



High-Level Schematic: The "GuardianAgent" Ecosystem

The project essentially builds a "brain" that has read every FDA failure from the last 10 years and uses that knowledge to prevent new trials from making the same multi-million dollar mistakes.

Phase 1: The "Memory" (Knowledge Extraction)

- **What it is:** The code you just wrote.
- **The Action:** It "scrapes" the FDA website, finds letters where drug companies got in trouble, and uses an AI (Gemini) to turn those long, boring letters into a clean database of "What NOT to do."
- **The Result:** A library of historical biostatistical sins (e.g., "Company X tried to hide their small sample size by ignoring 20% of the patients who dropped out").

Phase 2: The "Auditor" (The Critic Agent)

- **What it is:** An AI agent that acts like a strict FDA inspector.
- **The Action:** You give it a *new* protocol (the plan for a new drug trial). It scans the plan specifically looking for:
 - **P-Hacking:** "Are they measuring 50 things hoping one looks good by chance?"
 - **Underpowering:** "Are they testing only 20 people when they need 200 to prove the drug works?"
 - **Bias:** "Are they only testing healthy 20-year-olds for a heart drug meant for 80-year-olds?"
- **The Result:** A list of "Red Flags" backed by real historical examples.

Phase 3: The "Optimizer" (The Consultant Agent)

- **What it is:** An AI agent that acts like a Senior Biostatistician.
 - **The Action:** It takes the "Red Flags" from the Auditor and actually **fixes the math**.
 - It suggests a larger sample size (N).
 - It adds "Covariate Controls" (adjusting for age/weight) to make the results more scientifically sound.
 - **The Result:** A revised, "FDA-Ready" protocol.
-



The 4 Steps Clear in Your Mind

If you had to explain the "Workflow" in a job interview (or at the dinner table), here are the four steps:

1. **Ingestion:** We turn unstructured regulatory text into a **Structured Knowledge Base**.
 2. **Comparison:** We use **RAG (Retrieval-Augmented Generation)** to compare a *new* plan against *past* failures.
 3. **Specialized Audit:** We use an agent to perform **Deep Biostatistical Checks** (P-hacking, Power, Causal Inference).
 4. **Autonomous Correction:** The "Agentic" part—the system doesn't just say "this is bad"; it calculates a **statistically valid alternative** to solve the problem.
-



Why this is "Appetible" for a Job Post

You aren't just "writing a prompt." You are building a **Specialized AI Workforce**.

- **The Auditor** knows the law.
- **The Optimizer** knows the math.
- **The Orchestrator** manages the conversation between them.

This "Team of Experts" approach is exactly what companies mean when they ask for **Agentic AI skills**. It shows you can build systems that **reason, check their own work, and solve problems** without a human holding their hand at every step.

Yet, I would still like to have the human in the loop made very explicit. I still need a senior biostatistician to check what the agent is suggesting. So maybe part of the suggestion will need to include all the math and stats reasoning of why the agent made that specific proposal.

=====