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International Comparison of Ethics and Legal Issues in AI Diagnosis

Table of Contents:

Background and Process Leading to the Idea (1/3)

The Widening Gap in Medical AI

- **Artificial Intelligence** is rapidly integrating into diagnostic medicine, creating a divide between technological capability and regulatory understanding.

- There is a significant **"information asymmetry"** between complex global regulations and the **end-users (doctors, patients, policymakers).**

- Legal data remains largely inaccessible to those most affected, despite robust governance frameworks in the **EU, USA,** and **Japan.**

Background and Process Leading to the Idea (2/3)

The Challenge of Cross-Border Legal Research

Target Regions: The research focuses on comparing legal frameworks across three distinct jurisdictions:

- **EU:** AI Act, Focus on "Human Oversight".
- **USA:** FDA Total Product Life Cycle (TPLC), Focus on De-identification
- **Japan:** Emphasis on Physician Sovereignty and Trust.

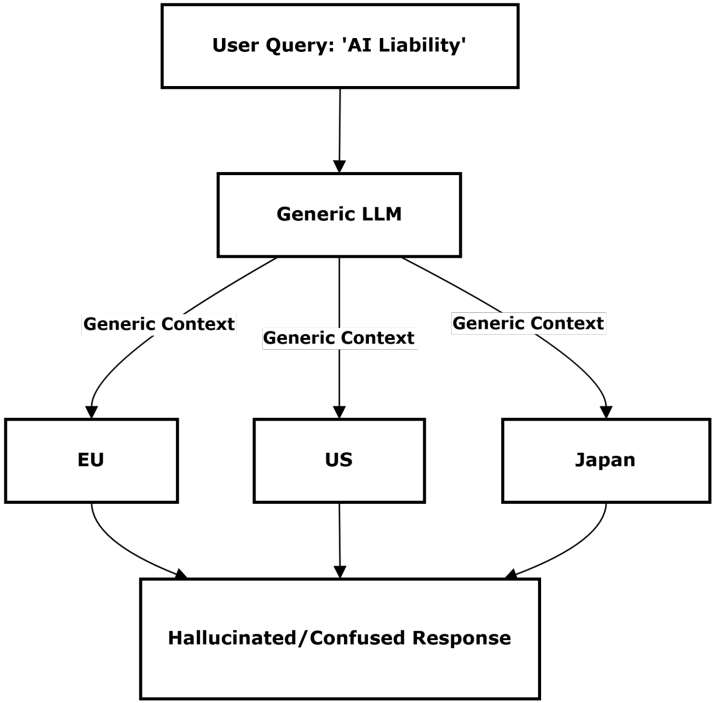
Research Goal: To create a "transparency engine" that allows non-experts to enlighten themselves on these policies.

Background and Process Leading to the Idea (3/3)

Technical Bottleneck

Issue: Standard Large Language Models (LLMs) knowledge often hallucinate and rely on data that they are trained on.

Failure Mode: A generic search for "data privacy" might return mixed results from the GDPR (EU) and HIPAA (USA), confusing the user.



Research Objective (1/1)

Operational Efficiency (Time-Saving):

- To drastically reduce the time stakeholders spend manually verifying sources.
- Shift from manual search to "instant retrieval" of verified legal contexts, allowing users to get immediate answers rather than digging through databases.

Universal Accessibility (Translation Layer):

- To make legal data accessible in any language by establishing a **Translation Layer.**
- All non-English documents are translated into English first to create a unified "Ground Truth" for accurate comparison.

Agentic Precision:

- To implement an architecture that allows specific "granular" retrieval (e.g., searching inside one specific file or country) to solve context contamination.

Idea (1/5)

The Solution - Agentic RAG Architecture

- Moving from a generic LLMs to golden standard database leveraging Agentic Retrieval Architecture.
- **Mechanism:** The system dynamically scopes searches based on user intent. It translates natural language into strict metadata filters, performs search from manually curated dataset from experts making the system more reliable and effective.
- **Granularity:**
  - Locking search to "Japan Only" or "EU Only".
  - Targeting specific documents (e.g., "Search inside the EU AI Act only").

Idea (2/5)

Trusted Data Foundation

- **Golden Standard:** The system does not scrape the web instead uses dataset manually curated by experienced professionals.
- **Human-in-the-Loop:** All vector store data is rigorously verified and manually selected by the Domain Expert (Matsuse) prior to ingestion.
- **Result:** The system retrieves only from authoritative, expert-curated sources.

Idea (3/5)

System Architecture & Ingestion Pipeline

- **Translation Layer:** Automatically detects non-English documents and translates them to English to ensure a unified vector space.
- **MinerU Processing:** Utilizing MinerU for high-quality data extraction and chunking before storage.[1][2]
- **Milvus Vector Storage:** Data is saved at the chunk level with precise metadata (Country, Filename) for the Agent to target. [3]

[1] OpenDataLab, "MinerU: A High-Quality Data Extraction Tool," GitHub Repository, 2024. [Online]. Available: https://github.com/opendatalab/MinerU. [Accessed: Jan. 31, 2026].

