HITLAB

JEEVA CLINICAL

Reimagining Clinical Trial Operations: Fragmentation to Integration Through a Unified AI-Ready Digital Platform

AN EVALUATION BY HITLAB

This report presents HITLAB's evaluation of Jeeva Clinical Trials, a web-based AI-ready platform supporting end-to-end digital management of decentralized and site-based clinical studies.

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Executive Summary

This whitepaper presents HITLAB's heuristic evaluation of Jeeva Clinical Trials, a web-based clinical research platform designed to support decentralized, hybrid, and site-based studies through an integrated digital infrastructure. The platform enables sponsors, research sites, and study teams to manage study setup, participant workflows, eConsent, ePRO/eCOA, communication, and reporting within a single, role-based environment.

HITLAB conducted a structured evaluation of Jeeva's web platform, using Jakob Nielsen's Usability Heuristics for User Interface Design. The assessment focused on how effectively the platform supports real-world clinical trial operations while minimizing cognitive load, reducing errors, and maintaining data clarity across multi-study and multi-user contexts.

The findings supported Jeeva Clinical Trial's effectiveness to support modern clinical trial operations through its unified AI-ready platform architecture, intuitive study setup, integrated participant management, compliance-focused features, and strong support for decentralized and hybrid workflows. However, opportunities remain to improve usability and trust, particularly around dashboard metric clarity, navigation consistency, documentation alignment, role-based access controls, internal collaboration, and participant lifecycle management.

Overall, HITLAB's evaluations demonstrate Jeeva Clinical Trials as a strong user-centered design with operational potential. The evaluation provides a focused roadmap to strengthen usability, data integrity, and efficiency for the platform to scale across studies and stakeholders.

Introduction

The Urgent Need to Rethink Clinical Trial Infrastructure

Clinical trials are essential to medical advancement, yet persistent challenges in patient recruitment, retention, and logistical burden continue to delay studies, increase costs, and threaten trial validity (Martinez et al., 2010; Ketter & Oroszi, 2022). Barriers such as travel requirements, frequent site visits, and significant time commitments disproportionately limit participation among underserved and geographically distant populations (Meropol, 2016; Heffernan et al., 2023).

These challenges are compounded by rising costs, growing operational complexity, and insufficient participant diversity, which undermine data quality and generalizability while exacerbating health inequities (Wilson & Gupta, 2017; Fisher-Hoch et al., 2023). Collectively, these systemic barriers slow innovation and restrict equitable access to clinical research.

Patient Recruitment and Retention Issues

Clinical trials struggle with participant enrollment and retention due to logistical burdens such as travel, time off work, and childcare, compounded by low awareness and complex study protocols. These challenges often result in delayed or failed trials, increased costs, and biased outcomes when enrolled participants differ systematically from those unable to participate or remain in the study (Martinez et al., 2010).

High Costs and Long Timelines

Clinical trials demand significant time and financial investment, with high operational, recruitment, and regulatory costs—often reaching $2–$2.5 billion per new drug. These pressures extend development timelines, delay patient access to new therapies, drive financial losses for sponsors, and can force smaller or academic sponsors to discontinue studies due to budget constraints (Rajasimha, 2022).

Introduction

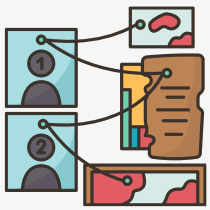
The Urgent Need to Rethink Clinical Trial Infrastructure

Lack of Diversity and Representativeness in Participants

Clinical trials frequently enroll predominantly white and affluent participants, resulting in the underrepresentation of ethnic minorities, women, children, and geographically diverse populations. This lack of diversity limits the generalizability of clinical findings, raises health equity concerns when safety and efficacy are not validated across populations, and increases the risk that treatments may be less effective or unsafe for underrepresented groups (Smith & Khan, 2022).

Data Quality and Evidence Generation Problems

Incomplete data, poor coordination across trial sites, and manual errors continue to undermine data quality in clinical research. These issues can trigger regulatory setbacks, introduce bias into trial results, and lead to flawed healthcare decisions, often necessitating additional studies that further increase costs and delay timelines (Brown et al., 2025).



