



HiroPharmaConsulting® Co., Ltd.

**HPVM (AI-PV HiroPharma Validation Method): Official Licensing Program Launched**

HiroPharmaConsulting® Co., Ltd. (Headquarters: Osaka, Japan; Representative Director & CEO: Hirotugu Atsumaru) is pleased to announce the launch of the official licensing program for “HPVM (AI-PV HiroPharma Validation Method),” a newly patented reliability assurance method for AI-enabled pharmacovigilance (PV) systems. Following the registration and publication of Japanese Patent No. 7778327, HPVM is now available for licensed use. HPVM is the first patented methodology in the PV domain that combines human-based evaluation principles with statistical validation techniques to ensure reliability in AI-assisted safety assessment processes.

**■ Launch of HPVM Licensing for Consulting Firms (Paid License)**

HiroPharmaConsulting now offers paid licenses of HPVM to consulting firms engaged in GVP/CSV services who support reliability assurance for AI-driven safety evaluation processes. As a specialized pharmacovigilance technology corporation operating with limited but highly expert resources, we will initiate license discussions and technical information sessions sequentially on a first-come, first-served basis.

**■ Complimentary License Program for Pharmaceutical and Medical Device Companies**

Marketing Authorization Holders (MAHs) may utilize HPVM at no cost when applying the method for their internal AI-GVP CSV quality management activities, provided that certain terms and conditions are agreed upon. Specific conditions will be explained individually upon request.

**■ International Expansion of HPVM: PCT Application Filed**

To support the international deployment of HPVM, HiroPharmaConsulting has filed a PCT international patent application as follows.

PCT Application Filed. International Application Number: PCT/JP2025/042095

(claiming priority from Japanese Patent Application 2024-213393).

International Filing Date: 03 December 2025.

This establishes the foundation for future patent protection in major markets, including the United States and Europe.

**■ Future Outlook**

HiroPharmaConsulting will further expand the deployment of “AI-PV GVP CSV Validation Service,” leveraging the HPVM patented technology and aligning with the emerging era of AI and Large Language Models (LLMs). We will continue creating collaboration opportunities with GVP consulting firms and supporting pharmaceutical and medical device companies in strengthening AI reliability assurance. In addition, we have initiated preliminary inquiries regarding a potential pre-consultation with Japan’s Pharmaceuticals and Medical Devices Agency (PMDA) to ensure appropriate alignment with regulatory requirements, and we will continue to examine these considerations carefully.



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■ **Contact**

For inquiries regarding licensing, technical details, or collaboration opportunities, please contact us via the following website:

<https://hiropharmaconsulting.com/top-english/contact/>

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