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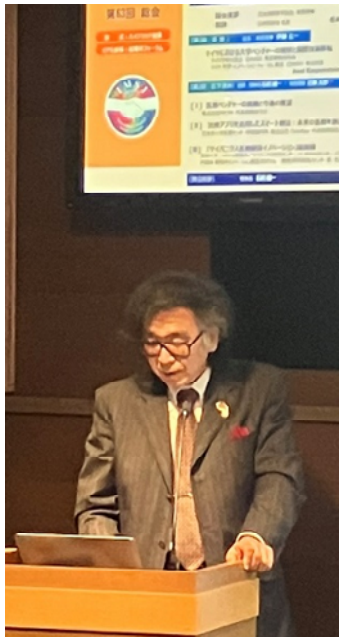
Since 1925



第 63 回 国際治療談話会総会

医療系ベンチャー～How to start up

No.521

2024.January

The 63nd International Congress on Therapy

Medical Ventures ～How to start up

Opening remarks: **Taro Kondo, MD** (Managing director, IMSJ)

Congratulatory remarks: **Kichiro Matsumoto, MD** (President, Japan Medical Association)

Discourse Chair：**Kenichi Ishibashi, MD, PhD** (Chairman, Board of Directors, IMSJ)

Discourse: Current trends in technology transfer and academic entrepreneurship in Germany
Axel KARPENSTEIN (Director, German Academic Exchange Service (DAAD) – Tokyo Office)

Medical Ventures ～How to start up

Medical Lectures Chair：**Koichi Ito, MD, PhD** (Managing director, IMSJ)

Taro Kondo, MD (Managing director, IMSJ)

Lecture I: Challenges and future outlook of a healthtech startup

Seigo Hara M.D

(CEO, MICIN, Inc.)

Lecture II: Digital Therapeutics: Shaping the Future of Medicine

Kohta Satake, MD, MPH, MBA.

(President/CEO, CureApp, Inc. & Representative Director, Department of Respiratory Medicine, Japanese Red Cross Medical Center)

Lecture Ⅲ: Leading Edge of Cybernics Medical Health Care Innovation

Yoshiyuki Sankai, Ph.D.

(Professor/ Executive Research Director/ Director,
Institute of Systems and Information Engineering/ Center for Cybernics Research/ R&D Center for Frontiers of MIRAI in Policy and Technology, University of Tsukuba.
President and CEO, CYBERDYNE Inc.
Program Director, SIP Program, Cabinet Office, Japan.)

Closing remarks: **Kenichi Ishibashi, MD, PhD** (Chairman, Board of Directors, IMSJ)

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Opening Remarks

Taro Kondo, MD
Managing director, IMSJ

Congratulatory message

Kichiro Matsumoto, MD
President,
Japan Medical Association

On behalf of the Japan Medical Association, I would like to extend my heartfelt congratulations on the occasion of the 63rd International Congress on Therapy.

With a deep commitment to advancing global healthcare, the Japan Medical Association endeavors to make international contributions to the field of medicine through enhanced collaborations with the World Medical Association (WMA), the Confederation of Medical Associations in Asia and Oceania (CMAAO), other national medical associations, relevant government ministries and agencies, and international organizations.

Following the earthquake in Turkey and Syria in February this year, the Japan Medical Association initiated a support fund for the Association of Medical Doctors of Asia (AMDA) to support their emergency relief efforts in the affected areas, which amounted to 5 million yen (including 3-million-yen contribution to the Turkish Medical Association). Our local medical associations and members across Japan also donated over 156 million yen, which was sent to

the Turkish Medical Association in May.

In addition, to aid Ukraine, which is grappling with a military invasion by Russia, the Japan Medical Association donated 213 million yen to the WMA in March. This fund was sourced from the contributions of our local medical associations, members, and the general public.

During the WMA Nairobi Council meeting held in April, emergency resolutions were adopted, including the WMA Council Resolution for an Immediate and Effective Ceasefire in Sudan and the Protection of Health Care, the WMA Council Resolution on Anti-LGBTQ Legislation in Uganda, and the WMA Council Resolution on Proposed Legislation in UK on the Treatment of Migrants Disregarding the Injunction Interim Measures Rule 39 of ECHR. Furthermore, the WMA Kigali General Assembly, held in October, adopted some urgent matters, including the WMA Resolution Condemning the Violence against Physicians in Nepal.

