AI-NATIVE CLINICAL TRIAL SITE ACTIVATION ACCELERATOR

HelixIQ²

Site Activation Command Center

Intelligence at Activation Speed.
Clinical Trial Site Activation, Transformed.

THE PROBLEM

Study Start-Up Is the Critical Bottleneck in Drug Development.

The Cost of Inaction

Clinical trial site activation averages 8+ months. Academic medical centers take 9.4 months. 70% of trials experience delays, and over half of those delays trace back to site activation problems. Every day a site sits unactivated costs sponsors $600K to $8M in lost post-market revenue — per site, per day.

CTA negotiations now average 90+ days — up from 60 days just a few years ago. The trend is worsening. 94% of that time is "white space" — the document sitting idle in someone's inbox between review cycles. This is a coordination problem, not a legal complexity problem. Active redlining takes days. Waiting takes months.

SSU Managers juggle 10-30 sites across spreadsheets, CTMS systems, and endless email threads. No one knows in real time why a specific site is stalled. The data exists — it's scattered across four systems with no unified view. An IRB approval decays while Legal sits on a CTA. Training certifications expire before the SIV. IP shipments arrive at sites that aren't ready to receive them. These cascading failures compound — and no system catches them.

The Scale of the Problem

240d
Avg Time to Activation

70%
Trials Delayed

90d+
Avg CTA Negotiation

94%
CTA White Space

$8M
Lost Revenue/Month (Phase III)

50%+
Delays from Activation

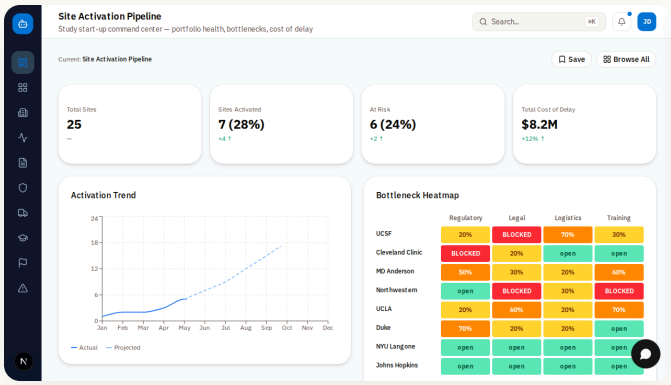
Regulatory Foundation

ICH GCP E6(R3) — finalized Jan 2025, FDA adopted Sep 2025. Risk-proportionate essential records, Quality by Design, remote consent with e-signatures. FDA Diversity Action Plans (Jun 2025) mandate enrollment diversity targets for Phase III studies. EU CTR 536/2014 fully in effect via CTIS portal. 21 CFR Parts 11, 50, 56, 312 govern every activation step.

THE SOLUTION

An AI Command Center That Knows Why Sites Are Stalled — and What to Do About It.

Not a dashboard. Not a CTMS. An AI-driven orchestration engine that diagnoses root causes, surfaces cascade impact across all four workstreams, and orchestrates resolutions — all through conversation.



Activation pipeline dashboard — KPIs, trend projections, bottleneck heatmap, and site readiness comparison in a single unified view.

Pipeline Visibility, Real-Time

Activation pipeline KPIs — activated, on-track, at-risk, stalled — with total cost of delay computed across the portfolio. Bottleneck heatmap identifies which workstreams are blocked per site. Activation trend charts project future activations based on current pipeline velocity. Site readiness comparison across institutions, CROs, and therapeutic areas.

Root Cause Diagnosis, Automated

Every stalled site gets a structured diagnosis: primary cause with confidence level, contributing factors ranked by impact, cascade impact across all four workstreams (regulatory, legal, logistics, training), and specific remediation recommendations with cost-benefit estimates. The agent doesn't just flag problems — it explains why they happened and what to do next.

