Product Architecture & Code Apps

1. Clinical Operations Portal

App A: The Clinical Operations Portal (SaaS)

This is the primary multi-tenant application used by pharmaceutical staff, clinicians, and researchers to manage trials and view insights. It focuses on usability, data visualization, and administrative control.

User Role: Org Admin

The Org Admin is responsible for the workspace configuration, compliance oversight, and user management. They do not necessarily interact with patient data daily but ensure the system is operational for their team.

- **User Management:** Invite/remove members, assign roles, manage seat licenses, and audit user login activity.
- **Data Governance:** Set data retention policies, manage API keys for RWE/EHR integrations, and configure RBAC (Role-Based Access Control) policies.
- **Audit Logs:** Access detailed logs of who viewed or exported sensitive patient suitability reports for HIPAA/GDPR compliance.
- **Billing & Subscription:** Manage the organization's SaaS tier, view usage limits (e.g., API calls, storage), and handle invoices.

User Role: Org Member (Researcher/Clinician)

The Org Member is the functional user who interacts with the clinical data to drive decisions.

- **Patient Suitability Predictor:** Interface to filter patient cohorts and run pre-trained AI models to determine eligibility scores.
- **Predict** and forecast the clinical trajectory (Drug Response, Adverse Events) for patients who have already passed screening.
- **Therapy Comparison Tool:** Side-by-side visualization of cohort outcomes across different treatment arms using interactive charts.
- **Trial Monitoring Dashboard:** View real-time metrics on recruitment progress, site performance, and adverse event trends.
- **Export Engine:** Generate compliance-ready PDF/Excel reports for regulatory stakeholders or internal presentations.
- **AI Co-Pilot (Chat):** A chat interface to query data naturally (e.g., "Show me the dropout rate for Trial X in Phase 2").

2. Functional Requirements Mapping

Priority	Feature	Role	Description
High	**Predict Patient Suitability**	Org Member	AI models to predict patient eligibility for clinical trials.
High	**Predict Trial Outcomes**	Org Member	For a particular patients predict the effectiveness of the trial.
High	**Therapy / Drug Comparison**	Org Member	AI-driven comparisons of alternative therapies for patient cohorts.
High	**Role-Based Access Control**	Org Admin	User-specific access permissions configuration.
Medium	**Customizable Dashboards**	Org Member	Dashboards with modifiable charts and filters.
Medium	**Chat-Based AI Co-Pilot**	Org Member	Interactive chatbot for querying clinical trial data.

Org Admin = Org Member + Role Based Access

2.1 Epics, User Stories & Acceptance Criteria

Epic 1: Data Ingestion and Transformation (App B)

- **User Story 1.1:** As a **Data Scientist**, I want to ingest patient data from multiple sources so that my team can analyze a comprehensive dataset.
- **User Story 1.2:** As a **Data Scientist**, I want to validate and transform ingested data so that it meets the quality standards required for AI model training.

Epic 2: Role-Based User Interface (App A)

- **User Story 2.1:** As an **Org Admin**, I want to assign and manage role-based access so that only authorized personnel can access specific features.
- **User Story 2.4:** As an **Org Admin**, I want to monitor system usage and generate audit logs for compliance.

3. User Flow: Clinical Operations Portal (App A) for Non-Technical Users

Phase 1: Entry & Workspace Setup

- **Authentication:** User logs in; the system presents a dashboard tailored to their specific trial assignments.
- **Dashboard:** Overview of active trials, current recruitment rates, and a "Quick Actions" panel to jump into **Screening** or **Predict**.

Phase 2: Screening Module (Eligibility & Recruitment)

This module focuses on the initial "Inclusion/Exclusion" gate to identify if a patient can join the trial.

1. **Patient Data Intake:**
    a. The user selects the **Screening Tool**.
    b. **Input:** User uploads a patient file or manually enters key criteria (e.g., Age, Biomarkers, Prior Treatments).
    c. **Automated Validation:** System flags missing values required for eligibility (e.g., "Missing LDH levels for Patient 402").
2. **Eligibility Scoring:**
    a. User clicks **"Run Screening."**
    b. **System Action:** The system matches patient data against the trial's formal Inclusion/Exclusion (I/E) criteria.
3. **Screening Results:**
    a. **Display:** A list showing **Eligible**, **Ineligible**, and **Borderline** status.
    b. **Drill-down:** User clicks an "Ineligible" patient to see the specific disqualifier (e.g., "History of cardiovascular events").
    c. **Action:** User confirms the "Enrolled" list, which then becomes available for the **Predict** tool.

Phase 3: Predict Module (Clinical Outcome Forecasting)

This module focuses on forecasting the clinical trajectory (Drug Response, Adverse Events) for patients who have already passed screening.

1. **Select Target Cohort:**
    a. User navigates to the **Predict Tool** and selects the "Enrolled" or "Screened" patient list from Phase 2.
2. **Model Selection & Variable Adjustment:**

    a. User selects the target outcome to predict (e.g., "Drug Response Score" or "Probability of Grade 3 Adverse Events").
    b. **Input Adjustments:** User can adjust sliders for "Attribute Weightages" to see how different factors (like dosage or baseline weight) might influence the predicted outcome.
3. **Outcome Generation:**
    a. **System Action:** The AI foundation model generates patient-level clinical event predictions.
4. **Results Visualization:**
    a. **Display:** Personalized prediction results with **Confidence Intervals**.
    b. **Insights:** The system identifies "Key Drivers" (e.g., "This patient's high response score is driven 60% by their Genomic Marker X").

Phase 4: Compare Tool (Therapy Benchmarking)

This module allows for "Apples-to-Apples" comparison between the target drug and alternatives.

1. **Define Comparison Frame:**
    a. User selects a **Comparator Drug** (Standard of Care) and the **Target Drug** (KolateAI Pharma).
2. **Cohort Refinement:**
    a. User filters the patient set by attributes (e.g., "Only patients with Normal LDH levels").
3. **Side-by-Side Visualization:**
    a. **Kaplan-Meier Curves:** Comparing survival or time-to-event between the two therapies for the *same* patient profiles.
    b. **Toxicity Comparison:** Heatmaps showing the predicted side-effect profile of the Target vs. Comparator.

Phase 5: Insights & Co-Pilot (Natural Language Layer)

- **Querying:** The user asks the **Co-Pilot**, *"Who are the top 5 high-responders in the current cohort?"* or *"Compare toxicity for Arm A vs Arm B."*
- **Interaction:** User "Stars" specific charts to add them to a "Clinical Insights" summary report.
- **Export:** User generates a PDF report summarizing the **Screening Success Rate**, **Predicted Outcomes**, and **Therapy Comparisons** for regulatory review.

Summary of Separation (Phase 2)

Feature	Primary Goal	Key Output
Screening	Determine Eligibility	Eligible/Ineligible List (Pass/Fail)
Predict	Forecast Trajectory	Clinical Event Scores & Confidence Intervals
Compare	Benchmark Performance	Comparative Efficacy & Safety Charts