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## DIGITAL THERAPEUTICS MARKET

### **Overview of the Digital Therapeutics Market**

Digital therapeutics (the "**DTx**") refer to software-driven medical solutions that assess patient conditions by collecting various types of patient input (such as pictures, texts, voices and video feeds) in order to deliver therapeutic interventions that prevent, treat, and manage various types of diseases. DTx digitize existing medical principles, guidance or standardized treatment plans into software-driven interventional measures that improve patients' access to and compliance with treatments. It is a subset of digital medicine, which is a part of digital health. Digital health is an umbrella term that encompasses various types of technology used in healthcare to manage the health of both patients and healthy individuals. Although still a relatively new field, DTx market shows promise for improving patient outcomes and reducing healthcare costs.

The value chain of China's cognitive impairment DTx industry primarily involves (i) upstream suppliers of DTx products (such as our Company) and health management platforms; (ii) midstream service providers that promote DTx products in the relevant markets and connect upstream suppliers of DTx products with downstream users and customers; and (iii) downstream users and customers, such as hospitals and patients. See "Business—Our Strategies" for details of our strategies to capture market demand.

### **Classification of DTx Products**

DTx is a type of healthcare assessment and intervention tool that uses digital technologies to prevent, diagnose, manage and treat diseases. There are two main categories of DTx: medical-grade DTx and non-medical-grade DTx.

o Medical-grade DTx are typically required to undergo rigorous evidence-based clinical evaluation processes to demonstrate safety and efficacy in clinical trials and can be prescribed as effective first-line treatments without the side effects associated with conventional drugs. In contrast to non-medical-grade DTx, medical-grade DTx

can provide diseases assessment and intervention either as monotherapy or in combination with existing drugs and other therapies. Because of the accessible nature of DTx, medical-grade DTx provide clinically validated therapeutic options that are appropriate for patients with chronic conditions that require ongoing treatment and monitoring and are consistent with government goals to promote access to healthcare in rural or underserved areas worldwide.

 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. The safety and efficacy of non-medical-grade DTx are typically not validated through rigorous evidence-based clinical processes. Non-medical-grade DTx includes applications for health promotion, disease prevention, self-diagnosis, management, rehabilitation, palliative care and epidemic or pandemic care.

#### **DTx Development History**

DTx is an emerging field of healthcare technology that uses software-driven medical tools to assess patient conditions and deliver therapeutic interventions that prevent, treat, and manage various types of diseases. The development of DTx has rapidly gained momentum worldwide, with more than 40 FDA-approved applications currently available. In 2015, the first FDA-approved DTx emerged to test and monitor blood glucose. In 2017, reSET became the first interactive FDA-cleared DTx for cognitive behavioral therapy, which marked a shift from the use of DTx for purely assessment purposes to their use for interventional and therapeutic purposes. In the same year, the Digital Therapeutics Alliance (the "DTA"), a global non-profit organization, was founded to promote the adoption of DTx. This collaboration aimed to accelerate the development and adoption of DTx, and to establish standards for the industry. In 2020, the FDA launched the Digital Health Center of Excellence. This center is dedicated to advancing digital health technologies and ensuring the safety and efficacy of DTx, suggesting that DTx will continue to play an increasingly important role in healthcare.

Despite a late start, China has made rapid progress in the development and adoption of DTx to meet the growing healthcare needs of its population. The focus on innovation and modernization is reflected in a number of milestones that have marked the development of DTx in China. In 2018, the General Office of the State Council introduced a policy of "internet plus healthcare, "which laid the groundwork for the industry's growth. In 2018, the NMPA granted our Company the country's first medical device registration certificate for cognitive impairment DTx on the assessment and intervention of cognitive impairment, according to Frost & Sullivan. In addition, the National Informatization Plan for the 14th Five-Year Plan, which was released in 2022, emphasizes the promotion of digital health development, including the development of DTx. This plan is expected to boost the industry by demonstrating the government's commitment to supporting the development of DTx in China, as the industry gains recognition and support from both the private and public sectors.

In March 2023, we co-authored the "Chinese expert consensus on digital therapeutics for cognitive impairment (2023 edition)" (《認知數字療法中國專家共識(2023)》), which systematically defined cognitive impairment DTx for the first time in China, according to Frost & Sullivan.

### Advantages of DTx

DTx represents a new approach to healthcare that offers numerous advantages over traditional therapies and complements them to create value for patients and healthcare providers.

- o *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.
- o *For healthcare providers.* DTx also improves the efficiency and reach of healthcare providers. DTx assists physicians to interact with, obtain information from and conduct medical assessment on multiple patients at the same time, which increases the physicians' assessment efficiency. Some DTx products could also utilize AI to offer highly customized and self-adaptive trainings for patients based on their specific conditions and stage of recovery, which could significantly increase intervention efficacy. In addition, DTx enables healthcare providers to extend patient care beyond the hospital by reaching patients in remote areas or outside of normal working hours, which is especially valuable where physicians and medical resources are in short supply.

## **Global DTx Competitive Landscape**

The global DTx market is fragmented and consists of many players offering a wide range of medical-grade and non-medical-grade products. There are around 40 players in the global DTx market with FDA-approved DTx products, including companies that offer cognitive training interactive games, cognitive behavioral therapies, health monitoring systems and other types of DTx covering indications such as attention deficient hyperactivity disorder (the "**ADHD**"), diabetes, hypertension, insomnia and anxiety, as well as cognitive impairment induced by various indications.

#### **Current Development and Future Trends**

#### AI and Future DTx Development

The integration of artificial intelligence (the "AI") technologies is a major trend within the DTx industry. DTx products are software-based and therefore compatible with advances in AI technologies. As a result, the DTx industry has invested heavily in advanced AI technologies to enhance the capabilities of DTx products.

A major potential of AI as applied in DTx is to improve assessment efficiency and produce more accurate diagnostic results. Another promising application of AI in DTx is virtual health coaching designed to help patient navigate through the course of treatment and improve patient adherence to treatment plans, ultimately leading to better treatment outcomes. AI technologies such as natural language processing and sentiment analysis can be used to enhance the functions of DTx by better understanding the emotional context of patient feedback and improving the patient experience. AI technology and algorithms in DTx products can also enhance the intervention efficacy of DTx by offering treatment plans that are more personalized based on the patient's background.

With the continued development of AI technologies and big data processing methods, the DTx industry is well-positioned to create even more innovative and effective products that can improve patient outcomes and contribute to the advancement of healthcare.

### Future Trends of the DTx Market

- o *Movement towards evidence-based therapeutics*. Evidence-based therapeutics is the foundation of digital therapeutics. Digital therapeutics use systematic and scientific methods to analyze and apply patient data to improve healthcare decision-making. An emphasis on evidence-based therapeutics ensures that they meet rigorous scientific standards, paving the way for their integration into the healthcare system.
- o *Increasing acceptance by patients*. In the future, there is likely to be a significant shift in patient attitudes toward DTx, with patients increasingly willing to pay for these therapies as they seek complementary or alternative approaches to traditional treatments. This shift will be driven by the desire for greater control over patient health outcomes and the convenience of remote access to therapy. The trend toward the use of DTx represents a promising future for the field.
- o *Shifting business model.* In certain markets, such as China, the DTx business model is likely to shift to a business-to-hospital approach, with healthcare institutions and hospitals becoming the primary adopters and providers of DTx. This trend will improve the overall safety and efficacy of DTx products while raising the barrier to entry. This shift represents the integration of digital therapeutics into mainstream healthcare systems, resulting in higher patient uptake when DTx are recommended by physicians, with lower associated risk due to physician guidance.

#### Entry Barriers of the DTx Market

DTx is a new and rapidly evolving industry that requires a high level of technical expertise, access to high-quality clinical information, collaborative relationship with industry participants and the ability to navigate an evolving regulatory landscape. Potential entrants face the following barriers to enter the DTx market.

