AI-PV HiroPharma Validation Method（HPVM）

― HPVM Core Concept ―

HiroPharmaConsulting Co., Ltd.

Hirotsugu Atsumaru

Copyright and Patent

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Core Concept of HPVM (Essence of the Patent)

For collaboration or licensing inquiries, and Press release 15-Dec-2025
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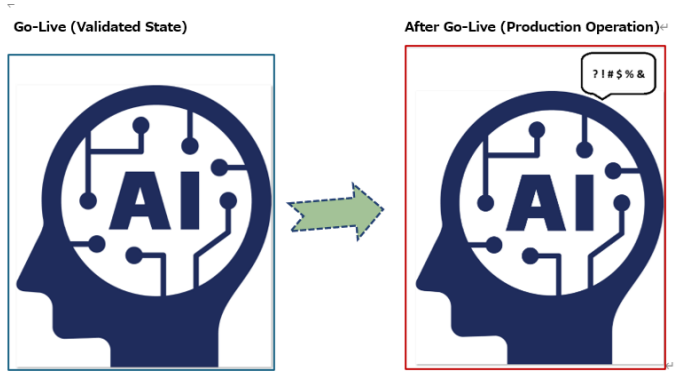
1-1. Core Concept of HPVM (Essence of the Patent)



In AI-enabled Pharmacovigilance (AI-PV), there is still no clear answer to the questions:

“Does AI continue to improve after go-live?” and

“Is the validated performance truly maintained during real-world operation?”

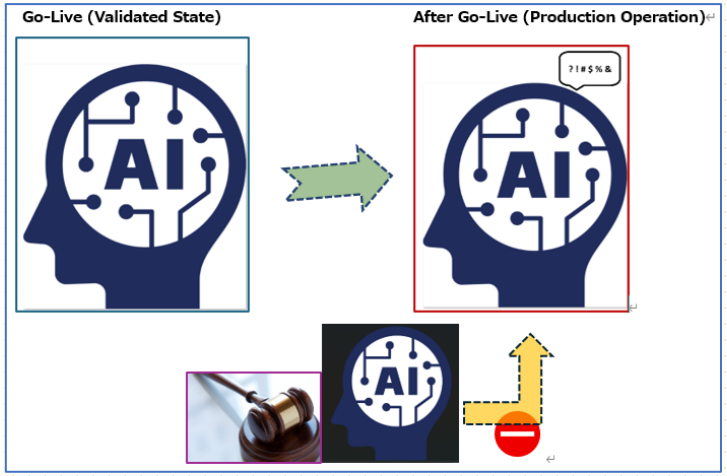
☞ Therefore, **continuous reliability assurance after production deployment** is essential.

The essence of HPVM (HiroPharma Validation Method) is based on the following principles:

1. AI performance is assumed to **change (shift) after go-live**.
2. The AI system is **periodically audited by a Human-based Evaluation System (HBES)**.
3. Errors and performance shifts are visualized, and it is confirmed that **performance above a predefined threshold is maintained**.
4. Evaluation cases are **randomly sampled by case category**, incorporating the concept of √N-based sampling.
5. This **technical framework (methodology)** is **exclusively protected** under **Japanese Patent No. 7778327**.

1-2. Overview and Value of the HPVM Patent (AI-PV HiroPharma Validation Method)

- **Japanese Patent (Granted):** Patent No. 7778327
- **PCT International Application:** PCT/JP2025/042095 (Filed on 03-Dec-2025)



Three Core Principles of HPVM:

1. AI must not evaluate itself

– Avoidance of self-referential validation

2. Adoption of a Human-based Evaluation System

– Calibration of AI performance using human-defined reference standards

3. Statistical assurance (√N+1 sampling, 95–99% confidence intervals)

– Enables detection and control of AI performance degradation (drift) after go-live

Business Value of HPVM:

- Clearly defines the boundary between **Vendor QA** and **MAH Validation** in the era of Safety-J / Safety-Cloud systems
- Highly aligned with regulatory directions from **CIOMS, FDA, and PMDA**
- Implementable as a **standard protocol for AI quality assurance**

HPVM represents one of the closest approaches to standardizing AI reliability assurance in the Pharmacovigilance

https://hiropharmaconsulting.com/
https://hiropharmaconsulting.com/top-english/

email : hiro_atsumaru@hiropharmaconsulting.com

Thank You