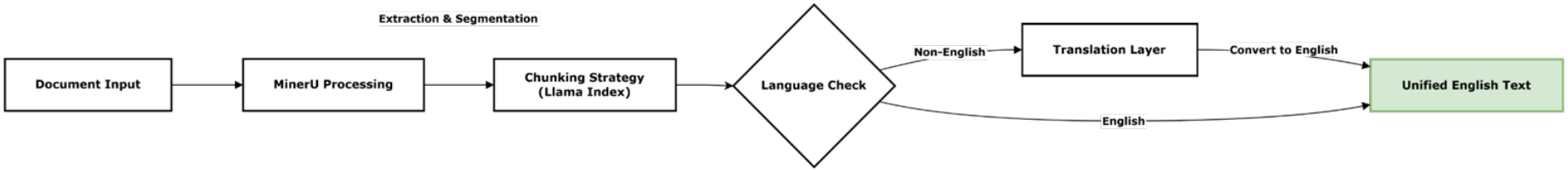
[2] J. Liu, "LlamaIndex," GitHub Repository, 2023. [Online]. Available: https://github.com/run-llama/llama_index. [Accessed: Jan. 31, 2026].

[3] J. Wang *et al.*, "Milvus: A Purpose-Built Vector Data Management System," in *Proc. 2021 Int. Conf. Management of Data (SIGMOD '21)*, Xi'an, China, 2021, pp. 2614–2627. doi: 10.1145/3448016.3457550

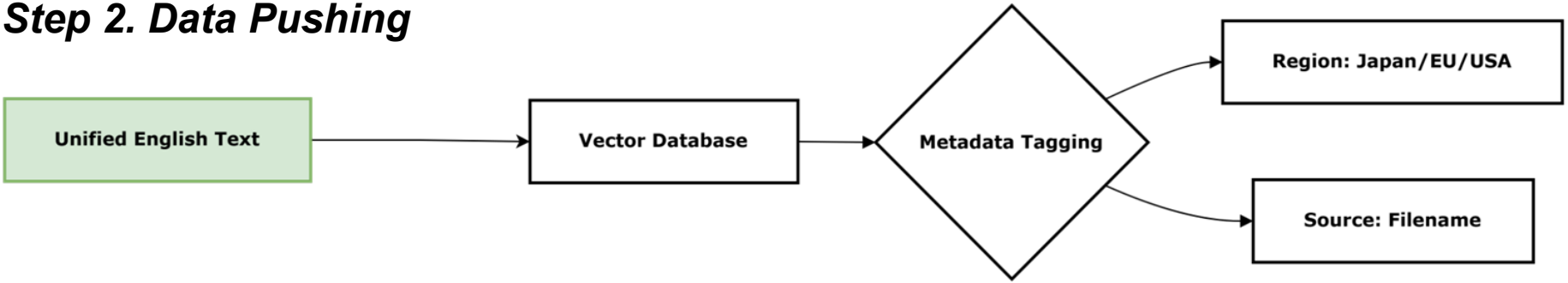
Idea (4/5)

