that does break the skin)
- Stress fractures (Small, hairline crack in the bone cause by overuse)
- Dislocation (A joint forced out of position)

Causes

- Physical violence
- Natural disasters
- Sports accidents
- Traffic accidents

Treatment

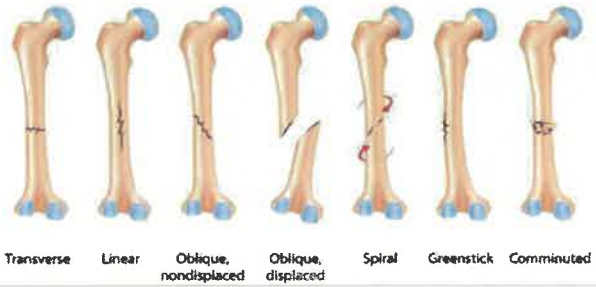
Nonsurgical treatment

- Non-operative treatment is possible for some fractures and dislocations which are not displaced, particularly those involving the clavicle, scapula, humerus, wrist, hand, and foot, in the form of traction or given a cast, sling, or splint outside of the injury for stability.

Surgical treatment

- Internal fixation is when a doctor performs major surgery on the bone to stabilize it with pins, wires, screws, and plates.
- Treatment options include many cutting-edge surgical techniques, such as minimally invasive surgery, advanced external fixation, and the use of bone graft substitutes and bone-forming proteins.

Types of Bone Fractures



Source: Literature review, Frost & Sullivan Analysis

Overview of Cognitive Impairment Due to Diabetes

- With the improvement of living standards and the acceleration of the population aging process, the prevalence of diabetes is increasing. Cognitive impairment is a chronic complication of diabetes, which leads to decreased memory and comprehension and spatial positioning impairment, seriously affecting the quality of life of patients.

Diabetes

- **Insulin Resistance**
  A risk factor for Alzheimer's disease which accelerates cognitive impairment
- **Hyperglycemia**
  Exert toxic effects on the central nervous system and damage nerve cells
- **Hypoglycemia**
  Cause insufficient energy supply to the brain, resulting in irreversible neuronal damage
- **Vascular Lesions in the Brain**
  Poorly controlled blood glucose levels and complications like cerebral atherosclerosis can lead to changes in cerebral hemodynamics and cause vascular lesions
- **Psychological Factors**
  The physical discomfort makes patients more likely to experience depression and anxiety

→ **Vascular Cognitive Impairment, Alzheimer's, and Other Cognitive Impairment**

Diagnosis

1. **Consultations for symptoms related to cognitive impairment**
2. **Targeted assessments:** inquiry of medical history and cognitive testing
3. **Classification based on examination results:** regular monitoring for patients with a low possibility for cognitive impairment; for others, referral to neurology to determine disease condition after ruling out other causes

Treatment

- **Lifestyle modifications and cognitive training:** improve brain function by controlling diet, exercise, and performing cognitive and memory training
- **Glucose-lowering treatment:** taking anti-glycemic drugs and other ways to control blood sugar levels
- **Medications for dementia:** medications for Alzheimer's disease such as acetylcholinesterase inhibitors

Source: Literature Review, Frost & Sullivan Analysis

Overview of Cancer Related Cognitive Impairment

- There are more than 40 million cancer survivors worldwide. This is expected to increase with advances in cancer screening and treatment. However, cancer treatment may have a negative impact on the cognitive function of patients.

Body's physiological response to a tumor

Cancer treatments:
- Chemotherapy
- Radiation therapies
- Endocrine therapies
- Surgery with anesthesia

Lapses in memory and attention

Difficulty concentrate on a single task

Anxiety and depression

Cancer-related Cognitive Impairment

Prevalence

- Not all patients who receive cancer treatment will develop cognitive impairment
- Patients who undergo chemotherapy are more likely to experience cognitive impairment compared to other treatments
- Most patients fully recover within a year, but some continue to experience symptoms for months to years after treatment ends

Diagnosis

- Patients are referred for neuropsychological testing when cognitive decline appears
- Cognitive impairment is often understated because patients are tested only after the problem has already occurred, so doctors don't know what the baseline was
- New neurocognitive tests are needed for cancer-related cognitive decline

Treatment

- There are no medications approved specifically for treating the syndrome
- Options to treat symptoms are limited
- Medications, such as Adderall, Ritalin, Modafinil, and donepezil, only offers short-term benefits and may have side effects
- Cognitive skills training needs further development

Source: Literature Review, Frost & Sullivan Analysis