> *"IRB approved but CTA stalled — you're burning 42 days of usable IRB window. No CTMS shows this cascade."*

CONVERSATIONAL COMMAND CENTER

Ask Questions. Get Visual Answers. Take Action.

No training. No IT ticket. No batch run. Ask questions in plain English and get visual answers — charts, diagnostic cards, site profiles, and one-click approval workflows. Every response is rendered as structured UI, never raw text.

Pipeline & Diagnostics

```
"Show me the activation pipeline across all trials"
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```
"What's happening with the Cleveland Clinic site? Show me everything"
```

```
"Alert me about any IRB approvals expiring in the next 30 days"
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```
"Which sites are stalled and what's blocking each one?"
```

Pattern Recognition & What-If Modeling

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"Show me all CTAs stuck on indemnification language across the portfolio"
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```
"What would it take to recover 4 weeks from the activation timeline?"
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```
"Compare CRO performance — which partners are fastest to activation?"
```

```
"If we switch these 3 sites from local to central IRB, what's the timeline impact?"
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Orchestration & Approval

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"Approve the CTA for Johns Hopkins — show me the budget context first"
```

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"Escalate the UCSF indemnification deadlock to VP Legal"
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```
"Schedule the SIV for all sites with completed training and finalized budgets"
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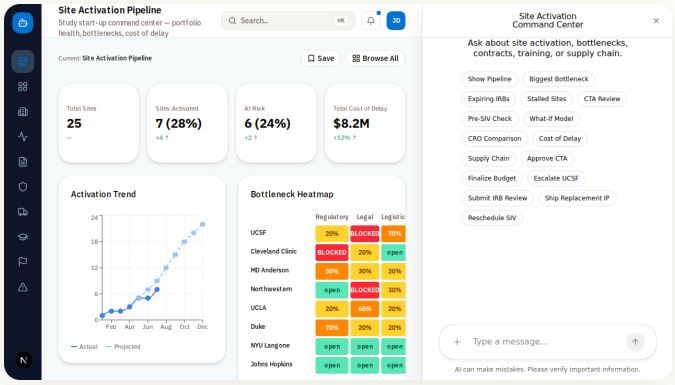
Hundreds of ad-hoc queries. Zero configuration. Every response is visual — pipeline views, diagnostic cards, trend charts, approval workflows, and projection models. Never raw text.



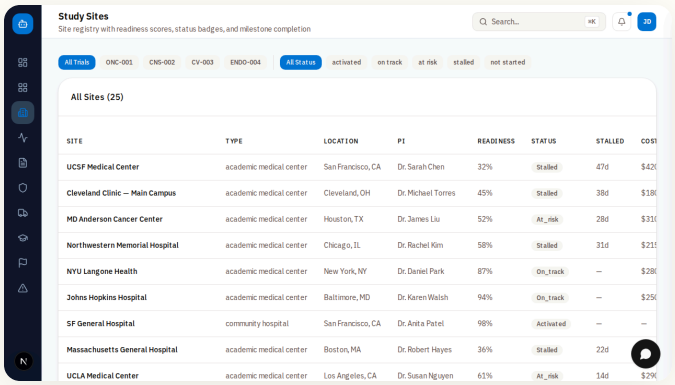
Conversational interface with structured diagnostic cards, HITL approval workflows, and one-click quick query suggestions — all rendered directly in the conversation.

DIAGNOSTIC INTELLIGENCE

Know Why a Site Is Stalled. Know What It's Costing You. Know What to Do Next.

Root Cause Analysis — Structured and Actionable

Every stalled site gets a structured diagnosis. The agent analyzes all four workstreams — regulatory, legal, logistics, training — and identifies the primary bottleneck, contributing factors, and cascade impact. It doesn't just tell you a site is delayed. It tells you the CTA is stuck on indemnification, the IRB approval has 42 days left before it expires, 3 staff members have expired GCP certifications, and the IP shipment is sitting in Dallas because no one confirmed the site's readiness.



Site registry with readiness scores, status badges, cost of delay, and CRO assignment — every site's activation health in one view.

Cascade Impact Analysis