Geographic and Regulatory Imbalance in Global Clinical Trials

Clinical trials are disproportionately concentrated in high-income countries, limiting data generalizability. Nearly 90% of trials occur in ~5% of countries, representing only 10% of the global population (Atal et al., 2015; Alemayehu et al., 2018; Justine Ra, 2024). This imbalance is reinforced by fragmented regulatory and data-privacy frameworks across regions (e.g., GDPR vs. HIPAA), which discourage trial conduct in low- and middle-income countries (FDA 21 CFR Part 11; EU CTR).

Introduction

The Urgent Need to Rethink Clinical Trial Infrastructure

Access and Geographic Barriers

Traditional site-based clinical trial models limit participation for individuals living far from research centers, leaving up to 95% of potential patients unreached. These geographic barriers result in the underrepresentation of rural and global populations, inequitable access to investigational therapies, and evidence that is less relevant to real-world and global health needs (Rajasimha, 2025).

Regulatory and Operational Complexity

Clinical trials are burdened by complex procedures and stringent regulatory requirements, requiring coordination across multiple systems and stakeholders. This complexity increases the risk of protocol deviations and compliance issues, drives higher administrative costs, and contributes to approval delays caused by operational bottlenecks (Wilson & Gupta, 2017).

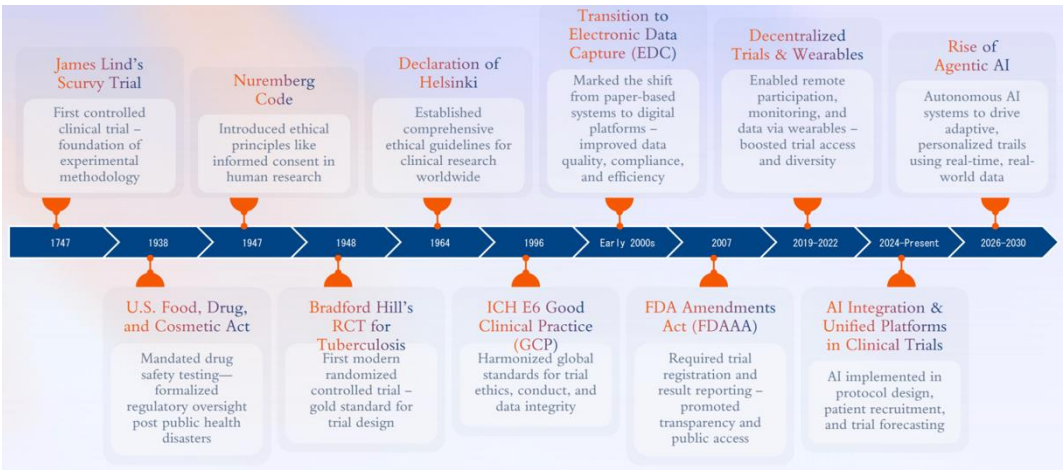
Together, these persistent challenges underscore a fundamental misalignment between the complexity of modern clinical research and the infrastructure used to support it. Fragmented systems, site-centric models, and manual workflows continue to constrain access, inflate costs, compromise data quality, and limit global representativeness. Addressing these systemic limitations requires more than incremental optimization—it calls for a reimagining of clinical trial infrastructure that is patient-centric, digitally enabled, operationally integrated, and scalable across geographies and study types.

Rearchitecting Trials: Historical Lessons and the Digital Imperative

The history of clinical trials reflects a shift from early observation to rigorously regulated, increasingly digital research models.

Early Foundations: Comparative experimentation dates to 500 BC (Book of Daniel), followed by Ambroise Paré's differential treatment in 1537. James Lind's 1747 scurvy study established the first controlled clinical trial, introducing control groups and standardized interventions (Bhatt, 2010).

Formalization & Ethics: The 20th century brought scientific rigor with the first randomized controlled trial (RCT) in 1948, led by Sir Austin Bradford Hill, alongside the development of ethical frameworks such as the Nuremberg Code, the Declaration of Helsinki, and Good Clinical Practice in response to past ethical failures (Bhatt, 2010).



