



HiroPharmaConsulting® Co., Ltd.

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HiroPharmaConsulting® Launches AI-PV POC/FS Consulting Service
Supporting AI Use in Intake & Triage and Literature Screening from a Human Oversight Perspective

Osaka, Japan – HiroPharmaConsulting® Co., Ltd. (Representative Director: Hirotugu Atsumaru) is pleased to announce the launch of its new service, “**AI-PV POC/FS Consulting Service**”, designed to support the assessment and planning phase for the introduction of artificial intelligence into pharmacovigilance (PV) operations.

This service provides practical consulting support during the POC (Proof of Concept) and FS (Feasibility Study) stages prior to the introduction of AI-PV solutions. It supports the development of evaluation design and decision-making criteria required for AI implementation by considering quality, regulatory, operational, and Human Oversight perspectives. Rather than evaluating AI functions based on general superiority or performance claims, the service helps clarify the intended use, scope of application, risks, human review structure, and evaluation methodology within actual PV operations. Through this approach, the service supports more practical and explainable decision-making for AI-PV implementation.

While the service is applicable to AI-PV initiatives in general, the initial focus will be on **ICSR Intake & Triage and Literature Screening**, where demand for AI implementation is expected to be particularly high. Specific target areas include the use of AI in adverse event case intake, classification, prioritization, potential seriousness assessment, literature screening, case relevance assessment, and related evaluation support for pharmaceutical companies and PV departments.

In recent years, interest has been growing in the use of AI to improve operational efficiency and quality in pharmacovigilance. At the same time, when AI-generated outputs are incorporated into actual PV operations, it is important to design not only the technical evaluation process but also the reliability of judgment, explainability, audit readiness, and appropriate human oversight framework in advance.

The AI-PV POC/FS Consulting Service provides support for AI-PV use case assessment, risk assessment from GxP/CSV/CSA perspectives, Human Oversight design, design of methods for comparing AI outputs with human evaluation, preparation of POC plans and POC reports, POC result review, and development of implementation roadmaps. Pricing will be provided on an



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individual estimate basis, depending on the target process, scope of support, and project duration.

HiroPharmaConsulting® has provided GxP/CSV consulting, AI-PV validation, and regulatory compliance support. The company has also developed and patented HPVM (HiroPharma Validation Method), a reliability assurance framework for AI-enabled PV systems. HPVM is based on the principle that AI should not evaluate itself; instead, AI outputs should be assessed against a human-based evaluation system involving physicians and PV specialists. In this newly launched service, HiroPharmaConsulting® will support practical evaluation design during the POC/FS stage prior to AI-PV implementation, while referring to the concept of the HPVM Patent Method as a background framework.

Hirotsugu Atsumaru, Representative Director of HiroPharmaConsulting® Co., Ltd., stated:

“The practical use of AI in PV operations is expected to continue expanding. At the same time, it is important to clarify, from the POC/FS stage before implementation, which processes AI will be applied to, where human review will be required, and how evaluation results will be organized in a recordable and reportable form. HiroPharmaConsulting® will support practical pre-implementation assessment for AI-PV from the perspectives of GVP/CSV and Human Oversight.”

This service is a consulting service that supports POC/FS planning, evaluation design, Human Oversight design, and the organization of GxP/CSV/CSA requirements and issues prior to AI-PV implementation. It does not include AI system development, AI model development, vendor system configuration, regulatory approval or acceptance assurance, or the provision of final medical judgment for individual cases.

Company Information

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