System Architecture & Ingestion Pipeline

Step 1. Data Conversion

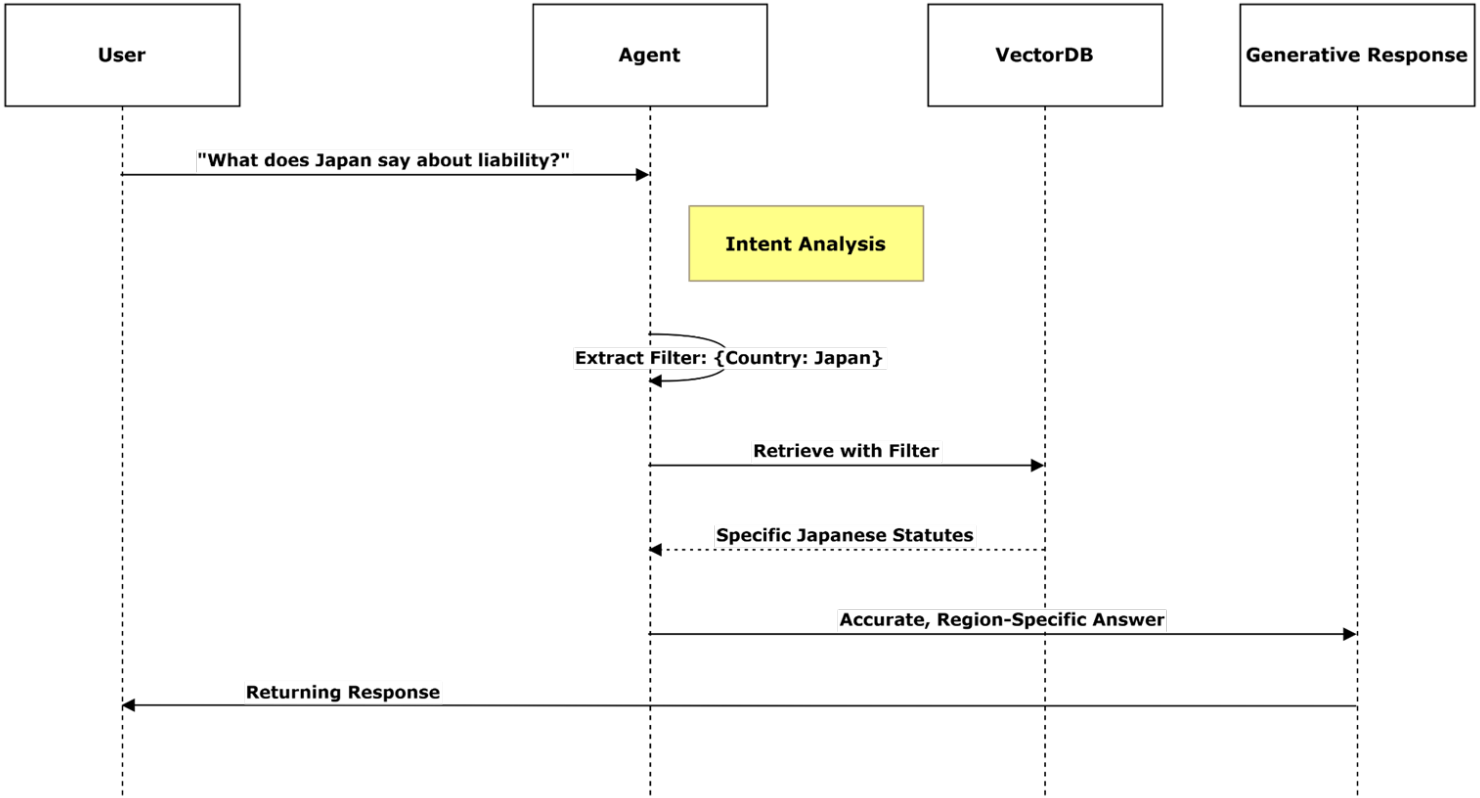


Step 2. Data Pushing



Idea (5/5)

High Level Architecture



Experiment & Results (1/3)

Methodology & Implementation

Phase 1 (June 2025 to Sept 2025):

- Scope defined for US, EU, and Japan.
- Structured repository built and annotated with metadata.
- Data ingested into Vector DB with chunking and embeddings.

Phase 2 (Oct 2025 to Jan 2026):

- Transition to Agentic RAG implementation.
- Implementation of Agentic filters based on natural language queries.

Experiment & Results (2/3)

Validation Testing

- **After Phase 1** we performed, a **comparative test**, where we validated the system against **10 specific questions** comparing policies across **all three regions.**

- **Result:** The system successfully compared the same policy against multiple regions simultaneously with human validation.

- **Agentic Capability**: Verified the Agent's ability to "search inside one country" or "specific file" (addressing previous limitations).

Experiment & Results (3/3)

System - Agentic Architecture (Sample Query and Trimmed Response)

Observation (1/2)

Addressing Expert Needs:

- **Observation:** Domain experts require more than just broad comparisons; they need precise control.
- **Feedback Loop:** Initial feedback indicated it was impossible to "search only inside one country" or "search for a specific file" effectively.
- **Resolution:** The Agentic filters now allow users to navigate the "Golden Standard" data with the precision of a legal scholar but the ease of a chatbot.

Observation (2/2)

Stakeholder Utility Analysis:

- **Medical Practitioners:** Can verify compliance (e.g., Human Oversight vs. Physician Sovereignty) to navigate liability.
- **Patients:** Can verify data sovereignty and privacy mandates (e.g., "Error-free" vs. "De-identification").
- **Policy Makers:** Can identify regulatory gaps by comparing risk classifications (e.g., US vs. EU).

Conclusion & Future Work (1/1)

Conclusion

- **Efficiency:** We successfully reduced the time for stakeholders to access legal insights, replacing manual verification with instant, citation-backed retrieval.
- **Accessibility:** The translation layer successfully unified multi-lingual legal texts into a single "ground truth," enabling accurate cross-border comparison.

A "Golden Standard" system that shifts AI governance from theoretical compliance to practical verification.

Future Scope:

- **Persona Testing:** Conduct testing with actual medical practitioners, patients, and policy makers to gather constructive feedback.
- **Expansion:** Include updated regulations and perform robust testing under higher data volumes.
- **Infrastructure:** Move from OpenAI API to local machine-runnable alternatives to reduce costs and enhance data security.

THANK YOU