- *Technology*. New DTx products integrate advanced AI technologies, making them more accurate, standardized and effective. However, optimizing AI and machine learning (the "**ML**") algorithms requires first-hand experience from medical, engineering and algorithmic scientists. The ability to create new AI and ML algorithms pose as a high entry barrier for potential entrants.
- Information. DTx face barriers to entry related to the collection and use of sufficient, high-quality clinical information. In particular, interventional DTx products require large amounts of diverse and representative patient information to train and refine algorithms. However, regulatory requirements can significantly impede information collection, which involves collaboration with healthcare providers and patients in order to obtain consent and ensure data privacy and security, which can be a significant challenge for emerging DTx companies.
- *Collaborations with healthcare providers.* DTx players in certain markets, such as China, need to cooperate with healthcare providers, primarily hospitals, to commercialize their products. The ability to establish such cooperation with healthcare providers poses as a significant entry barrier for new players in cognitive impairment DTx market. New players would need to expend significant efforts and costs to integrate its DTx product into a hospital's system before the products can reach patients.
- *Evolving regulatory environment.* The regulatory environment on DTx in most markets is constantly evolving. Market participants must have the ability to accurately interpret and adapt to the ever-changing regulatory environment to ensure compliance and capitalize on regulations or policies that favor the growth of the global DTx market.

## COGNITIVE IMPAIRMENT DTx 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. Cognitive impairment can vary from mild to severe. Mild cases involve changes in cognitive functions, but the individual is still able to perform everyday activities. Mid-term cases may include increased forgetfulness, especially of recent events, difficulty in communication, and the inability to live alone, leading to aimless wandering. Severe cases involve the inability to recognize friends and family, incontinence and increasingly abnormal behavior.

#### Types of Cognitive Impairment

The causes of cognitive impairment primarily include the following: vascular diseases, neurodegenerative diseases, psychiatric disorders and child development deficiency. Each category presents unique treatment challenges, and there is a growing need for effective, evidence-based solutions that can improve patients' cognitive functions and quality of life.

#### Vascular disease induced cognitive impairment

Vascular disease induced cognitive impairment (the "**VDCI**") is typically caused by brain damages due to impaired blood flow to the brain. The relevant types of vascular diseases generally include stroke, cerebral hemorrhage, or narrowed or chronically damaged blood vessels in the brain. Symptoms of VDCI include confusion, attention deficiency, difficulty with organization, unsteady gait and memory problems, among others.

#### Neurodegenerative disease induced cognitive impairment

NCI are caused by conditions that cause progressive damage to brain cells, resulting in long-term cognitive decline. Alzheimer's disease (the "AD") and amnestic mild cognitive impairment (the "AMCI") are two common examples.

#### Psychiatric disorder induced cognitive impairment

Psychiatric disorder induced cognitive impairment (the "**PCI**") is caused by psychiatric disorders, such as depression and anxiety, that can affect the brain's ability to process information, leading to problems with memory, attention and decision-making. Psychiatric disorders are characterized by a clinically significant disturbance in an individual's cognition, emotional regulation or behavior. These disorders are highly prevalent, affecting one in eight people worldwide, with anxiety and depressive disorders being the most common, according to Frost & Sullivan. A number of factors can contribute to or trigger psychiatric disorders, such as genetics, family history, life experiences, use of alcohol or recreational drugs and other biological factors. Treatment for psychiatric disorders typically involve a combination of drug therapy and psychotherapy and alternative therapies and brain stimulation therapies may also be useful.

### Child development deficiency induced cognitive impairment

Child development deficiency induced cognitive impairment (the "CDDCI"). are structural or functional abnormalities present at birth or during the growth and development of children that interfere with their normal physiological or psychological development. These defects can result in deficiencies in many areas of cognitive development, including intelligence, language, perceptual-motor, and can be caused by a variety of factors, including genetics, environment, medications, brain injury and immunodeficiency. Examples of CDDCI include ADHD, dyslexia and autism.

### Other applications

Cognitive impairment can also arise from other diseases, and cognitive training can serve as an effective treatment option. For example, 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. In particular, diabetes can cause insulin resistance, hyperglycemia, hypoglycemia, vascular lesions in the brain, and other psychological factors, which could lead to vascular cognitive impairment, Alzheimer's disease, and other types of cognitive impairment. Treatment for such cognitive impairments primarily involve (i) cognitive and memory training and medications for dementia, which are dedicated to treating cognitive impairment induced by diabetes; and (ii) lifestyle modification (dieting, exercising, among others) and glucose-lowering treatment, which are dedicated to treating the underlying diabetes.

In addition to diabetes, cancer could also lead to cognitive impairments. Prevailing cancer treatment therapies include chemotherapy, radiation, endocrine, and surgery (with the use of anesthesia), which could have a negative impact on patients' memory, attention, concentration, anxiety and depression, and could in turn lead to cancer-related cognitive impairment. Cognitive training products and services for the above indications are still under development, and is expected to work in tandem with drug and other therapies that are targeted on training cognitive impairments as well as on the underlying diseases.

### Current Treatment Paradigm and Unmet Clinical Needs of Cognitive Impairment

Cognitive impairment is an active area of research, but there is currently no standard treatment therapy. Clinical trials are underway to better understand cognitive impairments and to find treatments that may improve symptoms or prevent or delay dementia.

If the cognitive impairment is caused by underlying reversible causes, treating those causes may alleviate the cognitive impairment. For example, if the cognitive impairment is caused by side effects of certain medications which could affect thinking capabilities, such as benzodiazepines, anticholinergics, antihistamines, opioids and proton pump inhibitors, such impairments typically disappear when the patients stop taking the medications. Other neurological and physiological conditions, such as hypertension, depression and sleep apnea, can cause mild cognitive impairment. Treatment of these underlying conditions may improve patient's memory and overall mental function. Available drug treatments primarily involve medications such as cholinesterase inhibitors, Aricept, Razadyne, Exelon and Memantine. However, the effectiveness of such treatment may be limited to improving the conditions of patients suffering from cognitive impairments induced by neurodegenerative diseases such as AD or Parkinson's disease (the "**PD**").

#### **Cognitive Impairment DTx**

Cognitive impairment is common in patients with vascular diseases, neurodegenerative diseases, psychiatric diseases, and child development deficiencies, among others, and traditional drug therapies may not be effective or available for cognitive impairments induced by these diseases. Cognitive impairment DTx products leverage cutting-edge technology to deliver solutions that can be tailored to the specific needs of individual patients. According to Frost & Sullivan, the cognitive impairment DTx market has experienced significant growth and is expected to continue to grow as the number of people affected by cognitive impairments continues to increase.

Cognitive impairment DTx serves as both an assessment and intervention tool for cognitive impairment patients.

#### Assessment

Cognitive impairment DTx can provide a comprehensive assessment of cognitive function and psychiatric behavioral symptoms, as well as social and daily living skills. It can be used in a variety of scenarios, including clinical diagnosis, large-scale cognitive screening, and community health promotion. Cognitive impairment DTx can also be combined with other technologies, such as virtual reality (the "**VR**"), speech recognition and eye-tracking devices, to provide more accurate and efficient assessments. Compared to traditional assessment methods where physicians can only assess one patient at a time using non-digitized assessment tools, cognitive impairment DTx can provide comparable results while reducing medical costs and improving the efficiency of disease diagnosis and treatment accessibility.

The mechanism of action for DTx assessment of cognitive impairment involves the development of a cognitive computing model as well as the application of existing medical principles, guidance and standards in collaboration with medical experts. Once this model is developed and validated, it can be used to assess a patient's cognitive status by analyzing information collected from the patient. This includes age, gender, behavioral records from family and friends, and medical history. Cognitive tests, information from the patient's interaction with an AI chatbot, data from cognitive assessment scales, and information collected from human-computer interactions during a DTx training session, including the patient's behavioral patterns, word choices, voice patterns, and facial expressions, can all be used. From this data, AI can extract biomarkers of cognitive decline, such as a decline in language function. AI then uses this data to perform an analysis and generate a screening report which serve as a critical basis for medical professionals' diagnosis.

#### Intervention

Cognitive impairment DTx offers an innovative approach to treatment and helps to produce compensatory, transferable and long-lasting treatment effects. Cognitive impairment DTx can also be combined with pharmaceutical and non-pharmaceutical methods for maximum effect. In addition, cognitive impairment DTx offers a promising approach to improving treatment efficacy, optimizing treatment protocols and providing an interactive intervention process for patients where real-time monitoring of treatment outcomes promotes effective hospital-patient linkage.

Cognitive impairment DTx harnesses neuroplasticity, practices brain functions, and continuously strengthens brain function. This is achieved through self-adaptive interventions in multiple cognitive domains, including memory, reasoning, planning and concentration problems. Cognitive impairment DTx also incorporates bridging, which helps patients apply their training to real-life scenarios, and monitoring, which helps patients identify cognitive levels and exercises. By combining these elements, cognitive impairment DTx can effectively improve patients' cognitive functions.

