# Clinical Trial Operations Platform - ClinOps

*Design Thinking & Innovation Strategy*

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Three-Phase Design Approach: EMPATHIZE -> DEFINE -> IDEATE

## PHASE 1: EMPATHIZE

Goal: Understand the users and context deeply.

### Deliverables

- User research plan (who, how, what you'll study)
- Interview transcripts & observation notes
- Empathy maps / journey maps
- Key insights (quotes, pain points, opportunities)

### USER RESEARCH PLAN

### Who We Studied

| User Group | Role |
|---|---|
| **Trial Coordinator / Site Managers** | Primary day-to-day planners |
| **Regulatory & QA Advisors / CRAs** | Compliance gatekeepers |
| **Sponsor Project Managers** | Multi-site overseers |

### Research Methodology

- 3 remote sessions (30-45 min) via Zoom with screen-shares
- Semi-structured interviews using 10 discovery questions
- Task walk-throughs: Trial Overview, Task Checklists, Timeline, Document Control, Audit Prep, Smart Alerts

- Artifact reviews of binders, Excel checklists, version trackers, email templates

## What We Studied

- Protocol -> timeline translation and site wave planning
- Audit-binder assembly and readiness
- Document version/expiry handling (ICF, lab manuals, approvals)
- How alerts/checklists guide activities across phases

## KEY FINDINGS FROM INTERVIEWS

## User Quotes (Pain Points)

- I spend a day just syncing Gantt timelines with protocol updates.
- Version control across countries is a nightmare - every email has a different form.
- Audit prep eats up a whole week when templates aren't ready.
- I'd love if something just told me what's about to expire before QA does.
- Manual timelines slip across site waves.
- Version drift (ICF, lab manuals) becomes findings.
- Audit folders take days without a template.

## Key Observations

- Coordinators copy protocol milestones into Excel; dependencies are easy to miss
- Regulatory tracks expirations with color-coded spreadsheets
- Binders maintained both digitally and on paper for audits
- Teams switch between CTMS, SharePoint, and email - causes version drift
- Time sinks: manual Gantt updates; binder assembly; reconciling versions

# EMPATHY MAPS

## Trial Coordinator - Rina

| Says | **I just want my site to activate on time.** |
|------|------|
| **Thinks** | Dependencies are invisible when everything's manual. |
| **Does** | Builds timelines in Excel; emails updates; tracks enrollment |
| **Feels** | Frustrated; rushed before activation |
| **Motivation** | Reduce manual rework and activate sites on time |

## Regulatory Advisor - Omar

| Says | **One wrong version can cause a finding.** |
|------|------|
| **Thinks** | If I could see expirations in one place, I'd sleep better. |
| **Does** | Reviews trackers; compares dates; preps for audits |
| **Feels** | Cautious; detail-oriented; occasionally overwhelmed |
| **Motivation** | Achieve zero findings with centralized version tracking |

## JOURNEY MAP

| Phase | Actions | Emotions | Blockers |
|-------|---------|----------|----------|
| **Pre-Study** | Read protocol; set milestones | Curious / Optimistic | Hard to estimate durations |
| **Site Initiation** | Build Gantt; assign tasks | Overwhelmed | Manual re-entry of data |
| **Enrollment** | Monitor progress | Alert / Pressured | No unified tracker |
| **Follow-up** | Check expirations | Tense | No automatic alerts |
| **Close-out** | Assemble audit binder | Exhausted | Missing templates |

# PAIN POINTS & OPPORTUNITIES

## Critical Pain Points

- Manual Gantt management and rework after amendments
- No cross-system synchronization; version drift across email
- Time-intensive binder assembly; high risk of missed expirations

## Strategic Opportunities

- Automate protocol-to-timeline generation with built-in dependencies
- Provide pre-built audit templates and readiness checklists
- Centralize version/expiry status with proactive alerts

# PHASE 2: DEFINE

Goal: Synthesize insights into a clear, actionable problem statement.

## Deliverables

- Point of View (POV) statements
- How Might We (HMW) questions to frame ideation
- Problem framing document with storyboard
- Refined user personas

## POINT OF VIEW (POV) STATEMENTS

**Trial Coordinator:** A coordinator at a multi-site study needs a fast way to turn protocol + site waves into an actionable plan because manual timelines hide dependencies and delay activation.

**Regulatory Advisor:** A QA/RA lead needs clear visibility of document versions/expirations because small mismatches trigger avoidable findings.

