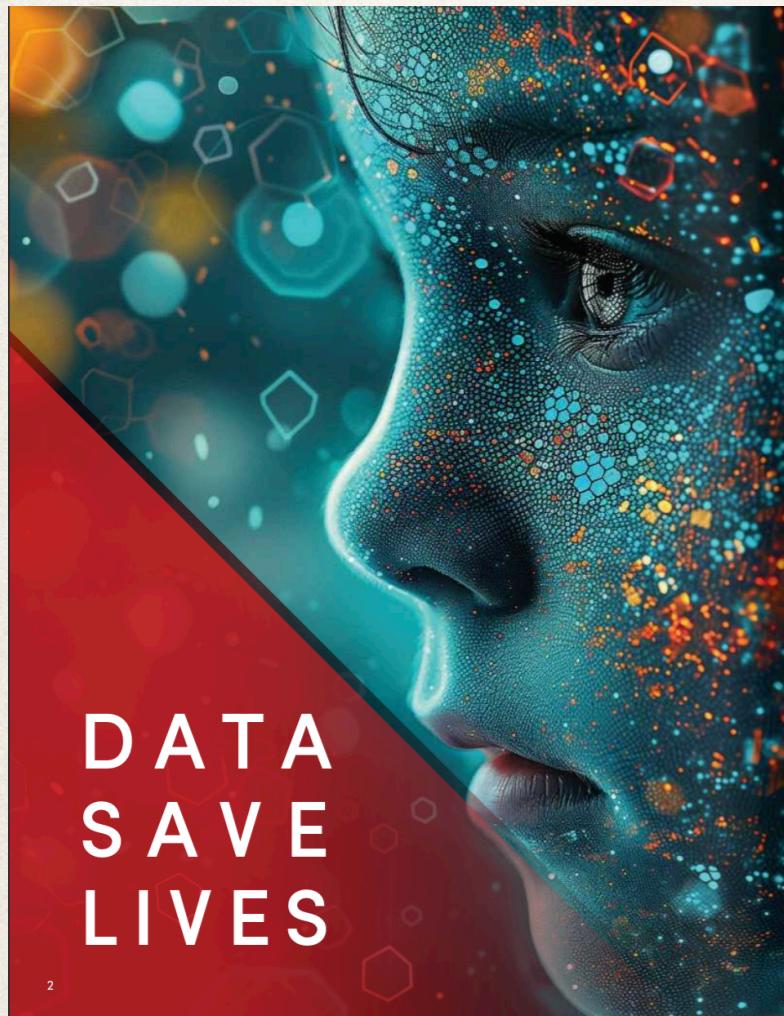


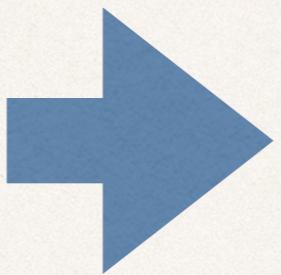
The Clinical Trial Accelerator

J. Michael Dean, M.D.
Jeeva Poongavanam

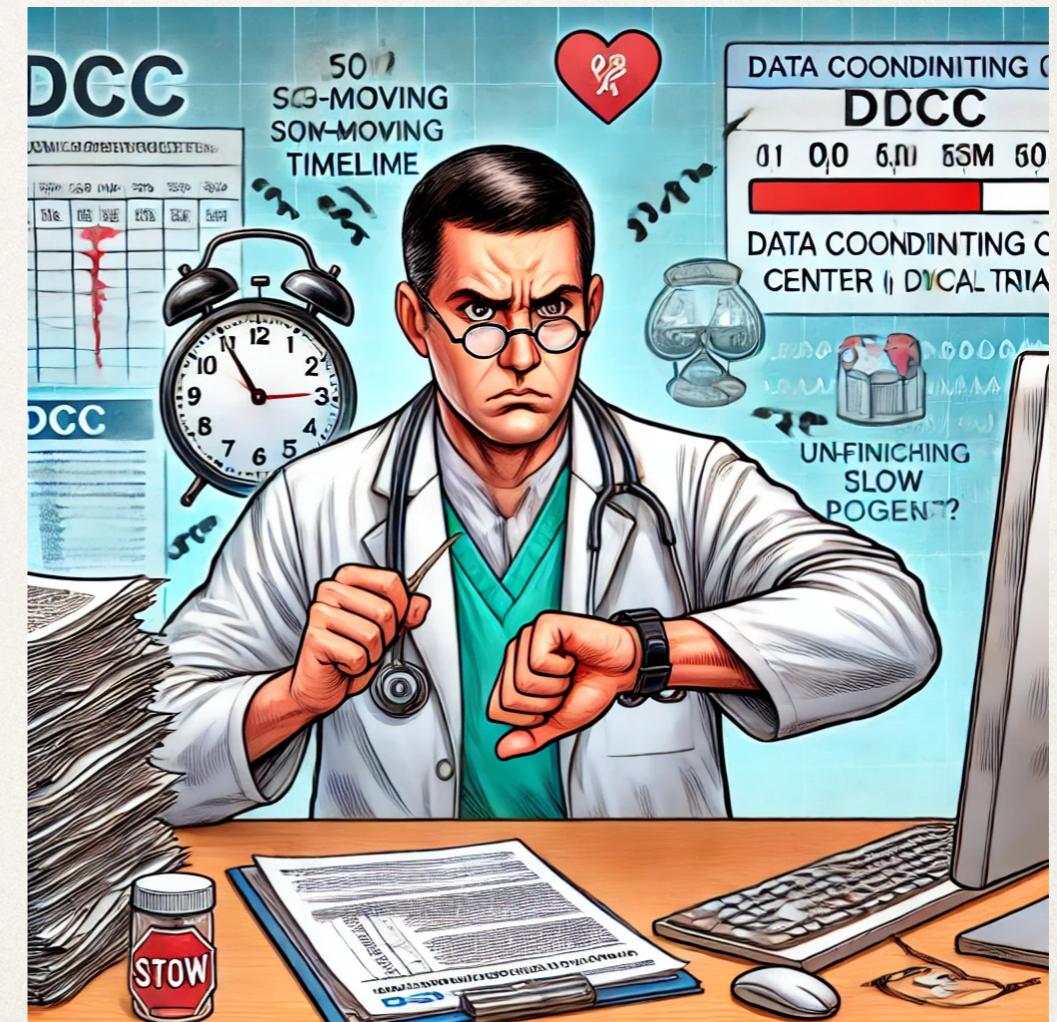


AI Makerspace Demo Day, October 24, 2024