### Advantages of Cognitive Impairment DTx over Traditional Options

#### Assessment

According to Frost & Sullivan, cognitive impairment has become a significant public health issue among the elderly population, requiring large-scale early detection. However, traditional assessment options such as diagnostic scales, evaluation of medical history, neurological examination and examination of bio-markers are complex and time-consuming. In contrast, cognitive impairment DTx can computerize some of the work and perform it without the involvement of professionals. This makes the process more efficient and suitable for large-scale use. Cognitive impairment DTx allows people to closely monitor their cognitive functions so they do not miss the optimal treatment window, which is critical for effective treatment.

### Intervention

Traditional treatments for cognitive impairment have limitations due to the unclear mechanisms of many cognitive disorders. As a result, these treatments can only delay disease progression to a certain extent. Non-pharmacological interventions, such as mental health therapy, are also limited by the scarcity of healthcare providers, making them expensive and inconvenient for patients. Cognitive impairment DTx offers a promising alternative. By combining cutting-edge technologies such as AI and VR, cognitive impairment DTx can deliver interventions that have the potential to be more effective. Cognitive impairment DTx can also provide one-to-many therapy and unsupervised cognitive training, making interventions more accessible and reducing the need for medical staff.

#### **Prevalence of Cognitive Impairment**

### Global

The global prevalence of the four major types of cognitive impairment increased from 1,574.3 million in 2018 to 1,736.3 million in 2023, representing a CAGR of 2.0% and is expected to reach 1,805.7 million in 2025 and further to 1,990.6 million in 2030, representing CAGRs of 2.0% and 2.0%, respectively. The following graph sets forth the global prevalence of the four major types of cognitive impairment during the years indicated, as well as CAGRs during the indicated years.



### **Global Prevalence of Cognitive Impairment, 2018-2030E**

Note: The overall prevalence and prevalence in each major type cognitive impairment include patients with comorbidities.

Source: Frost & Sullivan Analysis

#### China

The prevalence of the four major types of cognitive impairment in China increased from 314.2 million in 2018 to 345.3 million in 2023, representing a CAGR of 1.9% and is expected to reach 356.4 million in 2025 and further to 385.9 million in 2030, representing CAGRs of 1.6% and 1.6%, respectively. The following graph sets forth the prevalence of the four major types of cognitive impairment in China during the years indicated, as well as CAGRs during the indicated years.

#### Prevalence of the Four Major Types of Cognitive Impairment in China, 2018-2030E



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

Source: Frost & Sullivan Analysis

#### Market Size of Cognitive Impairment DTx

The global cognitive impairment DTx market size reached US\$2,529.4 million in 2023 and is expected to grow to US\$4,119.6 million in 2025 and US\$6,737.0 million in 2030, representing CAGRs of 27.6% and 10.3%, respectively. The following graph sets forth the historical and expected global cognitive impairment DTx market size in the years indicated, as well as CAGRs during the indicated years.



#### **Global Cognitive Impairment DTx Market Size, 2018-2030E**

Source: Frost & Sullivan Analysis

The market size of the cognitive impairment DTx in China reached RMB268.6 million in 2023 and is expected to increase to RMB1,046.7 million in 2025 and RMB8,927.4 million in 2030, representing CAGRs of 97.4% and 53.5%, respectively. The following graph sets forth the historical and expected cognitive impairment DTx market size in China in the years indicated, as well as CAGRs during the indicated years. In 2023, BrainAurora Zhejiang held 25.0% of the total cognitive impairment DTx market in China by revenue.



### Cognitive Impairment DTx Market Size in China, 2018-2030E

Source: Frost & Sullivan Analysis

The key assumptions and market policies used by Frost & Sullivan to estimate the above market size of the cognitive impairment DTx in China are as follows.

- Increasing prevalence. After surveying the relevant scientific literature and conducting expert interviews, Frost & Sullivan believes that the overall prevalence of the four major types of cognitive impairment in China is increasing as a result of a growing aging population. The prevalence of the four major types of cognitive impairment in China is expected to reach 356.4 million in 2025 and 385.9 million in 2030. This represents a large patient base, which is expected to generate large clinical demands and contribute to the growth of the cognitive impairment DTx market size from 2023 to 2030.
- *New market opportunities.* The market is expected to diversify with products targeting more cognitive impairment indications, thereby creating new market growth opportunities in the future.

- *Expected increase in market penetration.* According to expert interviews, the medical community is increasingly recognizing DTx as a viable therapy for cognitive impairment, as DTx offers numerous advantages and can complement traditional therapies to create value for patients and healthcare providers. As a result, the market penetration of DTx for cognitive impairment is expected to increase.
- Government policy support. Market growth is also driven by policies to promote digital health and cognitive health. In recent years, the State Council and local governments have issued policies to promote the development of DTx. For example, in February 2022, the National Development and Reform Commission (the "NDRC"), issued The 14th Five-Year Plan for the Development of the Bioeconomy (《"十四五"生物經濟發展規劃》), which aims to expand the clinical application of advanced therapeutic technologies such as intelligent surgical robots, particle radiotherapy and DTx. In December 2023, the NDRC issued the Overall Program of Construction of Guangdong-Macao In-Depth Cooperation Zone (《横琴粵澳深度合 作區建設總體方案》), which emphasizes support for the development of mobile healthcare and DTx in the cooperation zone. At the local government level, in November 2021, the Beijing Municipal People's Government issued the Plan for the Construction of an International Science and Technology Innovation Center in Beijing (《北京市"十四五"時期國際科技創新中心建設規劃》), which states that Beijing will support the technological research and development of DTx. Similarly, in October 2022, the Hainan Provincial People's Government issued Several Measures to Accelerate the Development of Digital Therapeutics Industry in Hainan Province (《海南省加快推進數字療法產業發展的若干措施》), which puts forward a total of 21 initiatives to promote the adoption and growth of DTx, including building the nation's leading clinical research capabilities for DTx and accelerating the registration and approval process of DTx. In addition, China has made increasing efforts in large-scale early assessment and intervention for various cognitive impairments. These initiatives are helping to build a supportive ecosystem for cognitive impairment DTx, paving the way for its sustainable and high-quality development, which will also increase the market penetration and size of cognitive impairment DTx.

### **Competitive Landscape of Cognitive Impairment DTx**

Key players in the global cognitive impairment DTx market (outside China) include companies that offer cognitive training interactive games, cognitive behavioral therapies, health monitoring systems and other types of cognitive impairment DTx products. As of December 31, 2023, there were approximately 19 FDA-approved products covering cognitive impairment induced by various indications by approximately 13 key global players. In China, as of the Latest Practicable Date, approximately 100 cognitive impairment DTx products by approximately 50 players, including our Company, had been approved by the NMPA or its local counterparts, and at least 20 cognitive impairment DTx products by 20 players are currently in the process of clinical trials and obtaining relevant medical device registration certificates, according to Frost & Sullivan. We have a 25.0% market share in China's cognitive impairment DTx market and 91.6% market share in China's medical-grade cognitive impairment DTx market in terms of revenue in 2023, according to Frost & Sullivan.

The following table sets forth the market share and background information of the top players in the cognitive impairment DTx market in China in the year indicated who are in direct competition with our Company according to Frost & Sullivan, as well as the key distinctions in target customers and usage scenario.