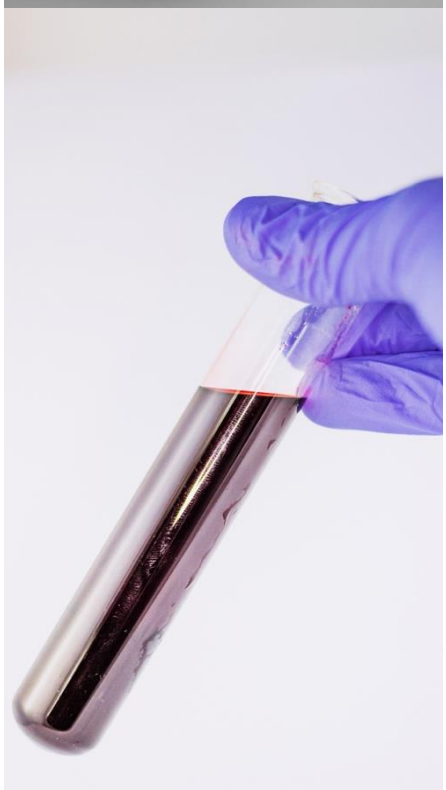
The Digital Transition:

- 1990s–2000s: Transition from paper-based Case Report Forms to Electronic Data Capture (EDC) systems (Applied Clinical Trials, 2022).
- 2010s–2020s: Expansion of eClinical technologies, including eConsent and wearables, alongside pandemic-driven adoption of Decentralized Clinical Trials (DCTs) (Applied Clinical Trials, 2022).

Current Frontier (2024–2030): Integration of AI and machine learning for predictive analytics and real-time monitoring, with the emergence of agentic AI to autonomously manage trial workflows (Applied Clinical Trials, 2022; Medrio, 2025).

Key Structural Shifts Redefining Modern Clinical Trials

- **Clinical trial inefficiencies persist** despite scientific advances, driven by geography, cost, fragmentation, and operational complexity.
- **Digital transformation is structural, not transient**, reinforced by regulatory guidance.
- **EDC, CDISC standards, and cloud platforms** have significantly improved data quality and regulatory readiness.
- **Decentralized clinical trials (DCTs)** enhance access, retention, and diversity while reducing overhead.
- **AI is a critical integrator,** enabling intelligent data harmonization, precision recruitment, adaptive trial designs, and real-time safety monitoring.
- **Fragmented point solutions limit impact,** necessitating unified, end-to-end platforms.
- **CRO-as-a-Service (CROaaS) models** reduce sponsor burden by combining technology with expert operational execution.
- **Patient-centric design** (remote participation, digital consent, simplified protocols) is central to efficiency, equity, and trial success.
- **Human oversight** remains essential to ensure ethical rigor, regulatory compliance, and scientific validity.
- **Future clinical trials will be modular, AI-driven, and interoperable,** integrating RWD/RWE and operating as learning systems.



The Cost Anatomy of Clinical Trials

The cost of developing a single new drug can exceed $2 billion, with clinical trials serving as the most resource-heavy phase. Expenses escalate across phases, particularly in Phase III trials, due to larger patient populations, longer durations, and increased operational complexity.

Patient recruitment accounts for up to 30% of the total budget due to the complexities of identifying and enrolling eligible participants (Meplis, 2025).

Site management and monitoring typically consume 20–25% of expenditures (ASPE, 2014).

Data management and statistical analysis account for 15–25% of costs (USGS, n.d.), while the manufacturing and distribution of the investigational product requires another 15–20% (ASPE, 2014).

Regulatory compliance (10–15%) and administrative overheads (exceeding 10%) round out the remaining financial burden (Nitya Maddodi, 2024; ASPE, 2014).

Investigational Product (IP) Manufacturing & Distribution (15–20%): It involves costs for investigational products, especially biologics and advanced therapies, including production, labeling, cold-chain logistics, etc. tc(ASPE, 2014).

Vendor Support Services (5–10%) Specialized vendors support trial execution but contribute to rising outsourcing costs for management, central labs, imaging, and eCOA platforms (ASPE, 2014).

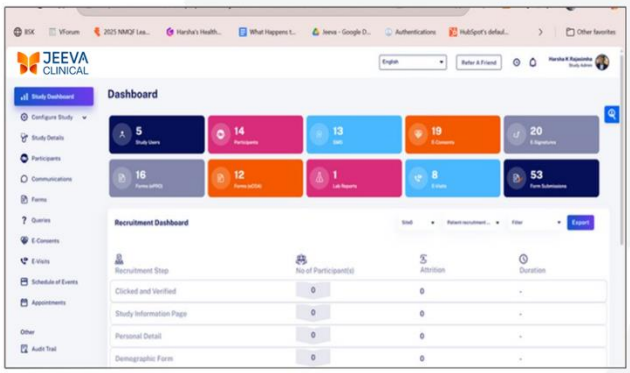
Administrative Overheads (>10%): Involve operational overheads such as investigator fees, IRB approvals, insurance, and project management, etc.