When one workstream stalls, others decay. An IRB approval has a fixed 12-month window. If the CTA takes 6 months, half your enrollment period is gone before the first patient is screened. A training gap discovered at SIV delays the visit by 2 weeks — and cascades to IP shipment rescheduling, CRA travel rebooking, and enrollment timeline compression. The command center models these cascades so you can see the true cost of every delay.

Pattern Recognition Across the Portfolio

85% of site activation delays follow predictable patterns. The agent spots when three academic medical centers are all stuck on the same indemnification clause and recommends a blanket amendment rather than fighting each site individually. It identifies that central IRB sites activate 39 days faster on average and flags local IRB sites for conversion. It surfaces when a specific CRO's sites consistently take longer on budget negotiations. Systemic fixes, not whack-a-mole.

The Four-Workstream Dependency Model

Regulatory: IRB approval, 1572, essential documents, ICF, continuing reviews. 12-month approval window with fixed expiry.

Legal: CTA negotiation, budget finalization, coverage analysis, indemnification, intellectual property terms. 94% white space between review cycles.

Logistics: SQV/SIV scheduling, IP shipment with temperature chain, lab kit provisioning, system access credentials. Dependent on regulatory + legal completion.

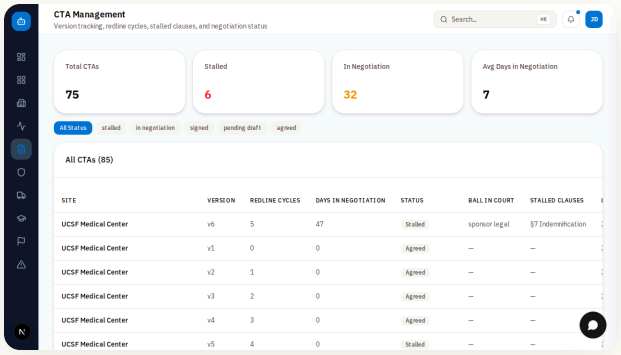
Training: GCP, protocol, EDC, IATA, safety reporting. 5-8 personnel per site across multiple certifications with staggered expiry dates.

CONTRACT & BUDGET INTELLIGENCE

The #1 Source of Activation Delays. Now Fully Transparent.

Clinical Trial Agreements — Managed at the Clause Level

CTAs are the single largest source of site activation delays — 41% of all bottlenecks trace to contract negotiation. The command center tracks every CTA at the clause level: version history, redline cycles, ball-in-court status, and stalled clause identification. You always know exactly what's stuck, who holds the ball, and how long it's been waiting.



CTA management dashboard — real-time KPIs, version tracking, ball-in-court status, and stalled clause identification across the portfolio.

90d+
Avg CTA Negotiation

94%
White Space

41%
of All Bottlenecks

The White Space Problem

Industry analysis shows 94% of CTA negotiation time is idle — the document sits in someone's inbox between review cycles. Active redlining takes days. Waiting takes months. The command center tracks ball-in-court status for every agreement and auto-escalates when white space exceeds a configurable threshold. No more contracts disappearing into inboxes for six weeks.

Portfolio-Wide Pattern Recognition

When three academic medical centers are all stuck on the same indemnification clause, the agent recommends a blanket amendment rather than fighting each site individually. When a specific CRO's budget templates consistently trigger 2+ extra negotiation rounds, the agent surfaces the pattern. One systemic fix replaces a dozen individual battles.

Budget Intelligence

Per-patient cost modeling with procedure-level detail. Budget-to-actual variance tracking. Coverage analysis integration to confirm Medicare/private insurance billing compliance. The agent flags budgets that deviate from protocol-expected ranges before they become negotiation sticking points.

