News Release

June 9,2025
ExaWizards Inc.
(TSE Code No.4259)

ExaMD, a Member of the ExaWizards Group, Partners with EPS Group Launching Accelerated Clinical Development for Diagnostic SaMD Commercialization

— Proprietary Algorithm Incorporating On-Site Expertise Achieves Up to 40% Reduction in Planning Time, Is Expected to Cut Annual Operating Costs by Several Hundred Million Yen —

ExaMD Inc. (Minato-ku, Tokyo, Representative Director: Koji Hazama; hereinafter, “ExaMD”), a member of the ExaWizards Group that specializes in AI solutions in the healthcare and medical fields, has established a clinical development scheme in collaboration with EPS Corporation (Shinjuku-ku, Tokyo; Representative Director: Noriyuki Takai; hereinafter, “EPS”), a subsidiary of EPS Holdings, Inc. This new scheme leverages the characteristics of diagnostic Software as a Medical Device (SaMD) powered by AI and is expected to achieve significant reductions in both clinical trial costs and timelines. The framework will be implemented in the clinical trial for ExaMD’s AI-based SaMD for dementia diagnosis through conversational speech.



Bringing together the expertise of ExaMD and the EPS group has allowed the two companies to construct a new, versatile scheme that significantly speeds up and reduces the cost of conventional clinical trial processes. This initiative promotes the industrialization* of diagnostic SaMD during the planning, development, and implementation phases and accelerates their widespread adoption.

*“Industrialization” refers to standardization, systematization, and streamlining of regulated processes for SaMD, from development to commercialization.

☑ **The New Clinical Development Scheme**

In Japan, clinical development of diagnostic SaMD has been a considerable hurdle for both healthtech enterprises and academic institutions due to high costs and the need for advanced expertise when conducting clinical trials.

To address these challenges, the two companies developed a clinical development scheme optimized for rapid, cost-effective diagnostic SaMD trials. Eliminating inefficiencies in conventional trial processes will provide efficiency, speed, and cost savings.

The trial procedures and required data collection standards have been revised to reflect these SaMD-specific attributes.This new scheme is tailored to the unique characteristics of diagnostic SaMDs, which include:

・Minimal user burden for both patients and physicians during app usage
・Low risk of device-related adverse effects
・Shorter trial and evaluation periods
・No requirement for detailed data on drug therapies or treatments

☑ **Future Plans**

ExaMD will demonstrate this scheme in a clinical trial for its AI-based conversational dementia diagnostic SaMD in 2025. This innovative clinical development model will serve as a foundation for the rapid development and societal integration of new digital health services grounded in clinical evidence.

Through this initiative, both companies will help shape new markets in the medical field and other health-related domains, accelerating the adoption of diagnostic SaMDs and digital health solutions and delivering new value to society.

☑ **Past Initiatives of ExaMD and EPS Group**

Since announcing their business alliance in August 2024 (https://exawizards.com/en/archives/28024/), ExaMD and the EPS Group have worked to industrialize diagnostic SaMDs by leveraging their respective strengths to create an end-to-end system spanning from AI development to SaMD commercialization. In the future, the two companies will continue to share information on post-clinical development activities such as sales and claims management, continuing advancement of the industry.

【EPS Corporate profile】
Company Name: EPS Corporation
Location: Tsuruya Building, 2-23 Shimomiyabicho, Shinjuku-ku, Tokyo
Established: July 2014
Representative: Noriyuki Takai, Representative Director
Business: Contract Research Organization (CRO) Services
URL: https://www.epsi-global.com/

【ExaMD Corporate Profile】
Company name: ExaMD Inc.
Location: 4-2-8 Shibaura, Minato-ku, Tokyo, 5F
Established: February 2024
Representative: Koji Hazama, Representative Director
Business: Planning, development, sales, and alliance of products and services using multi-modal AI technology to solve social issues related to healthcare
URL: https://examd.com/

【ExaWizards Corporate profile】
Company name: ExaWizards Inc
Location: 4-2-8 Shibaura, Minato-ku, Tokyo, 5F
Established: February 2016
Representative: Makoto Haruta, Representative Director & President CEO
Business: Industrial innovation and resolution of social issues via AI service development
URL: https://exawizards.com/en/

<Media Contact>
ExaWizards Inc. Public Relations: publicrelations@exwzd.com