Figure 1: Costs for Phase1-3 clinical trial in USA (in US$ million)

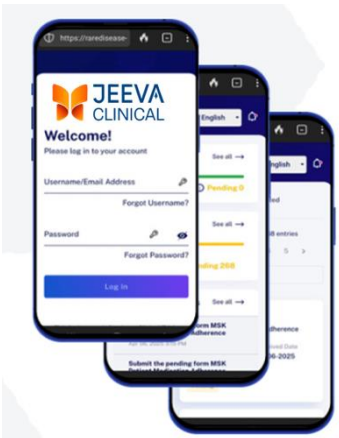
Jeeva Clinical Trials

A Unified B2B SaaS Platform: FDA and AI-Ready from Day 1: Modern Clinical Trial Infrastructure

Jeeva Clinical Trials is a cloud-native, AI-powered e-Clinical platform that is designed to modernize clinical research by unifying key trial components, such as electronic data capture (EDC), patient engagement, e-Consent, CTMS, and telehealth under a single login.



Trial Management Dashboard



Patient Portal/App

The platform offers an integrated suite of tools, including Electronic Data Capture (EDC), eConsent, eCOA, patient recruitment, decentralized trial management, and real-time monitoring, all within a single unified system. With multilingual support across 100+ languages, a patient-centric design enabling remote participation, and compliance with HIPAA, GDPR, and FDA 21 CFR Part 11, Jeeva aims to reduce clinical trial timelines, cut operational costs by up to 70%, and advance health equity by expanding access to underrepresented global populations.

- Jeeva Clinical Trials is an AI-assisted eClinical software platform designed to simplify, streamline, and automate clinical trial operations for emerging biopharma and MedTech sponsors.
- By combining protocol-aligned automation, compliance-ready workflows, and intuitive dashboards, Jeeva reduces operational complexity, improves data quality, and accelerates study timelines while enabling scalable, patient-centric clinical research across geographies.
- It leverages the Agentic AI engine to automate and streamline workflows, thereby reducing administrative burden by up to 70%.
- The platform supports decentralized and hybrid trial designs, real-time collaboration across sponsors, sites, and patients, and compliance with global regulations.

Jeeva Clinical Trials

A Unified B2B SaaS Platform For Modern Clinical Trial Infrastructure

Key features

Clean, intuitive user interface with organized dashboards that provide at-a-glance visibility into study activities, participants, forms, and workflows.

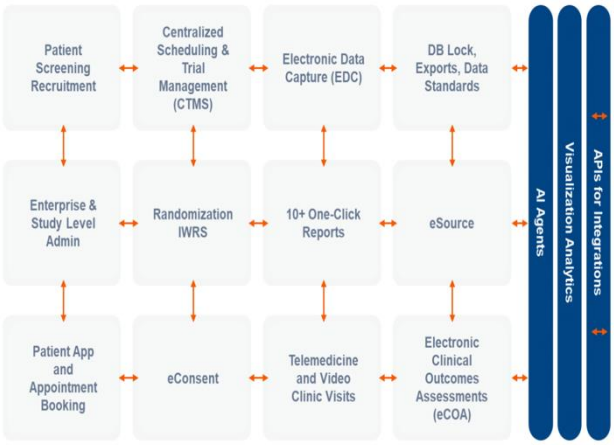
Strong security framework with two-factor authentication (OTP via SMS or email), supporting regulatory compliance and data protection.

Support for decentralized and hybrid trials through remote recruitment, enrollment, monitoring, and follow-up capabilities.

Automated, protocol-aligned workflows reduces manual processes, administrative, and operational burden.

AI-enabled alerts and compliance-ready features that help maintain data integrity and reduce protocol deviations.

Scalable architecture designed for multi-site, multi-country studies, including rare-disease research, registries, and long-term follow-up.



Multi-device accessibility across web, mobile, and tablet platforms, enabling flexible and remote work for research teams.

Pre-configured templates for participant communications and study components, supporting faster onboarding and workflow standardization.

Real-time validation and clear error messages during data entry help users identify and correct issues quickly.

Comprehensive user manual with step-by-step guidance and screenshots to support onboarding and independent system use.