Targeted Indication	Cognitive Function	Cognitive Function	Mild Cognitive Impairment (MCI)	Dyslexia		MCI, AD	Brain Dysfunction in Cognition, Speech, and Psychosomatic Functions Due to Brain Injury Disorders	Insomnia disorder	MC		WCI
Performance Indicator	The diagnostic accuracy of patients with cognitive impairment was 94.3% (sensitivity = 94.6%, specificity = 78.1%)	The system result is highly correlated with traditional clinical assessment scales. (p<10^-5)	The assessment part adopts electronic traditional scales; The intervention part found that he training effect was more than 2 times higher for patients with cognitive implarment.	Since there is no gold standard scale in the field of dyslexia, this system fills the gap as the objective assessment tool of this disorder.	The assessment system result has significant correlation with the MOCA-B (Monteal Cognitive Assessment – B, a widely used screening assessment for detering cognitive mpairment) assessment results. ( $r = 0.89$ )	The cognitive function score of the intervention group increased by 5,23%, and the cognitive score of MCT patients increased by 12,85%	No public information disclosed	No public information disclosed	The sensitivity of Cognitive Impairment = $85.3\%$ , and specificity = $95.1\%$	The diagnostic accuracy rate of Al Drug Craving Assessment System is 90%	68% of participants completed more than half of the course and had moderate to high compliance
Property	It is a multi-modal interactive evaluation system based on digital human and artifical intelligence, which provides functions such as voice interaction, internoin recognition, and automatic interpretation.	It is a computerized system that assesses the basic cognitive abilities in comprehensive aspects, with measuring different cognitive abilities in a task-based manuers.	It is a brain beth screening and cognitive exhabilitation intervention system based on the classical research paradigm of neuropsychology, combined with the cutting-edge theories of cognitive neuroscience and antificial intelligence recommendation algorithms.	It is a comprehensive system that includes both systematic "behavior-reading-cognitor assessments, as well as an customized, intelligent-based interventions for children with dystexia.	lt is a new generation of cognitive function assessment method using voice as a digital biomarker.	An innovative digital therapy with a multi-dimensional cognitive intervention system as its core. Through the collection and analysis of posture/bajectory, viore-orienting data, and subset on cognitive assessment results, it intelligently matches personalized training tasks for users.	The system uses the unique immersive, interactive, and imaginative features of virtual reality textology. (VR) and combines it with the principles and methods of traditional clinical psychology for the treatment of anxiety disorders.	The system uses virtual reality (VR) technology as an auxiliary treatment for sleep disorders	The system uses AI algorithms and big data analysis to achieve intelligent screening and analysis of cognitive impairment. It can queby complete cognitive risk assessment within a immutes and is suitable for screening large populations.	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 AI	algorithms to analyze and judge the data as quantitative evidence for the auxiliary diagnosis status. Specific stimulation interventions are then used to improve the corresponding indicators.
Approval Year	2022	2022	2018	2023		2022	2023	2023	2024		2022
Owned Type	Self-developed	Self-developed	Self-developed	Self-developed	Self-developed	Self-developed	Self-developed	Self-developed	Self-developed	No public	information disclosed
Relevant Products	Cognitive Ability Supplemental Screening and Assessment Software	Basic Cognitive Ability Testing Software	Brain Function Information Management Platform Software System	Dyslexia Assisted Screening Management Software	Intelligent Speech Cognitive Function Assessment System	Multidimensional Cognitive Rehabilitation System	VR Cognitive Assessment and Training Software	Sleep Disorder Assisted Therapy Software	Cognitive Self-Assessment Software	Cosmitive Dvsfunction	Treatment Software
Usage Scenario		Hospital & Medical institution: Divital	interventions for cognitive impairment		Individual & Community: Early screening	and intervention treatment for Atzheimer's Disease	Hospital & Medical institution: Mental illness	interventions	Indi vidual & Community: Early screening for Alzheimer's Disease and digital interventions for others mental illness	Hospital & Medical	institution: Mental illness interventions
Targeted Customers		People with cognitive	impairment, the elderly, children and adolescents		T the draw of the second se	Literity people with cognitive impairment	People with anxiety and insomnia, children with ADHD, autsm, 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
Medical Grade Market Share, 2023 <sup>23</sup>			91.60%			6.1%	1.2%		1.1%		%0
Market Share, 2023 <sup>(1)</sup>			25.00%			33.5%	3.2%		1.5%		0.4%
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	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 diagoids 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
Company		Our	Company		Comment	A	Company B		Company C	Company	D

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# **INDUSTRY OVERVIEW**

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Note:

- Market Share measured by percentage of 2023 cognitive impairment DTx revenue in China. Total size of China's cognitive impairment DTx market as measured by 2023 revenue was RMB268.6 million. (I)
- Market share measured by percentage of 2023 medical-grade cognitive impairment DTx revenue in China. Total size of China's medical-grade cognitive impairment DTx market as measured by 2023 revenue was RMB73.4 million.  $(\mathbf{2})$
- Data for Companies A, B, C and D and total market size data were not derived from audited financials; rather, they were prepared by Frost & Sullivan based on non-public searches and reasonable professional estimates. (3)

Source: Frost & Sullivan Analysis

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# **INDUSTRY OVERVIEW**

According to Frost & Sullivan, the industry standards and regulatory regime covering the cognitive impairment DTx industry are expected to become more mature, as more players and products emerge. While this increases the number of players in the industry, maturity in industry standards and regulatory regime provides more certainty as to how players should develop technologies and products, and how they should cooperate with upstream and downstream partners. Leveraging their current competitive advantages in relevant technologies and relationship with partners along the industry chain, top players are expected to enhance their R&D efforts and cooperation with upstream and downstream partners, which is expected to lead to further advantages in technology, economies of scale, cost reduction and business scale expansion. Thus, the cognitive impairment DTx market is expected to become more concentrated going forward, and top industry players are expected to enjoy a larger market share.

In addition, the potential reclassification of cognitive impairment DTx as Class III medical devices is also expected to affect the industry competitive landscape. Class II medical devices pose a moderate degree of risk and whose safety and efficacy should be ensured through strict control and administration. Class III medical devices pose a high degree of risk and must be ensured through strict control and administration by special measures to ensure safety and efficacy. As of the Latest Practicable Date, there are three recommendations from Chinese regulatory authorities regarding the reclassification of DTx medical devices from Class II to Class III. These represent advice from the relevant experts nationwide and are not binding regulations on medical device classification as of the Latest Practicable Date, according to our PRC Legal Advisor. As advised by Frost & Sullivan, such potential reclassifications would make a difference on the steps of clinical development and obtaining regulatory approvals that must be undertaken by players in the industry, not necessarily on the market demands or opportunities for such products. Players with the resources and experience in carrying out evidence-based clinical research and development would potentially enjoy competitive advantage with regards to cognitive impairments DTx products that may be reclassified into Class III medical device, according to Frost & Sullivan. As such, the potential reclassification of cognitive impairment DTx as Class III medical device in China, while not currently in effect, is an example of the abovementioned maturing regulatory regime, and top industry players with more accumulated experience and resources in conducting evidencebased clinical research is expected to enjoy a more significant edge.

## Growth Drivers of the Cognitive Impairment DTx Market

The development of the cognitive impairment DTx market is expected to be driven primarily by increasing demand for cognitive impairment treatment, advances in innovative technologies, supportive regulatory measures and growing awareness of cognitive impairment DTx as a therapeutic option.

- *High demand and large market potential.* Driven by an aging population and an increasing focus on cognitive health, the number of patients seeking treatment for cognitive impairment is increasing globally. Compared to traditional treatment options, cognitive impairment DTx offers a more personalized and cost-effective approach to managing these conditions. With more than 70% of the Chinese population having access to the Internet and mobile phones, cognitive impairment DTx can reach a population comparable to or potentially larger than traditional hospitals.
- Advances in innovative technologies. Innovative technologies are driving the development of cognitive impairment DTx. Advances in AI are being used to improve patient treatment outcomes by providing clinically valid assessment and intervention products that are personalized based on patient data. In addition, technologies such as VR can create an immersive and engaging environment for patients to train their cognitive functions and apply their newly acquired skills to real-life situations, thereby increasing treatment adherence and overall effectiveness. These innovative technologies are expected to drive the adoption of cognitive impairment DTx.
- Measures to support the development of cognitive impairment DTx. DTx is gaining official recognition and support. In recent years, the PRC government has issued policies to promote DTx, such as the 14th Five-Year Plan for National Informatization (《"十四五"國家信息化規劃》) and the Guiding Principles for Defining the Categorization of Digital Therapy Software Products in the Rehabilitation Category (Draft for Comments) (《康復類數字療法軟件產品分類界定指導原則(徵求意見稿)》). Similarly, the U.S. has established the Digital Health Center of Excellence to promote digital health innovation. In addition, cognitive impairment and dementia have become a global public health priority. To address this issue, WHO has launched the Global Action Plan on the Public Health Response to Dementia 2017-2025. Several governments have also emphasized the importance of early screening and intervention for cognitive impairment. This increased focus on cognitive impairment will drive the development and adoption of cognitive impairment DTx.

