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May 23, 2022

Tohoku University Tohoku Medical Megabank Organization  
Daiichi Sankyo Company, Limited  
Takeda Pharmaceutical Company Limited  
MICIN, Inc.

## **Launch of Joint Research to Collect a Year's Worth of Lifestyle Data Through Wearable Tracking Device**

**Objective tracking data combined with cohort data to drive medicine of the future**

### **Key points of the announcement**

- Tohoku University Tohoku Medical Megabank Organization, Daiichi Sankyo Company, Limited, Takeda Pharmaceutical Company Limited, and MICIN, Inc. today announced that they have started a joint research agreement for the application of a wearable tracking device.
- A wearable tracking device will be worn by 2,000 people to acquire data on people's lifestyle habits for an extended period.
- The acquired data will be analyzed in relation to the information accumulated through the Tohoku Medical Megabank Project cohort studies<sup>\*1</sup>.
- This research is also expected to serve as a model case for the era of personalized healthcare based on wearable tracking devices and further drive the launch and utilization of similar platforms in Japan and abroad.

### **Overview**

Tohoku University Tohoku Medical Megabank Organization (Executive Director: Masayuki Yamamoto, "ToMMo"), Daiichi Sankyo Company, Limited (Representative Director: Sunao Manabe, "Daiichi Sankyo"), Takeda Pharmaceutical Company Limited (President & Chief Executive Officer: Christophe Weber, "Takeda"), and MICIN, Inc. (CEO: Seigo Hara "MICIN") launched a collaborative research project on March 30, 2022 and will begin recruiting research participants this fall. This research tracks long-term lifestyle habits such as sleep status, heart rate, and activity level, which are difficult to accurately ascertain through self-reporting. The research will combine these

data with existing data from the Tohoku Medical Megabank Project cohort studies, such as health checkup, clinical and MRI imaging data and genomic information, and is expected to lead to the further creation of innovative drugs and medical technologies. This joint research combines objective assessments of sleep status and physical activity with data derived from the existing cohort study, which is expected to drive innovative pharmaceutical research such as drug discovery toward the realization of precision medicine and personalized healthcare.

## **Background**

Wearable tracking devices that can be worn on the body like a wristwatch to obtain biometric information on a daily and continuous basis are becoming increasingly popular around the world, both for general and medical use. Wearable tracking devices in general incorporate sensors that acquire information such as heart rate and body movement (acceleration). By analyzing these data, information including the wearer's sleep conditions, daytime activity, and stress levels can be easily and objectively obtained as quantitative data on a continuous basis.

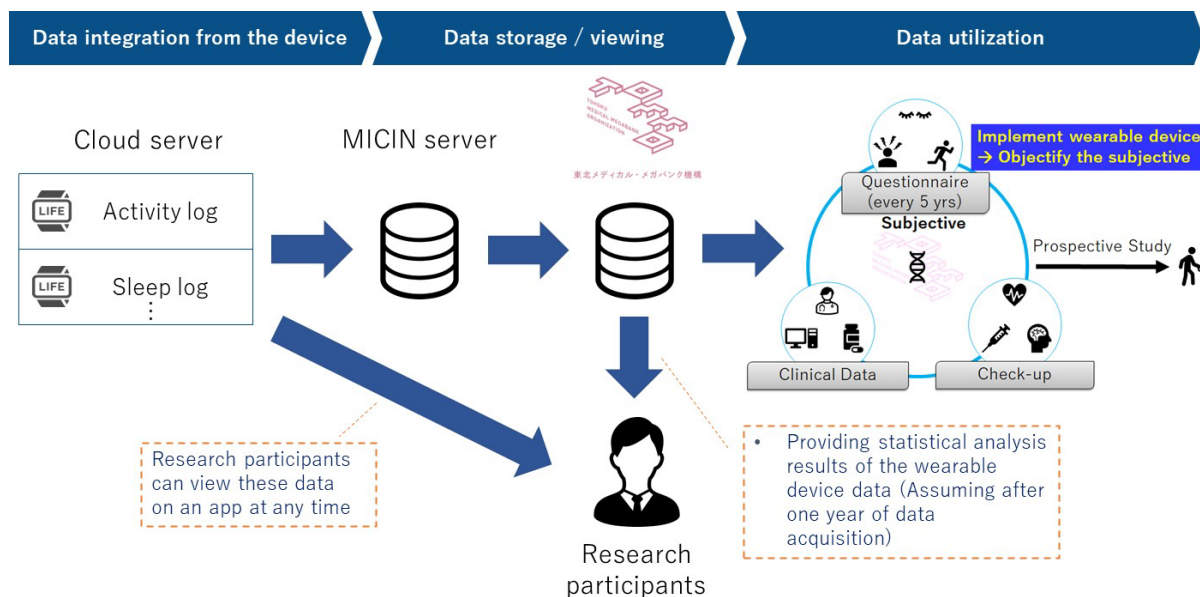
Studies have shown that lifestyle habits can affect an individual's health. In the current cohort study conducted by ToMMo, a variety of information has been collected from participants to identify the complex combination of environmental factors, of which lifestyle habits are a major component, and genetic factors, represented by genomic information, that lead to the onset of disease. The cohort study obtains information on lifestyle habits by means of a survey to be filled out by participants. While the information obtained from the survey is important, this information is based on the subjective responses of individual participants, which limits the ability to conduct objective and quantitative research.

