



HiroPharmaConsulting® Co., Ltd. Secures Official Patent Registration for Its GVP-Compliant Validation Method for AI-Enabled PV Systems

Osaka, Japan - HiroPharmaConsulting® Co., Ltd. (CEO: Hirotugu Atsumaru) is pleased to announce that its proprietary AI-PV HiroPharma Validation Method (HPVM) has been officially registered by the Japan Patent Office, with Patent No. **7778327** and Registration Date: **21-Nov-2015**. HPVM is a process-based reliability assurance framework designed specifically for AI-enabled pharmacovigilance (PV) systems. In line with a foundational principle that "AI must not validate itself," HPVM ensures that all AI outputs are benchmarked against a human-based evaluation system consisting of qualified physicians and PV specialists.

This patent does not protect a specific AI model or algorithm; rather, it covers the structured and repeatable validation logic required to maintain continuous reliability in AI-driven PV case evaluation. HPVM addresses AI-specific risks such as decision variability, model drift, and performance shifts after retraining through a systematic and regulatorily defensible validation process.

The HPVM patent protects a set of seven integrated elements that together define a continuous, reproducible, and transparent validation structure:

1. ICSR Template Cases (Expert-Confirmed): AI outputs are evaluated against medically confirmed template cases whose judgments have been verified by qualified physicians and PV specialists.
2. $\sqrt{N+1}$ Population-Proportional Sampling: Evaluation case volumes are determined using the $\sqrt{N+1}$ logic.
3. Production-Frozen Validation Environment: Validation and re-validation are conducted in a production-equivalent but operationally isolated environment.
4. Performance Criteria (100% or Confidence Interval): Acceptance thresholds are defined as 100% agreement or statistically justified CI levels.
5. Continuous Re-Validation Cycle: Scheduled re-validation ensures AI performance is regularly reassessed.
6. Alert Mechanism: Automated notifications prevent missed validation cycles.
7. Difference Evaluation & Full Traceability: Requires pre/post comparison and lifecycle traceability of model versions.

Future Outlook (Patent Licensing & PCT International Filing)

HiroPharmaConsulting® will incorporate HPVM into its own GVP CSV Services and begin offering:

- License agreements and collaboration proposals for GxP consulting firms and PV vendors.
- Conditional no-fee licenses for pharmaceutical companies.

To ensure international protection and enable collaboration with global PV system vendors, pharmaceutical companies, and regulators, a PCT international patent application will be initiated within CY2025.

"Our patented validation method establishes a new implementation model to ensure reliability, transparency, and regulatory compliance when integrating AI into pharmacovigilance operations," said Hirotugu Atsumaru, CEO of HiroPharmaConsulting® Co., Ltd. "We are committed to supporting more sustainable and efficient PV operations through this patented technology."



HiroPharmaConsulting® Co., Ltd.

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