REGULATORY & SUPPLY CHAIN

IRB Compliance. Document Readiness. IP Integrity. One View.

IRB Submission Tracking

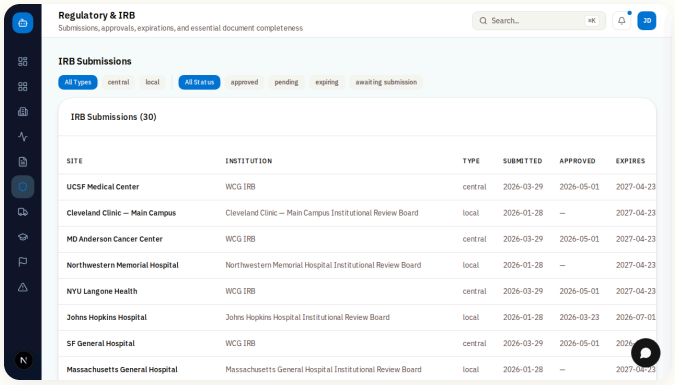
Central IRB submissions (WCG, Advarra, Schulman) average 27 days to approval. Local institutional IRBs average 66 days — a 39-day gap that directly impacts activation timelines. The command center tracks every submission with type, status, approval date, and expiration. Continuing review deadlines with escalating urgency notifications. Expiration risk scoring that factors in enrolled patient counts — a lapsed IRB with 8 active patients is a far more expensive problem than one with zero.

Essential Documents — ICH E6(R3) Compliance

Risk-proportionate essential document management per ICH E6(R3). Document count scales with trial complexity — the command center tracks every document with version history, expected vs. actual dates, and TMF reference mapping. Missing documents are flagged before they become audit findings. Expired documents trigger renewal workflows. The pre-SIV document checklist ensures no CRA travels to an unprepared site.

IRB Expiry Cascade — Why It Matters

A site with 8 active patients whose IRB approval expires must suspend enrollment immediately. Continuing review submission to re-approval typically takes 2-4 weeks. Every day of suspended enrollment costs the sponsor in lost data, delayed database lock, and extended trial timeline. The command center flags expirations 60 days out with patient-count-weighted urgency scoring.



IP Shipments & Lab Kit Logistics

Investigational product shipments with temperature chain monitoring, batch/lot traceability, and excursion alerts. Every shipment tracked from manufacturing through QA release to site receipt. Temperature excursions trigger automatic quarantine with impact assessment — how many patients are affected, whether a backup batch is available, and estimated reshipment timeline.

Lab kit management across safety, PK, biomarker, and urinalysis types. Reorder triggers based on enrollment velocity and expiration dates. Kit availability verified before SIV — no site visit where the CRA arrives but the kits haven't.

Temperature Excursion Response

Batch quarantined at 31.2°C (protocol limit 15-25°C). Command center identifies affected patients, locates backup batch availability, and initiates emergency cold chain reshipment — all through a single HITL approval workflow. 48-hour response instead of the typical 3-5 day manual process.

TRAINING & MILESTONES

Every Person. Every Certification. Every Milestone. Across Every Site.

Training Compliance Matrix

Every site has 5-8 personnel — PIs, Sub-Is, coordinators, pharmacists, lab staff — each requiring multiple certifications with staggered expiry dates. GCP (3-year expiry), IATA (2-year), protocol-specific, EDC, and safety reporting. The command center tracks every person, every certification, every expiry date across the entire portfolio.

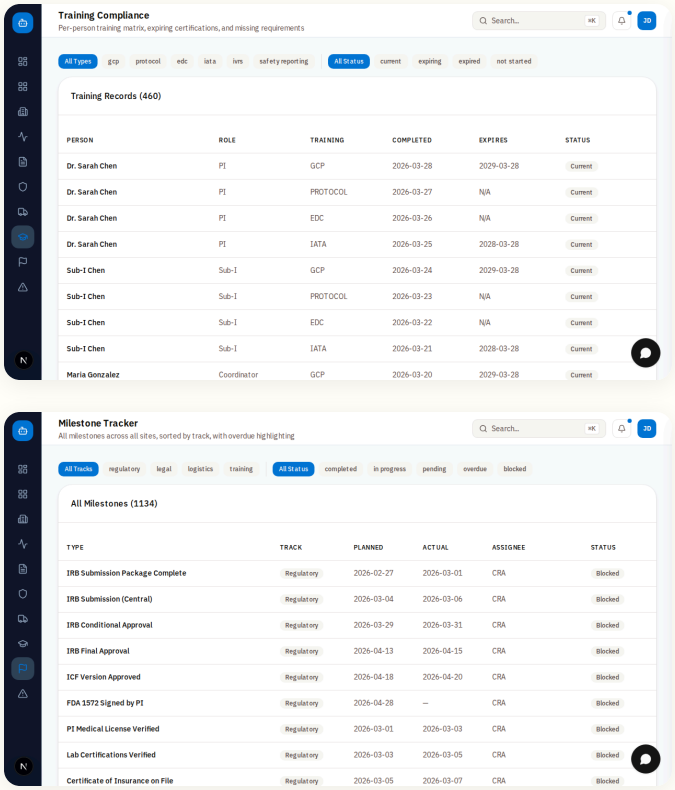