Against this background, ToMMo, the Japan Pharmaceutical Manufacturers Association (“JPMA”), and MICIN conducted a pilot study<sup>\*2</sup> using a wearable tracking device that started in November 2020. Wearable tracking devices are known for their ability to measure data including detailed activity and sleep time. The pilot study enrolled approximately 30 participants and demonstrated that it is possible to accumulate data by having participants wear a tracking device in a specified manner for at least one month, opening the prospect of obtaining more detailed and objective lifestyle data over a longer period. The JPMA also included the need for the accumulation of detailed lifestyle data using wearable tracking devices in its recommendations for 2021.

Through this joint research, a wearable tracking device will be loaned to research participants for a period of one year to accumulate detailed and objective lifestyle data over an extended period. The joint research will add new value to the data accumulated by the Tohoku Medical Megabank Project and further accelerate its application to innovative medical research, including drug discovery aimed at achieving precision medicine and personalized healthcare of the future. It will also ensure an environment in which the dissemination of information through wearable tracking devices is made possible to welcome the era of personalized healthcare.

## Details of the study

Research organization	ToMMo, Daiichi Sankyo, Takeda, MICIN
Duration of research	March 2022 to March 2025
Research participants	Recruitment of participants for the study with informed consent will begin in the fall of 2022 for existing participants of the study “The health surveillance of the brain and psychological state program with MRI.”*3
Target number of participants	2,000
Research method (participant side)	<ul style="list-style-type: none"> <li>• Wearing and charging a wearable tracking device for a period of one year and managing the dedicated smartphone app</li> <li>• Twice-daily, thirty-day measurement of blood pressure measurement using a home blood pressure monitor to be submitted every quarter</li> <li>• Thirty-day measurement of bedroom temperature and humidity using a loaned data-logging thermo-hygrometer*4 to be submitted every quarter (in some cases)</li> <li>• Filling out a questionnaire and submitting by mail every quarter</li> </ul>
Research method (researcher side)	<ul style="list-style-type: none"> <li>• Storage and use of data collected by the wearable tracking device, home blood pressure monitors, and data-logging thermometers</li> <li>• Return of statistical analysis values to participants</li> </ul>



## Expected outcomes of research

Masayuki Yamamoto, Director of ToMMo: "The addition of highly objective lifestyle information is expected to further enhance the Tohoku Medical Megabank Project integrative biobank."

Wataru Takasaki, General Manager of Research and Development Division, Daiichi Sankyo: "We expect that the addition of objective and sustained lifestyle information from wearable devices to the high-quality cohort information provided by the Tohoku Medical Megabank Project will greatly advance the early practical application of preventive and preemptive medical solutions."

Ceri Davies, Head of Neuroscience Drug Discovery Unit, Takeda: "The digitization and visualization of individual lifestyle data will dramatically accelerate patient-centered drug research and development. Combined with this, we hope to develop new methods of utilizing big data, which will not only lead to the creation of high-precision pharmaceuticals, but also contribute to medical care tailored to the characteristics of patients."

Seigo Hara, CEO, MICIN: "We hope that this research effort to implement the acquisition and use of data from wearable devices with a large local population will serve as a model case for the collection and use of diverse data under appropriate processes."

## Future prospects

This will be the first and pioneering study of its kind in Japan that integrates digitized lifestyle data accumulated over a one-year period with the wealth of existing data owned by the Tohoku Medical Megabank Project (TMM). The study demonstrates the feasibility of long-term lifestyle data acquisition to add to the TMM cohort study, and

the possibility of adding other devices and methods of information retrieval. Combined with the cohort information from the Tohoku Medical Megabank Project, it is expected to enable a more detailed analysis of the relationship between lifestyle habits and health/disease, and further accelerate the application of this information to innovative medical research such as drug discovery aimed at achieving precision medicine and personalized healthcare. We hope to further expand and develop the framework of this research. This research also serves as a model case for the era of personalized healthcare based on wearable tracking devices. It is expected to drive the launch and utilization of similar platforms in Japan and abroad.

## References

### About the Tohoku Medical Megabank Project (TMM)

The TMM Project is aimed at recovery from the Great East Japan Earthquake and the realization of personalized healthcare and prevention of diseases. Tohoku University Tohoku Medical Megabank Organization (ToMMo) and Iwate Medical University Iwate Tohoku Medical Megabank Organization (IMM) have been conducting a cohort study enrolling 150,000 participants for a Community-Based Cohort Study and Birth and Three-Generation Cohort Study since 2013 to develop a biobank that collects samples and information for the creative reconstruction of medical care in the areas affected by the Great East Japan Earthquake and for the promotion of the health of the affected population. The Japan Agency for Medical Research and Development (AMED) has held the role of the organization in charge of research support for the TMM project since FY2015.

## Glossary

\*1 Cohort study: A method of analytical epidemiology in which lifestyle habits and disease incidence are studied in a fixed population over an extended period to analyze the relationship between lifestyle habits or exposure to specific events and the risk of disease development.

\*2 Pilot study: A small-scale preliminary study conducted to measure feasibility of the planned research and to identify potential issues. The title of the pilot study referred to here is “Brain and Mental Health Survey: Preliminary Research to Acquire Lifestyle Data from Wearable Devices.”

\*3 Health surveillance of the brain and psychological state program with MRI: MRI testing and cognitive psychology testing that has been conducted since May 2014; approximately 12,000 people participated in the first survey and a second survey is currently being conducted.

\*4 Data-logging thermo-hygrometer: A device that automatically measures and stores temperature and humidity data from the surrounding environment.

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