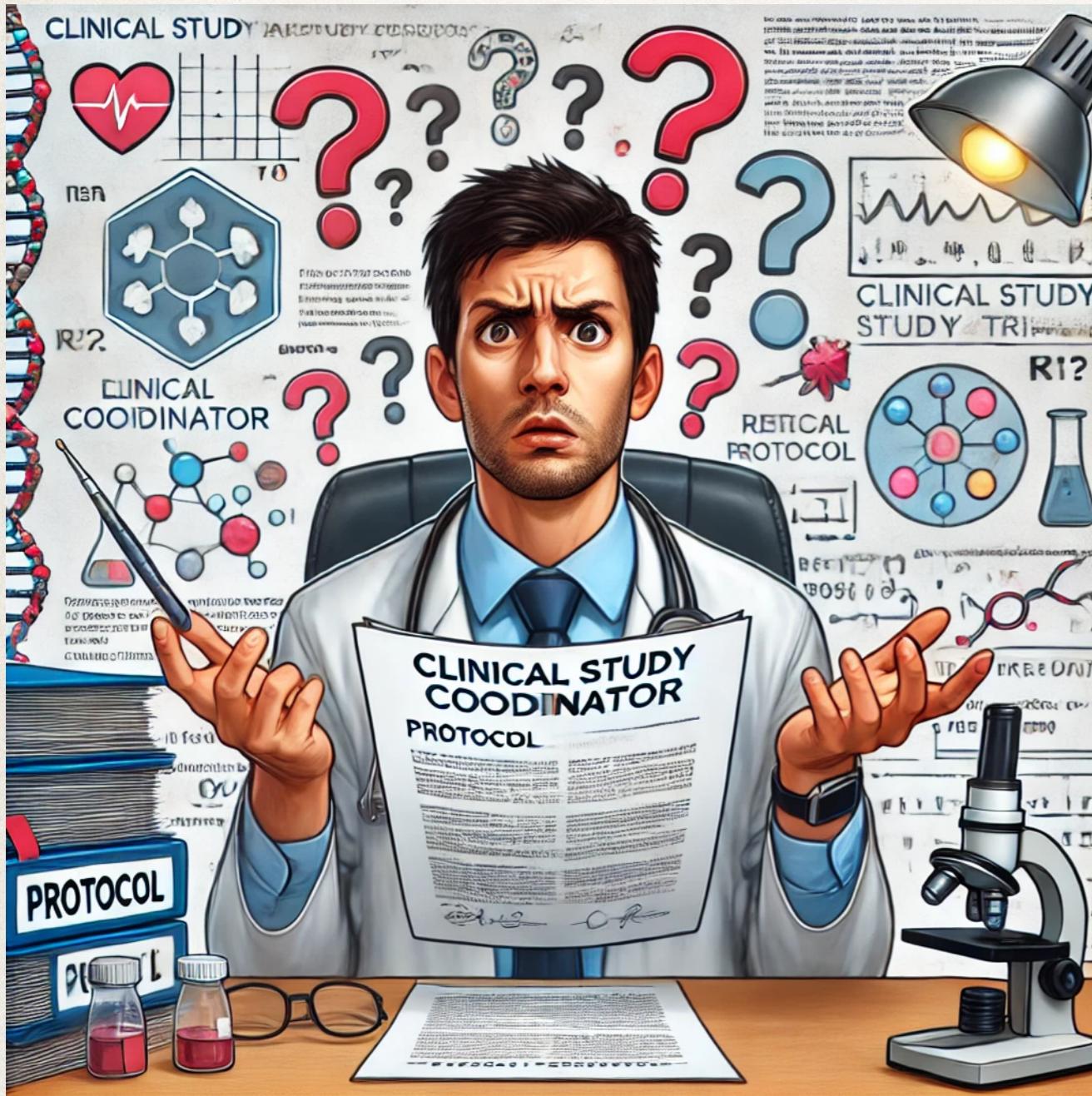
From Idea to Implementation



Data Coordinating Center



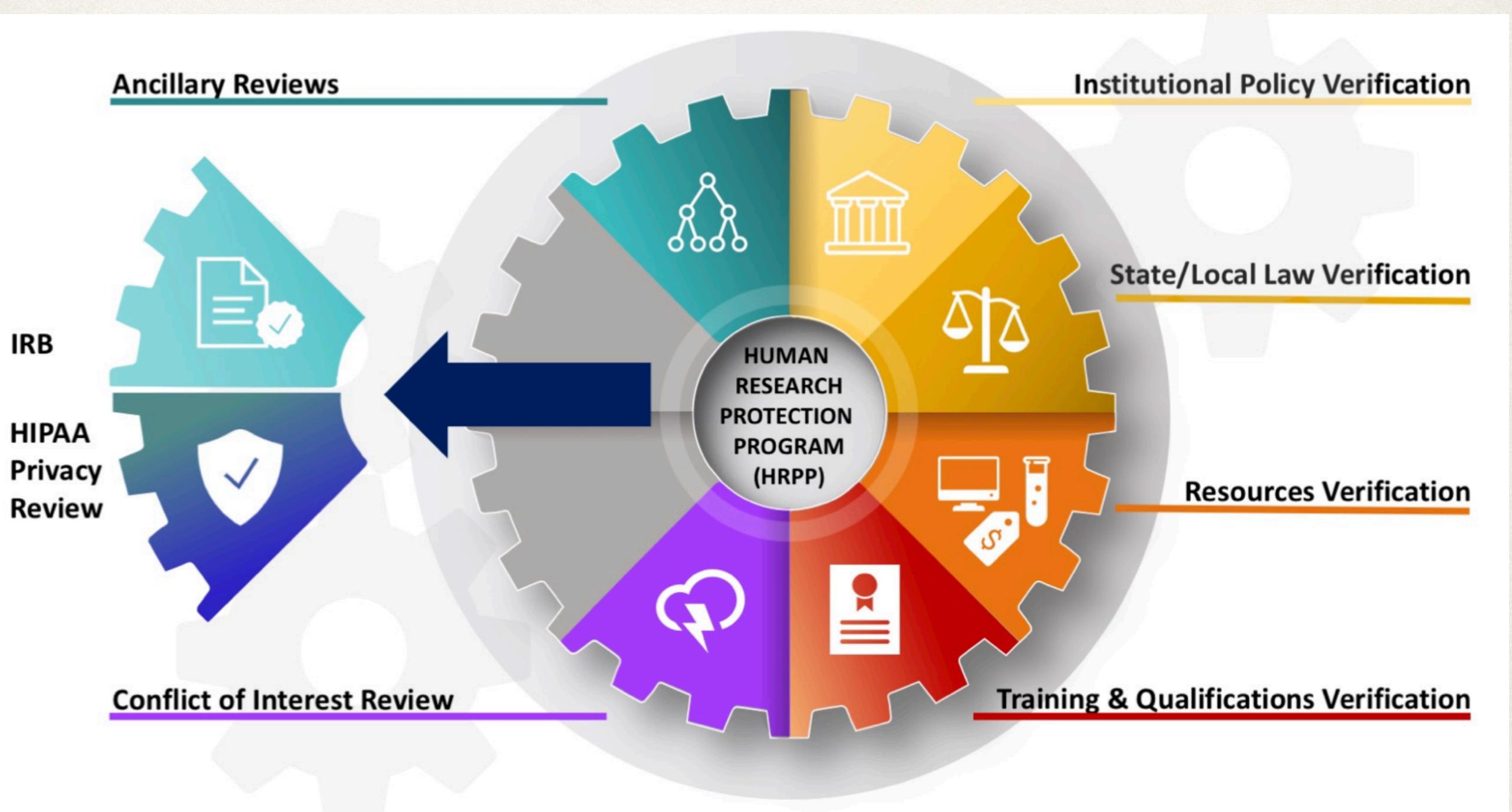
Coordinator Faces Challenges



Immediate Steps Include:

- ❖ Develop a project work plan for DCC team
- ❖ Develop checklists for each enrolling site, IRB approval, contract negotiations, reliance agreements, budgets, etc.
- ❖ Build database, develop statistical analysis plan
- ❖ Create training materials on everything for everyone involved in the study
- ❖ Human Research Protection Requirements

Human Research Protection



INFORMED CONSENT



INFORMED CONSENT

for informed consent form template that can be used



INFORMED CONSENT



Informed consent
is the process by which a patient is informed about proposed treatment