• Growing recognition of cognitive impairment DTx. Public awareness of cognitive impairment DTx has grown steadily in recent years. In 2023, the Chinese Expert Consensus on Cognitive Digital Therapeutics (《認知數字療法中國專家共識 (2023)》) was published, representing the growing recognition of cognitive impairment DTx by the medical community. More and more medical institutions, including hospitals and rehabilitation centers, are beginning to use cognitive impairment DTx to treat cognitive impairment. Leading cognitive impairment DTx companies are also beginning to participate in the establishment of cognitive centers in hospitals.

## Barriers to Entry of the Cognitive Impairment DTx Market

- *Early entrant opportunities.* Cognitive impairment DTx is an emerging field. Early entrants can take advantage of the formative years of the cognitive impairment DTx industry to influence guidelines and expert consensus and help set industry standards. They can also establish collaborations with researchers and hospitals for publications and research opportunities.
- *Challenges to achieving evidence-based medicine.* Future medical-grade cognitive impairment DTx products will need to undergo various clinical trials and real-world studies to verify their efficacy in order to achieve medical-grade safety and efficacy, and gain consumer confidence and regulatory approval. However, due to the cost and time required for clinical trials, conducting enough clinical trials and obtaining sufficient real-world data comparable to existing players is a significant barrier for new market entrants.
- Data access. cognitive impairment DTx can be enhanced with AI capabilities and become more effective by improving its algorithm with real-world patient information. As usage increases, cognitive impairment DTx can collect more patient information and continually update the algorithms to improve the efficacy of assessment and intervention. For new entrants with a smaller user base, obtaining enough patient information to train and improve their AI algorithms is a significant barrier.
- *Customer lock-in.* Cognitive impairment DTx typically requires patients to undergo diagnosis, intervention and feedback in sequential steps over a period of time. As a result, it is difficult to change therapy mid-stream. Because different cognitive impairment DTx for cognitive impairment may use different treatment modalities and intervention exercises, healthcare providers and patients may become accustomed to certain products, making it difficult to convince them to change and adopt new products.

#### VDCI DTx MARKET

#### **Overview of VDCI**

VDCI encompasses a broad spectrum of syndromes ranging from mild cognitive impairment to dementia. Risk factors for VDCI include age, atherosclerosis, smoking, obesity, high cholesterol, hypertension, diabetes and a history of heart attack or stroke.

#### VCI and VCIND

Vascular cognitive impairment (the "VCI") is a type of VDCI. Vascular cognitive impairment no dementia (the "VCIND") is a mild stage of VCI. It is characterized by mild impairment of concentration and executive function that does not rise to the level of dementia. Some patients with VCIND may go on to develop vascular dementia, while others may return to a healthy state of cognitive function. There is currently no approved treatment for VCIND, but clinical studies have shown that cognitive training through VDCI DTx may be helpful in improving cognitive function.

#### Aphasia

Aphasia is a type of cognitive impairment defined as a language disorder that affects the production or understanding of speech and the ability to read or write. Aphasia usually occurs suddenly after a stroke or head injury, but it can also develop gradually from a slow-growing brain tumor or a disease that causes progressive, permanent damage. The severity of aphasia depends on a number of things, including the cause and extent of the brain damage.

### Atrial Fibrillation Induced Cognitive Impairment

Atrial fibrillation (the "**AF**") is a common type of heart arrhythmia that occurs when the normal sinus rhythm of the atria is replaced by irregular and often rapid electrical depolarizations. Numerous observational studies over the past 10 years, including several meta-analyses, provide increasing evidence that AF is associated with cognitive impairment. AF could lead to cognitive impairment through several mechanisms: cerebral infarcts, reduced brain volume and cerebral microbleeding. Genetic factors and common risk factors may contribute to both AF and the associated cognitive impairment.

### Hypertension Induced Cognitive Impairment

Hypertension, or high blood pressure, is a common disease affecting a significant proportion of the world's population. Prospective cohort studies have reported a positive association between hypertension and the risk of cognitive impairment. Most of the vascular changes induced by hypertension contribute to cognitive impairment by causing hypoperfusion, ischemic and hemorrhagic stroke and white matter injury. No definitive studies have shown which antihypertensive agents and treatment regimens are optimal for maintaining cognitive health. There is a need to improve the detection of hypertension in the general population to reduce the global burden of cognitive impairment.

#### **Coronary Heart Disease Induced Cognitive Impairment**

Coronary heart disease (the "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.

#### Treatment Paradigm and Unmet Clinical Needs of VDCI

Currently there is no standard diagnostic scale for the assessment of VDCI. The current assessment paradigm involves a combination of reviewing the patient's medical history, performing neurological exams, and conducting laboratory tests such as blood pressure, cholesterol, and blood sugar. Brain imaging tests such as magnetic resonance imaging or computed tomography scans may also be used to diagnose the condition. In addition, neuropsychiatric tests can assess cognitive function and identify impairments. VDCI DTx can be a complementary or substitute method to traditional diagnostic methods for VDCI. VDCI DTx can use big data and AI to tailor the assessment to the patient's unique characteristics, such as age, medical history, and education level, resulting in a more accurate neuropsychological diagnosis. This approach provides a better assessment of disease state and can improve the accuracy of VDCI diagnosis, leading to better treatment and care for patients.

Once diagnosed, the interventional therapies for VDCI often focus on managing the risk factors that contribute to the condition. This includes (i) lowering blood pressure, cholesterol, and blood sugar levels; (ii) preventing blood clots; and (iii) controlling diabetes. These interventions can slow or in some cases prevent further cognitive decline. In addition, medications are often used as a treatment options but are limited in their scope and effectiveness. As such, VDCI DTx is a promising intervention tool for many aspects of VDCI. VDCI DTx uses computerized, multi-domain, adaptive training to practice impaired functions and improve cognitive functions. This type of cognitive remediation therapy improves brain function by practicing specific cognitive domains, which can help treat VDCI. By practicing these specific brain functions, the corresponding brain areas can improve and restore network connections between neurons, generate new nerve fibers, regulate trophic factors and consolidate neuronal remodeling. This results in the construction of specific synaptic connectivity patterns for specific cognitive functions, thereby improving overall cognitive abilities for patients with VDCI.

### Prevalence of the Major Types of VDCI

## Global

The global prevalence of the major types of VDCI increased from 414.0 million in 2018 to 455.1 million in 2023, representing a CAGR of 1.9% and is expected to reach 471.0 million in 2025 and further to 511.6 million in 2030, representing CAGRs of 1.7% and 1.7%. The following graph sets forth the global prevalence of the major types of VDCI during the years indicated, as well as CAGRs during the indicated years.



## Global Prevalence of the Major Types of VDCI, 2018-2030E

Notes:

(1) The overall prevalence of the major types of VDCI includes patients with comorbidities.

(2) Aphasia is a type of cognitive impairment.

Source: Frost & Sullivan Analysis

#### China

The prevalence of the major types of VDCI in China increased from 69.8 million in 2018 to 77.6 million in 2023, representing a CAGR of 2.1% and is expected to reach 80.5 million in 2025 and further to 88.0 million in 2030, representing CAGRs of 1.9% and 1.8%. The following graph sets forth the prevalence of the major types of VDCI in China during the years indicated, as well as CAGRs during the indicated years.

### Prevalence of the Major Types of VDCI in China, 2018-2030E



Notes:

- (1) The overall prevalence of the major types of VDCI includes patients with comorbidities.
- (2) Aphasia is a type of cognitive impairment.

Source: Frost & Sullivan Analysis

### **Competitive Landscape of VDCI DTx**

Key players in the global VDCI DTx market (outside China) include at least one player with two FDA-approved VDCI DTx products as of the Latest Practicable Date. The following table provides an overview of the FDA-approved VDCI DTx products.

### FDA-approved VDCI DTx Products

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

Source: FDA, Frost & Sullivan Analysis

In China, a total of approximately 28 VDCI DTx products by approximately 22 players, including our Company, had been approved by the NMPA or its local counterparts, and at least five VDCI DTx products by five players were in the process of clinical trials and obtaining relevant medical device registration certificates, as of the Latest Practicable Date, according to Frost & Sullivan. The following table provides an overview of the NMPA-approved VDCI DTx products as of the Latest Practicable Date, all of which are classified as Class II medical device.

