

7 Companies Established the Japan Digital Therapeutics Consortium and Launch Activities

~Joint Research for Policy Proposals and Industrial Promotion in the Digital Therapeutics Field~

7 companies that are active with digital therapeutics (DTx) products development have jointly established a non-profit industry group on October 18th, 2019, the Japan Digital Therapeutics Consortium, to provide brand-new medical options to patients and to boost the value of healthcare as a whole. To accomplish this, it will make joint efforts to introduce DTx products into the Japanese market in a timely manner, improve product quality and value (clinical benefits), and widely promote DTx to physicians, other healthcare professionals and patients.

DTx deliver evidence-based interventions to patients that are driven by high quality software programs to prevent, manage, or treat medical disorders or diseases. For manufacturing and distribution of a DTx product in Japan, an approval from the Ministry of Health, Labour and Welfare is required according to the Pharmaceuticals and Medical Devices Law. DTx are used as standalone or in combination with pharmaceuticals and/or medical devices. It is expected that DTx will offer benefits for patients that have typically experienced difficulties in management, intervention, and optimization with traditional pharmaceuticals and/or medical devices. Great things are also expected of DTx in terms of health economics, such as total costs of development, manufacturing, storage and distribution by keeping down costs especially with R&D and other postmarket costs.

In order to make sure that DTx can contribute to resolve medical issues and establish its medical value, it will be necessary to improve regulatory predictability, such as approval review and universal health insurance reimbursement, and to cultivate its specialists and build ecosystems. Activities will also be needed to bring DTx into widespread usage and gain societal acceptance with focuses on patients, their families, physicians, medical professionals and other related parties.

The Japan Digital Therapeutics Consortium is dedicated to striving to improve its medical value based on clinical evidence. To accomplish this, major corporations and start-ups aiming to promote DTx products development in the pharmaceutical, medical device, and IT fields will work together on research for overcoming challenges the DTx industry faces; seminars; research; policy proposals; in-depth discussions with industry-government-academia group(s); and release deliverables (e.g. guidance documents, etc.).

The Consortium will collaborate with other organizations and associations focusing on DTx around the world. In this way, the Consortium will promote the Japanese DTx industry and global developments of DTx products in/from Japan.

■ List of the member companies participating in the Japan Digital Therapeutics Consortium

Aillis Inc.; Astellas Pharma Inc.; Digital Garage, Inc.; Mitsubishi Tanabe Pharma Corporation; Shionogi & Co., Ltd.; SUSMED, Inc; Teijin Pharma Limited.

■ Inquiries about this release

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(Attachment)

Please refer below for information about past activities.

I. Seminars

Three seminars have been held in 2019, as the first-ever in Japan specialized in DTx. There, important perspectives and experience from the front lines were shared by leaders in the Japanese and the U.S. DTx industries (including the Digital Therapeutics Alliance and CureApp, Inc.), as well as the physicians and the business operators involved in introducing DTx to global medical settings. DTx fuses medical care and digital technologies and is revolutionizing healthcare as a new modality for diagnosis and treatments.

- Japan Bioindustry Association (JBA), Bio Business Seminar
 - The Impact of Digital Therapeutics (DTx), April 2019.
- DTx study meetings
 - No. 1, “Critical Path for Digital Therapeutics - Regulation, Business Model and Localization”, April 2019.
 - No. 2, “Introducing DTx To Medical Settings”, July 2019.

II. Survey on DTx start-ups

<Background>

Since there are variety of definitions and expressions of “Digital Therapeutics” or “DTx” globally, it is difficult to categorize the DTx start-ups in digital health space which basically do not require clearance or approval from the regulatory bodies for manufacturing and distribution. The survey proves that there is a barrier to companies which seek business partnerships with DTx start-ups for developing DTx business in Japan. We conducted a DTx start-up survey based on publicly released information (Survey by the Secretariat of The Consortium).

<Overview>

We visualized development in categories (such as prevention, diagnosis and treatments) by start-ups in the DTx and digital health fields which have publicly announced they possess products meeting the definition of “medical device” according to the law¹, or products that may meet the definition, mainly treatment apps and other medical software, etc.

- Method/information sources

Public information on company websites, PitchBookTM information

<Results>

While there are many overseas DTx start-ups working on various diseases, the number of Japanese companies is still small. We hope more companies will join the DTx industry and develop products to improve medical quality through the promotion of DTx in Japan. The Consortium aims to invigorate the Japanese DTx market through its activities.

¹ Refers to appliances or instruments, etc. that are intended for use in the diagnosis, treatment, or prevention of disease in humans or animals, or intended to affect the structure or functioning of the bodies of humans or animals (excluding regenerative medicine products). (The Pharmaceutical and Medical Device Law, Article 2-4)

Digital Therapeutics and Evidence Based Digital Health Companies Landscape Oct/2019

Prevention

Treatment/Management

Diagnostic/Monitoring

	Prevention	Treatment/Management	Diagnostic/Monitoring
PSYCHIATRIC	Stress and mental health ginger, Valera-Health, Emotion Sensing, FEEL	headspace, BehaVR, ORCAS, COcomfort, STORYUP, DEANVELLO mindstrong, happify, Limbix, Optimoood, ADDICTION, PEAR, CARROT, CURE MANAGEMENT, MINDSCIENTES, MIND COFFIN, DIGITHERA, CHRONO, WORKIT HEALTH, PIVOT, DYNAMIC CARE, WECONNECT PANIC ATTACK, FREESPIRA, GAIA, Sleep disorders, Big Health, iES	MOBIO, spring health
NEUROLOGICAL		Neuro-development: brainmarc, brain+, NeuroSigma, AKILI Pain relief: sana, appliedVR, SPELLBOUND, theranica Migraine: Migrate Rehab: vigo, GTX-medical, MEDRhythms BRAIN STIMULATION	Cognitive: NeuroTracker, Myrilite, BrainCheck, RightEye, Empatica Epilepsy: RightEye, Empatica Dementia: Dthera, PainCheck
PHYSIOLOGICAL	Heart Failure: biofourmis, CardioSecur ENDOTRONIX	Vision: Lumimagic Cancer: prosoma, Tired of Cancer, kaiku, jointacademy Musculoskeletal: JOGG, kaia, jointacademy Autoimmune: Qmymee, RA, SETPOINT Digestive: CARA CARE, Rx Health, BOLD metaHealth, vivante Dialysis: patientMover	Respiratory: stradosLABS, SONDE, SOUND, SEYONVERBAL, HEALTHYMIZE amiko, NUVOAIR, mymhealth
METABOLIC	Weight Loss: MODIUS, vida, noom, holmusk	Diabetes: amoda, newtopia, welldoc, VOLUNTIS, Better+, blue mesa, glooko, wellthy, DARIO, lark, COMMON SENSING	Cardiology: ONE DROP, HeartFlow, Eko, eko.ai, caiqacaeuae
OTHERS	Women's health: Virtue Health	Speech Disorder: NOVOTALK, Domolens Adherence monitoring: proteus, Rani	Infection: OAILLIS

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