Per-person, per-type status tracking with current/expiring/expired color coding. Proactive expiration alerts 90 days before expiry. Gap analysis that tells you exactly who needs what — "Sub-I #2's GCP expired, CRC's IATA expires in 3 weeks" — not "training incomplete." Pre-SIV readiness check verifies all personnel training before the CRA travels.

The Pre-SIV Gatekeeper

Before every Site Initiation Visit, the agent checks training compliance, document completeness, and system access for all site personnel. Sites with gaps get flagged before the CRA books a flight. The cost of discovering an expired certification at SIV — rebooked travel, rescheduled visit, compressed enrollment window — far exceeds the cost of proactive verification.

Milestone Tracking — 49 Types Across 4 Tracks

Regulatory (14 types): IRB submissions, Form 1572, ICF, certifications, continuing reviews. Legal (12 types): CTA versions, budget negotiations, coverage analysis, fully executed agreements. Logistics (15 types): SQV/SIV scheduling, IP shipments, lab kit provisioning, system access, site close-out. Training (8 types): GCP, protocol, EDC, IATA, safety reporting verification. Overdue highlighting with delay cascade visualization. Dependency tracking between milestones across different workstreams.



Training compliance matrix (top) and milestone tracker (bottom) — complete visibility into personnel readiness and activation progress across all four workstreams.

ISSUE MANAGEMENT

Escalate the Right Problems. Track Every Resolution. Identify Systemic Patterns.

Bottleneck Taxonomy — 10 Failure Modes

Every issue is categorized into a structured root cause taxonomy: CTA Clause Deadlock, IRB Queue Wait, Budget Disagreement, Document Churn, Site Staffing, IP Supply Gap, Visit Scheduling, Training Gap, System Access, and Coverage Analysis Delay. Each failure mode has known detection signals, typical durations, and proven resolution patterns. The agent matches issues to failure modes and recommends the intervention with the highest probability of resolution.

Critical
Active Enrollment at Risk
Auto-Escalate to VP

High
Timeline Impact > 30 Days
Active Intervention

Medium
Monitor Closely
Escalate if Unresolved

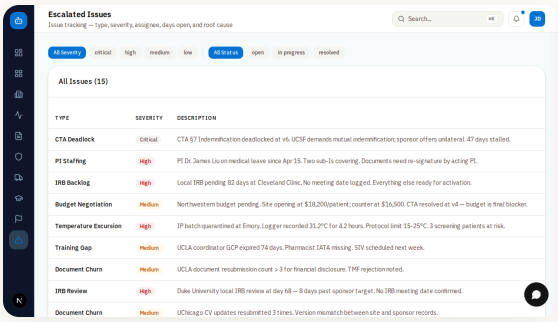
Low
Logged & Tracked
Resolve at Site Level

Severity-Weighted Escalation

Critical issues — active enrollment at risk, IRB expiry with patients enrolled, CTA deadlock with approaching milestone dates — auto-escalate with full context to the appropriate decision-maker. High issues surface in daily briefings with cost-of-delay estimates. Every issue tracks days open, assignee, root cause category, and resolution status. The agent monitors for stall patterns — an issue open 14+ days without activity triggers re-escalation.

Pattern: IRB Queue Wait Is the #1 Systemic Bottleneck

Across the industry, IRB queue delays are the most common systemic bottleneck — particularly at sites using local institutional IRBs, where median approval time is 66 days vs. 27 days for central IRBs. The command center identifies affected sites and recommends central IRB conversion with timeline impact projections. One recommendation can recover weeks from the activation timeline across multiple sites simultaneously.



Issue tracker with severity tiers, root cause taxonomy, assignee accountability, and days-open monitoring — every bottleneck categorized and actionable.