Functional in-platform links to support resources, privacy policies, and platform information, ensuring easy access to assistance

Compliance Programs Supported

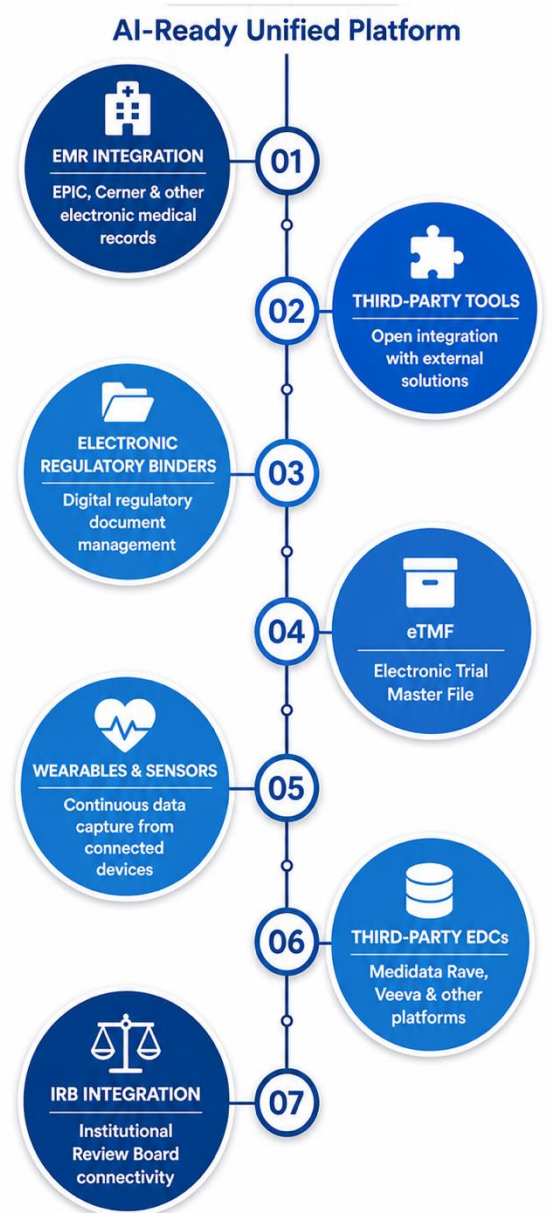
Jeeva's AI-Ready Unified Platform Ecosystem

Jeeva Clinical Trials has developed an Agentic AI Framework purpose-built to address one of the most persistent bottlenecks in clinical research — accurate, timely, and automated clinical data management. Unlike traditional rule-based data review systems, Jeeva's framework employs autonomous AI agents capable of reading, reasoning, and acting on complex trial data across three core goals.

Goal 1 — Adverse Event Detection forms the foundation of the framework. AI agents parse unstructured visit comments, clinical notes, and form fields using NLP — including negation handling to avoid false positives. Upon detecting a potential Adverse Event, the system automatically raises a data query, reducing the manual burden on Clinical Data Managers (CDMs) and ensuring no safety signal goes unreviewed.

Goal 2 — Cross-Form Contradiction Detection addresses data integrity across multi-visit, multi-form trial designs. The AI summarizes each eCRF form independently, then performs cross-form reasoning to flag contradictions and inconsistencies, raising targeted queries for faster, more precise data cleaning.

Goal 3 — Historical Range Validation ensures new form variable data is validated against historical trend data from the same or comparable trials. This allows the AI to distinguish genuine outliers from expected variations, raising queries only for clinically meaningful deviations — reducing query noise and improving overall data quality.