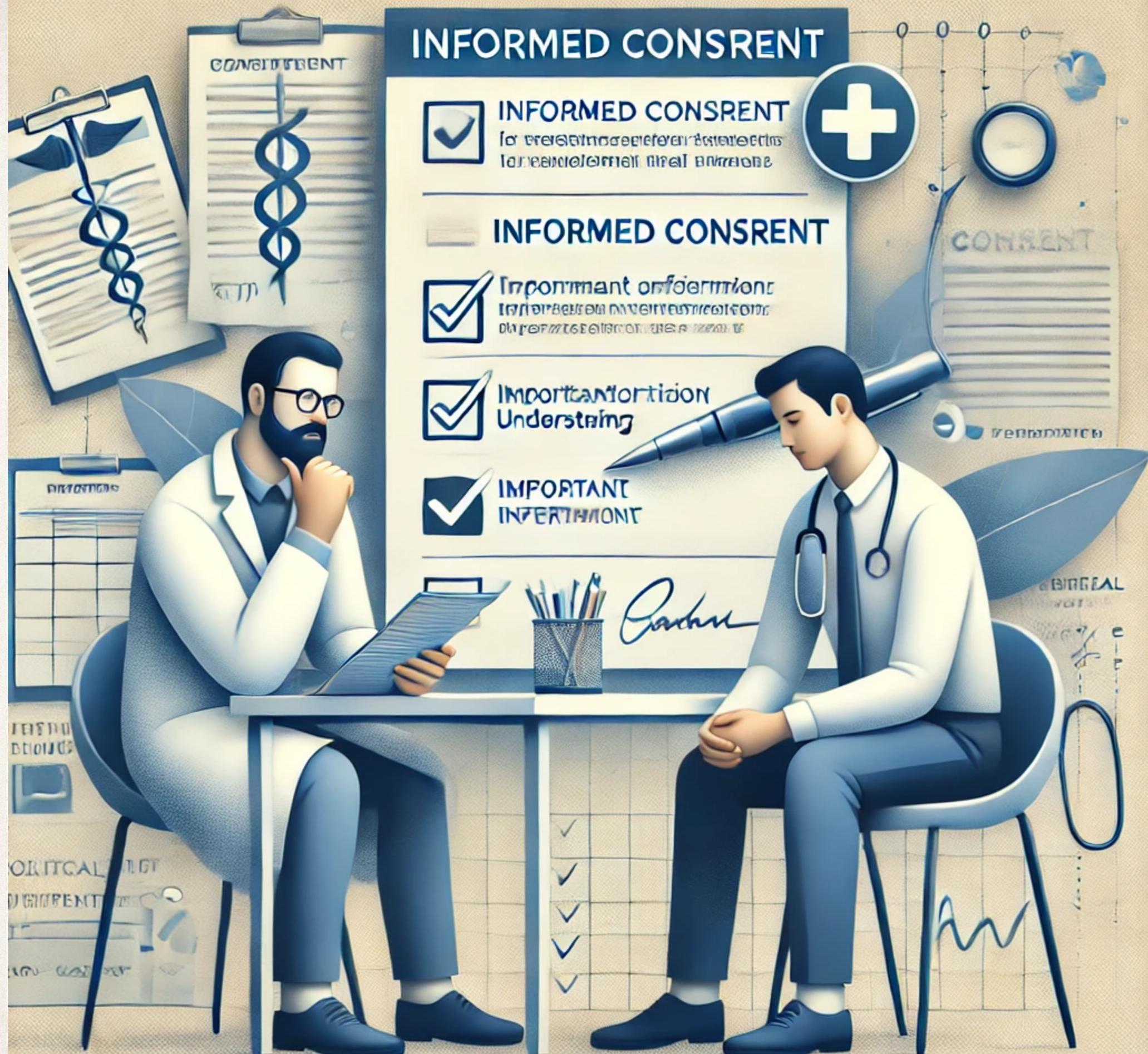
Important Information
Understanding



IMPORTANT
INFORMATION



Author

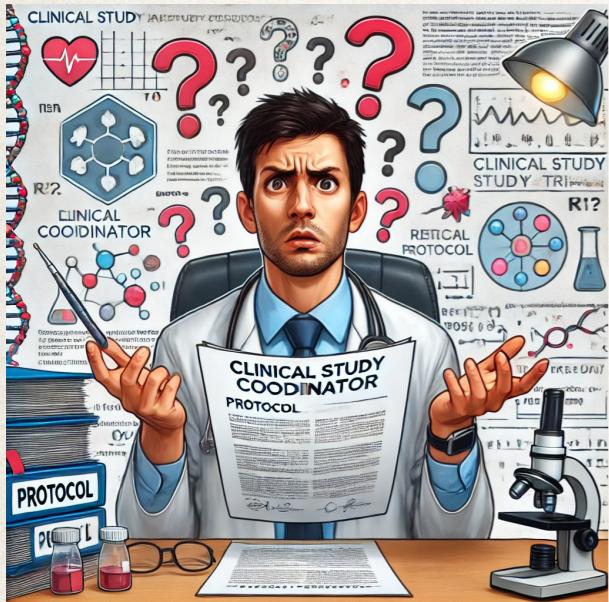


Informed Consent Document

- ✿ Must be understandable without technical expertise
- ✿ Has specific regulatory requirements for inclusion of different sections
- ✿ Must convey information for a patient, a parent, or an assenting child to make a decision about participating in a clinical trial