### NMPA-approved VDCI DTx Products

	Product Name	Company	Indication*	Approval Year
1	Cognitive Ability Supplemental Screening and Assessment Software**		Cognitive Function	2022
2	Basic Cognitive Ability Testing Software**	Our Company	Cognitive Function	2022
3	Brain Function Information Management Platform Software System**		Clinical Diagnosis, Treatment and Assessment	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	Verbal Cognitive Dysfunction Due to Brain Stroke	2023
15	Cognitive Rehabilitation Training System	Chinese Medicine Asset Management Co., Ltd	Cognitive Impairment Due to Brain Stroke	2023
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 JianbrainHealth Technology Co., Ltd	Cognitive Impairment Due to Brain Function Injury	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 scopes are related to VDCI.

- \* Represents the year in which the System first received regulatory approval for use of the System as a tool of "assistance of doctors in clinical diagnosis and treatment of patients with brain function impairments caused by various types of brain damages and diseases, assessment of brain function, and comprehensive management of medical information and brain function data."
- \*\* Self-developed, owned and operated by us.

Source: NMPA, Frost & Sullivan Analysis

#### NCI DTx MARKET

#### **Overview Of NCI**

#### AD

AD is a neurodegenerative disease that usually starts with mild symptoms that gradually deteriorate. Approximately 60-70% of cases of dementia were caused by AD. Like other chronic diseases, AD is not caused by a single factor but is often the result of a combination of risk factors. Advanced age is the greatest risk factor for AD.

#### AMCI

AMCI is the most common form of mild cognitive impairment. Its main symptoms are subtle changes in memory and thinking. People with AMCI have memory problems that are more severe than normal for their age and education, but not severe enough to interfere with daily life. The causes of AMCI are not completely understood. Experts believe that many, but not all, cases result from brain changes that occur in the very early stages of Alzheimer's disease or other neurodegenerative diseases that cause dementia.

#### Treatment Paradigm and Unmet Clinical Needs of NCI

#### Assessment

Current paradigm for the assessment of NCI involves detecting the underlying neurodegenerative disease causing the NCI. However, this leaves open significant the unmet medical needs of as most neurodegenerative diseases lacks a good early-stage assessment option. Using specific biomarkers, NCI DTx can help physicians accurately diagnose neurodegenerative diseases or alert patients to seek help. In addition, DTx can also help physicians speed up the screening process, enabling efficient, large-scale early detection.

### Intervention

There are currently no treatments available to stop the progression of the underlying neurodegenerative disease that causes NCI. Current paradigm for the intervention of NCI involves the treatment of the underlying neurodegenerative diseases. NCI DTx can provide cognitive training and help manage risk factors to delay disease progression, making it an effective complement to medication. NCI DTx has the potential to become a treatment option that targets specific brain functions to improve cognition and prevent disease progression based on the principle of neuroplasticity.

### Prevalence of the Major Types of NCI

## Global

The global prevalence of the major types of NCI increased from 144.7 million in 2018 to 156.5 million in 2023, representing a CAGR of 1.6% and is expected to reach 161.3 million in 2025 and further to 174.9 million in 2030, representing CAGRs of 1.5% and 1.6%. The following graph sets forth the global prevalence of the major types of NCI during the years indicated, as well as CAGRs during the indicated years.



### Global Prevalence of the Major Types of NCI, 2018-2030E

Note: The overall prevalence of the major types of NCI includes patients with comorbidities

Source: Frost & Sullivan Analysis

### China

The prevalence of the major types of NCI in China increased from 69.6 million in 2018 to 74.1 million in 2023, representing a CAGR of 1.3% and is expected to reach 75.8 million in 2025 and further to 80.7 million in 2030, representing CAGRs of 1.1% and 1.3%. The following graph sets forth the prevalence of the major types of NCI in China during the years indicated, as well as CAGRs during the indicated years.

#### Prevalence of the Major Types of NCI in China, 2018-2030E



Note: The overall prevalence of the major types of NCI includes patients with comorbidities

Source: Frost & Sullivan Analysis

#### Competitive Landscape of the NCI DTx Market

Key players in the global NCI DTx market (outside China) include at least three players that offers at least four FDA-approved NCI DTx products as of the Latest Practicable Date. The following table provides an overview of the FDA-approved NCI DTx products.

	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	MindMaga	Neurorehabilitation Neurological conditions such as stroke, brain injury, and neurodegenerative diseases	510(k)	2018
4	MindMotion® PRO	windwaze			2017

#### **FDA-approved NCI DTx Products**

Source: FDA, Frost & Sullivan Analysis

In China, a total of approximately 36 NCI DTx products by approximately 20 players, including our Company, had been approved by the NMPA or its local counterparts, and at least ten more NCI DTx products by at least ten players were in the process of clinical trials and obtaining relevant medical device registration certificates, as of the Latest Practicable Date, according to Frost & Sullivan. The following table provides an overview of the NMPA-approved NCI DTx products, all of which are classified as Class II medical device.

### **NMPA-approved NCI DTx Products**

	Product Name	Company	Indication*	Approval Year
1	Cognitive Ability Supplemental Screening and Assessment Software***		Cognitive Function	2022
2	Basic Cognitive Ability Testing Software***	Our Company	Cognitive Function	2022
3	Brain Function Information Management Platform Software System*** Cognitive Impairment assessment and		Clinical Diagnosis, Treatment and Assessment	2018**
4	training software 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	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	Digital cognitive dysfunction rehabilitation	Hunan Feisimaike Medical Technology Co., Ltd	Mild Cognitive Impairment	2024
13	training software	Hunan BQBrain Technology Co., Ltd	Mild Cognitive Impairment	2024
14	software	Hunan Thoven intelligent Technology Co., Ltd Precision Technology of Sight Care (Changsha)	Mild Cognitive Impairment	2024
15	Cognitive function training software	Medical Technology Co., Ltd	Mild Cognitive Impairment	2024
16	training software	Chengdu Base Interactive Technology Co., Ltd	Mild Cognitive Impairment	2024
17	Cognitive function training system	Changsha Huaquejing Medical Technology Co., Ltd	Function Injury and Stroke	2024
18	Cognitive Dysfunction Assessment and Training Software	Hunan Wanwu Chengli Medical Technology Co., Ltd	Cognitive Impairment	2023
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
36	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

Note: All indication descriptions are extracted from the NMPA website and their scopes are related to NCI.

\* As shown on the NMPA website.

- \*\* Represents the year in which the System first received regulatory approval for use of the System as a tool of "assistance of doctors in clinical diagnosis and treatment of patients with brain function impairments caused by various types of brain damages and diseases, assessment of brain function, and comprehensive management of medical information and brain function data."
- \*\*\* Self-developed, owned and operated by us.

Source: NMPA, Frost & Sullivan Analysis

#### PCI DTx MARKET

#### **Overview of PCI**

Psychiatric disorders are conditions in which individuals experience clinically significant disturbances in cognition, emotional regulation, or behavior. The causes of psychiatric disorders are complex and multifaceted, involving various factors such as genetics, family history, life experiences, substance use, and other biological factors. Treatment for cognitive impairments induced by psychiatric disorders varies depending on the type and severity of the disorder and often involves a combination of medication and psychotherapy. In addition to traditional treatment methods, alternative therapies and brain stimulation therapies have been shown to be effective in treating cognitive impairments induced by psychiatric disorders.

#### Depression

Depression is a common mental disorder characterized by a long-term depressed mood, loss of pleasure or interest in activities. In addition to affecting mood and emotions, depression can alter brain function. Cognitive impairment is a common feature of depression, including executive dysfunction, impaired learning and memory, decreased attention and concentration, and reduced processing speed. Cognitive deficits often persist even after other symptoms of depression have resolved, significantly impacting a patient's ability to function.

#### Schizophrenia

Schizophrenia is a chronic and severe mental disorder that affects the way a person thinks, behaves, expresses emotions, perceives reality and interacts with others. Cognitive impairment is a central feature of schizophrenia and results in moderate to severe deficits in several areas, including attention, working memory, verbal learning and memory, and executive functioning. Cognitive impairment is one of the major barriers to clinical and functional recovery in schizophrenia. Antipsychotic medications have little effect on cognitive impairment in schizophrenia. Current antipsychotics not only fail to reverse cognitive dysfunction but may directly or indirectly worsen it.

### Sleep disorders

Sleep disorders involve difficulties with the quality, duration, and quantity of sleep that can lead to daytime distress and impaired functioning. Sleep disorders are associated with cognitive impairment. Reduced sleep duration may also cause cognitive decline by promoting hippocampal degeneration through several pathways, including changes in neuronal excitability, reduced synaptic plasticity and decreased neurogenesis.