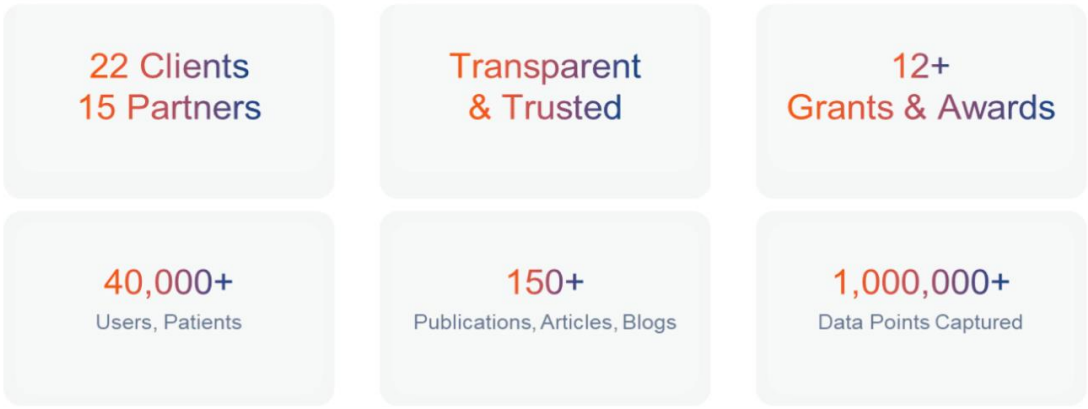


Together, these three goals create a **closed-loop data review cycle** that accelerates database lock, minimizes human error, and supports regulatory compliance through built-in audit trails.

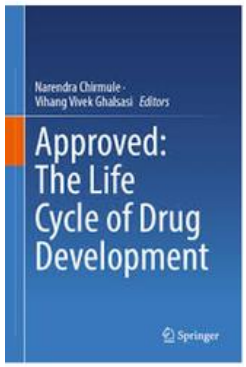
Proven Success In Delivering At Scale

Jeeva's Market Adoption

Jeeva has demonstrated meaningful adoption and validation across the clinical research ecosystem. With a growing customer base, strong partnerships, and sustained user engagement, Jeeva is establishing itself as a trusted, transparent, and scalable platform for modern clinical trials.



Validated by Academic Research



A comparative study conducted by Kennesaw State University (Atlanta, GA) found that users adapted more easily to Jeeva's unified platform compared to REDCap. Participants reported a more seamless, intuitive experience with Jeeva, leading to improved productivity & simpler management of clinical studies.

User Testimonials

Jeeva delivers measurable operational, financial, and workflow efficiencies for clinical research teams. Customers consistently report significant cost savings, reduced staff burden, and streamlined trial execution.

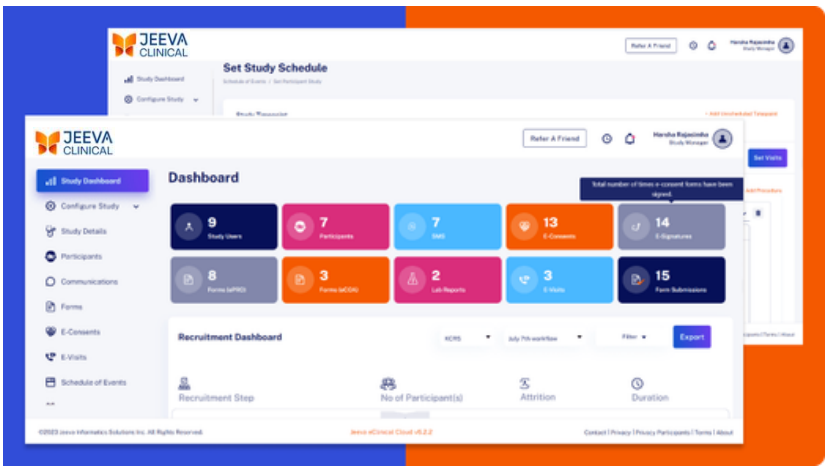
Heuristic Evaluation

Conducted by HITLAB

HITLAB conducted a heuristic evaluation of the Jeeva Clinical Trial Platform by applying structured usability inspection methods to assess its design, layout, functionality, navigation, and content, identifying areas where the platform diverges from established usability standards or creates barriers that could hinder the user experience.

Methodology

The evaluation was designed to simulate the perspective of end users, including individuals working in a hospital, while also providing the expert analysis of the app's design, usage, and functionality. The assessment was guided by Jakob Nielsen's Ten Usability Heuristics, a globally recognized framework for evaluating interface design. Each heuristic principle—visibility of system status; match between system and the real world; user control and freedom; consistency and standards; error prevention; recognition rather than recall; flexibility and efficiency of use; aesthetic and minimalist design; help users recognize, diagnose, and recover from errors; and help and documentation—was systematically applied to identify strengths and areas for refinement.



The evaluation involved a review of the Jeeva Clinical trial platform, exploring its usability, functionality, and overall user experience to identify strengths and opportunities for improvement. The test scenario was designed to mirror real-world user interactions, focusing on how well the platform supports secure, compliant, and intuitive trial workflows, including study setup, participant management, data capture, and collaboration across decentralized and multi-site research environments.