The CMAAO Dhaka General Assembly held in September adopted the “CMAAO Declaration of Dhaka: Pandemic preparedness is built upon a robust primary health care system.”

Now, the theme for this year’s International Congress on Therapy is “Medical Ventures: How to start up.” In alignment with the Startup Development Five-year Plan announced by the Kishida administration in November last year, the government is currently focusing its efforts on supporting startup initiatives. As medical DX continues to advance, the number of ventures is likely to increase not only in the field of IT but also in the medical domain, including drug discovery. A comprehensive promotion of such endeavors will hopefully lead to delivery of safe, secure, and high-quality healthcare services.

Lastly, I would like to express my best wishes for the success of this congress, the continued growth of the International Medical Society of Japan, and the wellbeing and professional accomplishments of all attendees. Thank you.

Congratulatory Telegram

Hideto Takahashi MD
President, Japan Dentist Association

Please accept our sincere congratulations on the success of the 63nd International Congress on Therapy.
We truly wish further development of your Society and the health of your members.

Nobuo Yamamoto MD
President, Japan Pharmaceutical Association

I'm delighted that the 63nd International Congress on Therapy is held in such a grand scale.
Through events and lectures such as these, your association contributes to both the improvement of health care in Japan and the development of international medical exchange as well. I truly respect everything you do.
I hope your association will continue to prosper and grow.

Introductory Message from the Chair

Kenichi Ishibashi, MD, PhD
Chairman, Board of Directors, IMSJ

Discourse

Current trends in technology transfer and academic entrepreneurship in Germany

Axel KARPENSTEIN
Director
German Academic Exchange Service (DAAD) – Tokyo Office

Lecture I

Challenges and future outlook of a healthtech startup

Seigo Hara M.D
CEO
MICIN, Inc.

The regulations on telemedicine were lifted in Japan in 2015, and the rules were clarified in the 2018 revision of reimbursement for medical services, and the institutional environment began to move forward. However, restrictions on eligible

diseases, low profitability, and strict implementation requirements have kept telemedicine from becoming widespread.

However, the situation changed drastically with the spread of the COVID-19 epidemic, and telemedicine received dramatic attention due to the temporary relaxation of restrictions on eligible diseases.

While patients were reluctant to visit hospitals due to the risk of infection during travel and in the hospital, telemedicine services were increasingly needed by both medical institutions and patients to continue treatment, reduce the burden of hospital visits, and prevent secondary infections.

In fact, the number of medical institutions that have adopted our telemedicine service “curon”, which we have been providing since 2016, now exceeds 6,000, and the number of consultations is now more than 10 times higher than before COVID-19.

With the revision of the medical service fee in April 2022, the reimbursement is closer to that of face-to-face consultations, and telemedicine can now be used for more diseases.

Digital therapeutics（DTx） has recently been reimbursed by insurance both in Japan and overseas, and evidence of its effectiveness has begun to be obtained in clinical trials, making it a viable treatment option.

We are also developing its Digital Therapeutics business, with products that support not only disease management but also prevention, diagnosis, treatment, and intervention through software interventions based on medical evidence, including the launch of the “MedBridge” treatment assistance application, the “BSA-01” biometric sound measurement application, a biometric information sharing application that has received regulatory approval, and the development of a cognitive behavioral therapy application.

While institutional arrangements, technological and environmental improvements, and issues of acceptance by both healthcare providers and patients are required for

the widespread use of DTx, with the progress of utilization and the accumulation of evidence, the value of DTx and the resolution of the process will increase, and it will be optimized as a product, leading to the creation of products that truly contribute to medical outcomes.