Clinical Trial Accelerator Demo

LLM drafts informed consent document in 14 seconds



100 pages



15 pages



Tech Stack

Frontend



Backend



+



FastAPI

LLM Models



+



GPT Model

Databases



+



Qdrant
Local File
System

Libraries / Frameworks



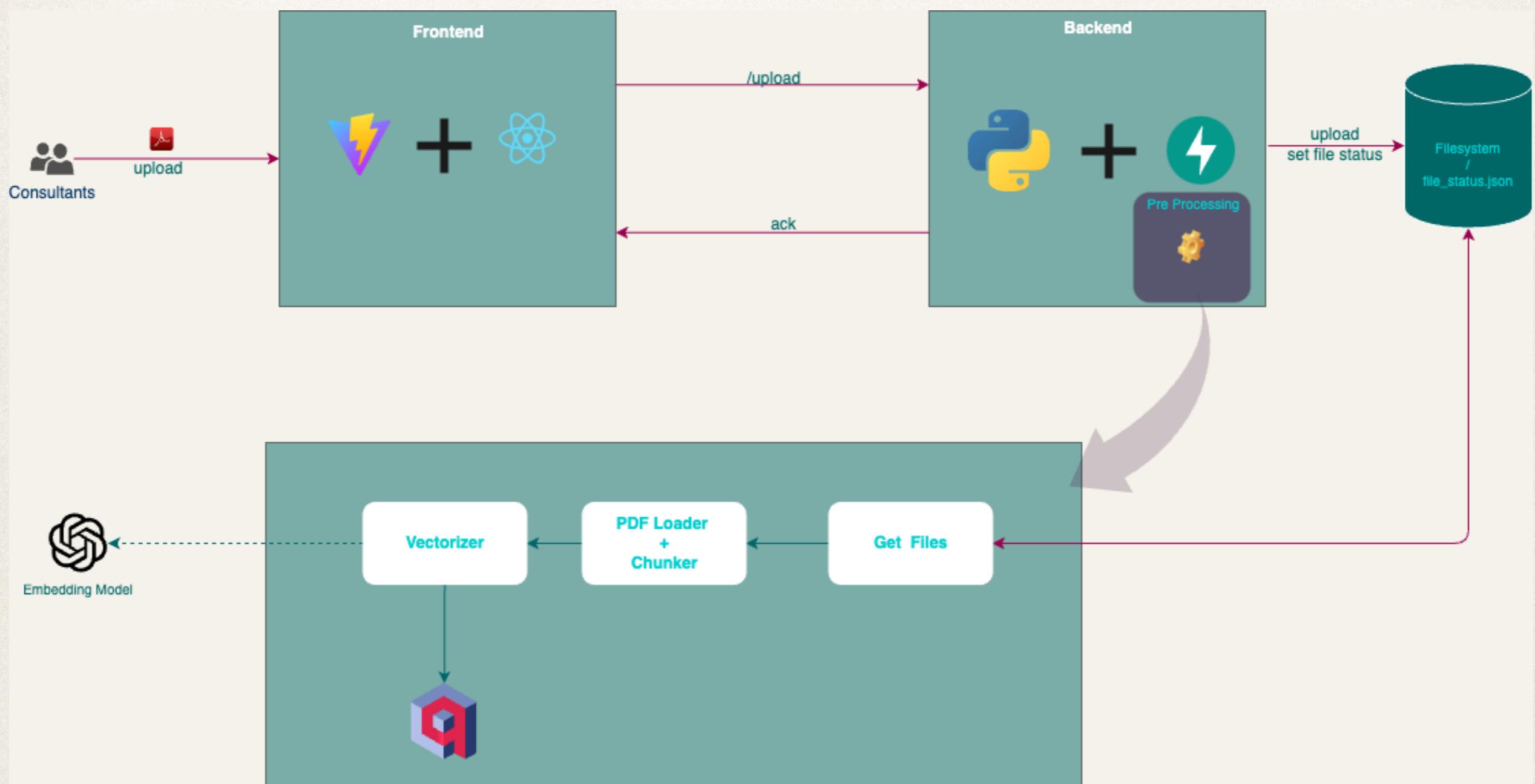
LangSmith



