HexaVax-MAPS: MedGemma PoC for Global Vaccine Safety Surveillance

1. Your Team

- **Lead Architect: Myeong-eun Cheon**, Medical Doctor (MD) & Deputy Director at the Korea Disease Control and Prevention Agency (KDCA).
- **Expertise: National Vaccine Safety Surveillance** & Pharmacovigilance.
- **Role:** Systems Architect responsible for the digital implementation of the **WHO AEFI Causality Assessment** logic, integrating the 22-day mechanistic threshold and NAM 2024 compliance.

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2. Problem Statement: The "Intelligence Gap"

There is a profound "Intelligence Gap" in global vaccine safety. While high-income nations utilize active surveillance, most countries rely on **National Vaccine Safety Surveillance** systems based on passive reporting. These systems face a critical bottleneck:

- **The Complexity of Attribution:** Implementing the **WHO AEFI Causality Assessment** requires specialized epidemiological training to distinguish between "Coincidental Events" and "Vaccine Product-Related Reactions."
- **Data Quality & Noise:** Passive reports are often unstructured, making the exclusion of alternative etiologies (**WHO Step 2**) difficult for non-experts.
- **Policy Integration:** Rapidly incorporating new evidence, such as the **NAM 2024 Evidence Review**, into national causality workflows is an administrative and scientific challenge.

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3. Overall Solution: From Diagnosis to Attribution

HexaVax-MAPS is a MedGemma-powered PoC designed to automate and standardize the **WHO AEFI Causality Assessment**. Unlike typical diagnostic AI, our system is engineered for **Epidemiological Attribution**—the process of determining the "Why" behind a confirmed diagnosis.

Adherence to HAI-DEF Principles & Global Standards:

- **WHO Implementation:** The system digitizes the WHO AEFI software logic, ensuring every case is audited through a rigorous, standardized workflow.

- **Mechanistic Logic:** It translates the biological mechanism of innate immune overactivation into a **22-day temporal threshold**, enhancing the "Temporal Relationship" audit (**WHO Step 1**).
- **Policy-as-Code:** It integrates **NAM 2024 standards** through "Shadow Scoring," re-classifying isolated pericarditis to maintain the purity of national safety signals.

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4. Technical Details: Hybrid Multi-Agent Pipeline

HexaVax-MAPS emulates the investigative steps of a national surveillance officer using a 6-stage hybrid pipeline. We utilize **MedGemma 4B** for high-throughput extraction and **Gemma-2-9B** for high-order causality synthesis.

1. **ICSR Extractor (MedGemma 4B):** Standardizes unstructured narratives into a structured ICSR format.
2. **Brighton Validator (MedGemma 4B):** Ensures cases meet **Brighton Collaboration** diagnostic criteria before causality is considered.
3. **Investigative Auditor:** Executes the **22-day biological threshold** audit to verify mechanistic plausibility.
4. **DDx Specialist (Gemma-2-9B):** Automates **WHO Step 2** (Exclusion of Alternative Causes) by calculating a **Negative Causality Index** for viral prodromes.
5. **Causality Integrator (Gemma-2-9B):** Synthesizes all evidence to produce a final WHO-aligned verdict (Consistent / Indeterminate / Inconsistent).
6. **Guidance Advisor:** Identifies investigative gaps and generates an actionable summary for regulatory decision-making.

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5. Results & Impact: 100-Case Stress Test

The PoC was validated using a curated cohort of **100 VAERS reports** (90 Myocarditis, 10 Pericarditis).

Validation Summary Table

Temporal Window	Myocarditis (n=90)	Pericarditis (n=10)	Total
Window A (1-7d)	56	5	61
Window B (8-21d)	7	3	10
Window C	7	1	8

(22-42d)			
Outside / Unknown	20	1	21

- **NAM 2024 Shadow Scoring:** Successfully identified that **90% of pericarditis cases (9/10)** lacked biomarkers of myocardial injury. HexaVax-MAPS automatically re-classified these to **Category B1 (Indeterminate)**.
- **Framework Fidelity:** 100% successful implementation of the WHO Causality Algorithm across diverse clinical narratives, effectively identifying alternative viral causes—a core requirement of national surveillance.

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6. Conclusion: Redefining National Safety Surveillance

HexaVax-MAPS establishes a new benchmark for responsible AI by strictly adhering to the **CIOMS 2025 Guidelines on AI in Pharmacovigilance**:

- **Radical Transparency:** Unlike "black-box" models, HexaVax-MAPS utilizes a traceable 6-stage architecture, ensuring every regulatory decision is auditable and clinically grounded.
- **Human-in-the-Loop (HITL) Synergy:** The system augments the expertise of surveillance officers. It identifies investigative gaps, ensuring human experts remain the final arbiter of causality while supported by AI audits.
- **Global Health Equity:** By utilizing a lightweight, hybrid model strategy, we have created a system deployable on standard hardware, allowing LMICs to maintain the same rigor in **National Vaccine Safety Surveillance** as high-resource agencies.

HexaVax-MAPS transforms passive surveillance data into actionable regulatory intelligence, strengthening global health security in the era of rapid vaccine development.