Heuristic Evaluation

Conducted by HITLAB

Evaluation Persona

The expert evaluators from HITLAB conducted the review by simulating the role of a 38-year-old Clinical Research Coordinator working in a hospital with 10+ years in clinical operations site management.

Dr. Amanda Turner

Occupation: Clinical Research Coordinator
Age: 38 years

> *Every day, I balance patient needs, study protocols, and endless documentation. I need a platform which should be clear, fast, and dependable—so that it simplifies my work and keeps me organised.*

Background	Goals	Challenges
Amanda is Clinical research coordinator who manages regularly patient recruitment, screening, documentation, and regulatory reporting in Phase II and III of clinical trials. This multitasking leads to cognitive overload. She needs a smart, streamlined solution to reduce the manual tasks and boosts participant engagement .	• Deliver safe, accurate and timely data to sponsors and CROs. • To stay organized and focused amid constant multitasking • To improve participant enrollment and retention • To ensure protocol compliance in less time with minimal errors	• Juggling work, life, and a fast-paced, unpredictable environment • Making quick, accurate decisions under time constraints tasks • Coping with stress and fatigue from limited time and energy • Balancing multiple tasks of workflow, heavy admin work and documentation demands
Motivations	**Frustrations**	**Needs**
• Empowered to be recognized as an efficient, high-performing coordinator • Driven to deliver high-quality care under pressure • Committed to streamline workflows instead of complicating them	• Can't prioritize personal health due to demanding shifts • Wastes time switching between disconnected tools for e-consent, scheduling and ePRO • Poor system tracking and unclear dashboards slows work and adds mental strain	• A single digital platform with Reliable Remote capabilities to manage patient enrollment, scheduling, e-consent and ePRO • Real-time communication channels with participant statuses, visit windows, tasks, and pending actions

Heuristic Evaluation

Conducted by HITLAB

Findings

The Jeeva Clinical Trials platform demonstrated a strong foundational design, with consistently positive performance across core usability dimensions, reflecting a robust, workflow-oriented system aligned with clinical research operations. The evaluation identified notable strengths in unified platform architecture, clarity of study setup workflows, support for decentralized and hybrid trials, and alignment with real-world research processes.

The findings also revealed targeted opportunities for refinement to further improve dashboard clarity, navigation consistency, role-based controls, and participant lifecycle management. Addressing these areas will enhance overall efficiency and trust as the platform scales across studies and stakeholders.

Heuristic Ratings (on a scale of 1 to 5)

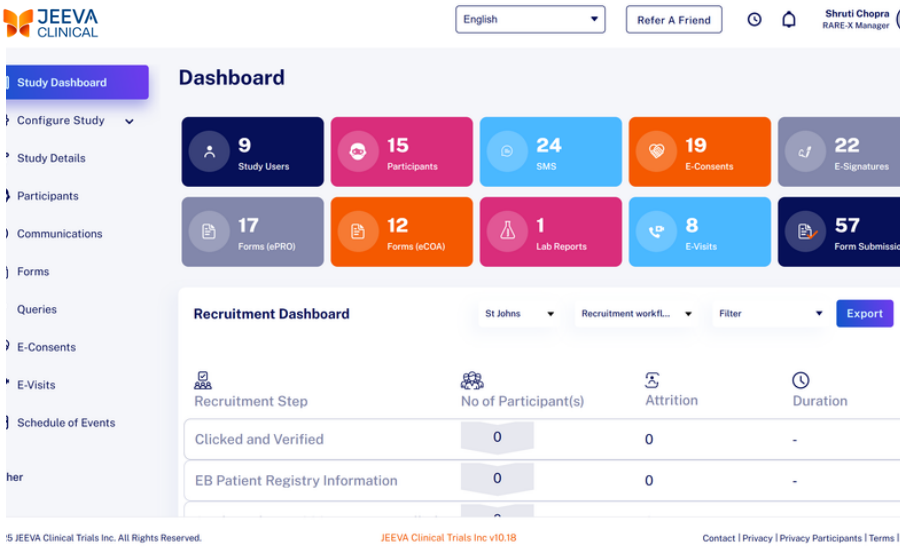
Visibility of system status	4
Match between system and the real world	4
User control and freedom	4
Consistency and standards	4
Error prevention	4
Recognition rather than recall	4
Flexibility and efficiency of use	4
Aesthetic and minimalist design	4
Help users recognize, diagnose, recover from errors	4
Help and documentation	5