Lecture Ⅱ

Digital Therapeutics: Shaping the Future of Medicine

Kohta Satake, MD, MPH, MBA.
President/CEO, CureApp, Inc.
Representative Director,
Department of Respiratory Medicine, Japanese Red Cross Medical Center

"Digital Therapeutics (DTx)" refer to applications used on general devices such as smartphones for therapeutic purposes, whose efficacy has been proven through clinical trials and have been approved by regulatory authorities as medical devices. These apps are gaining attention as a new modality of treatment options that target patients' behaviors and cognition. As of October 2023, in Japan, DTx for nicotine dependence and hypertension have been launched and are covered by insurance. "CureApp SC Nicotine Dependence Treatment App and CO Checker" is a DTx product for nicotine dependence, which demonstrated significant improvements in continuous smoking cessation rates in a randomized Phase III trial and was approved in 2020. Additionally, "CureApp HT Hypertension Treatment Support App (CureApp HT)" is a DTx product for essential hypertension that aims to improve lifestyle habits. It demonstrated significant improvements in 24-hour average blood pressure in a randomized Phase III trial and was approved in 2022.

With the advent of Therapeutic Apps, DTx as a new treatment option has emerged, combining Therapeutic Apps with medical consultation. DTx primarily targets behavioral changes in patients. When people change their behavior, they go through five stages: pre-contemplation, contemplation, preparation, action, and maintenance. To advance the stage of behavioral change, it is necessary to understand which stage the patient is currently situated and to intervene accordingly.

Key points include providing optimized interventions based on patient characteristics, making small steps instead of achieving significant changes at once, and providing positive feedback for desired behaviors. However, traditional outpatient lifestyle guidance was provided by healthcare professionals only during the patient's visit to the medical institution, making it challenging to provide detailed guidance due to time and location constraints. In DTx, combining physician guidance at medical institutions with Therapeutic Apps allows for overcoming these constraints and reaching out to patients. Furthermore, based on inputs from patients and connected devices, tailor-made guidance optimized for the patient at that time can be provided.

In Japan, as an example of DTx, we introduce DTx for hypertension using a Therapeutic Apps for hypertension. Hypertension is an established risk factor for stroke and cardiovascular events, and providing effective treatment is a significant societal challenge. Hypertension treatment guidelines strongly recommend "lifestyle modifications" for those with non-normal blood pressure, but it is challenging to provide adequate guidance within limited consultation time. To address this, the CureApp HT was developed to intervene in daily lifestyle habits and provide effective education within limited consultation time. This product consists of two apps: one for patients and one for doctors. Patients carry out the content delivered to the app daily and record daily measurements such as blood pressure taken at home. The information provided includes the purpose of treatment, knowledge about the disease, and suggestions for behavioral changes in daily life. Necessary actions are notified based on the patient's basic data and input, and are individually optimized for each patient. Patients are encouraged to record not only blood pressure but also weight, sleep duration, stress level, daily physical condition, behaviors, and diaries in the app daily. Physicians can check this information in the doctor's app before and during the consultation, allowing them to guide patients based on the transition of home blood pressure, learning content about hypertension, and changes in lifestyle habits at home. As a result, patients can understand how their actions affect their blood pressure, enhance their sense of self-efficacy, and function as positive feedback.

With the spread of DTx, it is anticipated that the patient's treatment experience will fundamentally change. As of October 2023, Therapeutic Apps in the fields of hypertension and smoking cessation have been launched, and preparations are

underway for insurance application after regulatory approval for a therapeutic app for insomnia. Development is also underway in various disease areas such as diabetes, mental disorders, and cancer. DTx products represent a new treatment method that merges medicine and technology, promoting behavioral changes and offering new approaches to diseases that were previously difficult to treat. By actively managing health in daily life, there is a shift from physician-centered to patient-centered healthcare. Moreover, by grasping the patient's condition and treatment progress at home in real-time, it becomes possible to address issues early and propose preventive measures. Such technological advancements and their applications are likely to shape the new direction of 21st-century healthcare.

Lecture Ⅲ

Leading Edge of Cybernics Medical Health Care Innovation

Yoshiyuki Sankai, Ph.D.
Professor/ Executive Research Director/ Director,
Institute of Systems and Information Engineering/ Center for Cybernics Research/
R&D Center for Frontiers of MIRAI in Policy and Technology, University of Tsukuba.
President and CEO, CYBERDYNE Inc.
Program Director, SIP Program, Cabinet Office, Japan.