#### Treatment Paradigm and Unmet Clinical Needs of PCI

There is currently no available treatment for PCI and it is typically addressed by treating the underlying psychiatric disorder. A commonly prescribed method of treating psychiatric disorder is cognitive-behavioral therapy (the "**CBT**"). Traditional CBT helps patients become aware of and respond more effectively to negative thinking and behavior patterns. PCI DTx provides a digitized version of CBT with additional benefits. For example, patients can access CBT remotely, providing the same benefits as traditional CBT but saving time and costs. In addition, virtual human technology can address patients' needs and collect feedbacks from patients on behalf of patients, allowing patients to seek help regardless of time or location and allowing physicians to serve multiple patients at once. Virtual human technology can also linguistically map psychological problems, and through linguistic analysis, AI can provide effective interventions tailored to the patient's needs.

Typically, the assessment of cognitive function in patients with psychiatric disorders using PCI DTx involves the construction of a model using clinical data and consultation with medical experts. The models are typically fed with data from two methods of data collection: patient completion of scales and paradigms to assess global cognitive level and various cognitive modules, and collection of patient conversations, voice patterns, and facial expressions through human-computer interaction using AI technology. The collected data, along with the patient's own information such as age and gender, is fed into the model to generate a risk report. The results of the AI analysis are then compared with the physician's final diagnosis to continuously improve the PCI DTx model and increase diagnostic accuracy.

### Prevalence of the major types of PCI

### Global

The global prevalence of the major types of PCI increased from 327.5 million in 2018 to 348.6 million in 2023, representing a CAGR of 1.3% and is expected to reach 356.9 million in 2025 and further to 376.5 million in 2030, representing CAGRs of 1.2% and 1.1%. The following graph sets forth the global prevalence of the major types of PCI during the years indicated, as well as CAGRs during the indicated years.





Note: The overall prevalence of the major types of PCI includes patients with comorbidities.

Source: Frost & Sullivan Analysis

#### China

The prevalence of the major types of PCI in China increased from 45.9 million in 2018 to 50.2 million in 2023, representing a CAGR of 1.8% and is expected to reach 51.5 million in 2025 and further to 54.6 million in 2030, representing CAGRs of 1.3% and 1.2%. The following graph sets forth the prevalence of the major types of PCI in China during the years indicated, as well as CAGRs during the indicated years.



Prevalence of the Major Types of PCI in China, 2018-2030E

Note: The overall prevalence of the major types of PCI includes patients with comorbidities. Source: Frost & Sullivan Analysis

## **Competitive Landscape of PCI DTx Market**

Key players in the global PCI DTx market (outside China) include at least 11 players that offer at least 15 FDA-approved PCI DTx products as of the Latest Practicable Date. The following table provides an overview of the FDA-approved PCI DTx products.

	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	Rejoyn®	Otsuka Pharmaceutical, Co. Ltd. (Otsuka) and Click Therapeutics, Inc., (Click)	MDD (Major Depressive Disorder); Emotional Cognitive Impairment	510(k)	2024
3	Prism for PTSD	GrayMatters Health	PTSD (Post-traumatic stress disorder )	510(k)	2023
4	Stanza	Swing Therapeutics	Fibromyalgia Symptoms; Chronic Pain, Fatigue, Sleep Disorders, Depression, and Cognitive symptoms	De Novo	2023
5	Sleepio		Insomnia	EUA	2023
6	Daylight	Big Health	Anxiety	EUA	2023
7	01 Depression		MDD (Major Depressive Disorder)	EUA	2023
8	02 Anxiety	Feel Therapeutics	GAD (Generalized Anxiety Disorder)	EUA	2023
9	SparkRx	Limbix	Adolescent depression	EUA	2021
10	Ensemble	Happify Health	Depression & Anxiety	EUA	2021
11	LIMBIX SparkRx	Limbix	Depression & Anxiety	EUA	2021
12	Somryst (SHUTi)	Pear Therapeutics	Chronic insomnia	510(k)	2020
13	Deprexis	Orexo, GAIA AG	Depression	510(k)	2020
14	reSET-O	<b>D</b>	Opioid use disorder	510(k)	2018
15	ReSet	Pear Therapeutics	Substance use disorders	De novo	2017

## FDA-approved PCI DTx Products

Source: FDA, Frost & Sullivan Analysis

In China, a total of approximately 32 PCI DTx products by approximately 31 players, including our Company, have been approved by the NMPA or its local counterparts, and at least five additional PCI DTx products by at least five players are currently in the process of clinical trials and obtaining relevant medical device registration certificates, as of the Latest Practicable Date, according to Frost & Sullivan. The following table provides an overview of the NMPA-approved PCI DTx products, all of which are classified as Class II medical device.

#### **NMPA-approved PCI DTx Products**

	Product Name	Company	Indication*	Approval Year
1	Cognitive Ability Supplemental Screening and Assessment Software***		Cognitive Function	2022
2	Basic Cognitive Ability Testing Software***	Our Company	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 rehabilitation training and evaluation system	ZD Medical Technology Co., Ltd	Cognitive Impairment Due to Brain Function Injury and Stroke	2024
7	Cognitive function rehabilitation software	Changsha Yuanyi Technology Co., Ltd	Cognitive Impairment Due to Brain Function Injury and Stroke	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 function training system	Changsha Huaquejing Medical Technology Co., Ltd	Cognitive Impairment Due to Brain Function Injury and Stroke	2024
16	Cognitive Dysfunction Assessment and Training Software	Hunan Wanwu Chengli Medical Technology Co., Ltd	Cognitive Impairment	2023
17	Cognitive Impairment Assessment Software	Hunan Hongjun Intelligent Technology Co., Ltd	Mild Cognitive Impairment	2023
18	Psychometric and Cognitive Assessment Software	Hunan Kaesman Technology Co., Ltd	Mental and Psychological Condition	2023
19	Cognitive impairment rehabilitation training software	Hunan Aiyun Digital Medical Technology Co., Ltd	Cognitive Function	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 function assessment and training software	Shenzhen Heling Medical Technology Co., Ltd	Cognitive Function	2023
22	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
23	Clinical Management Software for Cognitive Behavioral Therapy for Insomnia	Hunan Fujie Digital Medical Technology Co., Ltd	Sleeping disorders	2023
24	Cognitive dysfunction rehabilitation training software	Xidike (Zhengzhou) Intelligent Rehabilitation Equipment Co., Ltd	Cognitive Impairment due to Brain-Injuring diseases	2023
25	Cognitive Dysfunction Assessment and Training Software	Nanjing Weisi Medical Technology Co., Ltd	Mild Cognitive Impairment	2022
26	Cognitive Dysfunction Examination and Correction Software	Hunan Xinkang Medical Technology Co., Ltd	Mild Cognitive Impairment	2022
27	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
28	Cognitive Dysfunction Treatment Software	Hunan Wangli Medical Technology Co., Ltd	Mild Cognitive Impairment	2022
29	Cognitive Impairment Assessment of Rehabilitation Software	Guilin Yikang Electronic Technology Co., Ltd	Mild Cognitive Impairment	2022
30	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
31	Cognitive Function Assessment and Training Software	Changsha Zhisong Technology Co., Ltd	Mild Cognitive Impairment	2022
32	Rehabilitation Software for Cognitive Function	Hangzhou Yikang Medical Technology Co., Ltd	Schizophrenia, Schizotypal Disorder, Mood Disorders	2020

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

\* As shown on the NMPA website.

\*\* Represents the year in which the System first received regulatory approval for use of the System as a tool of "assistance of doctors in clinical diagnosis and treatment of patients with brain function impairments caused by various types of brain damages and diseases, assessment of brain function, and comprehensive management of medical information and brain function data."

\*\*\* Self-developed, owned and operated by us.

Source: NMPA, Frost & Sullivan Analysis

#### **CDDCI DTx MARKETS**

#### **Overview Of CDDCI**

CDDCI is present at birth and are caused by genetic conditions or brain damage that occurs during pregnancy or childbirth. Examples include ADHD, dyslexia and autism.

#### **ADHD**

ADHD is one of the most common neurodevelopmental disorders in children. The disorder is characterized by symptoms such as difficulty paying attention, difficulty controlling impulsive behavior and being overly active. There is no single test to diagnose ADHD; diagnosis is usually based on hearing and vision tests, information about the patient and family or ADHD rating scales or psychometric tests. Treatment options for ADHD primarily include behavioral therapy and drug therapy. Early intervention is important, and the best treatment plans involve close monitoring, follow-up assessments, and therapy adjustments over time.