Heuristic Evaluation

Conducted by HITLAB

Strengths Identified

- The platform maintains visibility of system status by presenting organized dashboards and immediate feedback that clearly reflect study progress and user actions.
- Jeeva aligns well with the real-world clinical trial context by using familiar research terminology and workflows that mirror routine site operations.
- The system supports user control and freedom by enabling smooth navigation across studies and allowing centralized management of key trial components.
- Consistency and standards are upheld through uniform layouts, terminology, and visual design across the platform.
- Error prevention is supported through inline validations, guided study setup, and automated compliance alerts that reduce incorrect entries.
- The interface favors recognition over recall by keeping essential actions and information visible within dashboards, minimizing cognitive burden.
- Flexibility and efficiency of use are demonstrated through multi-role support, multi-device accessibility, and scalability for multi-site and global trials.
- The platform follows an aesthetic and minimalist design, offering a clean, readable interface focused on essential information.
- Jeeva helps users recognize and recover from errors with clear, plain-language error messages and corrective guidance.
- Strong help and documentation are provided through a comprehensive user manual and accessible support links.



Heuristic Evaluation

Conducted by HITLAB

Opportunities for Improvement

Data Accuracy, Validation & Governance: Improving dashboard-data alignment, strengthening input validation, and refining role-based access controls will further enhance data integrity, security, and regulatory confidence.

Unified Interface & Design Consistency: Standardizing layouts, labels, and navigation across study modules can reduce cognitive load and improve overall usability.

Documentation & Feature Transparency: Aligning user manuals with visible, role-enabled features will accelerate onboarding and increase feature adoption.

Workflow Flexibility & Protocol Adaptability: Expanding configurable reminders and workflow options will better support diverse study designs and evolving protocol needs.

Integrated Communication & Query Management: Enhancing internal notes, flags, and system-level query capabilities will streamline collaboration and reduce reliance on external tools.

Participant Lifecycle Management: Introducing expanded participant status controls (e.g., dropped, invalid, removed) will improve operational accuracy and downstream reporting.

Recommended Next Steps

To systematically enhance the platform, HITLAB recommends a phased approach:

Immediate Refinements (0–2 months): Resolve dashboard metric inconsistencies, clarify navigation and empty states, standardize labels, enforce role-based access, and align documentation with live functionality.

User Experience Optimization (2–4 months): Standardize layouts, strengthen input validation, enable customizable reminders, add internal notes and system-level queries, and introduce participant lifecycle controls.

Pilot Validation & Scaling (4–6 months): Validate enhancements through pilot studies, refine workflows based on user feedback, and strengthen data integrity and access controls for multi-study scalability.

Conclusion

The heuristic evaluation conducted by HITLAB confirms that Jeeva Clinical Trials is a thoughtfully designed, research-focused digital platform that effectively supports the execution of modern clinical trials. Its unified interface, structured workflows, and integrated study management capabilities demonstrate strong adherence to usability principles while promoting clarity, efficiency, and regulatory confidence for clinical research teams.

The evaluation highlights Jeeva's ability to empower sponsors and research sites to manage study setup, participant engagement, data capture, and monitoring within a single, cohesive environment. By aligning system workflows with real-world trial operations across decentralized, hybrid, and site-based models, the platform reduces operational friction, improves coordination, and supports continuity throughout the study lifecycle. The platform's design reflects a strong emphasis on standardization, traceability, and operational control, which are critical for regulatory compliance and multi-site trial execution.

While the Jeeva platform demonstrates a strong foundation in usability and operational design, targeted opportunities remain to further enhance dashboard transparency, navigation consistency, role-based access controls, and collaboration features. Guided by HITLAB's evidence-based insights, these refinements are expected to strengthen usability, data integrity, and enterprise scalability—positioning Jeeva Clinical Trials as a robust, future-ready infrastructure for technology-enabled clinical research.

> *"Jeeva Clinical Trials reflects a fundamental shift in clinical research infrastructure—replacing fragmented, manual processes with a unified, digital, and workflow-driven model designed for scalable, efficient, and compliant trial execution."*
> *— Stan Kachnowski, Chair, HITLAB*

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HITLAB is a leading healthcare innovation lab dedicated to improving health outcomes worldwide. Through rigorous research, education, and collaboration, HITLAB identifies and supports the development of transformative health technologies.