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News Release

JVCKENWOOD Corporation

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JVCKENWOOD Announces Clinical Trial in Australia with an Eye to Obtaining Medical Device Certification for Gazefinder use as a Supplementary Clinical Tool for Autism Spectrum Disorder Diagnosis

JVCKENWOOD Corporation (JVCKENWOOD) is pleased to announce the launch of a clinical trial in Australia on Gazefinder, a supplementary clinical tool for Autism Spectrum Disorder (ASD) diagnosis. This gaze tracking system, Gazefinder, is being trialed in Australia for use with young children aged 2 to 4 years. The trial is being conducted jointly by Australian researchers at La Trobe University (Melbourne) and Telethon Kids Institute (a medical research institute, Perth) with a view for JVCKENWOOD to obtain medical device certification through the Australian Therapeutic Goods Administration (TGA).

■ Background to clinical trial

Gazefinder gaze tracking system

The global prevalence rate of ASD is estimated to be 1-2%. ASD is a developmental disorder, and signs appear in children before they are three years old, but the condition may not be diagnosed until much later. People with ASD have lifelong difficulties with daily living activities and social functioning. These difficulties persist into adulthood, and there are no established pharmaceutical or biological treatment methods for ASD. Carrying out individualized treatment approaches, including various behavioral interventions, can nevertheless lead to substantial improvement in life skills for people with ASD. Achieving the earliest possible diagnosis is critical to ensuring the best prognosis for children with ASD.

The diagnosis of ASD is currently based on a professional judgment made on the basis of detailed behavioral observation and clinical assessment findings. In most cases, the decision is made according to criteria specified in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), published by the American Psychiatric Association. The decision on whether a child meets the DMS-5 diagnostic criteria is left to the clinical judgment of physicians, based on their observations, and reliant on their prior knowledge and experiences. It has been shown that delays and difficulties in accurately diagnosing ASD may lead to delay in accepting the disorder by family members of the child with ASD, and therefore delays to clinical intervention access for the child.

Aiming to improve the process and timing of ASD diagnosis, JVCKENWOOD started a joint development project in 2011 to explore the potential application of Gazefinder gaze tracking system to this issue. The project was conducted with Japanese researchers, including Professor Kenji Tsuchiya, Center for Child Mental Development, Hamamatsu University School of Medicine, and Professor Taiichi Katayama, Graduate School of Osaka University and United Graduate School

of Child Development. In 2015, the group developed diagnostic systems of developmental disorders using eye-tracking technologies with the assistance of "'Project for the Development of Medical Devices and Systems for Advanced Medical Services' in Research and Development Project Concerning Medical Devices and Systems to Realize Future Medical Care" of the Japan Agency for Medical Research and Development.
Australia, where the clinical trial with young children is taking place, is a geographically large, and culturally and linguistically diverse country. Professionals face the complexity of providing medical treatment and care to people from diverse backgrounds and ensuring access to medical services in regional and remote areas. Another identified issue is that the process for conducting diagnostic assessment for questions of developmental disorders, including ASD, varies across Australia from state to state. In this context, JVCKENWOOD has initiated a joint research project – based on the findings from research in Japan – working with researchers at La Trobe University and the Telethon Kids Institute. These partnerships were facilitated by the initial introductions from Australian Trade and Investment Commission (Austrade, Japan office). JVCKENWOOD has decided to fund a clinical trial of Gazefinder for use with young children, conducted in Australia, with the aim of obtaining TGA certification for Gazefinder as a supplementary medical device for supporting ASD diagnosis.

■ Details of clinical trial

In this clinical trial, participating children are aged 2 to 4 years and either have an ASD or are Typically Developing (TD). Children view the ASD diagnosis program developed by JVCKENWOOD on the Gazefinder gaze tracking system – manufactured and sold by JVCKENWOOD – and the trial will examine the effectiveness (or accuracy) of the Gazefinder program against the children's ASD diagnosis (vs. TD group) as given by community professionals and confirmed by the experienced research teams.

Illustrative image of ASD assessment using Gazefinder

The use of Gazefinder has many potential advantages to support ASD diagnosis, such as requiring no language or compliance with instructions. The Gazefinder diagnosis decision is made based on gaze tracking analysis only and, with a quick implementation time of about two minutes, avoids the need for children to have any special skills in order to be assessed.
If Gazefinder can accurately differentiate children in the ASD and TD groups, obtaining TGA medical device certification for Gazefinder means JVCKENWOOD can provide opportunities for effective and efficient ASD diagnosis in Australia. Earlier diagnosis can then promote earlier access to clinical intervention to improve the prognosis of children with ASD. Gazefinder assessment may also enhance the acceptance and understanding of persons raising children with ASD, through providing an objective assessment.

[Clinical trial title]	Could "Gazefinder" Eye-Tracking Technology Support the Earlier Identification and Diagnosis of Autism in Young Children?
[Clinical trial objectives]	The clinical trial is designed to examine the diagnostic accuracy of Gazefinder gaze tracking system for ASD in young children. The trial examines participants with a diagnosis of ASD and TD participants, using Gazefinder and an integrated software program, for a gaze tracking system designed to differentiate children with and without ASD. The results of Gazefinder algorithm will be compared against

	children's diagnosis based on opinion of community professionals and confirmed by the research team (i.e., children in the ASD vs. TD group).
[Subject of clinical trial]	Children with a diagnosis of ASD and TD children aged from 24 months to 4 years and 11 months
[Clinical trial period]	Until March 2021 (scheduled)
[Clinical trial supervisor]	Kristelle Hudry PhD. Senior Lecturer in Developmental Psychology, La Trobe University
[Institutions conducting the clinical trial]	La Trobe University Kristelle Hudry PhD., Senior Lecturer in Developmental Psychology Telethon Kids Institute Professor Andrew Whitehouse Head, Autism Research Team

■ Comments from Dr. Kristelle Hudry of La Trobe University

Gazefinder eye-tracking technology has the potential to streamline the diagnostic process and build confidence in clinicians, resulting in earlier diagnosis in children. There are already some fantastic assessments and programs in place to identify the early signs of ASD in children in Australia, including surveillance tools used by child health nurses and comprehensive assessments used by medical and allied health professionals. Our research aims to examine whether Gazefinder could be used as a brief and accurate additional tool to support diagnosis.

■ Comments from Professor Andrew Whitehouse of Telethon Kids Institute

The average age for ASD diagnosis in Australia is 4 years old. We know that it's important to identify children on an ASD pathway as early as possible, so we can support the child and family with interventions that will maximize their potential. We are really excited about the potential the Gazefinder has to help speed up that process of diagnosis, enabling children and families to get the support they need much earlier.

<Trademarks>

・Gazefinder is a trademark or registered trademark of JVCKENWOOD Corporation.

Please click here for the press release published by La Trobe University.
https://www.latrobe.edu.au/news/articles/2019/release/identifying-autism-through-new-tech

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