Root Cause Taxonomy — 10 Failure Modes

CTA Clause Deadlock — indemnification, IP, publication rights. Detection: stalled version with no activity > 14 days.

IRB Queue Wait — local IRB backlog. Detection: submission-to-approval > 40 days for central, > 80 days for local.

Budget Disagreement — per-patient cost, procedure fees, overhead rates. Detection: > 3 negotiation rounds.

Document Churn — repeated revisions on ICF, protocol amendments. Detection: > 4 versions of same document.

Training Gap — expired GCP/IATA, untrained on protocol/EDC. Detection: certification expiry < 30 days before SIV.

HITL COMMAND CENTER

Approve. Escalate. Orchestrate. Every Action, in Conversation.

A command center isn't a dashboard — it's an accelerator for action. HITL workflows let SSU Managers approve, escalate, and orchestrate resolutions from the chat. The agent researches context, surfaces financial impact, recommends actions, then pauses for human confirmation. Every approval mutates live data, navigates to the relevant screen, and logs an audit trail entry. The workflow library grows with your operations — no artificial limit on approval types.

Contract & Budget

CTA Sign-off
Approve final contract terms with budget context, negotiation history, and clause-level summary. > CTA executed, legal blocker cleared.

Budget Finalization
Finalize per-patient budget with coverage analysis validation and protocol benchmark comparison. > Budget approved, milestone completed.

Regulatory & Logistics

IRB Continuing Review
Submit continuing review before expiration. Patient-count-weighted urgency scoring. > Review submitted, enrollment protected.

Emergency IP Reshipment
Initiate cold chain reshipment from backup depot for temperature excursions. > New batch in transit within 48 hours.

Executive Escalation
Escalate stalled negotiations or critical bottlenecks with full timeline and cost of delay. > Issue escalated, assignee notified, SLA clock starts.

Every approval: research context > present financial impact > pause for human approval > mutate data on confirm > navigate to relevant page > log to audit trail. Add new approval types without engineering.

100%
In-Chat Approvals

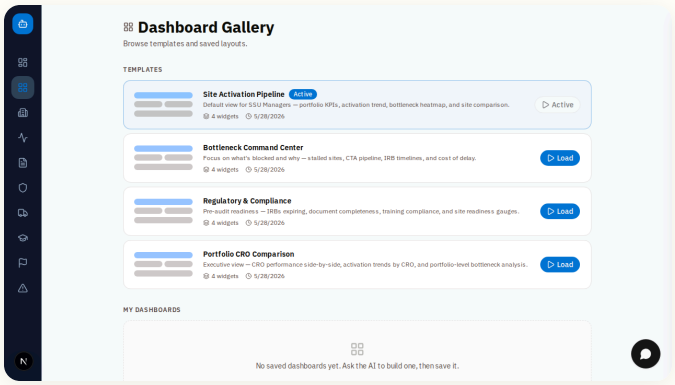
Full
Audit Trail on Every Action

All
Workstreams Covered

Extensible
Workflow Library

Diagnose > Analyze > Decide > Act

Pipeline review identifies the stall > root cause analysis shows cascade impact > agent recommends action with ROI estimate > HITL approval with full context > data mutation + navigation + audit log. All in chat. No email. No switching systems.



Pre-built dashboard templates — save, clone, and share layouts across the team. Customizable widget grid with clinical trial chart types.

ACCELERATOR CAPABILITIES

Built Different.
Built for Activation Speed.

Accelerator Architecture

Chat-First Interface
Conversation is the primary UI. Dashboards, diagnostic cards, and approval workflows render in response to natural language — no training, no IT tickets, no batch runs.

Multi-Agent Orchestration
Research and Projections agents run in isolated threads for parallel investigation and modeling. Each agent has domain-specific tools scoped to its task.