The number of patients and persons requiring care is increasing with the super-aging of society. Hospitals, facilities, and homes need to provide daily treatment, functional improvement, health management, and nursing care support for patients and persons requiring care. In addition, there is a need for innovative technologies that can handle progress observation, continuous treatment, health management, early detection, prevention, improvement and maintenance of physical function and physiological state, and measures against lifestyle-related diseases in an integrated manner. Against this background, we have been challenging to pioneer the future through researching, developing, and utilizing "Cybernics" (a fusion of Humans, AI Robots, and Information Systems) that integrates "Human" and "CyberPhysical space" in an integrated manner. Our pioneering areas include various robotics technologies from the cell culture level, cyborg technology, AI, IoH/IoT, human big data, cloud computing, supercomputer data analysis and AI processing, international standardization, social implementation, treatment, diagnosis, and prevention technologies, and health maintenance and promotion connecting medical and

non-medical fields. In order to develop "Cybernics Medical and Health Innovation" while solving various difficult problems from basic research to social implementation, commercialization, and international deployment, it is necessary to take on intense challenges with passion over a long period of time.

CYBERDYNE, a university-launched startup, initially started with five people (University of Tsukuba professors and Ph.D. students) and was listed on the Tokyo Stock Exchange Mothers in 2014. It is an R&D-oriented future pioneering company (capital 42.6 billion yen (including capital reserve)) that engages in research, development, manufacturing, sales, and services of cybernics-based medical devices, and is also a designated research institute designated by the International Medical Device Quality Management System (ISO13485), the Ministry of Education and Science and the Minister of Education, Culture, Sports, Science and Technology. In 2014, it was named IPO of the Year in 2014 and Innovative Equity of the Year in 2015, the company focuses on startups, IPOs, international expansion, funds, and the Cybernics industry, with a focus on R&D that integrates basic and practical aspects, social implementation, and human resource development to promote innovation. Cyberdyne is a leading Cybernics company in Japan.

One of the representative achievements of Cybernics is the wearable cyborg HAL. The wearable cyborg HAL connects humans to HAL using bio-potential signals derived from the cranial nervous system, and functionally integrates humans with AI technology, robots, and information systems. The HAL enables functional regeneration therapy in which synaptic connections between nerves and nerves, and between nerves and muscles, are strengthened and adjusted. Cybernics therapy with the medical HAL approved as a new medical device has been approved as a medical device throughout Europe and is covered by public workers' compensation insurance for spinal cord injuries in Germany.

In Japan, medical insurance has been applied through clinical trials for progressive neuromuscular intractable diseases (8 diseases) such as SMA, ALS, SMBA, CMT, and muscular dystrophy, and subsequent use-results surveys have also shown remarkable therapeutic results in long-term application. Recently, in Japan, two diseases, HAM and hereditary paraplegia, were shown to be effective through clinical trials, and the coverage was expanded to 10 diseases. As for medical HAL, Cybernics treatment platform for cranial nervous system diseases, motor instability, and other diseases is in progress in 20 countries around the world, and remarkable therapeutic effects have been demonstrated through the 4-year post-approval use-results survey after the medical insurance coverage. Recently, "combined therapy combining the latest drugs and medical HAL," such as the latest nucleic acid drug for spinal muscular atrophy (SMA), is attracting attention as a new treatment method with a high synergistic effect. Furthermore, as the next initiative, various developments of Cybernics technology in the field of regenerative medicine have also begun. A Cybernics Medical Innovation base for regenerative medicine has been constructed at the King Sky-Front facing Haneda Airport and has been in operation since

January 2023.

The HAL for independence assistance is used at home and in nursing care facilities, mainly for waist-type and single-joint types. The HAL series is IoH/IoT-enabled and data linkage is possible. Cyvis, which enables daily monitoring of various phisiological data (e.g., electrocardiogram, electroencephalogram, body temperature, oxygen saturation and respiratory status (optional)), will also be available as a medical device. With Cybernics, various cybernics technologies, and C-Cloud that realize the fusion of different fields, the realization of a "health future society" that encompasses regional and wider areas by connecting "hospitals and homes," "doctors and patients/users," "people and technology," and "people and people" is also on target.

In this speech, I would like to talk passionately about the "Cybernics Medical Health Innovation" initiative with the latest information.

Closing Remarks

Kenichi Ishibashi, MD, PhD
Chairman, Board of Directors, IMSJ