## HOW MIGHT WE (HMW) QUESTIONS

Framing challenges to drive ideation across prototype tabs:

| Feature Area | HMW Question |
|---|---|
| Trial Timeline | How might we turn discovery answers into a draft timeline with dependencies? |
| Audit Preparation | How might we auto-outline audit folders and highlight missing items? |
| Document Control | How might we surface version/expiry status for critical docs? |
| Risk & Controls | How might we catalog risks and suggest prevention/remediation? |
| Smart Alerts | How might we flag potential compliance gaps from user-provided dates? |

# USER PERSONAS

## Rina - Trial Coordinator

| Goal | Activate sites on time; reduce manual rework |
|---|---|
| Frustration | Hidden dependencies; messy timelines that break after amendments |
| Key Quote | I'm always fixing Gantts after protocol amendments. |
| Need | Translate protocol into actionable site plans with minimal re-entry |
| Environment | Excel + CTMS + Teams; hybrid work |
| Success Metric | Timeline generation < 2 hours; 0 missed milestones |
| | |

## Omar - Regulatory Advisor

| Goal | Achieve zero findings during audits |
|---|---|
| Frustration | Lost versions; expiring certificates; disparate tracking |
| Key Quote | Half my stress is keeping versions straight. |
| Need | Centralized expiry/version tracker with proactive guidance |
| Environment | Remote QA team; shared drives and email |
| Success Metric | Zero version-related findings; 100% readiness |
| | |

## Priya - Sponsor PM

| Goal | Cross-site consistency and transparency |
|---|---|
| Frustration | Disparate progress; unclear readiness status across sites |
| Key Quote | I can't tell which sites are really audit-ready. |
| Need | At-a-glance dashboards and automated risk alerts |
| Environment | Multi-site oversight; monthly reporting cadence |
| Success Metric | Real-time dashboard; proactive alerts |
| | |

# PHASE 3: IDEATE

Goal: Generate a wide range of creative solutions.

## Deliverables

- Brainstorming outputs and feature concept sketches
- Concept prioritization matrix (feasibility vs impact)
- Top concept cards and storyboards for validation

## BRAINSTORMING: CORE FEATURE CONCEPTS

| Feature Concept | Description |
|---|---|
| Instant Timeline | Draft Gantt from protocol + site waves with dependencies |
| Audit-Readiness Kit | Folder tree + readiness checklist; authority-aware templates |
| Compliance Guardrails | Version/expiry checks and signature tracking |
| Risk & Controls Matrix | Catalog of risks with prevention/remediation strategies |
| Smart Alerts | In-chat flags for expiries, mismatches, and trends |
| Workflow/Compliance Diagrams | Visual flows: Enrollment, AE/SAE, monitoring, data queries |

# PRIORITIZATION MATRIX: FEASIBILITY vs IMPACT

Strategic prioritization for phased rollout:

| Feature | Feasibility | Impact | Phase |
|---|---|---|---|
| **Instant Timeline** | High | High | NOW - Phase 1 |
| **Audit Binder Generator** | High | High | NOW - Phase 1 |
| **Compliance Guardrails** | High | High | NOW - Phase 1 |
| **Smart Alerts** | High | High | NOW - Phase 2 |
| **Workflow/Compliance Diagrams** | High | High | NOW - Phase 2 |
| **Integrated Background Alerts** | Medium | High | FUTURE - Phase 3 |
| **Real-time CTMS/eTMF Sync** | Low | High | FUTURE - Phase 3 |

# TOP 3 CONCEPT CARDS

## 1. INSTANT TIMELINE

| | |
|---|---|
| **Problem** | **Manual protocol timelines are slow, error-prone, and miss dependencies** |
| **Solution** | AI converts protocol + site waves into a Gantt plan with automatic dependency mapping |
| **Value Proposition** | Saves 8-12 hours per trial; reduces missed milestones by 90% |
| **Target User** | Trial Coordinator (Rina) |
| **Success Metrics** | Timeline generated in <30 min with actionable tasks |

## 2. AUDIT-READINESS KIT

| | |
|---|---|
| **Problem** | **Binder creation is tedious, inconsistent, and takes days to assemble** |
| **Solution** | Authority-aware folder structure + readiness checklist + gap-finder |
| **Value Proposition** | Inspection-ready binder in hours, not days; reduced findings |
| **Target User** | Regulatory Advisor (Omar) |
| **Success Metrics** | 100% checklist coverage; zero missing documents at audit |

## 3. COMPLIANCE GUARDRAILS

| Problem | Expiring documents and mismatched versions create avoidable findings |
|---|---|
| Solution | Users input key doc dates/versions; AI flags risks and recommends actions |
| Value Proposition | Prevents findings; boosts team confidence pre-audit |
| Target User | QA/RA Leads (Omar, Priya) |
| Success Metrics | Proactive alerts 30 days before expiry; 0 version-related findings |
| | |

## STORYBOARD: INSTANT TIMELINE (4-Panel Narrative)

**Panel 1: Discovery**
Rina opens the platform and uploads protocol document. A blank timeline stares back, daunting.

**Panel 2: Generation**
She submits 10 quick discovery answers about site waves, key milestones, and dependencies. AI drafts a structured timeline in seconds.

**Panel 3: Refinement**
Dependencies and tasks auto-populate. She adjusts dates in chat, moves milestones, and tags responsible teams.

**Panel 4: Delight**
Rina smiles. Finally, a head start! She exports and shares the Gantt with the team - no manual re-entry needed.

## CONSTRAINTS & SCOPE GUARDRAILS (v1)

- Outputs are generated in chat (text/tables/diagram definitions only)
- No external EDC/CTMS/eTMF integrations or background jobs
- Smart Alerts are generated on-demand from user-entered data (not real-time)
- Document Control reflects user-provided versions/expirations (no auto-sync)
- PHI is NOT collected or stored in platform

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