#### Autism

Autism is a neurodevelopmental condition caused by differences in the way the brains of individuals with Autism are wired and function. These neurodevelopmental differences can affect the way individuals with Autism process and respond to information, leading to difficulties with communication, social interaction, and behavior. While the exact nature of these differences is not fully understood, research suggests that they may be related to a combination of genetic and environmental factors. People with Autism often have problems with social communication and interaction, restricted or repetitive behaviors, and different ways of learning and moving. Doctors look at a child's developmental history and behavior to make a diagnosis, which can be made as early as 18 months of age. However, many children do not receive a final diagnosis until they are much older. Treatments for Autism primarily include behavioral, developmental, educational, social-relational, pharmacological, psychological and complementary and alternative therapies.

### Dyslexia

Dyslexia is also referred to as 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 a problem of intelligence, hearing or vision, but a result of individual differences in areas of the brain that process language. Dyslexia appears to be linked to certain genes that affect how the brain processes reading and language and tends to run in families. Dyslexia can have negative long-term impact on a child's educational social development.

#### Treatment Paradigm and Unmet Clinical Needs of CDDCI

The assessment of CDDCI in China is constrained by (i) a lack of education and training for healthcare providers to inform parents about developmental disorders; (ii) a lack of resources and difficulty in finding specialists; (iii) long waiting times for diagnosis due to lengthy diagnostic processes; (iv) multiple required doctor visits; and (v) risk of misdiagnosis. Furthermore, many patients in China have difficulty accessing quality medical resources because such resources are typically concentrated in large cities. This lack of access can lead to poor patient compliance and a significant financial burden on families. In addition, interventional therapies often require a high level of treatment environment, faculty, and standardization, making them difficult to implement at scale and resulting in low prevalence of institutional interventions.

CDDCI DTx incorporates AI to detect human behavior and speech information in images, videos and games. AI analyzes early behavioral warning signs and characteristics and compares them to screening guidelines and physician clinical data. The mechanism generates risk screening reports to aid in diagnosis.

There is currently no available treatment for CDDCI which is typically addressed by treating the underlying child development deficiency. A commonly used treatment method for child development deficiency is Applied Behavior Analysis (the "ABA"). It focuses on teaching children specific skills in areas such as socialization, academics, communication and hygiene. Digitizing ABA is possible with CDDCI DTx through the implementation of AI and VR or augmented reality (the "AR") technologies that can guide patients remotely, provide feedback to therapists and support individualized treatment plans. In addition, CDDCI DTx can provide a platform to connect patients and their families to support intervention programs and outcomes analysis through online patient communities. CDDCI DTx can also increase parents' awareness of developmental disorders through educational materials based on clinical research.

### Prevalence of the Major Types of CDDCI

### Global

The global prevalence of the major types of CDDCI increased from 688.1 million in 2018 to 776.1 million in 2023, representing a CAGR of 2.4% and is expected to reach 816.5 million in 2025 and further to 927.5 million in 2030, representing CAGRs of 2.6% and 2.6%, respectively. The following graph sets forth the global prevalence of the major types of CDDCI during the years indicated, as well as CAGRs during the indicated years.



## Global Prevalence of the Major Types of CDDCI, 2018-2030E

Note: The overall prevalence of the major types of CDDCI includes patients with comorbidities.

Source: Frost & Sullivan Analysis

### China

The following graph sets forth the prevalence of the major types of CDDCI in China in the years indicated, as well as CAGRs during the indicated years.

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



Note: The overall prevalence of the major types of CDDCI includes patients with comorbidities.

Source: Frost & Sullivan Analysis

## Competitive Landscape of CDDCI DTx Market

Key players in the global CDDCI DTx market (outside China) include two players that offer at least two FDA-approved CDDCI DTx products as of the Latest Practicable Date. The following table provides an overview of the FDA-approved CDDCI DTx products.

## FDA-approved CDDCI DTx Products

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

Source: FDA, Frost & Sullivan analysis

In China, a total of approximately 25 CDDCI DTx products by at least 22 players, including our Company, have been approved by the NMPA or its local counterparts, and at least ten CDDCI DTx products by at least ten players are currently in the process of clinical trials and obtaining relevant medical device registration certificates, as of the Latest Practicable Date according to Frost & Sullivan. The following table provides an overview of the NMPA-approved CDDCI DTx products, all of which are classified as Class II medical device.

#### NMPA-approved CDDCI DTx Products

	Product Name	Company	Indication*	Approval Year
1	Basic Cognitive Ability Testing Software***		Cognitive function	2022
2	Brain Function Information Management Platform Software System***	Our Company	Clinical diagnosis, treatment and assessment	2018**
3	Dyslexia Supplemental Screening and Assessment Software***		Dyslexia	2023
4	Dyslexia Supplemental Screening and Assessment Software	Changsha Zhijingling Education Technology	Dyslexia Supplemental Screening and Assessment Software	2024
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 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
8	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
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	Mid 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 dysfunction assessment and training software	Hunan Wanwu Chengli Medical Technology Co., Ltd	Cognitive impairment	2023
17	Cognitive function assessment training software	Changsha Braingine Network Technology Co., Ltd	Mild cognitive impairment	2023
18	Cognitive function assessment and training software	Changsha Zhisong Technology Co., Ltd	Mild cognitive impairment	2022
19	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
20	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
21	Cognitive dysfunction examination and correction software	Hunan Xinkang Medical Technology Co., Ltd	Mild cognitive impairment	2022
22	Cognitive ability testing and training system	Allite (Hunan) Medical Technology Co., Ltd	Linguistic cognitive ability	2022
23	Cognitive dysfunction assessment and training software	Nanjing Weisi Medical Technology Co., Ltd	Mild cognitive impairment	2022
24	Cognitive impairment assessment of rehabilitation software	Guilin Yikang Electronic Technology Co., Ltd	Mild cognitive impairment	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	Children's Cognitive Behavioral Ability Assessment Software	Beijing Peking University Medical Brain Health Technology Co., Ltd. Liuyang Rongbo Branch	Mild cognitive impairment	2022

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

- \* As shown on the NMPA website.
- \*\* Represents the year in which the System first received regulatory approval for use of the System as a tool of "assistance of doctors in clinical diagnosis and treatment of patients with brain function impairments caused by various types of brain damages and diseases, assessment of brain function, and comprehensive management of medical information and brain function data."
- \*\*\* Self-developed, owned and operated by us.

Source: NMPA, Frost & Sullivan analysis

### **REPORT COMMISSIONED BY FROST & SULLIVAN**

In connection with the [**REDACTED**], we have engaged Frost & Sullivan to conduct a detailed analysis and to prepare an industry report on the DTx market. Frost & Sullivan is an independent global market research and consulting company founded in 1961 and is based in the United States. Services provided by Frost & Sullivan include market assessments, competitive benchmarking, and strategic and market planning for a variety of industries.

We have included certain information from the Frost & Sullivan Report in this Document because we believe such information facilitates an understanding of the DTx market for potential [**REDACTED**]. Frost & Sullivan prepared its report based on its in-house database, independent third-party reports and publicly available data from reputable industry organizations. Where necessary, Frost & Sullivan contacts companies operating in the industry to gather and synthesize information in relation to the market, prices and other relevant information. Frost & Sullivan believes that the basic assumptions used in preparing the Frost & Sullivan Report, including those used to make future projections, are factual, correct and not misleading. Frost & Sullivan has independently analyzed the information, but the accuracy of the conclusions of its review largely relies on the accuracy of the information collected. Frost & Sullivan research may be affected by the accuracy of these assumptions and the choice of these primary and secondary sources.

We have agreed to pay Frost & Sullivan a fee of RMB580.0 thousand for the preparation of the Frost & Sullivan Report. The payment of such amount was not contingent upon our successful [**REDACTED**] or on the content of the Frost & Sullivan Report. Except for the Frost & Sullivan Report, we did not commission any other industry report in connection with the [**REDACTED**].

Our Directors confirm that after taking reasonable care, there has been no adverse change in the market information since the date of the report prepared by Frost & Sullivan which may qualify, contradict or have an impact on the information set forth in this section in any material respect.