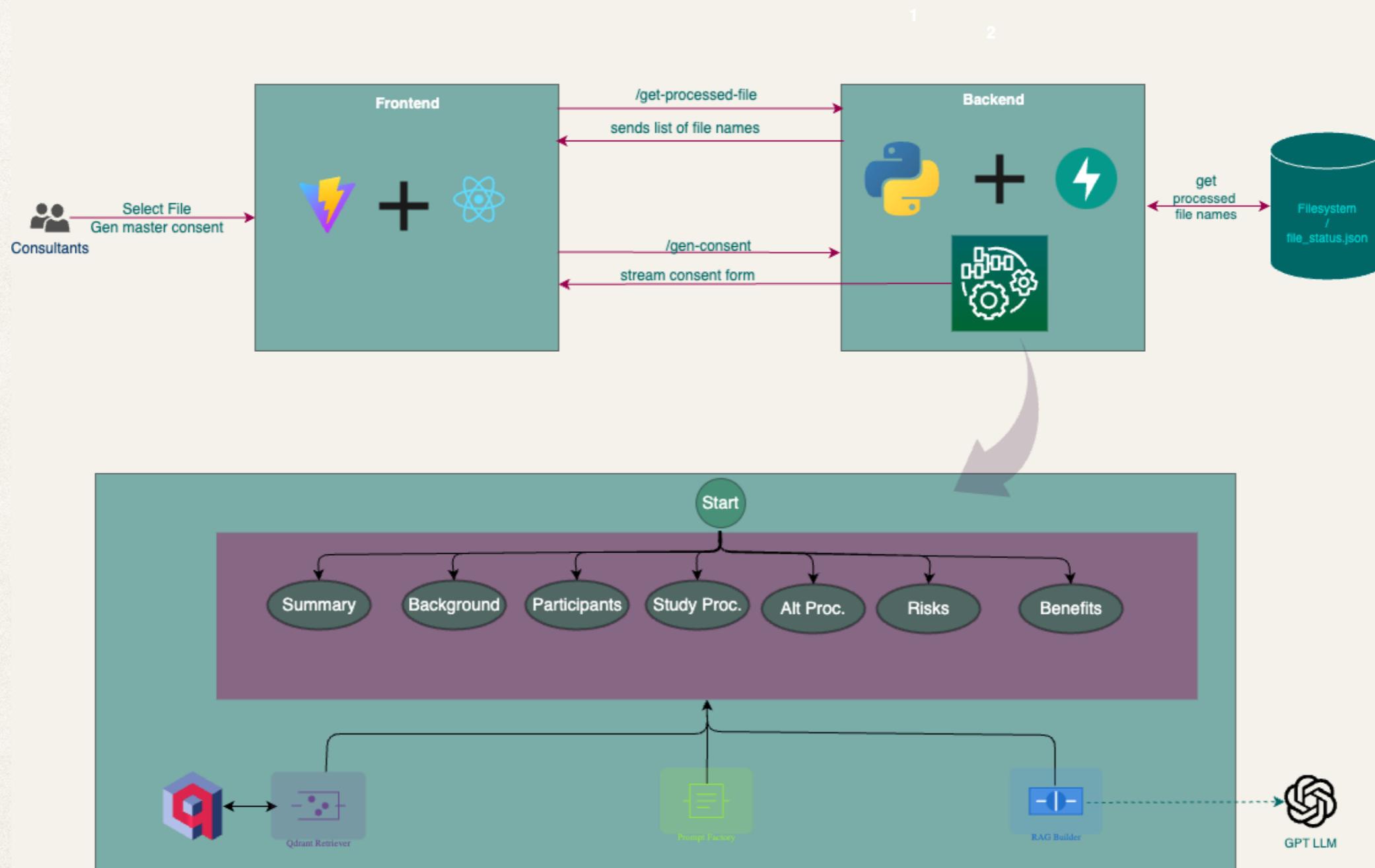
LangChain



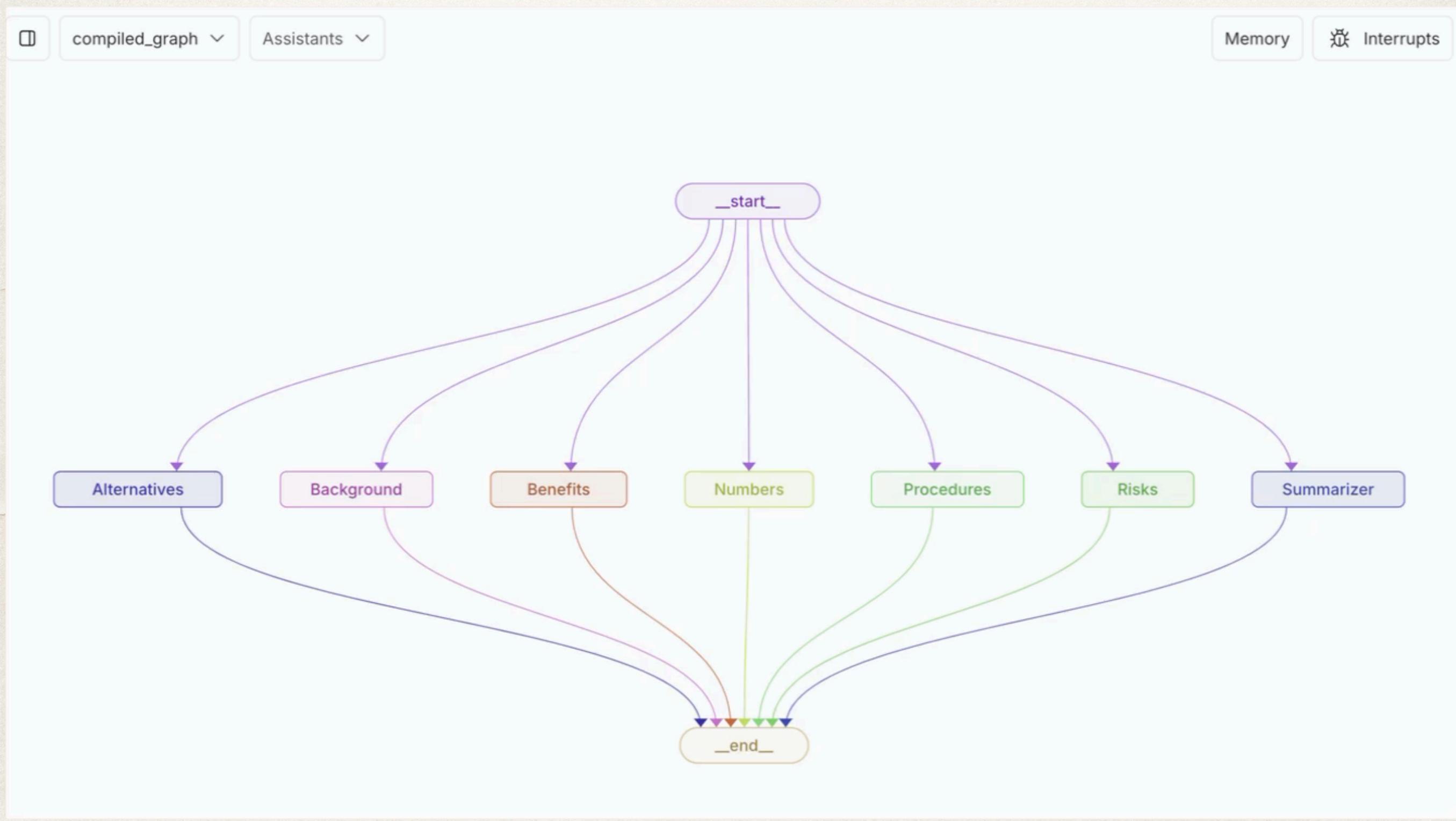
User Journey 1 - Offline processing



User Journey 2 - Generate Master Consent



Live Graph Showing Agents Writing ICF



Demo

Low hanging fruit first, then upward!

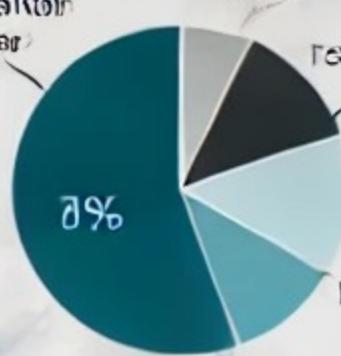
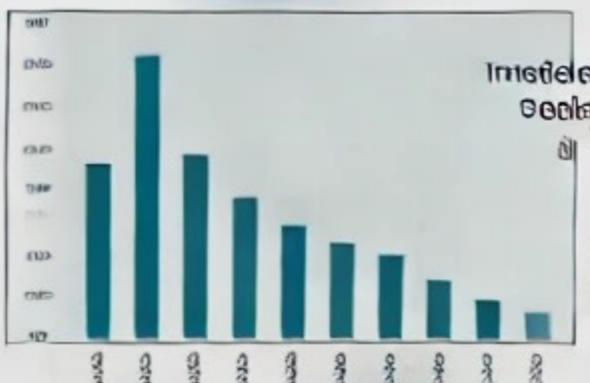


- Protocol itself
 - Data base build
 - Central monitoring
-
- Risk plans
 - DSMB charter
 - Statistical plan
-
- Checklists
 - Data elements
 - Training materials

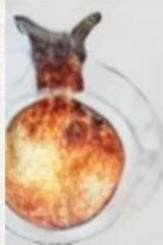
Any Questions?

Clinical Trials

Clinical Trials



Clinical Trial



CLINICAL TRIAL TRIAL