Real-Time Streaming
AG-UI protocol over SSE connects the LangGraph orchestrator to the React frontend. Results stream into the conversation as they're generated — no waiting for batch completion.

HITL by Design
Every mutation requires explicit human approval. The agent recommends — humans decide. Full audit trail with timestamp and user identity on every action. Auditor-ready at all times.

Dashboard Templates

Site Activation Pipeline
KPIs, activation trend, bottleneck heatmap, site comparison. Default operational view for SSU Managers.

Bottleneck Command Center
Stalled sites ranked by cost of delay, CTA pipeline, IRB timelines, budget impact funnel. Focus on what's blocked.

Regulatory & Compliance
IRB expiration calendar, document completeness gauges, training compliance matrix. Pre-audit readiness.

Portfolio CRO Comparison
CRO performance side-by-side — activation velocity, bottleneck frequency, budget variance. Executive oversight.

Clinical trial chart types: Site Readiness Gauge, Activation Trend, Contract Pipeline, IRB Timeline, Bottleneck Heatmap, Budget Impact Funnel, Training Compliance Matrix, Milestone Progress Radar, Site Comparison Bar, Site Readiness Heatmap. Pre-built templates, customizable layouts, save and share across teams. Plus 17 additional generic chart types available for custom dashboards.

What Makes It Different

Chat-First, Not Dashboard-First
Legacy platforms are dashboard-first — navigate menus, apply filters, interpret charts. The Command Center is conversation-first — ask a question, the agent researches across all four workstreams, and renders the answer as structured UI. Dashboards are outputs, not the interface.

Cascade Impact Analysis
Traditional systems track milestones in isolation. The Command Center models dependencies across all four workstreams: an IRB approval decays while Legal negotiates indemnification. A training gap cascades to SIV rescheduling and enrollment timeline compression. Every diagnosis shows the reasoning chain — which signals contributed, what patterns were matched, what assumptions were made. The agent doesn't just give you an answer. It shows its work.

Conversational What-If Modeling
Ask "what if we convert these sites to central IRB?" and get a timeline projection with site-specific ROI. Ask "what would it take to recover 4 weeks?" and get ranked interventions by impact. No modeling expertise required. No static reports. The model updates as new data arrives and you can refine assumptions mid-conversation.

Immediate Time-to-Value
No months of implementation. No CTMS migration. No end-user training. Deploy and start diagnosing stalls on day one. The accelerator learns your portfolio's patterns and gets smarter with every interaction. Cloud or on-premise. Works with your preferred AI provider. Operates alongside existing systems — ingest data from spreadsheets, CTMS exports, or direct API connections.

HelixIQ^2 Site Activation Command Center

Intelligence at Activation Speed.
Clinical Trial Site Activation, Transformed.

Powered by HelixIQ²

Pipeline monitoring • Bottleneck diagnosis • Acceleration modeling • HITL orchestration